UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, Virginia 22313-1450
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ACKNOWLEDGEMENT OF LOSS OF ENTITLEMENT TO ENTITY STATUS DISCOUNT

APPLICATION #	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET #	REQUEST ID
16/009,547	06/15/2018	Jonathan O'TOOLE	4944.0120004	184265

The entity status change request below filed through Patent Center on 03/19/2024 has been accepted.

Certifications

APPLICANT CHANGING TO REGULAR UNDISCOUNTED FEE STATUS

Signature

I certify, in accordance with 37 CFR 1.4(d)(4), that I am one of the signatories making the entity status change.

Signature	Name	Registration #
/Yangbeini Wang #800,005/	Yangbeini Wang	800005

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002

CONFIRMATION NO. 5958

POWER OF ATTORNEY NOTICE

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC00000013300312

Date Mailed: 04/08/2022

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/04/2022.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/009,547	06/15/2018	Jonathan O'TOOLE	4944.0120004

CONFIRMATION NO. 5958

26111
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

POA ACCEPTANCE LETTER

OC00000013003147

Date Mailed: 04/08/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/04/2022.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

PTO/AIA/81A (02-15)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT - POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Patent Number	10,926,011
Issue Date	2/23/2021
First Named Inventor	Jonathan O'TOOLE et al.
Title	BREAST PUMP SYSTEM
Attorney Docket No.	4944.0120004

I hereby revoke all previous powers of attorney given in the above-identified patent.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the Customer Number identified in the box at right as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 26111

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified patent to:

☒ The address associated with the above-identified Customer Number.

OR

☐ The address associated with the Customer Number identified in the box at right:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☒ Applicant.

OR

☐ Patent owner.

Statement under 37 CFR 3.73(c) (Form PTO/AIA/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Patent Owner

Signature	/ Gillian Grainge /	Date	01 March 2022
Name	Gillian Grainge	Telephone	+44 20 3745 5201
Title and Company	Head of Legal, Chiaro Technology Limited		

NOTE: Signatures of all the applicants or patent owners of the entire interest or their representative(s) are required. If more than one signature is required, submit multiple forms, check the box below, and identify the total number of forms submitted in the blank below.

☐ A total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	45390383
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Anupma Sahay/Robyn Badman
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	373499.00002
Receipt Date:	04-APR-2022
Filing Date:	15-JUN-2018
Time Stamp:	17:08:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	POA-Transmittal-4944-0120004.PDF	193024 b2c0dc609a1161a6513d872abbecdebc5b7cd7d2	no	1

Warnings:

Information:					
2	Power of Attorney	POA-aia0081a-4944-0120004.PDF	181239 cea4d66d805705bd3758de5e0ba4d88ffd63de63	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	374263	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	16/009,547
Filing Date	June 15, 2018
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120004

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☑ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	April 4, 2022	Reg. No.	78,704

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	02/23/2021	10926011	373499.00002	5958

78905 7590 02/03/2021

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM;
Jonathan O'TOOLE, London, UNITED KINGDOM;
Adam ROLLO, London, UNITED KINGDOM;
Andrew CARR, London, UNITED KINGDOM;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

SCORE Placeholder Sheet for IFW Content

Application Number: 16009547 Document Date: 01/12/2021

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via DAV or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

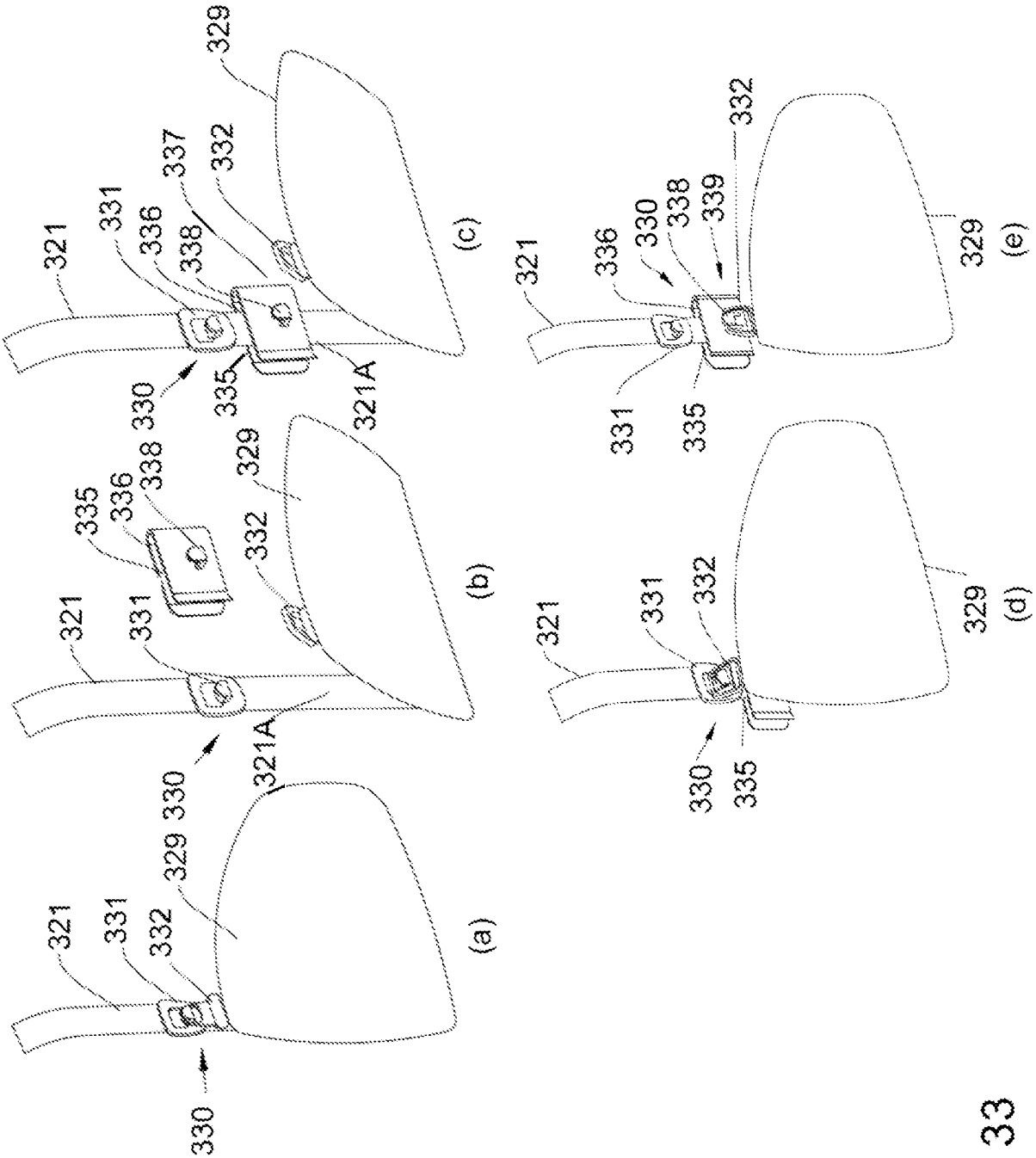

321
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(a)
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321A
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(b)
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(d)

FIGURE 33

36/44

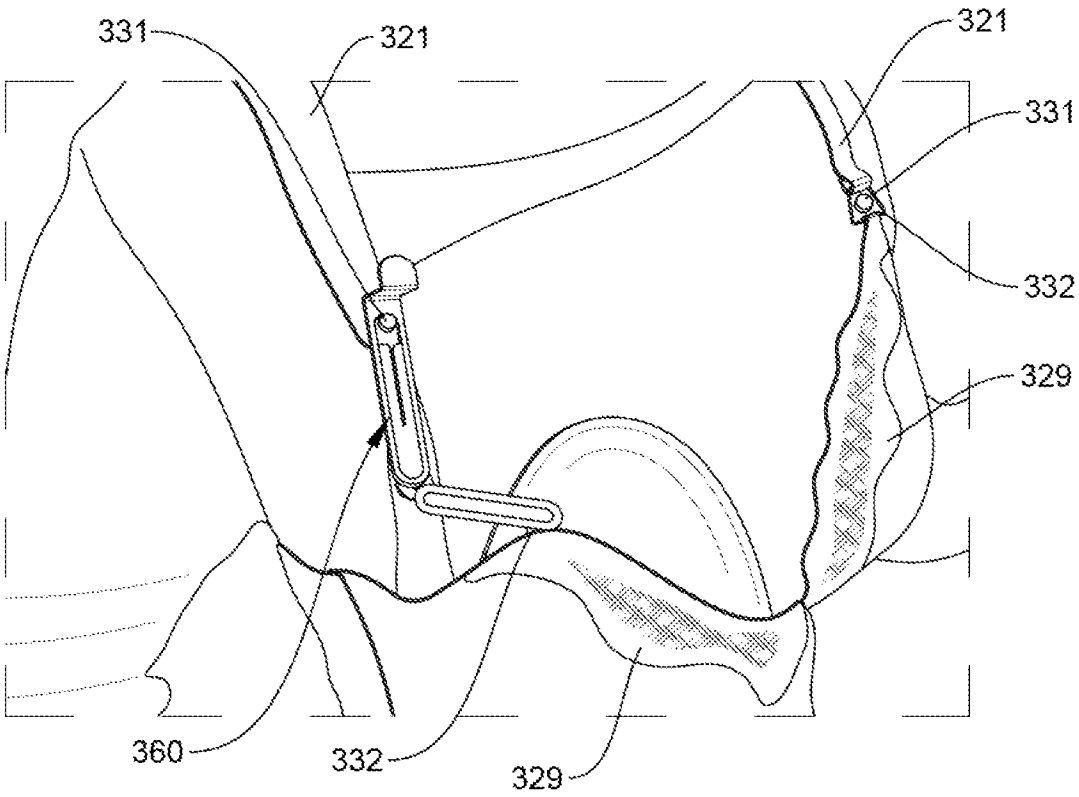


FIGURE 36

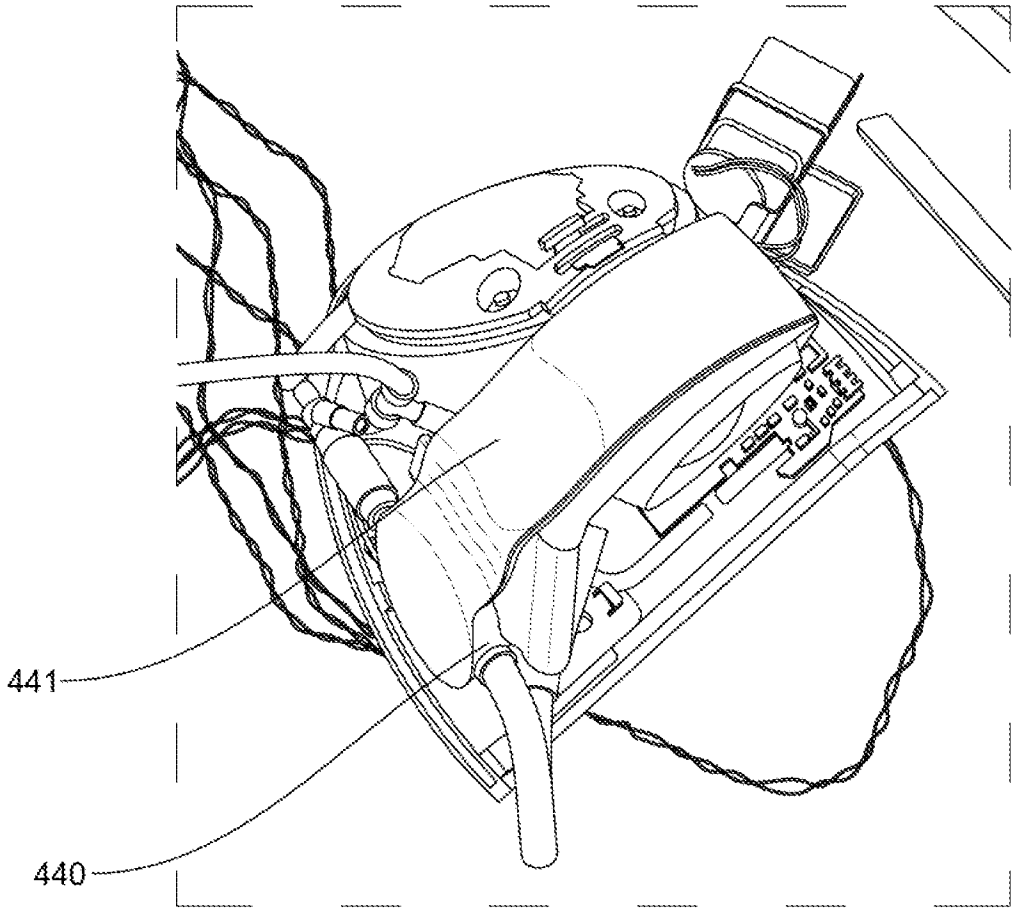


FIGURE 44

Electronic Acknowledgement Receipt

EFS ID:	41621947
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	12-JAN-2021
Filing Date:	15-JUN-2018
Time Stamp:	14:43:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	37950083_1.PDF	104121 c3433272067f26af8a9ca78b7a27ed97a27d5276	no	3

Warnings:

Information:					
2	Drawings-other than black and white line drawings	37941240_2.PDF	1266188 f32cde138ceb00e72c98b4cb35a2c9a3a2ddc36d	no	3
Warnings:					
Information:					
			Total Files Size (in bytes):	1370309	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No. **5958**
APPLICATION NO.	**16/009,547**	
FILED:	**June 15, 2018**	Examiner: **C. Fredrickson**
CASE NO.	**373499.00002**	Group Art Unit: **3783**

TITLE: **BREAST PUMP SYSTEM**

FILED ELECTRONICALLY ON January 12, 2021

MAIL STOP ISSUE FEE
COMMISSIONER OF PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO NOTICE TO FILE CORRECTED
APPLICATION PAPERS, DATED NOVEMBER 13, 2020

Sir:

This is in response to the Notice to File Corrected Application Papers, dated November 13, 2020, having a period for response set to expire on January 13, 2021.

Amendments to Figures 33, 36 and 44 are discussed on page 2 of this paper; Remarks begin on page 3 of this paper.

In the Drawings

Three (3) sheets of replacement drawings, containing Figures 33, 36 and 44 are submitted herewith. Figure 33 has been amended to correct the truncated/missing parts of the drawing. Figures 36 and 44 have been converted from photographs to line drawings in accordance with the Notice.

REMARKS

Three (3) sheets of replacement drawings, containing Figures 33, 36 and 44 are submitted herewith. Figure 33 has been amended to correct the truncated/missing parts of the drawing. Figures 36 and 44 have been converted from photographs to line drawings in accordance with the Notice. No new matter has been added by this amendment.

If there are any fees associated with this filing, kindly charge Deposit Account 50-4364.

Respectfully submitted,

Date: January 12, 2021 By /Mark D. Simpson/
Mark D. Simpson, Esq.
Reg. No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Email: Mark.Simpson@saul.com

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 11/25/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
11/25/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

Corrected ***Notice of Allowability***	**Application No.** 16/009,547	**Applicant(s)** O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	**Art Unit** 3783	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the IDS filed on 11/3/2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-6,8,10-21,23-34 and 37-40 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some *c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2017108555	WO	A1	2017-06-29	KONINKLIJKE PHILIPS N.V.		

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	Attorney Docket Number	373499.00002

	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	11/19/2020

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	3783
	Examiner Name	C. Fredrickson
	Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☑ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

✓ See attached certification statement.

✓ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2020-11-03
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 11/13/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
11/13/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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United States Patent and Trademark Office
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Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 16009547
Applicant : O'Toole
Filing Date : 06/15/2018
Date Mailed : 11/12/2020

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

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IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
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- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
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- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
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- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 33
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [X] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s) 36, 44
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

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Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

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	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)

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✓ See attached certification statement.

✓ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2020-11-03
Name/Print	Mark D Simpson	Registration Number	32942

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 June 2017 (29.06.2017)

W I P O | P C T

(10) International Publication Number
WO 2017/108555 A1

(51) International Patent Classification:
A61M 1/06 (2006.01) *A61M 1/00* (2006.01)

(21) International Application Number:
PCT/EP20 16/08 1109

(22) International Filing Date:
15 December 2016 (15. 12.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
15202295.0 23 December 201 5 (23. 12.2015) EP

(71) Applicant: **KONINKLIJKE PHILIPS N.V.** [NL/NL]; High Tech Campus 5, 5656 AE Eindhoven (NL).

(72) Inventors: **AALDERS, Arnold;** High Tech Campus 5, 5656 AE Eindhoven (NL). **VAN WIERINGEN, Arjan Teodor;** High Tech Campus 5, 5656 AE Eindhoven (NL). **EL BARAKAT, Hassan;** High Tech Campus 5, 5656 AE Eindhoven (NL).

(74) Agents: **VAN OUDHEUSDEN-PERSET, Laure E.** et al; Philips International B.V. - Intellectual Property & Standards High Tech Campus 5, 5656 AE Eindhoven (NL).

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on nextpage]

(54) Title: BREAST PUMP, METHOD AND COMPUTER PROGRAM

(57) Abstract: The present invention relates to a breast pump (1) for extracting milk from a female breast comprising an expression kit (2), a container (5) connected to the expression kit (2), and a vacuum unit (6) connected to the expression kit (2), wherein the combined volumes of the expression kit (2), the container (5), the vacuum unit (6) and the connections thereof define a system air volume, and a vacuum pressnre sensor for determining volnme changes in the system air volume in response to changes in vacuum pressure.

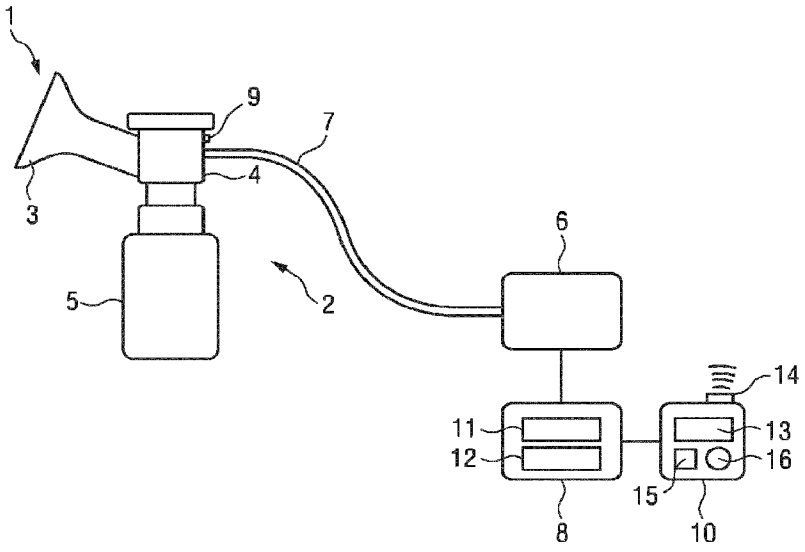


FIG.1

WO 2017/108555 A1

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(H))*

Published:

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Breast pump, method and computer program

FIELD OF THE INVENTION

The present invention relates to a breast pump with a functionality which allows monitoring of the milk expressed from a female breast during an expression session by way of a vacuum pressure sensor. The invention further relates to a method of determining the milk volume and to a computer program calculating a respective milk volume.

BACKGROUND OF THE INVENTION

WO 2010/095133 A1 refers to a device and a method for measuring an amount of breast milk suckled during a breastfeeding session, the device including a mechanism for determining the change in volume of a breast during the breastfeeding session (before breastfeeding and after breastfeeding), and a calculation unit for calculating therefrom the quantity of milk suckled during the breastfeeding session.

US 2015/01 12298 A1 discloses a breastfeeding device having a microprocessor having a memory embedded therein that can be pre-programmed to have a plurality of different sucking cycles interspersed with periodic pauses. These different cycles and pauses allow for an accurate modeling of a woman breastfeeding a child. In addition, this system and process can also result in a pre-programmable breastfeeding pump, which creates a preset time for initialization and a preset schedule of a series of events for breastfeeding over a period of time such as over a 24 hour or 30 hour period of time so that the user can automatically use the breast pump without having to use any of the keys on the keyboard of the device. In at least one embodiment, the device including any software which can be programmed thereon, is configured to mimic or model itself towards a suction pattern of a child.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved breast pump which allows easy monitoring the volume of milk expressed by the breast pump, thus ensuring a constant milk volume and avoiding premature drops in milk volume.

In a first aspect of the present invention a breast pump for extracting milk from a female breast is presented, comprising an expression kit, a container connected to the expression kit, and a vacuum unit connected to the expression kit, wherein the combined

volumes of the expression kit, the container, the vacuum unit and the connections thereof define a system air volume, a control unit for receiving a sensor signal of the vacuum pressure sensor and a processor for calculating a respective milk volume based on the sensor signal, and a vacuum pressure sensor configured to determine volume changes in the system air volume in response to changes in vacuum pressure.

In a further aspect of the present invention a method for determining the amount of milk expressed from a female breast by a breast pump is presented, comprising the step of determining volume changes in the system air volume in response to changes in vacuum pressure.

In yet a further aspect of the invention a computer program is presented comprising program code means for causing a computer to carry out the steps of the aforementioned method when said computer program is carried out on a computer.

Use of a sensor measuring the increase in vacuum pressure during expression is a very precise method for determining the milk volume expressed from a female breast. A lactating woman using the inventive breast pump has no effort in monitoring the milk volume, remembering the last session, accounting the sessions or making calculations by herself. Monitoring of the milk volume is carried out by the breast pump. The user is informed about the success of the expression and can relax thus making the expression even more effective. The use of a control unit allows effective monitoring of the milk volume based on a completely automatic process without the necessity of complicated operation by the user.

Preferred embodiments of the invention are defined in the dependent claims. It shall be understood that the claimed method has similar and/or identical preferred embodiments as the claimed device and as defined in the dependent claims.

Preferably the vacuum pressure sensor is arranged in the system air volume or is in air-ducting connection to the system air volume. By this arrangement the accuracy of the measurement is ensured.

According to a preferred embodiment of the invention a hygienic barrier, in particular a diaphragm with a porous membrane is arranged between the expression kit and the vacuum unit. By way of this a hygienic operation of the breast pump is possible without milk entering the pump unit. Thus the cleaning effort for the breast pump is restricted to the funnel and the hygienic barrier. The pump unit is not in contact with the milk and thus has not to be disassembled and cleaned.

The change in air volume is preferably defined by

$$\Delta V = (t_1 - t_2) * Q_0 \frac{p_{min}}{(p_{min} - p_0) Log \left[\frac{p_0 (p_1 - p_{min})}{p_1 (p_0 - p_{min})} \right]},$$

wherein pi is the sensor signal received from the vacuum pressure sensor () and wherein the parameters p_{min}, p_0 and Q_0 are known. This leaves the vacuum pressure being the only varible which has to be determined by the sensor. Any other parameter is known. The measurement thus is very precise and only depends on one source of potential error.

According to an embodiment of the invention the breast pump can further comprise a vacuum release valve. This release valve helps operating the breast pump with a hygienic barrier between the expression kit and the pump unit.

In an especially preferred embodiment of the invention the breast pump further comprises a flow sensor for measuring the milk flow from the expression kit to the container. This combination can improve accuracy of the measured values and thus of the calculated milk volume.

In an advantageous embodiment of the invention an orifice is arranged between the housing and the container. By way of the orifice, a delay in the evacuation of the container and a deviation from the expected target pressure is achived, thus resulting in a reduced power demand of the vacuum unit.

According to an alternative preferred embodiment a valve is arranged between the housing and the container, in particular a one-way-valve like a duck bill valve or a flap valve. The valve allows another possibility to reduce power consumption of the vacuum unit.

Advantageously, the valve is configured to close at a predetermined pressure difference between the housing and the container. Thus, the power demand of the vacuum source is reduced and further the milk volume expressed can be calculated based on a different parameter additionally to the change in vaccum pressure during expression.

Preferably the breast pump comprises a user interface including one or more of a display, a speaker, a vibrational element, an actuating element. An interface can convey information to the user of the breast pump thus calming the user down by reporting a successful session. Various possibilities to convey the information can include displaying parameters on a display, or emitting a vibrational or audio signal when a desired milk volume is exceeded. Actuating elements allow easy manipulation of the breast pump like turning the device on or off.

Advantageously the vacuum pressure sensor can be configured to determine pressure changes during a vacuum stroke of the vacuum unit, during a vacuum release stroke of the vacuum unit or in a single stroke modus.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiment(s) described hereinafter. In the following drawings

Fig. 1 shows a schematic view of a breast pump according to the invention,

Figs. 2A and 2B show a schematic view of an alternative embodiment of a breast pump according to the invention and a corresponding vacuum profile, and

Figs. 3A and 3B shows a shematic view of yet another embodiment of a breast pump according to the invention and a corresponding pressure diagram.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Fig. 1 shows in a very schematic illustration an embodiment of a breast pump 1 suitable for the invention. Lactating women need to regularly express milk to maintain a good milk supply. Without expressing milk regularly, the milk supply is liable to drop. For expressing milk from the female breast, commonly electric breast pumps 1 are used. The embodiment of the breast pump 1 comprises an expression kit 2 with a funnel 3 which is designed to receive a female breast therein. The funnel 3 is coupled to a housing 4, as is a container 5 which is to receive the milk expressed from the female breast.

A vacuum unit 6 is connected to the expression kit 2 by way of a pipe 7. The vacuum unit 6 exerts a suction force to the breast thus sucking milk from the breast by applying a vacuum to the nipple. This process is analogous to the sucking action of a baby during breast feeding.

Electrical breast pumps 1 can be split into two groups. One group of known breast pumps 1 is equipped with a hygienic shield between the vacuum unit 6 and the breast, while the other group lacks this feature. The latter ones comprise a one-way valve which can be housed in the housing 4 to avoid breast milk from flowing back to the funnel 3. Alternatively, the housing 4 can contain a diaphragm or membrane to establish a vacuum or air tight interface between the funnel 3 and the container 5 to prevent milk from entering the vacuum system. Most breast pumps 1 are equipped with a silicone membrane between the vacuum unit 6 and the breast. The vacuum produced by the vacuum unit 6 causes the membrane to move upwards, thereby expanding the air in the funnel 3 in which the breast is

positioned. This expansion creates the required vacuum at the breast for the expression of milk therefrom. When the vacuum is released the membrane will move to its rest position again. Thus the vacuum at the vacuum unit 6 is indirectly causing the vacuum at the breast.

When milk is expressed from the breast the milk flows through the funnel 3 via the housing 4 to the container 5. While the container 5 fills, air needs to escape since the available volume is filled by the expressed milk. This air will leak out of the container 5 via a leakage feature between the container 5 and the funnel 3.

A general problem of expressing milk by way of an electrical breast pump 1 is the effort a user has to take to keep count of the milk expressed from the breast. The invention is directed to a new way of determining the expressed milk volume without relying on or requiring the user inputting the amount of milk expressed herself.

Currently a lactation expert would require input from the user of an electric breast pump 1 to keep track of the success rate of the expression. The risk of the user forgetting to monitor the amount is quite high. Besides, the effort for keeping track is high. Due to this lack of correct milk volume data the user is at risk that the milk supply will drop, while the lactation expert is unable to correct the expression schedule timely. Further to this the lactating woman can be quite insecure about the milk supply she has. This insecurity can be relieved by giving feedback to the woman via the breast pump or its peripherals.

In the following the inventive concept that will enable the user to leave the administrative task of keeping track of expressed volume to the electric breast pump will be described.

To allow keeping track of the milk volume which is expressed during a session, a sensor is required which is arranged in the air volume of the breast pump 1. The air volume of the breast pump 1 is defined as the sum of the air volumes of the housing 4, the container 5, the vacuum unit 6 and the connecting pipes 7. Sensors known from the state of the art can e.g. be airflow sensors in the vacuum path or current measurement sensors on the electric motor of the vacuum unit 6. The present invention deals with a pressure sensor in the vacuum path. In the following description a vacuum pressure sensor which is preferably arranged in the housing 4 or in the vacuum unit 6, in any case however in the vacuum air volume or in air-ducting connection herewith, is described.

The basic measurement principle behind the calculation is the observation that in a closed volume of air the pressure will rise when fluid entering the system displaces air. When milk from the female breast fills the container 5, the air in the system will be compressed resulting in a higher pressure. The increase of the pressure is a measure for the

milk volume entering the system. To calculate the milk volume the performance of the vacuum unit 6 should be known. Generally, the flow-pressure curve of a vacuum unit is typically part of the specifications of the vacuum unit 6 and thus known as such, but the curve can also be determined during production. Especially the latter method will result in a very precise curve and thus in very precise measurements later.

The invention can be used for breast pumps with a hygienic barrier in form of a membrane or diaphragm as well as for breast pumps without a hygienic barrier between the milk and the vacuum unit. However, the use of a closed system with a hygienic diaphragm will be easier to handle due to the closed air volume inside the breast pump 1. Open systems can be handled, too, when the vacuum has been built up and the system is closed to the environment by air-tight placement of the breast in the funnel 3. The values measured by the vacuum pressure sensor can then be used to determine the air volume in the system which in turn is dependent on the milk volume expressed from the female breast and collected in the container 5.

The thus determined amount of milk can be stored in a control unit 8 which is connected to the vacuum unit 6. To improve the effectiveness of expression, the values can be conveyed to the user of the breast pump 1 e.g. by way of a user interface 10 or via a connection to a separate device (not shown) e.g. via wireless connection to the cloud or to a smart device like a mobile phone. To see the expression session being successful will calm down the user and help to make the session even more effective by inducing a relaxed feeling and security about the success. The user interface 10 can for example comprise a display 13 to show the amount of milk expressed during the session, a speaker 14 for a voice feedback, a vibrational unit 15 for a vibrational signal e.g. announcing a certain milk volume which has ben expressed, and one or more actuating elements 16 like a Start-/Stop-button.

In the preferred embodiment according to Fig. 1, a vacuum/air tight interface between the funnel 3 and the container 5 is described exemplary. A one-way valve is not necessary. Instead, the system will contain a vacuum release valve 9 which can for example be integrated in the housing 4. The breast pump 1 comprises a porous membrane as a hygienic barrier to prevent breast milk from entering the vacuum pump. The membrane can also be housed in the housing as described above. The vacuum pressure sensor is arranged between the porous membrane and the vacuum unit 6. For example, the vacuum pressure sensor can be arranged in the housing 4, in the pump unit 6 or in the connecting pipe 7.

At the start of the expression session, the vacuum unit 6 is operated in a stimulation phase with short vacuum cycles. This is physiologically necessary to stimulate

the milk flow. The vacuum pressure sensor will measure the change of the vacuum pressure, which will increase during this phase. This value can directly be used to calculate a vacuum system air volume or starting volume.

After the stimulation phase the milk begins to flow and fills the container 5. By this, the speed of increase of the vacuum will rise because the dead air volume contained in the breast pump 1 is decreased. While the speed of increase of the vacuum is a measure of the dead volume, the difference between the start volume and the current volume is a measure for the expressed amount of milk.

The mathematics involved is not very complex but requires a processor 11 in form of a microcontroller with mathematic capabilities for log calculations. The processor 11 is preferably arranged in the control unit 8. It can communicate with the vacuum pressure sensor in the breast pump 1 and with a storage unit 12 which is preferably also housed in the control unit 8.

As a starting point for the mathematics the breast pump 1 can be interpreted as a pump unit 6 emptying an unknown volume V. The parameters of the pump unit 6 are known and are idealized as a linear Q-H curve defined by its maximum flow rate Q_0 (in m^3/s) and p_{mm} (in Pa). This leads to the following equation which can be rewritten to a ordinary differential equation (ODE):

$$\frac{dp}{dt} = \frac{da.}{\Lambda} \frac{HI^{*}}{\mathbf{V}}$$

$$\frac{dm}{dt} = Q(p)\rho\frac{RT}{V} = Q(p)\frac{p}{RT}$$

$$Q(p) \approx -Q_0\frac{p - p_{min}}{p_0 - p_{min}}$$

It is to be noted that Q(p) is negative due to flow going out. From this follows:

$$\frac{dp}{dt} = -\frac{Q_0}{\mathrm{V}}\frac{p(p - p_{mm})}{p_0 - p_{mm}}$$

The ODE can be solved which leads to:

$$p(t) = p_{min}\left(1 + \frac{p_0 - p_{min}}{p0\left(e^{\frac{p_{min}Qn^t}{V(p_0 - p_{min})}} - 1\right) + p_{min}}\right).$$

In the ODE, the following values are present: m = mass, p = density, V = volume, Q = flow rate, p = pressure, t = time. p_{min} is given by the pump unit's 6 characteristic, as is Qo. po denotes the pressure in the beginning and is assumed to be known.

If a vacuum pressure sensor is present it is now possible to measure the time ti to a certain required vacuum level pi at the start when there is definitely no milk in the container 5. Using this measurement it is possible to calculate the empty volume Vi as follows:

$$V_1 = t_1 * Q_0 \frac{p_{min}}{(p_{min} - p_0) Log\left[\frac{p_0}{p_1}\frac{(p_1 - p_{min})}{(p_0 - p_{min})}\right]}.$$

During expression the air volume will reduce as milk is entering the container 5. It is now possible to measure the time needed t_2 to get to the same required vacuum level (which will be quicker) and calculate the new volume. However it is also possible to calculate directly the volume difference dV:

$$\Delta V = (t_1 - t_2) * Q_0 \frac{p_{min}}{(p_{min} - p_0) Log\left[\frac{p_0}{p_1}\frac{(p_1 - p_{min})}{(p_0 - p_{min})}\right]}.$$

A control loop for determining the milk volume could be implemented by measuring multiple vacuum profiles/cycles. This will increase the accuracy because errors are averaged out. The disadvantage of this is that the vacuum profile that is expected will deviate more from the profile that is generated (correcting will take multiple cycles).

Besides this the control loop could be implemented within one vacuum cycle. The control loop would compare a predetermined vacuum profile with the error measured between the expected and the real vacuum. The advantage of this control principle is that the user is less aware of the measurement that is going on, while the vacuum profile is what is expected.

The combination of a vacuum pressure sensor with a flow sensor could improve the accuracy of the measurement, while the variation in pump behavior (flow-pressure curve) and the variation in pressure drop over the porous membrane could be eliminated from the equation.

One of the error factors will be the breast/nipple. The nipple will act somewhat elastic and visco-elastic, but the effect is relative small. An exemplary start volume can be in the order of 175ml of which 50ml are dead volume and 125ml in the empty container 5. The elastic behavior of the nipple will result in a 2ml volume error which can be partially compensated while it is quite standard. The visco-elastic behavior will result in an additional 2ml volume error, also this can be estimated and partially compensated. The milk volume expected is in the order of 75ml. This results in an error of 1...5%.

While measuring the vacuum stroke is preferred, the measurement could also be performed in the vacuum release stroke. For a multiple stroke pump unit 6 this stroke is typically very short and therefore the accuracy is likely to be smaller. Nevertheless it is possible to measure a vacuum release pressure-time curve. The air volume and therefor also the milk volume information is also part of the sensor signal. The release of the vacuum is typically achieved via a known air restriction. A large air volume corresponding to a small milk volume will result in a slow vacuum release, while a small air volume corresponding to a large milk volume will result in a fast vacuum release. To increase the resolution of this measurement the restriction can temporarily be made quite small leading to a higher resolution.

Figs. 2A, 2B, 3A and 3B show two alternative embodiments of the invention which are based on the principle of measurement of the changes in vacuum pressure. Both embodiments use a breast pump 1 which has a hygienic barrier 21 to prevent breast milk from entering the vacuum system. The breast pumps 1 each comprise a funnel 3, a housing 4 and a container 5 as decribed previously with reference to Fig. 1. The breast pumps 1 further are connected to a vacuum unit 6 via a connecting pipe 7. In the connecting pipe 7, a release valve 9 and a pressure sensor 17 and a flow sensor 18 are present. Alternatively, the release valve can be arranged in the vacuum unit 6.

In contrast to Fig. 1, where the container 5 had to be evacuated to the same vacuum level as a chamber 22 at the breast 23 in the funnel 3, the embodiments according to Figs. 2A and 3A provide a solution which allows a minor vacuum at the container 5, which results in a decrease in power demand at the vacuum source.

In Fig. 2A, a small inlet orifice 19 is provided at the entry of the container 5. The small inlet orifice 19 causes a delay in the vacuum of the container 5. This delay will result in a deviation from the expected target vacuum value. The deviation is then a measure for the amount of milk in the container 5.

Fig. 2B shows a respective diagram of the pressure measured at the breast 23 in the chamber 22, which is represented by the lower of the two curves of Fig. 2B. The upper curve represents the pressure in the container 5. The latter does not reach the base line of Fig. 2B representing the expected target pressure. Thus, the power demand per cycle is not as high as in the breast pump 1 according to Fig. 1.

In Fig. 3A, another alternative embodiment is shown which features a duck bill valve 20 instead of the small inlet orifice 19 of Fig. 2B. The duck bill valve 20 is configured to close at a pressure difference of e.g. approximately 10 mbar. During the time in which the vacuum source 6 evacuates the chamber 22 in the funnel 3 and the container 5, the milk volume is measured. Due to the duck bill valve 20 also containing an orifice, a pressure difference will occur between the breast chamber 22 and the container 5 which will cause the duck bill valve 20 to close. Thus, after the valve 20 is closed, only the breast chamber 22 has to be evacuated. As soon as the vacuum is released, the duck bill valve 20 opens again. The time required to reset the vacuum system of breast pump 1 to atmospheric pressure is a measure for the milk volume in the container 5.

The vacuum diagram of Fig. 3B shows the pressure difference at which the duck bill valve 20 is closed. The resulting vacuum is significantly lower than the expected vacuum level without closed valve 20. The resulting power demand for the vacuum unit 6 is lower, thus resulting in less wear, less noise and less power consumption. Alternatively, also a flap valve may be used.

Alternatively to these preferred embodiments the invention can also used with a single stroke principle that does not use a release valve. This would require a large stroke volume to compensate for the dead volume in the container 5. Besides, the breast pump 1 can be operated without a silicone hygienic barrier as mentioned above. The silicone hygienic barrier will need to make quite a large stroke to compensate for the large dead volume in the container 5 when empty. With a silicone hygienic barrier the milk volume and the pressure in the pipe 7 at the pump unit 6 side has a direct link to the pressure in the funnel 3 via the stiffness of the silicone hygienic barrier.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or

exemplary and not restrictive; the invention is not limited to the disclosed embodiments. Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims.

In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single element or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

A computer program may be stored/distributed on a suitable medium, such as an optical storage medium or a solid-state medium supplied together with or as part of other hardware, but may also be distributed in other forms, such as via the Internet or other wired or wireless telecommunication systems.

Any reference signs in the claims should not be construed as limiting the scope.

CLAIMS:

1. Breast pump (1) for extracting milk from a female breast comprising:

- an expression kit (1),
- a container (2) connected to the expression kit (2), and
- a vacuum unit (6) connected to the expression kit (2),

wherein the combined volumes of the expression kit (2), the container (5), the vacuum unit (6) and the connections thereof define a system air volume,

- a vacuum pressure sensor, and

a control unit (8) for receiving a sensor signal of the vacuum pressure sensor and a processor (11) for calculating a respective milk volume based on the sensor signal, wherein the vacuum pressure sensor is configured to determine volume changes in the system air volume in response to changes in vacuum pressure.

2. Breast pump (1) according to claim 1, wherein the vacuum pressure sensor is arranged in the system air volume or is in air-ducting connection to the system air volume.

3. Breast pump (1) according to claim 1 or 2, wherein a hygienic barrier, in particular a diaphragm with a porous membrane is arranged between the expression kit (2) and the vacuum unit (6).

4. Breast pump (1) according to one of the preceding claims, wherein the change in the system air volume is defined by

$$\Delta V = (t_1 - t_2) * Q_0 \frac{p_{min}}{(p_{min} - p_0) Log\left[\frac{p_0}{p_1}\frac{(p_1 - p_{min})}{(p_0 - p_{min})}\right]},$$

wherein pi is the sensor signal received from the vacuum pressure sensor and wherein the parameters pmin, p0 and Q0 are known.

5. Breast pump (1) according to any of the preceding claims, further comprising a vacuum release valve (9).

6. Breast pump (1) according to any of the preceding claims, further comprising a flow sensor for measuring the milk flow from the expression kit (2) to the container (5).

7. Breast pump (1) according to one of the preceding claims, wherein an orifice (19) is arranged between the housing (4) and the container (5).

8. Breast pump (1) according to one of the preceding claims, wherein a valve (20) is arranged between the housing (4) and the container (5), in particular a one-way-valve like a duck bill valve or a flap valve.

9. Breast pump according to claim 8, wherein the valve (20) is configured to close at a predetermined pressure difference between the housing (4) and the container (5).

10. Breast pump (1) according to any of the preceding claims, further comprising a user interface (10) including one or more of a display (13), a speaker (14), a vibrational element (15), an actuating element (16).

11. Breast pump (1) according to any of the preceding claims, wherein the vacuum pressure sensor is configured to determine pressure changes during a vacuum stroke of the vacuum unit (6), during a vacuum release stroke of the vacuum unit (6) or in a single stroke modus.

12. Method for determining the amount of milk expressed from a female breast by a breast pump (1) according to any of the preceding claims, comprising the step of determining volume changes in the system air volume in response to changes in vacuum pressure.

13. Computer program comprising program code means for causing a computer to carry out the steps of the method as claimed in claim 12 when said computer program is carried out on a computer.

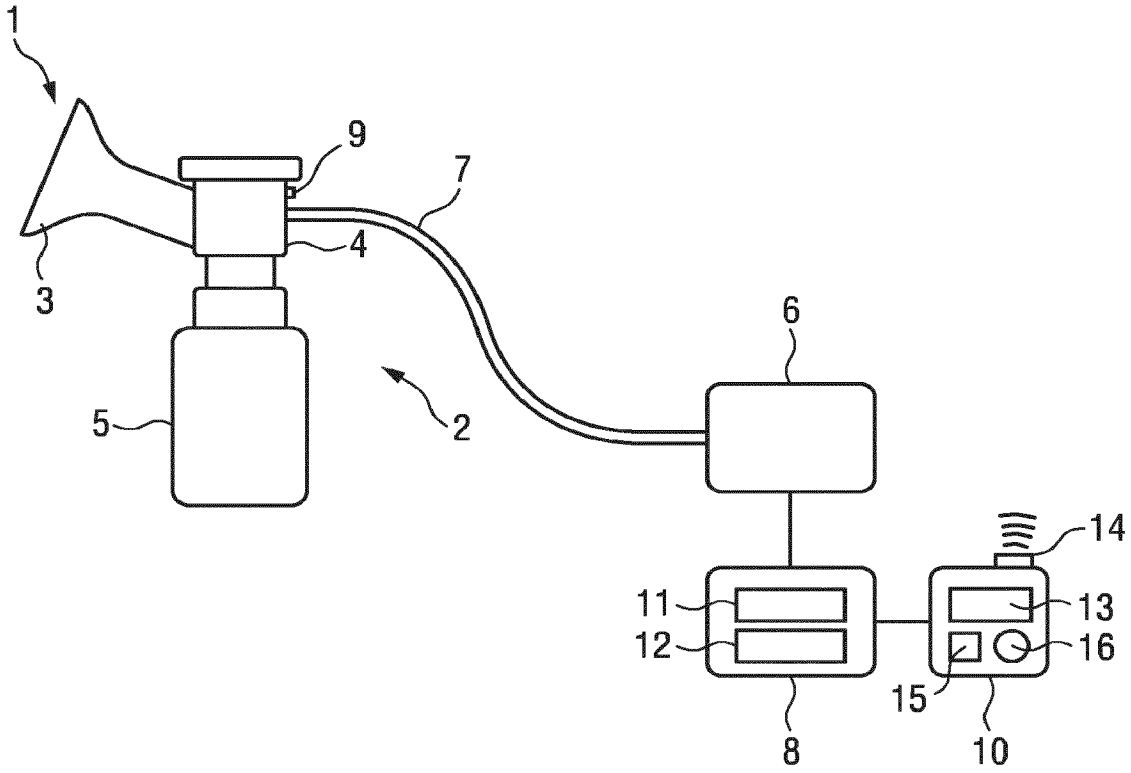


FIG.1

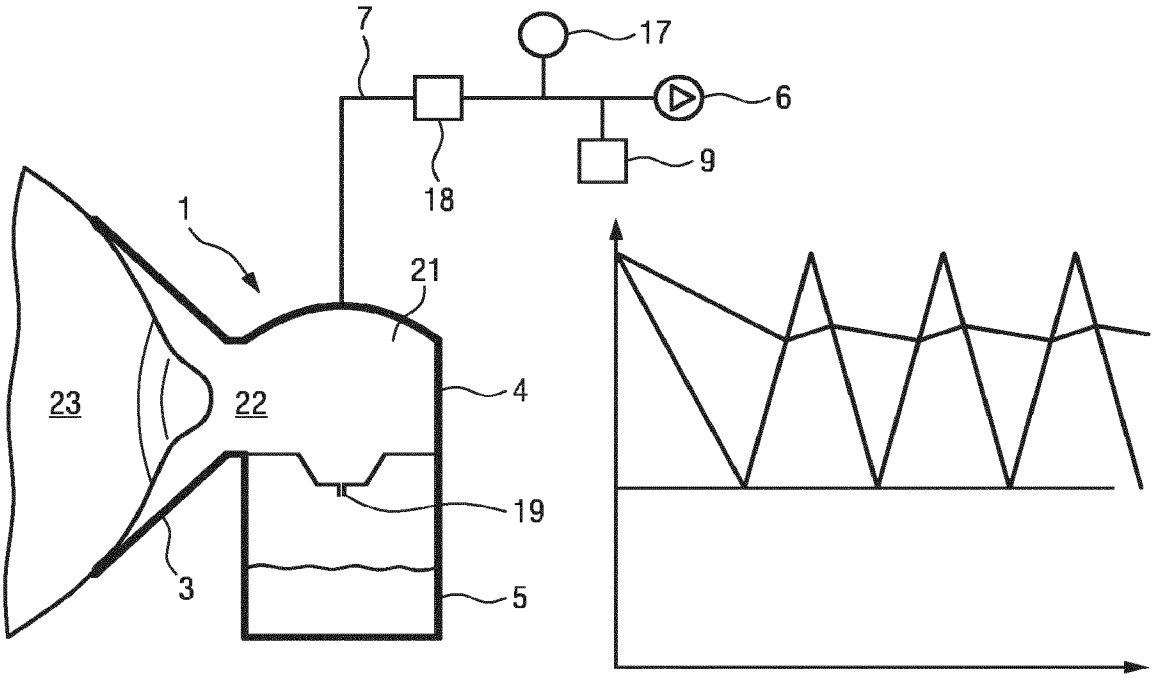


FIG.2A

FIG.2B

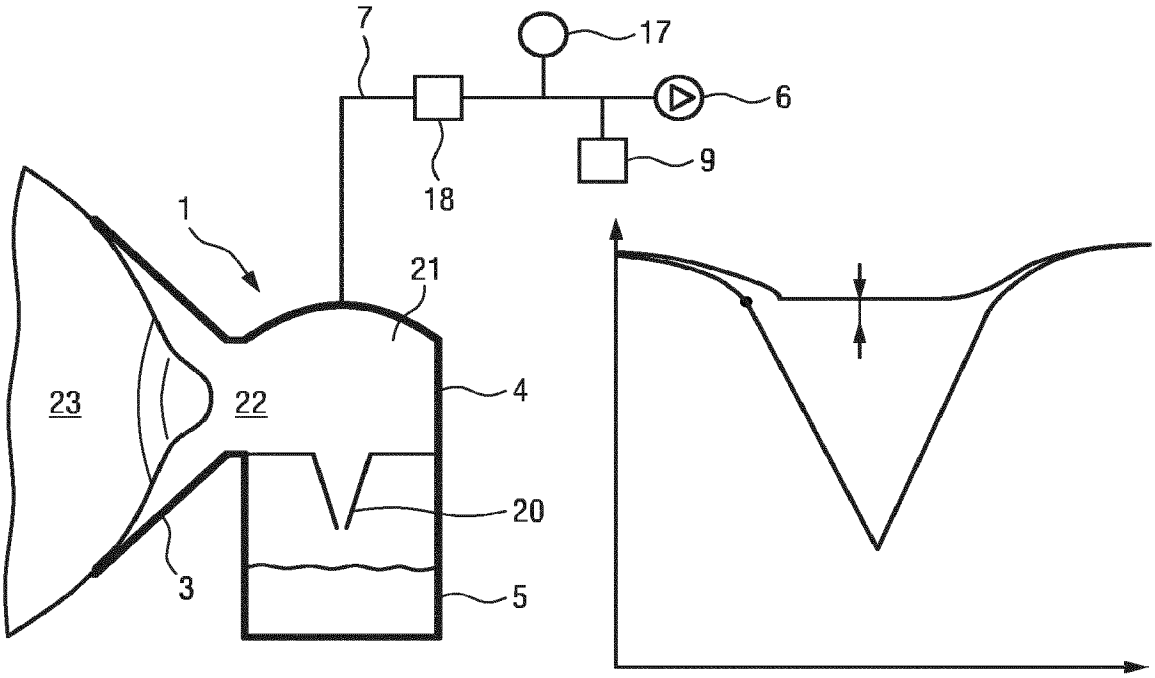


FIG.3A

FIG.3B

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081109

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/095133 A1 (INNOVIA MEDICAL LTD [IL]; HARARI TZACH [IL]; HULLER-HARARI LIAT [IL];) 26 August 2010 (2010-08-26) cited in the application	1-6, 10-13
Y	page 11, line 21 - page 17, line 25 figures 1, 12, 13, 15 pages 6, 16-21	7-9

X,P	WO 2016/014469 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) paragraphs [0135] - [0144], [0219] - [0222] figures 1, 2	1, 12, 13

X,P	WO 2016/014488 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) paragraphs [0154], [0184] - [0185] figures 1, 2, 20	1, 12, 13

	-/-	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" documentwhich may throw doubts on priority claim(s) orwhich is cited to establish the publication date of another citation or other special reason (as specified)

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search	Date of mailing of the international search report
14 February 2017	21/02/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2015/120321 A1 (NAIA HEALTH INC [US]) 13 August 2015 (2015-08-13)	7-9
A	paragraphs [0089] - [0097] figures 11c, d	1,12,13
A	US 2015/112298 A1 (PIRZADA SHAHZAD SAAD [US] ET AL) 23 April 2015 (2015-04-23) cited in the application paragraphs [0017] [0020], [0042] [0046] figures 1, 2, 8-10	1,12,13

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/081109

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2010095133 A1	26-08-2010	EP 2398384 A1	28-12-2011
		US 2012004603 A1	05-01-2012
		WO 2010095133 A1	26-08-2010
WO 2016014469 A1	28-01-2016	CA 2955939 A1	28-01-2016
		US 2016206794 A1	21-07-2016
		US 2016287769 A1	06-10-2016
		US 2016303298 A1	20-10-2016
		US 2016310649 A1	27-10-2016
		US 2016310650 A1	27-10-2016
		WO 2016014469 A1	28-01-2016
WO 2016014488 A1	28-01-2016	NONE	
WO 2015120321 A1	13-08-2015	AU 2015213782 A1	18-08-2016
		CA 2938435 A1	13-08-2015
		EP 3102023 A1	14-12-2016
		WO 2015120321 A1	13-08-2015
US 2015112298 A1	23-04-2015	US 2015112298 A1	23-04-2015
		WO 2013166462 A1	07-11-2013

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

78905 7590 10/15/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Lynn M. White	(Typed or printed name)
/Lynn M. White/	(Signature)
3 November 2020	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

TITLE OF INVENTION: BREAST PUMP SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	01/15/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FREDRICKSON, COURTNEY B	3783	604-067000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Saul Ewing Arnstein & Lehr LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: CHIARO TECHNOLOGY LIMITED

(B) RESIDENCE: (CITY and STATE OR COUNTRY): London, UNITED KINGDOM

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ☒ Corporation or other private group entity ❑ Government

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge ~~the required fee(s)~~, any deficiency, or credit any overpayment to Deposit Account No. 504364

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Mark D. Simpson/ Date 3 November 2020

Typed or printed name Mark D. Simpson Registration No. 32942

Electronic Patent Application Fee Transmittal

Application Number:	16009547
Filing Date:	15-Jun-2018
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**730**

Electronic Acknowledgement Receipt

EFS ID:	41018936
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	03-NOV-2020
Filing Date:	15-JUN-2018
Time Stamp:	10:40:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$730
RAM confirmation Number	E2020A3A40263480
Deposit Account	504364
Authorized User	Lynn White

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	37678168_1.PDF	1037030 2cbf701b7ed5190922930ac3a76fe4141043d9d1	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Foreign Reference	37678034_1.PDF	912521 0e671894b948d82e47de12d3c66ce51a2ba6a475	no	20
Warnings:					
Information:					
3	Non Patent Literature	37678027_1.PDF	2891413 aa95ca34da8d52a47092cd17a34e881e7680e813	no	10
Warnings:					
Information:					
4	Issue Fee Payment (PTO-85B)	37678217_1.PDF	94999 3e7ed8ba72a3b33a18f5e2b2d36095950518d472	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	32044 76022c7bb6560b0a5ea737d141c91a86b26617f2	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4968007		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

78905 7590 10/15/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER
FREDRICKSON, COURTNEY B

ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 10/15/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

TITLE OF INVENTION: BREAST PUMP SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	01/15/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

78905 7590 10/15/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

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(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

TITLE OF INVENTION: BREAST PUMP SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	01/15/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FREDRICKSON, COURTNEY B	3783	604-067000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 10/15/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 10/15/2020

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/009,547	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the amendment filed on June 22, 2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some *c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783

Continuation of 3. The allowed claim(s) is/are: 1-6,8,10-21,23-34 and 37-40

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Mark Simpson on September 30, 2020.

The application has been amended as follows:

Amend **claim 1, line 4** as follows:

"...having a front surface that is configured [[showed, in use,]] to fit inside a bra...

Amend **claim 1, line 10** as follows:

"...in the rear surface of the housing [[thehousing]]"

Amend **claim 1, the last 3 lines** as follows:

"which the diaphragm fully separates [[the]] a piezo air pump side from [[the]] a milk side, preventing any contamination of the milk by eliminating contact with the piezo air pump [[system]]; and preventing any contamination of the piezo air pump system by any milk."

Amend **claim 33, line 2** as follows:

"…is a single element [[moulding]] that…"

Amend **claim 37** as follows:

"the breast shield includes a generally cylindrical or tube shaped nipple tunnel shaped to receive a nipple, and in which the diaphragm is a generally flat diaphragm that is seated against a [[generally flat]] diaphragm holder that is formed as the recess in the rear surface of the housing, the [[flexible]] deformable diaphragm [[flexing]] deforming in response to changes in air pressure caused by the closed loop system [[piezo air-pump]] to create negative air pressure in the nipple tunnel."

Amend **claim 38** as follows:

"in which the [[generally flat]] diaphragm holder and associated generally flat diaphragm lie over [[the]] a top of the nipple tunnel and do not surround the nipple tunnel."

Amend **claim 39, line 2** as follows:

"…beyond an [[the]] end of a nipple…"

Allowable Subject Matter

Claims 1-6, 8, 10-21, 23-34, and 37-40 are allowed over the prior art of record.

The following is an examiner's statement of reasons for allowance: The claims in this application are allowed because the prior art of record fails to disclose either singly or in combination the claimed breast pump system.

The closest prior art of record is Khalil (US 20150023821).

Regarding independent claim 1, Khalil fails to teach among all the limitations or render obvious a diaphragm being removably mounted against a recess in the rear surface of the housing, in combination with the total structure and function as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached on Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	16/009,547	O'TOOLE et al.	
	Examiner	Art Unit	AIA (FITF) Status
	COURTNEY FREDRICKSON	3783	Yes

All participants (applicant, applicant's representative, PTO personnel):

(1) COURTNEY FREDRICKSON. (3) _____.

(2) Mark Simpson. (4) _____.

Date of Interview: 30 September 2020.

Type: ☑ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☑ No.
If Yes, brief description: _____.

Issues Discussed ☐ 101 ☑ 112 ☐ 102 ☐ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1,33 and 37-39.

Identification of prior art discussed: None.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

The Examiner initiated an interview to discuss minor outstanding claim objections and 112 issues. After discussing with the inventor, Applicant's representative authorized the Examiner to enter the proposed amendments via Examiner's amendment to pass the application to allowance..

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M 1/062, 1/066, 1/06, 1/066, 1/068	8/25/2018	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See EAST search history	8/25/2018	cbf
Searched inventors in PALM and EAST	8/25/2018	cbf
Updated search	03/14/2019	cbf
Updated search	08/09/2019	cbf
Updated search	01/15/2020	cbf
Updated search	09/30/2020	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see EAST search history	09/30/2020	cbf

/JASON E FLICK/ Primary Examiner, Art Unit 3783	/COURTNEY FREDRICKSON/ Examiner.Art Unit 3763

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/25/2018	03/14/2019	08/09/2019	01/15/2020	09/30/2020				
1	1	✓	✓	✓	✓	✓				
2	2	✓	✓	✓	✓	✓				
3	3	✓	✓	✓	✓	✓				
4	4	✓	✓	✓	✓	✓				
5	5	✓	✓	✓	✓	✓				
6	6	✓	✓	✓	✓	✓				
	7	✓	✓	✓	-	-				
7	8	✓	✓	✓	✓	✓				
	9	✓	✓	✓	-	-				
8	10	✓	✓	✓	✓	✓				
9	11	✓	✓	✓	✓	✓				
11	12	✓	✓	✓	✓	✓				
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	22	✓	-	-	-	-				
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29	32				✓	✓				
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	35				✓	-				
	36				✓	-				
32	37					✓				
33	38					✓				
34	39					✓				
35	40					✓				

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					**Type**	**Version**
A61M	/	1	/	062	F	2014-02-04
A61M	/	1	/	066	I	2013-01-01
G16H	/	40	/	63	I	2018-01-01
A61M	/	1	/	06	I	2013-01-01
A41C	/	3	/	04	A	2013-01-01
A61J	/	9	/	00	A	2013-01-01
A61M	/	39	/	223	A	2013-01-01
A61M	/	39	/	24	A	2013-01-01
A61M	/	2205	/	07	A	2013-01-01
A61M	/	2205	/	10	A	2013-01-01
A61M	/	2205	/	3313	A	2013-01-01
A61M	/	2205	/	3327	A	2013-01-01
A61M	/	2205	/	3334	A	2013-01-01
A61M	/	2205	/	3344	A	2013-01-01
A61M	/	2205	/	3389	A	2013-01-01
A61M	/	2205	/	3553	A	2013-01-01
A61M	/	2205	/	3584	A	2013-01-01
A61M	/	2205	/	3606	A	2013-01-01
A61M	/	2205	/	502	A	2013-01-01
A61M	/	2205	/	505	A	2013-01-01
A61M	/	2205	/	52	A	2013-01-01
A61M	/	2205	/	581	A	2013-01-01
A61M	/	2205	/	582	A	2013-01-01
A61M	/	2205	/	583	A	2013-01-01
A61M	/	2205	/	584	A	2013-01-01
A61M	/	2205	/	587	A	2013-01-01
A61M	/	2205	/	6054	A	2013-01-01
A61M	/	2205	/	702	A	2013-01-01
A61M	/	2205	/	7536	A	2013-01-01
A61M	/	2205	/	80	A	2013-01-01
A61M	/	2205	/	8206	A	2013-01-01

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783 (Assistant Examiner)	30 September 2020 (Date)	**Total Claims Allowed:** 35	
/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783 (Primary Examiner)	01 October 2020 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					**Type**	**Version**
A61M	/	2209	/	082	A	2013-01-01
A61M	/	2209	/	088	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	30 September 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	35	
/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783	01 October 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20200930

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61M	/	1	/	06

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	30 September 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	35	
/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783	01 October 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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	7	14	16	22	25	31	34								
7	8	15	17	23	26		35								
	9	16	18	24	27		36								

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	30 September 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	35	
/NATHAN R PRICE/ Supervisory Patent Examiner, Art Unit 3783	01 October 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office Part of Paper No.: 20200930

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	57,377	breast.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:16
L2	398,558	pump$4.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:16
L3	92,405	(piezo piezoelectric).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:16
L4	72,010	diaphragm.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:17
L5	26,553	(db decibal).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:17
L6	27,368	(db decibal).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/09/30 15:17
L7	2	1 and 2 and 3 and 4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:17

L8	2	1 and 2 and 3 and 7	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/30 15:17
S1	65	("20020193731" | "20040056641" | "20040074281" | "20040267215" | "20050219302" | "20060122575" | "20070051172" | "20070051727" | "20080262420" | "20120277636" | "20140052056" | "20150217036" | "20150217037" | "20150283311" | "20160000980" | "20160058929" | "20160082165" | "20160082166" | "20160151551" | "20160158424" | "20160206794" | "20160220743" | "20160220745" | "20160287767" | "20160296681" | "20160310650" | "20170021068" | "20170035951" | "20170143879" | "20170220753" | "20180021490" | "2849881" | "4390024" | "5474683" | "5941847" | "5973770" | "6045529" | "6090065" | "6383163" | "6440100" | "6461324" | "6547756" | "6579258" | "6663587" | "6749582" | "7048519" | "7201735" | "7312554" | "7314400" | "7776008" | "8057425" | "8118772" | "8187227" | "8262606" | "8282596" | "8376986" | "8702646" | "8801495" | "8876760" | "8926556" | "9033913" | "9173587" | "9345274" | "9539377" | "D548831").PN.	US-PGPUB; USPAT	OR	OFF	2018/08/07 13:17
S2	214	(jonathan near3 o'toole).inv. (adam near3 rollo).inv. (andrew near3 carr).inv.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:42
S3	63	(a61m1/062 a61m1/066 a61m1/06).cpc. and piezo$9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:45
S4	19	("20040122358" | "20060226108" | "20080077042" | "20080167579" | "20120004603" | "3895533" | "4024856" | "4338953" | "5347656" | "5666104" | "5827191" | "7316653" | "7621797" | "7794425" | "8308648" | "8777864" |	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:50

		"8801658" | "8827911").PN. OR ("8992445").URPN.				
S5	7	("5730139" | "6423010" | "6602199" | "7479154" | "8206414" | "8425426" | "8992445").PN. OR ("9192325").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:59
S6	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:16
S7	3,369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S8	2,787	(a61m1/062 a61m1/066 a61m1/06).cpc. not S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S9	45	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$).did. or (WO-2015174330-$ or WO-2016024558-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 14:59

S10	14	S9 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:59
S11	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 15:04
S12	143	a61j13/00.cpc.	US-PGPUB; USPAT	OR	OFF	2018/08/10 10:30
S13	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:30
S14	3,369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:43
S15	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S16	0	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S14)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S17	2,665	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S13)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S18	71	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 11:47

		US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$).did.				
S19	37	S18 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:48
S20	4	S18 and ((air with pump$4) same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:50
S21	16	S18 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/10 12:15

			FPRS; EPO; JPO			
S22	1	S18 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:40
S23	0	a61m1/1058.cpc. and breast and diaphragm	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:42
S24	5	breast same pump$4 same piezo$8 same air	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:43
S25	1	("9884172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/10 13:58
S26	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 08:40
S27	2	"59563385".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S28	1	"59563425".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S29	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:26

		US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S30	44	S29 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:26
S31	17	S29 and (pump$4 with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:27
S32	51	S26 and "air pump"	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/24 11:07

			FPRS; EPO; JPO			
S33	4	"47900902".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:13
S34	10	("20030212374" | "20050251089" | "20050283900" | "20070135778" | "20110054389" | "3084691" | "4229029" | "5295957" | "6070659").PN. OR ("9511176").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/24 11:16
S35	2	"51149640".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:17
S36	271	S26 and (control$4 same select$4 left same right same breast)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 12:50
S37	3	S29 and (recharg$4 with battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 13:04
S38	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S39	9	S38 and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S40	11	S38 and (light with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:48
S41	0	S38 and (radiation with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/24 14:51

			FPRS; EPO; JPO			
S42	2	S38 and (radiation same milk same (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S43	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S44	10	S43 and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S45	1	a61m1/1058 and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S46	27	a61m1/1058.cpc. and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S47	23	S43 and (indicator same milk same (express$4 flow$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:26
S48	51	S43 and (air same pressure same sens$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:30
S49	19	S43 and ((indicat$4 record$4) same (right and left))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/24 19:38

			FPRS; EPO; JPO			
S50	56	S43 and (pump$4 with series)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:42
S51	77	S43 and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:47
S52	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 19:59

		9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S53	44	S52 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S54	5	S53 and (air with filter$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S55	3	S43 and (pump$4 with (db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S56	6	S43 and ((db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S57	26	S43 and (sens$4 with (orientation angle tilt placement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:16
S58	9	S43 and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:31
S59	484	a61m$/$.cpc. and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB;	OR	OFF	2018/08/24 20:32

			USPAT; USOCR; FPRS; EPO; JPO			
S60	1	S43 and "social media"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:52
S61	408	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:13
S63	3,606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:18
S64	359	a61m$/$.cpc. and ((pump$4 with weigh$4) same (portable lightweight carry$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:30
S65	1	("20160166745").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:16
S66	1	("20160058928").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:23
S67	1	("20110004154").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/26 10:55
S68	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 11:09

		US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S69	2	S68 and (radiation same (height quantity amount volume))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 11:09

S70	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 12:24

		or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S71	3	S70 and ((diaphragm membrane) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 12:24
S72	3,606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S73	137	S72 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S74	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S75	9	S74 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S76	19	S74 and (shield with snap$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:16
S77	1	("20110152855").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 13:20
S78	32	S74 and (flow with rate with air)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:33

S79	3	S74 and (stall with pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:56
S80	98	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 13:56

		6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S81	17	S80 and (pressure same (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:57
S82	18	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 14:08
S83	0	S82 and breast	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S84	10	S82 and (lactat$3 milk)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S85	14	S80 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:10
S86	5	S74 and ((piezo piezoelectric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:47

S87	230	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:48
S88	6	S87 and (breast milk lactat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:53
S89	161	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:11
S90	0	(2017/0072118).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S91	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S92	40	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:22
S93	3	"45513973".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 15:23
S94	364	(((piezo piezoelectric) with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:32
S95	3	"20170035951"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:33

S96	1	S95 and (suction$4 with piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:34
S97	1	("20130064683").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:38
S98	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:39
S99	1	(US-20170172485-$).did.	US-PGPUB	OR	OFF	2018/08/28 16:48
S100	0	S99 and "function of"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 16:48
S101	100	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/28 17:19

		US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S102	0	S101 and ((meaur$4 with milk) same rate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S103	0	S101 and ((meaur$4 with milk) same (frequency speed))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S104	16	S101 and ((measur$4 with milk) same (frequency speed rate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:21
S105	0	S101 and ((measur$4 with milk) with "function of")	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/28 17:23

			FPRS; EPO; JPO			
S106	6	S101 and (decrease with (rate speed frequency strong))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:10
S107	2	S101 and (latch$4 with adjust$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:22
S108	50	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:24
S109	0	(a61m$/$).cpc. and (wear$4 with pump$4) and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:25
S110	83	(a61m$/$).cpc. and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:26
S111	101	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 09:43

		or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S112	3	S111 and (shield with (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:43
S113	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:47

S114	86	S113 and ((diapragm housing) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:53
S115	9	S113 and ((diapragm membrane) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:54
S116	34	S111 and (diaphragm membrane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:07
S117	28	S113 and (diaphragm membrane) and (shield with dispos$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:10
S118	28	S113 and ((diaphragm membrane) with (coupl$4 attach$4 mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:23
S119	0	a61j16/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:41
S120	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:42
S121	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23

S122	23	S121 and (sens$4 same (orient$4 plac$4 situat$4) same (nipple shield))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S123	11	S121 and ((sens$4 accelerometer) with breast with (move moved moving movement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:32
S124	10	S121 and accelerometer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:33
S125	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 14:27
S126	259	S121 and ((lower$4 decrea$4) with (suction$4 intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:51
S127	45	S121 and ((lower$4 decrea$4) with (intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:59
S128	11	(a61m$/$.cpc.) and ((miniature compact small) same (piezoelectric piezo-electric piezo) same pump$4 same (suction$4 vacuum$4) same (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 15:40
S129	127	S121 and ((pressure suction$4) with (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:16
S130	2	"60479361".FMID.	US-PGPUB;	OR	OFF	2018/08/29 17:29

			USPAT; FPRS			
S131	106	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:31

		10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S132	104	S131 and @ad<="20170615"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:32
S133	14	(US-20160166745-$ or US-20150283311-$ or US-20180110906-$ or US-20140378895-$ or US-20140031744-$ or US-20160220743-$ or US-20160256617-$ or US-20080177224-$ or US-20130023821-$ or US-20160058928-$ or US-20170043065-$ or US-20110004154-$).did. or (US-10039871-$ or US-6358226-$).did.	US-PGPUB; USPAT	OR	OFF	2018/08/29 18:08
S134	1	"52574056".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 18:46
S135	0	("2009024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S136	1	("20090024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S137	3,390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S138	203	S137 and ((shield nipple) with (remov$4 replac$4 clean$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30

S139	1	("4535627").PN.	US-PGPUB; USPAT	OR	OFF	2019/01/08 12:52
S140	74	(("20180361040") or ("20180236147") or ("20120277728") or ("7785305") or ("20080208116") or ("7223255") or ("7789865") or ("8118772") or ("20080275385") or ("9956331") or ("8057425") or ("20070219486") or ("20020193731") or ("10046097") or ("20140378946") or ("20180326130") or ("20120316493") or ("8568350") or ("20030191427") or ("8070716") or ("9539377") or ("20160303298") or ("20160206794") or ("9539376") or ("20160310649") or ("20160287769") or ("20160310650") or ("20180001002") or ("20090099511") or ("7776008") or ("20090062731") or ("20160296682") or ("20050154349") or ("20030191433") or ("5749850") or ("20100292636") or ("7559915") or ("20080262420") or ("20160325031") or ("20170173232") or ("7749188") or ("6887217") or ("6139521") or ("20180021490") or ("20150065994") or ("20180028732") or ("20150196460") or ("9636282") or ("7758540") or ("8945046") or ("20080243059") or ("20110251552") or ("20170119942") or ("20130023821") or ("6997897") or ("9033913") or ("20150157776") or ("20090254028") or ("5514166") or ("20010038799") or ("20070161947") or ("20130046234") or ("8926556") or ("7255681") or ("7008400") or ("6257847") or ("20100145264") or ("20170151380") or ("20070078383") or ("5542921") or ("20180333523") or ("8075516") or ("20180369464") or ("20110071466")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/08 12:54
S141	111	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2019/01/08 13:02

		20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				

S142	35	S141 and (heavy weight "center of gravity" "centre of gravity" mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:03
S143	3,497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S144	284	S143 and (heavy weight "center of gravity" "centre of gravity")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S145	3,497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S146	18	S145 and (weight with distribut$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S147	1	("4535627").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/03/14 14:19
S148	112	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-	US-PGPUB; USPAT; FPRS	OR	ON	2019/04/16 15:00

		20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S149	21	S148 and (pump$4 with (lightweight mass weight heavy))	US-PGPUB; USPAT; USOCR;	OR	ON	2019/04/16 15:00

			FPRS; EPO; JPO			
S150	94	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (weight lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 15:14
S151	47	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (mass heavy))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 17:04
S152	26	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (mass heavy)) not S150	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 17:04
S153	1	("20110274566").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/04/19 13:51
S154	1	("20110274566").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/09 12:52
S155	57	(breast with pump) and (noise same pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:04
S156	1	(16/009547).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/15 09:08
S157	1	S156 and (pressure same noise)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:08
S158	635	((piezo piezoelectric) with pump) and (noise same pressure)	US-PGPUB; USPAT; USOCR;	OR	OFF	2019/08/15 09:10

			FPRS; EPO; JPO			
S159	1	S156 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:16
S160	26	(breast with pump) and (mmhg and noise)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:24
S161	1	S156 and (liter litre)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:30
S162	1	((piezo piezoelectric) with pump) and "YIP Ventus"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:33
S163	19	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9234518") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/15 09:36
S164	5	S163 and (mmhg mbar kpa)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:36
S165	0	S163 and (litre liter)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:37

S166	2	S163 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:37
S167	17	S163 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:37
S168	1	S163 and (piezo piezoelectric) and (noise same pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:38
S169	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:50
S170	1	S169 and gravity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:50
S171	1	S169 and (gravity same nipple)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:51
S173	61	(breast with pump$4) and ((centre center) with container)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 10:55
S174	1	S169 and (gravity same container)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:55

S175	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 11:54
S176	1	S175 and (high height)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 11:54
S177	25	(breast with pump$4) and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 12:55
S178	113	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-	US-PGPUB; USPAT; FPRS	OR	ON	2020/01/09 15:02

		20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$ or US-20180361040-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S179	30	S178 and noise	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 15:02
S180	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/13 13:45
S181	1	S180 and gravity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/13 13:45
S182	1	S180 and length	US-PGPUB;	OR	ON	2020/01/13 13:46

			USPAT; USOCR; FPRS; EPO; JPO			
S183	1	S180 and height	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/13 13:48
S184	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/14 14:29
S185	1	S184 and "half-way"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:29
S186	113	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or	US-PGPUB; USPAT; FPRS	OR	ON	2020/01/14 14:36

		US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$ or US-20180361040-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S187	3	S186 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:37
S188	2	S186 and (top with heavy)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:37
S189	1	16/009547.app.	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/01/15 11:06

			FPRS; EPO; JPO			
S190	1	S189 and (weight mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:06
S191	1	S189 and (housing same battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:07
S192	1	S189 and (shield same (mold$4 mould$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:08
S193	1	S189 and (diaphragm same seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:09
S194	0	S189 and (diaphragm same tunnel same flange)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S195	0	S189 and (diaphragm same spaced)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S196	0	S189 and (diaphragm same surround)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S197	1	verhoef.inv. and dog and figure	US-PGPUB	OR	OFF	2020/01/15 13:27
S198	1	16/009547.app.	US-PGPUB; USPAT;	OR	OFF	2020/01/15 14:28

			USOCR; FPRS; EPO; JPO			
S199	1	S198 and (shield with single)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:28
S200	67	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
S201	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
S202	1	S201 and (shield with single)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
S203	1	S201 and (shield with piece)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:33
S204	0	S201 and ((housing diagraphm) with spac$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 15:18
S205	1	S201 and (shield with housing with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 15:19
S206	1	S201 and ((housing diaphragm) with spac$4)	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/01/15 15:19

			FPRS; EPO; JPO			
S207	143	(breast with pump) and (piezo piezoelectric) and (membrane diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/09/28 11:42
S208	78	("20030191433" | "20040024351" | "20040101414" | "20050059928" | "20050131332" | "20050234370" | "20060106334" | "20080045888" | "20080177224" | "20080243059" | "20090024080" | "20100010682" | "20100106082" | "20100217148" | "20110071466" | "20110196291" | "20110245763" | "20110270162" | "20120101575" | "20120277728" | "20130023821" | "20130123688" | "20130131588" | "20130177455" | "20140066734" | "20140378895" | "20140378946" | "20150065994" | "20150100016" | "20150148709" | "20150196247" | "20150292500" | "20160015876" | "20160256618" | "20160287769" | "20170072118" | "20170080134" | "20170173232" | "4263912" | "4311141" | "4768547" | "4821580" | "5542921" | "5634468" | "5658133" | "5810772" | "5827191" | "6273868" | "6287252" | "6328082" | "6440100" | "6547756" | "6579258" | "6712785" | "6840918" | "7201735" | "7223255" | "7621797" | "7824363" | "7972297" | "7988661" | "8057425" | "8070715" | "8070716" | "8262606" | "8282596" | "8353865" | "8357116" | "8376986" | "8671701" | "8684961" | "8801495" | "9050404" | "9162016" | "9173587" | "9199017" | "9278167" | "D459233").PN. OR ("10625005").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/28 12:42
S209	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/28 14:57
S210	1	S209 and 19a	US-PGPUB; USPAT; USOCR;	OR	ON	2020/09/28 14:57

			FPRS; EPO; JPO			
S211	132,289	"201" and recess	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/09/28 15:02
S212	0	S209 and recess	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/09/28 15:02
S213	645,454	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. diaphragm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/28 15:06
S214	574	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and diaphragm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/28 15:06
S215	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/29 09:51
S216	1	S215 and flat	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/09/29 09:51

EAST Search History (Interference)

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6227936	B1	2001-05-08	MENDOZA	
	2	6328709	B1	2001-12-11	HUNG, et al.	
	3	7662018	B1	2010-02-16	THOMPSON	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080275386	A1	2008-11-06	MYERS	
	2	20110196291	A1	2011-08-11	VISCHER, et al.	
	3	20140275857	A1	2014-09-18	TOTH, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

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Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

	4	20170072117	A1	2017-03-16	KURIHARA, et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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	1		

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EXAMINER SIGNATURE

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	09/30/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☑ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

✓ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2020-06-23
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

EFS Web 2.1.18

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Bibliographic Data

Application No: 16/009,547

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /COURTNEY B FREDRICKSON/ Examiner's Signature | Initials

Title: BREAST PUMP SYSTEM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
06/15/2018	604	3783	373499.00002
RULE			

APPLICANTS

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Adam ROLLO, London, UNITED KINGDOM

Andrew CARR, London, UNITED KINGDOM

CONTINUING DATA

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/02/2018

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UNITED STATES

FILING FEE RECEIVED

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6227936	B1	2001-05-08	MENDOZA	
	2	6328709	B1	2001-12-11	HUNG, et al.	
	3	7662018	B1	2010-02-16	THOMPSON	

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	1	20080275386	A1	2008-11-06	MYERS	
	2	20110196291	A1	2011-08-11	VISCHER, et al.	
	3	20140275857	A1	2014-09-18	TOTH, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16009547
	Filing Date	2018-06-15
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	C. Fredrickson
	Attorney Docket Number	373499.00002

	4	20170072117	A1	2017-03-16	KURIHARA, et al.	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16009547
	Filing Date	2018-06-15
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	C. Fredrickson
	Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☑ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

✓ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2020-06-23
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	39796113
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	23-JUN-2020
Filing Date:	15-JUN-2018
Time Stamp:	08:58:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	37118836_1.PDF	1037113 b1968f3521b6a3e68243d9d5748fc505e0e7382d	no	4

Warnings:

Information:	
Total Files Size (in bytes):	1037113

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No. **5958**
APPLICATION NO.	**16/009,547**	
FILED:	**June 15, 2018**	Examiner: **C. Fredrickson**
CASE NO.	**373499.00002**	Group Art Unit: **3783**
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON June 22, 2020

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY AND AMENDMENT UNDER 37 CFR 1.111
TO OFFICE ACTION MAILED JANUARY 22, 2020

Sir:

This is in response to the non-final Office Action mailed January 22, 2020, having a period for response set to expire on April 22, 2020. A Petition extending the period for response for two months, to June 22, 2020, is included herein, and the extension fee is being paid by credit card. The following amendments and remarks are respectfully submitted.

Amendments to the claims begin on page 2 of this paper; Remarks begin on page 9 of this paper.

In the Claims

1. (Currently amended) A wearable breast pump system including:

(a) a housing and a milk container, shaped at least in part to fit inside a bra, the entire length of the housing and the milk container in normal upright use having a height and the housing having a front surface that is showed, in use, to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, a breast shield;

(b) a deformable diaphragm, and [[a]] the breast shield;

(c) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives the deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted against a recess in the rear surface of thehousing ~~on the breast shield, wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below either (i) half-way of the height of the entire length of the housing and the milk container, or (ii) the horizontal line that passes through a nipple tunnel or filling point on the breast shield, so that the breast pump system is not top-heavy for a woman using the breast pump system,~~ ~~and~~ where the breast pump system makes less than 30dB noise at maximum power and in which the diaphragm fully separates the piezo air pump side from the milk side, preventing any contamination of the milk by eliminating contact with the piezo air pump system; and preventing any contamination of the piezo air pump system by any milk.

2. (Original) The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. (Previously presented) The wearable breast pump system of Claim 1, in which the piezo air-pump is positioned at a base of the housing.

4. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. (Cancelled)

8. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. (Cancelled)

10. (Currently amended) The wearable breast pump system of Claim 1, in which a diaphragm housing includes an air hole that transfers negative air pressure to ~~the~~ a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away

from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. (Previously presented) The wearable breast pump system of Claim 1, in which the piezo air-pump has a mass less than 10gm.

13. (Previously presented) The wearable breast pump system of Claim 11, in which, in normal operation, the breast pump system makes less than 25dB at normal power, against a 20dB ambient noise.

14. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump is fed by air that passes through an air filter.

15. (Previously presented) The wearable breast pump system of Claim 1, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the milk container, which is a rigid, non-collapsible milk container.

16. (Original) The wearable breast pump system of Claim 1, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. (Original) The wearable breast pump system of Claim 1, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. (Currently amended) The wearable breast pump system of Claim 1, in which the housing includes a sensor[[,]] that measures or determines the movement and/or tilt angle of the housing[[,]] during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. (Original) The wearable breast pump system of Claim 1, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. (Original) The wearable breast pump system of Claim 1, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container; the breast pump system including:

(a) at least one light emitter, configured to direct radiation towards the surface of the milk;

(b) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the milk container.

22. (Cancelled)

23. (Original) The wearable breast pump system of Claim 1, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. (Original) The wearable breast pump system of Claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. (Currently amended) The wearable breast pump system of Claim 1, in which the breast shield includes ~~the~~ a nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and wherein the milk container is a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal upright use.

30. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is removable from the housing and is shaped or

configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

31. (Currently amended) The wearable breast pump system of Claim 1, having a ~~weight~~ mass, unfilled, of less than 250g.

32. (Previously presented) The wearable breast pump system of Claim 1, in which the housing is shaped at least in part to contact an inner surface of the bra and to include a rechargeable battery and control electronics, as well as the piezo air-pump.

33. (Previously presented) The wearable breast pump system of Claim 1, in which the breast shield is a single moulding that presents in use a single continuous surface to the nipple and breast.

34. (Currently amended) The wearable breast pump system of Claim 1, in which the diaphragm ~~seals,~~ self-seals, self-energising seals or interference fit seals against the recess in the rear surface of the housing ~~a diaphragm housing that is spaced apart from any side or surface of the breast shield~~.

Claims 35-36 (Cancelled)

37. (New) The wearable breast pump system of Claim 1, in which the breast shield includes a generally cylindrical or tube shaped nipple tunnel shaped to receive a nipple, and in

which the diaphragm is a generally flat diaphragm that is seated against a generally flat diaphragm holder that is formed as the recess in the rear surface of the housing, the flexible diaphragm flexing in response to changes in air pressure caused by the closed loop piezo air-pump to create negative air pressure in the nipple tunnel.

38. (New) The wearable breast pump system of Claim 37, in which the generally flat diaphragm holder and associated generally flat diaphragm lie over the top of the nipple tunnel and do not surround the nipple tunnel.

39. (New) The wearable breast pump system of Claim 37, in which the generally flat diaphragm extends at least in part, in normal use, beyond the end of a nipple inserted in the nipple tunnel, when viewed vertically from below, in normal upright use.

40. (New) The wearable breast pump system of Claim 37, in which the generally flat diaphragm extends at least in part, over a milk opening in the nipple tunnel, when viewed vertically from below, in normal upright use.

REMARKS

Petition for Extension of Time Under 37 CFR 1.136(a)

It is hereby requested that the term to respond to the Examiner's Action of January 22, 2020, be extended two months, from April 22, 2020, to June 22, 2020.

The extension fee is being paid by credit card. The Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 50-4364.

In the Office Action, the Office indicated that claims 1-6, 7 and 10-36 are pending in the application, and the Office rejected all claims.

Amendments and Basis

Claim 1 has been amended.

Claim 1 recites "**the housing having a front surface that is showed, in use, to fit inside a bra and to contact an inner surface of the bra and a rear surface that is shaped to contact, at least in part, a breast shield".**

Basis is found at least in Figures 1-6 showing the housing 1 having a front surface and a rear surface and also showing the breast shield 7, and Para. [0079], Para. [0080] of the published application (US Patent Application Publication No. 2020/0139026 A1).

Claim 1 now recites that the diaphragm is removably mounted "**against a recess in the rear surface of the housing".** Basis is found at least in Page 18 Lines 31-34, Page 19 Lines 1 -11, Page 22 Lines 16-25 of the application as filed and Figure 4 showing the second half 19B of the diaphragm housing as a recess in the rear surface of the housing.

The language "in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below (i) half-way of the height of the housing and milk container, or (ii) the horizontal line that passes through the nipple tunnel or filling point on a breast shield, so that the breast pump system is not top-heavy for a woman using the breast pump system" has been deleted from Claim 1.

Amended Claim 1 also now recites that "**the diaphragm fully separates the piezo air pump side from the milk side, preventing any contamination of the milk by eliminating contact with the piezo air pump system; and preventing any contamination of the piezo air pump system by any milk".** Basis is found at least in Page 18 lines 5-11 and in Page 24 lines 13-22 and in Figure 10 of the application as filed, as shown in the following:

> "As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.
>
> The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side)." Page 18, lines 5-11 of the application as filed.
>
> "Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B." Page 24, lines 13-22 of the application as filed.

Claims 10 and 29 have been amended in accordance with the amendments of Claim 1.

Claim 31 has been amended to overcome the rejection by the Examiner.

Claim 34 has been amended to overcome the rejections by the Examiner. Basis is found at least in page 18, lines 31-34, page 19, lines 1 -11, page 22, lines 16-25, and Figure 4 of the application as filed.

Claims 35 and 36 have been cancelled.

Claim 37 is newly presented. Basis is found at least in page 18, lines 31-34, page 19, lines 1 -11, page 22, lines 16-25, of the application as filed, and Figure 4 showing the second half 19B of the diaphragm housing as a recess portion of the housing. Page 11, lines 4 – 9, page 24, lines 13 – 34, of the application as filed.

Claim 38 is newly presented. Basis is found at least in Figures 1-6 of the application as filed in which it would have been clear for an ordinary skill that, when assembled, the generally flat diaphragm holder 19A and generally flat diaphragm 13 lie over the nipple tunnel 9 and do not surround the nipple tunnel 9.

Claim 39 is newly presented. Basis is found at least in Figure 14, page 30, lines 22-34, page 31, lines 1 – 8, of the application as filed.

Claim 40 is newly presented. Basis is found at least in Figure 14, page 30, lines 22-34, page 31, lines 1 – 8, of the application as filed.

Claim Objection

On page 3 of the Office Action, claim 18 has been objected to for a minor informality. Applicant has amended claim 18 to overcome this objection. Accordingly, the Office is respectfully requested to reconsider and withdraw the objection to claim 18.

The §112 Rejections

On page 3 of the Office Action, claims 1-6, 8 and 10-36 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. On page 5 of the Office Action, claims 1-6, 8 and 10-36 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claim 1 has been amended to overcome the rejection by the Office.

Basis for previously presented Claim 33 is at least in Figures 3-6 of the and in page 62, lines 27-28, of the application as shown in the following:

> "Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple."

Claims 31 and 34 has been amended to overcome the Office's rejections.

Claims 35 and 36 have been cancelled.

35 U.S.C. §103

Although the claims were not rejected under 35 U.S.C. §103, Applicant briefly addresses the lack of obviousness as well.

U.S. Patent Application Publication No. 2013/0023821 to Khalil discloses a wearable breast pump including an air pump but fails to disclose a piezo air pump.

Additionally, the membrane 3 of Khalil (see Figure 11) is arranged in between membrane housing parts 2,4 and Khalil fails to disclose that the membrane is "removably mounted **against a recess in the rear surface of the housing**" as disclosed by amended Claim 1.

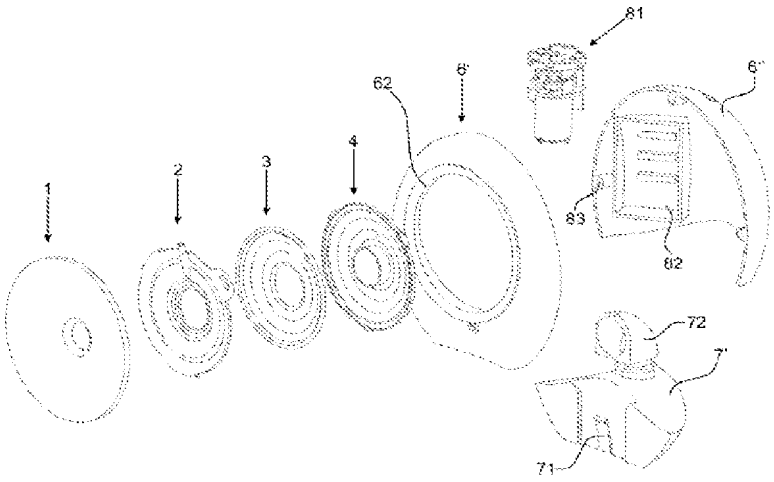


FIG. 11

Khalil, Fig. 11.

Therefore, amended claim 1 is novel over Khalil.

A *Prima Facie* Case of Obviousness Has Not Been Established

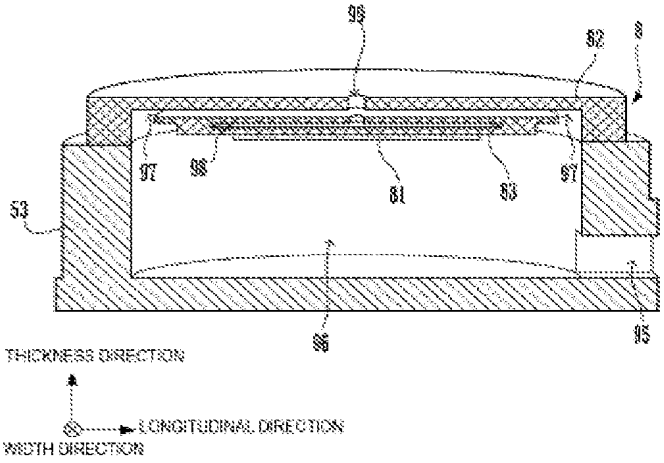
KSR (KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) requires that the Office provide "some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness." Further, the Office must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does," In addition, the Office must make "explicit" this rationale of "the apparent reason to combine the known elements in

the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art."

The words of a Claim describe and point out the invention by a series of limiting words or phrases – limitations (*Corning Glass Works v. Sumitomo Elec. USA Inc.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989)).

Khalil fails to provide any teaching or suggestion of a wearable breast pump including a piezo air pump. Therefore amended Claim 1 is not obvious over U.S. Patent Application Publication No. 2013/0023821 to Khalil.

U.S. Patent Application Publication No. 2017/0043065 to Takeuchi discloses a device for suctioning bodily fluids from the body comprising a piezoelectric element (81) and a diaphragm (83) (see Figure 3).



Takeuchi, Fig. 3.

Takeuchi discloses:

"FIG. 3 is an enlarged sectional side view of the surroundings of the piezoelectric driving unit **8**. The piezoelectric driving unit **8** includes a piezoelectric element **81** and a structure **82**. The outer shape of the structure **82** roughly has a disc shape that is thin in the thickness direction. Inside the structure **82**, a flow passage **97** and a pump chamber **98** are provided. Near the center of a top surface of the structure **82**, the discharge port **99** is open. The flow passage **97** communicates with the discharge port **99** in the top surface of the structure **82**, extends from a portion near the center toward the outer periphery inside the structure **82**, and is open in a bottom surface of the structure **82**. The flow passage **97** communicates with the flow passage **96** provided on the inner side of the annular portion **53** in the bottom surface of the structure **82**. The pump chamber **98** is a thin cylindrical space provided on a bottom side of a communicating portion between the discharge port **99** and the flow passage **97**, and is open in the communicating portion between the discharge port **99** and the flow passage **97**. The pump chamber **98** forms a part of the flow passage in the suction device **1** together with the flow passage **97**." Para. [0046]

"The piezoelectric element **81** and the diaphragm **83** are bonded to each other to form a unimorph structure, and are displaced in the thickness direction by driving of the piezoelectric element **81**. Specifically, when the piezoelectric element **81** is going to expand from a stationary state illustrated in FIG. 4A, the diaphragm **83** bends convexly toward the piezoelectric element **81** (toward the bottom surface) and the volume of the pump chamber **98** increases, as illustrated in FIG. 4B. Thus, a negative pressure is generated in the pump chamber **98**, the negative pressure is transmitted to the flow passage **97** communicating with the pump chamber **98**, and the fluid in the flow passage **97** is sucked into the pump chamber **98** [Para. 0049]

In Takeuchi, the piezoelectric element (81) is bonded to the diaphragm (83) and in direct contact with the flow passage (97) and bodily fluids. Therefore Takeuchi fails to disclose that the piezo air pump is "forming part of a closed loop system that drives the deformable diaphragm" and in which "the diaphragm fully separates the piezo air pump side from the milk side, preventing any contamination of the milk by eliminating contact with the piezo air pump system; and preventing any contamination of the piezo air pump system by

any milk" as disclosed by amended Claim 1. Additionally Takeuchi fails to disclose a system that makes less than 30dB noise at maximum power as disclosed by amended Claim 1.

It follows that amended Claim 1 is also not obvious over Khalil in view of Takeuchi. First, there are no teachings or suggestions in Takeuchi on how to attach the piezoelectric element on a diaphragm that is of annular, circle or part circle shape as disclosed by Khalil. In addition, even the combination of Khalil and Takeuchi would not arrive at amended Claim 1 limitation. By combining Khalil and Takeuchi, one ordinary skill would have attached the piezoelectric element of Takeuchi onto the diaphragm of Khalil and this combination would not arrive at amended Claim 1 which requires that the piezo air pump is "forming part of a closed loop system that drives the deformable diaphragm" and in which "the diaphragm fully separates the piezo air pump side from the milk side, preventing any contamination of the milk by eliminating contact with the piezo air pump system; and preventing any contamination of the piezo air pump system by any milk" as disclosed by amended Claim 1.

Amended Claim 1 is therefore not obvious over Khalil in view of Takeuchi.

The dependent Claims are not obvious, at least by virtue of their dependence on amended Claim 1.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims. An early Notice of Allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any fee deficiencies associated with this communication to applicant's Deposit Account No. 50-4364.

Respectfully submitted

June 22, 2020
Date

/Mark D. Simpson/
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Electronic Patent Application Fee Transmittal

Application Number:	16009547
Filing Date:	15-Jun-2018
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	2	50	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 2 months with $0 paid	2252	1	300	300
Miscellaneous:				
			Total in USD ($)	**400**

Electronic Acknowledgement Receipt

EFS ID:	39790252
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	22-JUN-2020
Filing Date:	15-JUN-2018
Time Stamp:	16:12:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$400
RAM confirmation Number	E20206LG13039355
Deposit Account	504364
Authorized User	Lynn White

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.21 (Miscellaneous fees and charges)

37 CFR 1.19 (Document supply fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		37117145_1.PDF	267578 0c701efe758e8b34ce447794f6539ea4b2d27c53	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	9
	Amendment/Req. Reconsideration-After Non-Final Reject	10	18

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	32441 4fa49b907e13a55548d502a0a415fc407aa31217	no	2

Warnings:

Information:

Total Files Size (in bytes):	300019

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/009,547	Filing Date 06/15/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/22/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 35	Minus	** 33	= 2		x $50 =	100
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	100

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LASHAWN R MORGAN/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 01/22/2020

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
01/22/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

Office Action Summary	Application No. 16/009,547	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 23December2019.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-6,8 and 10-36 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-6,8 and 10-36 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 15June2018 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2019 has been entered.

Response to Amendment

This office action is responsive to the amendment filed on December 23, 2019. As directed by the amendment: claims 1, 10, 15, and 29 have been amended, claims 7 and 9 have been cancelled, and claims 31-36 have been added. Thus, claims 1-6, 8, and 10-36 are presently pending in this application.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot because the arguments do not apply to the current grounds of rejection as necessitated by applicant's amendments.

Claim Objections

Claim 18 is objected to because of the following informalities: the claim should be amended to recite "…a sensor[[,]]…housing[,]].." in lines 2 and 3 of the claim to correct minor grammatical issues. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, and 10-36 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, the claim has been amended to recite "the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below… (i) half-way of the height of the entire length of the housing and the milk container" in lines 8-11 of the claim. The disclosure as originally

filed does not provide support for the center of gravity, when the milk container is attached and empty, being at or below the half-way height of the entire length of the housing and milk container. The specification consistently refers to the center of gravity being at or below the half-way height of the housing and not the half-way height of the housing plus the milk container. In applicant's arguments, applicant asserts that support is provided on pg. 13, lines 1-11 of the specification. However, this portion of the specification discloses that the center of gravity is around 60mm from the base of the pump when the container is empty and does not relate the center of gravity to the half-way height line of the housing plus the milk container.

Regarding claims 33 and 35, the claim recites that the breast shield is a single moulding; however, the specification is devoid of any discussion regarding the breast shield being moulded. Applicant asserts that support for the newly added claim is found on pg. 65, lines 29 and 30 of the specification; however, this portion of the specification focuses on the milk container and not the breast shield.

Regarding claim 34, the claim recites "a diaphragm housing that is spaced apart from any side or surface of the breast shield" in lines 2 and 3 of the claim. However, paragraph 119 of the published application discloses that the diaphragm housing is integral to the breast shield. Further, figures 3-6 appear to show the diaphragm housing attached to the breast shield in a way that it cannot be considered "spaced apart from any side or surface of the breast shield".

Regarding claim 35, the claim recites "the diaphragm housing is spaced apart from the breast shield". However, as discussed previously, paragraph 119 of the published application discloses that the diaphragm housing is integral to the breast

shield. Further, figures 3-6 appear to show the diaphragm housing attached to the breast shield in a way that it cannot be considered "spaced apart from the breast shield".

Regarding claim 36, the claim recites "a housing diaphragm (considered to be the diaphragm housing for examination purposes) that is…not on any side of this opening". Figure 5 appears to show the diaphragm housing 19a positioned above the opening 9A, which is considered to "a side" of the opening. Therefore, the disclosure as originally filed does not provide support for this limitation.

Claims 2-6, 8, and 10-32 are also rejected by virtue of being dependent on claim 1.

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, and 10-36 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claim 1, there is a lack of antecedent basis in the limitation "the horizontal line that passes through a nipple tunnel or filling point on the breast shield" in lines 10-11 of the claim. Since the claim has not defined the specific line, it further cannot be determined which line the claim intends to define since many horizontal lines pass through the nipple tunnel or filling point on the breast shield.

Regarding claim 31, the claim recites that the breast pump system has a weight of 250g. However, grams are a measurement of mass and not weight.

Regarding claim 34, the claim recites that the "the diaphragm seals, self-seals, self-energising seals or interference fit seals…". Therefore, the claim requires that the diaphragm seals against a diaphragm housing, which encompasses the subsequent types of seals recited in the claim. Therefore, the other sealing types do not seem to further limit the claim since any type of seal against the diaphragm housing would meet the claimed limitation.

Regarding claim 36, the claim recites "a housing diaphragm" in line 3. It cannot be determined if the claim intends to recite a second diaphragm or the diaphragm housing. For examination purposes, the latter interpretation was used.

Claims 2-6, 8, 10-30, 32, 33, and 35 are also rejected by virtue of being dependent on claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached on Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M 1/062, 1/066, 1/06, 1/066, 1/068	8/25/2018	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See EAST search history	8/25/2018	cbf
Searched inventors in PALM and EAST	8/25/2018	cbf
Updated search	03/14/2019	cbf
Updated search	08/09/2019	cbf
Updated search	01/15/2020	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/JASON E FLICK/ Primary Examiner, Art Unit 3783	/COURTNEY FREDRICKSON/ Examiner.Art Unit 3763

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/25/2018	03/14/2019	08/09/2019	01/15/2020					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	-					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	-					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	✓	✓	✓	✓					
	13	✓	O	O	✓					
	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
	16	✓	✓	✓	✓					
	17	✓	✓	✓	✓					
	18	✓	✓	✓	✓					
	19	✓	✓	✓	✓					
	20	✓	✓	✓	✓					
	21	✓	✓	✓	✓					
	22	✓	-	-	-					
	23	✓	✓	✓	✓					
	24	✓	✓	✓	✓					
	25	✓	✓	✓	✓					
	26	✓	✓	✓	✓					
	27	✓	✓	✓	✓					
	28	✓	✓	✓	✓					
	29	✓	✓	✓	✓					
	30	✓	✓	✓	✓					
	31				✓					
	32				✓					
	33				✓					
	34				✓					
	35				✓					
	36				✓					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	67	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
L2	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
L3	1	L2 and (shield with single)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:32
L4	1	L2 and (shield with piece)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:33
S1	65	("20020193731" | "20040056641" | "20040074281" | "20040267215" | "20050219302" | "20060122575" | "20070051172" | "20070051727" | "20080262420" | "20120277636" | "20140052056" | "20150217036" | "20150217037" | "20150283311" | "20160000980" | "20160058929" | "20160082165" | "20160082166" | "20160151551" | "20160158424" | "20160206794" | "20160220743" | "20160220745" | "20160287767" | "20160296681" | "20160310650" | "20170021068" | "20170035951" | "20170143879" | "20170220753" | "20180021490" | "2849881" | "4390024" | "5474683" | "5941847" | "5973770" | "6045529" | "6090065" | "6383163" | "6440100" | "6461324" | "6547756" | "6579258" | "6663587" | "6749582" | "7048519" | "7201735" | "7312554" | "7314400" | "7776008" | "8057425" | "8118772" | "8187227" | "8262606" | "8282596" | "8376986" | "8702646" |	US-PGPUB; USPAT	OR	OFF	2018/08/07 13:17

		"8801495" | "8876760" | "8926556" | "9033913" | "9173587" | "9345274" | "9539377" | "D548831").PN.				
S2	214	(jonathan near3 o'toole).inv. (adam near3 rollo).inv. (andrew near3 carr).inv.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:42
S3	63	(a61m1/062 a61m1/066 a61m1/06).cpc. and piezo$9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:45
S4	19	("20040122358" | "20060226108" | "20080077042" | "20080167579" | "20120004603" | "3895533" | "4024856" | "4338953" | "5347656" | "5666104" | "5827191" | "7316653" | "7621797" | "7794425" | "8308648" | "8777864" | "8801658" | "8827911").PN. OR ("8992445").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:50
S5	7	("5730139" | "6423010" | "6602199" | "7479154" | "8206414" | "8425426" | "8992445").PN. OR ("9192325").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:59
S6	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:16
S7	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S8	2787	(a61m1/062 a61m1/066 a61m1/06).cpc. not S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S9	45	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 14:59

		US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$).did. or (WO-2015174330-$ or WO-2016024558-$).did.				
S10	14	S9 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:59
S11	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 15:04
S12	143	a61j13/00.cpc.	US-PGPUB; USPAT	OR	OFF	2018/08/10 10:30
S13	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:30
S14	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:43
S15	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S16	0	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S14)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S17	2665	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S13)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44

S18	71	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 11:47
S19	37	S18 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:48
S20	4	S18 and ((air with pump$4) same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:50
S21	16	S18 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:15
S22	1	S18 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:40

S23	0	a61m1/1058.cpc. and breast and diaphragm	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:42
S24	5	breast same pump$4 same piezo$8 same air	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:43
S25	1	("9884172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/10 13:58
S26	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 08:40
S27	2	"59563385".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S28	1	"59563425".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S29	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:26

		2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S30	44	S29 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:26
S31	17	S29 and (pump$4 with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:27
S32	51	S26 and "air pump"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 11:07
S33	4	"47900902".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:13
S34	10	("20030212374" | "20050251089" | "20050283900" | "20070135778" | "20110054389" | "3084691" | "4229029" | "5295957" | "6070659").PN. OR ("9511176").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/24 11:16
S35	2	"51149640".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:17
S36	271	S26 and (control$4 same select$4 left same right same breast)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 12:50
S37	3	S29 and (recharg$4 with battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 13:04
S38	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/24 14:41

			JPO			
S39	9	S38 and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S40	11	S38 and (light with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:48
S41	0	S38 and (radiation with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S42	2	S38 and (radiation same milk same (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S43	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S44	10	S43 and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S45	1	a61m1/1058 and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S46	27	a61m1/1058.cpc. and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S47	23	S43 and (indicator same milk same (express$4 flow$4))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/24 19:26

			FPRS; EPO; JPO			
S48	51	S43 and (air same pressure same sens$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:30
S49	19	S43 and ((indicat$4 record$4) same (right and left))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:38
S50	56	S43 and (pump$4 with series)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:42
S51	77	S43 and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:47
S52	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 19:59

		$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S53	44	S52 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S54	5	S53 and (air with filter$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S55	3	S43 and (pump$4 with (db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S56	6	S43 and ((db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S57	26	S43 and (sens$4 with (orientation angle tilt placement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:16
S58	9	S43 and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:31
S59	484	a61m$/$.cpc. and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:32
S60	1	S43 and "social media"	US-	OR	OFF	2018/08/24

			PGPUB; USPAT; USOCR; FPRS; EPO; JPO			20:52
S61	408	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:13
S63	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:18
S64	359	a61m$/$.cpc. and ((pump$4 with weigh$4) same (portable lightweight carry$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:30
S65	1	("20160166745").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:16
S66	1	("20160058928").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:23
S67	1	("20110004154").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/26 10:55
S68	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 11:09

		20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S69	2	S68 and (radiation same (height quantity amount volume))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 11:09
S70	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 12:24

		$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S71	3	S70 and ((diaphragm membrane) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 12:24
S72	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S73	137	S72 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S74	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S75	9	S74 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S76	19	S74 and (shield with snap$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:16
S77	1	("20110152855").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 13:20
S78	32	S74 and (flow with rate with air)	US-	OR	OFF	2018/08/27

			PGPUB; USPAT; USOCR; FPRS; EPO; JPO			13:33
S79	3	S74 and (stall with pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:56
S80	98	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 13:56
S81	17	S80 and (pressure same (mmhg kpa mbar pa bar))	US-PGPUB;	OR	OFF	2018/08/27 13:57

			USPAT; USOCR; FPRS; EPO; JPO			
S82	18	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 14:08
S83	0	S82 and breast	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S84	10	S82 and (lactat$3 milk)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S85	14	S80 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:10
S86	5	S74 and ((piezo piezoelectric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:47
S87	230	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:48
S88	6	S87 and (breast milk lactat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:53
S89	161	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/27 15:11

			JPO			
S90	0	(2017/0072118).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S91	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S92	40	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:22
S93	3	"45513973".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 15:23
S94	364	(((piezo piezoelectric) with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:32
S95	3	"20170035951"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:33
S96	1	S95 and (suction$4 with piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:34
S97	1	("20130064683").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:38
S98	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:39
S99	1	(US-20170172485-$).did.	US-PGPUB	OR	OFF	2018/08/28 16:48
S100	0	S99 and "function of"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 16:48
S101	100	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or	US-PGPUB;	OR	OFF	2018/08/28 17:19

		US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.	USPAT; FPRS			
S102	0	S101 and ((meaur$4 with milk) same rate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S103	0	S101 and ((meaur$4 with milk) same (frequency speed))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S104	16	S101 and ((measur$4 with milk) same (frequency speed rate))	US-PGPUB;	OR	OFF	2018/08/28 17:21

			USPAT; USOCR; FPRS; EPO; JPO			
S105	0	S101 and ((measur$4 with milk) with "function of")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:23
S106	6	S101 and (decrease with (rate speed frequency strong))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:10
S107	2	S101 and (latch$4 with adjust$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:22
S108	50	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:24
S109	0	(a61m$/$).cpc. and (wear$4 with pump$4) and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:25
S110	83	(a61m$/$).cpc. and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:26
S111	101	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 09:43

		20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S112	3	S111 and (shield with (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:43
S113	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:47
S114	86	S113 and ((diapragm housing) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:53
S115	9	S113 and ((diapragm membrane) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:54

S116	34	S111 and (diaphragm membrane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:07
S117	28	S113 and (diaphragm membrane) and (shield with dispos$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:10
S118	28	S113 and ((diaphragm membrane) with (coupl$4 attach$4 mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:23
S119	0	a61j16/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:41
S120	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:42
S121	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S122	23	S121 and (sens$4 same (orient$4 plac$4 situat$4) same (nipple shield))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S123	11	S121 and ((sens$4 accelerometer) with breast with (move moved moving movement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:32
S124	10	S121 and accelerometer	US-PGPUB; USPAT; USOCR; FPRS;	OR	OFF	2018/08/29 13:33

			EPO; JPO			
S125	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 14:27
S126	259	S121 and ((lower$4 decrea$4) with (suction$4 intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:51
S127	45	S121 and ((lower$4 decrea$4) with (intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:59
S128	11	(a61m$/$.cpc.) and ((miniature compact small) same (piezoelectric piezo-electric piezo) same pump$4 same (suction$4 vacuum$4) same (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 15:40
S129	127	S121 and ((pressure suction$4) with (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:16
S130	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:29
S131	106	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:31

		20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S132	104	S131 and @ad<="20170615"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:32
S133	14	(US-20160166745-$ or US-20150283311-$ or US-20180110906-$ or US-20140378895-$ or US-20140031744-$ or US-20160220743-$ or US-20160256617-$ or US-20080177224-$ or US-20130023821-$ or US-20160058928-$ or US-20170043065-$ or US-20110004154-$).did. or (US-10039871-$ or US-6358226-$).did.	US-PGPUB; USPAT	OR	OFF	2018/08/29 18:08
S134	1	"52574056".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 18:46
S135	0	("2009024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S136	1	("20090024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S137	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30

S138	203	S137 and ((shield nipple) with (remov$4 replac$4 clean$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S139	1	("4535627").PN.	US-PGPUB; USPAT	OR	OFF	2019/01/08 12:52
S140	74	(("20180361040") or ("20180236147") or ("20120277728") or ("7785305") or ("20080208116") or ("7223255") or ("7789865") or ("8118772") or ("20080275385") or ("9956331") or ("8057425") or ("20070219486") or ("20020193731") or ("10046097") or ("20140378946") or ("20180326130") or ("20120316493") or ("8568350") or ("20030191427") or ("8070716") or ("9539377") or ("20160303298") or ("20160206794") or ("9539376") or ("20160310649") or ("20160287769") or ("20160310650") or ("20180001002") or ("20090099511") or ("7776008") or ("20090062731") or ("20160296682") or ("20050154349") or ("20030191433") or ("5749850") or ("20100292636") or ("7559915") or ("20080262420") or ("20160325031") or ("20170173232") or ("7749188") or ("6887217") or ("6139521") or ("20180021490") or ("20150065994") or ("20180028732") or ("20150196460") or ("9636282") or ("7758540") or ("8945046") or ("20080243059") or ("20110251552") or ("20170119942") or ("20130023821") or ("6997897") or ("9033913") or ("20150157776") or ("20090254028") or ("5514166") or ("20010038799") or ("20070161947") or ("20130046234") or ("8926556") or ("7255681") or ("7008400") or ("6257847") or ("20100145264") or ("20170151380") or ("20070078383") or ("5542921") or ("20180333523") or ("8075516") or ("20180369464") or ("20110071466")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/08 12:54
S141	111	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2019/01/08 13:02

		20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S142	35	S141 and (heavy weight "center of gravity" "centre of gravity" mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:03
S143	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S144	284	S143 and (heavy weight "center of gravity" "centre of gravity")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S145	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS;	OR	OFF	2019/01/08 16:06

			EPO; JPO			
S146	18	S145 and (weight with distribut$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S147	1	("4535627").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/03/14 14:19
S148	112	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-	US-PGPUB; USPAT; FPRS	OR	ON	2019/04/16 15:00

		2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S149	21	S148 and (pump$4 with (lightweight mass weight heavy))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/04/16 15:00
S150	94	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (weight lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 15:14
S151	47	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (mass heavy))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 17:04
S152	26	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (pump$4 with (mass heavy)) not S150	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/04/16 17:04
S153	1	("20110274566").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/04/19 13:51
S154	1	("20110274566").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/09 12:52
S155	57	(breast with pump) and (noise same pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:04
S156	1	(16/009547).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/15 09:08
S157	1	S156 and (pressure same noise)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:08
S158	635	((piezo piezoelectric) with pump) and (noise	US-	OR	OFF	2019/08/15

		same pressure)	PGPUB; USPAT; USOCR; FPRS; EPO; JPO			09:10
S159	1	S156 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:16
S160	26	(breast with pump) and (mmhg and noise)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:24
S161	1	S156 and (liter litre)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:30
S162	1	((piezo piezoelectric) with pump) and "YIP Ventus"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/08/15 09:33
S163	19	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9234518") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/08/15 09:36
S164	5	S163 and (mmhg mbar kpa)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:36
S165	0	S163 and (litre liter)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:37
S166	2	S163 and piezo	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2019/08/15 09:37

			EPO; JPO			
S167	17	S163 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:37
S168	1	S163 and (piezo piezoelectric) and (noise same pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2019/08/15 09:38
S169	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:50
S170	1	S169 and gravity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:50
S171	1	S169 and (gravity same nipple)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:51
S173	61	(breast with pump$4) and ((centre center) with container)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 10:55
S174	1	S169 and (gravity same container)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 10:55
S175	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/09 11:54
S176	1	S175 and (high height)	US-PGPUB; USPAT;	OR	OFF	2020/01/09 11:54

			USOCR; FPRS; EPO; JPO			
S177	25	(breast with pump$4) and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 12:55
S178	113	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$ or US-20180361040-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-	US-PGPUB; USPAT; FPRS	OR	ON	2020/01/09 15:02

		2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S179	30	S178 and noise	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/09 15:02
S180	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/13 13:45
S181	1	S180 and gravity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/13 13:45
S182	1	S180 and length	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/13 13:46
S183	1	S180 and height	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/13 13:48
S184	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/14 14:29
S185	1	S184 and "half-way"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:29
S186	113	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or	US-PGPUB; USPAT; FPRS	OR	ON	2020/01/14 14:36

		US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$ or US-20180361040-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$ or US-5542921-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S187	3	S186 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:37
S188	2	S186 and (top with heavy)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2020/01/14 14:37
S189	1	16/009547.app.	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/01/15 11:06

			FPRS; EPO; JPO			
S190	1	S189 and (weight mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:06
S191	1	S189 and (housing same battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:07
S192	1	S189 and (shield same (mold$4 mould$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:08
S193	1	S189 and (diaphragm same seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:09
S194	0	S189 and (diaphragm same tunnel same flange)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S195	0	S189 and (diaphragm same spaced)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S196	0	S189 and (diaphragm same surround)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 11:15
S197	1	verhoef.inv. and dog and figure	US-PGPUB	OR	OFF	2020/01/15 13:27
S198	1	16/009547.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:28

S199	1	S198 and (shield with single)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2020/01/15 14:28

EAST Search History (Interference)

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PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16009547	Filing Date	2018-06-15	Docket Number (if applicable)	373499.00002	Art Unit	3783
First Named Inventor	Jonathan O'TOOLE			Examiner Name	C. Fredrickson		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☒ Other Petition for Extension of Time (included in Reply)

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 504364

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

X Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Signature of Registered U.S. Patent Practitioner			
Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2019-12-23
Name	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No. **5958**
APPLICATION NO.	**16/009,547**	
FILED:	**June 15, 2018**	Examiner: **C. Fredrickson**
CASE NO.	**373499.00002**	Group Art Unit: **3783**
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON December 23, 2019

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUIRED SUBMISSION ACCOMPANYING THE FILING OF A REQUEST FOR CONTINUED EXAMINATION (RCE)

Sir:

This is the required submission accompanying the filing of a Request for Continued Examination (RCE) being filed in response to the final Office Action mailed August 22, 2019, having a period for response set to expire on November 22, 2019. A Petition extending the period for response for one month, to December 23, 2019 (December 22 being a Sunday), is included herein, and the RCE filing fee and extension fee are being paid by credit card. The following amendments and remarks are respectfully submitted.

Amendments to the claims begin on page 2 of this paper; Remarks begin on page 9 of this paper.

In the Claims

1. (Currently amended) A wearable breast pump system including:

(a) a housing and a milk container, shaped at least in part to fit inside a bra, the entire length of the housing and the milk container in normal upright use having a height;

(b) a deformable diaphragm, and a breast shield~~, and a milk container~~;

(c) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives~~,~~ the deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on the breast shield, wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below either (i) half-way of the height of the entire length of the housing and the milk container, or (ii) the horizontal line that passes through a nipple tunnel or filling point on the breast shield, so that the breast pump system is not top-heavy for a woman using the breast pump system, and where the breast pump system makes less than 30dB noise at maximum power.

2. (Original) The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. (Previously presented) The wearable breast pump system of Claim 1, in which the piezo air-pump is positioned at a base of the housing.

4. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. (Cancelled)

8. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. (Cancelled)

10. (Currently amended) The wearable breast pump system of Claim 1, in which a diaphragm housing includes an air hole that transfers negative air pressure to [[a]] the nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. (Previously presented) The wearable breast pump system of Claim 1, in which the piezo air-pump has a mass less than 10gm.

13. (Currently amended) The wearable breast pump system of Claim 11, in which, in normal operation, the breast pump system makes ~~less than 30dB noise at maximum power and~~ less than 25dB at normal power, against a 20dB ambient noise.

14. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump is fed by air that passes through an air filter.

15. (Currently amended) The wearable breast pump system of Claim 1, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the milk container, which is a rigid, non-collapsible milk container.

16. (Original) The wearable breast pump system of Claim 1, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. (Original) The wearable breast pump system of Claim 1, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. (Previously presented) The wearable breast pump system of Claim 1, in which the housing includes a sensor, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. (Original) The wearable breast pump system of Claim 1, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. (Original) The wearable breast pump system of Claim 1, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container; the breast pump system including:

(a) at least one light emitter, configured to direct radiation towards the surface of the milk;

(b) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the milk container.

22. (Cancelled)

23. (Original) The wearable breast pump system of Claim 1, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. (Original) The wearable breast pump system of Claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container that when connected to

the housing forms an integral, lower part of the housing, with a surface shaped to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. (Currently amended) The wearable breast pump system of Claim 1, in which the breast shield includes [[a]] the nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and wherein the milk container is a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal upright use.

30. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

31. (New) The wearable breast pump system of Claim 1, having a weight, unfilled, of less than 250g.

32. (New) The wearable breast pump system of Claim 1, in which the housing is shaped at least in part to contact an inner surface of the bra and to include a rechargeable battery and control electronics, as well as the piezo air-pump.

33. (New) The wearable breast pump system of Claim 1, in which the breast shield is a single moulding that presents in use a single continuous surface to the nipple and breast.

34. (New) The wearable breast pump system of Claim 1, in which the diaphragm seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that is spaced apart from any side or surface of the breast shield.

35. (New) The wearable breast pump system of Claim 1, in which the breast shield is a single moulding that includes (a) the nipple tunnel configured to receive a nipple and (b) a flange to rest against the breast, and the diaphragm housing is spaced apart from the breast shield and positioned so that the diaphragm does not at least partially surround the nipple tunnel.

36. (New) The wearable breast pump system of Claim 35, in which the nipple tunnel includes an opening through which milk flows, and the diaphragm is arranged on a housing diaphragm that is positioned a distance from, or away from, this opening and not on any side of this opening.

REMARKS

Petition for Extension of Time Under 37 CFR 1.136(a)

It is hereby requested that the term to respond to the Examiner's Action of August 22, 2019, be extended one month, from November 22, 2019, to December 23, 2019 (December 22 being a Sunday).

The extension fee is being paid by credit card. The Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 50-4364.

In the Office Action, the Office indicated that claims 1-21 and 23-30 are pending in the application, claims 1-12, 14-21 and 23-30 have been rejected and claim 13 is objected to.

Amendments and Basis

Independent Claim 1 has been amended to recite "**the entire length of the** housing **and the milk container** in normal upright use having a height" and that the center of gravity of the breast pump system with an empty milk container is "substantially at or below **either (i)** half-way of the height of the **entire length of the** housing **and the milk container, or (ii) the horizontal line that passes through a nipple tunnel or filling point on the breast shield**". Basis is found in at least Claim 22 as originally filed and in Lines 1-11 Page 13 of the application as filed where it would be clear for a skilled person that the measured centre of gravity, if measured from the base of the breast pump system, is substantially at or below the half-way of the height of the housing and milk container or the horizontal line that passes through the nipple tunnel or filling point on the breast shield. Claim 1 also now recites **"the breast pump system makes less than 30dB noise at maximum power"**. Basis is found at least in Claim 13 and in Lines 13-16 Page 55 of the application as filed.

Claims 7 and 9 have been cancelled.

Claim 10 has been amended.

Claim 13 has been amended. The deleted feature is now introduced in amended Claim 1.

Claim 15 has been amended.

Claim 29 has been amended.

Claim 31 is newly presented. Basis is found at least in Line 19 Page 118 of the application as filed.

Claim 32 is newly presented. Basis is found at least in Lines 19-21 Page 10 and Figures 1 and 2 of the application as filed.

Claim 33 is newly presented. Basis is found at least in Lines 29-30 Page 65 and Figures 3 to 6 of the application as filed.

Claim 34 is newly presented. Basis is found at least in Lines 10-25 Page 11 and Figures 3 to 6 of the application as filed.

Claim 35 is newly presented. Basis is found at least in Lines 27-28 Page 62 and Figures 3 to 6 of the application as filed.

Claim 36 is newly presented. Basis is found at least in Lines 11-13 Page 17 and Figures 3 to 6 of the application as filed.

Allowable Subject Matter

On page 23 of the Office Action, the Office has indicated that claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims. Applicant thanks the Office for this indication of allowable subject matter.

Rejections under 35 U.S.C. §103

On page 5 of the Office Action, claims 1, 3, 7-10, 17, 22 and 27-30 have again been rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi. (We note that the heading for this rejection indicates "...1-10, ...," but based upon the discussion of the rejection, we believe it should be "...7-10...".) On page 9 of the Office Action, claims 2, 23 and 24 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2017/0072118 to Makower. On page 12 of the Office Action, claims 4 and 6 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2018/0110906 to Barack; and claims 4 and 5 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0166745 to Aalders. On page 13 of the Office Action, claim 11 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0256617 to Hansen and in further view of U.S. Patent Application Publication No. 2014/0031744 to Chen. On page 14 of the Office Action, claims 12 and 13 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2011/0274566 to Amirouche; and

claim 14 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No. 6,358,226 to Ryan. On page 15 of the Office Action, claim 15 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0323962 to Kooijker. On page 16 of the Office Action, claim 16 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No. 10,039,871 to Pollen; and on page 17, claim 18 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2015/0283311 to Alvarez and in further view of Makower. On page 18 of the Office Action, claim 19 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0378895 to Barack ("Barack '895"). On page 19, claim 20 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2011/0004154 to Van Schijndel; and claim 21 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0220743 to Guthrie. On page 21 of the Office Action, claim 25 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2008/0177224 to Kelly; and on page 22, claim 26 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of Alvarez.

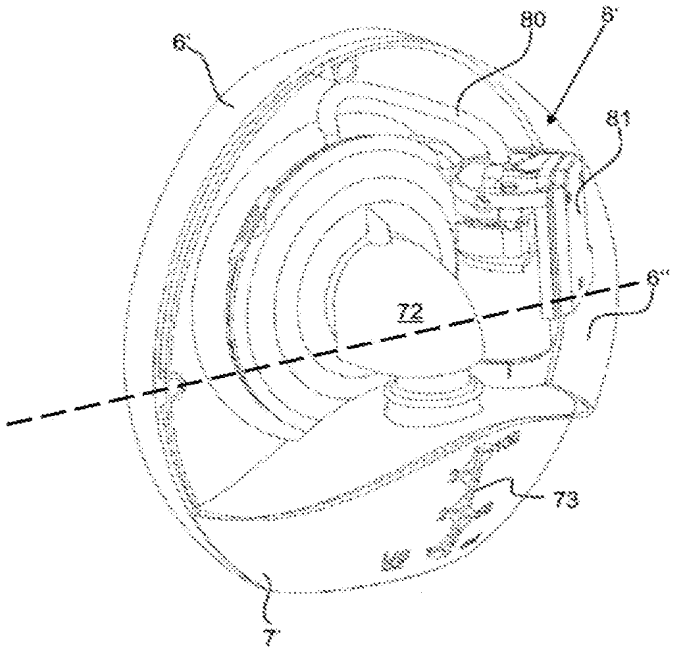
A *Prima Facie* Case of Obviousness Has Not Been Established

KSR (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)) requires that the Office provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Further, the Office must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." In addition, the Office must make "explicit" this rationale of "the apparent reason to combine the known elements in the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art."

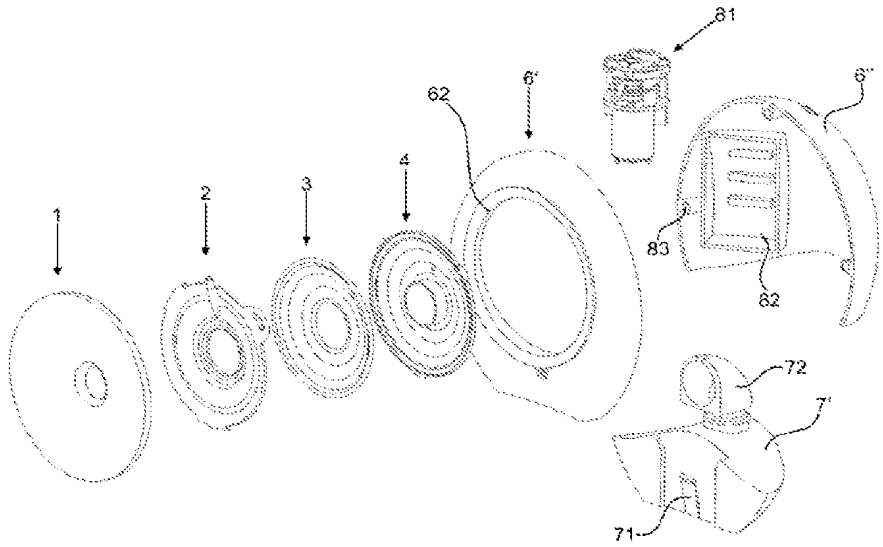
The words of a Claim describe and point out the invention by a series of limiting words or phrases – limitations (*Corning Glass Works v. Sumitomo Elec. USA Inc.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989)).

On pages 5 and 6 of the Office Action, the Office rejected former Claim 1 under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi.

For amended Claim 1, the following graphical analysis in relation to Khalil Fig. 10 applies, in which the dashed line is a line indicating "half-way of the height of the **entire length of the** housing **and the milk container".**



The above analysis is justified, because if in Khalil, the housing is the cover 6'' as indicated by the Examiner on Page 5 of the Office Action and the milk container is the milk collection container 7' (Khalil para. [069]), then half way of the height of entire length of the cover 6'' and milk collection container 7' therefore corresponds to the dashed line inserted in Fig. 10 of Khalil reproduced above. Further, the position of the dashed line above also indicates **"the horizontal line that passes through a nipple tunnel or filling point on the breast shield"** as disclosed by amended Claim 1. In Khalil, the nipple tunnel corresponds to an opening "preferably arranged centrally within the breast interface 1" (Khalil para. [049]) as shown in Khalil Fig. 11 below.



For the system of Khalil shown in Figs. 10-11 in the above graphical analysis, the center of gravity of the breast pump system would appear to be above half-way of the height of the entire length of the cover 6'' and milk collection container 7' and above the horizontal line that passes through the opening of the breast interface 1, which is the opposite to what is expressed in amended Claim 1. This conclusion is supported by the pump and power source being mainly situated above half way of the height of the entire length of the cover 6'' and milk collection container 7', in normal upright use, as shown in Khalil Figs. 10-11.

Khalil discloses:

> "A pump seat 82, in which a vacuum pump 81 is held, is formed integrally in this cover 6". A power source is preferably integrated in this vacuum pump 81." Para. [0067].

And from the position of the pump seat 82 in the cover 6'', it is clear that in normal upright use, that the pump 81 and power source are mainly situated above half way of the height of the cover 6'' and milk collection container 7', therefore resulting in a breast pump system that would be top-heavy for a woman using the breast pump system.

Claim 1 is therefore not obvious over Khalil.

The invention of amended Claim 1 has the advantage that the breast pump does not feel top-heavy to a woman while using the breast pump system. As disclosed in the application as filed Lines 25-26 Page 12, "the weight of the system has also been distributed to ensure that the breast pump 25 is not top heavy, ensuring comfort and reliable suction against the breast." Additionally amended Claim 1 discloses the use of a "piezo air pump" and that "**the breast pump system makes less than 30dB noise at maximum power**". This results in a "fully wearable system that delivers a quiet, comfortable and discreet operation in normal use" (see Lines 3-5 Page 55 of the application as filed), which is a further advantage of the invention of amended Claim 1.

As stated by the examiner Takeuchi discloses a device for suctioning bodily fluids from the body comprising a piezo air pump. However Takeuchi does not disclose or teach a fully wearable breast pump system "**where the breast pump system makes less than 30dB noise at maximum power**."

Further Khalil does not teach or suggest any other positions of its pump seat 82 and its vacuum pump 81. Even in combination, Khalil and Takeuchi do not arrive at the amended Claim 1 limitations.

Amended Claim 1 is therefore not obvious over Khalil in view of Takeuchi.

The dependent Claims are not obvious, at least by virtue of their dependence on amended Claim 1.

Accordingly, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1-30 under 35 USC §103.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims. An early Notice of Allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any fee deficiencies associated with this communication to applicant's Deposit Account No. 50-4364.

Respectfully submitted

December 23, 2019
Date

/Mark D. Simpson/
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Electronic Patent Application Fee Transmittal

Application Number:	16009547
Filing Date:	15-Jun-2018
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	3	50	150
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	650	650
		Total in USD ($)		**900**

Electronic Acknowledgement Receipt

EFS ID:	38118296
Application Number:	16009547
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Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	36350253_1.PDF	1364393 d3559a5eade77ca482f9d134e2d7c1e53db0a61e	no	3
Warnings:					
Information:					
2		36357774_2.PDF	630086 542555dd333bf6110e9129555000117a8bb8f44e	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment Submitted/Entered with Filing of CPA/RCE	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	17

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	34101 4db9957ac661a1ff2e91e63a7a49185844dc029f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2028580		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

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EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
08/22/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

Office Action Summary	Application No. 16/009,547	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 25July2019.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-21 and 23-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-12,14-21 and 23-30 is/are rejected.

8) ☑ Claim(s) 13 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 15June2018 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

This office action is responsive to the amendment filed on July 25, 2019. As directed by the amendment: claims 1 and 12 have been amended. Thus, claims 1-21 and 23-30 are presently pending in this application.

Applicant's amendments to the Specification, Drawings, and Claims have overcome each and every 112(b) rejections previously set forth in the Non-Final Office Action mailed April 26, 2019.

Response to Arguments

Applicant's arguments filed July 25, 2019 have been fully considered but they are not persuasive.

The Applicant argues on pgs. 12-114 that Khalil does not teach the limitation regarding the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below half-way of the height of the housing due to the size of shell ring 6'. The Examiner respectfully asserts that, as set forth in the previous correspondence, the shell ring 6' was not relied upon for the teaching of the housing. Instead, cover 6" was relied upon for that teaching and using

The Applicant further argues on pg. 15 of the Remark that "*Because the pump disclosed in Amirouche is suitable for pumping nanoliter volumes, the pump disclosed in Amirouche would have been unsuitable for pumping the volume of in the region of 100*

ml of breast milk required in Khalil". The Examiner respectfully disagrees and asserts Amirouche teaches pumps using piezoelectric actuation can be made very small and since the pump of Khalil is intended to be worn in a bra, one of ordinary skill would look to Amirouche for the teaching of having a piezoelectric pump of low mass to enhance comfort for the wearer. Additionally, Amirouche merely discloses that the field of microfluidics generally involves handling very small volumes of fluids and provides no indication that the pump is not capable of handling large volumes.

The Applicant further argues on pg. 16 of the Remarks that "*because in Khalil, a principle of operation is that the membrane is removable from the housing in normal use, because e.g. Khalil para. [021] discloses that the membrane is easy to assemble and easy to clean. Because the proposed modification cannot change the principle of operation of a reference (MPEP 2143.01.VI), the combination of Kooijker with Khalil does not make obvious the Claim 15 limitation that only two parts are directly removable from the housing in normal use or normal dis-assembly*". As indicated in the previous response, the Examiner respectfully asserts that Khalil merely discloses that the membrane is easy to assemble and easy to clean. Khalil does not disclose that the membrane is removed during normal disassembly. Likewise, the published application of the instant application also discloses "Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning" in paragraph 118 of the published application. Accordingly, the modification of Khalil with Kooijker

does not modify the principal operation of the device of Khalil since the modification of Kooijker teaches a breast shield liner which can be easy removed during normal use.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

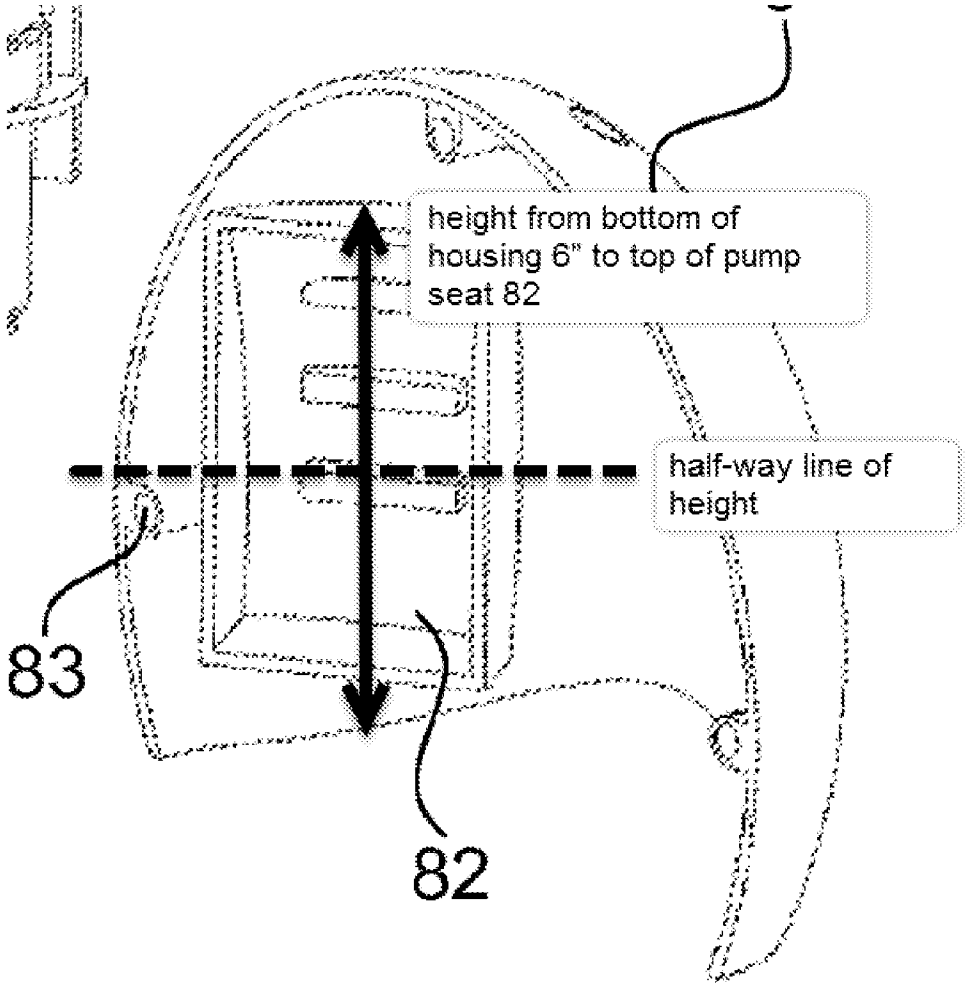
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1, 3, 1-10, 17, and 27-30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (U.S. Patent 2013/0023821) in view of Takeuchi (U.S. Patent Publication No. 2017/0043065).

Regarding claim 1, Khalil discloses a wearable breast pump system (fig. 9) including: (a) a housing (6") shaped at least in part to fit inside a bra (paragraph 32, lines 1-5), the housing in normal upright use having a height (see below; the examiner notes that "having a height" does not require the entire length of the housing); a deformable diaphragm (3; fig. 11), a breast shield (1; fig. 11), and a milk container (7'; fig. 11); an air pump (81) fitted in the housing (fig. 10) and forming part of a closed loop system (paragraphs 58-62, 66) that drives a separate, deformable diaphragm (3; paragraph 54) to generate negative air pressure (paragraph 61, lines 6-11), that diaphragm being removably mounted (paragraph 59 discloses that the breast shield 1 has a groove 100 which would allow for the membrane to be removed from the shield; fig. 11) on the breast shield (1), wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below half-way of the height of the housing, so that the breast pump system is not top-heavy for a woman using the breast pump system (see below).



However, Khalil does not teach or disclose a piezo air pump.

Takeuchi teaches a device (101) for suctioning bodily fluids from the body (paragraph 3) comprising a piezo air pump (104; paragraph 8, lines 8-10) mounted in a housing (fig. 6) further comprising a piezoelectric element (106) attached to a diaphragm (105). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the air pump of Khalil to be a piezo air pump and to have attached the piezoelectric element onto the diaphragm of Khalil. This modification would provide the added advantage of reducing

motor sound and vibration typically caused by electric motors, as taught by Takeuchi (paragraph 7).

Regarding claim 3, in the modified system of Khalil, Khalil discloses the piezo air-pump is positioned at the base of the housing (fig. 11 shows the pump 81 fitting into pump seat 82, therefore part of the pump is positioned at the base of the housing).

Regarding claim 7, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a unitary or one-piece object (fig. 3 shows the diaphragm 3 as a single object) that is removably mounted against a part of the breast shield (fig. 4/5).

Regarding claim 8, in the modified system of Khalil, Khalil discloses the deformable diaphragm is not physically connected to the piezo air-pump (fig. 10 shows the diaphragm is connected to the pump through vacuum line 80).

Regarding claim 9, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a flexible generally circular diaphragm (fig. 3; paragraph 54) that removably sits over a diaphragm housing (10; thefreedictionary.com defines "housing" as "something that supports"; fig. 4/5 shows element 10 supporting the diaphragm assembly) that is an integral part of the breast shield (fig. 4/5).

Regarding claim 10, in the modified system of Khalil, Khalil discloses a diaphragm housing (4) includes an air hole (42) that transfers negative air pressure (fig. 5) to a nipple tunnel in the breast shield (10), the negative air pressure arising when the diaphragm moves away from the diaphragm housing (fig. 5), and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed (fig. 5).

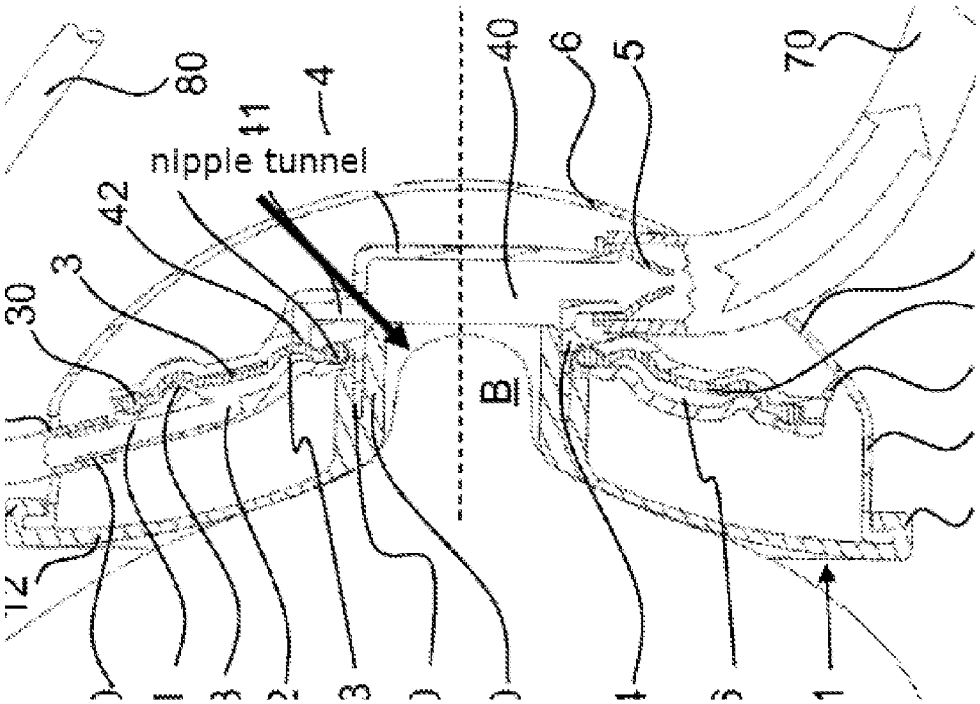
Regarding claim 17, in the modified system of Khalil, Khalil discloses a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container (73; paragraph 14-19 discloses that the container has a scale which can serve as a visual indicator if milk is flowing into the container since the level of the surface would change depending on if milk is flowing or not).

Regarding claim 27, in the modified system of Khalil, Khalil discloses the milk container is a re-useable rigid or non- collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused) that when connected to the housing forms an integral, lower part of the housing (fig. 10), with a surface shaped to continue a curved shape of the housing (fig. 10), so that the pump system can be held comfortably inside the bra (paragraph 70).

Regarding claim 28, in the modified system of Khalil, Khalil discloses the milk container is a milk container (7') that is attachable to the housing (paragraph 69, lines 6-7) with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action (paragraph 69, lines 3-6).

Regarding claim 29, in the modified system of Khalil, Khalil discloses the breast shield includes a nipple tunnel (see below) shaped to receive a nipple (fig. 4 and 5), and includes an opening that defines the start of a milk flow path (13); and the milk container is a re-useable milk container (7'; paragraph 69, lines 6-7 discloses the container being releasable indicating that it can be reused) that when connected to the housing is

positioned entirely below the opening or the milk flow path (fig. 10 shows the container positioned below the opening), when the breast pump is positioned or oriented for normal, upright use.



Regarding claim 30, in the modified system of Khalil, Khalil discloses the milk container is a milk container (7') that is removable from the housing (paragraph 69, lines 6-7) and is shaped or configured to also serve as a drinking bottle (container 7' is functionally capable of acting as a drinking bottle once coupling part 72 is removed; paragraph 69, 7-14 discloses that the coupling part has a non-return valve integrated therein indicating that the coupling part must be capable of being removed from the container for the purpose of retrieving the expressed milk) that is readily held by a baby because it is wider than it is tall (fig. 10).

Claims 2, 23, and 24 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Makower (U.S. Patent Publication No. 2017/0072118).

Regarding claim 2, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the vacuum can have a power supply integrated therein (paragraph 32, lines 7-9). However, modified Khalil fails to teach or disclose a rechargeable battery.

Rechargeable batteries are well known in the art. Additionally, Makower teaches a similar breast pump system (fig. 1B) and further contemplates the use of a rechargeable battery (paragraph 151). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the power source disclosed by Khalil to be a rechargeable battery. This modification would provide the added advantage of being able to repeatedly reuse the battery.

Regarding claim 23, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Makower teaches a breast pump system (fig. 1B) which comprises a measurement sub- system (54) that measures or infers milk flow into the milk container (paragraph 190, lines 10-14); and in which the measurement sub-system provides data (paragraph 187, lines 16-23) to a data analysis system (52) that determines metrics (paragraph 206) that correlate with user-defined requirements for milk-flow rate or milk expression (paragraph 203, lines 13-27). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified

the system of modified Khalil to incorporate a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression, as taught by Makower. This modification would enable a user to manually enter a desired milk expression volume which can be tracked while a user is pumping and enabling the system to adjust accordingly, as taught by Makower (paragraph 206)

Regarding claim 24, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Makower teaches a breast pump system (fig. 1B) which comprises a data sub-system (52) that collects and provides data (paragraph 196) to a connected device or remote application or remote server (470); and in which the collected data, in whole or in part, is used by a data analysis system (474) that provides inputs to a social media or community function or platform (paragraph 209). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to incorporate a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform, as taught by Makower. This modification would allow data generated to be transmitted to

insurance companies for reimbursement/coverage purposes (paragraph 196) or transmitted to health care professionals to ensure patient safety and proper care (paragraph 209).

Claims 4 and 6 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2018/0110906).

Regarding claims 4 and 6, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a parallel arrangement [**claim 6**].

Barack teaches a breast pump system (10; fig. 1) which comprises two or more individual pumps (fig. 1; 14) which are mounted in a parallel arrangement (paragraph 52; fig. 1). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in parallel, as taught by Barack. This modification would allow for pumps to better cool between use and decreases the pumping times to reach a given target pressure, as taught by Barack (paragraphs 51 and 52).

Claims 4 and 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Aalders (U.S. Patent Publication No. 2016/0166745).

Regarding claims 4 and 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump

comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a series arrangement [**claim 5**].

Aalders teaches a breast pump system (fig. 1; paragraph 1) and further contemplates the use of multiple pumps mounted in series (paragraph 57). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in series, as taught by Aalders. This modification would facilitate in increasing the vacuum level of the pump system, as taught by Aalders (paragraph 57).

Claim 11 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Hansen (U.S. Patent Publication No. 2016/0256617) and in further view of Chen (U.S. Patent Publication No. 2014/0031744).

Regarding claim 11, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Hansen teaches a breast pump (100) which produces a suction in the range of 0-330 mmHg (paragraph 22). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump of modified Khalil to produce a maximum suction of 330 mmHg for the purpose of preventing suction levels too high which can lead to tissue damage, as taught by Hansen (paragraph 22).

Chen also teaches a breast pump system (fig. 1; 30) which produces at least 9 L/min of free air flow (paragraph 39). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to have an air flow rate of not less than 9 L/min for the purpose of establishing an effective suckling frequency, as taught by Chen (paragraph 39).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Amirouche (U.S. Patent Publication No. 2011/0274566).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump has a mass of less than 10gm.

Amirouche teaches a micropump (10; abstract) which has piezoelectric actuation (paragraph 73) which has a mass of less than 10gm (paragraph 98). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo pump of modified Khalil to be less than 10 gm. This modification would render the pump more compact and lightweight to better fit and be supported by the breast pump of Khalil.

Claim 14 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Ryan (U.S. Patent No. 6,358,226).

Regarding claim 14, modified Khalil teaches all of the claimed limitations recited in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump is fed by air that passes through an air filter.

Ryan teaches a breast pump system (fig. 1) comprising an air pump (55) which is fed by air that passes through an air filter (53; 4:29-33). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of Khalil to incorporate an air filter, as taught by Ryan. This modification provides the added advantage of filtering out contaminants and ensuring the system remains relatively clean.

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kooijker (U.S. Patent Publication No. 2014/0323962).

Regarding claim 15, regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, and further discloses a rigid, non-collapsible milk container (7'; paragraph 69, lines 1-3) is removable under normal conditions (paragraph 69, lines 6-7). However, modified Khalil does not teach or disclose the only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

Kooijker teaches a breast shield assembly (1) which comprises a three-part assembly of a removable liner (5), a flexible insert (3) and a rigid body (2). Kooijker also teaches that the removable liner is removable (paragraph 42). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the breast shield of Khalil to be the three-part

assembly with the removable liner, as taught by Kooijker to further interface with the diaphragm of Khalil. This modification would allow for the breast-contacting portion of the shield to be removed and cleaned without the need to disassemble the rest of the pump.

Claim 16 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Pollen (U.S. Patent No. 10,039,871).

Regarding claim 16, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the breast shield is configured to attach to the housing with a circumferential securing lip (11; paragraph 48). However, modified Khalil does not teach or disclose the breast shield is configured to attach to the housing with a single, sliding push action.

Pollen teaches a similar breast pump system (10) comprising a breast shield (22) which can removably attach (3:20-22) to a housing (24) via a flange (40). Accordingly, Pollen teaches that the breast shield is configured to attach to the housing with a single, sliding push action since a user would just have to slide the housing into the flange part, as shown in fig. 5. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the connection mechanism between the shield and the housing of Khalil to be that of Pollen. This modification would provide for an equivalent structure which allows for the shield to be easily attached to the housing.

Claim 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, further in view of Alvarez (U.S. Patent Publication No. 2015/0283311) and in further view of Makower.

Regarding claim 18, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a sensor, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Alvarez teaches a breast pump system (100) which comprises two accelerometer (473 and 478) with one accelerometer (473) coupled to the housing (paragraph 98, lines 29-32) and configured to measure the movement of the housing (paragraph 31, lines 5-7) and the other accelerometer (478) coupled to a valve (paragraph 31, lines 3-5) and configured to measure the movement of the valve (paragraph 31, lines 7-8). The resulting sensor data can be used to estimate milk expression (paragraph 24). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil by incorporating the accelerometers coupled to the housing and the non-return valve 5 of Khalil. This modification would enable an accurate measurement of milk expression since background motion can be accounted for.

Makower teaches a breast pump system (100) which has a controller (52) which receives data from sensor (54) relating to expression of milk (paragraph 190). Makower further discloses that the sensor data automatically affects the pump operation since the controller keeps track of the expressed milk and ceases pumping once a targeted

expression volume has been achieved (paragraph 206). Therefore, it would have been obvious to one of ordinary skill in the art to have modified the breast pump system of modified Khalil to include the controller coupled to the accelerometers which can shut off pumping operations once a target has been reached, as taught by Makower. This modification would enable the pump to be automatically disabled once a goal has been achieved.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2014/0378895), hereinafter referred to as "Barack '895".

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

Barack '895 teaches a breast pump system (fig. 1) which comprises a control interface (30) that the user selects to indicate or record if milk is being expressed from the left or the right breast (paragraph 43). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to include a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast, as taught by Barack '895. This modification would allow users to save breast-specific parameters for that particular breast which can later be retrieved and used for a subsequent pumping session (paragraph 8).

Claim 20 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Van Schijndel (U.S. Patent Publication No. 2011/0004154).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

Van Schijndel teaches a breast pump system (1; paragraph 1) which comprises (i) an air pressure sensor (4; paragraph 6) configured to measure the negative pressure (paragraph 5) and (ii) a measurement sub-system (3) that measures or infers milk flow or milk volume (paragraph 7). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system to include an air pressure sensor configured to measure the negative pressure and a measurement sub-system that measures or infers milk flow or milk volume, as taught by Van Schijndel. This modification would allow for the measuring of the actual negative pressure applied to the breast which can prevent the damage of breast tissue (paragraph 5) and the modification of measuring milk volume can increase efficiency of the breast pump system and the optimal settings can be better determined, as taught by Van Schijndel (paragraph 7).

Claim 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Guthrie (U.S. Patent Publication No. 2016/0220743).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is a re-useable rigid or non-collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused).

However, modified Khalil does not teach or disclose at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Guthrie teaches a breast pump system network (paragraph 3) which discloses a sensor system in the neck of a collection container (paragraph 63, lines 1-2), the sensor system comprising at least one light emitter (606), configured to direct radiation towards the surface of the milk (paragraph 63, lines 26-30; fig. 6B); at least one light detector (607), configured to detect reflected radiation from the surface of the milk (paragraph 63, lines 26-30; fig. 6B); and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container (paragraph 63, lines 24-26). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the milk container of Khalil to incorporate the at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and

detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container, as taught by Guthrie. This modification would allow a user to track pumping trends in terms of volume of milk produced in a pumping session which can assist in identifying optimal pumping times and to monitor the general state of the user's health, as taught by Guthrie (paragraph 7).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kelly (U.S. Patent Publication No. 2008/0177224).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches a microcontroller programmed to control the pumping mechanism (paragraph 68). While fig. 9 appears to show control buttons which would allow a user to manually select to adjust suction pressure, modified Khalil does not teach or disclose the microcontroller being permitted to allow the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Kelly teaches a breast pump system (1) which comprises a controller (19, 21, 69) which controls the pump (paragraph 29) and allows the user to manually indicate the level of comfort that they are experiencing when the system is in use (paragraph 10, lines 15-19 discloses adjusting the vacuum level/rate to achieve a desired comfort level; if a user adjusts the level/rate, a user is indicating that the level of comfort needs to be adjusted thereby allowing a user to manually indicate the level of comfort they are experiencing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the microcontroller of

Khalil to allow a user to manually indicate the level of comfort that they are experiencing when the system is in use by providing a selector which a user to select to adjust the pumping rates/levels. This modification would allow a user to tailor the pumping speed/level to a degree which is most comfortable to the user, as taught by Kelly (paragraph 10).

Claim 26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Alvarez.

Regarding claim 26, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses a microcontroller programmed to automatically change one or more parameters of the pumping mechanism (paragraph 68). However, modified Khalil is silent regarding the microcontroller programmed to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Alvarez teaches a breast pump system (100) comprising a controller (115) which is coupled (paragraph 98, lines 15-20) to sensors which automatically calculate milk expression data (paragraph 27), which data can be reported as a function of a value of a pumping parameter (paragraph 94). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the microcontroller of Khalil to automatically measure or relate milk expression data as a function of different values of one or more of these parameters, as taught by Alvarez. This modification would allow a user to view total milk produced at a given parameter to best optimize pumping settings.

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached on Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M 1/062, 1/066, 1/06, 1/066, 1/068	8/25/2018	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See EAST search history	8/25/2018	cbf
Searched inventors in PALM and EAST	8/25/2018	cbf
Updated search	03/14/2019	cbf
Updated search	08/09/2019	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/JASON E FLICK/ Primary Examiner, Art Unit 3783	/COURTNEY FREDRICKSON/ Examiner.Art Unit 3763

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/25/2018	03/14/2019	08/09/2019						
	1	✓	✓	✓						
	2	✓	✓	✓						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	O	O						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	✓	✓	✓						
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	23	✓	✓	✓						
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	26	✓	✓	✓						
	27	✓	✓	✓						
	28	✓	✓	✓						
	29	✓	✓	✓						
	30	✓	✓	✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	65	("20020193731" | "20040056641" | "20040074281" | "20040267215" | "20050219302" | "20060122575" | "20070051172" | "20070051727" | "20080262420" | "20120277636" | "20140052056" | "20150217036" | "20150217037" | "20150283311" | "20160000980" | "20160058929" | "20160082165" | "20160082166" | "20160151551" | "20160158424" | "20160206794" | "20160220743" | "20160220745" | "20160287767" | "20160296681" | "20160310650" | "20170021068" | "20170035951" | "20170143879" | "20170220753" | "20180021490" | "2849881" | "4390024" | "5474683" | "5941847" | "5973770" | "6045529" | "6090065" | "6383163" | "6440100" | "6461324" | "6547756" | "6579258" | "6663587" | "6749582" | "7048519" | "7201735" | "7312554" | "7314400" | "7776008" | "8057425" | "8118772" | "8187227" | "8262606" | "8282596" | "8376986" | "8702646" | "8801495" | "8876760" | "8926556" | "9033913" | "9173587" | "9345274" | "9539377" | "D548831").PN.	US-PGPUB; USPAT	OR	OFF	2018/08/07 13:17
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S4	19	("20040122358" | "20060226108" | "20080077042" | "20080167579" | "20120004603" | "3895533" | "4024856" | "4338953" | "5347656" | "5666104" | "5827191" | "7316653" | "7621797" | "7794425" | "8308648" | "8777864" | "8801658" | "8827911").PN. OR ("8992445").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:50
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			USOCR			
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S7	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S8	2787	(a61m1/062 a61m1/066 a61m1/06).cpc. not S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S9	45	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$).did. or (WO-2015174330-$ or WO-2016024558-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 14:59
S10	14	S9 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:59
S11	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 15:04
S12	143	a61j13/00.cpc.	US-PGPUB; USPAT	OR	OFF	2018/08/10 10:30
S13	409	a61j13/00.cpc.	US-PGPUB;	OR	OFF	2018/08/10 10:30

			USPAT; USOCR; FPRS; EPO; JPO			
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S17	2665	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S13)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S18	71	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$).did. or (WO-2015174330-$ or WO-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 11:47

		2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$).did.				
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S20	4	S18 and ((air with pump$4) same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:50
S21	16	S18 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:15
S22	1	S18 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:40
S23	0	a61m1/1058.cpc. and breast and diaphragm	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:42
S24	5	breast same pump$4 same piezo$8 same air	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:43
S25	1	("9884172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/10 13:58
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S28	1	"59563425".FMID.	US-PGPUB; USPAT;	OR	OFF	2018/08/24 10:20

			FPRS			
S29	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:26
S30	44	S29 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:26
S31	17	S29 and (pump$4 with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:27
S32	51	S26 and "air pump"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/24 11:07

			JPO			
S33	4	"47900902".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:13
S34	10	("20030212374" | "20050251089" | "20050283900" | "20070135778" | "20110054389" | "3084691" | "4229029" | "5295957" | "6070659").PN. OR ("9511176").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/24 11:16
S35	2	"51149640".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:17
S36	271	S26 and (control$4 same select$4 left same right same breast)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 12:50
S37	3	S29 and (recharg$4 with battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 13:04
S38	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S39	9	S38 and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S40	11	S38 and (light with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:48
S41	0	S38 and (radiation with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S42	2	S38 and (radiation same milk same (volume quantity amount height))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/24 14:51

			FPRS; EPO; JPO			
S43	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S44	10	S43 and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S45	1	a61m1/1058 and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S46	27	a61m1/1058.cpc. and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S47	23	S43 and (indicator same milk same (express$4 flow$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:26
S48	51	S43 and (air same pressure same sens$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:30
S49	19	S43 and ((indicat$4 record$4) same (right and left))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:38
S50	56	S43 and (pump$4 with series)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:42
S51	77	S43 and (pump$4 with weigh$4)	US-PGPUB;	OR	OFF	2018/08/24 19:47

			USPAT; USOCR; FPRS; EPO; JPO			
S52	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 19:59
S53	44	S52 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S54	5	S53 and (air with filter$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S55	3	S43 and (pump$4 with (db decibal?))	US-PGPUB;	OR	OFF	2018/08/24 20:07

			USPAT; USOCR; FPRS; EPO; JPO			
S56	6	S43 and ((db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S57	26	S43 and (sens$4 with (orientation angle tilt placement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:16
S58	9	S43 and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:31
S59	484	a61m$/$.cpc. and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:32
S60	1	S43 and "social media"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:52
S61	408	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:13
S63	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:18
S64	359	a61m$/$.cpc. and ((pump$4 with weigh$4) same (portable lightweight carry$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:30

S65	1	("20160166745").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:16
S66	1	("20160058928").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:23
S67	1	("20110004154").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/26 10:55
S68	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 11:09
S69	2	S68 and (radiation same (height quantity amount volume))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/26 11:09

			FPRS; EPO; JPO			
S70	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 12:24
S71	3	S70 and ((diaphragm membrane) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 12:24
S72	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/27 13:09

			JPO			
S73	137	S72 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S74	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S75	9	S74 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S76	19	S74 and (shield with snap$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:16
S77	1	("20110152855").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 13:20
S78	32	S74 and (flow with rate with air)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:33
S79	3	S74 and (stall with pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:56
S80	98	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 13:56

		20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S81	17	S80 and (pressure same (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:57
S82	18	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 14:08
S83	0	S82 and breast	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S84	10	S82 and (lactat$3 milk)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08

S85	14	S80 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:10
S86	5	S74 and ((piezo piezoelectric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:47
S87	230	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:48
S88	6	S87 and (breast milk lactat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:53
S89	161	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:11
S90	0	(2017/0072118).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S91	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S92	40	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:22
S93	3	"45513973".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 15:23
S94	364	(((piezo piezoelectric) with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:32

S95	3	"20170035951"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:33
S96	1	S95 and (suction$4 with piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:34
S97	1	("20130064683").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:38
S98	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:39
S99	1	(US-20170172485-$).did.	US-PGPUB	OR	OFF	2018/08/28 16:48
S100	0	S99 and "function of"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 16:48
S101	100	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/28 17:19

		or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S102	0	S101 and ((meaur$4 with milk) same rate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S103	0	S101 and ((meaur$4 with milk) same (frequency speed))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S104	16	S101 and ((measur$4 with milk) same (frequency speed rate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:21
S105	0	S101 and ((measur$4 with milk) with "function of")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:23
S106	6	S101 and (decrease with (rate speed frequency strong))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:10
S107	2	S101 and (latch$4 with adjust$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:22
S108	50	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB;	OR	OFF	2018/08/28 18:24

			USPAT; USOCR; FPRS; EPO; JPO			
S109	0	(a61m$/$).cpc. and (wear$4 with pump$4) and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:25
S110	83	(a61m$/$).cpc. and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:26
S111	101	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 09:43

		3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S112	3	S111 and (shield with (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:43
S113	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:47
S114	86	S113 and ((diapragm housing) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:53
S115	9	S113 and ((diapragm membrane) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:54
S116	34	S111 and (diaphragm membrane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:07
S117	28	S113 and (diaphragm membrane) and (shield with dispos$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:10
S118	28	S113 and ((diaphragm membrane) with (coupl$4 attach$4 mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:23
S119	0	a61j16/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:41

S120	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:42
S121	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S122	23	S121 and (sens$4 same (orient$4 plac$4 situat$4) same (nipple shield))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S123	11	S121 and ((sens$4 accelerometer) with breast with (move moved moving movement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:32
S124	10	S121 and accelerometer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:33
S125	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 14:27
S126	259	S121 and ((lower$4 decrea$4) with (suction$4 intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:51
S127	45	S121 and ((lower$4 decrea$4) with (intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:59
S128	11	(a61m$/$.cpc.) and ((miniature compact small) same (piezoelectric piezo-electric piezo) same pump$4 same (suction$4 vacuum$4) same (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 15:40
S129	127	S121 and ((pressure suction$4) with (mmhg	US-	OR	OFF	2018/08/29

		kpa mbar pa bar))	PGPUB; USPAT; USOCR; FPRS; EPO; JPO			17:16
S130	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:29
S131	106	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:31
S132	104	S131 and @ad<="20170615"	US-	OR	OFF	2018/08/29

			PGPUB; USPAT; USOCR; FPRS; EPO; JPO			17:32
S133	14	(US-20160166745-$ or US-20150283311-$ or US-20180110906-$ or US-20140378895-$ or US-20140031744-$ or US-20160220743-$ or US-20160256617-$ or US-20080177224-$ or US-20130023821-$ or US-20160058928-$ or US-20170043065-$ or US-20110004154-$).did. or (US-10039871-$ or US-6358226-$).did.	US-PGPUB; USPAT	OR	OFF	2018/08/29 18:08
S134	1	"52574056".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 18:46
S135	0	("2009024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S136	1	("20090024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S137	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S138	203	S137 and ((shield nipple) with (remov$4 replac$4 clean$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S139	1	("4535627").PN.	US-PGPUB; USPAT	OR	OFF	2019/01/08 12:52
S140	74	(("20180361040") or ("20180236147") or ("20120277728") or ("7785305") or ("20080208116") or ("7223255") or ("7789865") or ("8118772") or ("20080275385") or ("9956331") or ("8057425") or ("20070219486") or ("20020193731") or ("10046097") or ("20140378946") or ("20180326130") or ("20120316493") or ("8568350") or ("20030191427") or ("8070716") or ("9539377") or ("20160303298") or ("20160206794") or ("9539376") or ("20160310649") or ("20160287769") or ("20160310650") or ("20180001002") or ("20090099511") or ("7776008") or ("20090062731") or ("20160296682") or ("20050154349") or ("20030191433") or ("5749850") or ("20100292636") or	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/08 12:54

		("7559915") or ("20080262420") or ("20160325031") or ("20170173232") or ("7749188") or ("6887217") or ("6139521") or ("20180021490") or ("20150065994") or ("20180028732") or ("20150196460") or ("9636282") or ("7758540") or ("8945046") or ("20080243059") or ("20110251552") or ("20170119942") or ("20130023821") or ("6997897") or ("9033913") or ("20150157776") or ("20090254028") or ("5514166") or ("20010038799") or ("20070161947") or ("20130046234") or ("8926556") or ("7255681") or ("7008400") or ("6257847") or ("20100145264") or ("20170151380") or ("20070078383") or ("5542921") or ("20180333523") or ("8075516") or ("20180369464") or ("20110071466")).PN.				
S141	111	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$).did. or (WO-2015174330-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2019/01/08 13:02

		WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S142	35	S141 and (heavy weight "center of gravity" "centre of gravity" mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:03
S143	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S144	284	S143 and (heavy weight "center of gravity" "centre of gravity")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S145	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S146	18	S145 and (weight with distribut$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S147	1	("4535627").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/03/14 14:19

EAST Search History (Interference)

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3/ 14/ 2019 4:00:13 PM
C:\ Users\ cfredrickson\ Documents\ EAST\ Workspaces\ 16009547.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No. **5958**
APPLICATION NO.	**16/009,547**	
FILED:	**June 15, 2018**	Examiner: **C. Fredrickson**
CASE NO.	**373499.00002**	Group Art Unit: **3783**
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON July 25, 2019

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY AND AMENDMENT UNDER 37 C.F.R. §1.112
TO EXAMINER'S ACTION MAILED APRIL 26, 2019

Sir:

This is in response to the Office Action mailed April 26, 2019, having a period for response set to expire on July 26, 2019. The following amendments and remarks are respectfully submitted.

Amendments to the claims begin on page 2 of this paper; Remarks begin on page 8 of this paper.

In the Claims

1. (Currently amended) A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra, the housing in normal upright use having a height;

(b) a deformable diaphragm, a breast shield, and a milk container;

(c) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives, the deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on the breast shield, wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below ~~the~~ half-way of the height ~~line~~ of the housing, so that the breast pump system is not top-heavy for a woman using the breast pump system.

2. (Original) The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. (Previously presented) The wearable breast pump system of Claim 1, in which the piezo air-pump is positioned at a base of the housing.

4. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of the breast shield.

8. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is a flexible generally circular diaphragm that removably sits over a diaphragm housing that is an integral part of the breast shield.

10. (Original) The wearable breast pump system of Claim 1, in which a diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. (Currently amended) The wearable breast pump system of Claim 1, in which the piezo air-pump ~~weighs~~ has a mass less than 10gm.

13. (Previously presented) The wearable breast pump system of Claim 11, in which, in normal operation, the breast pump system makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

14. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump is fed by air that passes through an air filter.

15. (Original) The wearable breast pump system of Claim 1, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

16. (Original) The wearable breast pump system of Claim 1, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. (Original) The wearable breast pump system of Claim 1, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. (Previously presented) The wearable breast pump system of Claim 1, in which the housing includes a sensor, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. (Original) The wearable breast pump system of Claim 1, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. (Original) The wearable breast pump system of Claim 1, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container; the breast pump system including:

(a) at least one light emitter, configured to direct radiation towards the surface of the milk;

(b) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the milk container.

22. (Cancelled)

23. (Original) The wearable breast pump system of Claim 1, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. (Original) The wearable breast pump system of Claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a re-useable rigid or non-collapsible milk container that when connected to

the housing forms an integral, lower part of the housing, with a surface shaped to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. (Previously presented) The wearable breast pump system of Claim 1, in which the breast shield includes a nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and wherein the milk container is a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal upright use.

30. (Previously presented) The wearable breast pump system of Claim 1, wherein the milk container is a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

REMARKS

In the Office Action, the Office indicated that claims 1-21 and 23-30 are pending in the application, claims 1-12, 14-21 and 23-30 have been rejected and claim 13 is objected to.

Amendments and Basis

Independent Claim 1 has been amended, for clarity. Basis is in Claim 1 previously on file. The limitation "in normal upright use" is included, for clarity. Basis includes that the Description mentions "positioned upright for normal use" in several places.

Dependent Claim 12 is amended. Basis is in Claim 12 as filed.

Allowable Subject Matter

On page 24 of the Office Action, the Office has indicated that claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant thanks the Office for this indication of allowable subject matter.

The §112 Rejection

On page 4 of the Office Action, claims 1-21 and 23-30 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Independent Claim 1 and dependent claim 12 have been amended, so as to overcome the objection. Accordingly, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1-21 and 23-30 under 35 U.S.C. §112.

Rejections under 35 U.S.C. §103

On page 5 of the Office Action, claims 1, 3, 7-10, 17, 22 and 27-30 have again been rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi. (Applicant notes that the heading for this rejection indicates "...1-10, ...," but based upon the discussion of the rejection, believes it should be "...7-10...".) On page 10 of the Office Action, claims 2, 23 and 24 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2017/0072118 to Makower. On page 13 of the Office Action, claims 4 and 6 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2018/0110906 to Barack; and claims 4 and 5 have again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0166745 to Aalders. On page 14 of the Office Action, claim 11 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0256617 to Hansen and in further view of U.S. Patent Application Publication No. 2014/0031744 to Chen. On page 15 of the Office Action, claims 12 and 13 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of newly-cited U.S. Patent Application Publication No. 2011/0274566 to Amirouche; and claim 14 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No. 6,358,226 to Ryan. On page 16 of the Office Action, claim 15 has again been rejected under 35 U.S.C. §103 as

being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0323962 to Kooijker. On page 17 of the Office Action, claim 16 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No. 10,039,871 to Pollen; and on page 18, claim 18 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2015/0283311 to Alvarez and in further view of Makower. On page 19 of the Office Action, claim 19 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0378895 to Barack ("Barack '895"). On page 20, claim 20 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2011/0004154 to Van Schijndel; and claim 21 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0220743 to Guthrie. On page 22 of the Office Action, claim 25 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2008/0177224 to Kelly; and on page 23, claim 26 has again been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of Alvarez.

A *Prima Facie* Case of Obviousness Has Not Been Established

KSR (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)) requires that the Office provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Further, the Office must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." In addition, the Office must make "explicit" this rationale of "the apparent reason to combine the known elements in the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art."

The words of a Claim describe and point out the invention by a series of limiting words or phrases – limitations (*Corning Glass Works v. Sumitomo Elec. USA Inc.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989)).

On pages 4 to 7 of the Office Action, the Office rejected former Claim 1 under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi. The Examiner's analysis includes:

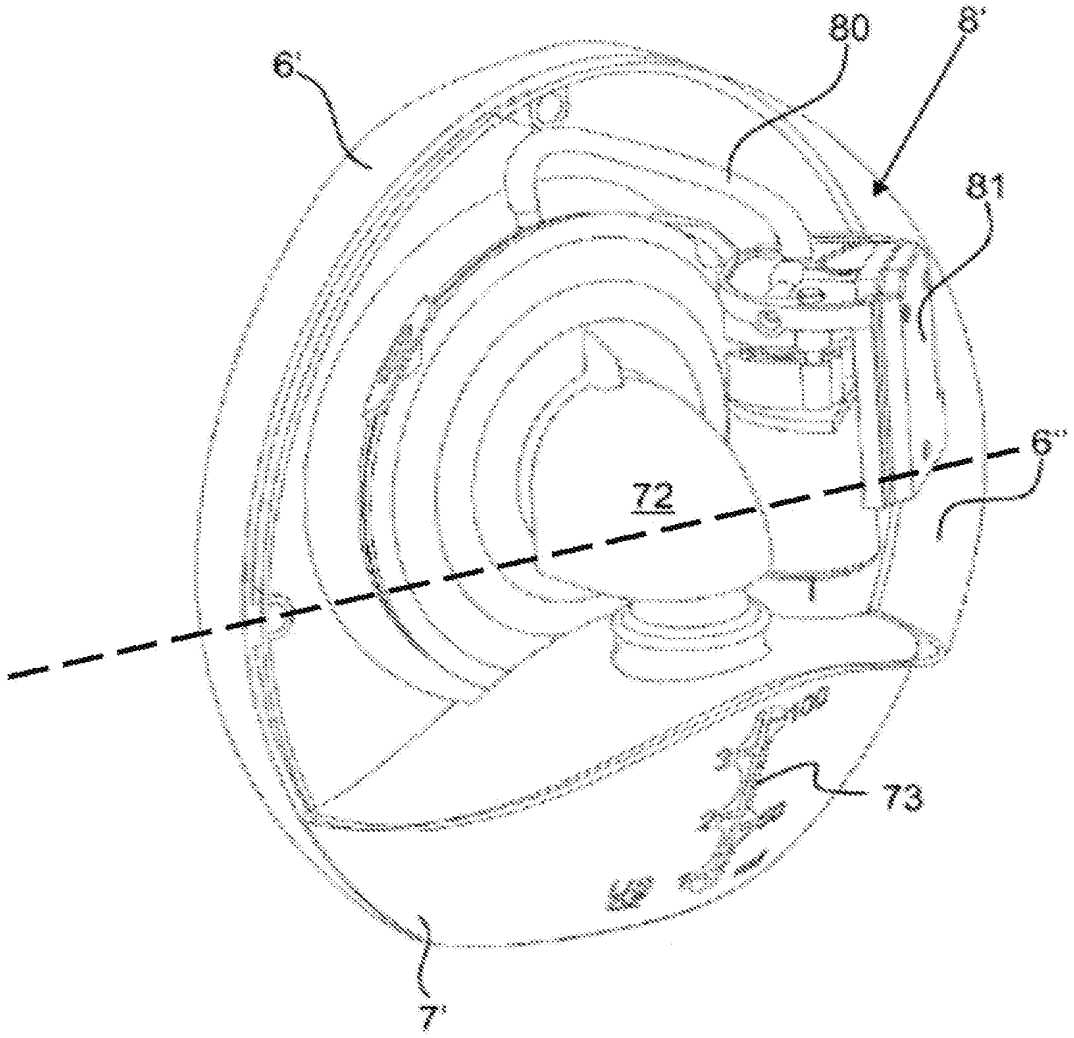
> "(see below; the examiner also notes that the "half-way height" line has not been defined by the claim, as such any line which is at or above the center of gravity is considered to read on the claimed limitation)" page 6.

Therefore, the rejection of Claim 1 made in the Office Action by the Office no longer applies for amended Claim 1, because amended Claim 1 includes the amended limitations

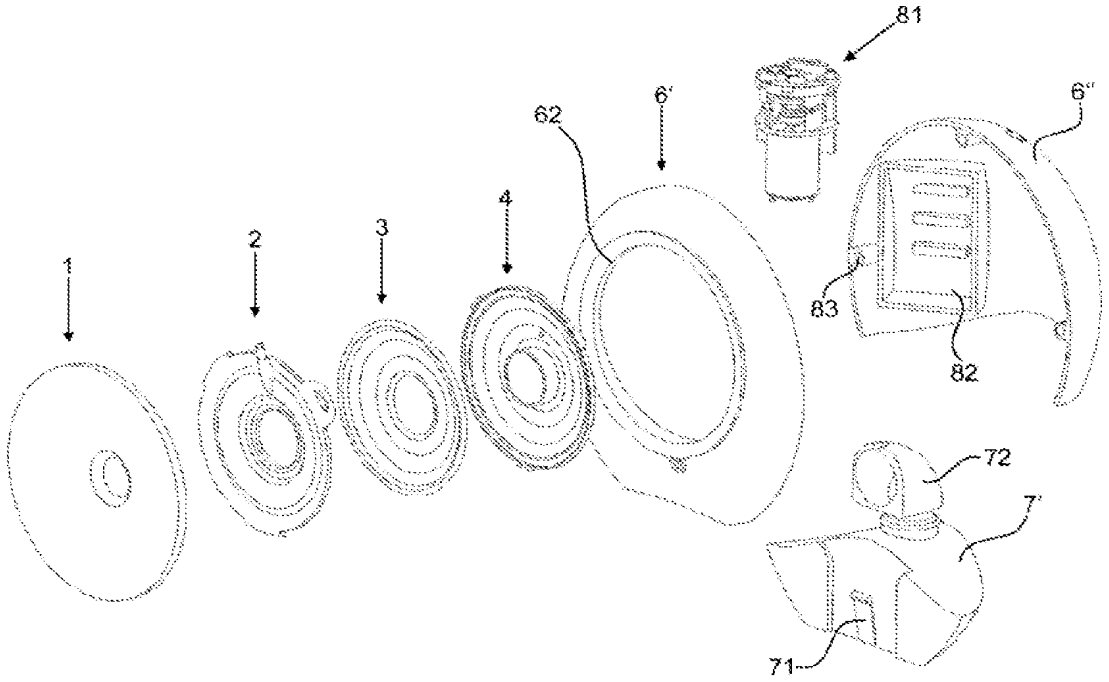
"**the housing in normal upright use having a height**"

"the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way **of the** height line of the housing"

Therefore for amended Claim 1, the following graphical analysis in relation to Khalil Fig. 10 applies, in which the dashed line is a line indicating half-way of the height of the housing:



The position of the line indicating half-way of the height of the housing in the above analysis is justified, because in Khalil, the housing includes a shell ring 6' (Khalil para. [0067]), which is the tallest piece of the housing and half way of the height therefore corresponds to half way of the height of the shell ring 6' in normal upright use. That the shell ring 6' is the tallest piece of the housing is confirmed by Khalil Fig. 11, reproduced below



Khalil, Fig. 11

Khalil Fig. 11 also shows a pump seat 82 (Khalil, para. [0067]). From the position of the pump seat 82 in the cover 6'', it is clear that in normal upright use, the pump 81 is mainly situated above half way of the height of the shell ring 6'.

The above graphical analysis in relation to Khalil Fig. 10 does not make obvious the amended Claim 1 limitation "wherein, in normal upright use, the center of gravity of the

breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way **of the** height line of the housing", because for the system of Khalil Figs. 10-11 in the above graphical analysis, the center of gravity would appear to be above half-way of the height of the housing, which is the opposite to the limitation of amended Claim 1. This conclusion is supported by the pump being mainly situated above half way of the height of the shell ring 6', in normal upright use, as shown in Khalil Fig. 11, because from the position of the pump seat 82 in the cover 6'', it is clear that in normal upright use, the pump 81 is mainly situated above half way of the height of the shell ring 6'.

Amended Claim 1 is therefore not obvious over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi.

The invention of amended Claim 1 has the advantage that the breast pump system does not feel top-heavy to a woman while using the breast pump system. This provides stability of the breast pump system inside the bra, with the additional advantage that a greater range of bras are compatible with the breast pump system, rather than requiring a specialized bra such as a sports bra or a maternity bra. The breast pump system further provides greater comfortableness to the woman while using the breast pump system, for example because the lower center of gravity compresses a breast less, and the lower center of gravity leads to more weight being supported by the bra cup.

On page 15 of the Office Action, Examiner rejects Claim 12 under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1, and further in view of U.S. Patent Application Publication No. 2011/0274566 to Amirouche.

But Amirouche does not mention use of the pump it discloses in a breast pump application. Amirouche discloses

> "[0002] The present disclosure relates to a magnetically driven micropump for handling small fluid volumes. In particular, the present disclosure related to a micropump including a magnetically actuated membrane to transfer fluids.
>
> [0003] The field of microfluidics generally encompasses handling very small fluid volumes on the order of several nanoliters." Amirouche paras. [0002] to [0003].

The skilled person would understand that the volume of breast milk collected in Khalil would be in the region of 100 ml. Because the pump disclosed in Amirouche is suitable for pumping nanoliter volumes, the pump disclosed in Amirouche would have been unsuitable for pumping the volume of in the region of 100 ml of breast milk required in Khalil, and therefore the skilled person would not have combined Amirouche with Khalil.

Accordingly, amended Claim 12 is not obvious over Khalil in view of Takeuchi, and further in view of Amirouche.

On pages 16 to 17 of the Office Action, Claim 15 is rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1, and further in view of Kooijker (U.S. Patent Publication No. 2014/0323962).

The MPEP 2143.01.VI states

> "**VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE**
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti,* 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of

> references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. The seal construction taught in the primary reference required rigidity for operation, whereas the seal in the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.")."

The proposed modification of Khalil by Kooijker, made by the Office, changes the principle of operation of Khalil, because in Khalil, a principle of operation is that the membrane is removable from the housing in normal use, because e.g. Khalil para. [0021] discloses that the membrane is easy to assemble and easy to clean. The membrane is not the breast shield, or a rigid, non-collapsible milk container. Because the proposed modification cannot change the principle of operation of a reference (MPEP 2143.01.VI), the combination of Kooijker with Khalil does not make obvious the Claim 15 limitation that only two parts are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container, because Khalil discloses that the membrane is removable from the housing in normal use, because e.g. Khalil para. [0021] discloses that the membrane is easy to assemble and easy to clean. Hence Claim 15 is not obvious over Kooijker in combination with Khalil and Takeuchi for this reason.

The dependent Claims are not obvious, at least by virtue of their dependence on amended Claim 1.

Accordingly, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1-21 and 23-30 under 35 USC §103.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims. An early Notice of Allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any fee deficiencies associated with this communication to applicant's Deposit Account No. 50-4364.

Respectfully submitted

July 25, 2019
Date

/Mark D. Simpson/
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Electronic Acknowledgement Receipt

EFS ID:	36689358
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	25-JUL-2019
Filing Date:	15-JUN-2018
Time Stamp:	15:21:19
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		35677296_1.PDF	877540 06766e36d05962cc6518c02c93f85da0272df826	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	17
Warnings:			
Information:			
	Total Files Size (in bytes):	877540	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/009,547	Filing Date 06/15/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/25/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/MONIQUE BENJAMIN/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 04/26/2019

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
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1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
04/26/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

Office Action Summary	Application No. 16/009,547	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07December2018.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-21 and 23-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-12,14-21 and 23-30 is/are rejected.

8) ☑ Claim(s) 13 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 15June2018 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the amendment filed on December 7, 2018. As directed by the amendment: claims 1, 3, 13, and 18 have been amended and claim 22 has been cancelled. Thus, claims 1-21 and 23-30 are presently pending in this application.

Applicant's amendments to the Specification, Drawings, and Claims have overcome each and every objection and 112(b) rejections previously set forth in the Non-Final Office Action mailed September 7, 2018.

Response to Arguments

Applicant's arguments filed December 7, 2018 have been fully considered but they are not persuasive.

The Applicant argues on pgs. 12-15 that Khalil does not teach the subject matter of newly amended claim 1. The Examiner asserts that using a different interpretation of the housing, Khalil discloses the newly added claim matter, as discussed in more detail below.

The Applicant further argues on pg. 18 of the Remarks that "*because in Khalil, a principle of operation is that the membrane is removable from the housing in normal use, because e.g. Khalil para. [021] discloses that the membrane is easy to assemble and easy to clean. Because the proposed modification cannot change the principle of operation of a reference (MPEP 2143.01.VI), the combination of Kooijker with Khalil does not make obvious the Claim 15 limitation that only two parts are directly removable from the housing in normal use or normal dis-assembly*". The Examiner respectfully asserts that Khalil merely discloses that the membrane is easy to assemble and easy to clean. Khalil does not disclose that the membrane is removed during normal disassembly. Likewise, the published application of the instant application also discloses "Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning" in paragraph 118 of the published application. Accordingly, the modification of Khalil with Kooijker does not modify the principal operation of the device of Khalil since the modification of Kooijker teaches a breast shield liner which can be easy removed during normal use.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 23-30 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claim 1, there is a lack of antecedent basis in the limitation "the half-way height line".

Regarding claim 12, the claim uses grams to convey the upper range of the pump. However, grams is a unit of mass, not weight.

Claims 2-11, 13-21, and 23-30 are also rejected by virtue of being dependent on claim 1.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

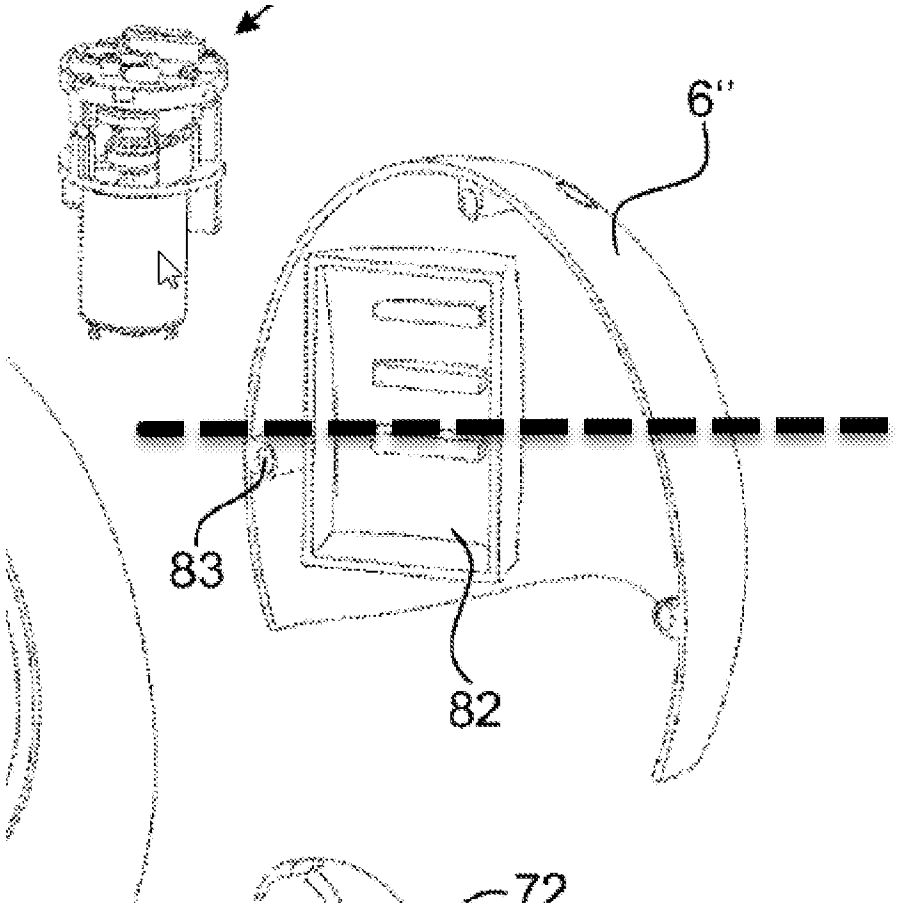
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1, 3, 1-10, 17, and 27-30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (U.S. Patent 2013/0023821) in view of Takeuchi (U.S. Patent Publication No. 2017/0043065).

Regarding claim 1, Khalil discloses a wearable breast pump system (fig. 9) including: (a) a housing (6") shaped at least in part to fit inside a bra (paragraph 32, lines 1-5); a deformable diaphragm (3; fig. 11), a breast shield (1; fig. 11), and a milk container (7'; fig. 11); an air pump (81) fitted in the housing (fig. 10) and forming part of

a closed loop system (paragraphs 58-62, 66) that drives a separate, deformable diaphragm (3; paragraph 54) to generate negative air pressure (paragraph 61, lines 6-11), that diaphragm being removably mounted (paragraph 59 discloses that the breast shield 1 has a groove 100 which would allow for the membrane to be removed from the shield; fig. 11) on the breast shield (1), wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way height line of the housing, so that the breast pump system is not top-heavy for a woman using the breast pump system (see below; the examiner also notes that the "half-way height" line has not been defined by the claim, as such any line which is at or above the center of gravity is considered to read on the claimed limitation). However, Khalil does not teach or disclose a piezo air pump.



Takeuchi teaches a device (101) for suctioning bodily fluids from the body (paragraph 3) comprising a piezo air pump (104; paragraph 8, lines 8-10) mounted in a housing (fig. 6) further comprising a piezoelectric element (106) attached to a diaphragm (105). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the air pump of Khalil to be a piezo air pump and to have attached the piezoelectric element onto the diaphragm of Khalil. This modification would provide the added advantage of reducing motor sound and vibration typically caused by electric motors, as taught by Takeuchi (paragraph 7).

Regarding claim 3, in the modified system of Khalil, Khalil discloses the piezo air-pump is positioned at the base of the housing (fig. 11 shows the pump 81 fitting into pump seat 82, therefore part of the pump is positioned at the base of the housing).

Regarding claim 7, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a unitary or one-piece object (fig. 3 shows the diaphragm 3 as a single object) that is removably mounted against a part of the breast shield (fig. 4/5).

Regarding claim 8, in the modified system of Khalil, Khalil discloses the deformable diaphragm is not physically connected to the piezo air-pump (fig. 10 shows the diaphragm is connected to the pump through vacuum line 80).

Regarding claim 9, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a flexible generally circular diaphragm (fig. 3; paragraph 54) that removably sits over a diaphragm housing (10; thefreedictionary.com defines "housing" as "something that supports"; fig. 4/5 shows element 10 supporting the diaphragm assembly) that is an integral part of the breast shield (fig. 4/5).

Regarding claim 10, in the modified system of Khalil, Khalil discloses a diaphragm housing (4) includes an air hole (42) that transfers negative air pressure (fig. 5) to a nipple tunnel in the breast shield (10), the negative air pressure arising when the diaphragm moves away from the diaphragm housing (fig. 5), and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed (fig. 5).

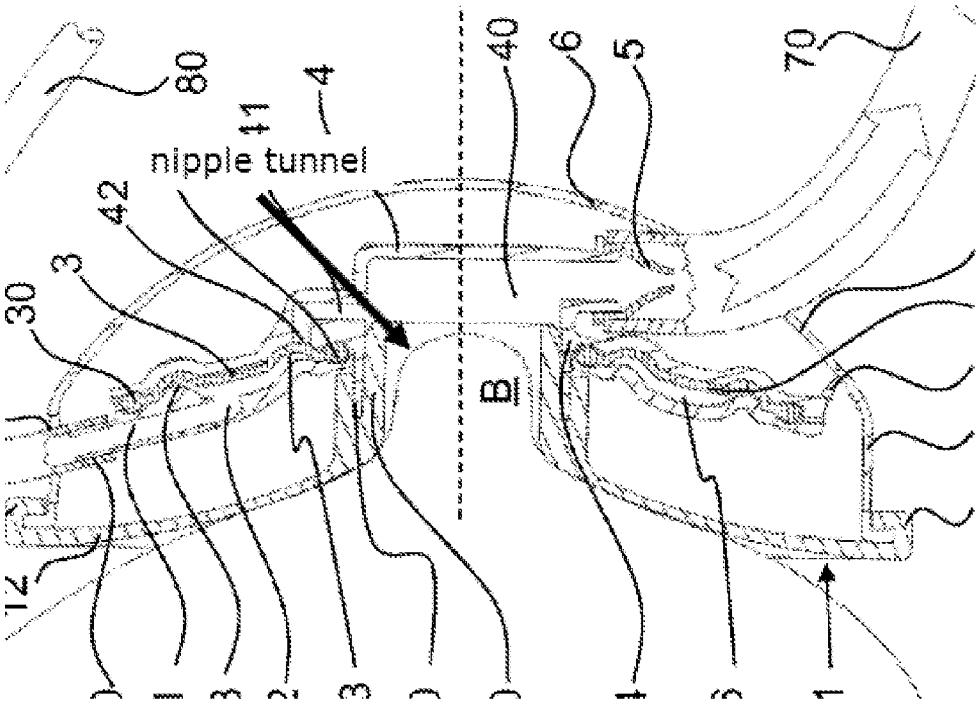
Regarding claim 17, in the modified system of Khalil, Khalil discloses a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container (73; paragraph 14-19 discloses that the container has a scale which can serve

as a visual indicator if milk is flowing into the container since the level of the surface would change depending on if milk is flowing or not).

Regarding claim 27, in the modified system of Khalil, Khalil discloses the milk container is a re-useable rigid or non- collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused) that when connected to the housing forms an integral, lower part of the housing (fig. 10), with a surface shaped to continue a curved shape of the housing (fig. 10), so that the pump system can be held comfortably inside the bra (paragraph 70).

Regarding claim 28, in the modified system of Khalil, Khalil discloses the milk container is a milk container (7') that is attachable to the housing (paragraph 69, lines 6-7) with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action (paragraph 69, lines 3-6).

Regarding claim 29, in the modified system of Khalil, Khalil discloses the breast shield includes a nipple tunnel (see below) shaped to receive a nipple (fig. 4 and 5), and includes an opening that defines the start of a milk flow path (13); and the milk container is a re-useable milk container (7'; paragraph 69, lines 6-7 discloses the container being releasable indicating that it can be reused) that when connected to the housing is positioned entirely below the opening or the milk flow path (fig. 10 shows the container positioned below the opening), when the breast pump is positioned or oriented for normal, upright use.



Regarding claim 30, in the modified system of Khalil, Khalil discloses the milk container is a milk container (7') that is removable from the housing (paragraph 69, lines 6-7) and is shaped or configured to also serve as a drinking bottle (container 7' is functionally capable of acting as a drinking bottle once coupling part 72 is removed; paragraph 69, 7-14 discloses that the coupling part has a non-return valve integrated therein indicating that the coupling part must be capable of being removed from the container for the purpose of retrieving the expressed milk) that is readily held by a baby because it is wider than it is tall (fig. 10).

Claims 2, 23, and 24 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Makower (U.S. Patent Publication No. 2017/0072118).

Regarding claim 2, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the vacuum can have a

power supply integrated therein (paragraph 32, lines 7-9). However, modified Khalil fails to teach or disclose a rechargeable battery.

Rechargeable batteries are well known in the art. Additionally, Makower teaches a similar breast pump system (fig. 1B) and further contemplates the use of a rechargeable battery (paragraph 151). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the power source disclosed by Khalil to be a rechargeable battery. This modification would provide the added advantage of being able to repeatedly reuse the battery.

Regarding claim 23, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Makower teaches a breast pump system (fig. 1B) which comprises a measurement sub- system (54) that measures or infers milk flow into the milk container (paragraph 190, lines 10-14); and in which the measurement sub-system provides data (paragraph 187, lines 16-23) to a data analysis system (52) that determines metrics (paragraph 206) that correlate with user-defined requirements for milk-flow rate or milk expression (paragraph 203, lines 13-27). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the system of modified Khalil to incorporate a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system

provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression, as taught by Makower. This modification would enable a user to manually enter a desired milk expression volume which can be tracked while a user is pumping and enabling the system to adjust accordingly, as taught by Makower (paragraph 206)

Regarding claim 24, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Makower teaches a breast pump system (fig. 1B) which comprises a data sub-system (52) that collects and provides data (paragraph 196) to a connected device or remote application or remote server (470); and in which the collected data, in whole or in part, is used by a data analysis system (474) that provides inputs to a social media or community function or platform (paragraph 209). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to incorporate a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform, as taught by Makower. This modification would allow data generated to be transmitted to insurance companies for reimbursement/coverage purposes (paragraph 196) or

transmitted to health care professionals to ensure patient safety and proper care (paragraph 209).

Claims 4 and 6 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2018/0110906).

Regarding claims 4 and 6, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a parallel arrangement [**claim 6**].

Barack teaches a breast pump system (10; fig. 1) which comprises two or more individual pumps (fig. 1; 14) which are mounted in a parallel arrangement (paragraph 52; fig. 1). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in parallel, as taught by Barack. This modification would allow for pumps to better cool between use and decreases the pumping times to reach a given target pressure, as taught by Barack (paragraphs 51 and 52).

Claims 4 and 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Aalders (U.S. Patent Publication No. 2016/0166745).

Regarding claims 4 and 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump

comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a series arrangement [**claim 5**].

Aalders teaches a breast pump system (fig. 1; paragraph 1) and further contemplates the use of multiple pumps mounted in series (paragraph 57). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in series, as taught by Aalders. This modification would facilitate in increasing the vacuum level of the pump system, as taught by Aalders (paragraph 57).

Claim 11 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Hansen (U.S. Patent Publication No. 2016/0256617) and in further view of Chen (U.S. Patent Publication No. 2014/0031744).

Regarding claim 11, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Hansen teaches a breast pump (100) which produces a suction in the range of 0-330 mmHg (paragraph 22). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump of modified Khalil to produce a maximum suction of 330 mmHg for the purpose of preventing suction levels too high which can lead to tissue damage, as taught by Hansen (paragraph 22).

Chen also teaches a breast pump system (fig. 1; 30) which produces at least 9 L/min of free air flow (paragraph 39). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to have an air flow rate of not less than 9 L/min for the purpose of establishing an effective suckling frequency, as taught by Chen (paragraph 39).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Amirouche (U.S. Patent Publication No. 2011/0274566).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump weighs less than 10gm.

Amirouche teaches a micropump (10; abstract) which has piezoelectric actuation (paragraph 73) which weighs less than 10gm (paragraph 98). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo pump of modified Khalil to be less than 10 gm. This modification would render the pump more compact and lightweight to better fit and be supported by the breast pump of Khalil.

Claim 14 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Ryan (U.S. Patent No. 6,358,226).

Regarding claim 14, modified Khalil teaches all of the claimed limitations recited in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump is fed by air that passes through an air filter.

Ryan teaches a breast pump system (fig. 1) comprising an air pump (55) which is fed by air that passes through an air filter (53; 4:29-33). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of Khalil to incorporate an air filter, as taught by Ryan. This modification provides the added advantage of filtering out contaminants and ensuring the system remains relatively clean.

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kooijker (U.S. Patent Publication No. 2014/0323962).

Regarding claim 15, regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, and further discloses a rigid, non-collapsible milk container (7'; paragraph 69, lines 1-3) is removable under normal conditions (paragraph 69, lines 6-7). However, modified Khalil does not teach or disclose the only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

Kooijker teaches a breast shield assembly (1) which comprises a three-part assembly of a removable liner (5), a flexible insert (3) and a rigid body (2). Kooijker also teaches that the removable liner is removable (paragraph 42). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the breast shield of Khalil to be the three-part

assembly with the removable liner, as taught by Kooijker to further interface with the diaphragm of Khalil. This modification would allow for the breast-contacting portion of the shield to be removed and cleaned without the need to disassemble the rest of the pump.

Claim 16 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Pollen (U.S. Patent No. 10,039,871).

Regarding claim 16, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the breast shield is configured to attach to the housing with a circumferential securing lip (11; paragraph 48). However, modified Khalil does not teach or disclose the breast shield is configured to attach to the housing with a single, sliding push action.

Pollen teaches a similar breast pump system (10) comprising a breast shield (22) which can removably attach (3:20-22) to a housing (24) via a flange (40). Accordingly, Pollen teaches that the breast shield is configured to attach to the housing with a single, sliding push action since a user would just have to slide the housing into the flange part, as shown in fig. 5. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the connection mechanism between the shield and the housing of Khalil to be that of Pollen. This modification would provide for an equivalent structure which allows for the shield to be easily attached to the housing.

Claim 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, further in view of Alvarez (U.S. Patent Publication No. 2015/0283311) and in further view of Makower.

Regarding claim 18, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a sensor, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Alvarez teaches a breast pump system (100) which comprises two accelerometer (473 and 478) with one accelerometer (473) coupled to the housing (paragraph 98, lines 29-32) and configured to measure the movement of the housing (paragraph 31, lines 5-7) and the other accelerometer (478) coupled to a valve (paragraph 31, lines 3-5) and configured to measure the movement of the valve (paragraph 31, lines 7-8). The resulting sensor data can be used to estimate milk expression (paragraph 24). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil by incorporating the accelerometers coupled to the housing and the non-return valve 5 of Khalil. This modification would enable an accurate measurement of milk expression since background motion can be accounted for.

Makower teaches a breast pump system (100) which has a controller (52) which receives data from sensor (54) relating to expression of milk (paragraph 190). Makower further discloses that the sensor data automatically affects the pump operation since the controller keeps track of the expressed milk and ceases pumping once a targeted

expression volume has been achieved (paragraph 206). Therefore, it would have been obvious to one of ordinary skill in the art to have modified the breast pump system of modified Khalil to include the controller coupled to the accelerometers which can shut off pumping operations once a target has been reached, as taught by Makower. This modification would enable the pump to be automatically disabled once a goal has been achieved.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2014/0378895), hereinafter referred to as "Barack '895".

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

Barack '895 teaches a breast pump system (fig. 1) which comprises a control interface (30) that the user selects to indicate or record if milk is being expressed from the left or the right breast (paragraph 43). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to include a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast, as taught by Barack '895. This modification would allow users to save breast-specific parameters for that particular breast which can later be retrieved and used for a subsequent pumping session (paragraph 8).

Claim 20 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Van Schijndel (U.S. Patent Publication No. 2011/0004154).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

Van Schijndel teaches a breast pump system (1; paragraph 1) which comprises (i) an air pressure sensor (4; paragraph 6) configured to measure the negative pressure (paragraph 5) and (ii) a measurement sub-system (3) that measures or infers milk flow or milk volume (paragraph 7). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system to include an air pressure sensor configured to measure the negative pressure and a measurement sub-system that measures or infers milk flow or milk volume, as taught by Van Schijndel. This modification would allow for the measuring of the actual negative pressure applied to the breast which can prevent the damage of breast tissue (paragraph 5) and the modification of measuring milk volume can increase efficiency of the breast pump system and the optimal settings can be better determined, as taught by Van Schijndel (paragraph 7).

Claim 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Guthrie (U.S. Patent Publication No. 2016/0220743).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is a re-useable rigid or non-collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused).

However, modified Khalil does not teach or disclose at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Guthrie teaches a breast pump system network (paragraph 3) which discloses a sensor system in the neck of a collection container (paragraph 63, lines 1-2), the sensor system comprising at least one light emitter (606), configured to direct radiation towards the surface of the milk (paragraph 63, lines 26-30; fig. 6B); at least one light detector (607), configured to detect reflected radiation from the surface of the milk (paragraph 63, lines 26-30; fig. 6B); and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container (paragraph 63, lines 24-26). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the milk container of Khalil to incorporate the at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and

detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container, as taught by Guthrie. This modification would allow a user to track pumping trends in terms of volume of milk produced in a pumping session which can assist in identifying optimal pumping times and to monitor the general state of the user's health, as taught by Guthrie (paragraph 7).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kelly (U.S. Patent Publication No. 2008/0177224).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches a microcontroller programmed to control the pumping mechanism (paragraph 68). While fig. 9 appears to show control buttons which would allow a user to manually select to adjust suction pressure, modified Khalil does not teach or disclose the microcontroller being permitted to allow the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Kelly teaches a breast pump system (1) which comprises a controller (19, 21, 69) which controls the pump (paragraph 29) and allows the user to manually indicate the level of comfort that they are experiencing when the system is in use (paragraph 10, lines 15-19 discloses adjusting the vacuum level/rate to achieve a desired comfort level; if a user adjusts the level/rate, a user is indicating that the level of comfort needs to be adjusted thereby allowing a user to manually indicate the level of comfort they are experiencing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the microcontroller of

Khalil to allow a user to manually indicate the level of comfort that they are experiencing when the system is in use by providing a selector which a user to select to adjust the pumping rates/levels. This modification would allow a user to tailor the pumping speed/level to a degree which is most comfortable to the user, as taught by Kelly (paragraph 10).

Claim 26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Alvarez.

Regarding claim 26, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses a microcontroller programmed to automatically change one or more parameters of the pumping mechanism (paragraph 68). However, modified Khalil is silent regarding the microcontroller programmed to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Alvarez teaches a breast pump system (100) comprising a controller (115) which is coupled (paragraph 98, lines 15-20) to sensors which automatically calculate milk expression data (paragraph 27), which data can be reported as a function of a value of a pumping parameter (paragraph 94). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the microcontroller of Khalil to automatically measure or relate milk expression data as a function of different values of one or more of these parameters, as taught by Alvarez. This modification would allow a user to view total milk produced at a given parameter to best optimize pumping settings.

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached on Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/JASON E FLICK/
Primary Examiner, Art Unit 3783
04/23/2019

Notice of References Cited	Application/Control No. 16/009,547	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20110274566-A1	11-2011	Amirouche; Farid	A61M5/14224	417/322
	B					
	C					
	D					
	E					
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	K					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/25/2018	03/14/2019							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
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	14	✓	✓							
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	26	✓	✓							
	27	✓	✓							
	28	✓	✓							
	29	✓	✓							
	30	✓	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/009,547	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M 1/062, 1/066, 1/06, 1/066, 1/068	8/25/2018	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See EAST search history	8/25/2018	cbf
Searched inventors in PALM and EAST	8/25/2018	cbf
Updated search	03/14/2019	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/JASON E FLICK/ Primary Examiner, Art Unit 3783	/COURTNEY FREDRICKSON/ Examiner.Art Unit 3763

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	1	("4535627").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/03/14 14:19
S1	65	("20020193731" | "20040056641" | "20040074281" | "20040267215" | "20050219302" | "20060122575" | "20070051172" | "20070051727" | "20080262420" | "20120277636" | "20140052056" | "20150217036" | "20150217037" | "20150283311" | "20160000980" | "20160058929" | "20160082165" | "20160082166" | "20160151551" | "20160158424" | "20160206794" | "20160220743" | "20160220745" | "20160287767" | "20160296681" | "20160310650" | "20170021068" | "20170035951" | "20170143879" | "20170220753" | "20180021490" | "2849881" | "4390024" | "5474683" | "5941847" | "5973770" | "6045529" | "6090065" | "6383163" | "6440100" | "6461324" | "6547756" | "6579258" | "6663587" | "6749582" | "7048519" | "7201735" | "7312554" | "7314400" | "7776008" | "8057425" | "8118772" | "8187227" | "8262606" | "8282596" | "8376986" | "8702646" | "8801495" | "8876760" | "8926556" | "9033913" | "9173587" | "9345274" | "9539377" | "D548831").PN.	US-PGPUB; USPAT	OR	OFF	2018/08/07 13:17
S2	214	(jonathan near3 o'toole).inv. (adam near3 rollo).inv. (andrew near3 carr).inv.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:42
S3	63	(a61m1/062 a61m1/066 a61m1/06).cpc. and piezo$9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:45
S4	19	("20040122358" | "20060226108" | "20080077042" | "20080167579" | "20120004603" | "3895533" | "4024856" | "4338953" | "5347656" | "5666104" | "5827191" | "7316653" | "7621797" | "7794425" | "8308648" | "8777864" | "8801658" | "8827911").PN. OR	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:50

		("8992445").URPN.				
S5	7	("5730139" | "6423010" | "6602199" | "7479154" | "8206414" | "8425426" | "8992445").PN. OR ("9192325").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:59
S6	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:16
S7	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S8	2787	(a61m1/062 a61m1/066 a61m1/06).cpc. not S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S9	45	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$).did. or (WO-2015174330-$ or WO-2016024558-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 14:59
S10	14	S9 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:59
S11	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 15:04
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S13	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:30
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S17	2665	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S13)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S18	71	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 11:47

		4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$).did.				
S19	37	S18 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:48
S20	4	S18 and ((air with pump$4) same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:50
S21	16	S18 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:15
S22	1	S18 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:40
S23	0	a61m1/1058.cpc. and breast and diaphragm	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:42
S24	5	breast same pump$4 same piezo$8 same air	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:43
S25	1	("9884172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/10 13:58
S26	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 08:40
S27	2	"59563385".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20

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S29	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:26
S30	44	S29 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:26
S31	17	S29 and (pump$4 with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:27
S32	51	S26 and "air pump"	US-PGPUB; USPAT;	OR	OFF	2018/08/24 11:07

			USOCR; FPRS; EPO; JPO			
S33	4	"47900902".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:13
S34	10	("20030212374" | "20050251089" | "20050283900" | "20070135778" | "20110054389" | "3084691" | "4229029" | "5295957" | "6070659").PN. OR ("9511176").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/24 11:16
S35	2	"51149640".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:17
S36	271	S26 and (control$4 same select$4 left same right same breast)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 12:50
S37	3	S29 and (recharg$4 with battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 13:04
S38	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S39	9	S38 and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S40	11	S38 and (light with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:48
S41	0	S38 and (radiation with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S42	2	S38 and (radiation same milk same (volume	US-	OR	OFF	2018/08/24

		quantity amount height))	PGPUB; USPAT; USOCR; FPRS; EPO; JPO			14:51
S43	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S44	10	S43 and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S45	1	a61m1/1058 and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S46	27	a61m1/1058.cpc. and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S47	23	S43 and (indicator same milk same (express$4 flow$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:26
S48	51	S43 and (air same pressure same sens$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:30
S49	19	S43 and ((indicat$4 record$4) same (right and left))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:38
S50	56	S43 and (pump$4 with series)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/24 19:42

			JPO			
S51	77	S43 and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:47
S52	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 19:59
S53	44	S52 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S54	5	S53 and (air with filter$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2018/08/24 19:59

			JPO			
S55	3	S43 and (pump$4 with (db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S56	6	S43 and ((db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S57	26	S43 and (sens$4 with (orientation angle tilt placement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:16
S58	9	S43 and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:31
S59	484	a61m$/$.cpc. and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:32
S60	1	S43 and "social media"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:52
S61	408	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:13
S63	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:18
S64	359	a61m$/$.cpc. and ((pump$4 with weigh$4) same (portable lightweight carry$4))	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/25 18:30

			FPRS; EPO; JPO			
S65	1	("20160166745").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:16
S66	1	("20160058928").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/25 19:23
S67	1	("20110004154").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/26 10:55
S68	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 11:09

S69	2	S68 and (radiation same (height quantity amount volume))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 11:09
S70	96	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/26 12:24
S71	3	S70 and ((diaphragm membrane) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/26 12:24
S72	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB;	OR	OFF	2018/08/27 13:09

			USPAT; USOCR; FPRS; EPO; JPO			
S73	137	S72 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:09
S74	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S75	9	S74 and ((centre center) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:10
S76	19	S74 and (shield with snap$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:16
S77	1	("20110152855").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 13:20
S78	32	S74 and (flow with rate with air)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:33
S79	3	S74 and (stall with pressure)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:56
S80	98	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 13:56

		US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$).did.				
S81	17	S80 and (pressure same (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 13:57
S82	18	(("7550034") or ("8123502") or ("8297947") or ("8371829") or ("8409160") or ("8646479") or ("8734131") or ("8763633") or ("8821134") or ("9051931") or ("9127665") or ("9239059") or ("9279421") or ("9334858") or ("9506463") or ("9752565") or ("9709042") or ("9777851")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 14:08
S83	0	S82 and breast	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:08
S84	10	S82 and (lactat$3 milk)	US-PGPUB; USPAT;	OR	OFF	2018/08/27 14:08

			USOCR; FPRS; EPO; JPO			
S85	14	S80 and (piezo piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:10
S86	5	S74 and ((piezo piezoelectric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:47
S87	230	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:48
S88	6	S87 and (breast milk lactat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 14:53
S89	161	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:11
S90	0	(2017/0072118).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S91	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:19
S92	40	(((piezo piezoelectric) with air with pump$4) same (miniature small compact lightweight)) same (vacuum$4 suction$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:22
S93	3	"45513973".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/27 15:23
S94	364	(((piezo piezoelectric) with pump$4) same (miniature small compact lightweight)) same	US-PGPUB;	OR	OFF	2018/08/27 15:32

		(vacuum$4 suction$4)	USPAT; USOCR; FPRS; EPO; JPO			
S95	3	"20170035951"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:33
S96	1	S95 and (suction$4 with piezoelectric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/27 15:34
S97	1	("20130064683").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:38
S98	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/27 15:39
S99	1	(US-20170172485-$).did.	US-PGPUB	OR	OFF	2018/08/28 16:48
S100	0	S99 and "function of"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 16:48
S101	100	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/28 17:19

		20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S102	0	S101 and ((meaur$4 with milk) same rate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S103	0	S101 and ((meaur$4 with milk) same (frequency speed))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:20
S104	16	S101 and ((measur$4 with milk) same (frequency speed rate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:21
S105	0	S101 and ((measur$4 with milk) with "function of")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 17:23
S106	6	S101 and (decrease with (rate speed frequency strong))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:10
S107	2	S101 and (latch$4 with adjust$4)	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/08/28 18:22

			FPRS; EPO; JPO			
S108	50	(a61m$/$).cpc. and (wear$4 with pump$4) and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:24
S109	0	(a61m$/$).cpc. and (wear$4 with pump$4) and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:25
S110	83	(a61m$/$).cpc. and (((center centre) with gravity) same comfort$5)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/28 18:26
S111	101	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 09:43

		6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S112	3	S111 and (shield with (diaphragm membrane))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:43
S113	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:47
S114	86	S113 and ((diapragm housing) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:53
S115	9	S113 and ((diapragm membrane) with (housing case mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 09:54
S116	34	S111 and (diaphragm membrane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:07
S117	28	S113 and (diaphragm membrane) and (shield with dispos$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:10
S118	28	S113 and ((diaphragm membrane) with (coupl$4 attach$4 mount$4) with shield)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:23
S119	0	a61j16/00.cpc.	US-PGPUB;	OR	OFF	2018/08/29 10:41

			USPAT; USOCR; FPRS; EPO; JPO			
S120	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 10:42
S121	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S122	23	S121 and (sens$4 same (orient$4 plac$4 situat$4) same (nipple shield))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:23
S123	11	S121 and ((sens$4 accelerometer) with breast with (move moved moving movement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:32
S124	10	S121 and accelerometer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 13:33
S125	1	("20170072118").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 14:27
S126	259	S121 and ((lower$4 decrea$4) with (suction$4 intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:51
S127	45	S121 and ((lower$4 decrea$4) with (intens$4 pain comfort discomfort))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 14:59
S128	11	(a61m$/$.cpc.) and ((miniature compact small) same (piezoelectric piezo-electric piezo) same pump$4 same (suction$4	US-PGPUB; USPAT;	OR	OFF	2018/08/29 15:40

		vacuum$4) same (diaphragm membrane))	USOCR; FPRS; EPO; JPO			
S129	127	S121 and ((pressure suction$4) with (mmhg kpa mbar pa bar))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:16
S130	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:29
S131	106	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 17:31

		2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S132	104	S131 and @ad<="20170615"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 17:32
S133	14	(US-20160166745-$ or US-20150283311-$ or US-20180110906-$ or US-20140378895-$ or US-20140031744-$ or US-20160220743-$ or US-20160256617-$ or US-20080177224-$ or US-20130023821-$ or US-20160058928-$ or US-20170043065-$ or US-20110004154-$).did. or (US-10039871-$ or US-6358226-$).did.	US-PGPUB; USPAT	OR	OFF	2018/08/29 18:08
S134	1	"52574056".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/29 18:46
S135	0	("2009024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S136	1	("20090024080").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/29 18:53
S137	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S138	203	S137 and ((shield nipple) with (remov$4 replac$4 clean$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/29 19:30
S139	1	("4535627").PN.	US-PGPUB; USPAT	OR	OFF	2019/01/08 12:52
S140	74	(("20180361040") or ("20180236147") or ("20120277728") or ("7785305") or ("20080208116") or ("7223255") or ("7789865") or ("8118772") or ("20080275385") or ("9956331") or ("8057425") or ("20070219486") or ("20020193731") or ("10046097") or ("20140378946") or ("20180326130") or ("20120316493") or ("8568350") or ("20030191427") or ("8070716") or ("9539377") or ("20160303298") or ("20160206794") or ("9539376") or ("20160310649") or ("20160287769") or	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/08 12:54

		("20160310650") or ("20180001002") or ("20090099511") or ("7776008") or ("20090062731") or ("20160296682") or ("20050154349") or ("20030191433") or ("5749850") or ("20100292636") or ("7559915") or ("20080262420") or ("20160325031") or ("20170173232") or ("7749188") or ("6887217") or ("6139521") or ("20180021490") or ("20150065994") or ("20180028732") or ("20150196460") or ("9636282") or ("7758540") or ("8945046") or ("20080243059") or ("20110251552") or ("20170119942") or ("20130023821") or ("6997897") or ("9033913") or ("20150157776") or ("20090254028") or ("5514166") or ("20010038799") or ("20070161947") or ("20130046234") or ("8926556") or ("7255681") or ("7008400") or ("6257847") or ("20100145264") or ("20170151380") or ("20070078383") or ("5542921") or ("20180333523") or ("8075516") or ("20180369464") or ("20110071466")).PN.				
S141	111	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-20140180205-$ or US-20170368244-$ or US-20160228626-$ or US-20170172485-$ or US-20160166745-$ or US-20160058928-$ or US-20110004154-$ or US-20140031744-$ or US-20090206699-$ or US-20180228949-$ or US-20080177224-$ or US-20160135998-$ or US-20170043065-$ or US-20100292632-$ or US-20160256617-$ or US-20110071466-$ or US-20180333523-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2019/01/08 13:02

		5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$ or US-10039871-$ or US-9155924-$ or US-7223255-$ or US-10046097-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$ or CN-203075300-$ or WO-2015085450-$ or WO-2013029407-$).did.				
S142	35	S141 and (heavy weight "center of gravity" "centre of gravity" mass)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:03
S143	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S144	284	S143 and (heavy weight "center of gravity" "centre of gravity")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 13:22
S145	3497	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06
S146	18	S145 and (weight with distribut$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2019/01/08 16:06

EAST Search History (Interference)

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Doc code: IDS
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4535627		1985-08-20	Prost	(English equivalent of DE3311982)

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	1	3311982	DE	C2	1983-10-13	Battelle Memorial Institute	(English equivalent USP 4535627)	
	2	197 50 620	DE	A1	1999-06-02	Siemens AG	(English abstract only)	☒
	3	9 503 280	EP	A2	1992-02-08	Pierburg GmbH	(English abstract only)	☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

	4	2016010524	JP	A	2016-01-21	Murata Manufacturing Co	(English abstract only)	☒
	5	2344380	RU	C1	2009-01-20	G Obrazovatel Noe Uchrezhdenie	(English abstract only)	☒
	6	2441367	RU	C2	2010-01-20		(English abstract only)	☒
	7	105288759	CN	A	2016-02-03	Univ Shanghai	(English abstract only)	☒

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	03/14/2019

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First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2018-12-07
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002

CONFIRMATION NO. 5958

PUBLICATION NOTICE

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC000000104613491

Title:BREAST PUMP SYSTEM

Publication No.US-2018-0361040-A1
Publication Date:12/20/2018

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The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	16009547
Filing Date	2018-06-15
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4535627		1985-08-20	Prost	(English equivalent of DE3311982)

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	1	3311982	DE	C2	1983-10-13	Battelle Memorial Institute	(English equivalent USP 4535627)	
	2	197 50 620	DE	A1	1999-06-02	Siemens AG	(English abstract only)	☒
	3	9 503 280	EP	A2	1992-02-08	Pierburg GmbH	(English abstract only)	☒

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	C. Fredrickson
	Attorney Docket Number	373499.00002

	4	2016010524	JP	A	2016-01-21	Murata Manufacturing Co	(English abstract only)	☒
	5	2344380	RU	C1	2009-01-20	G Obrazovatel Noe Uchrezhdenie	(English abstract only)	☒
	6	2441367	RU	C2	2010-01-20		(English abstract only)	☒
	7	105288759	CN	A	2016-02-03	Univ Shanghai	(English abstract only)	☒

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	Examiner Name	C. Fredrickson
	Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2018-12-07
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Bibliographic data: DE19750620 (A1) — 1999-06-02

Determining liquid level in closed tank

Inventor(s): HENN MICHAEL DR [DE] ± (HENN, MICHAEL, DR., 74842 BILLIGHEIM, DE)

Applicant(s): SIEMENS AG [DE] ± (SIEMENS AG, 80333 MUENCHEN, DE)

Classification: **- international:** ***B60K15/06; G01F17/00; G01F23/14;*** (IPC1-7): B60K15/077; G01F23/14
- cooperative: **B60K15/061**; **G01F17/00**; **G01F22/02**; **G01F23/14**; B60K2015/03217

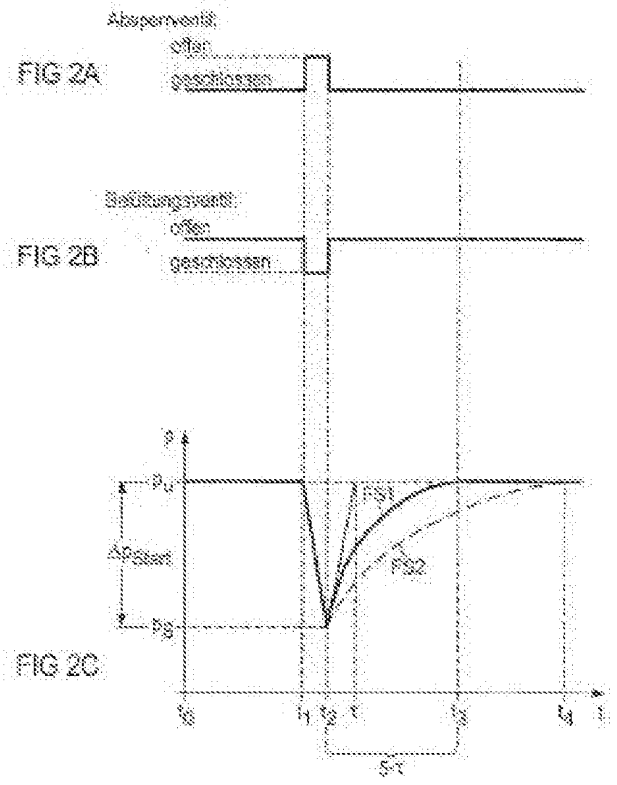
Application number: DE1997150620 19971114

Priority number(s): DE1997150620 19971114

Also published as: FR2771170 (A1) FR2771170 (B1)

Abstract of DE19750620 (A1)

A pump or vacuum pump (7) is connected to a tank (1) through a pipe (4) which has a pump valve (5) and atmosphere valve (6). Tank pressure is measured (3) the equipment is monitored by a processor (8) with look up tables (9). Where a vacuum pump is used a depression is produced in the tank and restored by connection to atmosphere. The time constant of the changing pressure is used to measure liquid level


Absperrventil
offen
geschlossen
FIG 2A
Saugabgasventil
offen
geschlossen
FIG 2B
p
p_u
Δp_{Saug}
p_s
FIG 2C
FS1
FS2
t_0
t_1
t_2
t
t_3
t_4
t
Δt

Bibliographic data: EP0503280 (A2) — 1992-09-16

Device to measure the fuel content in a tank.

Inventor(s): HAERTEL GUENTER [DE]; LOESING KARL-HEINRICH DR-ING [DE]; SCHUERFELD ARMIN [DE]; KERKMANN HARALD [DE]; BLASCZYK JOHANN [DE] ± (HAERTEL, GUENTER, ; LOESING, KARL-HEINRICH, DR.-ING, ; SCHUERFELD, ARMIN, ; KERKMANN, HARALD, ; BLASCZYK, JOHANN)

Applicant(s): PIERBURG GMBH [DE] ± (PIERBURG GMBH)

Classification: **- international:** ***G01F17/00; G01F23/14;*** (IPC1-7): G01F17/00; G01F23/14; G01F7/00
- cooperative: **G01F17/00; G01F23/14**

Application number: EP19920102126 19920208 Global Dossier

Priority number(s): DE19914107787 19910311 ; DE19914121185 19910627

Also published as: EP0503280 (A3) EP0503280 (B1) DE4121185 (A1) US5315867 (A)

Abstract of EP0503280 (A2)

2.1 Known devices in which the amount of liquid fuel is deduced from a volume forced into the tank and the resulting pressure change are no longer up-to-date, take up a lot of space and cannot be connected to the tank as desired. <??>2.2 The device according to the invention is therefore characterised in that the diaphragm (26) of an electric motor (46) is adjusted according to signals from an electronic control instrument (22), a reduction gear (47) and a spindle drive (48) being arranged between motor (46) and diaphragm (26). <??>2.3 This device takes up little space and permits arrangement anywhere on the tank and additional diagnoses of the leak-tightness of the tank and/or of the activated charcoal container system and/or of the air flow rate of the recovery system.

Bibliographic data: JP2016010524 (A) — 2016-01-21

MILKING WEAR

Inventor(s): TANAKA NOBUHIRO ± (田中 伸拓)

Applicant(s): MURATA MANUFACTURING CO ± (株式会社村田製作所)

Classification: **- international:** ***A41D1/22; A61M1/06***
- cooperative:

Application number: JP20140133454 20140630 Global Dossier

Priority number(s): JP20140133454 20140630

Abstract of JP2016010524 (A)

PROBLEM TO BE SOLVED: To provide a milking wear with which a user can express breast milk while moving.SOLUTION: In a milking wear 10, milking cups 12A and 12B, piezoelectric pumps 13A and 13B and a milking bottle 14 are provided in a clothing 11. The milking cups 12A and 12B are arranged in the positions corresponding to the user's breast. The piezoelectric pumps 13A and 13B are connected to the milking cups 12A and 12B. The milking bottle 14 is communicated to the milking cups 12A and 12B through the tubes 15A and 15B. Check valves 16A and 16B are attached to flow paths of the tubes 15A and 15B.

Bibliographic data: RU2344380 (C1) — 2009-01-20

METHOD OF MEASURING VOLUME OF LIQUID IN CLOSED RESERVOIR

Inventor(s): NOVIKOV MIKHAIL GEORGIEVICH [RU]; GOLOVANCHIKOV ALEKSANDR BORISOVICH [RU]; GORELIK VALERIJ MIKHAJLOVICH [RU]; LAPITSKIJ VLADIMIR IL ICH [RU]; TARASENKO VIKTORIJA IGOREVNA [RU] ± (Новиков Михаил Георгиевич (RU), ; Голованчиков Александр Борисович (RU), ; Горелик Валерий Михайлович (RU), ; Лапицкий Владимир Ильич (RU), ; Тарасенко Виктори Игоревна (RU))

Applicant(s): G OBRAZOVATEL NOE UCHREZHDENIE [RU] ± (GOSUDARSTVENNOE OBRAZOVATEL'NOE UCHREZHDENIE VYSSHEGO PROFESSIONAL'NOGO OBRAZOVANIJA VOLGOGRADSKIJ GOSUDARSTVENNYJ TEKHNICHESKIJ UNIVERSITET (VOLGGTU))

Classification: **- international:** ***G01F23/00***
- cooperative:

Application number: RU20070117891 20070514

Priority number(s): RU20070117891 20070514

Abstract of RU2344380 (C1)

FIELD: physics; measurement. ^ SUBSTANCE: present invention pertains to measurement of level of liquid in wells, bore holes and sealed containers and can be used in drilling technology, chemical and petrochemical industry and sanitary engineering. The method involves increasing volume of gas over the surface of the liquid, by a known value DeltaV and determination of the pressure of gas before and after increasing the volume. The volume of gas is increased by pumping out a volume of liquid from the closed container equal to DeltaV. Pressure of gas on the surface of the liquid is measured before and after pumping out the liquid and the volume of liquid in the container is calculated using formula where V0, V is the volume of liquid in the closed container and the total volume of the container respectively, in m3, DeltaV is the volume of liquid, pumped out of the container, in m3, p0 and p1 is the pressure of gas on the surface of the liquid before and after pumping volume DeltaV of liquid, respectively, in Pa (atm). ^ EFFECT: simplification of the method of measuring volume of liquid in a closed container due to less number of required operations, simplification of implementation, and consequently, shorter time spent on measuring. ^ 1 dwg

Bibliographic data: RU2008127946 (A) — 2010-01-20

METHOD OF MILK VOLUME MEASURING IN TANK

Inventor(s): Бродский Лазарь Ефимович (RU)

Applicant(s): Общество с ограниченной ответственностью "Научно-производственное предприятие "Автомаш" (RU), ; OBSHCHESTVO S OGRANICHENNOJ OTVETSTVENNOST'JU "NAUCHNO-PROIZVODSTVENNOE PREDPRIJATIE "AVTOMASH-VLADIMIR"

Classification: **- international:** ***A01J7/00***
- cooperative:

Application number: RU20080127946 20080708

Priority number(s): RU20080127946 20080708

Also published as: RU2441367 (C2)

Abstract of RU2441367 (C2)

FIELD: measuring and refrigeration engineering. ^ SUBSTANCE: milk is mixed in advance. Then distance from a proximity sensor mounted on an overhead gauge to milk surface is measured. Removable ranging laser with integrated battery power can be used as an overhead gauge. Further, this value is deducted from the distance to the bottom of an empty tank, and milk volume in tank is calculated according to an individual rating table, composed by sequential tank filling from zero to max. level using reference volumeter with 50 litre increment. ^ EFFECT: increase in accuracy and convenience of milk volume measuring, easy to apply. ^ 6 dwg

Bibliographic data: CN105288759 (A) — 2016-02-03

Electric breast pump for pressure feedback control based on flexible pressure sensor

Inventor(s): TAN YONGHONG; SHU YINGYA; DONG RUILI ± (TAN YONGHONG, ; SHU YINGYA, ; DONG RUILI, ; 谭永红, ; 束迎亚, ; 董瑞丽)

Applicant(s): UNIV SHANGHAI ± (SHANGHAI NORMAL UNIVERSITY, ; 上海师范大学)

Classification: - international: ***A61M1/06***
- cooperative: **A61M1/06**; A61M2210/1007 more

Application number: CN20151672651 20151016 Global Dossier

Priority number(s): CN20151672651 20151016

Also published as: CN105288759 (B)

Abstract of CN105288759 (A)

The invention relates to an electric breast pump for pressure feedback control based on a flexible pressure sensor. The electric breast pump comprises a breast pump shield, a main body, an air suction tube, a vacuum pump and a control host, and further comprises a piezoelectric film sensor and a feedback unit, wherein the breast pump shield is connected to the main body; the main body is connected to the vacuum pump by virtue of the air suction tube; the vacuum pump is arranged inside the control host; a receiving container is connected to the lower end of the main body; the piezoelectric film sensor is arranged on the inner side of the breast pump shield; the feedback unit is arranged inside the control host; the piezoelectric film sensor is connected to the feedback unit; the piezoelectric film sensor is used for detecting negative pressure born by surface tissues of breasts and for transmitting the negative pressure to the feedback unit; and the feedback unit is used for controlling suction force of the vacuum pump according to feedback information. Compared with the prior art, the electric breast pump disclosed by the invention can monitor pressure on the breasts of a breast pump user in real time and can dynamically regulate the vacuum suction force of the breast pump, so as to avoid breast injury caused by the excessive vacuum suction force and to protect the healthy breasts of the user.

Electronic Patent Application Fee Transmittal

Application Number:	16009547
Filing Date:	15-Jun-2018
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
		Total in USD ($)		**120**

Electronic Acknowledgement Receipt

EFS ID:	34520936
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	07-DEC-2018
Filing Date:	15-JUN-2018
Time Stamp:	14:55:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$120
RAM confirmation Number	121018INTEFSW14554700
Deposit Account	504364
Authorized User	Lynn White

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		16009547_ReplytoOA.PDF	1090335 bff38fdf36d2e81b0d7c3f6668fba8962c6d8ef4	yes	20
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	20	
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	Supp_IDS.PDF	1049797 684649a9557da20a5a8c108a922f6605af203221	no	4
Warnings:					
Information:					
3	Foreign Reference	DE19750620_English_Abstract.PDF	71890 853ad03a997286283e642a3053fd42294768e60e	no	2
Warnings:					
Information:					
4	Foreign Reference	EP0503280_English_Abstract.PDF	63122 6eef2f2ef007c275d78e6a56404afc229e275b8b	no	1
Warnings:					
Information:					
5	Foreign Reference	JP2016010524_English_Abstract.PDF	54256 06987eea1c87258e45174c91f16a8be715eca939	no	1

Warnings:					
Information:					
6	Foreign Reference	RU2344380_English_Abstract.PDF	58167 2a7f00e3b63134e90e81c3bb66fabc1120ba182b	no	1
Warnings:					
Information:					
7	Foreign Reference	RU2441367_English_Abstract.PDF	61032 c9de20d24d01e7f45eb12bbf525de6e682f54f5d	no	1
Warnings:					
Information:					
8	Foreign Reference	CN105288759_English_Abstract.PDF	53435 1fdbb2188428728811326l4b05480b6509d14563	no	1
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	30460 9f6f642d9774233b2e5a413fbf65bed4a62af5ca	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2532494		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No. **5958**
APPLICATION NO.	**16/009,547**	
FILED:	**June 15, 2018**	Examiner: **C. Fredrickson**
CASE NO.	**373499.00002**	Group Art Unit: **3783**
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON December 7, 2018

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY AND AMENDMENT UNDER 37 C.F.R. §1.111
TO EXAMINER'S ACTION MAILED SEPTEMBER 7, 2018

Sir:

This is in response to the Office Action mailed September 7, 2018, having a period for response set to expire on December 7, 2018. The following amendments and remarks are respectfully submitted.

Amendments to the claims begin on page 2 of this paper; Remarks begin on page 8 of this paper.

In the Claims

1. (Currently amended) A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a deformable diaphragm, a breast shield, and a milk container;

(c) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives ~~a separate,~~ the deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on [[a]] the breast shield, wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way height line of the housing, so that the breast pump system is not top-heavy for a woman using the breast pump system.

2. (Original) The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. (Currently amended) The wearable breast pump system of Claim 1, in which the piezo air-pump is positioned at ~~or close to the~~ a base of the housing.

4. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. (Original) The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of the breast shield.

8. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. (Original) The wearable breast pump system of Claim 1, in which the deformable diaphragm is a flexible generally circular diaphragm that removably sits over a diaphragm housing that is an integral part of the breast shield.

10. (Original) The wearable breast pump system of Claim 1, in which a diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump weighs less than 10gm.

13. (Currently amended) The wearable breast pump system of Claim 11, in which, in normal operation, the breast pump system makes less ~~then~~ than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

14. (Original) The wearable breast pump system of Claim 1, in which the piezo air-pump is fed by air that passes through an air filter.

15. (Original) The wearable breast pump system of Claim 1, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

16. (Original) The wearable breast pump system of Claim 1, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. (Original) The wearable breast pump system of Claim 1, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. (Currently amended) The wearable breast pump system of Claim 1, in which the housing includes a sensor, ~~such as an accelerometer,~~ that measures or determines the

movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. (Original) The wearable breast pump system of Claim 1, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. (Original) The wearable breast pump system of Claim 1, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. (Currently amended) The wearable breast pump system of Claim 1, wherein ~~including:~~

~~(a)~~ the milk container is a re-useable rigid or non-collapsible milk container; the breast pump system including:

[[(b)]] (a) at least one light emitter, configured to direct radiation towards the surface of the milk;

[[(c)]] (b) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the milk container.

22. (Cancelled)

23. (Original) The wearable breast pump system of Claim 1, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. (Original) The wearable breast pump system of Claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. (Original) The wearable breast pump system of Claim 1, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. (Currently amended) The wearable breast pump system of Claim 1, ~~including~~ wherein the milk container is a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped

to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. (Currently amended) The wearable breast pump system of Claim 1, ~~including~~ wherein the milk container is a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. (Currently amended) The wearable breast pump system of Claim 1, in which the breast shield includes a nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and wherein the ~~system includes~~ milk container is a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal upright use.

30. (Currently amended) The wearable breast pump system of Claim 1, ~~including~~ wherein the milk container is a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

REMARKS

In the Office Action, the Office indicated that claims 1 through 30 are pending in the application and the Office rejected all of the claims.

Amendments and Basis

Independent Claim 1 has been amended. Basis is in Claims 1 and 22 as filed. The limitation "in normal upright use" is included, for clarity. Basis includes that the Description mentions "positioned upright for normal use" in several places. Claim 22 has been cancelled.

Dependent Claims 3, 13 and 18 have been amended. Basis is in the respective Claim as filed. Dependent Claim 13 is amended to be dependent on Claim 11. Dependent Claims 21 and 27-30 are amended for consistency with amended Claim 1.

Objection to the Claims

On page 2 of the Office Action, claim 13 has been objected to for a minor informality. Claim 13 has been amended to overcome this objection. Accordingly, the Office is respectfully requested to reconsider and withdraw the objection to claim 13.

The §112 Rejection

On page 3 of the Office Action, claims 3, 17 and 18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicant has amended the claims to overcome this rejection. Accordingly, the Office is respectfully requested to reconsider and withdraw the rejection of claims 3, 17 and 18 under 35 U.S.C. §112.

Rejections under 35 U.S.C. §103

On page 4 of the Office Action, claims 1, 3, 7-10, 17, 22 and 27-30 have been rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi. (Applicant notes that the heading for this rejection indicates "...1-10, ...," but based upon the discussion of the rejection, it is believed that it should be "...7-10...".).

On page 9 of the Office Action, claims 2, 23 and 24 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2017/0072118 to Makower.

On page 12 of the Office Action, claims 4 and 6 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2018/0110906 to Barack.

On page 13 of the Office Action, claims 4 and 5 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0166745 to Aalders; and claim 11 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0256617 to Hansen and in further view of U.S. Patent Application Publication No. 2014/0031744 to Chen.

On page 14 of the Office Action, claims 12 and 13 have been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0058928 to Nowroozi.

On page 16 of the Office Action, claim 14 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No.

6,358,226 to Ryan; and claim 15 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0323962 to Kooijker.

On page 17 of the Office Action, claim 16 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent No. 10,039,871 to Pollen; and on page 18, claim 18 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2015/0283311 to Alvarez and in further view of Makower.

On page 19 of the Office Action, claim 19 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2014/0378895 to Barack ("Barack '895"), and on page 20, claim 20 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2011/0004154 to Van Schijndel.

On page 21, claim 21 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2016/0220743 to Guthrie.

On page 22 of the Office Action, claim 25 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of U.S. Patent Application Publication No. 2008/0177224 to Kelly; and on page 23, claim 26 has been rejected under 35 U.S.C. §103 as being unpatentable over Khalil in view of Takeuchi, and further in view of Alvarez.

A *Prima Facie* Case of Obviousness Has Not Been Established

KSR (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)) requires that the Office provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Further, the Office must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." In addition, the Office must make "explicit" this rationale of "the apparent reason to combine the known elements in the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art."

The words of a Claim describe and point out the invention by a series of limiting words or phrases – limitations (*Corning Glass Works v. Sumitomo Elec. USA Inc.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989)).

Amended Claim 1 derives from Claims 1 and 22 previously on file.

On pages 4 and 6 to 7 of the Office Action, the Office rejected former Claim 22 under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi, as follows.

> "**Regarding claim** 22, in the modified system of Khalil, Khalil discloses "the centre of gravity of the pump system is, when a milk container attached to the housing is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump" since the term "below" is a relative direction. A horizontal line which passes through the nipple tunnel can be drawn and the breast pump system can be rotated in a way which shows the pumping mechanism below

the horizontal line which passes through the nipple housing, as shown below."

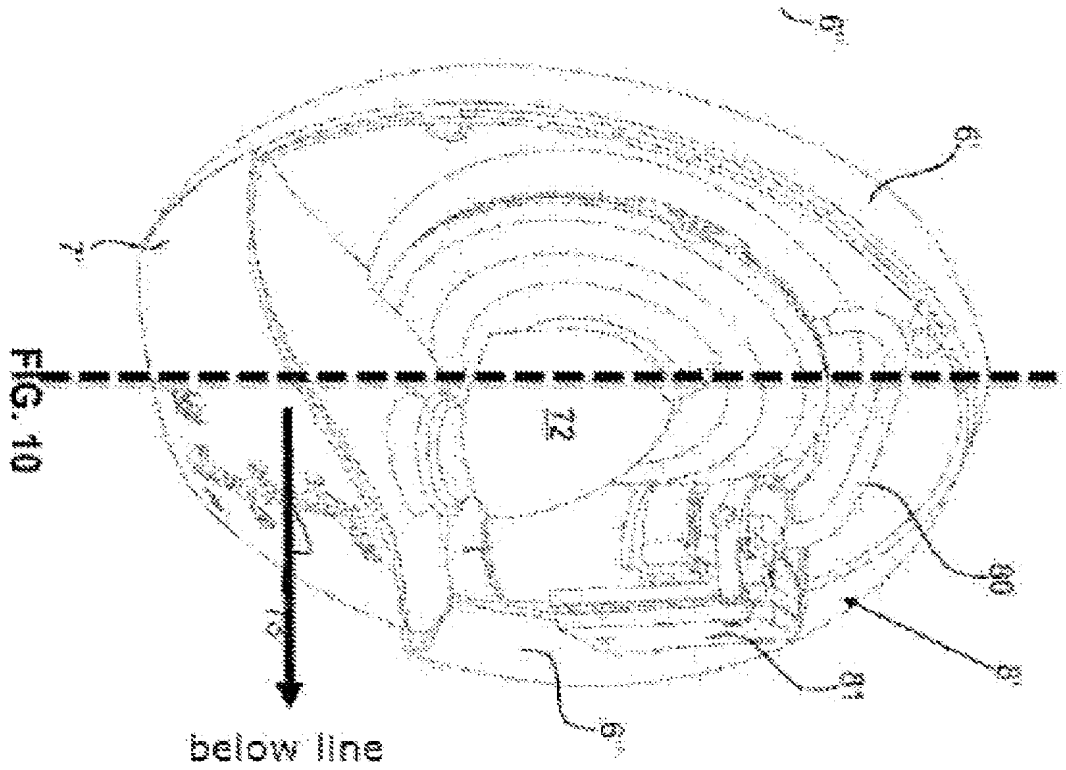


FIG. 1b

Amended Claim 1 includes the limitation "in normal upright use".

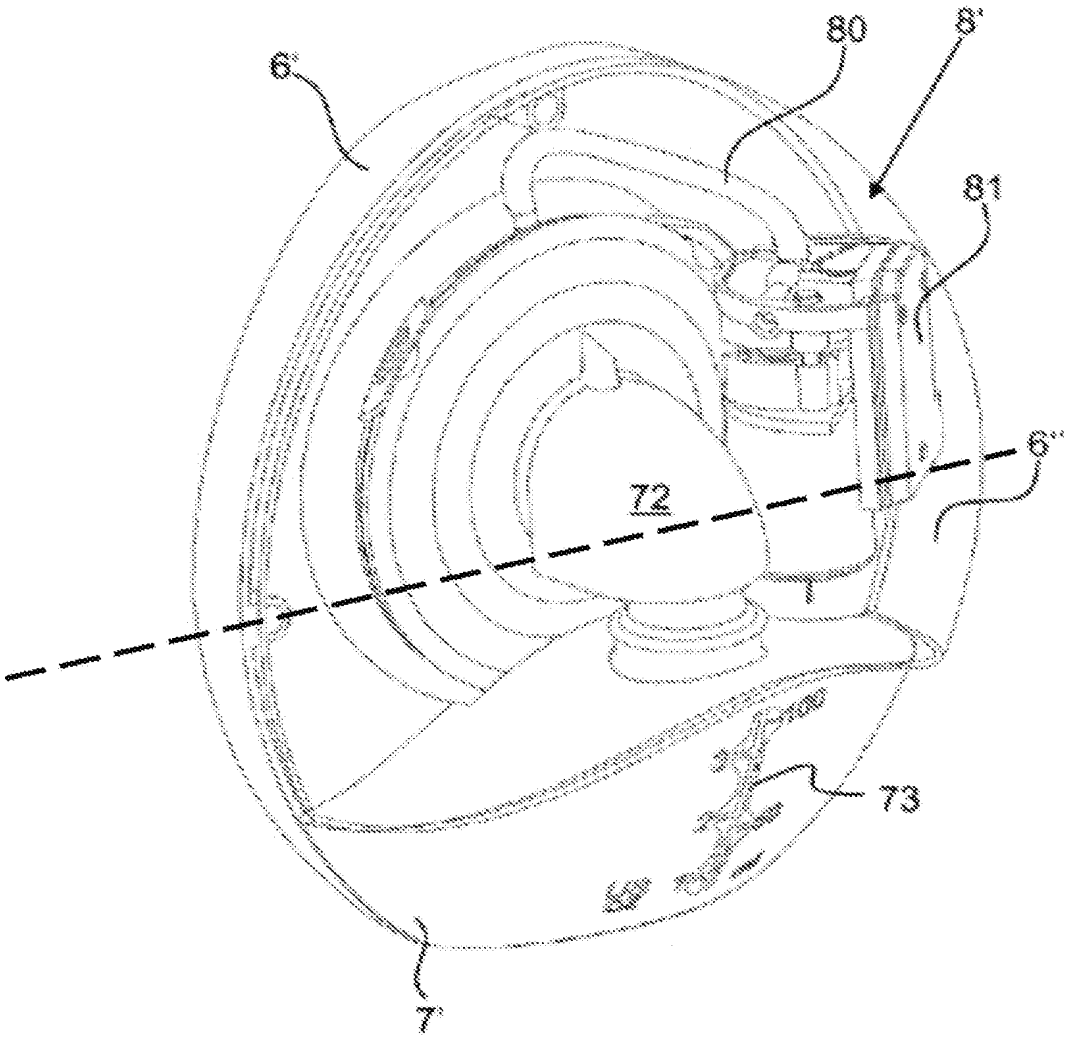
Regarding amended dependent Claim 29, which includes the limitation "in normal upright use", on pages 4 and 8 of the Office Action, the Office rejected former Claim 29 under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi, as follows.

> "**Regarding claim 29**, in the modified system of Khalil, Khalil discloses the breast shield includes a nipple tunnel (see below) shaped to receive a nipple (fig. 4 and 5), and includes an opening that defines the start of a milk flow path (13); and the system includes a re-useable milk container (7'; paragraph 69, lines 6-7 discloses the container being releasable indicating that it can be

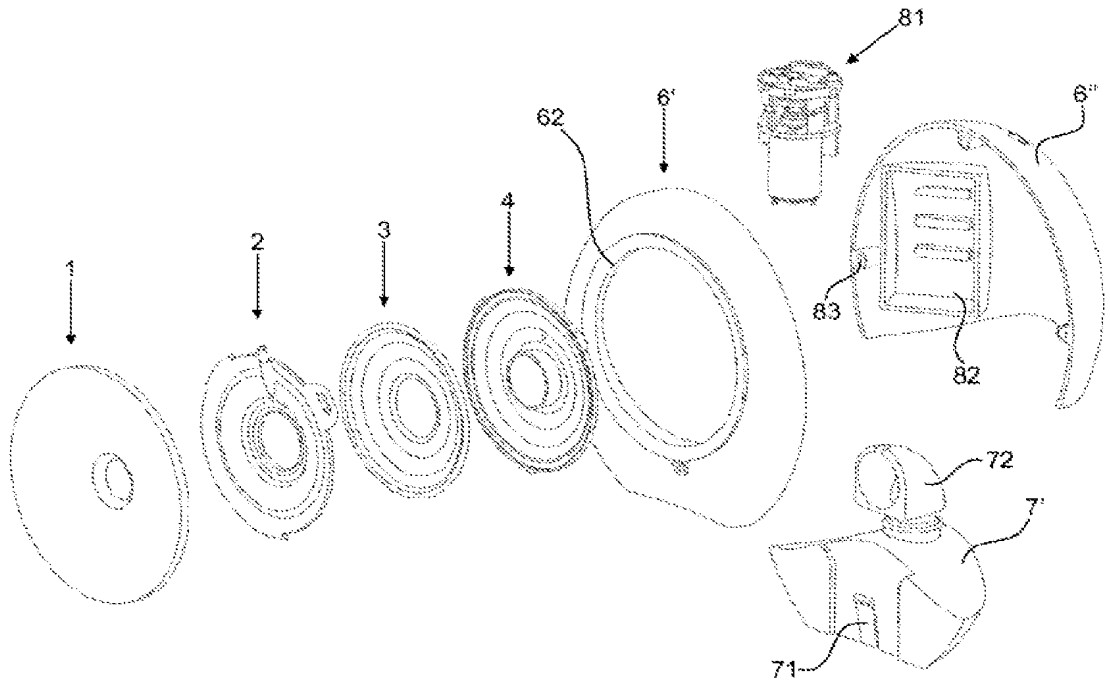
> reused) that when connected to the housing is positioned entirely below the opening or the milk flow path (fig. 10 shows the container positioned below the opening), when the breast pump is positioned or oriented for normal use."

Dependent Claim 29 is dependent on amended Claim 1. An independent Claim must not be interpreted in a way that is inconsistent with a Claim that depends on it (*Wright Med. Tech. Inc. v. Osteonics Corp.*, 122 F.3d 1440, 43 USPQ2d 1837 (Fed. Cir. 1997)).

Therefore, the rejection of Claim 22 made in the Office Action by the Examiner is no longer tenable for amended Claim 1, because amended Claim 1 includes the further limitation "in normal upright use", and because in the rejection of Claim 29 made on page 8 of the Office Action by the Examiner, the Examiner has interpreted that in Khalil, in normal use, the milk container is positioned below the opening. Therefore the position of the horizontal line in the graphical analysis by the Examiner on page 7 of the Office Action is no longer tenable, because that line slices through the milk container, and in normal upright use, the horizontal line should instead be perpendicular to the dashed line drawn by the Examiner. Therefore for amended Claim 1, the graphical analysis by the Examiner on page 7 of the Office Action, in relation to Fig. 10 of Khalil, should be replaced by the following, in which the dashed line is the half-way height line of the housing:



The position of the half-way height line of the housing in the above analysis is justified, because in Khalil, the housing includes a shell ring 6' (Khalil para. [067]), which is the tallest piece of the housing and the half way height line therefore corresponds to the half way height line of the shell ring 6'. That the shell ring 6' is the tallest piece of the housing is confirmed by Khalil Fig. 11, reproduced below:



Khalil, Fig. 11

Khalil Fig. 11 also shows a pump seat 82 (Khalil, para. [067]). From the position of the pump seat 82 in the cover 6'', it is clear that in normal upright use, the pump 81 is mainly situated above the half way height line of the shell ring 6'.

The above graphical analysis in relation to Khalil Fig. 10 does not make obvious the amended Claim 1 limitation "**wherein, in normal upright use, the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way height line of the housing**", because for the system in the above graphical analysis, the center of gravity would appear to be above the half-way height line of the housing, which is the opposite to the limitation of amended Claim 1. This conclusion is supported by the pump being mainly situated above the half way height line of

the shell ring 6', in normal upright use, as shown in Khalil Fig. 11, because from the position of the pump seat 82 in the cover 6'', it is clear that in normal upright use, the pump 81 is mainly situated above the half way height line of the shell ring 6'.

Amended Claim 1 is therefore not obvious over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent Application Publication No. 2017/0043065 to Takeuchi.

The invention of amended Claim 1 has the advantage that the breast pump system does not feel top-heavy to a woman while using the breast pump system. This provides stability of the breast pump system inside the bra, with the additional advantage that a greater range of bras are compatible with the breast pump system, rather than requiring a specialized bra such as a sports bra or a maternity bra. The breast pump system further provides greater comfort for the woman while using the breast pump system, for example because the lower center of gravity compresses a breast less, and the lower center of gravity leads to more weight being supported by the bra cup.

On pages 14 to 15 of the Office Action, Examiner rejects Claim 12 under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1, and further in view of Nowroozi (U.S. Patent Publication No. 2016/0058928).

The Office holds that because Nowroozi teaches a pump which weighs less than 80 g (Nowroozi, para. [100]), Nowroozi teaches a pump which weighs less than 10 g. The MPEP 2131.03 II states:

> "When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the

> reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent."

Applicant asserts that because the upper limit of the range claimed in Claim 12 (10 g) is eight times less than the upper limit of the range disclosed in Nowroozi, para. [100] (80 g), Nowroozi does not disclose the range claimed in Claim 12 with sufficient specificity. A reduction in the upper weight limit by a factor of eight is a large reduction, hence the limitations of Claim 12 are not obvious over Khalil in view of Takeuchi, and further in view of Nowroozi. Accordingly, Claim 12 is not obvious.

On pages 14 to 15 of the Office Action, the Office rejects Claim 13 under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1, and further in view of Nowroozi (U.S. Patent Publication No. 2016/0058928). Claim 13 has been amended so as to be dependent on Claim 11.

Amended Claim 13 is not obvious because whereas the Office cites Hansen para. [022] against the limitation of Claim 11 that the piezo air pump delivers in excess of 400 mBar stall pressure, the Examiner cites Nowroozi para. [100] against the limitation that the breast pump system makes less than 30dB noise at maximum power and less than 25dB at normal power, but Nowroozi para. [100] states that the maximum negative pressure generated by the pump is 160 mmHg, which is about 210 mBar. Such a disclosure is not consistent with a maximum negative pressure of 330 mmHg (about 440 mBar) in Hansen para. [022], and therefore amended Claim 13 is not obvious.

On pages 16 to 17 of the Office Action, Claim 15 is rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1, and further in view of Kooijker (U.S. Patent Publication No. 2014/0323962).

The MPEP 2143.01.VI states

"**VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE**

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti,* 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. The seal construction taught in the primary reference required rigidity for operation, whereas the seal in the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.")."

The proposed modification of Khalil by Kooijker, made by the Office, changes the principle of operation of Khalil, because in Khalil, a principle of operation is that the membrane is removable from the housing in normal use, because e.g. Khalil para. [021] discloses that the membrane is easy to assemble and easy to clean. Because the proposed modification cannot change the principle of operation of a reference (MPEP 2143.01.VI), the combination of Kooijker with Khalil does not make obvious the Claim 15 limitation that only two parts are directly removable from the housing in normal use or normal dis-assembly: the

breast shield and a rigid, non-collapsible milk container. Hence, Claim 15 is not obvious over Kooijker in combination with Khalil and Takeuchi for this reason.

The dependent Claims are not obvious, at least by virtue of their dependence on amended Claim 1.

Accordingly, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1-30 under 35 USC §103.

Information Disclosure Statement

Submitted herewith is an Information Disclosure Statement, listing those publications previously presented in the IDS filed on June 15, 2018, but lined-through by the Examiner. English language abstracts are provided for the following foreign publications: DE19750620; EP0503280; JP2016010524; RU2344380; RU2441367; and CN105288759. Applicant cites U.S. Patent No. 4,535,627 as an English language equivalent for German Patent No. DE3311982. Consideration of these publications is respectfully requested.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims. An early Notice of Allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any fee deficiencies associated with this communication to applicant's Deposit Account No. 50-4364.

Respectfully submitted

December 7, 2018
Date

/Mark D. Simpson/
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/009,547	Filing Date 06/15/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	12/07/2018	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0	X $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
DAWN BREWER

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 09/07/2018

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
09/07/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

Office Action Summary	Application No. 16/009,547	Applicant(s) O'TOOLE ET AL.	
	Examiner Courtney Fredrickson	Art Unit 3763	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15June2018*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-30* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-30* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *15June2018* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement filed June 15, 2018 fails to comply with 37 CFR 1.98(a)(3)(i) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each reference listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

3. **Claim 13** is objected to because of the following informalities: the claim should recite "…the breast pump system makes less than 30 dB noise…". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 3, 17, and 18** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The term "close to" in **claim 3** is a relative term which renders the claim indefinite. The term "close to" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 17 recites the limitation "the milk container" in claim 17. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 18, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

7. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have

> been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

10. Claims 1, 3, 1-10, 17, 22, and 27-30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (U.S. Patent 2013/0023821) in view of Takeuchi (U.S. Patent Publication No. 2017/0043065).

Regarding claim 1, Khalil discloses a wearable breast pump system (fig. 9) including: (a) a housing (6', 6'') shaped at least in part to fit inside a bra (paragraph 32,

lines 1-5); an air pump (81) fitted in the housing (fig. 10) and forming part of a closed loop system (paragraphs 58-62, 66) that drives a separate, deformable diaphragm (3; paragraph 54) to generate negative air pressure (paragraph 61, lines 6-11), that diaphragm being removably mounted (paragraph 59 discloses that the breast shield 1 has a groove 100 which would allow for the membrane to be removed from the shield; fig. 11) on a breast shield (1). However, Khalil does not teach or disclose a piezo air pump.

Takeuchi teaches a device (101) for suctioning bodily fluids from the body (paragraph 3) comprising a piezo air pump (104; paragraph 8, lines 8-10) mounted in a housing (fig. 6) further comprising a piezoelectric element (106) attached to a diaphragm (105). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the air pump of Khalil to be a piezo air pump and to have attached the piezoelectric element onto the diaphragm of Khalil. This modification would provide the added advantage of reducing motor sound and vibration typically caused by electric motors, as taught by Takeuchi (paragraph 7).

Regarding claim 3, in the modified system of Khalil, Khalil discloses the piezo air-pump is positioned at or close to the base of the housing (fig. 11 shows the pump 81 fitting into pump seat 82 which is considered to be close to the base of the housing 6").

Regarding claim 7, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a unitary or one-piece object (fig. 3 shows the diaphragm 3 as a single object) that is removably mounted against a part of the breast shield (fig. 4/5).

Regarding claim 8, in the modified system of Khalil, Khalil discloses the deformable diaphragm is not physically connected to the piezo air-pump (fig. 10 shows the diaphragm is connected to the pump through vacuum line 80).

Regarding claim 9, in the modified system of Khalil, Khalil discloses the deformable diaphragm is a flexible generally circular diaphragm (fig. 3; paragraph 54) that removably sits over a diaphragm housing (10; thefreedictionary.com defines "housing" as "something that supports"; fig. 4/5 shows element 10 supporting the diaphragm assembly) that is an integral part of the breast shield (fig. 4/5).

Regarding claim 10, in the modified system of Khalil, Khalil discloses a diaphragm housing (4) includes an air hole (42) that transfers negative air pressure (fig. 5) to a nipple tunnel in the breast shield (10), the negative air pressure arising when the diaphragm moves away from the diaphragm housing (fig. 5), and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed (fig. 5).

Regarding claim 17, in the modified system of Khalil, Khalil discloses a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container (73; paragraph 14-19 discloses that the container has a scale which can serve as a visual indicator if milk is flowing into the container since the level of the surface would change depending on if milk is flowing or not).

Regarding claim 22, in the modified system of Khalil, Khalil discloses "the centre of gravity of the pump system is, when a milk container attached to the housing is empty, substantially at or below (i) the half-way height line of the housing or (ii) the

horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump" since the term "below" is a relative direction. A horizontal line which passes through the nipple tunnel can be drawn and the breast pump system can be rotated in a way which shows the pumping mechanism below the horizontal line which passes through the nipple housing, as shown below.

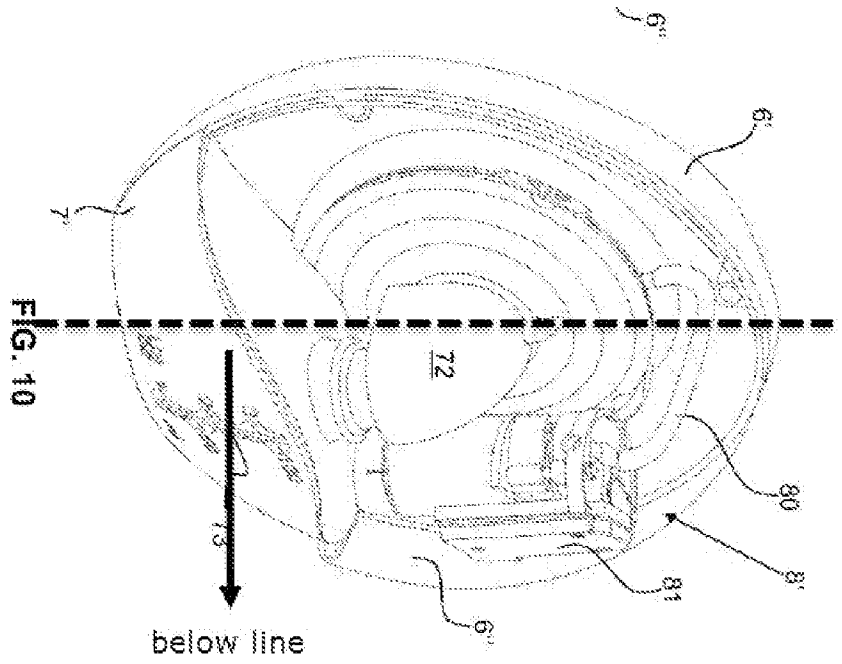


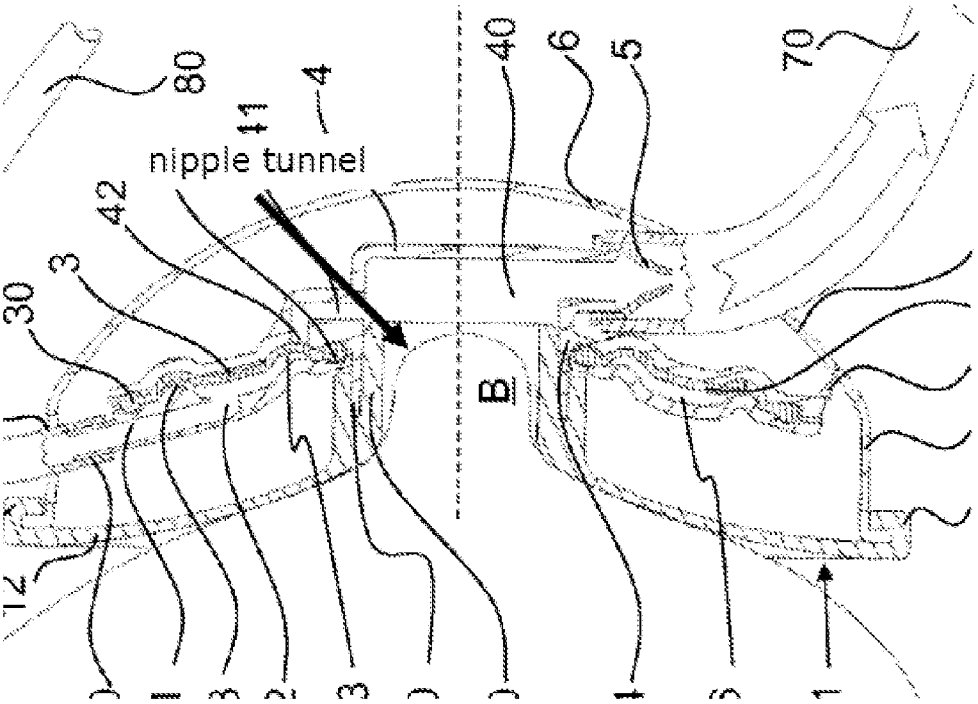
FIG. 10

Regarding claim 27, in the modified system of Khalil, Khalil discloses a re-useable rigid or non- collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused) that when connected to the housing forms an integral, lower part of the housing (fig. 10), with a surface shaped to continue a

curved shape of the housing (fig. 10), so that the pump system can be held comfortably inside the bra (paragraph 70).

Regarding claim 28, in the modified system of Khalil, Khalil discloses a milk container (7') that is attachable to the housing (paragraph 69, lines 6-7) with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action (paragraph 69, lines 3-6).

Regarding claim 29, in the modified system of Khalil, Khalil discloses the breast shield includes a nipple tunnel (see below) shaped to receive a nipple (fig. 4 and 5), and includes an opening that defines the start of a milk flow path (13); and the system includes a re-useable milk container (7'; paragraph 69, lines 6-7 discloses the container being releasable indicating that it can be reused) that when connected to the housing is positioned entirely below the opening or the milk flow path (fig. 10 shows the container positioned below the opening), when the breast pump is positioned or oriented for normal use.



Regarding claim 30, in the modified system of Khalil, Khalil discloses a milk container (7') that is removable from the housing (paragraph 69, lines 6-7) and is shaped or configured to also serve as a drinking bottle (container 7' is functionally capable of acting as a drinking bottle once coupling part 72 is removed; paragraph 69, 7-14 discloses that the coupling part has a non-return valve integrated therein indicating that the coupling part must be capable of being removed from the container for the purpose of retrieving the expressed milk) that is readily held by a baby because it is wider than it is tall (fig. 10).

11. Claims 2, 23, and 24 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Makower (U.S. Patent Publication No. 2017/0072118).

Regarding claim 2, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the vacuum can have a power supply integrated therein (paragraph 32, lines 7-9). However, modified Khalil fails to teach or disclose a rechargeable battery.

Rechargeable batteries are well known in the art. Additionally, Makower teaches a similar breast pump system (fig. 1B) and further contemplates the use of a rechargeable battery (paragraph 151). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the power source disclosed by Khalil to be a rechargeable battery. This modification would provide the added advantage of being able to repeatedly reuse the battery.

Regarding claim 23, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Makower teaches a breast pump system (fig. 1B) which comprises a measurement sub- system (54) that measures or infers milk flow into the milk container (paragraph 190, lines 10-14); and in which the measurement sub-system provides data (paragraph 187, lines 16-23) to a data analysis system (52) that determines metrics (paragraph 206) that correlate with user-defined requirements for milk-flow rate or milk expression (paragraph 203, lines 13-27). Therefore, it would have been obvious to one

of ordinary skill before the effective filing date of the claimed invention to have modified the system of modified Khalil to incorporate a measurement sub- system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression, as taught by Makower. This modification would enable a user to manually enter a desired milk expression volume which can be tracked while a user is pumping and enabling the system to adjust accordingly, as taught by Makower (paragraph 206)

Regarding claim 24, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Makower teaches a breast pump system (fig. 1B) which comprises a data sub-system (52) that collects and provides data (paragraph 196) to a connected device or remote application or remote server (470); and in which the collected data, in whole or in part, is used by a data analysis system (474) that provides inputs to a social media or community function or platform (paragraph 209). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to incorporate a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis

system that provides inputs to a social media or community function or platform, as taught by Makower. This modification would allow data generated to be transmitted to insurance companies for reimbursement/coverage purposes (paragraph 196) or transmitted to health care professionals to ensure patient safety and proper care (paragraph 209).

12. Claims 4 and 6 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2018/0110906).

Regarding claims 4 and 6, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a parallel arrangement [**claim 6**].

Barack teaches a breast pump system (10; fig. 1) which comprises two or more individual pumps (fig. 1; 14) which are mounted in a parallel arrangement (paragraph 52; fig. 1). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in parallel, as taught by Barack. This modification would allow for pumps to better cool between use and decreases the pumping times to reach a given target pressure, as taught by Barack (paragraphs 51 and 52).

13. Claims 4 and 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Aalders (U.S. Patent Publication No. 2016/0166745).

Regarding claims 4 and 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump comprises two or more individual piezo air-pumps [**claim 4**] and the individual piezo air-pumps are mounted in a series arrangement [**claim 5**].

Aalders teaches a breast pump system (fig. 1; paragraph 1) and further contemplates the use of multiple pumps mounted in series (paragraph 57). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to be comprised of two or more piezo air pumps which are mounted in series, as taught by Aalders. This modification would facilitate in increasing the vacuum level of the pump system, as taught by Aalders (paragraph 57).

14. Claim 11 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Hansen (U.S. Patent Publication No. 2016/0256617) and in further view of Chen (U.S. Patent Publication No. 2014/0031744).

Regarding claim 11, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Hansen teaches a breast pump (100) which produces a suction in the range of 0-330 mmHg (paragraph 22). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump of modified Khalil to produce a maximum suction of 330 mmHg for the purpose of preventing suction levels too high which can lead to tissue damage, as taught by Hansen (paragraph 22).

Chen also teaches a breast pump system (fig. 1; 30) which produces at least 9 L/min of free air flow (paragraph 39). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to have an air flow rate of not less than 9 L/min for the purpose of establishing an effective suckling frequency, as taught by Chen (paragraph 39).

15. Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Nowroozi (U.S. Patent Publication No. 2016/0058928).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump weighs less than 10gm.

Nowroozi teaches a breast pump system (fig. 7) comprising a micro air pump (26; paragraph 100) which weighs less than 80 grams. Accordingly, Nowroozi teaches a pump which weighs less than 10 gm since it has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie

case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the piezo air pump of modified Khalil to weigh less than 10 gm, as taught by Nowroozi, for the purpose of enhancing the comfort of the patient when wearing the breast pump.

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose in normal operation, the breast pump system makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Nowroozi teaches a breast pump system (fig. 7) comprising a micro air pump (26; paragraph 100) which produces a maximum noise of less than 50 dB (paragraph 100). Accordingly, Nowroozi teaches a pump which makes less than 30dB noise at maximum power and less than 25dB at normal power since it has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to make less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise, as taught by Nowroozi. This modification would ensure that the breast pump system is not excessively noisy and thereby increase the comfort of the user.

16. Claim 14 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Ryan (U.S. Patent No. 6,358,226).

Regarding claim 14, modified Khalil teaches all of the claimed limitations recited in claim 1, as discussed above, but fails to teach or disclose the piezo air-pump is fed by air that passes through an air filter.

Ryan teaches a breast pump system (fig. 1) comprising an air pump (55) which is fed by air that passes through an air filter (53; 4:29-33). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of Khalil to incorporate an air filter, as taught by Ryan. This modification provides the added advantage of filtering out contaminants and ensuring the system remains relatively clean.

17. Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kooijker (U.S. Patent Publication No. 2014/0323962).

Regarding claim 15, regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, and further discloses a rigid, non-collapsible milk container (7'; paragraph 69, lines 1-3) is removable under normal conditions (paragraph 69, lines 6-7). However, modified Khalil does not teach or disclose the only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

Kooijker teaches a breast shield assembly (1) which comprises a three-part assembly of a removable liner (5), a flexible insert (3) and a rigid body (2). Kooijker also teaches that the removable liner is removable (paragraph 42). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the breast shield of Khalil to be the three-part assembly with the removable liner, as taught by Kooijker to further interface with the diaphragm of Khalil. This modification would allow for the breast-contacting portion of the shield to be removed and cleaned without the need to disassemble the rest of the pump.

18. Claim 16 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Pollen (U.S. Patent No. 10,039,871).

Regarding claim 16, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses that the breast shield is configured to attach to the housing with a circumferential securing lip (11; paragraph 48). However, modified Khalil does not teach or disclose the breast shield is configured to attach to the housing with a single, sliding push action.

Pollen teaches a similar breast pump system (10) comprising a breast shield (22) which can removably attach (3:20-22) to a housing (24) via a flange (40). Accordingly, Pollen teaches that the breast shield is configured to attach to the housing with a single, sliding push action since a user would just have to slide the housing into the flange part, as shown in fig. 5. Therefore, it would have been obvious to one of ordinary skill before

the effective filing date of the claimed invention to have modified the connection mechanism between the shield and the housing of Khalil to be that of Pollen. This modification would provide for an equivalent structure which allows for the shield to be easily attached to the housing.

19. Claim 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, further in view of Alvarez (U.S. Patent Publication No. 2015/0283311) and in further view of Makower.

Regarding claim 18, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Alvarez teaches a breast pump system (100) which comprises two accelerometer (473 and 478) with one accelerometer (473) coupled to the housing (paragraph 98, lines 29-32) and configured to measure the movement of the housing (paragraph 31, lines 5-7) and the other accelerometer (478) coupled to a valve (paragraph 31, lines 3-5) and configured to measure the movement of the valve (paragraph 31, lines 7-8). The resulting sensor data can be used to estimate milk expression (paragraph 24). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil by incorporating the accelerometers coupled to the housing and the non-return

valve 5 of Khalil. This modification would enable an accurate measurement of milk expression since background motion can be accounted for.

Makower teaches a breast pump system (100) which has a controller (52) which receives data from sensor (54) relating to expression of milk (paragraph 190). Makower further discloses that the sensor data automatically affects the pump operation since the controller keeps track of the expressed milk and ceases pumping once a targeted expression volume has been achieved (paragraph 206). Therefore, it would have been obvious to one of ordinary skill in the art to have modified the breast pump system of modified Khalil to include the controller coupled to the accelerometers which can shut off pumping operations once a target has been reached, as taught by Makower. This modification would enable the pump to be automatically disabled once a goal has been achieved.

20. Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Barack (U.S. Patent Publication No. 2014/0378895), hereinafter referred to as "Barack '895".

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

Barack '895 teaches a breast pump system (fig. 1) which comprises a control interface (30) that the user selects to indicate or record if milk is being expressed from

the left or the right breast (paragraph 43). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system of modified Khalil to include a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast, as taught by Barack '895. This modification would allow users to save breast-specific parameters for that particular breast which can later be retrieved and used for a subsequent pumping session (paragraph 8).

21. Claim 20 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Van Schijndel (U.S. Patent Publication No. 2011/0004154).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but fails to teach or disclose (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

Van Schijndel teaches a breast pump system (1; paragraph 1) which comprises (i) an air pressure sensor (4; paragraph 6) configured to measure the negative pressure (paragraph 5) and (ii) a measurement sub-system (3) that measures or infers milk flow or milk volume (paragraph 7). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast pump system to include an air pressure sensor configured to measure the negative pressure and a measurement sub-system that measures or infers milk flow or milk volume, as taught by Van Schijndel. This modification would allow for the measuring of

the actual negative pressure applied to the breast which can prevent the damage of breast tissue (paragraph 5) and the modification of measuring milk volume can increase efficiency of the breast pump system and the optimal settings can be better determined, as taught by Van Schijndel (paragraph 7).

22. Claim 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Guthrie (U.S. Patent Publication No. 2016/0220743).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses a re-useable rigid or non-collapsible milk container (7'; paragraph 69, lines 1-3 discloses that the milk container is made from the same plastic as the cover 6 and paragraph 50 discloses that the cover is rigid; paragraph 69, lines 6-7 discloses the container as being releasable indicating that is can be reused). However, modified Khalil does not teach or disclose at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Guthrie teaches a breast pump system network (paragraph 3) which discloses a sensor system in the neck of a collection container (paragraph 63, lines 1-2), the sensor system comprising at least one light emitter (606), configured to direct radiation towards the surface of the milk (paragraph 63, lines 26-30; fig. 6B); at least one light detector (607), configured to detect reflected radiation from the surface of the milk (paragraph

63, lines 26-30; fig. 6B); and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container (paragraph 63, lines 24-26). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the milk container of Khalil to incorporate the at least one light emitter, configured to direct radiation towards the surface of the milk; at least one light detector, configured to detect reflected radiation from the surface of the milk; and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container, as taught by Guthrie. This modification would allow a user to track pumping trends in terms of volume of milk produced in a pumping session which can assist in identifying optimal pumping times and to monitor the general state of the user's health, as taught by Guthrie (paragraph 7).

23. Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Kelly (U.S. Patent Publication No. 2008/0177224).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches a microcontroller programmed to control the pumping mechanism (paragraph 68). While fig. 9 appears to show control buttons which would allow a user to manually select to adjust suction pressure, modified Khalil does not teach or disclose the microcontroller being permitted to allow the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Kelly teaches a breast pump system (1) which comprises a controller (19, 21, 69) which controls the pump (paragraph 29) and allows the user to manually indicate the level of comfort that they are experiencing when the system is in use (paragraph 10, lines 15-19 discloses adjusting the vacuum level/rate to achieve a desired comfort level; if a user adjusts the level/rate, a user is indicating that the level of comfort needs to be adjusted thereby allowing a user to manually indicate the level of comfort they are experiencing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the microcontroller of Khalil to allow a user to manually indicate the level of comfort that they are experiencing when the system is in use by providing a selector which a user to select to adjust the pumping rates/levels. This modification would allow a user to tailor the pumping speed/level to a degree which is most comfortable to the user, as taught by Kelly (paragraph 10).

24. Claim 26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Takeuchi, as applied to claim 1 above, and further in view of Alvarez.

Regarding claim 26, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses a microcontroller programmed to automatically change one or more parameters of the pumping mechanism (paragraph 68). However, modified Khalil is silent regarding the microcontroller programmed to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Alvarez teaches a breast pump system (100) comprising a controller (115) which is coupled (paragraph 98, lines 15-20) to sensors which automatically calculate milk expression data (paragraph 27), which data can be reported as a function of a value of a pumping parameter (paragraph 94). Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the microcontroller of Khalil to automatically measure or relate milk expression data as a function of different values of one or more of these parameters, as taught by Alvarez. This modification would allow a user to view total milk produced at a given parameter to best optimize pumping settings.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney Fredrickson whose telephone number is (571)270-7481. The examiner can normally be reached on MONDAY - FRIDAY: 8AM-5PM EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Courtney Fredrickson/
Examiner, Art Unit 3763

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3763

Notice of References Cited	Application/Control No. 16/009,547	Applicant(s)/Patent Under Reexamination O'TOOLE ET AL.	
	Examiner Courtney Fredrickson	Art Unit 3763	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6,358,226 B1	03-2002	Ryan; Audrey M.	A61M1/062	604/113
*	B	US-2008/0177224 A1	07-2008	Kelly; Patricia A.	A61M1/0037	604/74
*	C	US-2011/0004154 A1	01-2011	Van Schijndel; Nicolle Hanneke	A61M1/06	604/74
*	D	US-2013/0023821 A1	01-2013	KHALIL; Gamal	A61M1/064	604/74
*	E	US-2014/0031744 A1	01-2014	CHEN; CHEAN-SHUI	A61M1/06	604/74
*	F	US-2014/0323962 A1	10-2014	Kooijker; Klaas	A61M1/06	604/74
*	G	US-2014/0378895 A1	12-2014	Barack; Doron	A61M1/064	604/74
*	H	US-2015/0283311 A1	10-2015	Alvarez; Jeffery B.	A61M1/0031	604/514
*	I	US-2016/0058928 A1	03-2016	Nowroozi; Bryan Neema	A61M1/064	604/74
*	J	US-2016/0166745 A1	06-2016	AALDERS; ARNOLD	A61M1/06	604/500
*	K	US-2016/0220743 A1	08-2016	Guthrie; Gabrielle V.	A61M1/062	1/1
*	L	US-2016/0256617 A1	09-2016	Hansen; Jan Erik Vest	A61M1/0066	1/1
*	M	US-2017/0043065 A1	02-2017	TAKEUCHI; Susumu	A61M1/00	1/1

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 16/009,547	Applicant(s)/Patent Under Reexamination O'TOOLE ET AL.	
	Examiner Courtney Fredrickson	Art Unit 3763	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2017/0072118 A1	03-2017	Makower; Joshua	A61M1/06	1/1
*	B	US-2018/0110906 A1	04-2018	BARACK; Doron	A61M1/0035	1/1
*	C	US-10,039,871 B2	08-2018	Pollen; Ashia M.	A61M1/06	1/1
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	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16009547	O'TOOLE ET AL.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/25/2018								
	1	✓								
	2	✓								
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	28	✓								
	29	✓								
	30	✓								

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	408	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:13
L2	161	a61m$/$.cpc. and ((piezo piezoelectric piezo-electric) with air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:17
L3	3606	a61m$/$.cpc. and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:18
L4	359	a61m$/$.cpc. and ((pump$4 with weigh$4) same (portable lightweight carry$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/25 18:30
S1	65	("20020193731" | "20040056641" | "20040074281" | "20040267215" | "20050219302" | "20060122575" | "20070051172" | "20070051727" | "20080262420" | "20120277636" | "20140052056" | "20150217036" | "20150217037" | "20150283311" | "20160000980" | "20160058929" | "20160082165" | "20160082166" | "20160151551" | "20160158424" | "20160206794" | "20160220743" | "20160220745" | "20160287767" | "20160296681" | "20160310650" | "20170021068" | "20170035951" | "20170143879" | "20170220753" | "20180021490" | "2849881" | "4390024" | "5474683" | "5941847" | "5973770" | "6045529" | "6090065" | "6383163" | "6440100" | "6461324" | "6547756" | "6579258" | "6663587" | "6749582" | "7048519" | "7201735" | "7312554" | "7314400" | "7776008" | "8057425" | "8118772" | "8187227" | "8262606" | "8282596" | "8376986" | "8702646" |	US-PGPUB; USPAT	OR	OFF	2018/08/07 13:17

		"8801495" | "8876760" | "8926556" | "9033913" | "9173587" | "9345274" | "9539377" | "D548831").PN.				
S2	214	(jonathan near3 o'toole).inv. (adam near3 rollo).inv. (andrew near3 carr).inv.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:42
S3	63	(a61m1/062 a61m1/066 a61m1/06).cpc. and piezo$9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 13:45
S4	19	("20040122358" | "20060226108" | "20080077042" | "20080167579" | "20120004603" | "3895533" | "4024856" | "4338953" | "5347656" | "5666104" | "5827191" | "7316653" | "7621797" | "7794425" | "8308648" | "8777864" | "8801658" | "8827911").PN. OR ("8992445").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:50
S5	7	("5730139" | "6423010" | "6602199" | "7479154" | "8206414" | "8425426" | "8992445").PN. OR ("9192325").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/07 13:59
S6	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:16
S7	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S8	2787	(a61m1/062 a61m1/066 a61m1/06).cpc. not S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:58
S9	45	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 14:59

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S10	14	S9 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/07 14:59
S11	2	"60479361".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/07 15:04
S12	143	a61j13/00.cpc.	US-PGPUB; USPAT	OR	OFF	2018/08/10 10:30
S13	409	a61j13/00.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:30
S14	3369	(a61m1/062 a61m1/066 a61m1/06).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:43
S15	582	(a61m1/062 a61m1/066 a61m1/06 a41c4/04 a61j13/00).cpc. and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S16	0	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S14)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S17	2665	(a61m1/062 a61m1/066 a61m1/06).cpc. not (S15 S13)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 10:44
S18	71	(US-20020193731-$ or US-20040056641-$ or	US-	OR	OFF	2018/08/10

		US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$).did.	PGPUB; USPAT; FPRS			11:47
S19	37	S18 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:48
S20	4	S18 and ((air with pump$4) same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 11:50
S21	16	S18 and (pump$4 same diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:15
S22	1	S18 and piezo	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/10 12:40
S23	0	a61m1/1058.cpc. and breast and diaphragm	US-	OR	OFF	2018/08/10

			PGPUB; USPAT; FPRS			12:42
S24	5	breast same pump$4 same piezo$8 same air	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/10 12:43
S25	1	("9884172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/10 13:58
S26	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 08:40
S27	2	"59563385".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S28	1	"59563425".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:20
S29	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 10:26

		2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S30	44	S29 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:26
S31	17	S29 and (pump$4 with diaphragm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 10:27
S32	51	S26 and "air pump"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 11:07
S33	4	"47900902".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:13
S34	10	("20030212374" | "20050251089" | "20050283900" | "20070135778" | "20110054389" | "3084691" | "4229029" | "5295957" | "6070659").PN. OR ("9511176").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/24 11:16
S35	2	"51149640".FMID.	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 11:17
S36	271	S26 and (control$4 same select$4 left same right same breast)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 12:50
S37	3	S29 and (recharg$4 with battery)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 13:04
S38	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41

S39	9	S38 and ((center centre) with gravity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:41
S40	11	S38 and (light with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:48
S41	0	S38 and (radiation with milk with (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S42	2	S38 and (radiation same milk same (volume quantity amount height))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 14:51
S43	3390	(a61m1/062 a61m1/066 a61m1/06 a61m1/068 a61j/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S44	10	S43 and ((piezo piezoelectric piezo-electric) same air same pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:13
S45	1	a61m1/1058 and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S46	27	a61m1/1058.cpc. and (suction$4 vacuum$4 aspirat$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:23
S47	23	S43 and (indicator same milk same (express$4 flow$4))	US-PGPUB; USPAT; USOCR; FPRS;	OR	OFF	2018/08/24 19:26

			EPO; JPO			
S48	51	S43 and (air same pressure same sens$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:30
S49	19	S43 and ((indicat$4 record$4) same (right and left))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:38
S50	56	S43 and (pump$4 with series)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:42
S51	77	S43 and (pump$4 with weigh$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:47
S52	87	(US-20020193731-$ or US-20040056641-$ or US-20150283311-$ or US-20160000980-$ or US-20160206794-$ or US-20180021490-$ or US-20120004603-$ or US-20170173233-$ or US-20080077042-$ or US-20010044593-$ or US-20030139702-$ or US-20050080376-$ or US-20060270973-$ or US-20070005006-$ or US-20070219486-$ or US-20080275386-$ or US-20090118573-$ or US-20100086419-$ or US-20130123689-$ or US-20140323962-$ or US-20140330200-$ or US-20140378946-$ or US-20150065994-$ or US-20160158424-$ or US-20160287768-$ or US-20160296682-$).did. or (US-20170072118-$ or US-20170173232-$ or US-20180008758-$ or US-20180110906-$ or US-20180126052-$ or US-20160287481-$ or US-20080039781-$ or US-20110301533-$ or US-20110314587-$ or US-20130023821-$ or US-20140142501-$ or US-20140263611-$ or US-20140378895-$ or US-20160095967-$ or US-20160183602-$ or US-20180078687-$ or US-20030027491-$ or US-20030191433-$ or US-20040024352-$ or US-20060106334-$ or US-20070161330-$ or US-20080208116-$ or US-20140052056-$ or US-20160082166-$ or US-20160220745-$ or US-20160220743-$ or US-20170312409-$).did. or (US-6440100-$ or US-6547756-$ or US-6749582-$ or US-8057425-$ or US-8118772-$ or US-8801495-$ or US-9033913-$ or US-8992445-$ or US-4024856-$ or US-5827191-$ or US-9192325-$ or US-6699213-$ or US-7662018-$ or US-	US-PGPUB; USPAT; FPRS	OR	OFF	2018/08/24 19:59

		5571084-$ or US-6227936-$ or US-8414353-$ or US-3840012-$ or US-4270538-$ or US-6358226-$).did. or (WO-2015174330-$ or WO-2016024558-$ or WO-2011012228-$ or EP-2502639-$ or CA-2955939-$ or CA-2955605-$ or WO-2016014488-$ or EP-3058967-$ or WO-2016156173-$ or WO-2016161050-$ or WO-2017139437-$ or WO-2017190024-$ or EP-2388026-$ or CA-2953333-$).did.				
S53	44	S52 and (air with pump$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S54	5	S53 and (air with filter$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 19:59
S55	3	S43 and (pump$4 with (db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S56	6	S43 and ((db decibal?))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:07
S57	26	S43 and (sens$4 with (orientation angle tilt placement))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:16
S58	9	S43 and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:31
S59	484	a61m$/$.cpc. and ((indicat$4 input$4 document$4 record$4) with comfort)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2018/08/24 20:32
S60	1	S43 and "social media"	US-PGPUB; USPAT;	OR	OFF	2018/08/24 20:52

			USOCR; FPRS; EPO; JPO			

EAST Search History (Interference)

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'TOOLE
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00002

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6440100	B1	2002-08-27	Prentiss	
	2	6547756	B1	2003-04-15	Greter et al.	
	3	7201735	B2	2007-04-10	Atkin et al.	
	4	8118772	B2	2012-02-21	Dao et al.	
	5	8187227	B2	2012-05-29	Luzbetak et al.	
	6	8262606	B2	2012-09-11	Greter et al.	
	7	8282596	B2	2012-10-09	Greter et al.	
	8	8376986	B2	2013-02-19	Van Schijndel et al.	

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	9	9033913	B2	2015-05-19	Khalil et al.	
	10	9173587	B2	2015-11-03	Van Schijndel et al.	
	11	2849881		1958-09-02	Anderson	
	12	5474683		1995-12-12	Bryant et al.	
	13	7048519	B2	2006-05-23	Fong et al.	
	14	7312554	B2	2007-12-25	Vogeley	
	15	4390024		1983-06-28	Williams	
	16	5973770		1999-10-26	Carter et al.	
	17	7314400	B2	2008-01-01	Fildan et al.	
	18	5941847		1999-08-24	Huber et al.	
	19	6045529		2000-04-04	Nuesch	

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	20	6090065		2000-07-18	Giles	
	21	6383163	B1	2002-05-07	Kelly et al.	
	22	6461324	B1	2002-10-08	Schlensog	
	23	6579258	B1	2003-06-17	Atkin et al.	
	24	6663587	B2	2003-12-16	Silver et al.	
	25	6749582	B2	2004-06-15	Britto et al.	
	26	7776008	B2	2010-08-17	Renz et al.	
	27	8057425	B1	2011-11-15	Myers et al.	
	28	8801495	B1	2014-08-12	Guindon	
	29	8926556	B2	2015-01-06	Van Eijkelenborg et al.	
	30	D548831	S	2007-08-14	Charlez	

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	Attorney Docket Number	373499.00002

	31	9539377	B2	2017-01-10	Makower et al.	
	32	8702646	B2	2014-04-22	Garbez et al.	
	33	9345274	B1	2016-05-24	Prill	
	34	8876760	B2	2014-11-04	Bosman et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20150283311	A1	2015-10-08	Alvarez et al.	
	2	20160082166	A1	2016-03-24	Guthrie et al.	
	3	20160220743	A1	2016-08-04	Guthrie et al.	
	4	20160310650	A1	2016-10-27	Makower et al.	
	5	20170021068	A1	2017-01-26	Gaskin et al.	

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	Attorney Docket Number	373499.00002

	6	20170143879	A1	2017-05-25	Okaguchi	
	7	20040074281	A1	2004-04-22	Lobdell et al.	
	8	20050219302	A1	2005-10-06	Vogeley	
	9	20070051172	A1	2007-03-08	Perinet et al.	
	10	20160000980	A1	2016-01-07	Alvarez et al.	
	11	20160082165	A1	2016-03-24	Alvarez et al.	
	12	20160151551	A1	2016-06-02	Felber	
	13	20160220745	A1	2016-08-04	Guthrie et al.	
	14	20160296681	A1	2016-10-13	Gaskin et al.	
	15	20040056641	A1	2004-03-25	Myers et al.	
	16	20040267215	A1	2004-12-30	Charlez et al.	

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	17	20060122575	A1	2006-06-08	Wakabayashi	
	18	20070051727	A1	2007-03-08	Holley, Jr.	
	19	20150217037	A1	2015-08-06	Pollen et al.	
	20	20160158424	A1	2016-06-09	Chen et al.	
	21	20160206794	A1	2016-07-21	Makower et al.	
	22	20160287767	A1	2016-10-06	Simmons et al.	
	23	20120277636	A1	2012-11-01	Blondheim et al.	
	24	20160058929	A1	2016-03-03	Nowroozi et al.	
	25	20170035951	A1	2017-02-09	Tanaka	
	26	20170220753	A1	2017-08-03	Guthrie et al.	
	27	20180021490	A1	2018-01-25	Chang et al.	

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	Examiner Name	
	Attorney Docket Number	373499.00002

	28	20080262420	A1	2008-10-23	Dao et al.	
	29	20140052056	A1	2014-02-20	Garbez et al.	
	30	20020193731	A1	2002-12-19	Myers et al.	
	31	20150217036	A1	2015-08-06	Pollen et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	1 263 487	EP	B2	2016-11-23	Medela Holding AG		
	2	1 430 918	EP	B1	2008-05-14	Medela Holding AG		
	3	2 077 868	EP	B1	2016-07-27	Medela Holding AG		
	4	2 210 628	EP	B1	2013-02-13	Medela Holding AG		
	5	2016/014469	WO	A1	2016-01-28	Exploramed NC7, LLC		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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First Named Inventor	Jonathan O'TOOLE
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Examiner Name	
Attorney Docket Number	373499.00002

	6	2016/014488	WO	A1	2016-01-28	Exploramed NC7, LLC		
	7	3311982	DE	C2	1983-10-13	Battelle Memorial Institute		
	8	197 50 620	DE	A1	1999-06-02	Siemens AG		
	9	0 503 280	EP	A2	1992-02-08	Pierburg GmbH		
	10	2016-10524	JP	A	2016-01-23			
	11	2 344 380	RU	C1	2009-01-20			
	12	94/20158	WO	A1	1994-09-15	Deka Products Limited Partnership		
	13	2005/114113	WO	A3	2005-12-01	Accu-Gauge Limited		
	14	2005/114116	WO	A1	2005-12-01	Lane et al.		
	15	2015/116749	WO	A1	2015-11-05	Murata Manufacturing Co., Ltd.		
	16	2015/174330	WO	A1	2015-11-19	Murata Manufacturing Co., Ltd.		

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Attorney Docket Number	373499.00002

	17	2016/002606	WO	A1	2016-01-07	Murata Manufacturing Co., Ltd.		
	18	2016/006494	WO	A1	2016-01-14	Murata Manufacturing Co., Ltd.		
	19	2016/006496	WO	A1	2016-01-14	Murata Manufacturing Co., Ltd.		
	20	2016/007560	WO	A1	2016-01-14	Naya Health, Inc.		
	21	2016/024558	WO	A1	2016-02-18	Murata Manufacturing Co., Ltd.		
	22	2016/039083	WO	A1	2016-03-17	Murata Manufacturing Co., Ltd.		
	23	2016104673	WO	A1	2016-06-30	Murata Manufacturing Co., Ltd.		
	24	2473022	GB	B	2011-12-14	Drew		
	25	2499248	GB	B	2014-04-02	Morana		
	~~26~~	~~2 441 367~~	~~RU~~	~~C2~~	~~2012-02-10~~			
	~~27~~	~~105280759~~	~~CN~~	~~A~~	~~2016-02-03~~			

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	28	1 404 393	EP	B1	2014-12-24	Medela Holding AG		
	29	2015/081459	WO	A1	2015-06-11	Chen		
	30	2015/120321	WO	A1	2015-08-13	Naia Health, Inc.		
	31	2015150225	WO	A1	2015-10-08	Koninklijke Philips N.V.		
	32	2016/164853	WO	A1	2016-10-13	Naya Health, Inc.		
	33	2017/061349	WO	A1	2017-04-13	Murata Manufacturing Co., Ltd.		
	34	2009/134271	WO	A1	2009-11-05	Dao et al.		
	35	2 436 277	EP	A1	2012-04-04	Drew		
	36	2017/139480	WO	A1	2017-08-17	Exploramed NC7, Inc.		
	37	1 586 340	EP	A2	2005-10-19	Sea Profit (Hong Kong) Limited		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	GB Search Report, dated 15 November 2017, issued in priority GB Application No. GB1709561.3	
	2	GB Search Report, dated 28 November 2017, issued in priority GB Application No. GB1709566.2	
	3	GB Search Report, dated 29 November 2017, issued in priority GB Application No. GB1709564.7	

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EXAMINER SIGNATURE

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	08/07/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Art Unit	
Examiner Name	
Attorney Docket Number	373499.00002

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2018-06-14
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Bibliographic Data

Application No: 16/009,547

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /COURTNEY B FREDRICKSON/ Examiner's Signature | Initials

Title: BREAST PUMP SYSTEM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
06/15/2018	604	3763	373499.00002
RULE			

APPLICANTS

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM

INVENTORS

Jonathan O'TOOLE London, UNITED KINGDOM

Adam ROLLO London, UNITED KINGDOM

Andrew CARR London, UNITED KINGDOM

CONTINUING DATA

FOREIGN APPLICATIONS

UNITED KINGDOM 1709566.2 06/15/2017

UNITED KINGDOM 1709564.7 06/15/2017

UNITED KINGDOM 1709561.3 06/15/2017

UNITED KINGDOM 1809036.5 06/01/2018

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08/02/2018

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16009547	O'TOOLE ET AL.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3763

CPC- SEARCHED		
Symbol	Date	Examiner
A61M 1/062, 1/066, 1/06, 1/066, 1/068	8/25/2018	cbf

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST search history	8/25/2018	cbf
Searched inventors in PALM and EAST	8/25/2018	cbf

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/COURTNEY FREDRICKSON/ Examiner.Art Unit 3763	

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/009,547	06/15/2018	3763	1565	373499.00002	30	1

CONFIRMATION NO. 5958

REPLACEMENT FILING RECEIPT

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC000000101444898

Date Mailed: 08/03/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jonathan O'TOOLE, London, UNITED KINGDOM;
Adam ROLLO, London, UNITED KINGDOM;
Andrew CARR, London, UNITED KINGDOM;

Applicant(s)

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number 78905

Domestic Applications for which benefit is claimed - None.
A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
UNITED KINGDOM 1709561.3 06/15/2017 Access Code Provided
UNITED KINGDOM 1709564.7 06/15/2017 Access Code Provided
UNITED KINGDOM 1709566.2 06/15/2017 Access Code Provided
UNITED KINGDOM 1809036.5 06/01/2018 Access Code Provided

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 08/02/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/009,547**
Projected Publication Date: 12/20/2018
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

BREAST PUMP SYSTEM

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002

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POA ACCEPTANCE LETTER

78905
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OC000000101445024

Date Mailed: 08/03/2018

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This is in response to the Power of Attorney filed 08/01/2018.

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Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

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Concept House
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NP10 8QQ

Application number GB1809036.5

1.	Your reference	**Elvie Pump (UK)**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **63 - 66 Hatton Garden** **London EC1N 8LE** **United Kingdom**
	Patents ADP number *(if you know it)*	11287869002
3.	Title of the invention	**Breast pump system**
4.	Name of your agent *(if you have one)* "Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Langley, Mr Peter** **Origin Limited** **Twisden Works** **Twisden Road** **London NW5 1DN** **United Kingdom**
	Patents ADP number *(if you know it)*	11436136001 ~~**09541046001**~~
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

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7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**No**	

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Description:	**121**
Claim*(s)*:	**n/a**
Abstract:	**n/a**
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Date: **01 Jun 2018**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

Langley, Mr Peter
Email: roland@origin.co.uk
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Fax: 02072090643

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BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed

breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the

product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided

at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as

well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra and including a pumping mechanism; a breast shield; a rigid or non-collapsible milk container; and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

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SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2…IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2…IRn.

By comparing the emitted radiation intensities IE1; IE2…IEn with the received radiation intensities IR1; IR2…IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2…IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter. In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series

configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 41 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise. The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the

diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25g.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

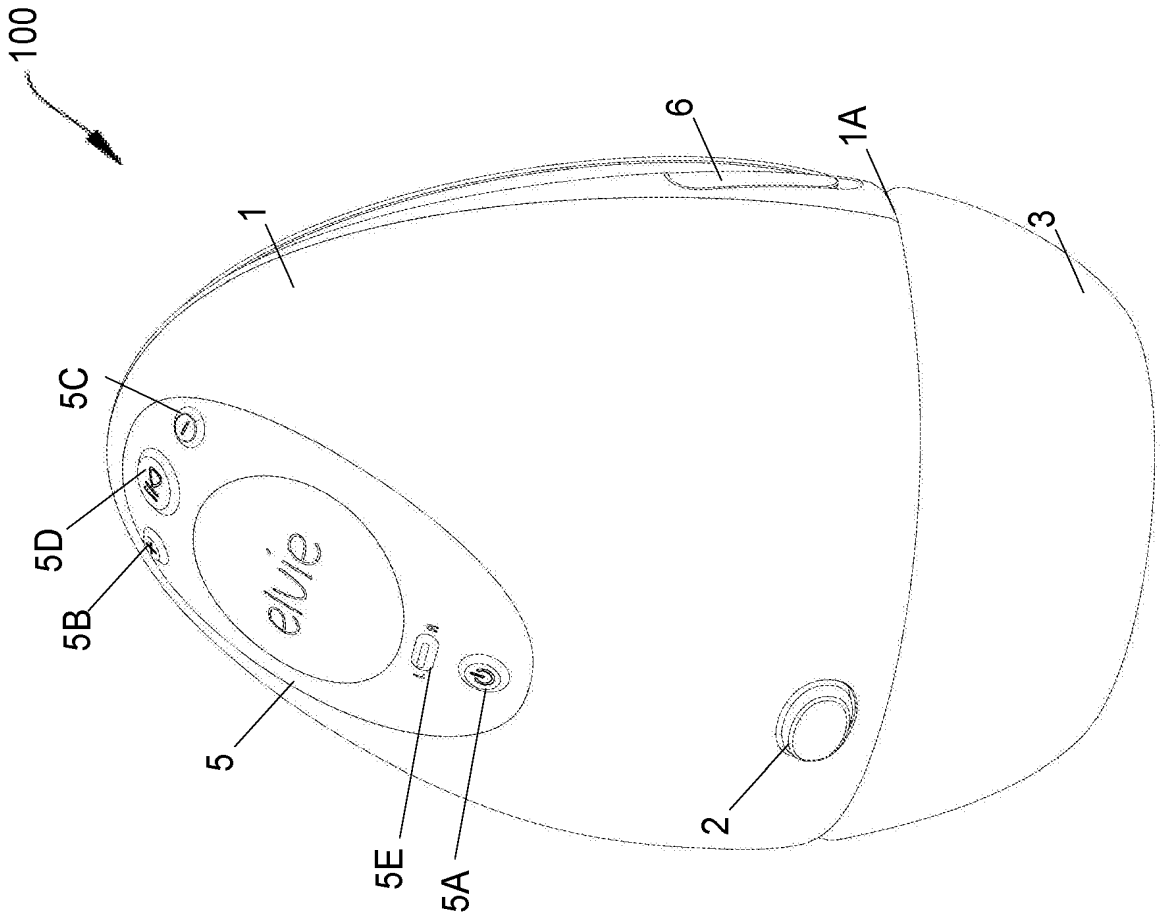


FIGURE 1

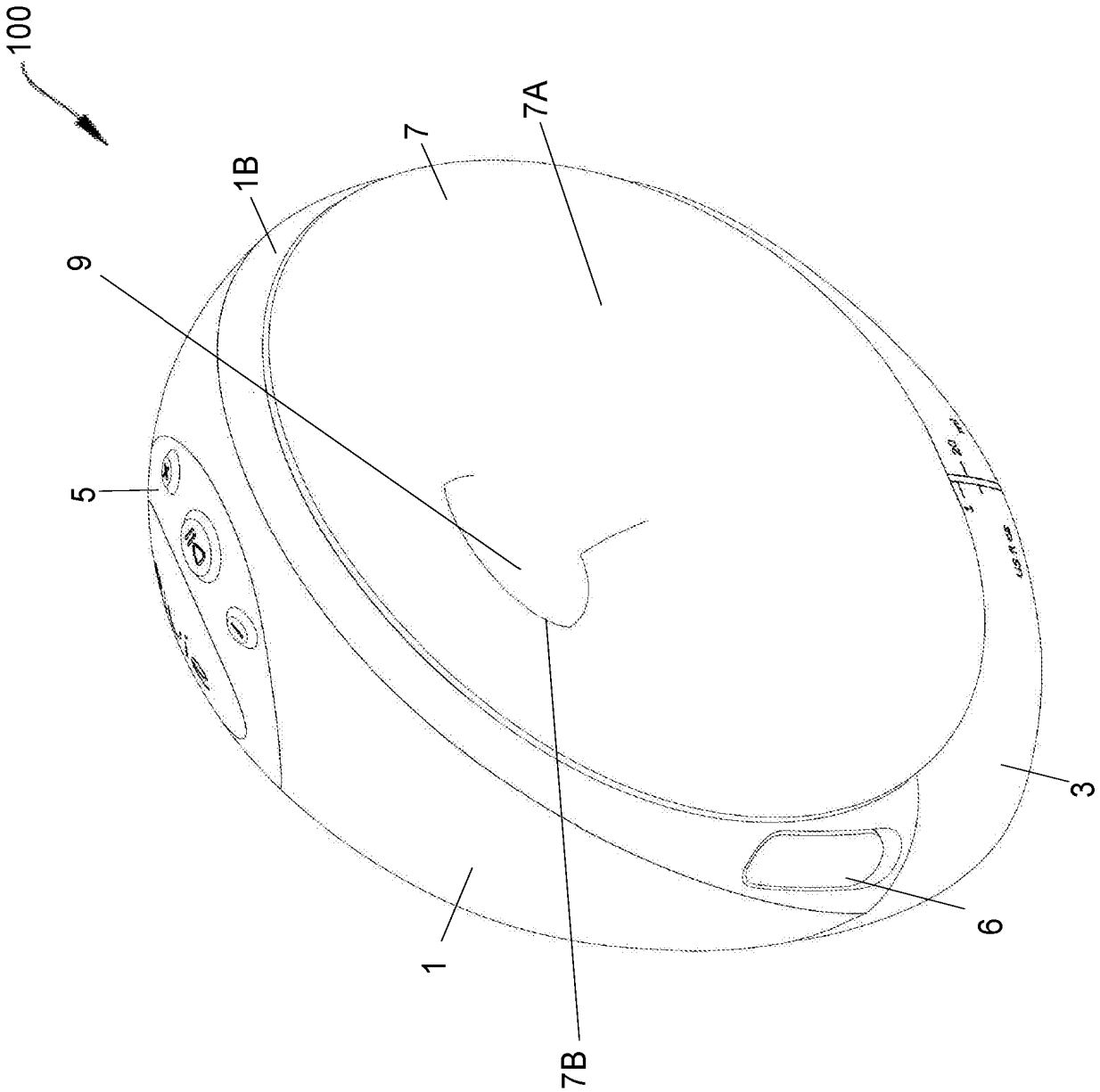


FIGURE 2

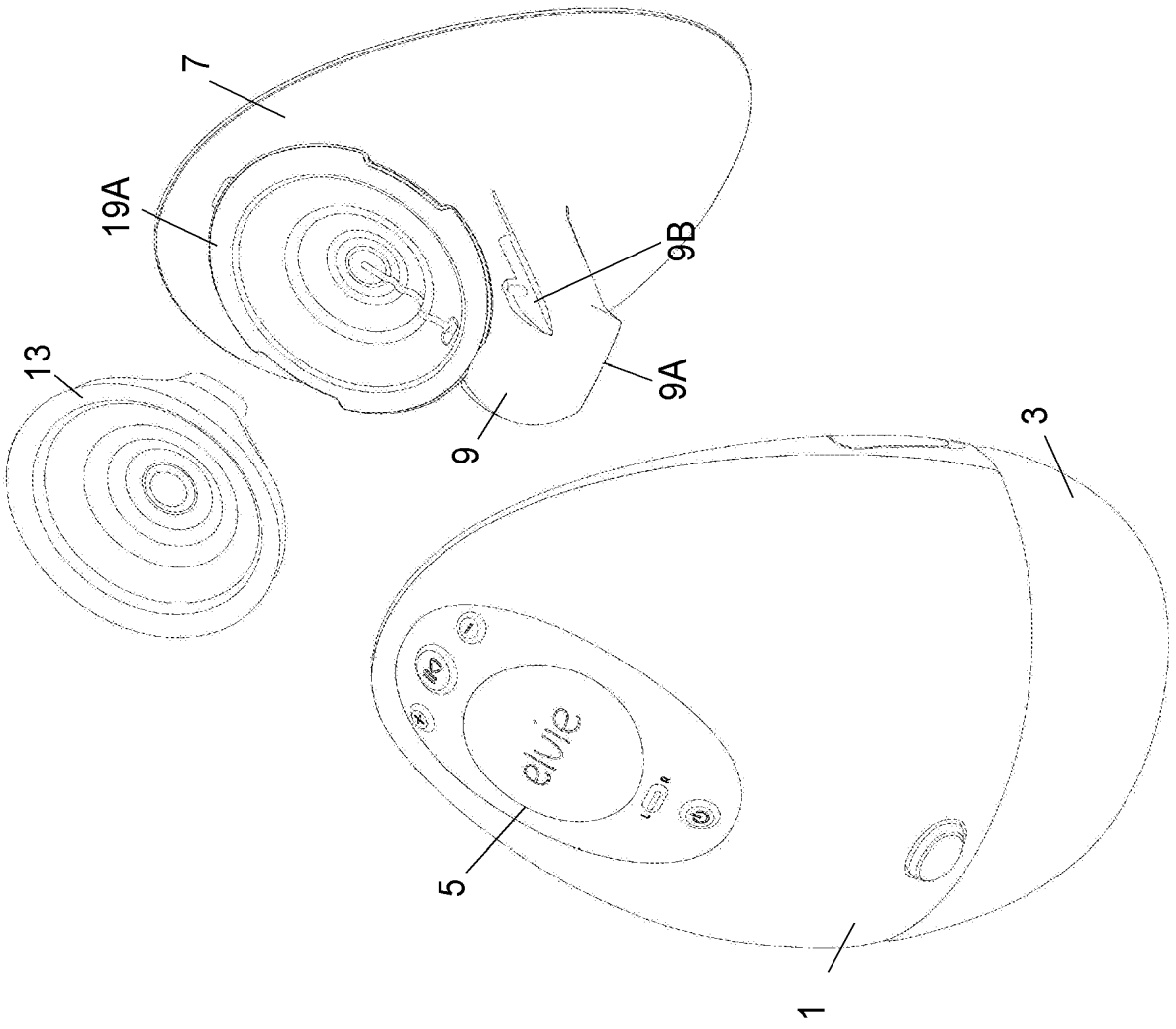


FIGURE 3

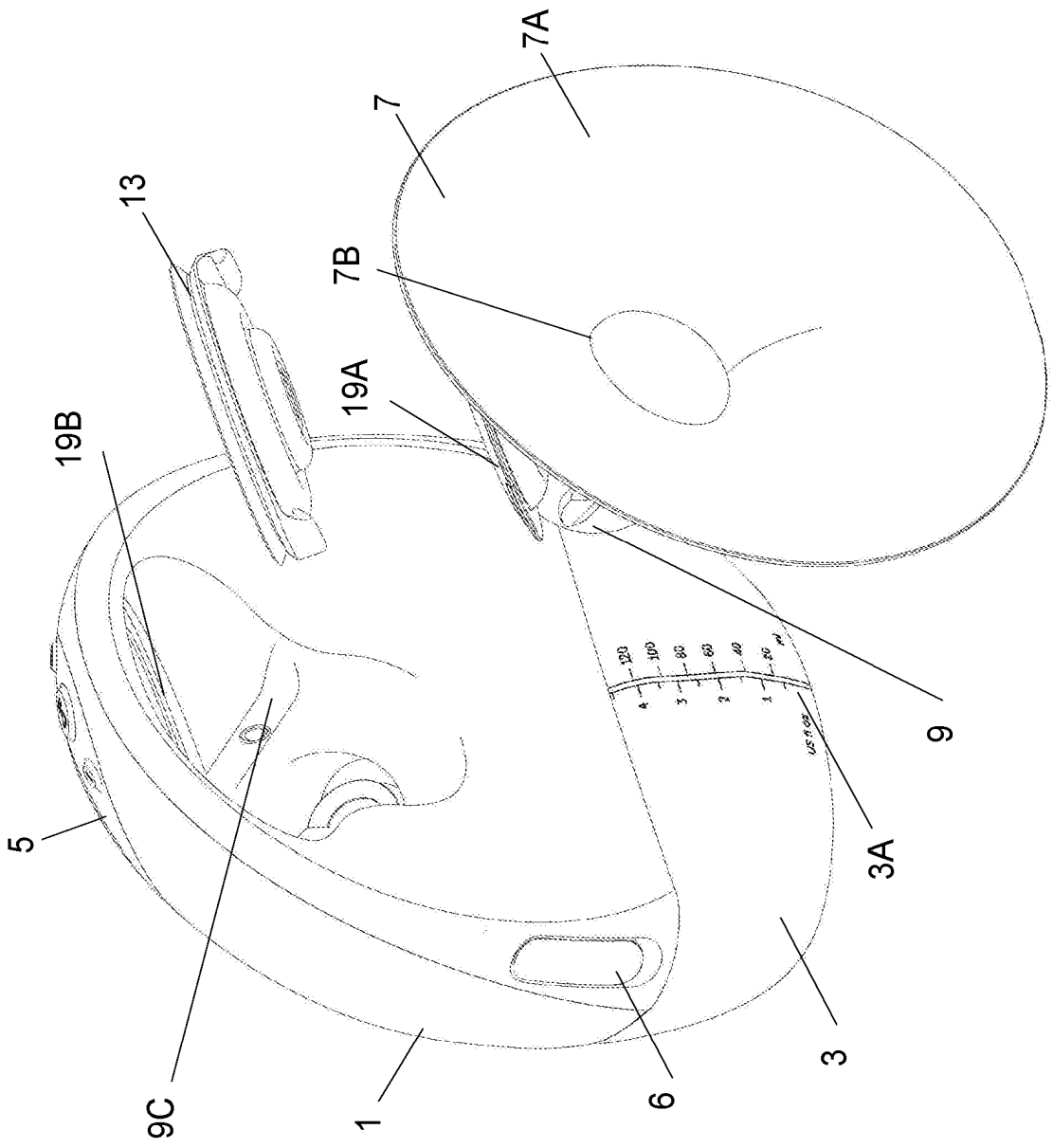


FIGURE 4

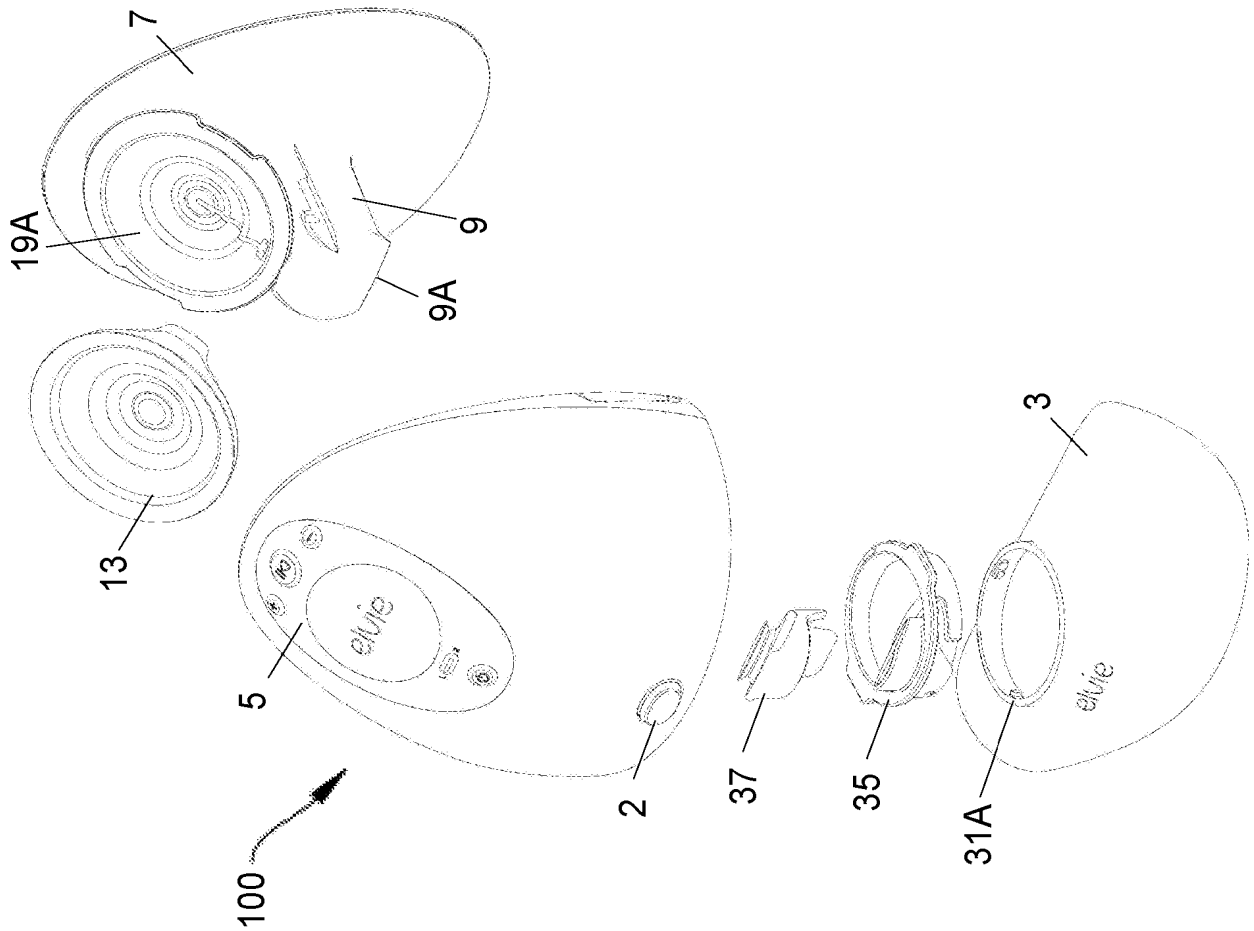


FIGURE 5

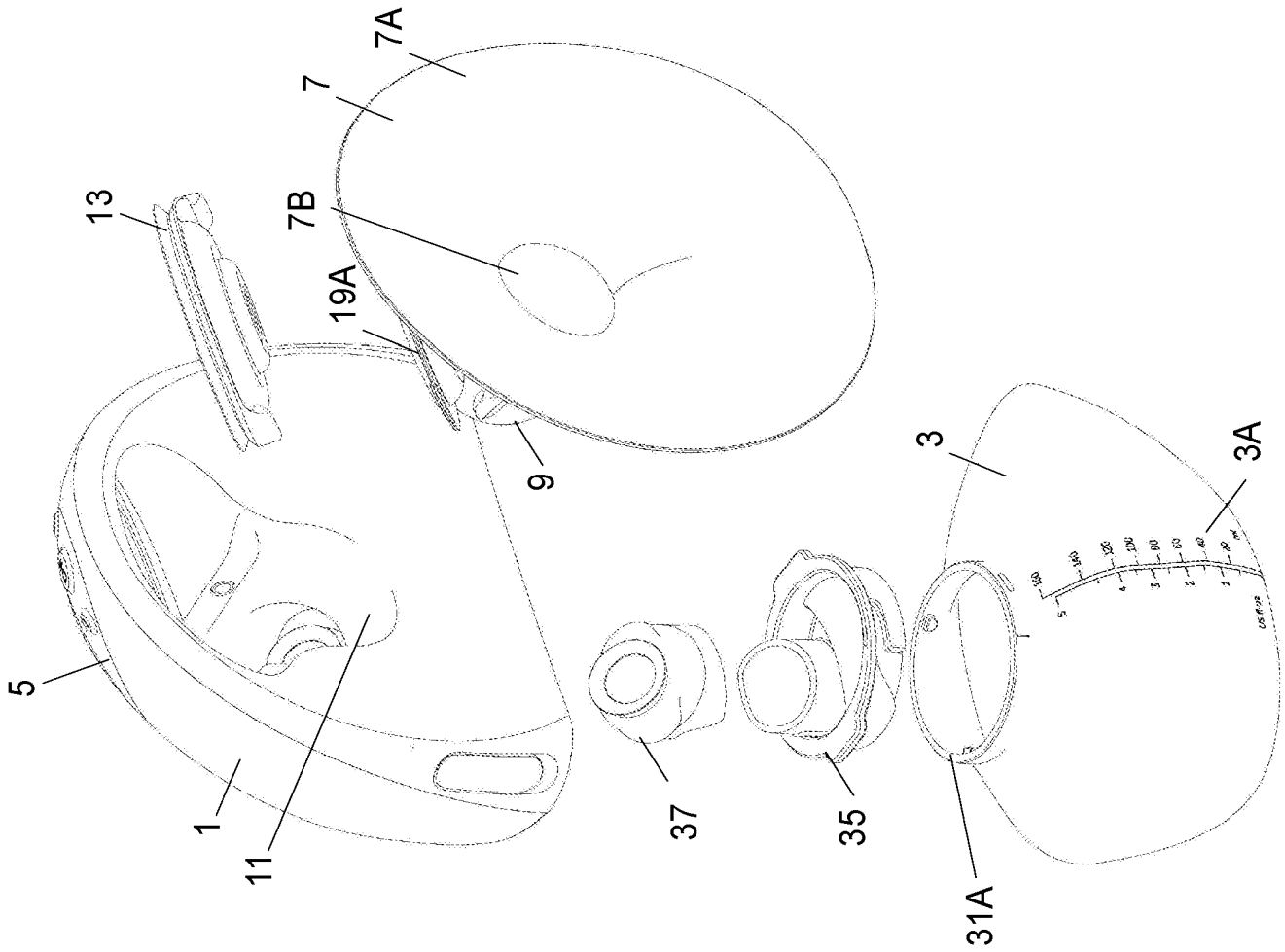


FIGURE 6

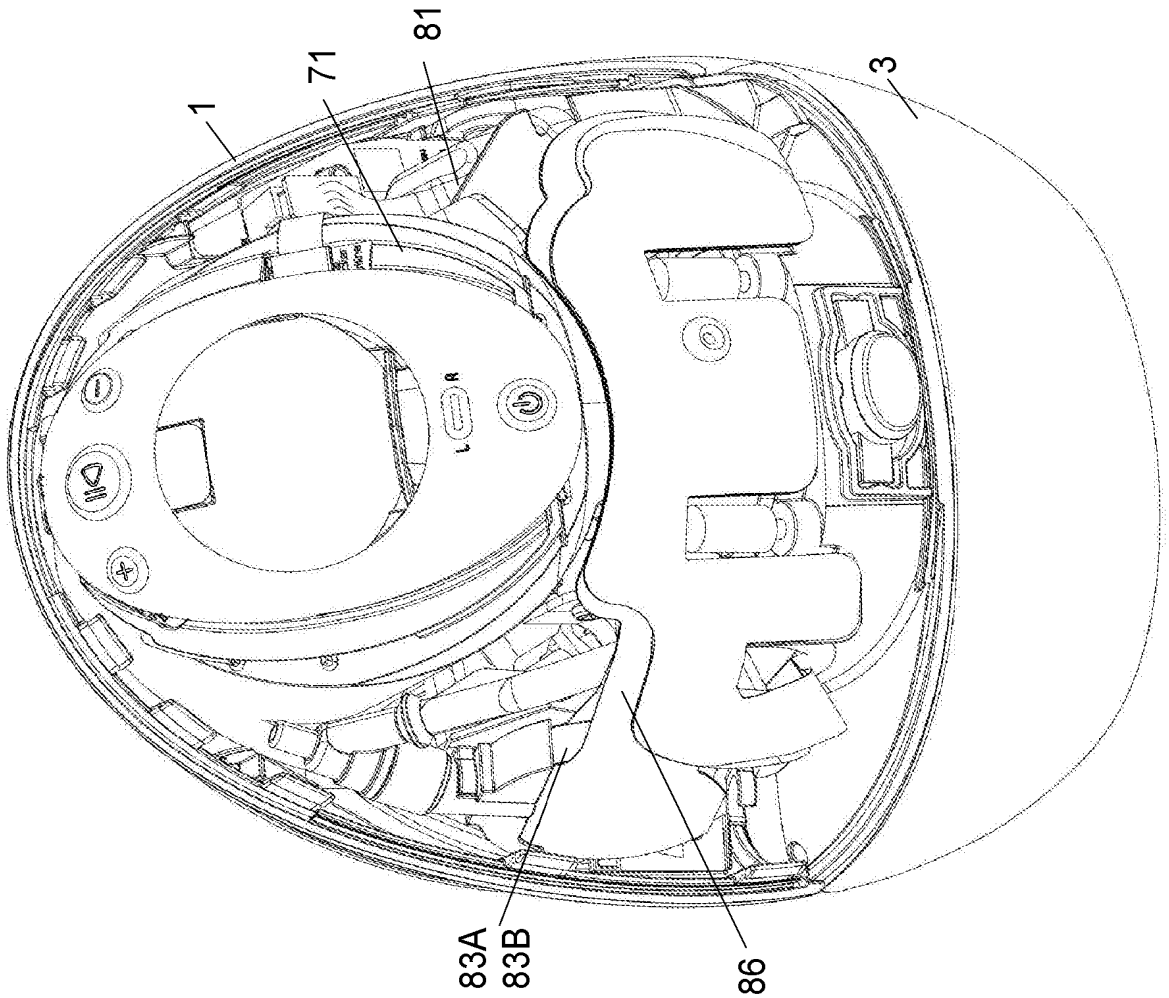


FIGURE 7

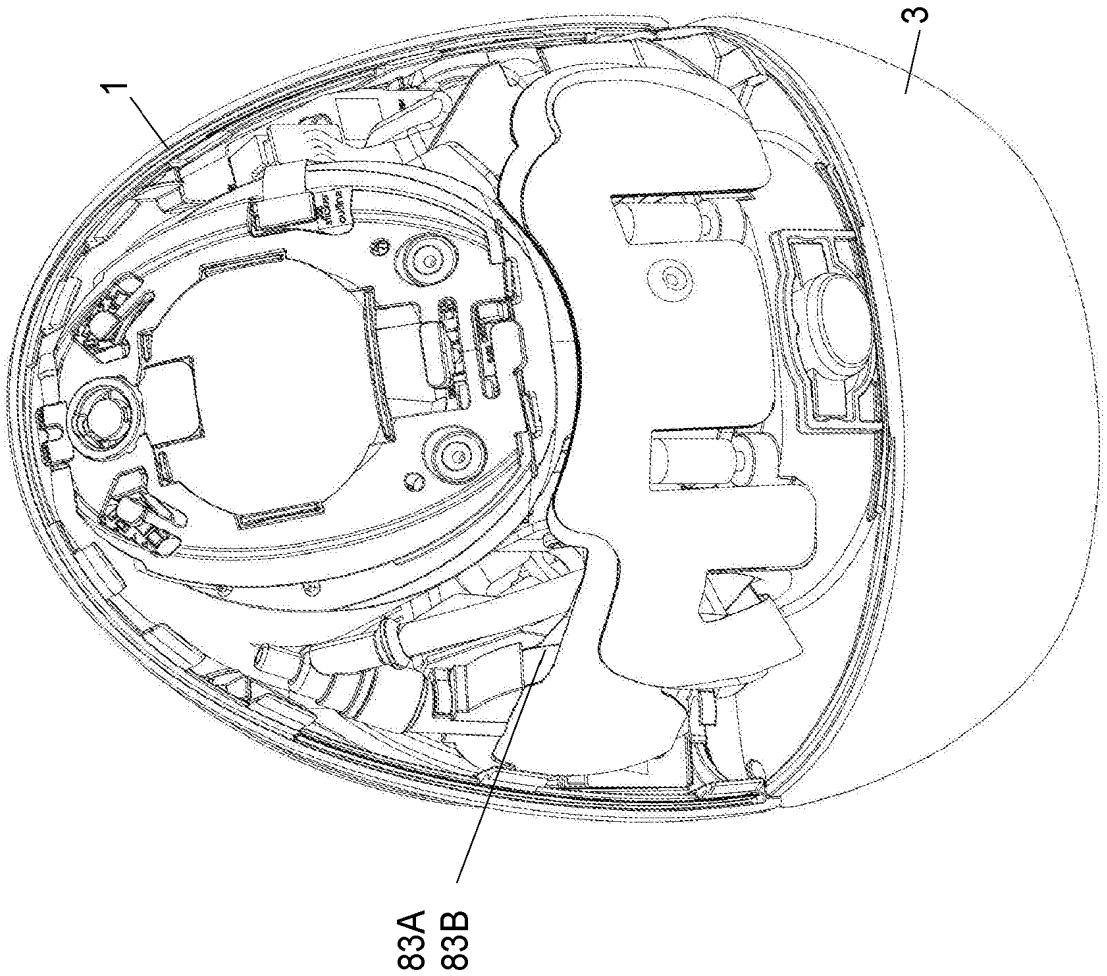


FIGURE 8

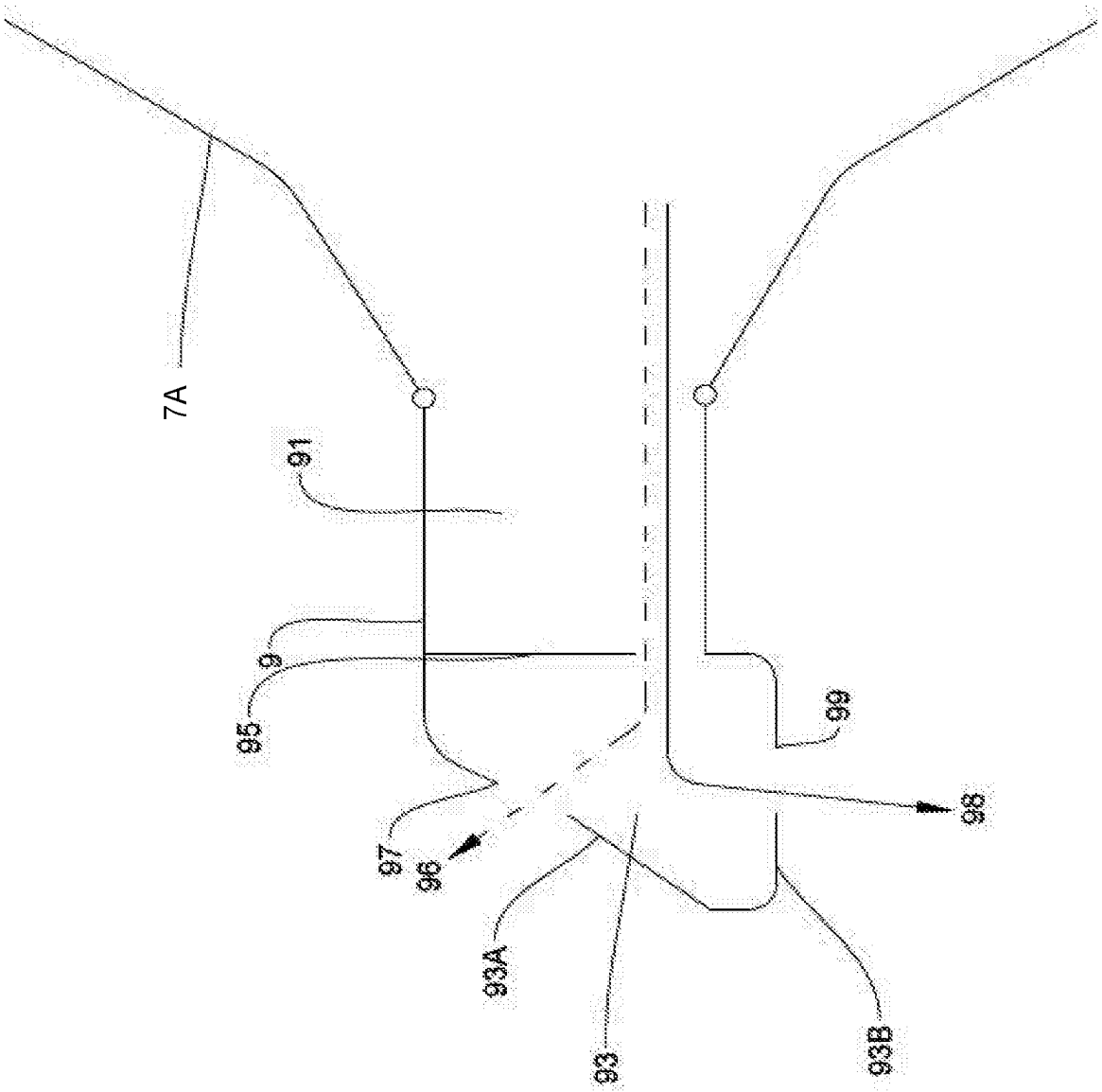


FIGURE 9

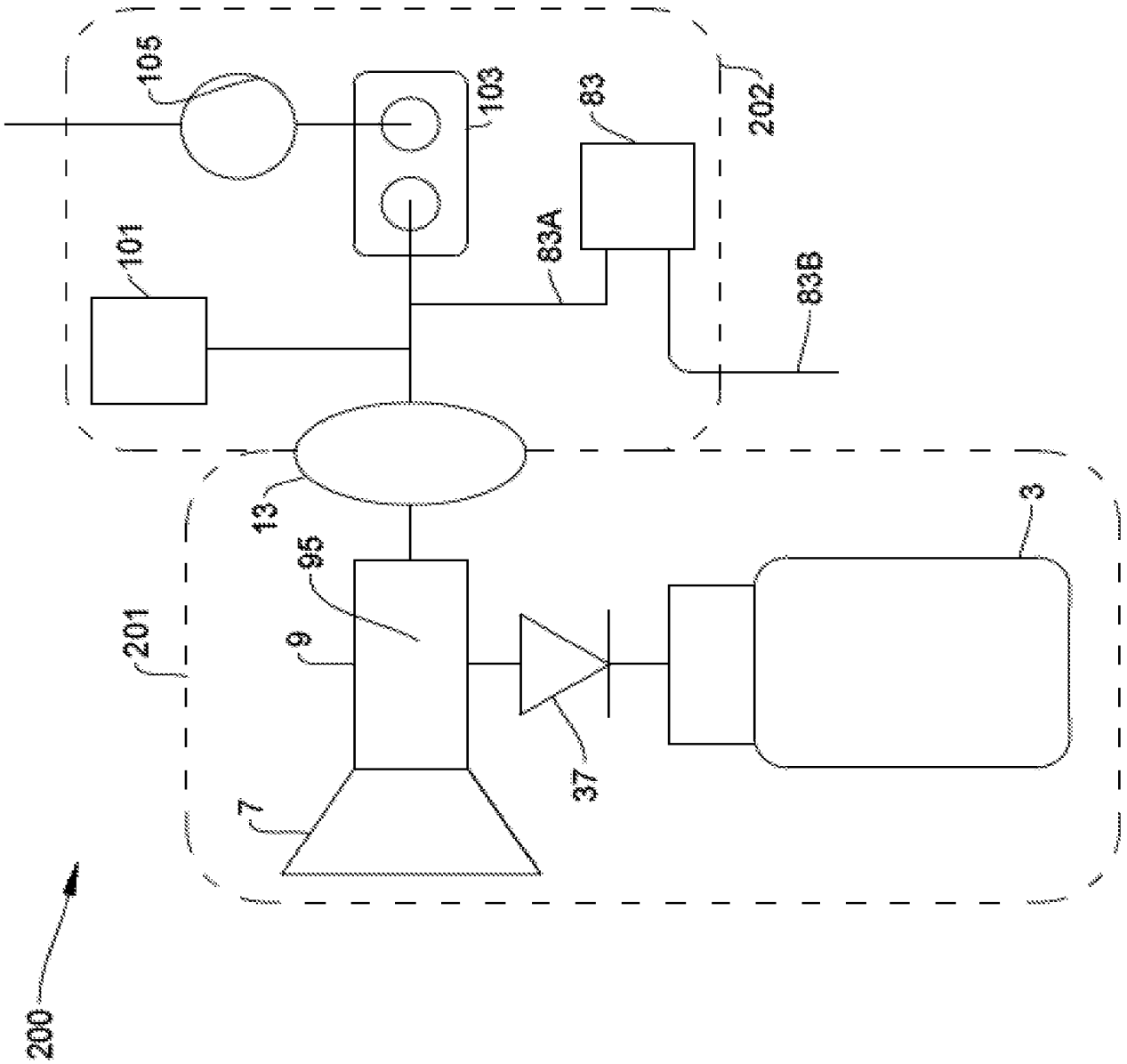


FIGURE 10

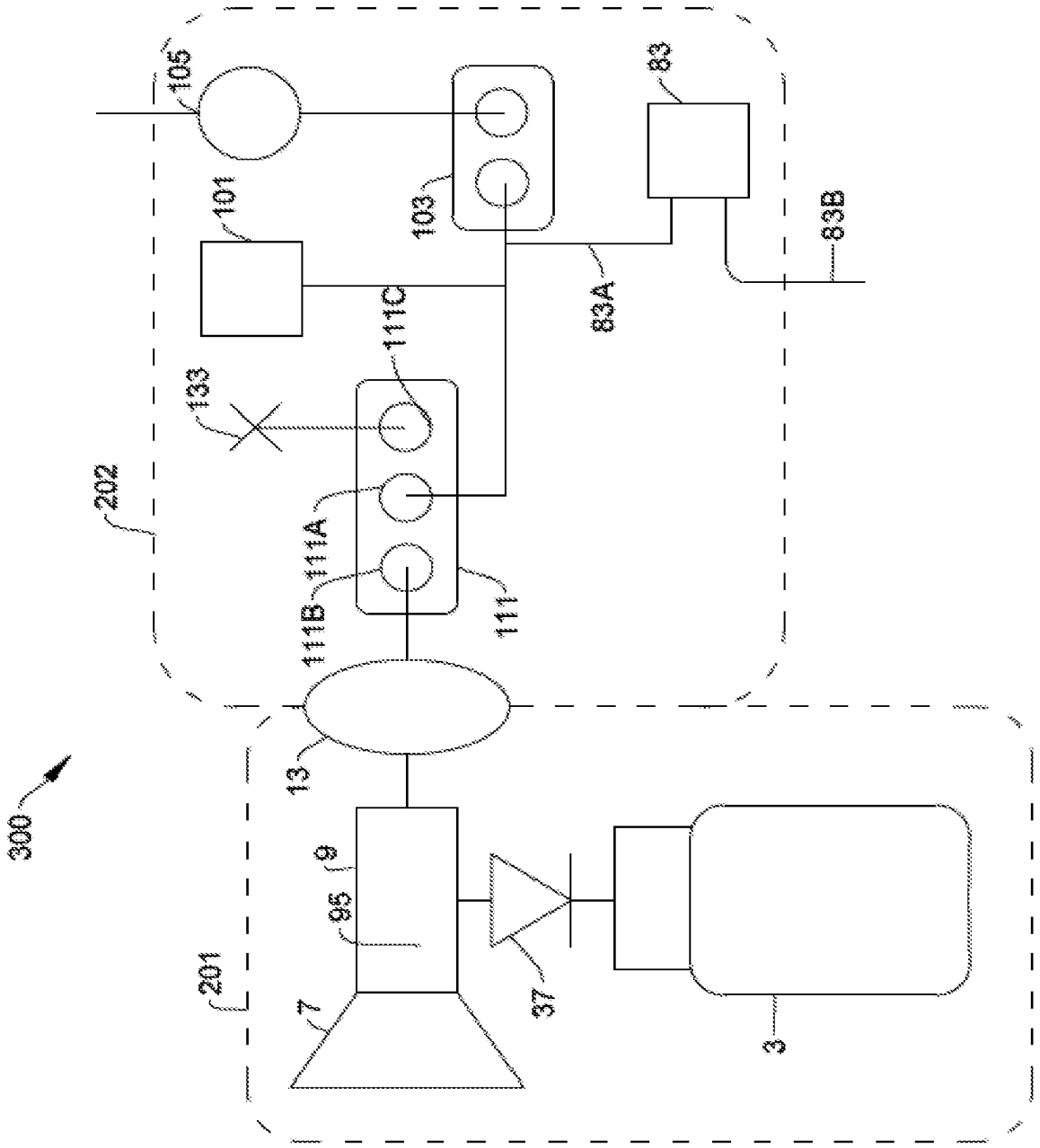

300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

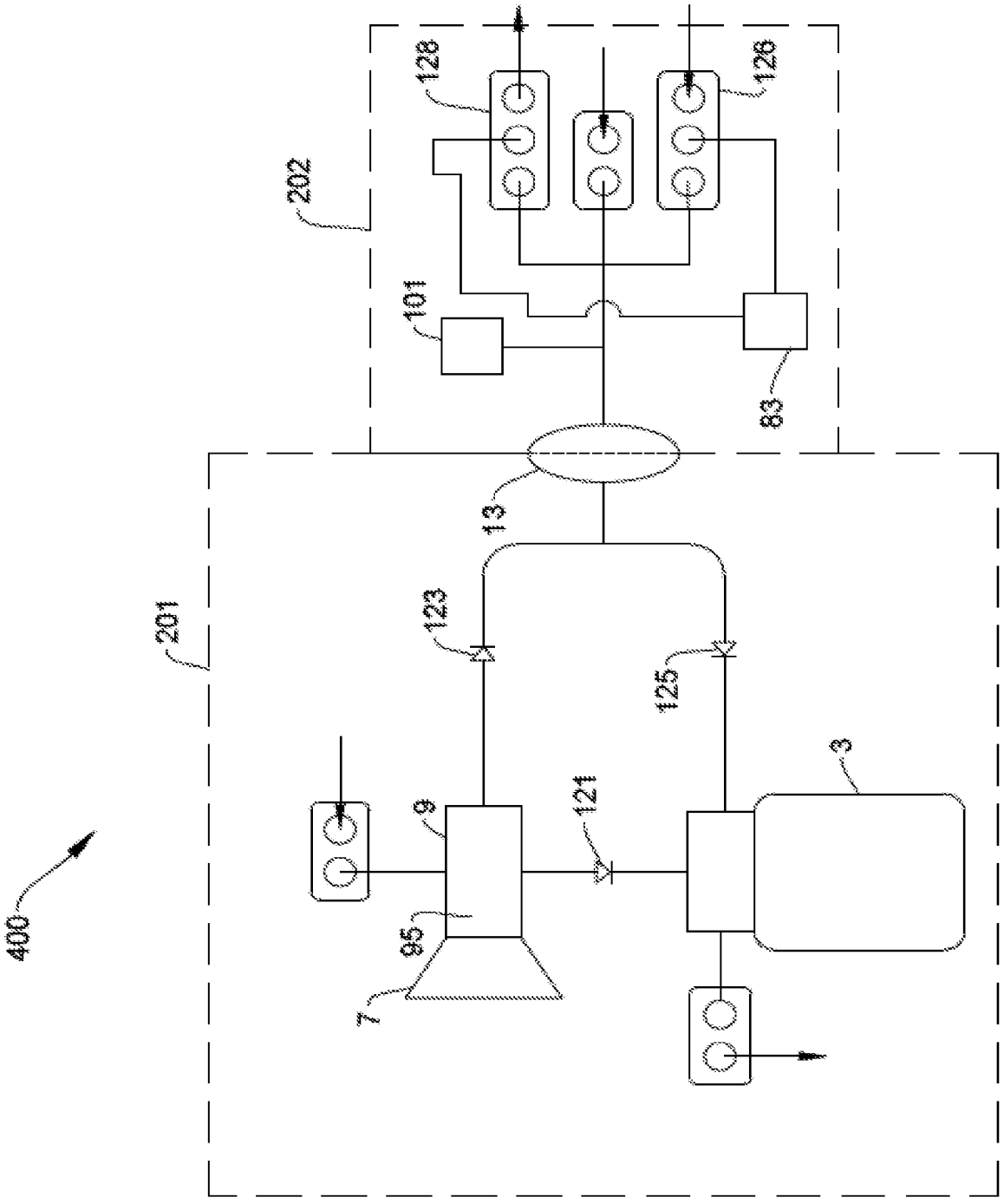


FIGURE 12

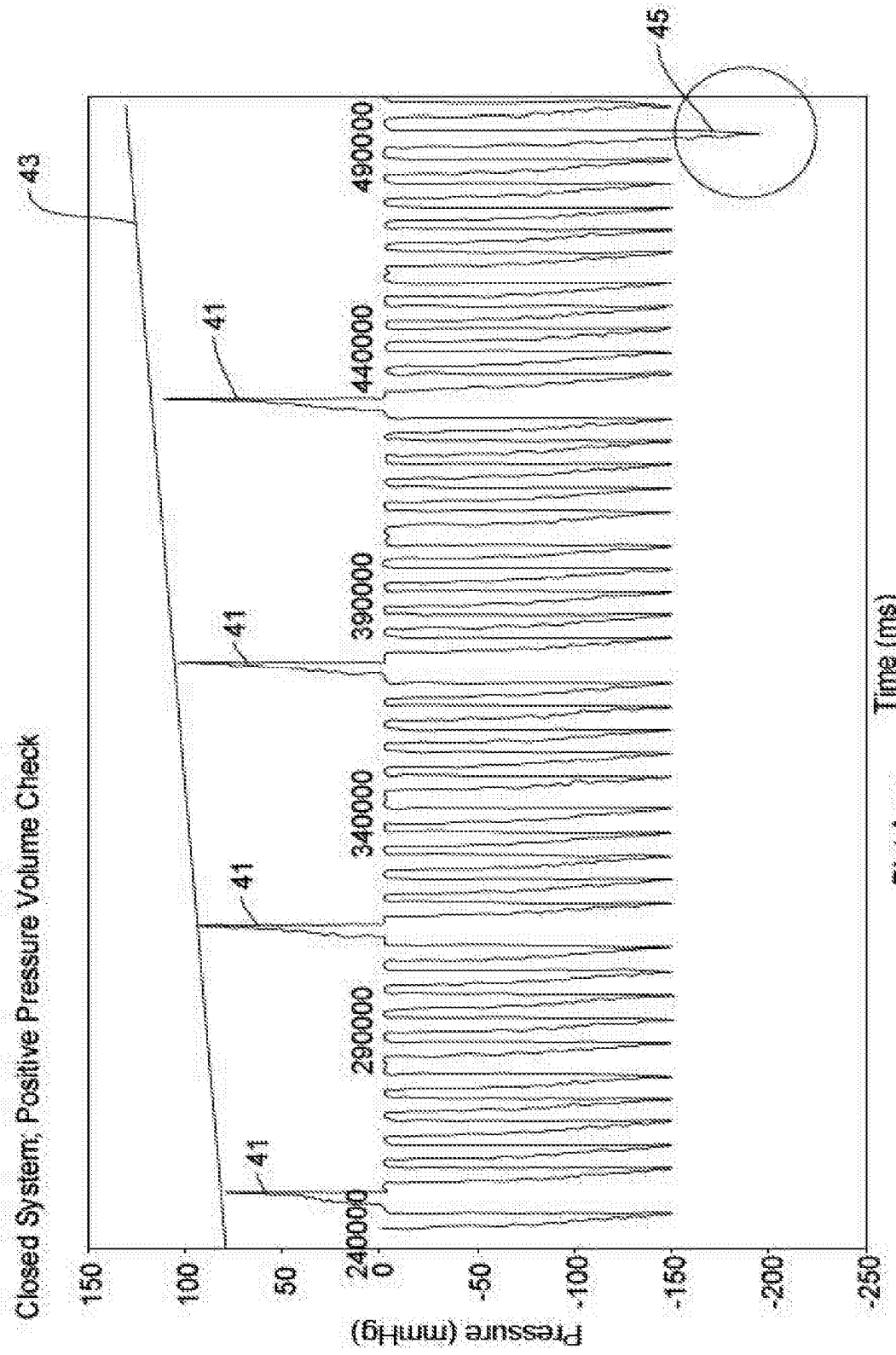

Closed System; Positive Pressure Volume Check
43
45
41
41
41
41
41
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

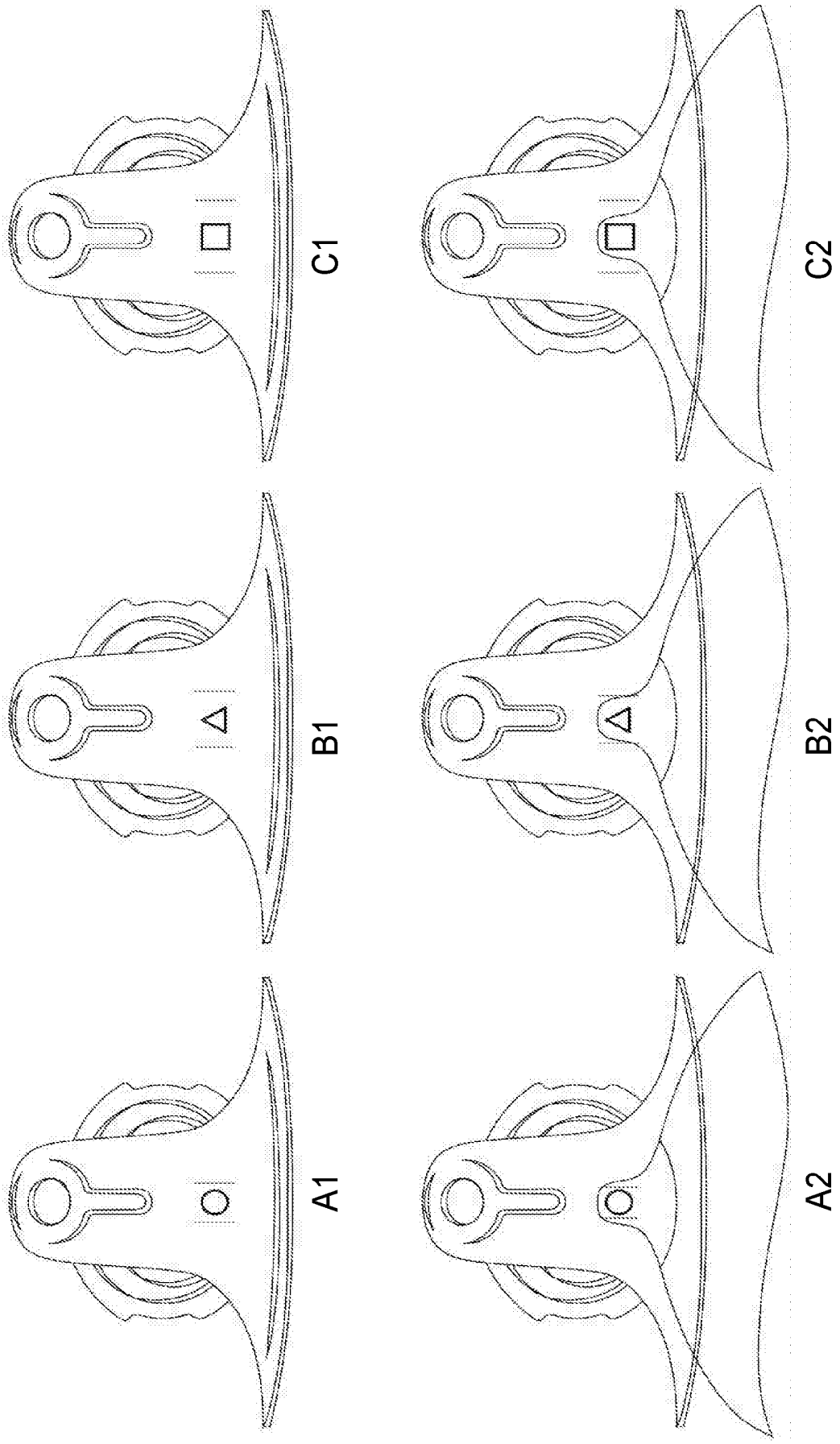


FIGURE 14

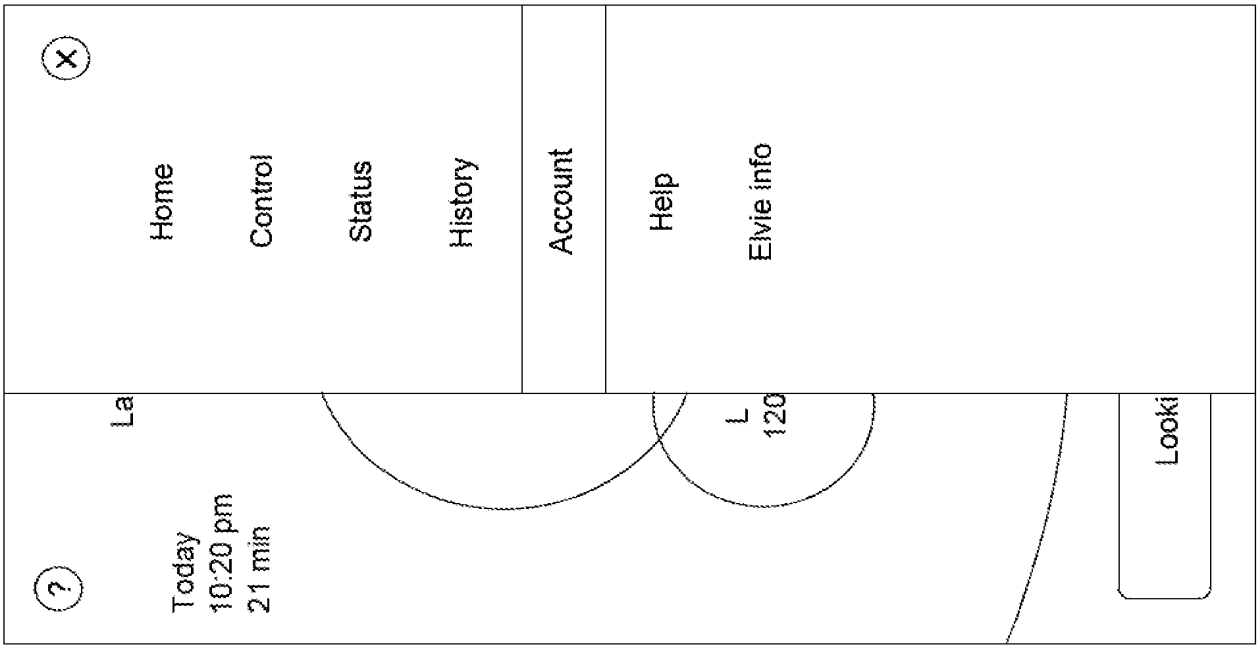

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

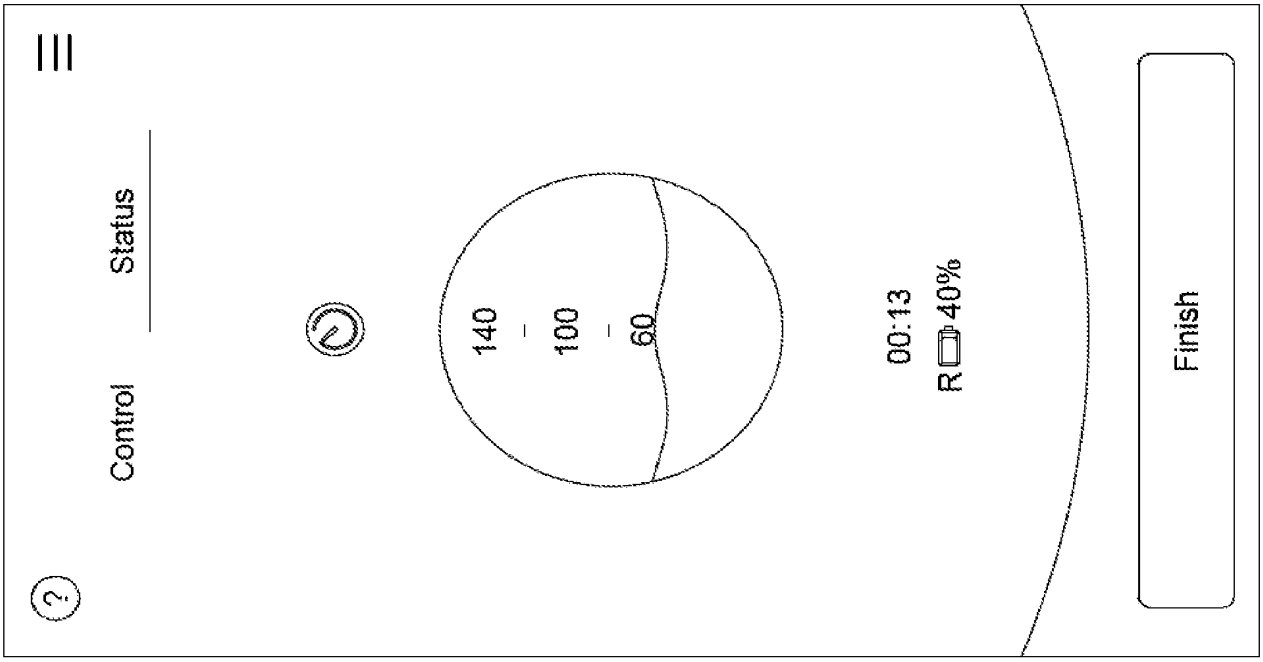
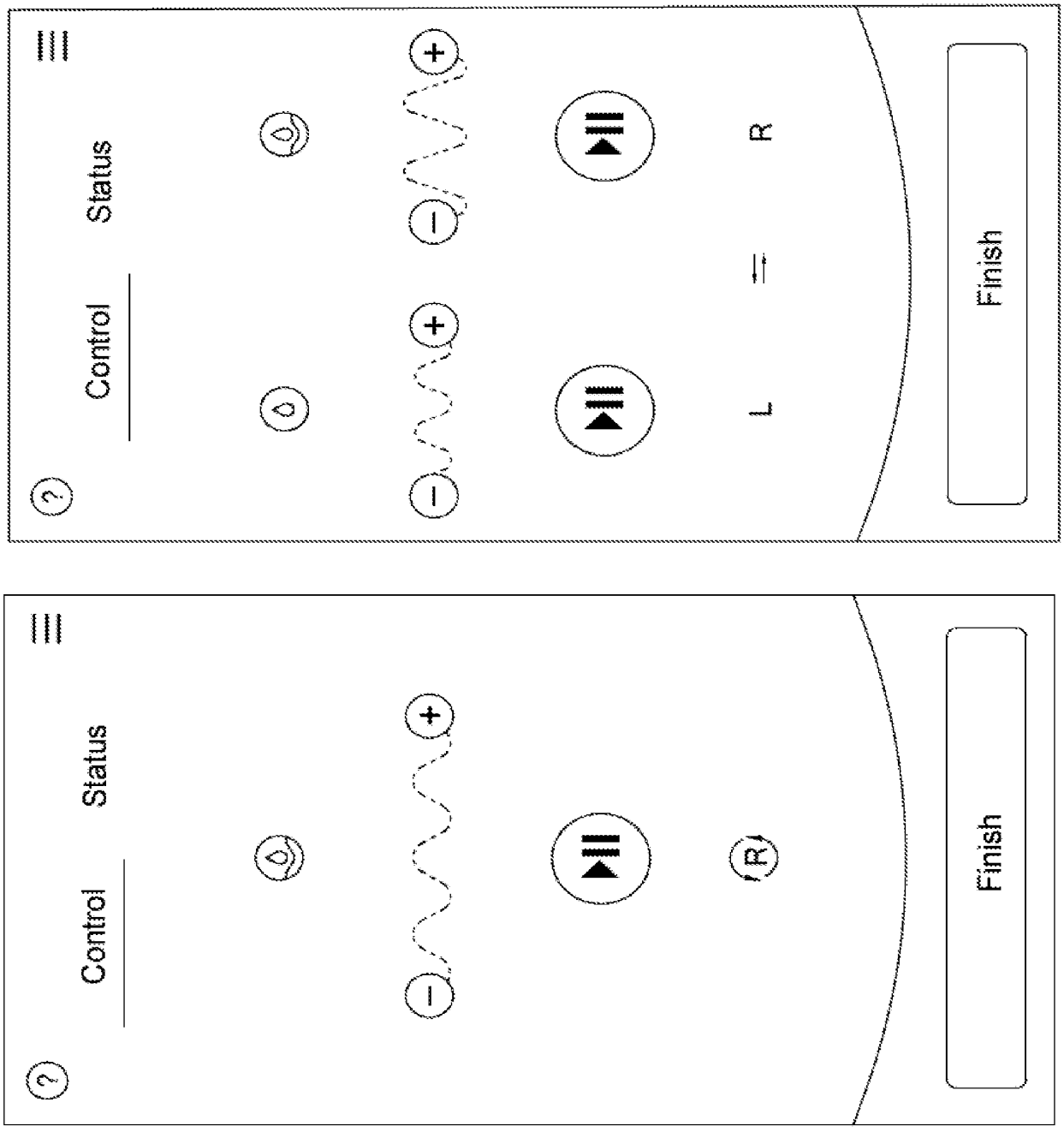


FIGURE 16



A B

FIGURE 17

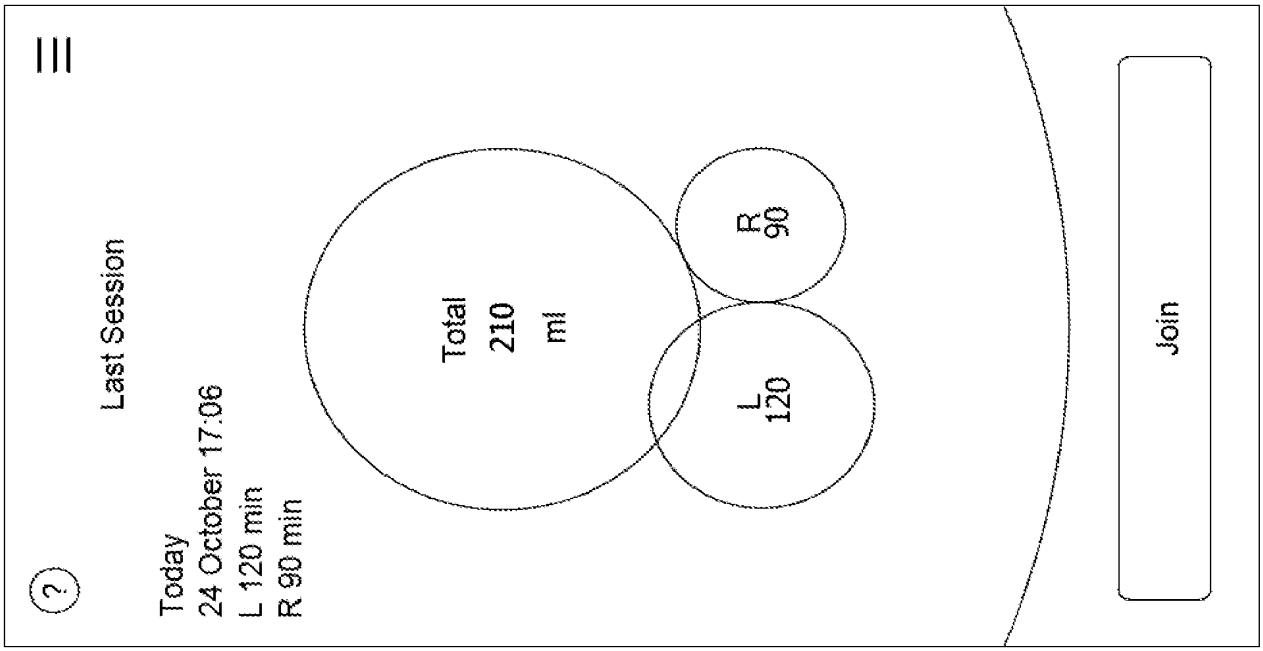

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
L
120
R
90
Join

FIGURE 18

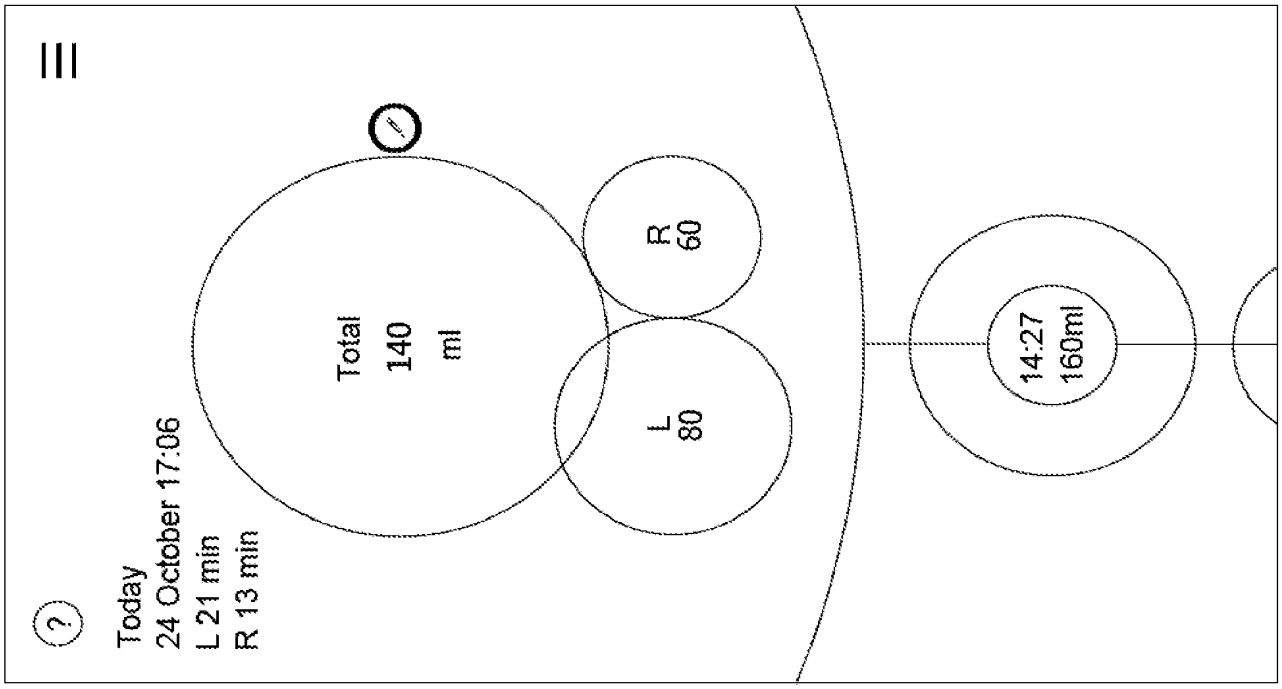

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

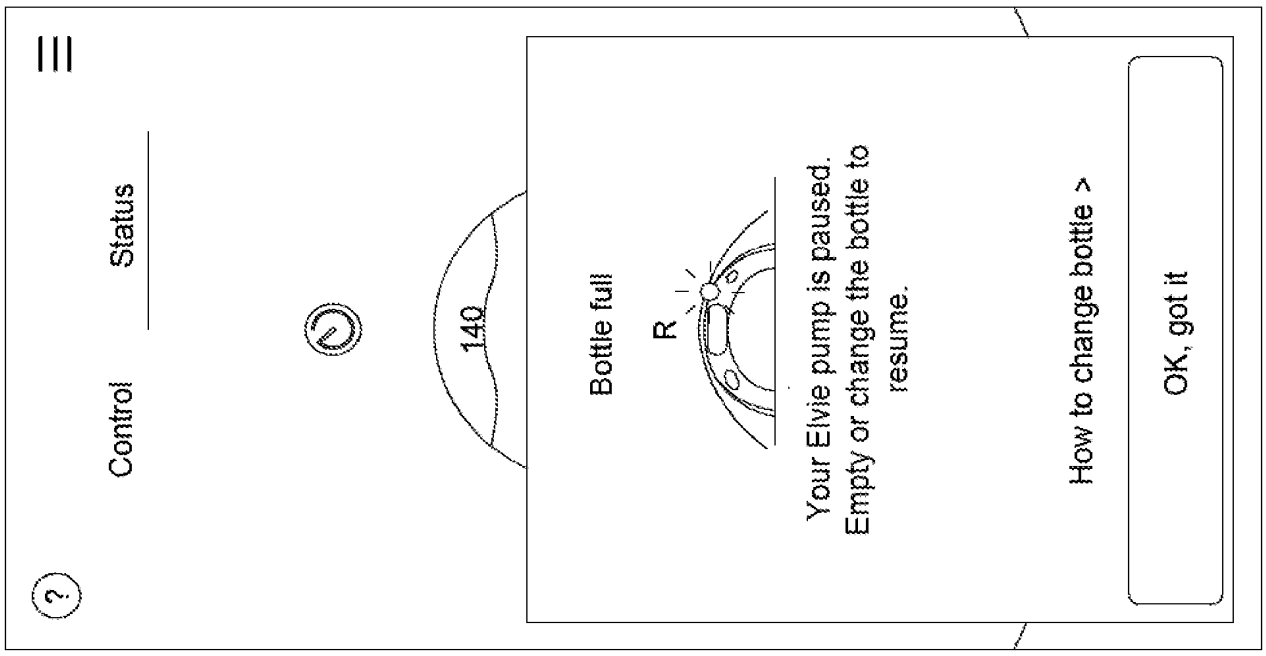

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

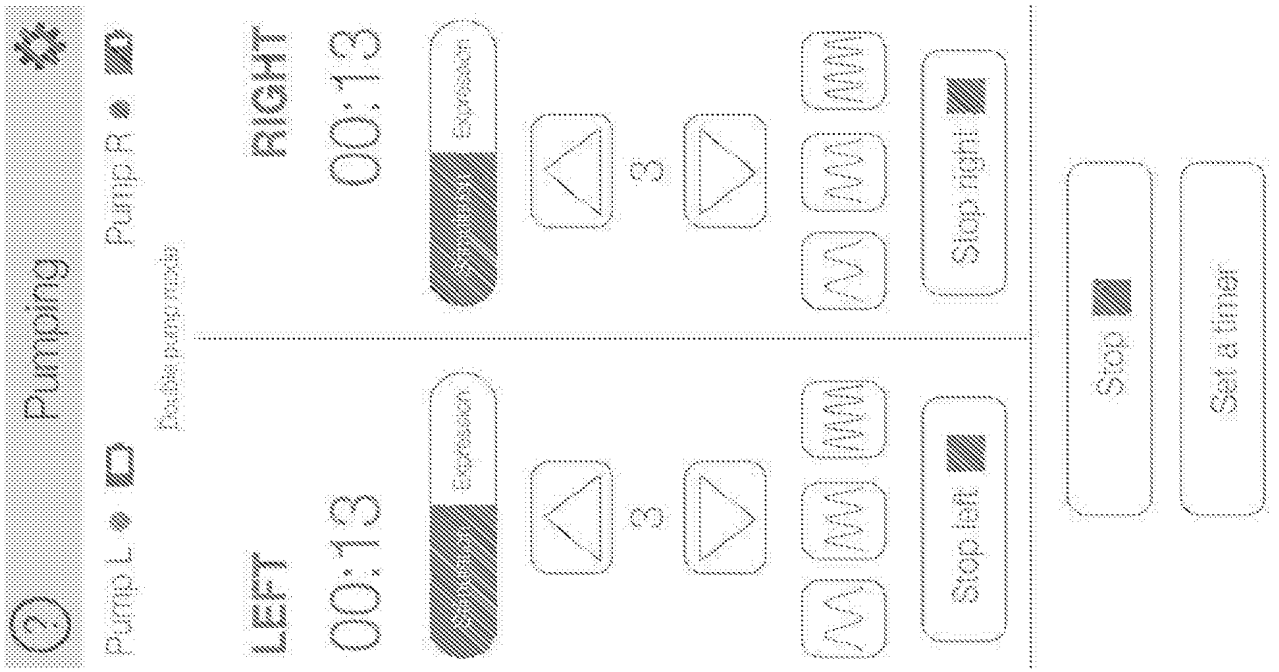

2
Pumping
Pump L
Pump R
Double pump mode
LEFT
00:13
Expansion
RIGHT
00:13
Expansion
Stop left
Stop right
Stop
Set a timer

FIGURE 21

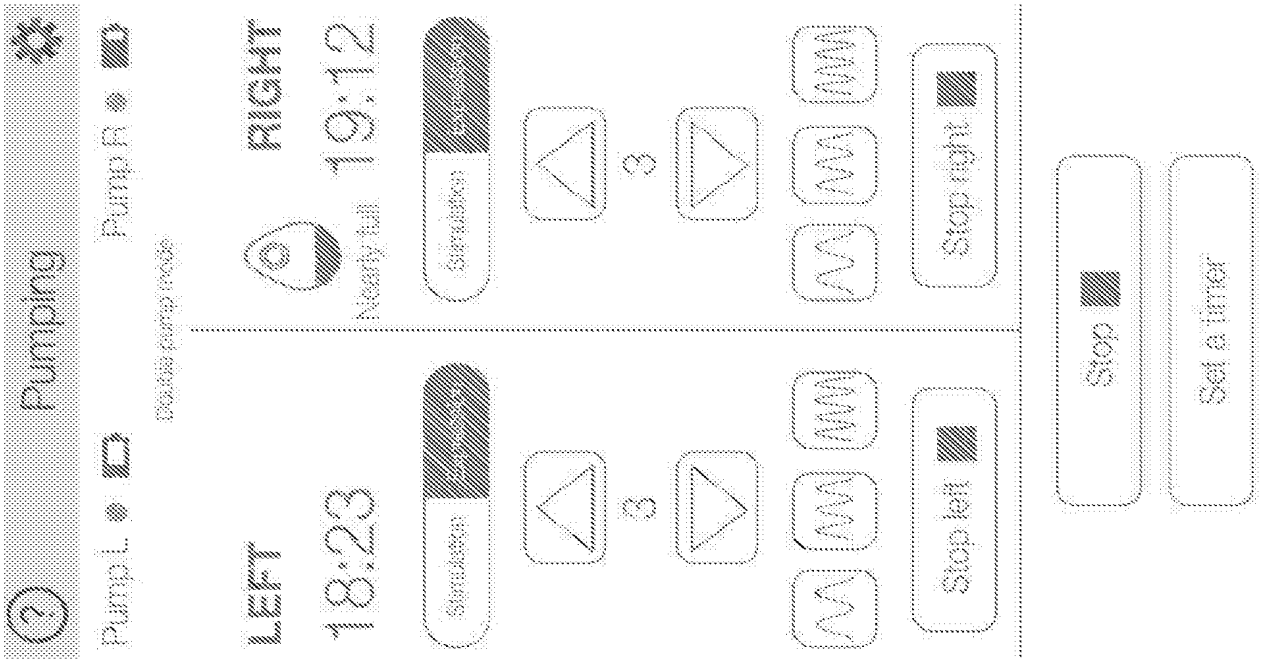

Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
Simulation
RIGHT
19:12
Nearly full
Simulation
Stop left
Stop right
Stop
Set a timer

FIGURE 22

Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Change or empty the bottle before resuming pumping.
OK
Stop
Settings

FIGURE 23

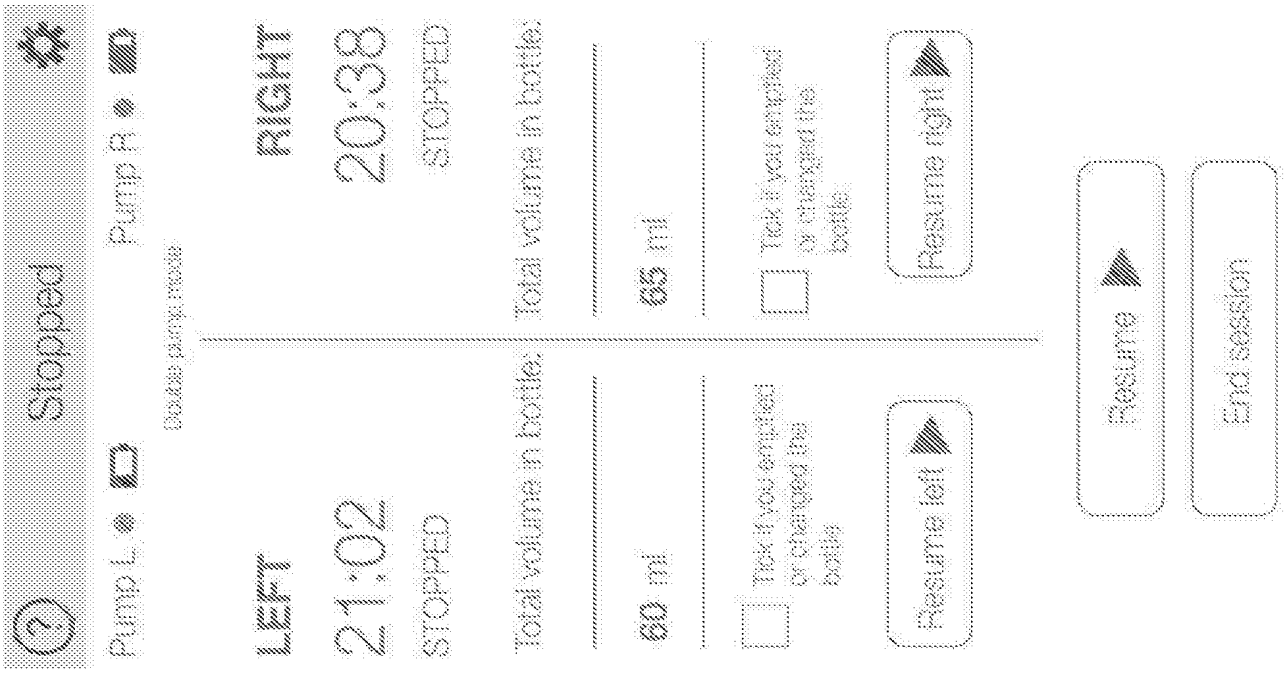

Stopped
Pump L
Pump R
Update pump volume
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Tick if you emptied or changed the bottle
Resume left
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
Pump R
Double-pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

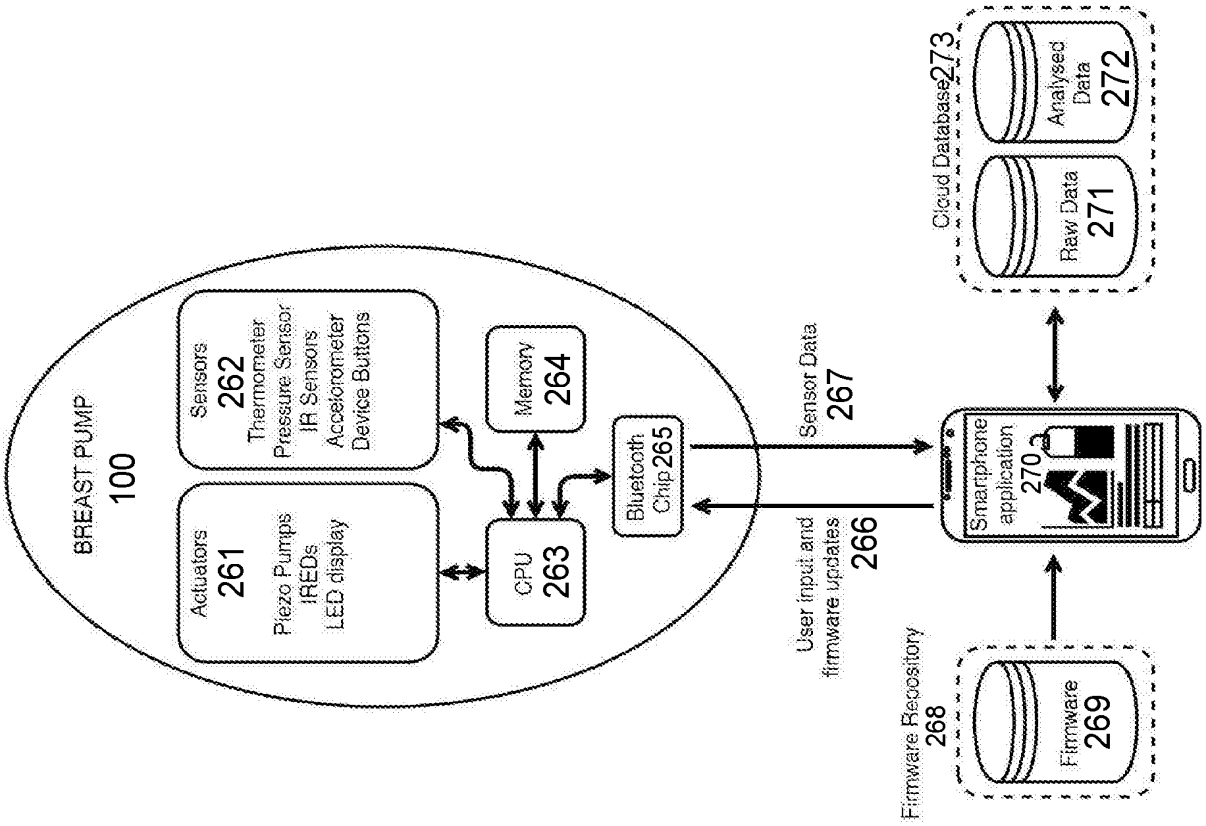

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelorometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

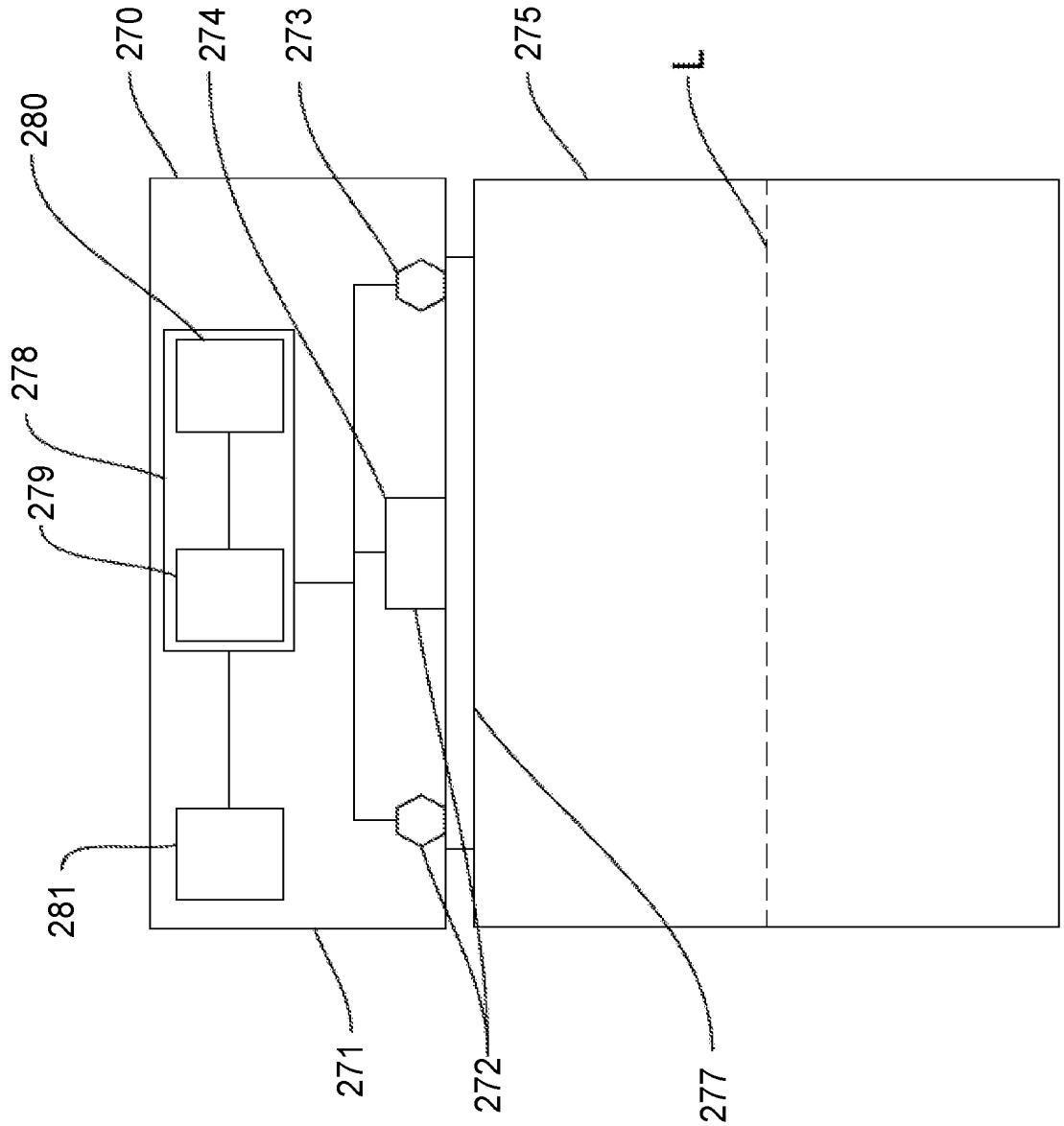


FIGURE 27

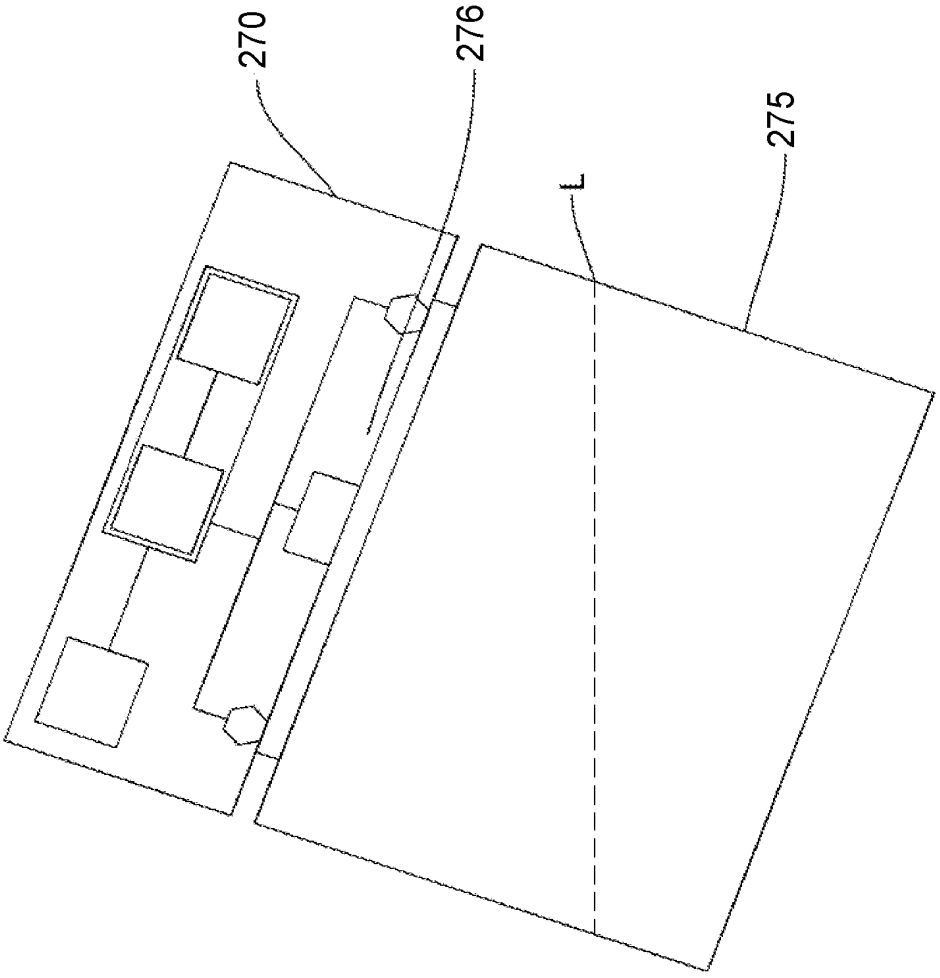


FIGURE 28

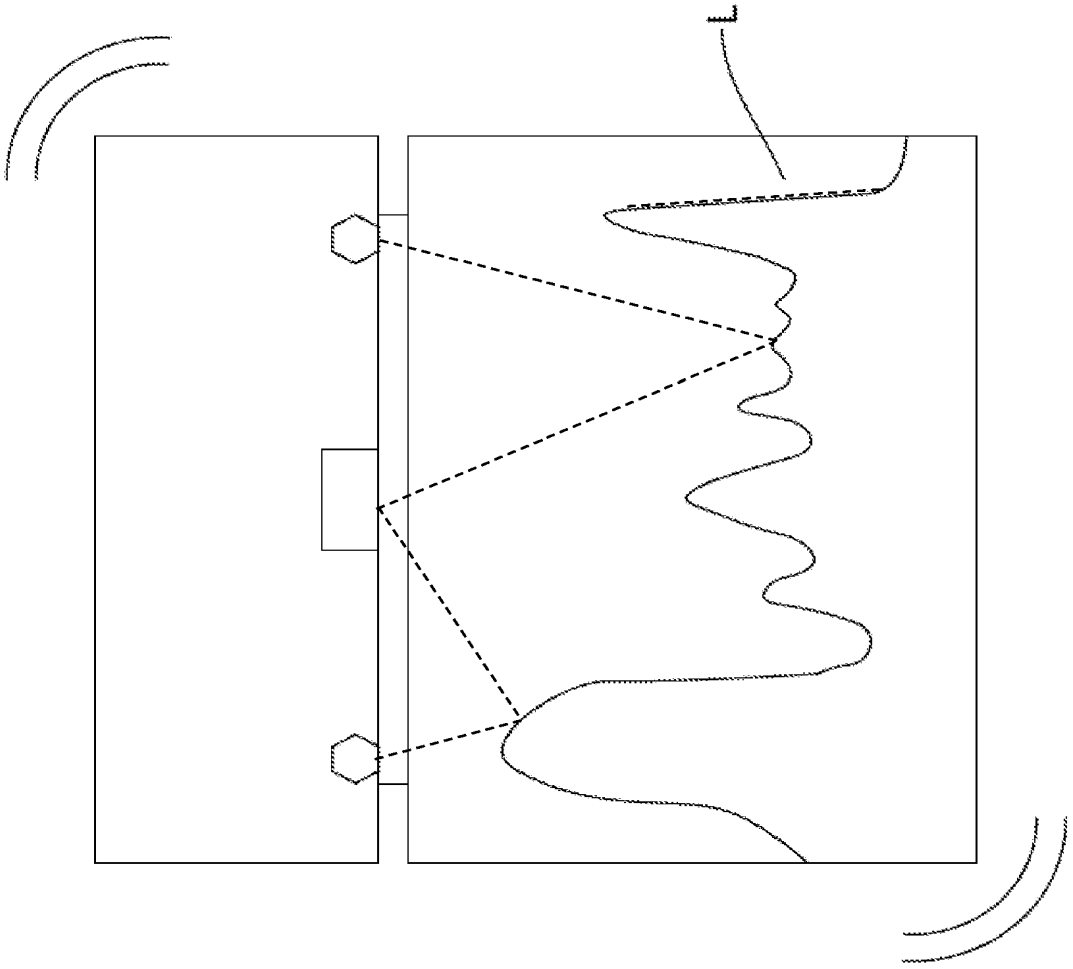


FIGURE 29

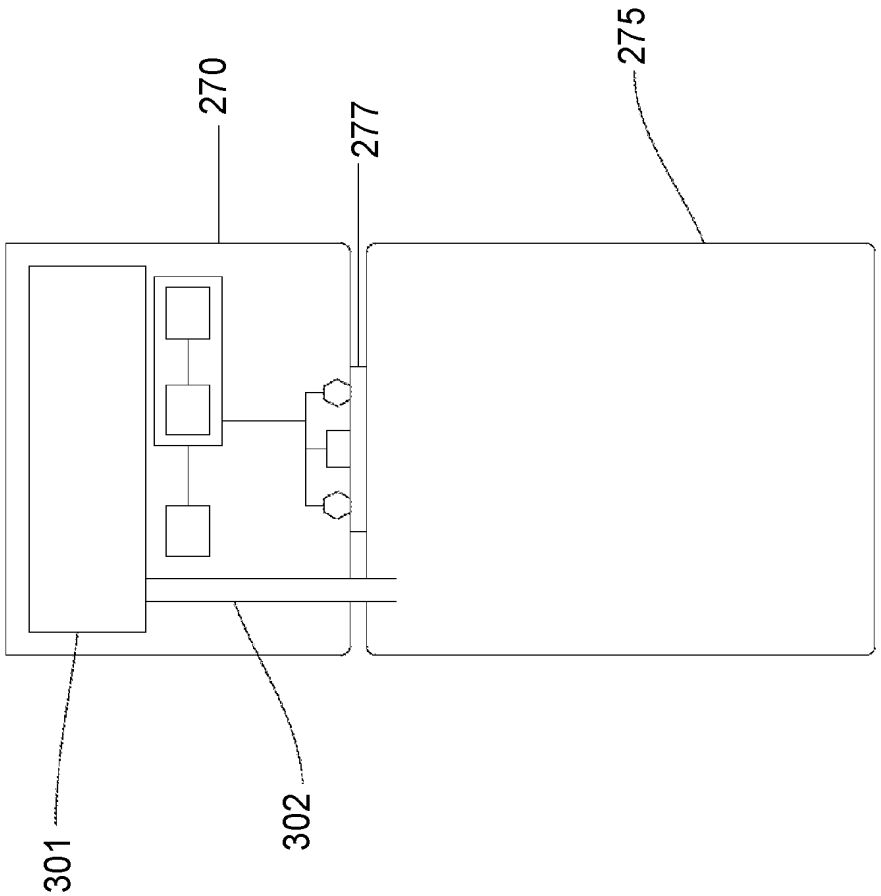


FIGURE 30

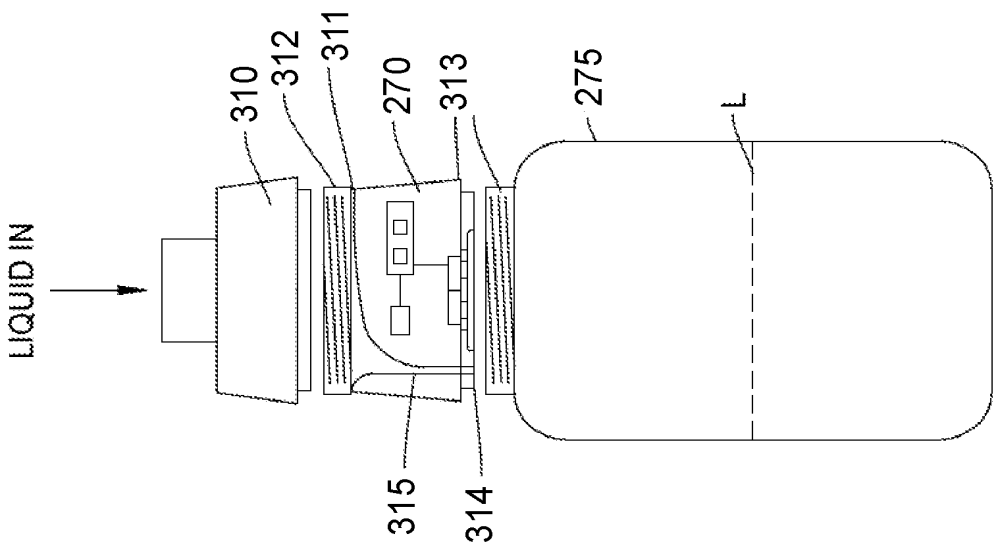


FIGURE 31

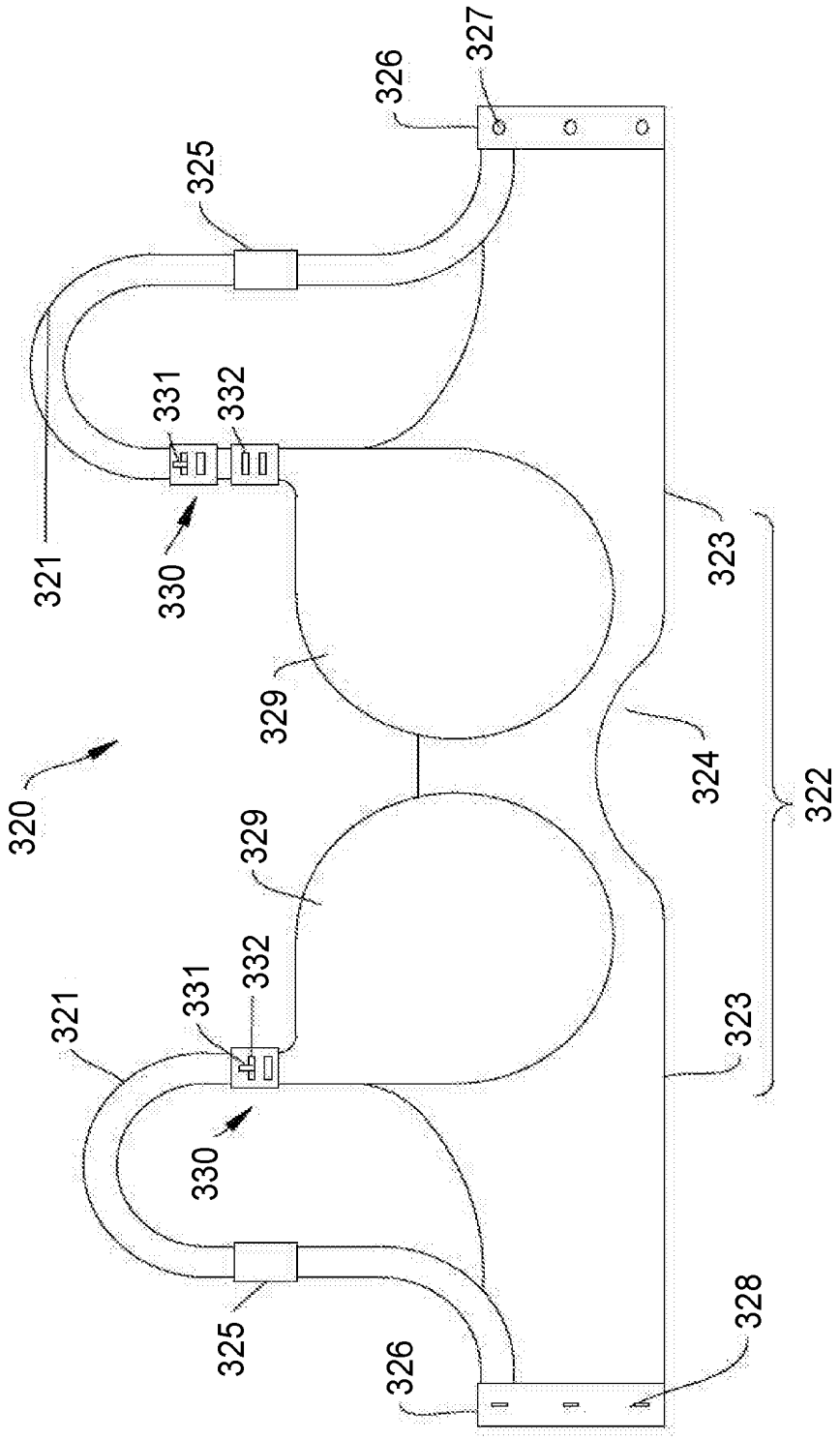


FIGURE 32

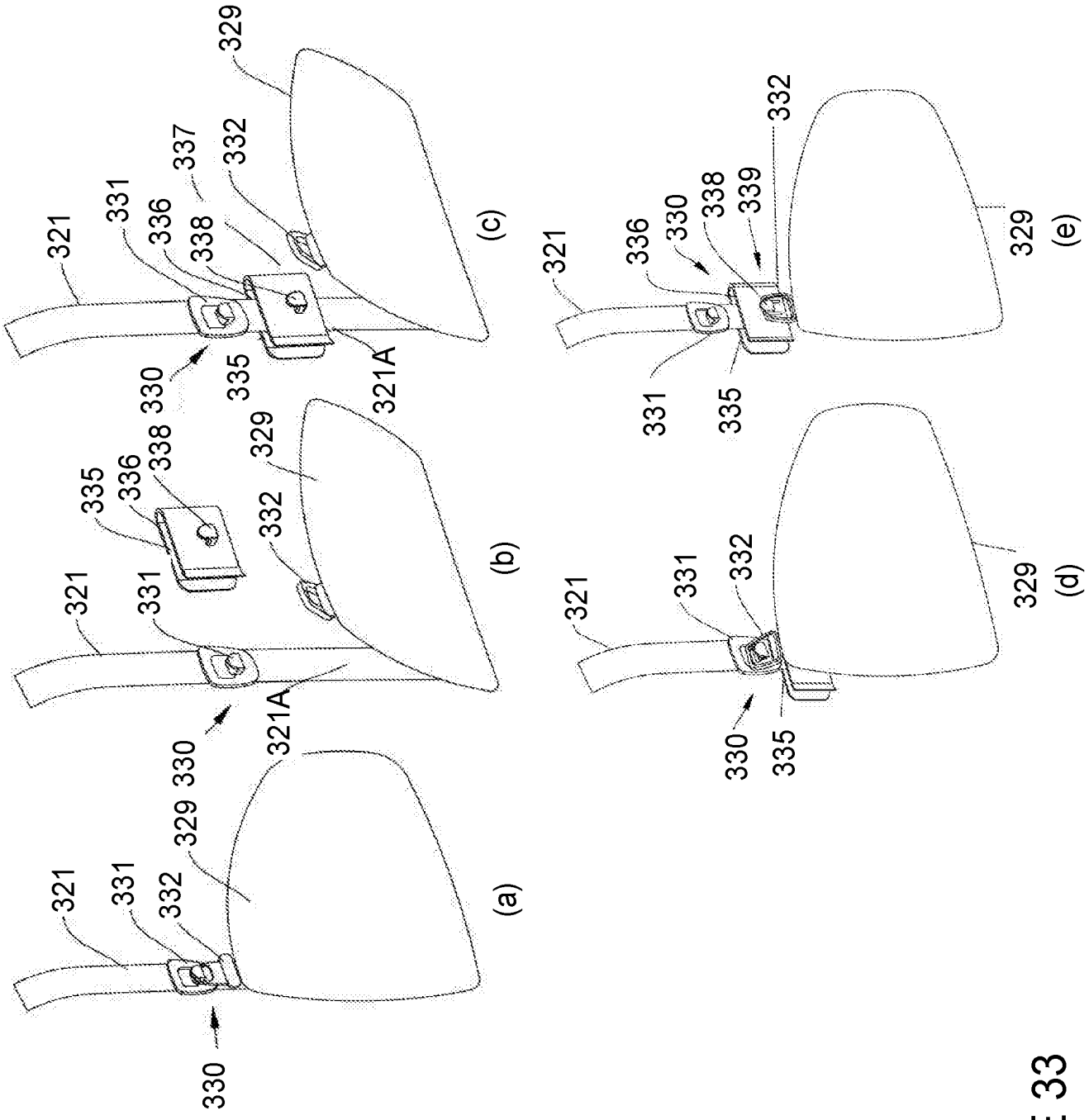

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
338
337
332
329
330
335
321A
(c)
321
331
336
330
338
339
332
329
(e)
321
331
332
329
330
335
(d)

FIGURE 33

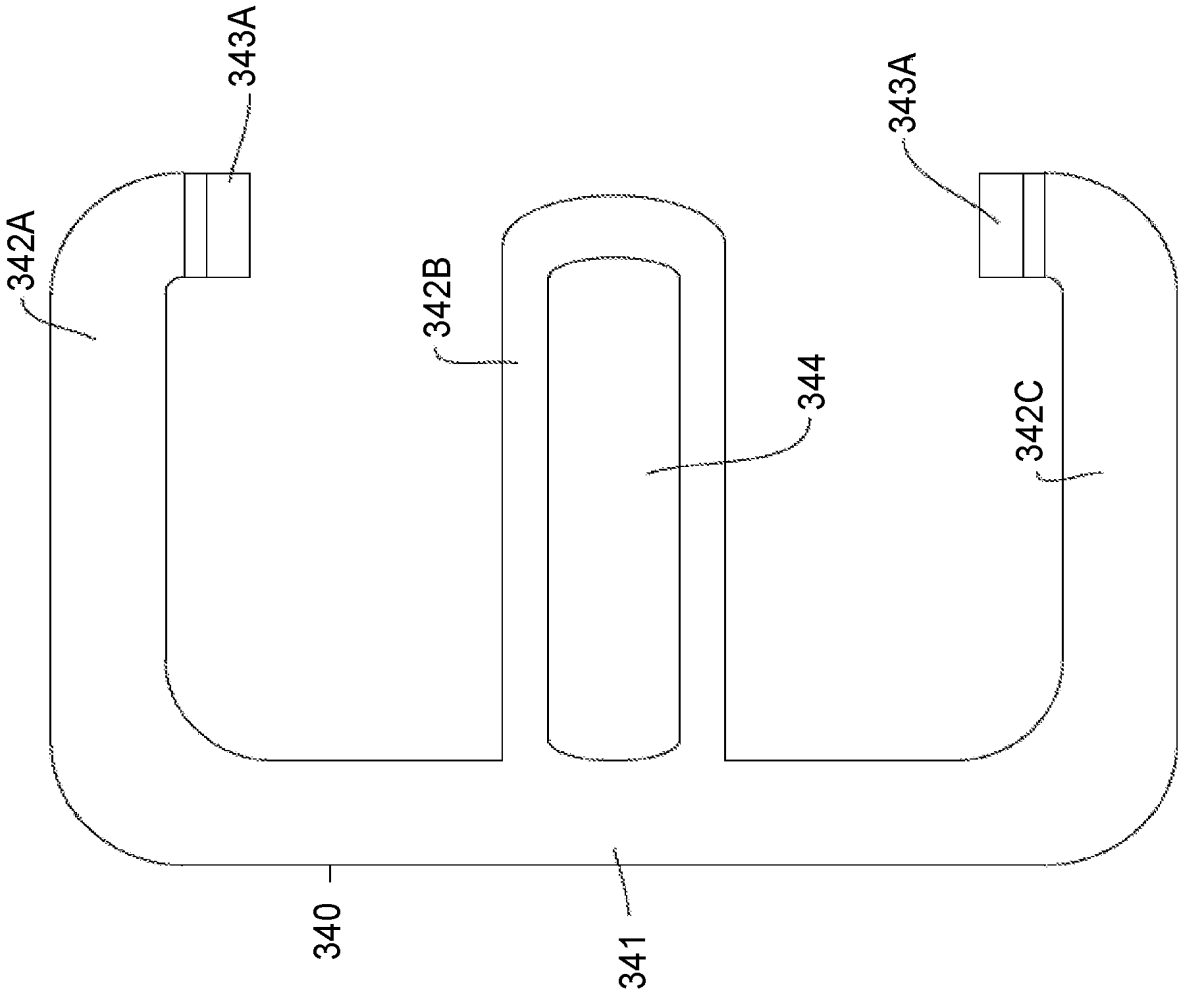


FIGURE 34

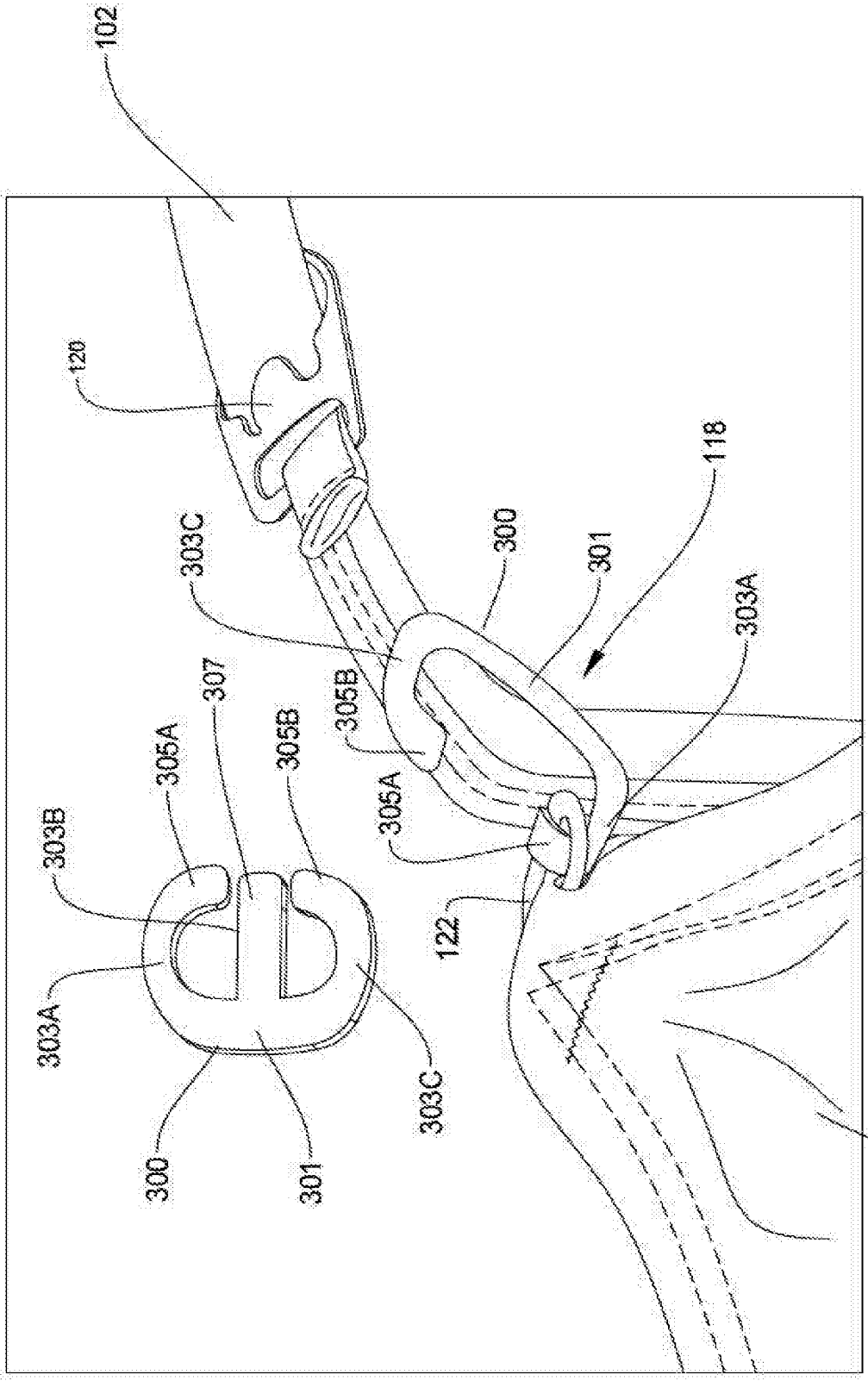

102
120
303C
300
301
118
303A
307
305B
305A
303B
305A
305B
303A
122
303C
300
301
116

FIGURE 35

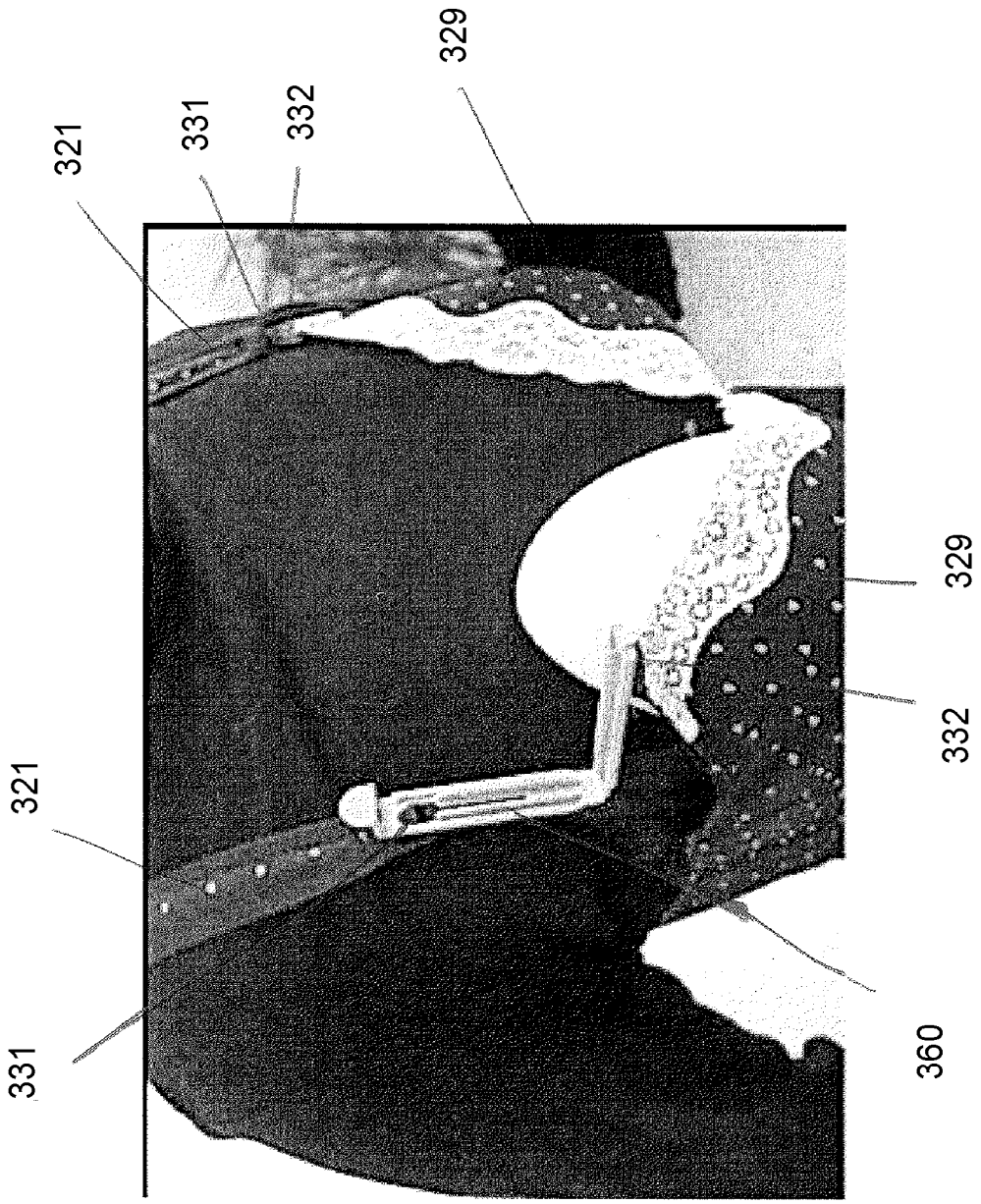


FIGURE 36

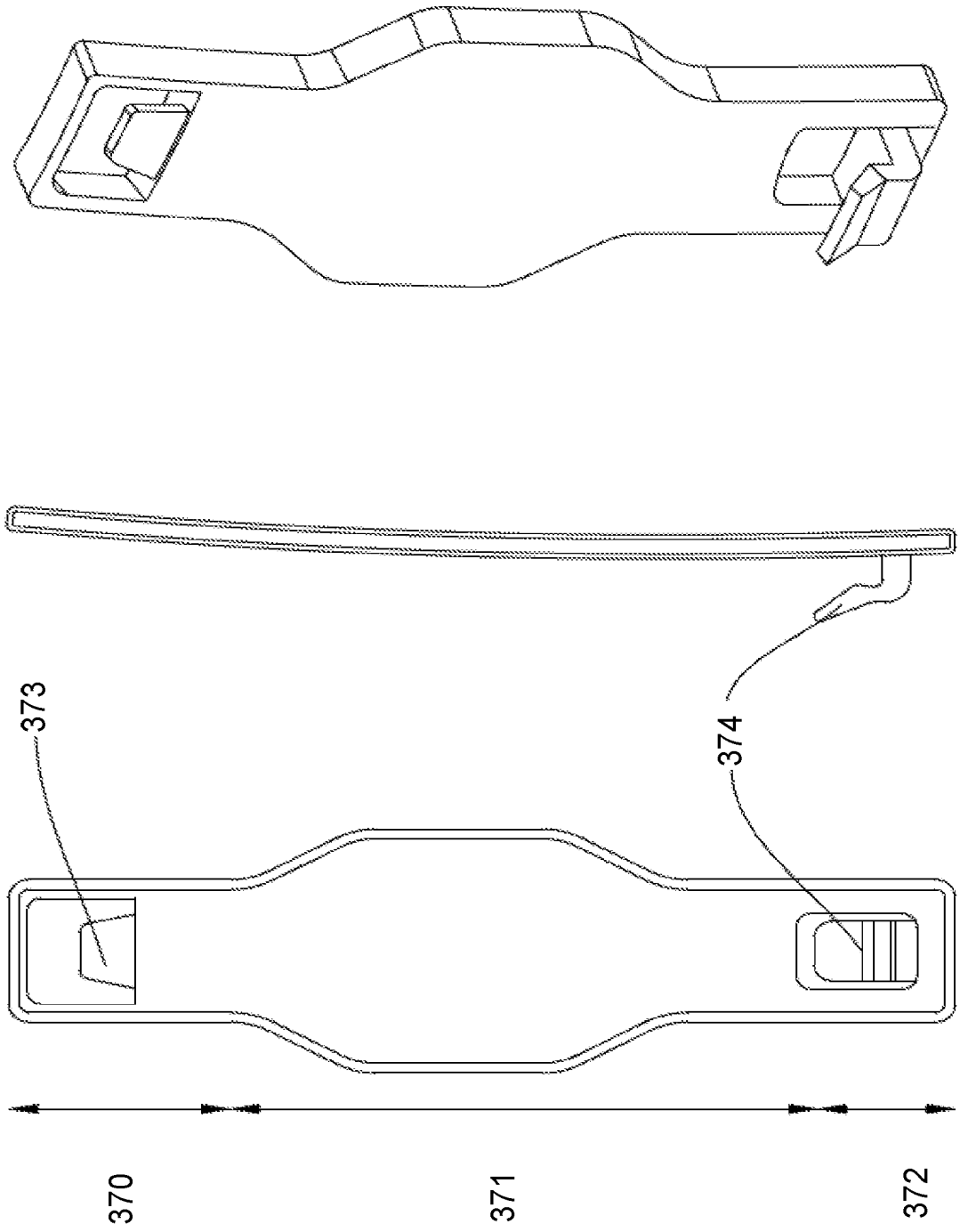


FIGURE 37

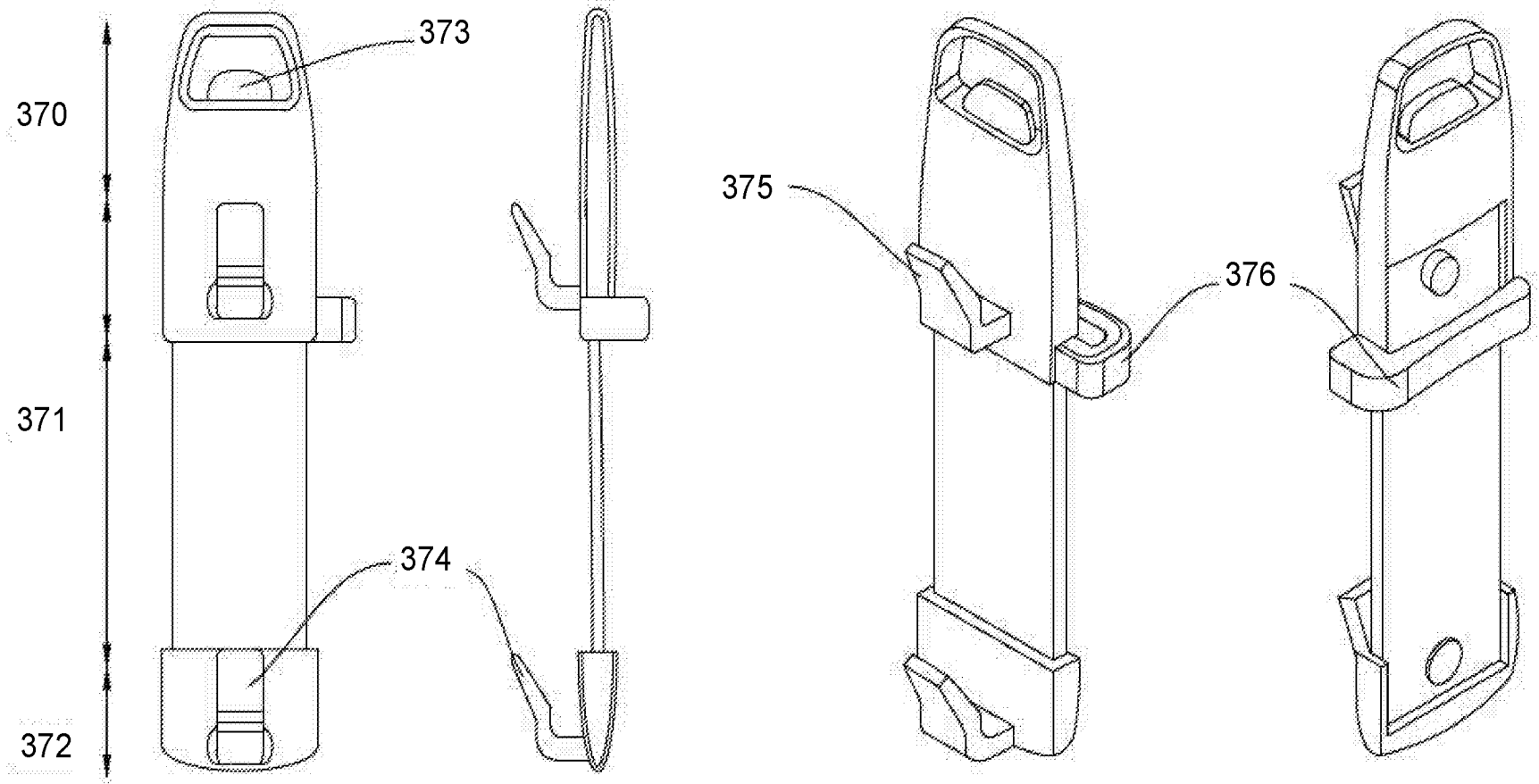


FIGURE 38

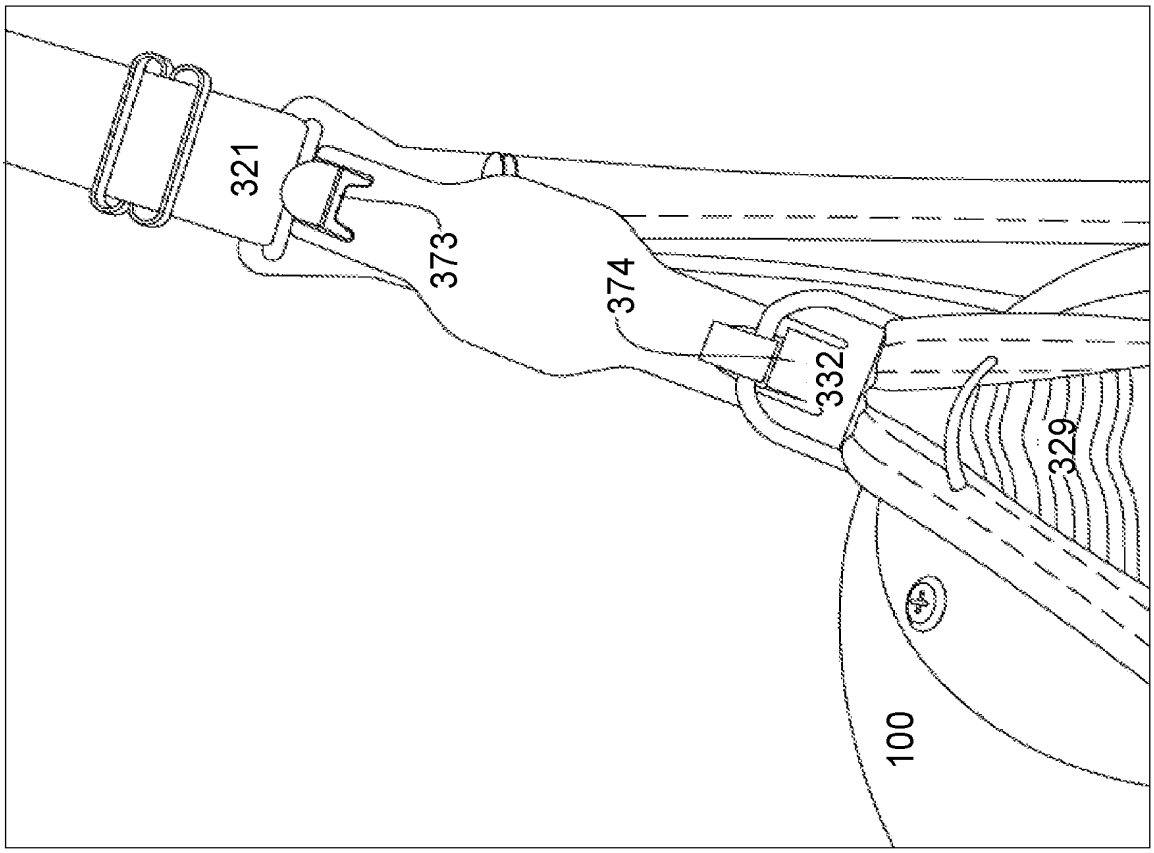


FIGURE 39

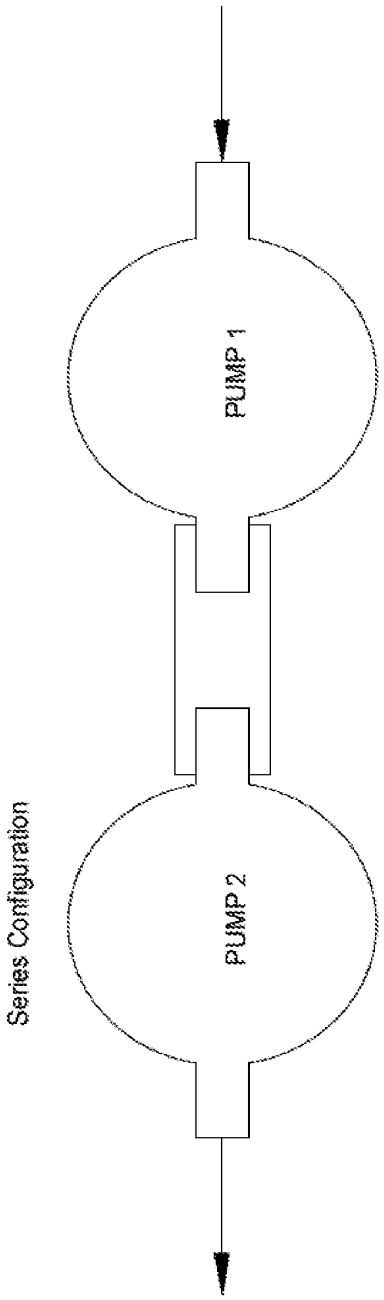


FIGURE 40

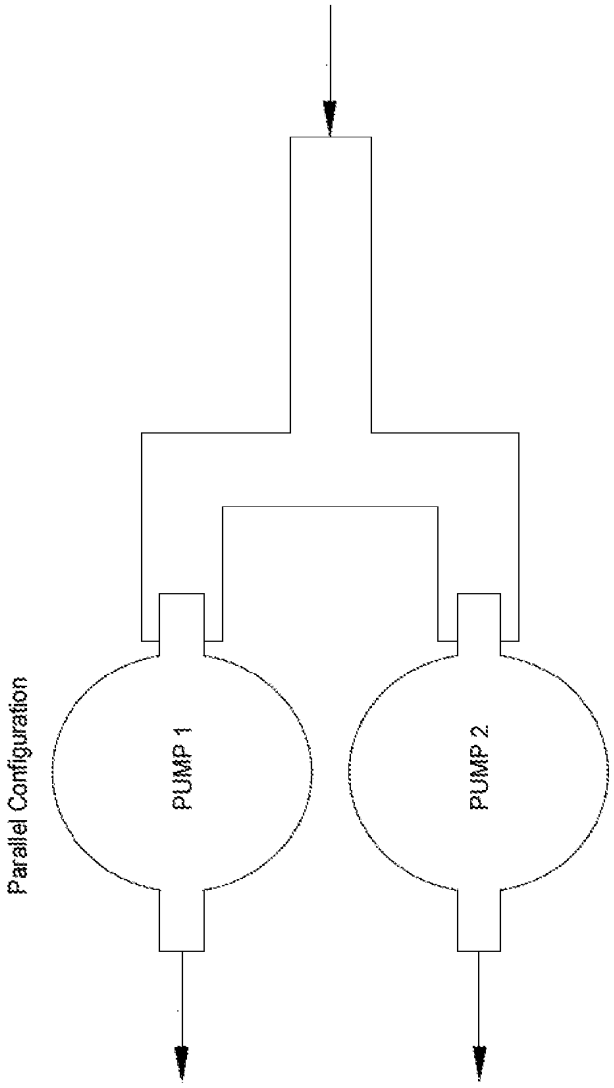


FIGURE 41

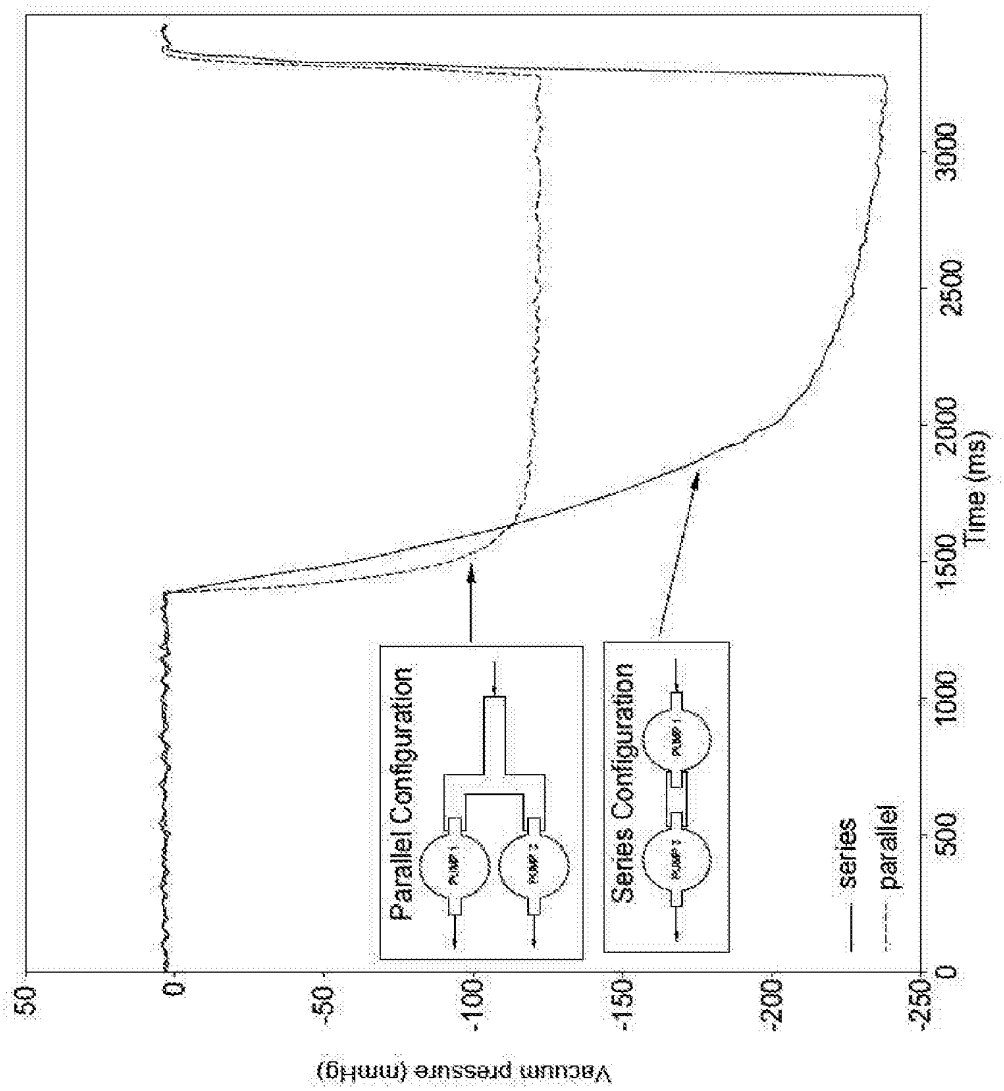

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

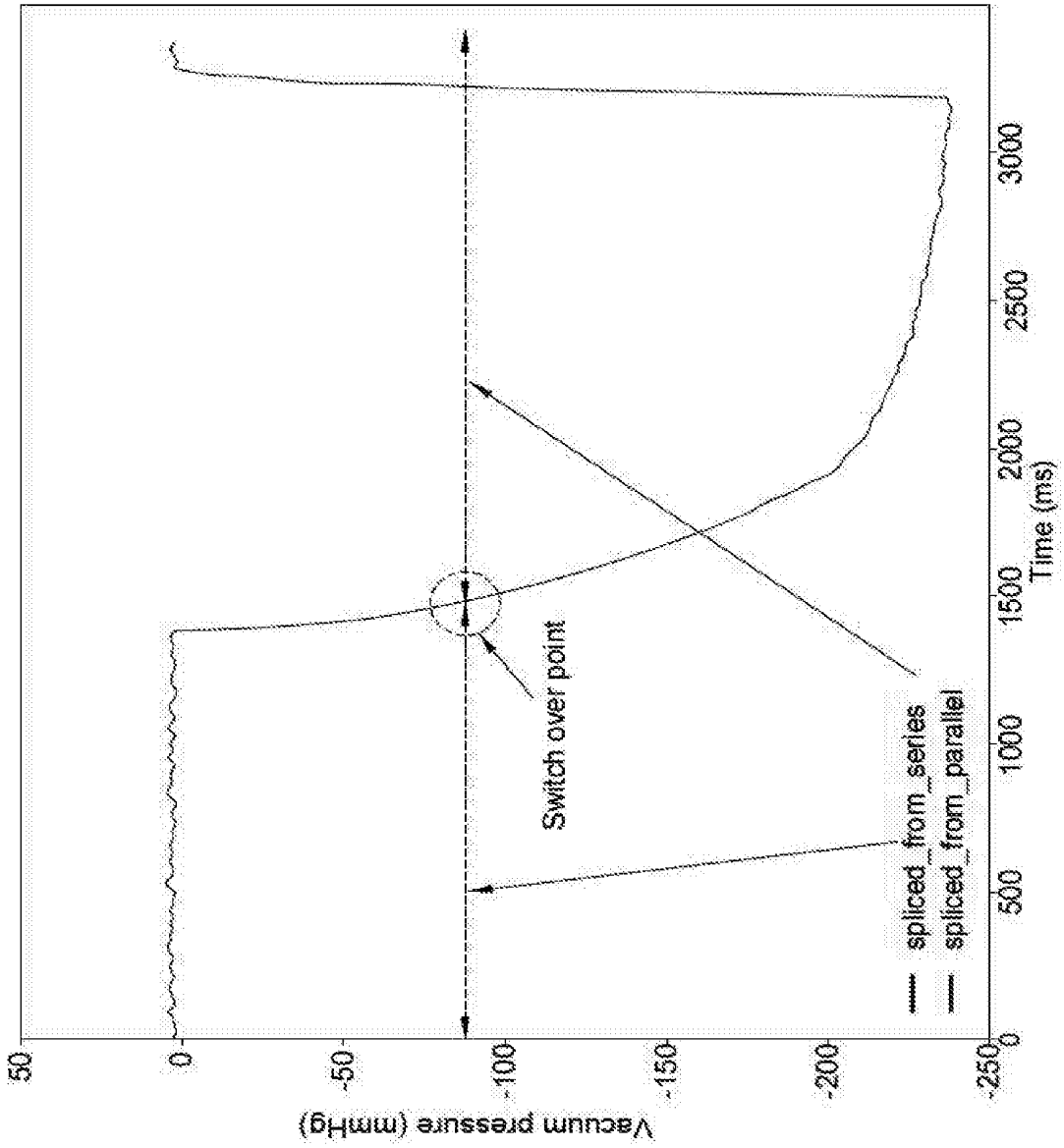

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

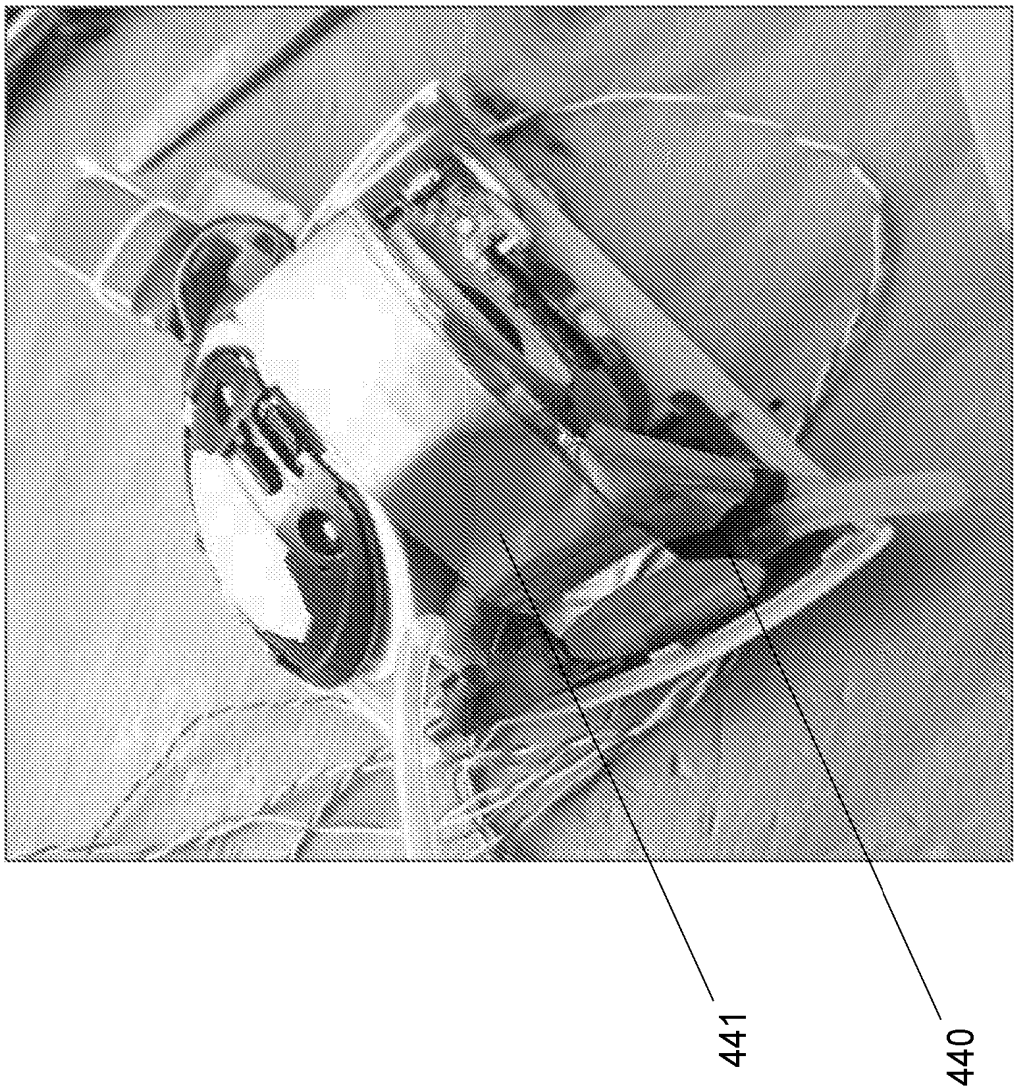


FIGURE 44

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
16/009,547	15 June 2018

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 78905

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

CHIARO TECHNOLOGY LIMITED

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	18 JULY 2018
Name	ANDREA ZITNA		
Title	CHIEF REVENUE OFFICER		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BREAST PUMP SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/009,547 filed on 15 June 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Jonathan O'TOOLE

Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Title of Invention	BREAST PUMP SYSTEM

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This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 16/009,547

filed on 15 June 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Adam ROLLO Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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Title of Invention	BREAST PUMP SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/009,547

filed on 15 June 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Andrew CARR Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	Jonathan O'TOOLE et al.	Art Unit 3763
US APPL. NO.	16/009,547	Confirmation No. 5958
FILING DATE	15 June 2018	
TITLE	BREAST PUMP SYSTEM	

FILED ELECTRONICALLY ON August 1, 2018

COMMISSIONER OF PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF EXECUTED
DECLARATIONS AND POWER OF ATTORNEY

Dear Sir:

Submitted herewith are the executed Declarations of inventors Jonathan O'TOOLE, Adam ROLLO and Andrew CARR.

Also submitted herewith is a Power of Attorney, executed by Andrea Zitna, Chief Revenue Officer of Applicant, Chiaro Technology Limited.

Applicant respectfully requests that the enclosed Declaration and Power of Attorney documents be accepted and receipt thereof be acknowledged.

If there are any fees associated with this filing, kindly charge Deposit Account 50-4364.

Respectfully submitted,

Date: August 1, 2018 By /Mark D. Simpson/
Mark D. Simpson, Esq.
Reg. No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Email: Mark.Simpson@saul.com

PTO/SB/38 (10-14)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Request to Retrieve Electronic Priority Application(s)

Send completed form to: Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

COMPLETE IF KNOWN	
Application Number	16009547
Filing Date	June 15, 2018
First Named Inventor	Jonathan O'TOOLE
Art Unit	3763
Examiner Name	C. Fredrickson
Attorney Docket Number	373499.00002

Pursuant to 37 CFR 1.55(h), the undersigned hereby requests that the USPTO retrieve an electronic copy of each of the following foreign applications for which priority has been claimed under 35 U.S.C. 119(a)-(d) from a foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement. This Request must be submitted:

- within the later of sixteen months from the filing date of the prior foreign application or four months from the actual filing date of an application under 35 U.S.C. 111(a),
- within four months from the later of the date of commencement (37 CFR 1.491(a)) or the date of the initial submission under 35 U.S.C. 371 of an application entering the national stage under 35 U.S.C. 371, or
- with a petition under 37 CFR 1.55(e).

☐ **OPTION A**

Please retrieve the priority application identified in Column C, a certified copy of which is contained in the EP or JP application identified in Columns A and B:

	A	B		C	
	Code for Participating Office (EP or JP only)	Application containing the non-participating priority application		Non-participating priority application to be retrieved	
		App. No.	Filing Date	Country Code	App. No.
1					

☑ **OPTION B**

This Request may be used for the infrequent circumstance when a claim for priority to an application filed in a participating foreign intellectual property office was made prior to that foreign intellectual property office becoming a participating foreign intellectual property office.

Please retrieve the priority application identified in Columns A and B:

	A	B		
	Code for Participating Office (e.g., EP, JP, KR, CN) or WIPO DAS Depositing Office (e.g., AU, DK, ES, FI, GB, IB, SE)	Application to be retrieved		
		App. No.	Filing Date	Access Code (for WIPO DAS Depositing Office)
1	GB	1809036.5	2018-06-01	D82C
2				

The USPTO will not attempt to retrieve the identified priority application(s) unless an identical claim for foreign priority to the application identified above is made pursuant to 37 CFR 1.55(d) or a petition is granted under 37 CFR 1.55(e). Applicants are advised to consult Private PAIR (accessed through www.uspto.gov) to assure that the retrieval has been successful. The applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period set forth in 37 CFR 1.55(g)(1).

I hereby declare that I have the authority to grant access to the above-identified foreign application(s).

/Mark D. Simpson/	2018-08-01
Signature	Date
Mark D. Simpson	215 972 7880
Printed or Typed Name	Telephone Number
Attorney for Applicant	32942
Title	Registration Number, if applicable

This collection of information is required by 37 CFR 1.55(d). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	33345619
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	01-AUG-2018
Filing Date:	15-JUN-2018
Time Stamp:	15:14:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		16009547_TransmittalofDecsandPOA.PDF	225755 d5d55c608ccade176af2c9b947c25136eaaa03ff	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Power of Attorney	6	6
	Oath or Declaration filed	3	5
	Transmittal Letter	1	2

Warnings:					
Information:					
2	Request for USPTO to retrieve priority docs	16009547_Request_to_Retrieve.PDF	215294 478a183c77524bc6be28f52fba13c501e9b40ea6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	441049		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002	5958

78905 7590 07/27/2018

Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

EXAMINER	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
07/27/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@saul.com

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Commissioner for Patents
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Doc Code:
TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 16/009,547

1. THE REQUEST FILED June 15, 2018 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination
- A. ☒ for an original nonprovisional application (Track I).
- B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

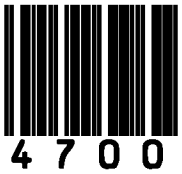
- A. filing a **petition for extension of time** to extend the time period for filing a reply;
- B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
- C. filing a **request for continued examination**;
- D. filing a notice of appeal;
- E. filing a request for suspension of action;
- F. mailing of a notice of allowance;
- G. mailing of a final Office action;
- H. completion of examination as defined in 37 CFR 41.102; or
- I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Cheryl Gibson-Baylor at (571)272-3213, Office of Petitions. In his/her absence, calls may be directed to Brian W. Brown, (571)272-5338.

Cheryl Gibson-Baylor
/Cheryl Gibson-Baylor/
[*Signature*]

Petitions Paralegal Specialist
(Title)

Office of Petitions: Routing Sheet



Application No. 16009547

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

Mailing Month: 7

Application No.: 16009547

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: GIBSON-BAYLOR, CHERYL

Count (1) - Palm Credit 16009547

Decision: GRANT

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: 643 - Track One request

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box ☐

Printed on: 7/24/2018

Office of Petitions Internal Document - Ver. 5.0

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Document details: Country/Office: GB
Filing date: 15 Jun 2017 (15.06.2017)
Application number: 1709566.2

Date of availability of document: 27 Jul 2017 (27.07.2017)

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Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Certified Office Copy

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with patent application GB1709566.2 filed on 15th June 2017.and as stored electronically on the Patents Electronic Case file System.

The Patents Electronic Case-file System is compliant with British Standard BS10008 - Evidential weight and legal admissibility of information stored electronically and ISO15801 - Electronic imaging – information stored electronically, recommendations for trustworthiness and reliability.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed A HAYES

Dated 19 June 2017

1200242974
1017015616 D02882
15/06/2017 150.00 DepositAccount

Intellectual Property Office

Patents Form 1
Patents Act 1977 *(Rule 12)*

Request for grant of a patent

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Application number GB 1709566.2

1.	Your reference	**MJD/P153992GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BREAST PUMP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**Yes**	

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

   Continuation sheets of this form

   Description: **20**

   Claim*(s)*: **6**

   Abstract: **n/a**

   Drawing*(s)*: **13**

   If you are not filing a description, please give details of the previous application you are going to rely upon

Country	Application number	Date of filing	PDAS Access Code

10. If you are also filing any of the following, state how many against each item.

    Priority documents: **0**

    Statement of inventorship and right to grant of a patent (Patents Form 7): **1**

    Request for search (Patents Form 9A): **1**

    Request for a substantive examination (Patents Form 10): **0**

    Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

    Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

    DRAPER, Mr Martyn
    Email: boult@boult.com
    Telephone: 020 7430 7500
    Fax: 020 7430 7600

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After an application for a patent has been filed, the Comptroller will consider whether publication or communication of the invention should be prohibited or restricted under section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you are resident in the United Kingdom and your application contains information which relates to military technology, or would be prejudicial to national security or the safety of the public, section 23 of the Patents Act 1977 prohibits you from applying for a patent abroad without first getting written permission from the Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked. Until such time or until the revocation of any direction, for any such application the address for service referred to at part 4 above must be in the United Kingdom.

Although you may have an address for service in the Channel Islands, any agent instructed to act for you must reside or have a place of business in the European Economic Area or Isle of Man.

BREAST PUMP

BACKGROUND

A breast pump is a mechanical device that extracts milk from the breasts of a lactating woman.

The typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child. The suction generating device is a large component that connects to mains power to operate the pumps therein.

Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. However, in alternative embodiments there may be a single bottle with tubing connecting the breast shields thereto. For a mother to use this somewhat discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the spout of the breast shield to extend through are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not been significantly altered from this, with minor technical improvements being the main developments.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to the mains power, the user may feel tethered to the wall. The devices also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting.

Fully integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a

user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the breast pump has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras.

As the collection bag systems are collapsible, it will be very difficult for a user to extract all of their milk from the bag due to the small cut opening and capillary action between the bonded plastic sheets. This waste can be disheartening for the user as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with a plurality of compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, a relatively small bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump is shown in US 2013 0023821 A1. In the third embodiment in this document, an integral breast pump is provided including a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing components and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device.

There is therefore a need for improved integrated breast pump systems.

SUMMARY OF THE INVENTION

A breast pump according to a first embodiment of the present invention is provided according to claim 1. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and being in connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow side of the barrier, the barrier having an outer periphery, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the milk-flow pathway extends past the outer periphery of the barrier.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The milk-flow path extending past the outer periphery of the barrier allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality of the device.

A breast pump according to a second embodiment of the present invention is provided according to claim 2. The breast pump is for wearing inside a bra, the breast pump comprising: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into

the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The shield flange and spout being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilisation.

A breast pump according to a third embodiment of the present invention is provided according to claim 3. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a piezo pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The piezo pump is ideally suited for this environment as it is low noise and high strength with a compact size.

The breast shield of embodiments 1 or 3 may further comprise a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

The shield flange and spout may be detachable from the housing together. Preferably, the spout will be integral with the breast shield. This helps to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

The breast shield cup may extend over a majority of the inner surface of the unit, preferably the breast shield extends over 80% of the inner surface of the unit. This reduces the risk of milk contacting a part of the device which cannot be easily sterilised. This also helps to disperse the pressure applied to the user's breast across a larger area. Additionally, by covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning.

The spout may connect directly to the container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The spout may comprise an opening directly above the milk collection container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The breast pump of the second or third embodiments may further comprise a barrier mounted in the breast pump, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

Preferably, the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier. This allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier.

Preferably the milk-flow pathway extends beneath the barrier. This provides an added benefit of having gravity tend the milk away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier. This results in a simpler and smaller barrier design.

Preferably, the barrier is mounted on a housing on the breast shield. More preferably, the housing is integral with the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "dirty" side can be removed.

Preferably, the barrier is not an annulus.

The barrier may provide a seal to isolate the pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the "dirty" airflow side.

Preferably, the only seal is around an outer edge of the barrier. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

Preferably, the barrier is a diaphragm.

Preferably, the diaphragm is a continuous membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller to have the same working area.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Preferably, the width of the breast pump is less than 110 mm.

Preferably, the height of the breast pump is less than 180 mm.

Preferably, the plane to plane depth of the breast pump less than 100 mm.

Preferably, in use, the breast pump extends from the user's breasts by between 3 to 4 cup sizes as per the European standard EN 13402.

Preferably, the milk container has a volume of greater than 120 ml. More preferably, the milk container has a volume of greater than 140 ml.

Preferably, the milk container has a volume of less than 150 ml.

The milk container and housing may form a substantially continuous outer surface of the breast pump. This helps ensure that the breast pump in use fits within a conventional bra system discretely.

The milk container may be at least partially transparent on the outer surface of the breast pump. This allows the level of milk within the container to be easily observed even while pumping.

The milk container may be provided with a spout. This makes it easier for the end user to pour the collected milk into other containers for use or storage.

The milk container may be provided with attachment means for attaching a teat to the container. This allows the milk container to be used directly as a drinking vessel for a child.

The breast shield may be removable. This allows the shield to be easily washed and sterilised.

The milk collection container may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use.

The breast pump may further comprise a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

The one-way valve may be located in an opening to the container.

The pump of the first or second embodiments may be a piezo pump.

The breast shield may be detachable from the breast pump.

The breast pump of the may further comprise a single pole, double throw pneumatic valve, wherein: the pole is in pneumatic connection with the pump and pressure sensor; one of the throws is in pneumatic connection with a dead-end.

The breast pump may further comprise: a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

A method of estimating the pressure applied by a breast pump according to an aspect of the present invention is provided according to claim 42, comprising the steps of: providing a breast pump according to the third embodiment; selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

A method of estimating the milk collected by a breast pump according to an aspect of the present invention is provided according to claim 44, comprising the steps of: providing a breast pump according to claim 33; generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

DESCRIPTION OF THE FIGURES

The invention will now be described with respect to the Figures in which:

Figure 1 is a front view of an assembled breast pump;

Figure 2 is a rear view of the assembled breast pump of Figure 1;

Figure 3 is a front view of a partially disassembled breast pump;

Figure 4 is a rear view of the partially disassembled breast pump of Figure 3;

Figure 5 is a front view of a further partially disassembled breast pump;

Figure 6 is a rear view of the further partially disassembled breast pump of Figure 5;

Figure 7 is a front view of the breast pump of Figure 1, with the outer shell translucent for ease of explanation;

Figure 8 is a further front view of the breast pump of Figure 1, with the front of the outer shell removed for ease of explanation;

Figure 9 is a schematic view of a spout for a breast shield;

Figure 10 is a schematic of a pneumatic system for a breast pump;

Figure 11 is a schematic of an alternative pneumatic system for a breast pump;

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump; and

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

DETAILED DESCRIPTION

Figure 1 is a front view of a breast pump 100 according to the present invention. The breast pump 100 comprises a housing 1 and a milk collection container (or bottle) 3. The milk collection container 3 is attached to a lower face 1A of the housing 1. While the breast pump 100 may be arranged to be used with one of the right or the left breast specifically, it is preferred the breast pump 100 can be used with either breast without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on, specifying which breast is being pumped, or increasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up

button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence applied to the user's breast. In preferable embodiments, the pump up button 5B is physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device on and off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, which is discussed in more detail later, or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the leftmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E will illuminate.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a breast. This allows the breast pump 100 to fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 3 by means of a latch system, which is released by button 2.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The

housing 1, milk collection container 3 and breast shield 7 form the three major sub-components of the breast pump 100. In use, these sub-components clip together to provide the functioning breast pump 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 further comprises a spout 9 extending from an opening 7B in the breast shield 7. In preferable embodiments the spout 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable spouts may be used. The opening 7B is aligned with the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion. This spout 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the spout 9 and into the milk collection container 3. The spout 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. In particular, the spout 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm,

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a slot 11 for receiving the spout 9 of the breast shield 7. The breast shield 7 is held in place by means of a clip 15 engaging with a slot 17 in the housing 1. While this clip 15 is shown at the top of the breast shield 7, it may be placed at any suitable point on the shield 7, with the slot 17 in a corresponding location. The spout 9 of the breast shield 7, is provided with a protrusion 9A on its lower surface. This protrusion 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this is flexible diaphragm 13. However, it is appreciated that the barrier could be any other suitable component such as a filter or an air transmissive material.

The diaphragm 13 is arranged so that the milk-flow pathway extends past the outer periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, is appreciated that the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings.

The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the spout 9 and hence the milk-flow pathway. In preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for

cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped.

Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted therein, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three part system is easy to empty, easily cleanable, and easily re-usable.

However, in the preferred embodiments the milk bottle 3 is a single integral part with a cap 35. The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml).

To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This

ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A to allow the container 3 to be used directly as a bottle. Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring.

Figures 7 and 8 show front views of a breast pump 100 according to the present invention. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface 5 comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separate pumping data for the left and right breasts.

There should also be charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump.

Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B.In preferable embodiments, the pumps 83A, 83B are piezoelectric pumps (or piezo pump). A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow.

The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will not be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative pressure which is transmitted via the connection spout 85 to a first side of the diaphragm 13 in the diaphragm housing 19. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred from the first side of the diaphragm housing 19A to the opening 7B of the breast shield 7 via the spout 9. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the spout 9, through the one way valve 37 and into the milk collection container 3. The negative pressure is then released, and periodically reapplied in a manner to imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a spout 9 for a breast pump 100. The spout 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the spout 9 to provide a tortuous air-liquid labyrinth path through the spout 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the spout 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown

with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a spout 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous spout 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A.

In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "clean" air-flow side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "dirty" milk-flow side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the "dirty" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept "clean" by ensuring it does not contact the mechanical components.

While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit pressure while isolating either side of the system may be used.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield spout 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "dirty" side 201.

The rest of the pneumatic system 200 forms the "clean" side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air-flow side 13B.

The “clean” side 202 of the system 200 is a closed system. This side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to clean half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder against the breast. This massage bladder may be used to help mechanically encourage milk expression.

The “clean” side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user’s breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13.

Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoidal valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve, with the diaphragm 13 connected to one of the throws 111B. The pump 83 is connected to the pole 111A. The final throw 111C is connected to a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

Using this function, material fatigue of the pump 83 can be assessed directly. Principally, this knowledge can be used to ensure user experience is not altered, despite the changing output of the pump 83 as it degrades over time. For example, the pump cycle may be changed to drive longer or operate under increased voltage to ensure the same pressures are met. This is particularly relevant for piezo pumps where the output may vary significantly.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the “clean” airflow part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As

such, this valve 126 is connected to a “bleed in” 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a “bleed out” 129 for bleeding air in the system 202 to the atmosphere.

During a milking pump cycle, the pump 83 applies negative pressure on the “clean” side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the “dirty” side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3.

To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the “dirty side” 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The resulting pressure increase is monitored behind the diaphragm 13 from the “clean” side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable.

The inventor has proved this method for estimating milk volume. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping

proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike 45 shows the application of negative pressure directly to the pressure sensor 101.

CLAIMS:

1. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and

a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier, the barrier having an outer periphery,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the milk-flow pathway extends past the outer periphery of the barrier.

2. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

3. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a piezo pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

4. The breast pump according to claim 1 or 3 wherein the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opneing extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

5. The breast pump of claim 4, wherein the shield flange and spout are detachable from the housing together

6. The breast pump of claim 2, 4 or 5, wherein the spout is integral with the breast shield.

7. The breast pump according to claim 2 or 4 to 6, wherein the breast shield cup extends over a majority of the inner surface of the unit.

8. The breast pump of claim 7, wherein the breast shield extends over 80% of the inner surface of the unit.

9. The breast pump of any of claims 2 or 4 to 8, wherein the spout connects directly to the container.

10. The breast pump of any of claims 2 or 4 to 9, wherein the spout comprises an outflow opening for depositing milk directly above the milk collection container.

11. The breast pump of any of claims 2 or 3, and claims 4 to 10 when dependent upon claims 2 or 3, further comprising a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

12. The breast pump of claim 10, wherein the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier.

13. The breast pump of any of claims 2, 11 or 12, wherein the milk-flow pathway is beneath the barrier.

14. The breast pump of any of claims 2 or 11 to 13, wherein the milk-flow pathway does not pass through the barrier.

15. The breast pump of any of claims 2 or 11 to 14, wherein the barrier is mounted in a housing on the breast shield.

16. The breast pump of claim 15, wherein the housing is integral with the breast shield.

17. The breast pump of any of claims 2 or 11 to 16, wherein the barrier is not an annulus.

18. The breast pump of any of claims 2 or 11 to 17, wherein the barrier provides a seal to isolate the pump from the milk-flow side of the barrier.

19. The breast pump of claim 18, wherein the only seal is around an outer edge of the barrier.

20. The breast pump of any of claims 2 or 11 to 19, wherein the barrier is a diaphragm.

21. The breast pump of claim 20, wherein the diaphragm is a continuous membrane which is devoid of any openings or holes.

22. The breast pump according to any preceding claim, further comprising a pressure sensor in pneumatic connection with the pump.

23. The breast pump of any preceding claim, wherein the width of the breast pump is less than 110 mm.

24. The breast pump of any preceding claim, wherein the height of the breast pump is less than 180 mm.

25. The breast pump of any preceding claim, wherein the plane to plane depth of the breast pump is less than 100 mm.

26. The breast pump of any preceding claim, wherein, in use, the breast pump extends from the user's breasts by 3 to 4 cup sizes as per the European standard EN 13402.

27. The breast pump of any preceding claim, wherein the milk container has a volume of greater than 120 ml.

28. The breast pump of claim 27, wherein the milk container has a volume of greater than 140 ml.

29. The breast pump of claim 27 or 28, wherein the milk container has a volume of less than 150 ml.

30. The breast pump of any preceding claim, wherein the milk container and housing form a substantially continuous outer surface of the breast pump.

31. The breast pump of any preceding claim, wherein the milk container is at least partially transparent on the outer surface of the breast pump.

32. The breast pump of any preceding claim, wherein the milk container is provided with a spout.

33. The breast pump of any preceding claim, wherein the milk container is provided with attachment means for attaching a teat to the container.

34. The breast pump of any preceding claim, wherein the breast shield is removable.

35. The breast pump of any preceding claim, wherein the milk collection container is formed of at least two rigid sections which are connectable.

36. The breast pump of any preceding claim, further comprising a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

37. The breast pump of claim 36, wherein the one-way valve is located in an opening to the container.

38. The breast pump of claim 1 or 2, wherein the pump is a piezo pump.

39. The breast pump of any of any preceding claim, wherein the breast shield is detachable from the breast pump.

40. The breast pump of any of claims 22 or 23 to 39 when dependent upon claim 22, further comprising a single pole, double throw pneumatic valve, wherein:

the pole is in pneumatic connection with the pump and pressure sensor;

one of the throws is in pneumatic connection with the diaphragm; and

the other throw is in pneumatic connection with a dead-end.

41. The breast pump of any of claim22 or 23 to 40 when dependent upon claim 22, further comprising:

a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump;

a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and

a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

42. A method of estimating the pressure applied by a breast pump according to claim 40, comprising the steps of:

providing a breast pump according to claim 40;

selecting a pressure cycle from a pre-defined list of pressure cycles;

applying pressure with the pump to stimulate milk expression;

reading the output of the pressure sensor;

adjusting the applied pressure of the pump to match the pressure profile selected by the user.

43. The method of claim 42, further comprising:

approximating the elasticity and extension of the diaphragm at the relevant pressure; and

calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

44. A method of estimating the milk collected by a breast pump according to claim 41, comprising the steps of:

providing a breast pump according to claim 41;

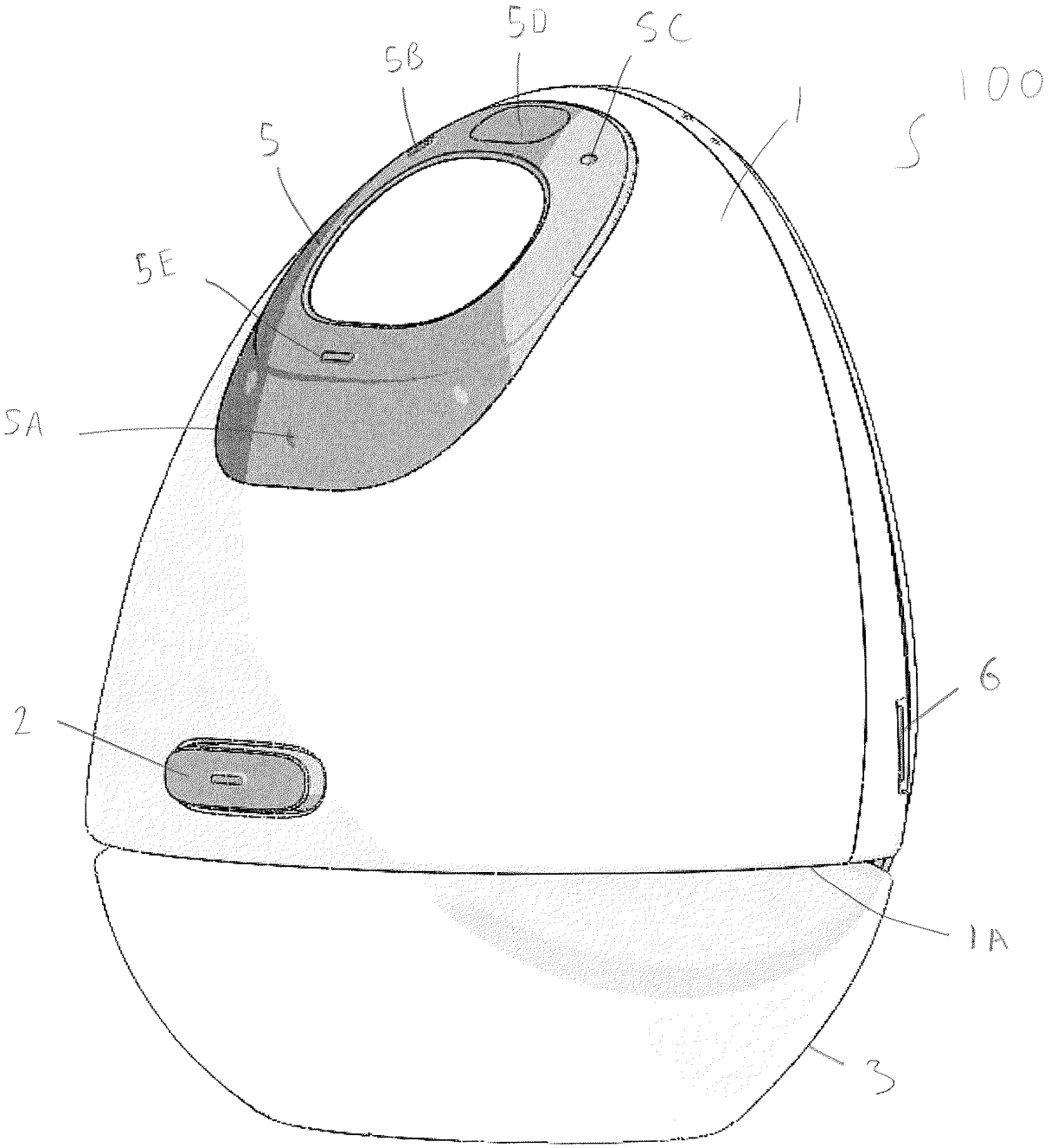
generating a positive pressure with the pump;

transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container;

measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm;

estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure.

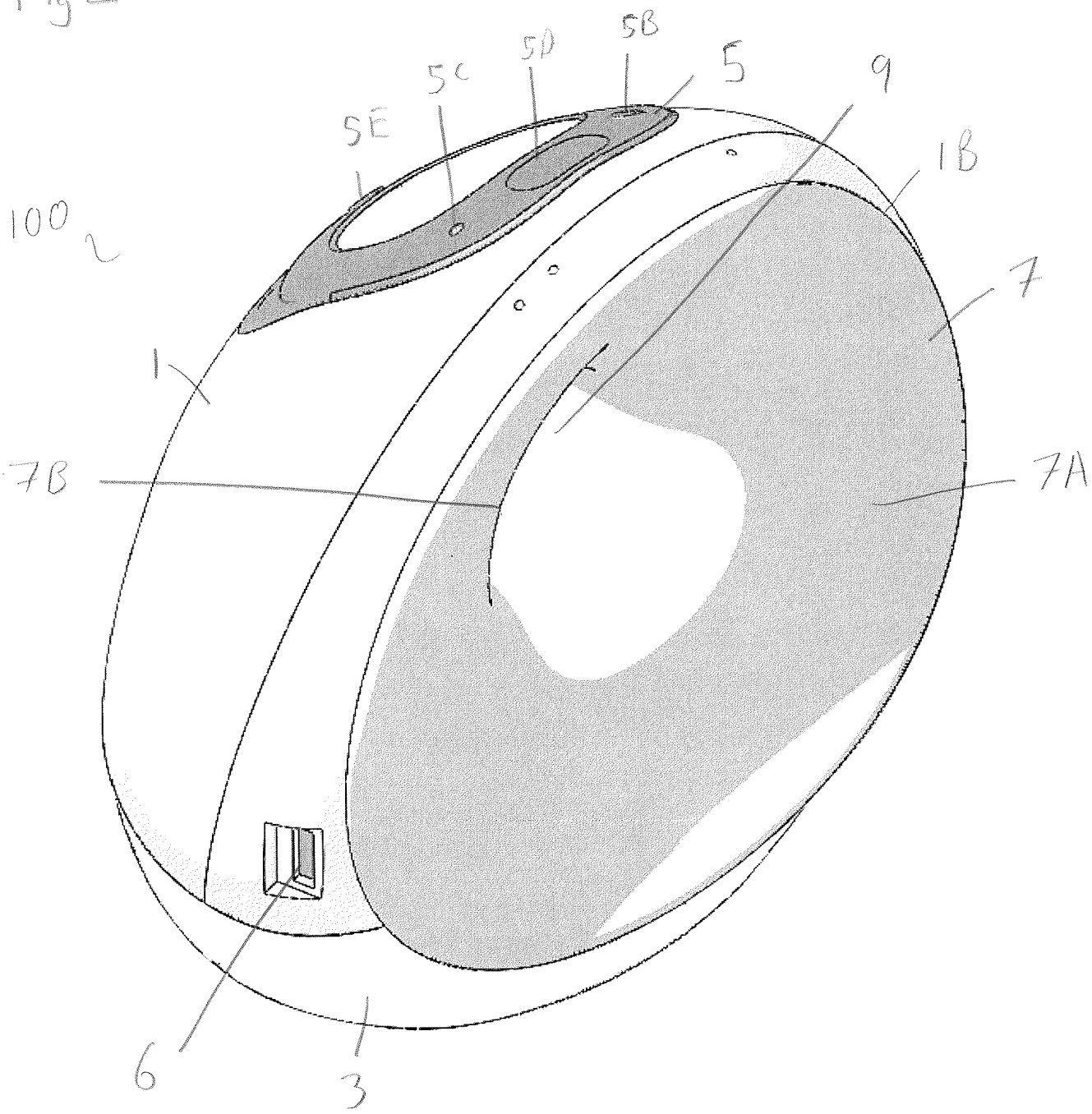
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7397102; JCP2; JCP2

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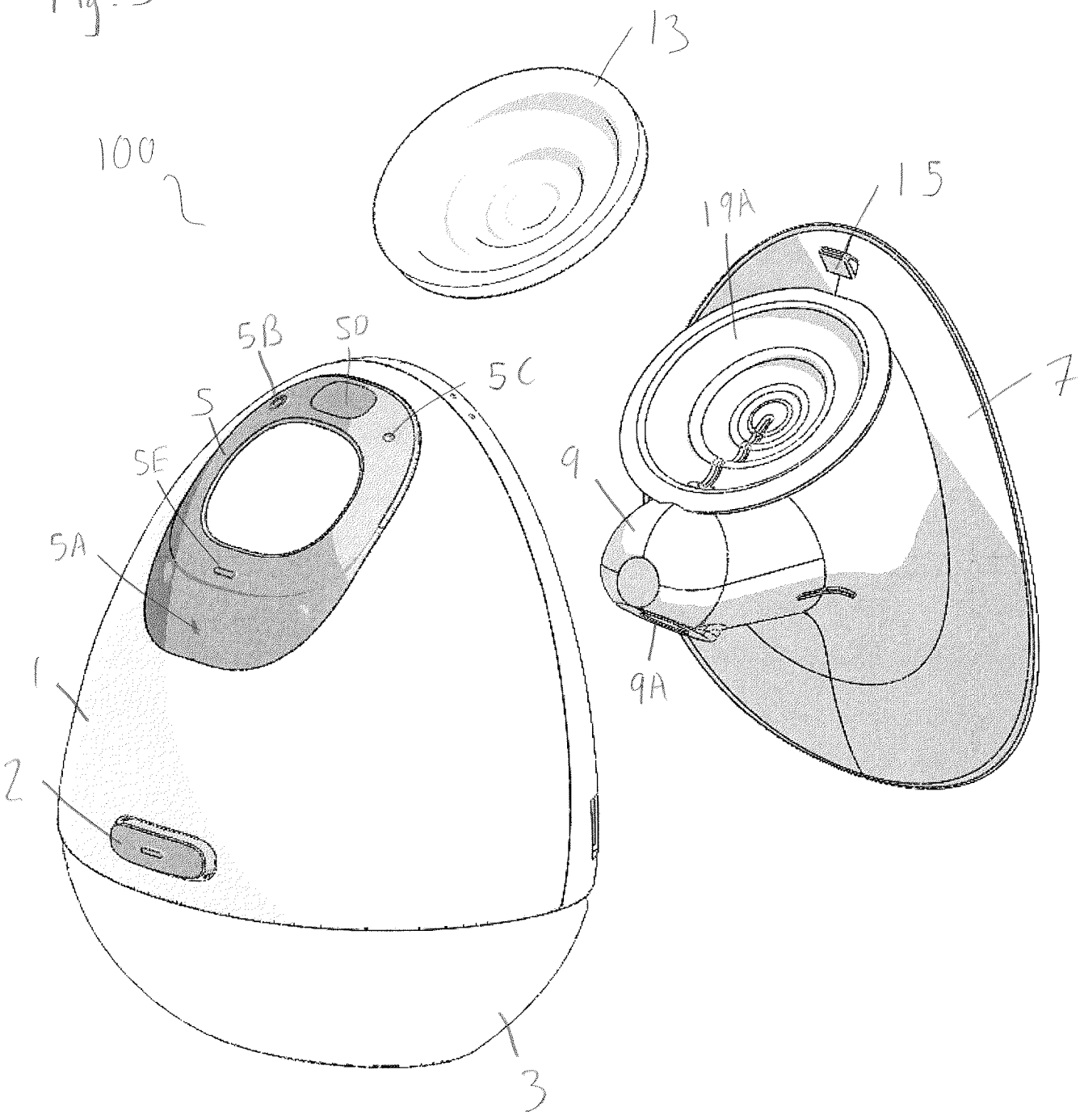
Fig 2



7397102; JCP2; JCP2

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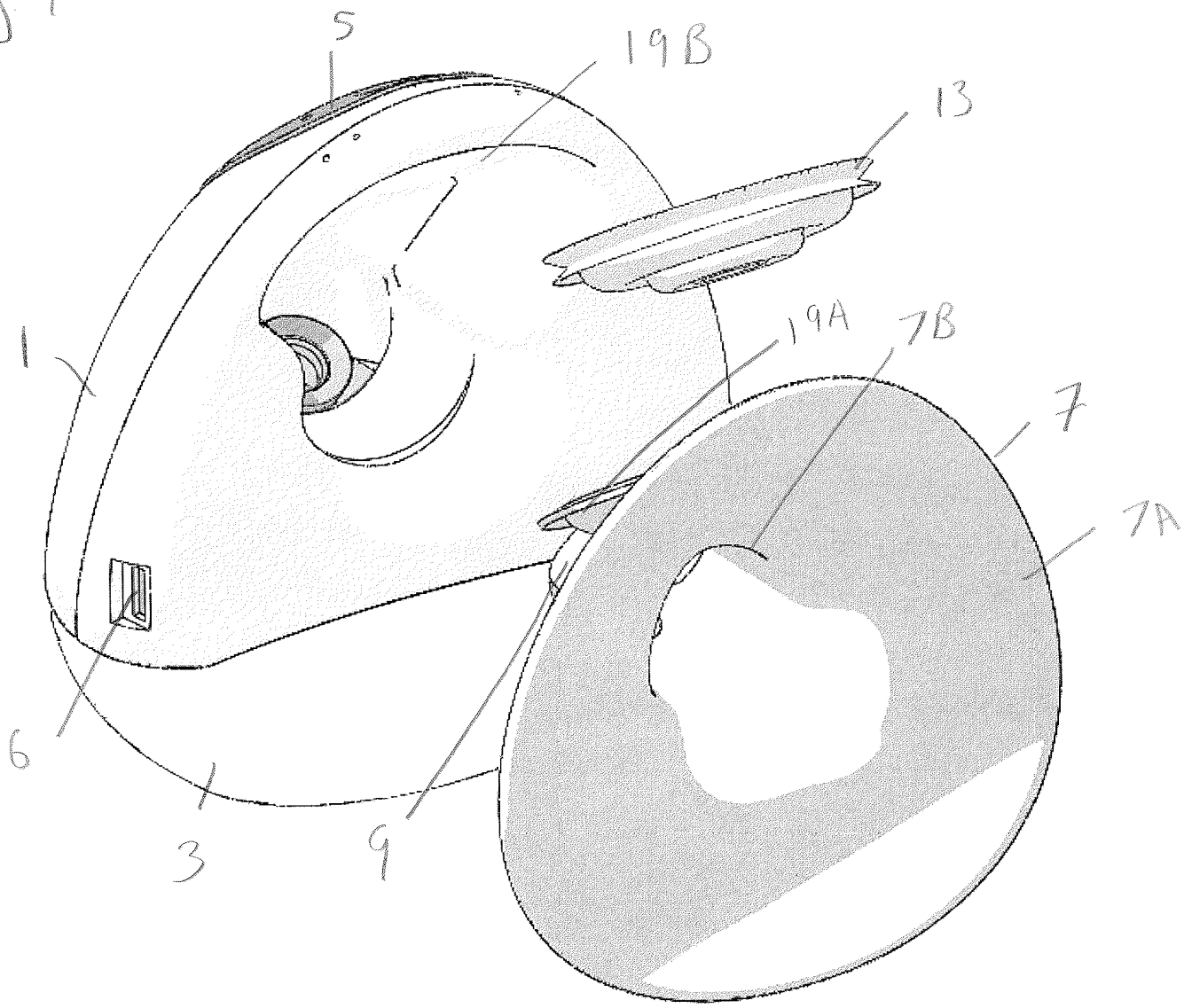
Fig. 3



7397102; JCP2; JCP2

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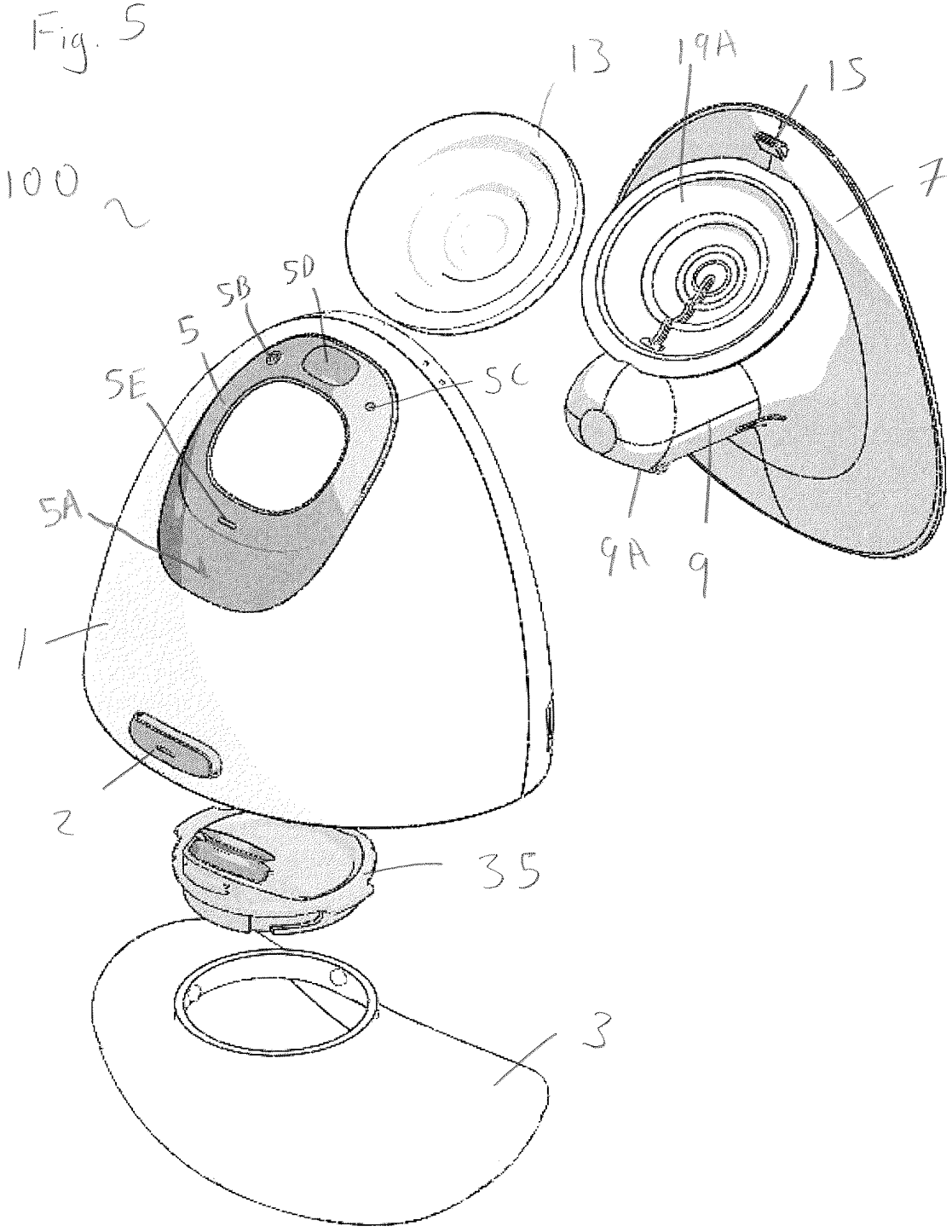
Fig 4



7397102; JCP2; JCP2

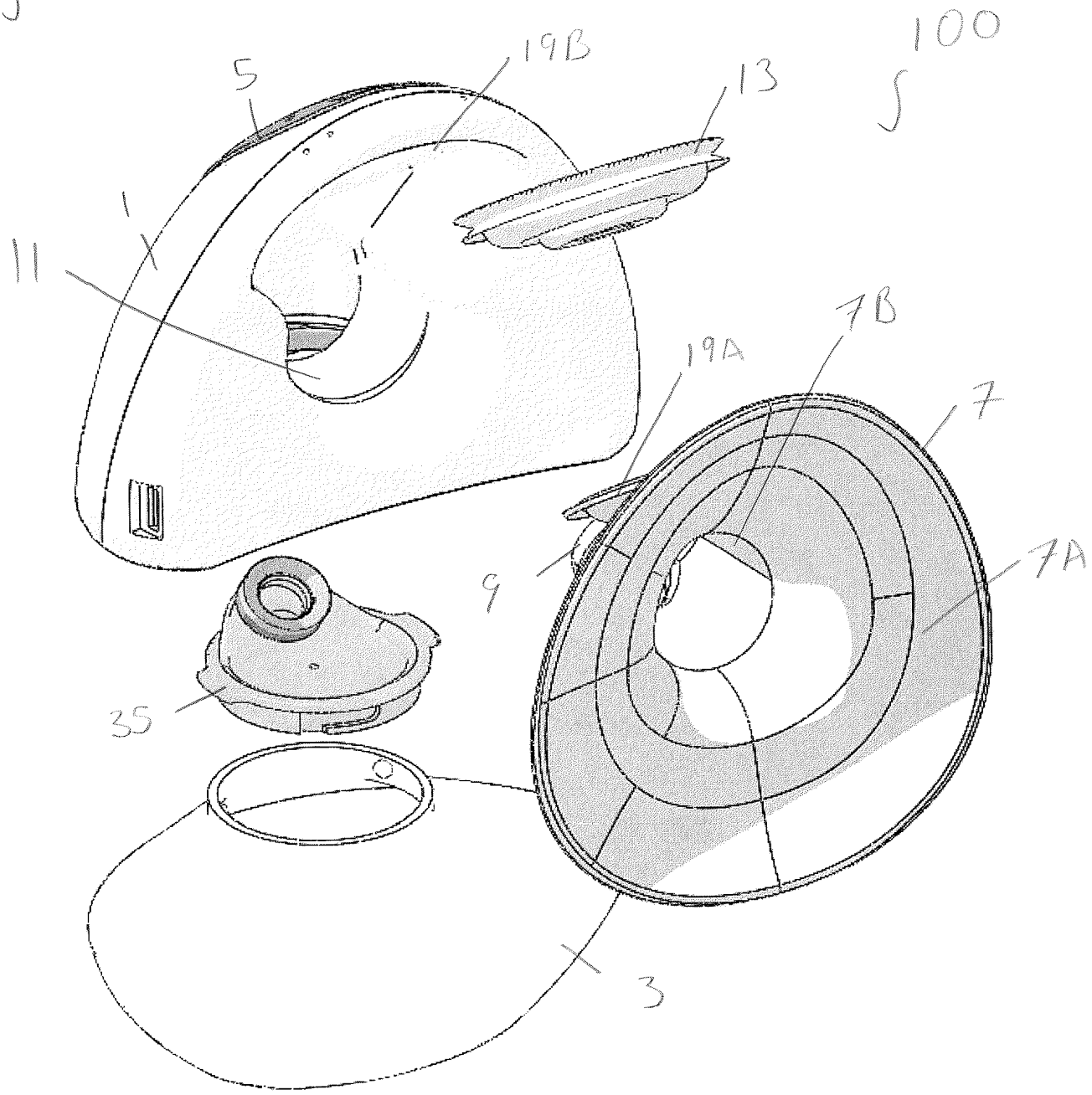
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Fig. 5



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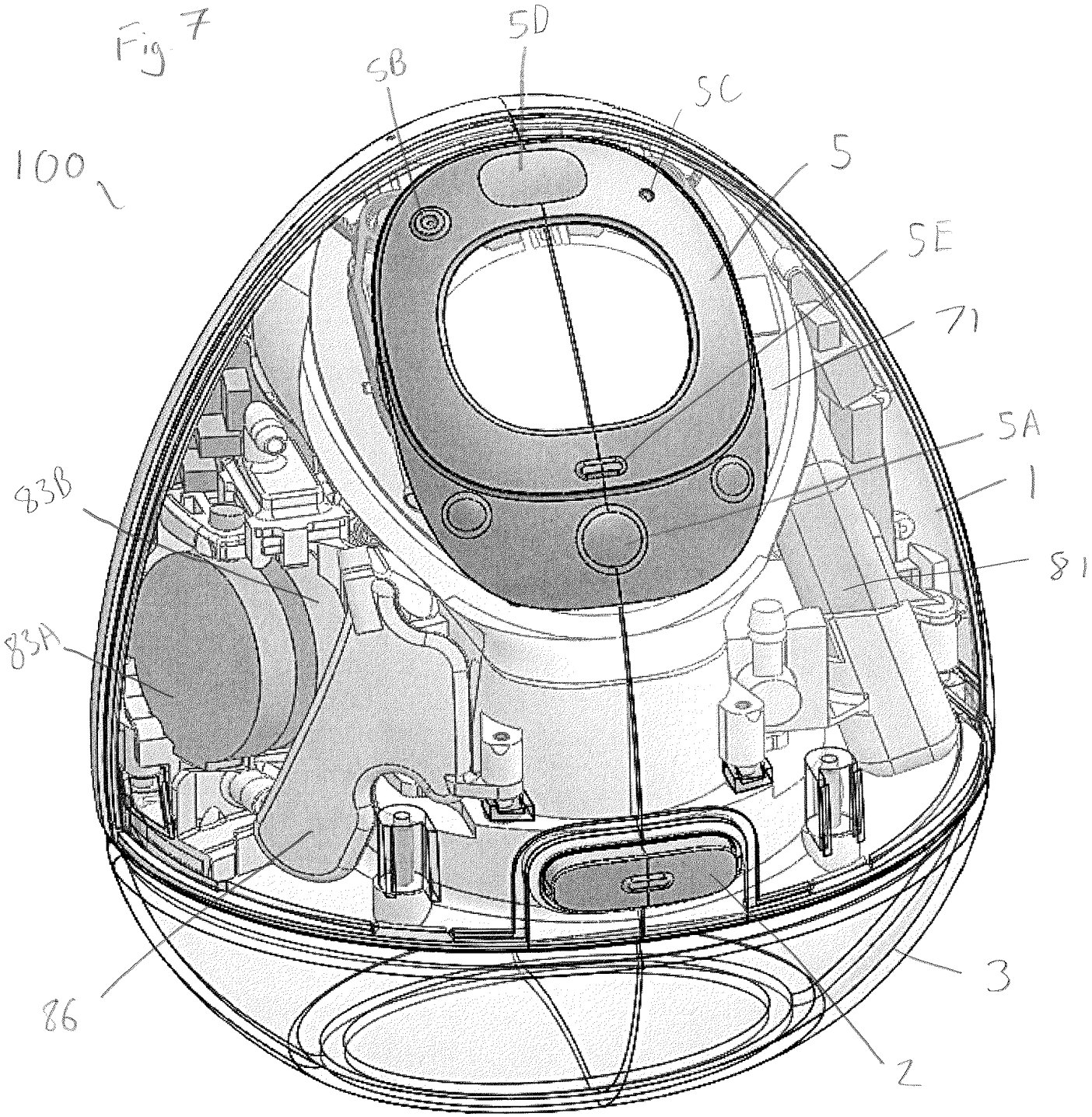
Fig. 6



7397102; JCP2; JCP2

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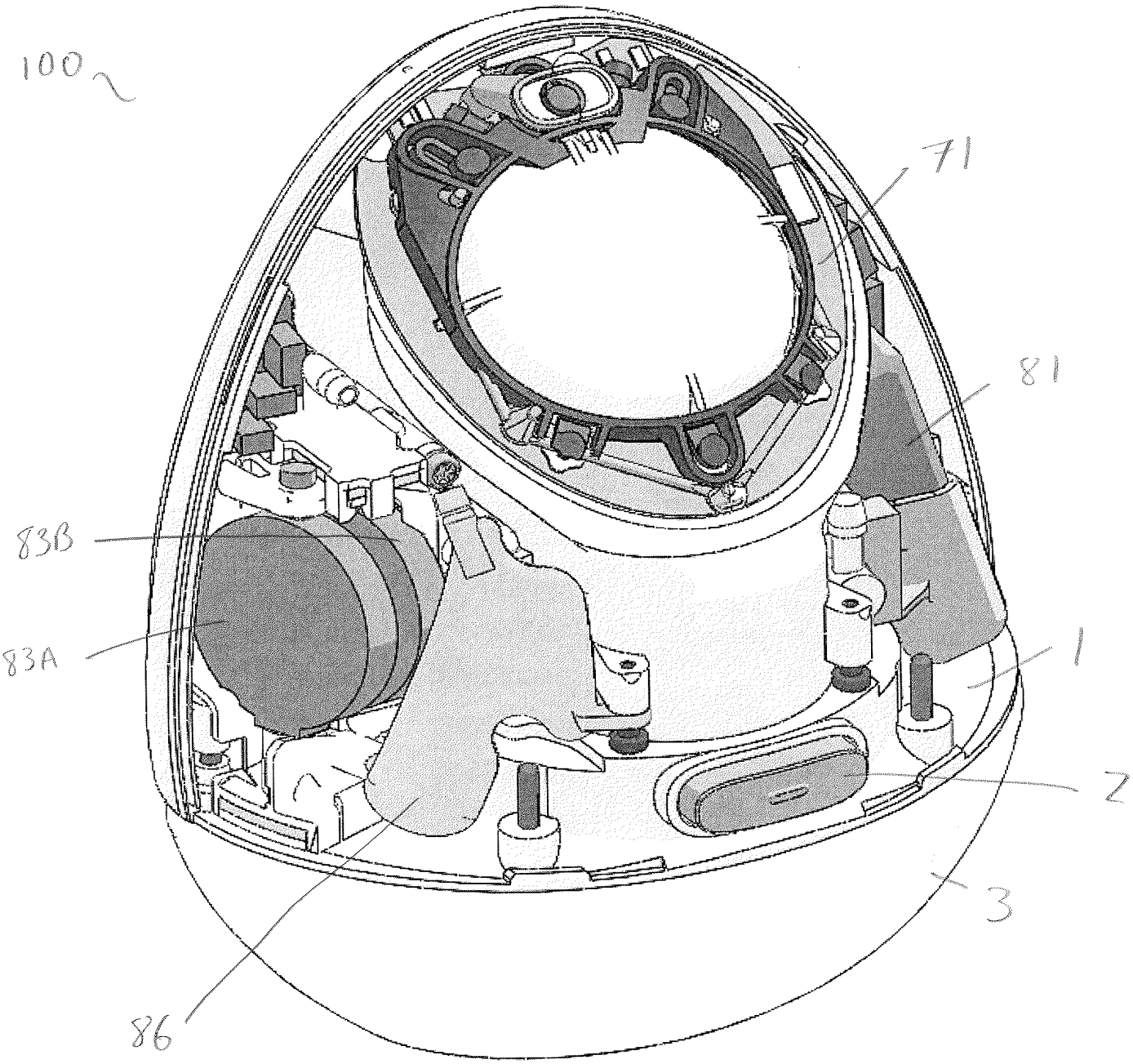
Fig 7



7397102; JCP2; JCP2

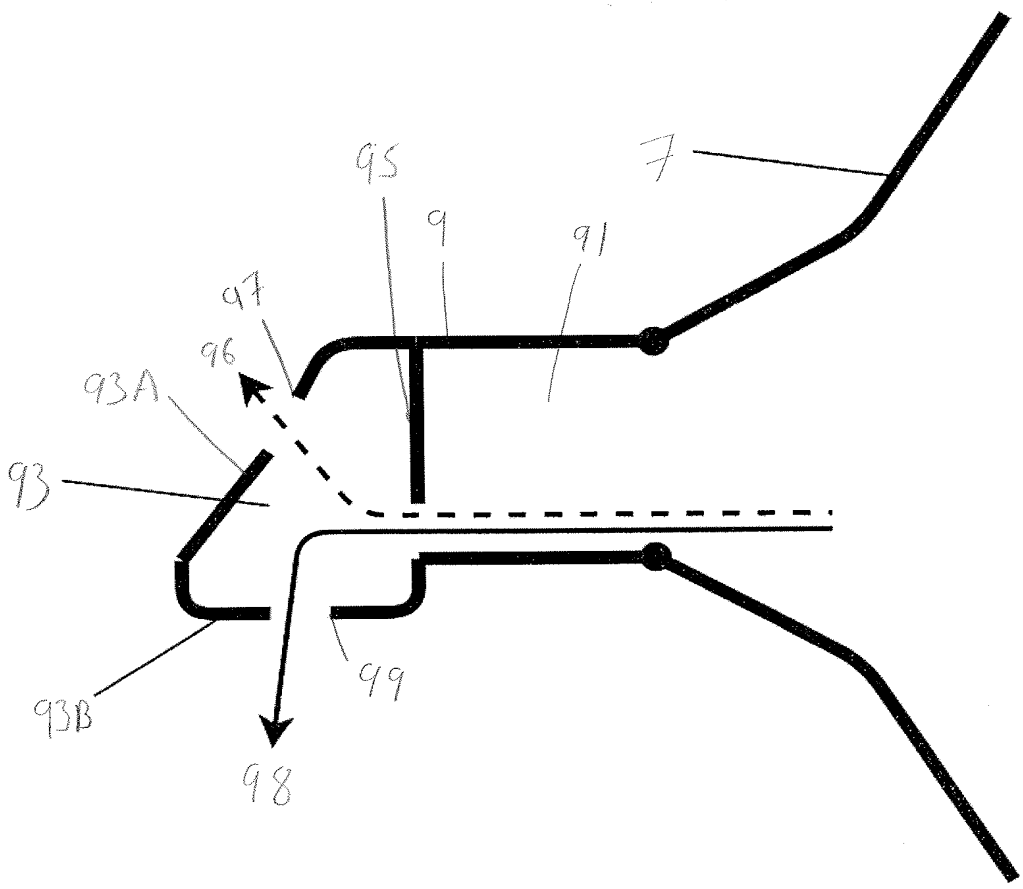
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Fig. 8



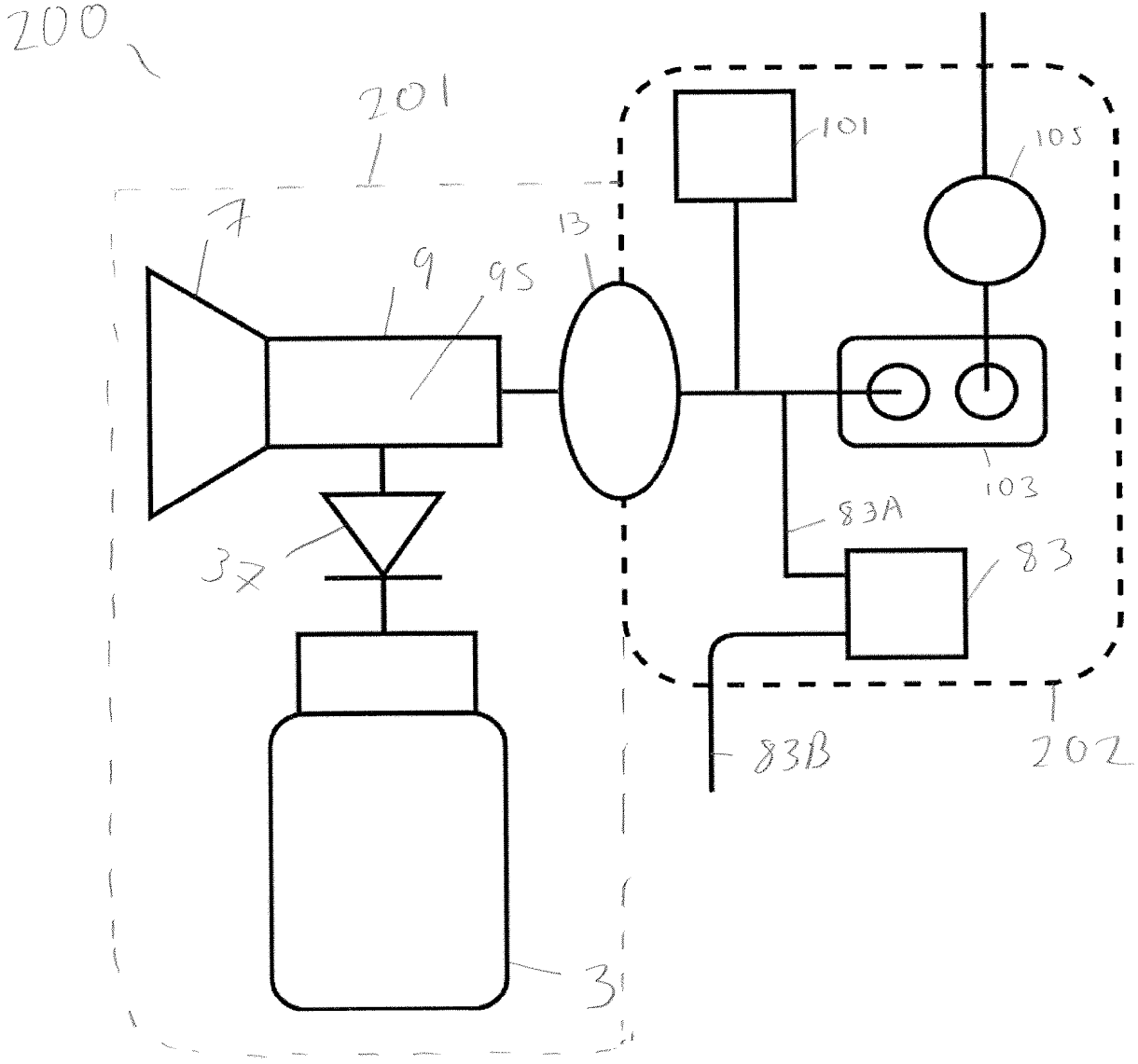
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Fig 9



P153992GB00

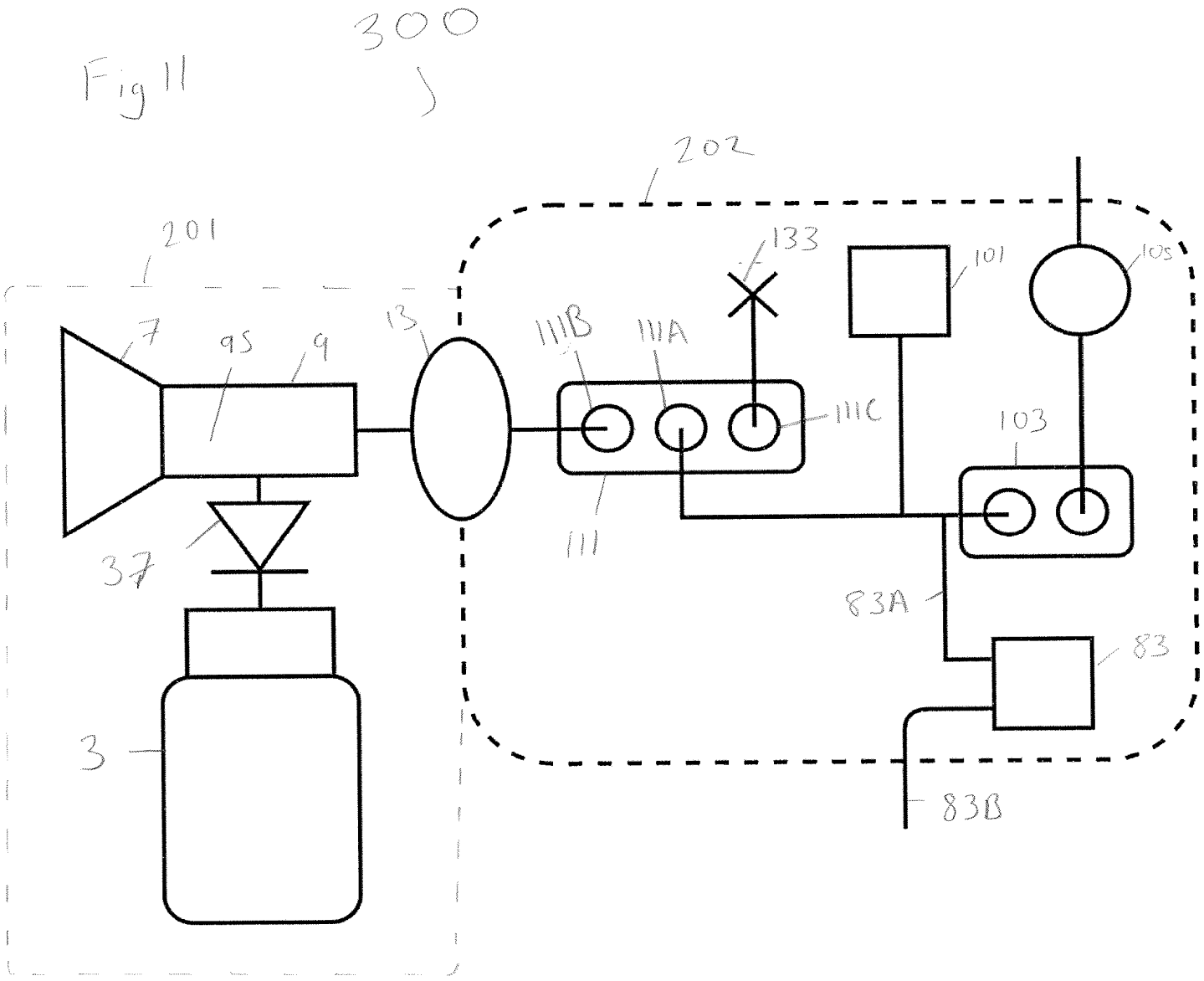
Fig. 10



7397102; JCP2; JCP2

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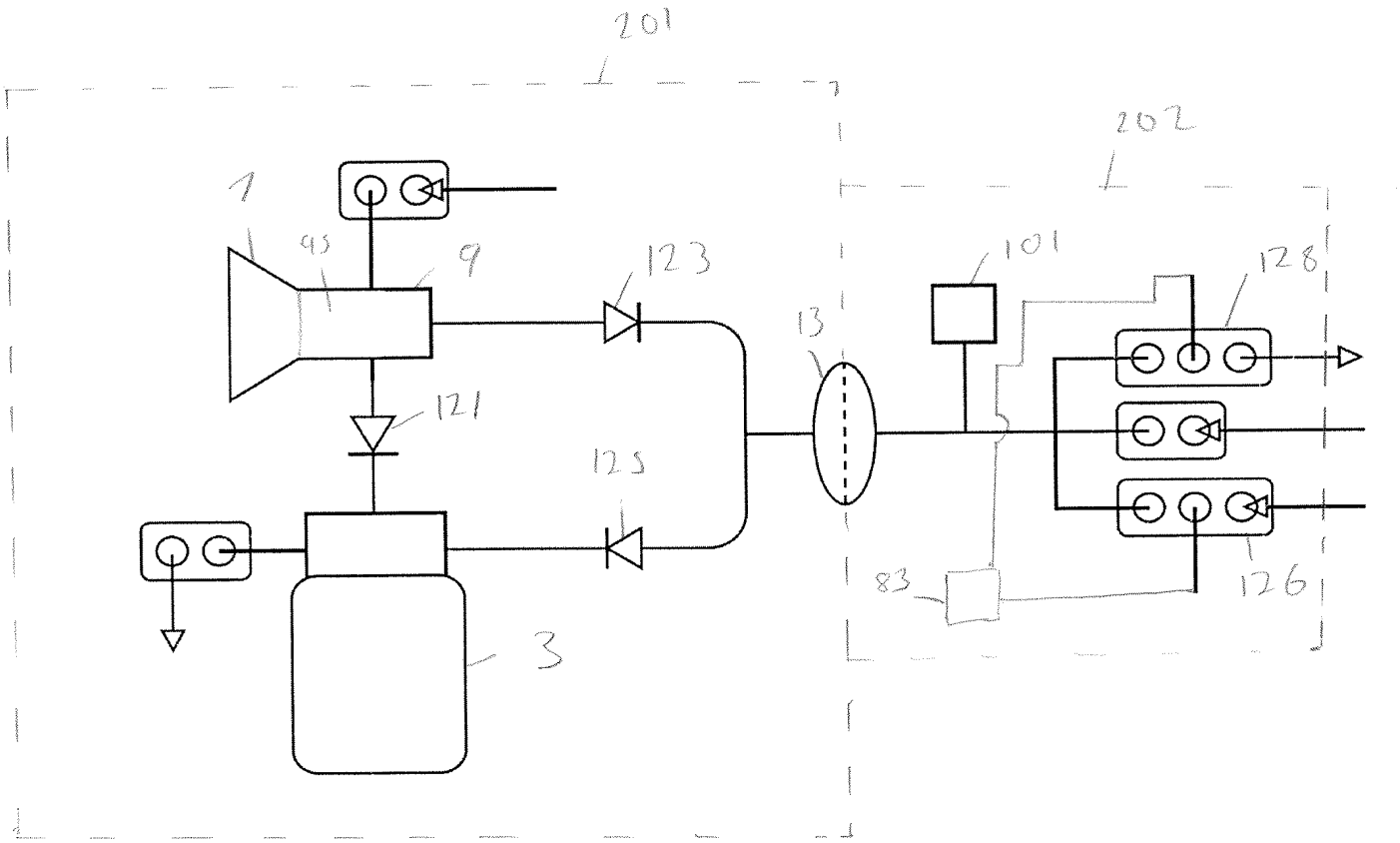
Fig 11



7397102; JCP2; JCP2

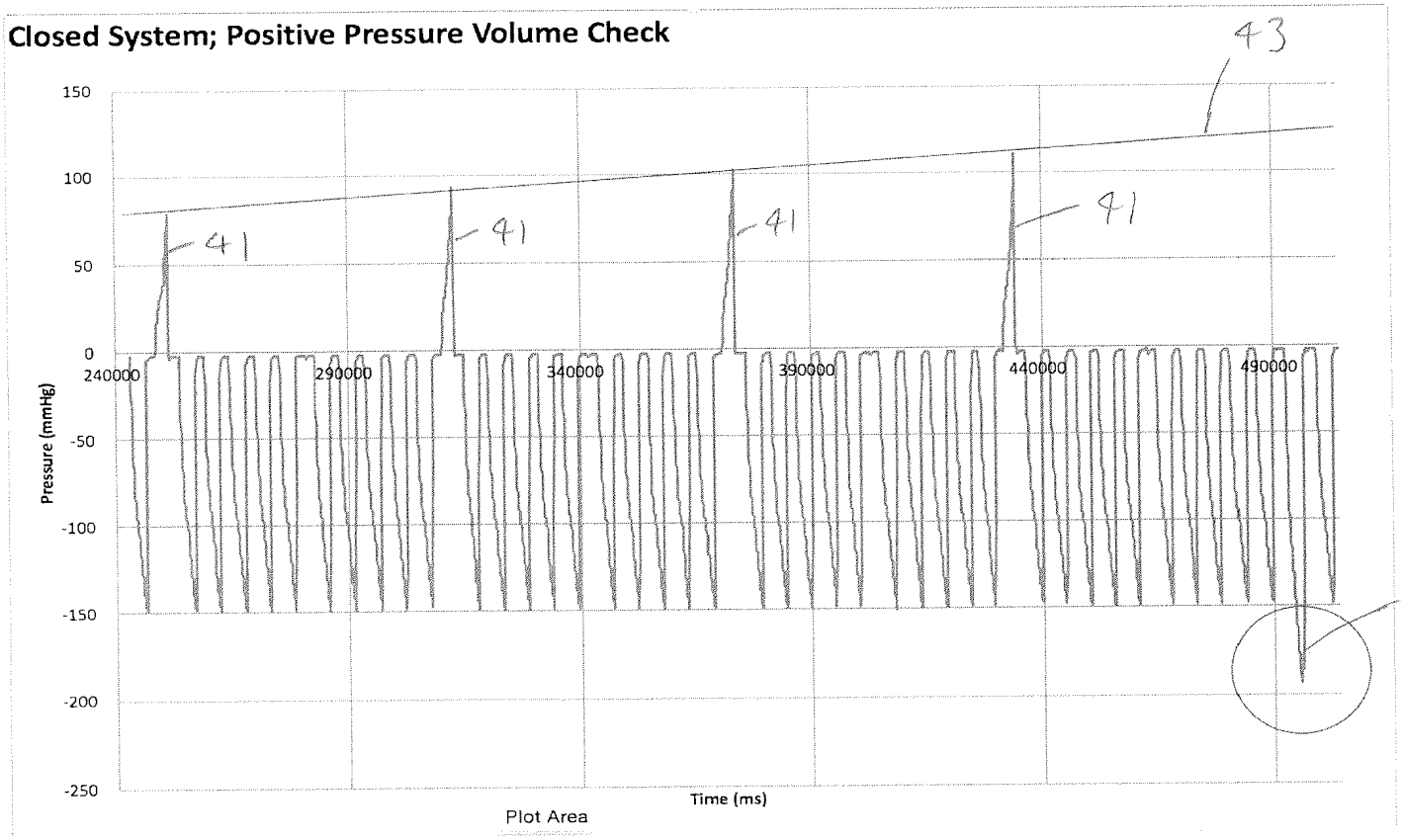
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Fig. 12



P153992GB00

Fig 13



7397102; JCP2; JCP2

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Application number GB 1709564.7

1.	Your reference	**MJD/P153993GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**A LIQUID LEVEL MEASUREMENT SYSTEM**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
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   Continuation sheets of this form

Description:	**12**
Claim*(s)*:	**3**
Abstract:	**n/a**
Drawing*(s)*:	**4**

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Request for search (Patents Form 9A):	**1**
Request for a substantive examination (Patents Form 10):	**0**
Any other documents (please specify):	**PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

DRAPER, Mr Martyn
Email: boult@boult.com
Telephone: 020 7430 7500
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A LIQUID LEVEL MEASUREMENT SYSTEM

BACKGROUND

The present invention relates to a sensing mechanism for detecting the level of liquid in a container. In a particular arrangement, the present invention relates to such a sensing mechanism when used along with a breast pump.

In the context of breast pumps, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container affixed to the breast pump, through which the level of expressed milk inside the container can be visibly determined. However, such visual determinations are not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which measures droplets of liquid, specifically breast milk, entering the container. By measuring the properties of these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container. Particularly at times when large flow rates of liquid enter the container, this accuracy cannot be guaranteed leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process.

Preferably, the at least one optical emitter comprises at least two optical emitters. In this way, the sensing assembly from the breast pump can determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Preferably, each optical emitter is equidistant from the optical receiver. In this way, the controller can more easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

Preferably, the optical emitter may emit radiation in the visible range of wavelengths. Alternatively it may be UV or IR light. The emitted wavelength is preferably between 10nm and 1mm.

The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Preferably, the sensing assembly comprises at least one accelerometer electrically connected to the controller. In one embodiment, the controller may be configured to record an accelerometer parameter from the accelerometer, and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

In some cases, the coupling may be a screw thread.

Preferably, the breast pump is sized to be similar to that of a female breast. On this basis, the breast pump is preferably no longer than 20cm in any given linear direction; more preferably no longer than 18cm in any given linear direction; and even more preferably no longer than 15cm in any given linear direction.

The breast pump may contain any suitable power source, such as a battery. The power source is preferably located in the housing.

In some cases, the container may comprise a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between the optical emitters/receiver and the inside of the container via the window. In other cases, the container may be made entirely of a material through which the optical radiation can pass.

When the container is connected to the housing, each optical emitter and the optical receiver are preferably located adjacent to the container, to ensure reliable transmission of radiation between the device and the container.

In this case, the portion of the container adjacent to each optical emitter and the optical receiver preferably comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver. In this way the formation of milk on this surface, which would cause erroneous signals from the optical receiver, can be inhibited.

To further inhibit the formation of milk in the vicinity of each optical emitter/receiver, the portion of the container adjacent to each optical emitter and the optical receiver may comprise a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

Preferably, the container has a volumetric capacity of no more than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle.

It will be appreciated that the sensing assembly from the above breast pump has applications in other fields. Thus according to a second aspect of the present invention, there is provided a sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non-perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Although not fully recited herein, it will be appreciated that the sensor module according to the second aspect of the invention may include any or all of the optional features described in relation to the breast pump from the first aspect of the present invention.

According to a third aspect of the present invention, there is provided a collar incorporating the sensor module according to the second aspect of the invention, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

In the above case, the second coupling may be a screw thread.

According to fourth aspect of the present invention, there is provided a lid attachable to a container, wherein the lid comprises the sensor module according to the second aspect of the invention.

DESCRIPTION OF THE FIGURES

Figure 1A shows a sectional view of a device being used to determine the level of liquid in a container; and

Figure 1B shows a sectional view of the device and the container from Figure 1A being used at a different orientation.

Figure 2 shows a sectional view of the device and the container from Figure 1A being used whilst undergoing acceleration.

Figure 3 shows a sectional view of the device from Figure 1A being used as part of a breast pump assembly.

Figure 4 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

DETAILED DESCRIPTION

With reference to Figures 1A and 1B, there is shown a device 10 for use in detecting the level of liquid inside a container 100.

The device 10 is formed of a housing 12 in which is located a sensing assembly 14 comprising a series of optical emitters 16 which are angled relative to, and each located equidistant from, an optical receiver 18. In operation of the device as will be described, each optical emitter 16 is operable to emit radiation which is received by the optical receiver 18.

The optical emitters 16 and the optical receiver 18 from the sensing assembly 14 are located in a portion 20 of the device 10 which faces the container 100 when the device 10 is connected to the container 100. The portion 20 of the device 10 containing the optical emitters 16 and the optical receiver 18 comprises a window 22 of material which is transparent to optical radiation. In this way, each of the optical emitters 16 and the optical receiver 18 have a line of sight through the window 22 into the container 100 when the device 10 is connected thereto.

A controller 30 comprising a CPU 32 and a memory 34 is provided in the device 10 for controlling the operation of the sensing assembly 14. An accelerometer 36 is also provided in the housing 10, which is operatively connected to the controller 30.

Operation of the device 10 when connected to the container 100 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 100, the controller 30 instructs the optical emitters 16 to each emit radiation towards the surface of the liquid inside the container 100 at a given intensity. The optical receiver 18 receives the reflected radiation from each optical emitter 16 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 14, the controller 30 records the intensities of radiation emitted by each of the optical emitters 16 as intensities IE_1; $IE_{2...}IE_n$ (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 18 from each of the optical emitters 16 as received intensities IR_1; $IR_{2...}IR_n$.

By comparing the emitted radiation intensities IE_1; $IE_{2...}IE_n$ with the received radiation intensities IR_1; $IR_{2...}IR_n$, the controller 30 calculates a series of intensity ratios IE_1:IR_1; IE_2:IR_2…IE_n:IR_n, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE_1:IR_1 is the same as IE_2:IR_2,

given the optical emitters 16 are equidistant from the optical receiver 18, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 1A. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 1B.

To accurately determine the level and the quantity of liquid inside the container 100, the controller 30 processes the recorded intensity ratios using a database located in the memory 34. The database contains an individual record for each container which is operable to connect with the device 10. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE_1:IR_1 and IE_2:IR_2) for the container 100 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 30 calculates the level and quantity of liquid inside the container 100 and stores this information in the memory 34.

In situations where a container 100 to the device 10 contains no stored record in the database, the sensing assembly 14 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 14 is operated as the container is filled, and as it is located at different orientations. At each point during the calibration mode, the controller 30 calculates the recorded intensity ratios (IE_1:IR_1 and IE_2:IR_2) and stores them in the record relating to the container 100. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 100.

To improve the accuracy of the results obtained by the device 10 during its use, the controller 30 when recording each intensity ratio also records a parameter from the accelerometer 36 relating to the acceleration experienced by the device 10. For each recorded acceleration parameter, the controller 30 determines whether the parameter exceeds a predetermined threshold acceleration parameter stored in the memory 34. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 100 connected to the device 10. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 30 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 36, the controller 30 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 30 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 30 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 2. In this event, the controller 30 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 16 with the radiation received by the optical emitter 18, the controller 30 could instead record the time taken for radiation emitted by each of the optical emitters 16 to be received by the optical receiver 18. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 10, it will be appreciated that the device can be used in a wide variety of applications.

One possible application is the use of the device 10 to determine the level of liquid located within a container 100, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 10 is associated with a breast pump 200 which assists with the expression of milk from a breast. The breast pump may be located in the housing 12 of the device 10 as shown in Figure 3, or it may be realisably connected to the housing 12. Either way, the device 10 would be connectable to the container 100 such that milk expressed by the breast pump can pass from the pump via a channel 202 into the container 100.

Another application for the device 10 is as a collar for detecting the level/quantity of liquid in a container 100, such as a baby bottle, via its lid 102. An example of the device 10 being used as such a collar is shown in Figure 4. In this arrangement, the device 10 is located between the container 100 and the lid 102, and comprises a first end 42 having a first coupling 44 for attaching the collar to the lid 102. The device comprises a second end 46 having a second coupling 48 for attaching the device 10 to the container 100. In Figure 4,

the first and second couplings are shown as screw threads which engage with respective screw heads on the lid 102 and the container 100.

To allow the device 10 to pass liquid from the lid 102 to the container 100, the device comprises a channel 50 passing from the first end 42 to the second end 46.

In a further application, the device 10 may be integrated into the lid 102 of a container 100. In this application, the device 10 has a similar configuration to that shown in Figure 4, except that the first end 42 is covered and has no coupling 44.

It will be appreciated the device may be connected to a wide variety of different containers 100. In some applications, the container 100 may be a baby bottle, or a drinks bottle.

In certain applications, the container 100 connected to the device 10 may have a volumetric capacity of no more than 500ml, less than 400ml, less than 300ml, and/or less than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle/drink bottle.

It will also be appreciated that the container 100 connected to the device 10 may comprise an inside surface which comprises an oleophobic and/or hydrophobic coating. In this way, the container 100 is easy to clean between uses. When such a coating is applied to the portion of the container 100 which is adjacent to the optical emitters 16 and the optical receiver 18 from the device 10, this coating also helps prevent liquid from forming in front of these emitters/receiver, which might cause erroneous signals to be recorded by the optical receiver 18 from the sensing assembly 14.

To further reduce such erroneous signals, the portion of the container adjacent to the optical emitters and the optical receiver may comprise a surface inside the container having at least one channel and/or feature for directing liquid away from the optical emitters and/or the optical receiver.

To improve the accuracy of the sensing assembly 14, the container 100 may be made opaque to prevent ambient radiation outside the container 100 from reaching the optical receiver 18. Other possibilities to improve the accuracy to the accuracy of the sensing assembly 14 include the provision of a distinctive pattern/colour/texture on the bottom

inside surface of the container 100. In this way, the distinctive bottom inside surface can be used by the sensing assembly 14 to more easily calibrate itself to the container 100 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 100 the device is connected to, and thus which record should be used from the database when the device 10 is used.

To further improve the accuracy of the sensing assembly 14, the controller 30 may also be configured to use the recorded information from the accelerometer 36, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 30 may poll the accelerometer 36 prior to each operation of the sensing assembly 14 to verify that the device 10 is not currently undergoing excessive acceleration. In the event of the controller 30 determining excessive acceleration in the device 10, the controller 30 would continually re-poll the accelerometer, and not operate the sensing assembly 14, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 34.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 10 can more accurately determine the level/quantity of different liquids used in a particular container 100.

As described herein, the sensing assembly 14 has been described as having a plurality of optical emitters 16. It will be appreciated however that the sensing assembly could operate using a single optical emitter 16 and plurality of optical receivers 18. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In use of the device 10, the controller 30 would then similarly record the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In an alternate arrangement, there may be provided a plurality of optical emitters 16 and a plurality of optical receivers 18, wherein each optical emitter 16 is associated with a respective optical

receiver 18. In its simplest arrangement, the sensing assembly 14 may comprise a single optical emitter 16 and a single optical receiver 18.

In certain configurations, the optical emitters 16 may together emit radiation having the same wavelength. In other configurations, the optical emitters 16 may each emit radiation having a different wavelength. In this latter configuration, the optical receiver 18 would then be able to determine which optical emitter 16 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 16 may also each emit radiation at different times, such to allow the controller 30 to more easily process the signals from the optical receiver 18, and more easily distinguish between the radiation emitted by each of the optical emitters 16.

In relation to the electrical connection between the controller 30 and the sensing assembly 14, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 10 herein described is preferably powered by a battery or some other power source located in the device 10. In other embodiments, the device 10 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 30 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 100, the controller 30 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 34. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 10, the device could be used to detect the level of a solid, as opposed to a liquid, in a container.

As used herein, the terms ‘optical emitter’ and ‘optical receiver’ are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful

effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to 400nm).

CLAIMS:

1. A breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

2. A breast pump according to claim 1, wherein the at least one optical emitter comprises at least two optical emitters.

3. A breast pump according to claim 2, wherein each optical emitter is equidistant from the optical receiver.

4. A breast pump according to claim 2 or 3, wherein each optical emitter is operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters.

5. A breast pump according to any preceding claim, wherein each optical emitter is an IR optical emitter, and the optical receiver is an IR optical receiver.

6. A breast pump according to any preceding claim, wherein the signals from the optical receiver comprise information relating to the intensity of the radiation received by the optical receiver.

7. A breast pump according to any preceding claim, wherein the sensing assembly comprises at least one accelerometer electrically connected to the controller.

8. A breast pump according to any preceding claim, wherein the coupling is a screw thread.

9. A breast pump according to any preceding claim, wherein the breast pump is no longer than 20cm in any given linear direction.

10. A breast pump according to any preceding claim, wherein the breast pump contains a power source.

11. A breast pump according to any preceding claim, wherein the container comprises a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between each optical emitter/receiver and the inside of the container via the window.

12. A breast pump according to any preceding claim, wherein when the container is connected to the housing, each optical emitter and the optical receiver are located adjacent to the container.

13. A breast pump according to claim 12, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver.

14. A breast pump according to claim 12 or 13, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

15. A breast pump according to any preceding claim, wherein the container has a volumetric capacity of no more than 200ml.

16. A sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

17. A collar incorporating the sensor module according to claim 16, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

18. A collar according to claim 17, wherein the second coupling is a screw thread.

19. A lid attachable to a container, wherein the lid comprises the sensor module according to claim 16.

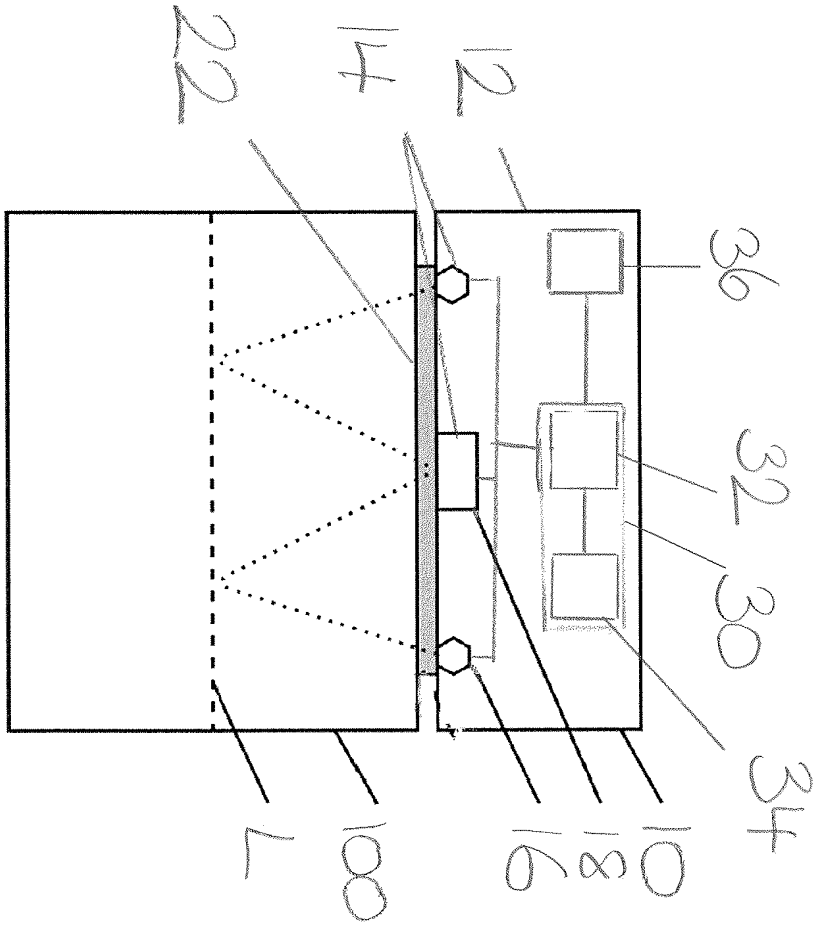


FIG 1A

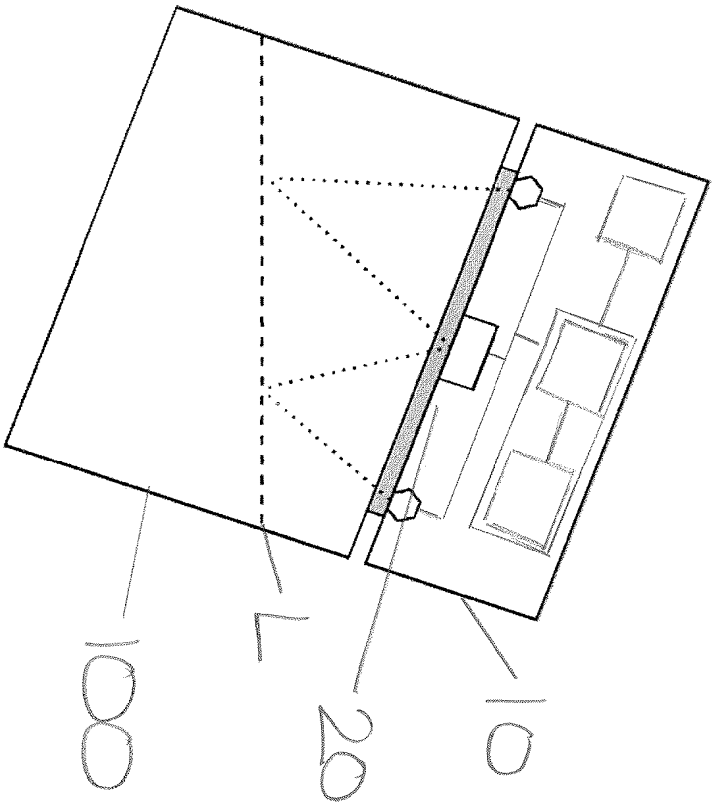


FIG 1B

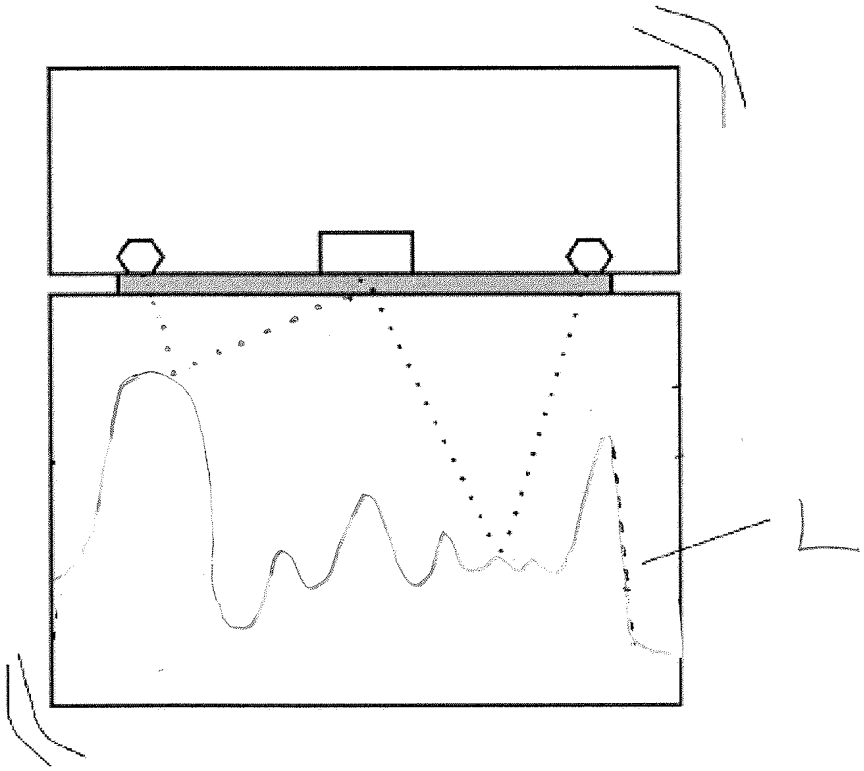


FIG 2

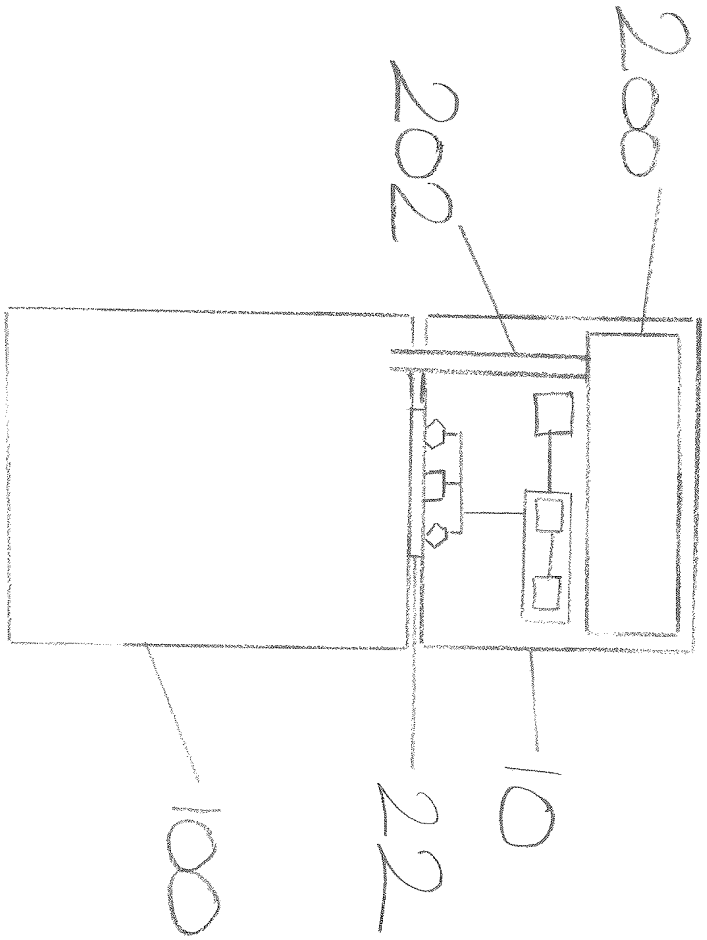


Fig 3

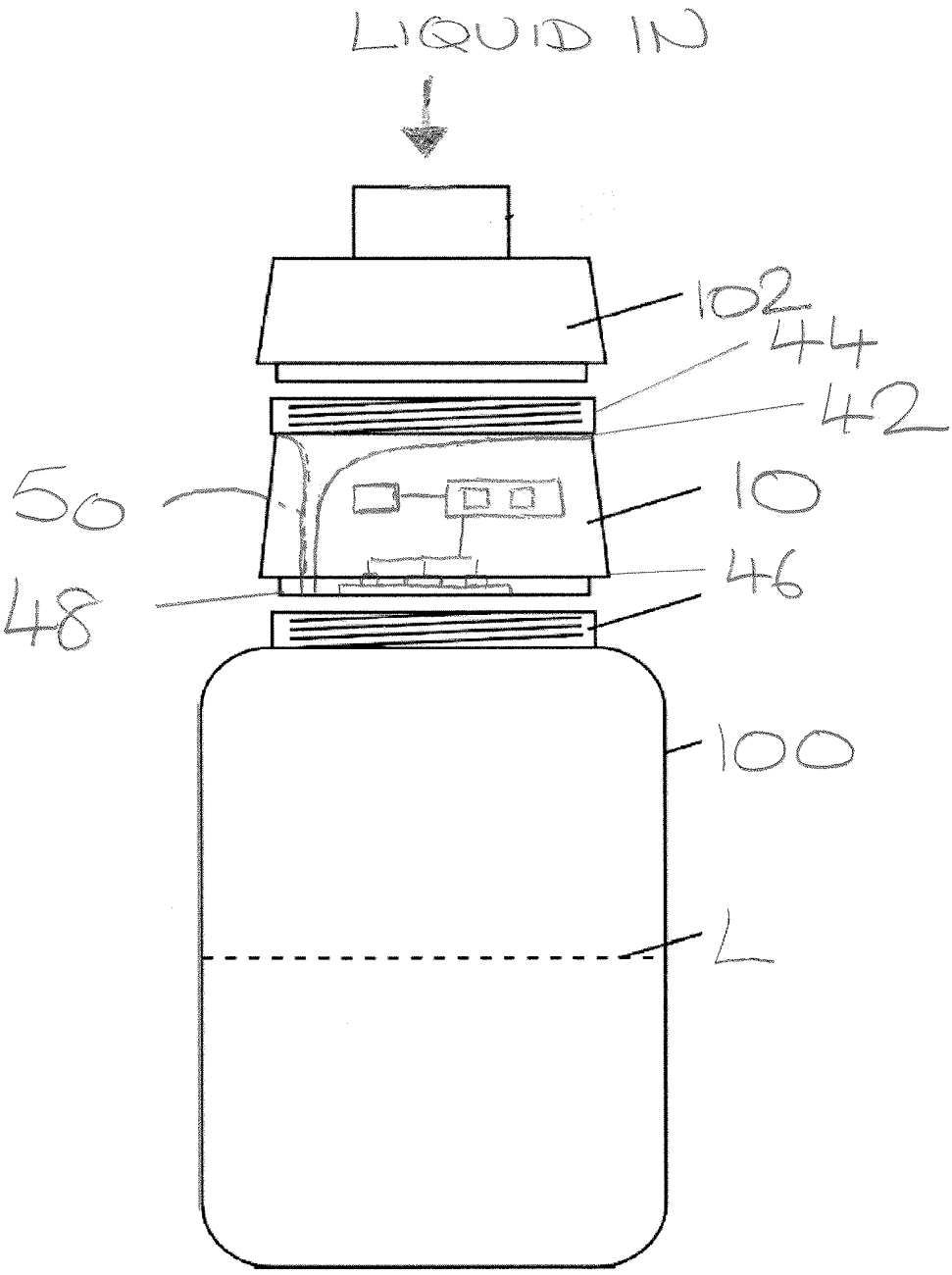


FIG 4.

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Application number GB 1709561.3

1.	Your reference	**MJD/P153994GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BRA CLIP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**

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   Continuation sheets of this form

Description:	**9**
Claim*(s)*:	**3**
Abstract:	**n/a**
Drawing*(s)*:	**7**

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Request for search (Patents Form 9A):	**1**
Request for a substantive examination (Patents Form 10):	**0**
Any other documents (please specify):	**PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

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Fax: 020 7430 7600

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BRA CLIP

BACKGROUND

Many specialised bras (or brassieres) exist for maternity that facilitate nursing and/or breast pumping for milk collection without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pumps comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus connected thereto outside of the bra. These require the user to remove or unbutton any over-garments, and are uncomfortable for use when not pumping.

Integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the applicant has appreciated that the added size of the breast pump means that the combination of the user's breast and the breast pump may no longer fit within the user's regular bra. This is particularly relevant as over-compression of the user's breast will result in the closing of the user's milk ducts and hence reduced expression. To address this, the breast pump of US 2016 206794 A1 has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras. This works by breast milk leaving the breast and enters the bag, and the breast shrinking in a corresponding volume to the expansion of the bag. The inventors consider that this is unlikely to be a perfect 1 to 1 transfer of volume, and hence the compression on the breast may increase as the collapsible bags fill.

In addition to these systems being particularly complex and wasteful, a relatively smaller bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session. Additionally, even this small increase in cup size may make bras less comfortable for the user.

It is our understanding that in the product which has been brought to market based on the disclosure of US 2016 206794 does increase the effective cup size of the wearer by around 2 cup sizes based upon European standard EN 13402 which is discussed later.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with a plurality of attaching means provided along the bra strap for attaching the cups to the strap. The cup can then be attached to different points in order to adjust the support provided. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump.

Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

A maternity bra system is provided according to the present invention comprising: a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point, the system further comprising: a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

This system allows a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present

system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

The clip may be configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point for the adjusted cup size.

The clip may be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip may be extendable between an unextended and an extended state, and attaches to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

An extendable clip like this allows quick switching between the two states in use.

Preferably, the attachment point is on at least one of the shoulder straps. Again this matches the standard system used in most maternity bras.

A clip is provided for use in the system described above according to the present invention. The clip comprising first and section engagement mechanisms and being releasably attachable to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support

structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

DESCRIPTION OF THE FIGURES

The following invention will be described with reference to the following Figures in which:

Figure 1 depicts a prior art design for a maternity bra;

Figures 2A and 2B depict a clip and clasp according to the present invention;

Figures 3A, 3B and 3C depict the clip of Figures 2A and 2B being fitted to a maternity bra according to the present invention;

Figures 4A and 4B depict adjustment of the maternity bra of Figures 3A, 3B and 3C according to the present invention;

Figure 5 depicts an alternative clip for adjustment of a maternity bra according to the present invention;

Figure 6 depicts the alternative clip of Figure 5; and

Figure 7 depicts an alternative clip for adjustment of a maternity bra according to the present invention.

DETAILED DESCRIPTION

As shown in Figure 1, a typical maternity bra 100 comprises a support structure made up of shoulder straps 102 which support the bra 100 on the wearer's shoulders, and a bra band 104 for extending around a user's ribcage, comprising two wings 106 and a

central panel or bridge 108. The straps 102 are typically provided with adjustment mechanisms 103 for varying the length of the straps 102 to fit the bra 100 to the wearer.

At the outermost end of each wing, an attachment region 110 is provided. Typically, hooks 112 and loops 114 are provided for securing the bra 100 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 110 may be provided at the front of the bra 100 in the bridge region 108, with a continuous wing 106 extending continuously around the wearer's back. Typically, a number of sets of loops 114 are provided to allow for variation in the tightness of the bra 100 on the wearer.

While shown as having a separation in Figure 1, the wings 106 and bridge 108 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 1, the shoulder straps 102 and the wings 106 may likewise form a single continuous piece.

The maternity bra 100 is further provided with two breast-supporting cups 116 attached to the support structure. The cups 116 define a cup size, which defines the difference in protrusion of the cups 116 from the band 104. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 116 from the band 104. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups 116 may be stitched to the bra band 102. At least one of the cups 116, is in detachable attachment with the corresponding strap 102. In particular, this is achieved at attachment point 118 where a hook 120 attached to the bra strap 102 engages with a clasp 122 attached to the cup 116. The hook 120 and the bra strap adjuster 103 are set such that in the closed position, the cup size of the bra 100 fits the wearer's breasts. In Figure 1, the left cup 116 is shown attached to its attachment point 118, which the right cup 116 is unattached. In this manner, the wearer is able to detach the cup 116 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 116 is reattached and the maternity bra 100 continues to function as a normal bra.

While in the depicted embodiments, a hook 120 is shown on the bra strap 102 and a clasp 122 is shown on the cup 116, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

In other embodiments, the detachable attachment point 118 may be provided at a different location, such as at the attachment between the bra band 104 and the cup 116. The mechanism for such an attachment point is the same as described above.

Figure 2A and 2B depict a clip 200 according to the present invention, along with a clasp 122 shown in isolation from the bra cup 116 it is normally attached to. The clip 200 is provided with a material pathway 203 which receives a portion of the bra strap 102. In the particular embodiment of these Figures, the clip 200 is substantially U-shaped, with a narrowing profile towards its open end 202. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 200 is designed to be attached to the bra strap 102 in a releasable manner, with the slot 203 acting as a support engaging mechanism. The releasable manner means that the clip 200 may be simply removed from the bra 100 without causing any damage to the functioning of the bra 100. To enhance the ease of attachment, the clip 200 may be provided with outwardly extending wings 204 which help direct the bra strap 102 into the clip 200. The clip 200 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 122.

Figures 3A, 3B and 3C show the clip 200 being attached to a bra strap 102 in order to provide a second attachment point 228 for the clasp 122 to attach to, and hence to provide a second cup size for the bra 100. In this particular embodiment, the clip 200 is attached in a portion of strap 102A below the original attachment point 118 and hence the second attachment point 228 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 200 engages with the support structure in a direction transverse to the direction in which it engages with the cup.

Figures 4A and 4B show how a wearer is able to move between the first and second cup sizes. In Figure 4A, the cup 116 is attached at the first attachment point 118 to provide a first cup size. The wearer then disengages the clasp 122 from the hook 120 at the first engagement point 118. As shown in Figure 4B, the clasp 122 is then engaged with

the hook 220 at the second engagement point 218. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 5 and 6 show an alternative design for a clip 300. This clip 300 is substantially "E-shaped", with a back portion 301 and first, second and third prongs 303A, 303B, 303C extending transverse from this back portion 301. The three prongs 303A, 303B, 303C are spaced apart along the length of the back portion 301. The first and third prongs 303A, 303C are provided with attachment clips 305A, 305B.

These attachment clips 305A, 305B are engageable with the clasp 122 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 305A, 305B will be used to attach the clasp 122 of the bra. By providing these clips 305A, 305B on both of the first and the third prongs 303A, 303C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 300 is also symmetrical, to aid the reversibility of the clip 300.

Figure 6 shows the clip 300 attached to a bra. As can be seen, the first and third prongs 303A, 303C extend on the front side of the bra strap, with the second prong 303B extending on the rear side of the bra strap. In this manner, the clip 300 is attached to the strap. In preferably embodiments, a grip-enhancing member 307 such as a number of projections and/or roughened patches can be provided on the second prong 303B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 303B. In such an arrangement, the centremost prong 303B would be on the outside of the bra, with the first and third prongs 303A, 303C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options. This allows the use of integrated wearable breast pumps which increase the user's cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. As such, the present invention allows a

user to discretely switch between the two configurations, and insert the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

An alternative embodiment may be provided, with an extendable clip as shown in Figure 7. In such an embodiment the clip is attached to the hook 120 on the strap 102 in a releasable manner, with the clasp 122 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 122 is held in substantially the same position as the first attachment point 118 to provide the first cup size, and an expanded state, where the clasp 122 is held in a second position away from the first attachment point 118 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 120 is provided at the first end, and a second attachment point for attaching to the clasp 122 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 122 is held in substantially the same location as the first attachment point 118 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 118 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

CLAIMS:

1. A maternity bra system comprising:

a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

the system further comprising:

a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

2. The maternity bra system of claim 1, wherein the clip is configured to be attached to the support structure at a position away from the attachment point.

3. The maternity bra system of claim 2, wherein the clip is attachable to the support structure at a plurality of non-discrete positions.

4. The maternity bra system of claim 1, wherein:

the clip is extendable between an unextended and an extended state, and attaches to the support structure at the attachment point;

the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state;

the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

5. The maternity bra system of any preceding claim, wherein the attachment point is on at least one of the shoulder straps.

6. The maternity bra system of any preceding claim, wherein the second cup size is larger than the first cup size.

7. A clip for use in a system according to any preceding claim, the clip comprising first and section engagement mechanisms and being attachable in a releasable manner to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

8. The maternity bra system or clip of any preceding claim, wherein the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction.

9. The maternity bra system of clip of any preceding claim, wherein the second engagement mechanism is one or more of a hook or a snap or a clip.

10. The maternity bra system or clip of any preceding claim, wherein the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip.

11. The maternity bra system or clip of any preceding claim, wherein the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra.

12. The maternity bra system or clip of claim 11, wherein the clip is substantially U-shaped, and the material pathway is between the arms of the U.

13. The maternity bra system or clip of any of claims 1 to 11, wherein the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism.

14. The maternity bra system or clip of claim 13, wherein both outer prongs are each provided with a respective second engagement mechanism.

15. A method of adjusting the cup size of a maternity bra, comprising:

providing a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

providing a clip comprising first and section engagement mechanisms;

attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra;

attaching one of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

16. The method of claim 15, further comprising the step of inserting a breast pump into the one of the detachable cup.

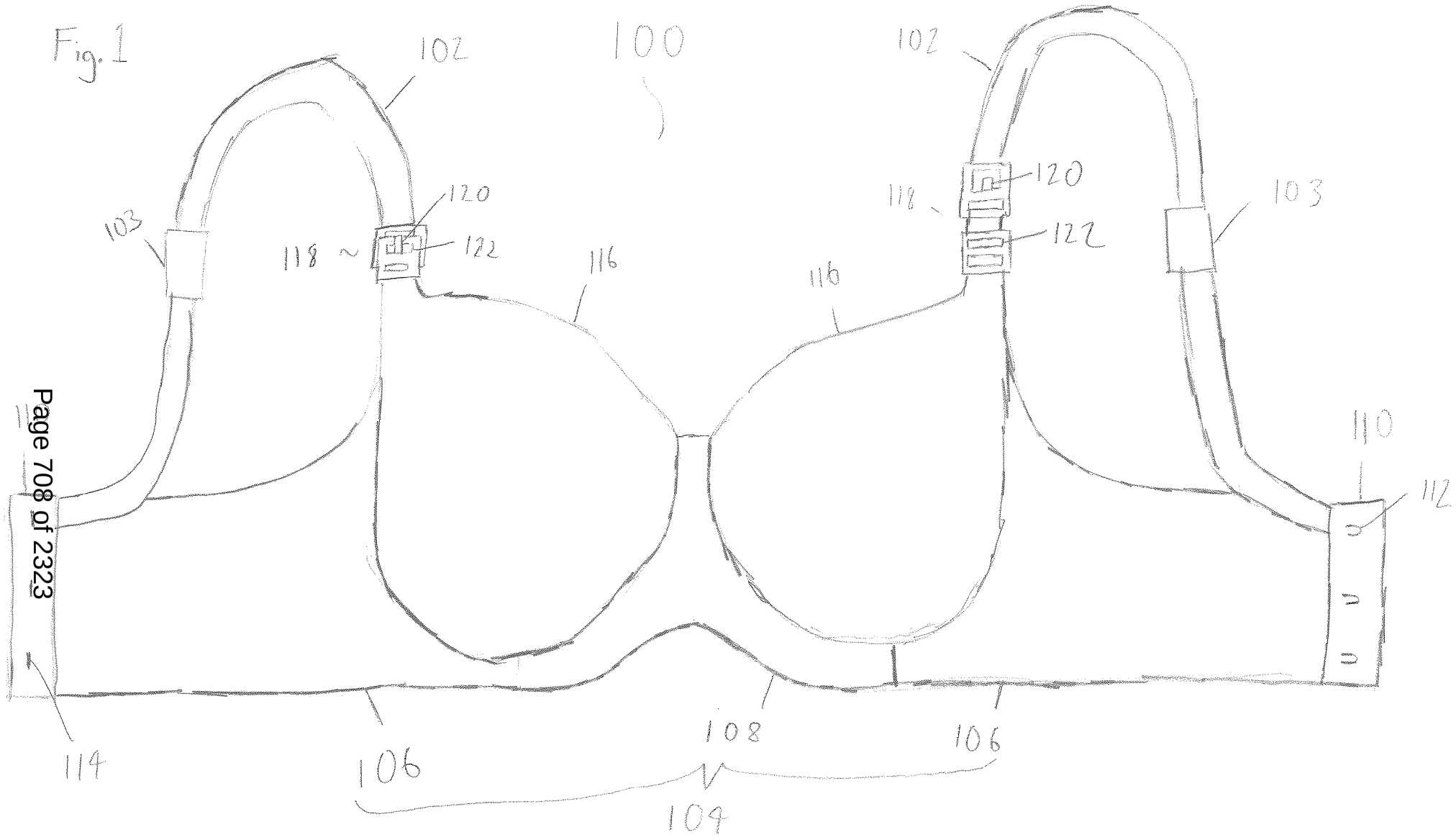
17. The method of claim 15 or 16, further comprising the steps of:

detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra;

attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and

attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

Fig. 1



PRIOR ART

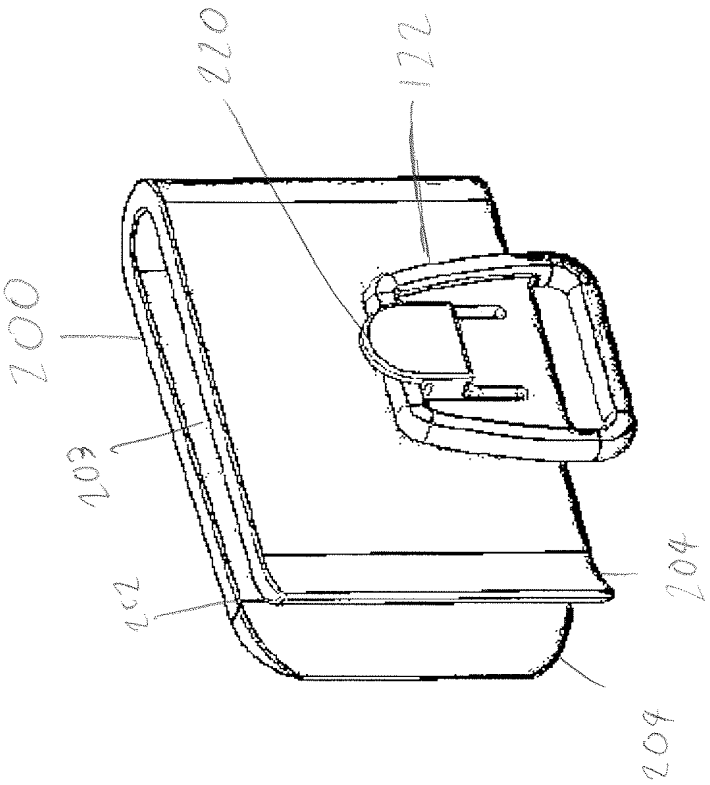


Fig 2B

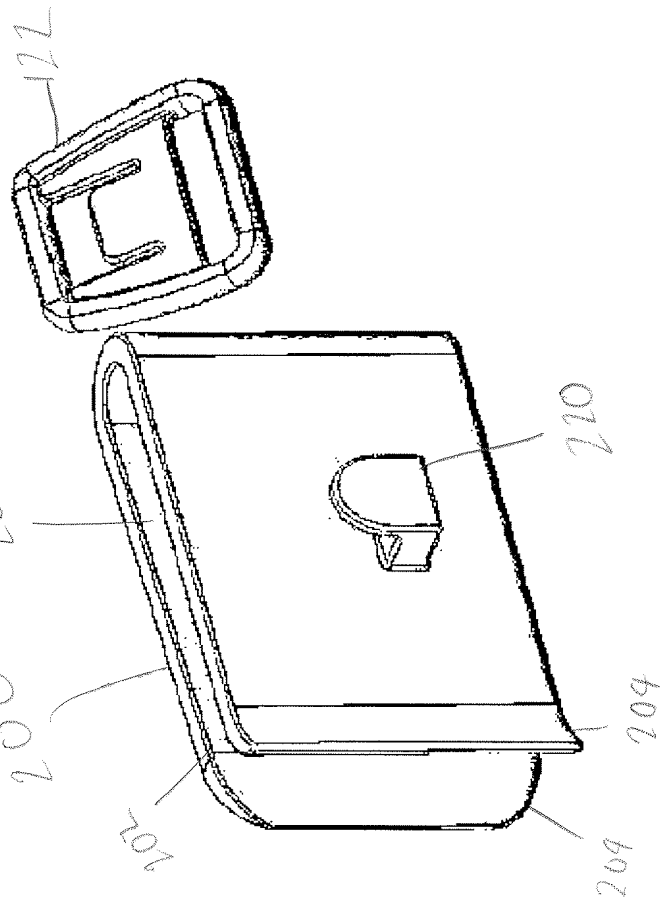


Fig 2A

Fig. 3A

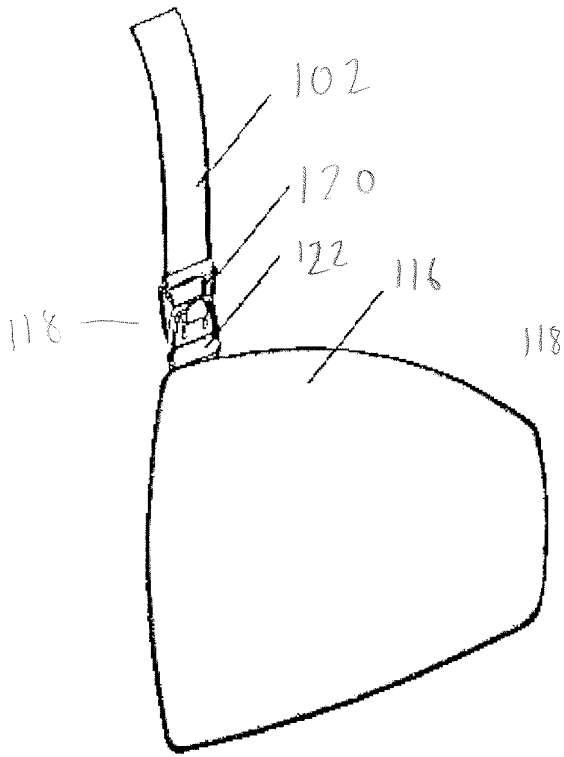


Fig. 3B

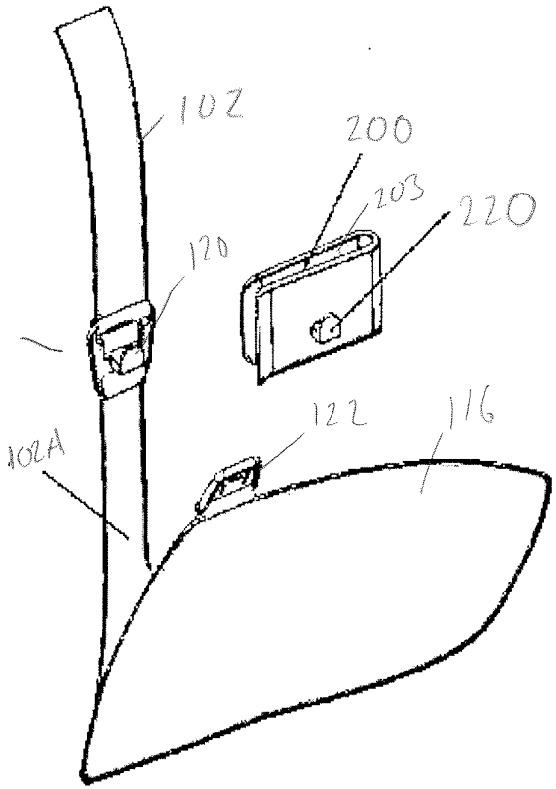


Fig. 3C

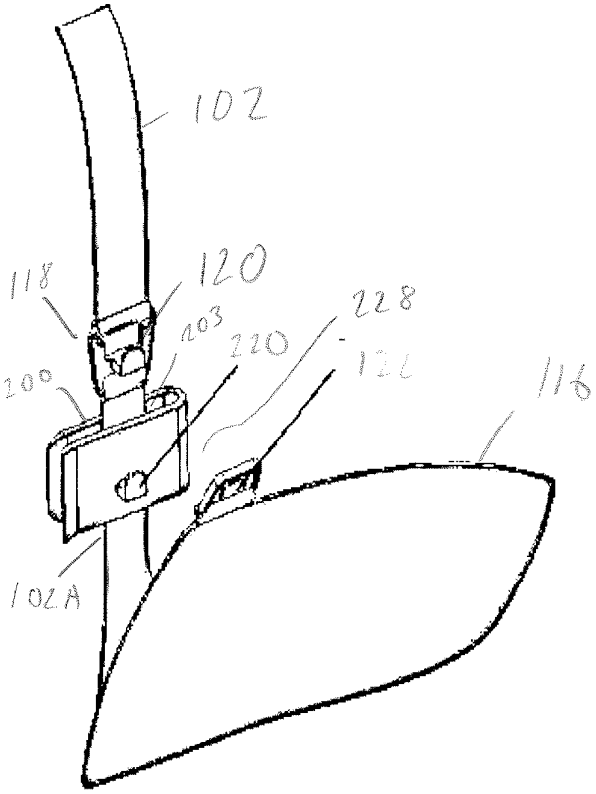


Fig. 4A

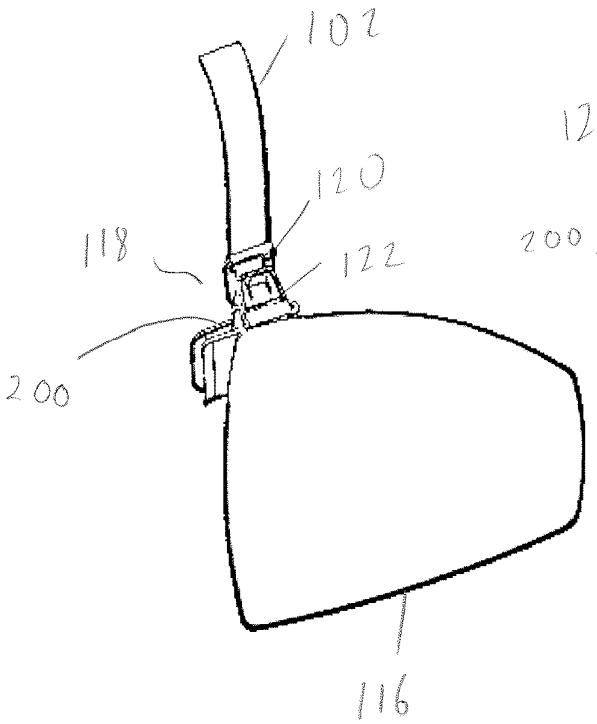
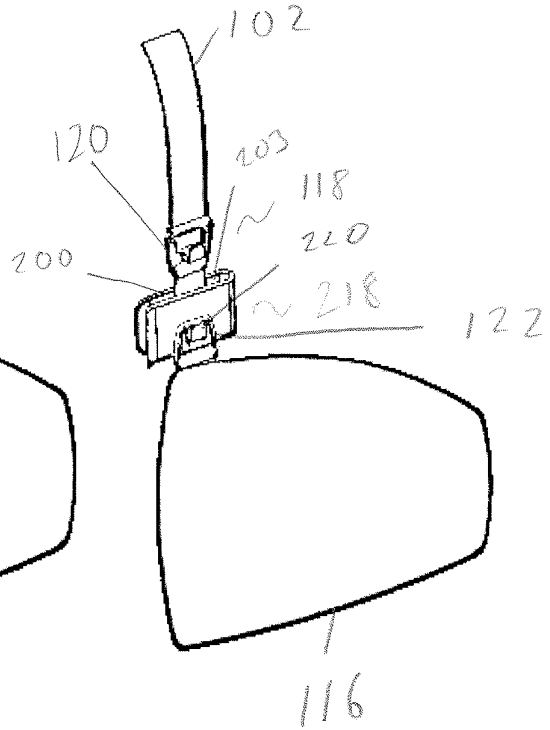


Fig. 4B



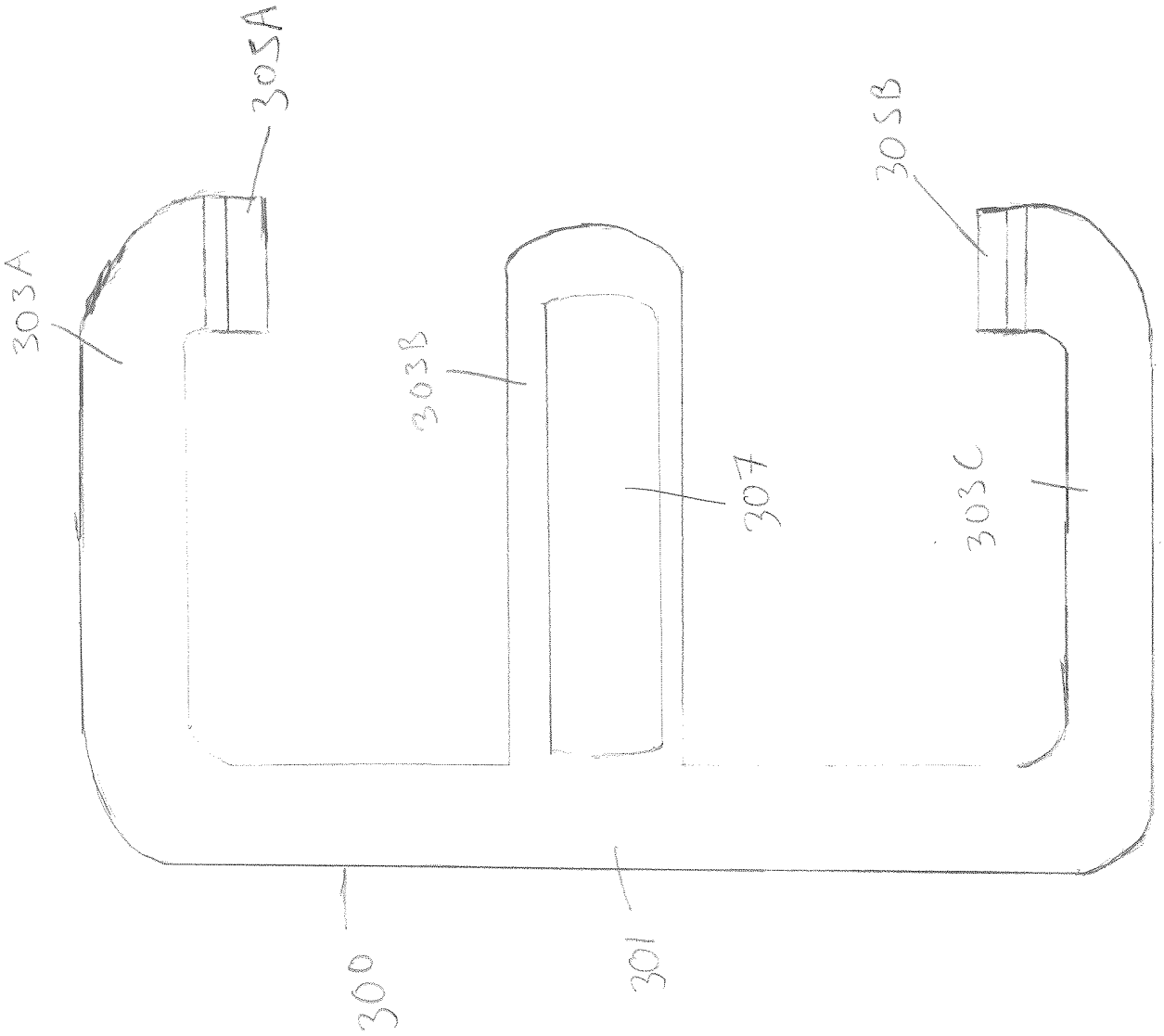


Fig. 5

6/7

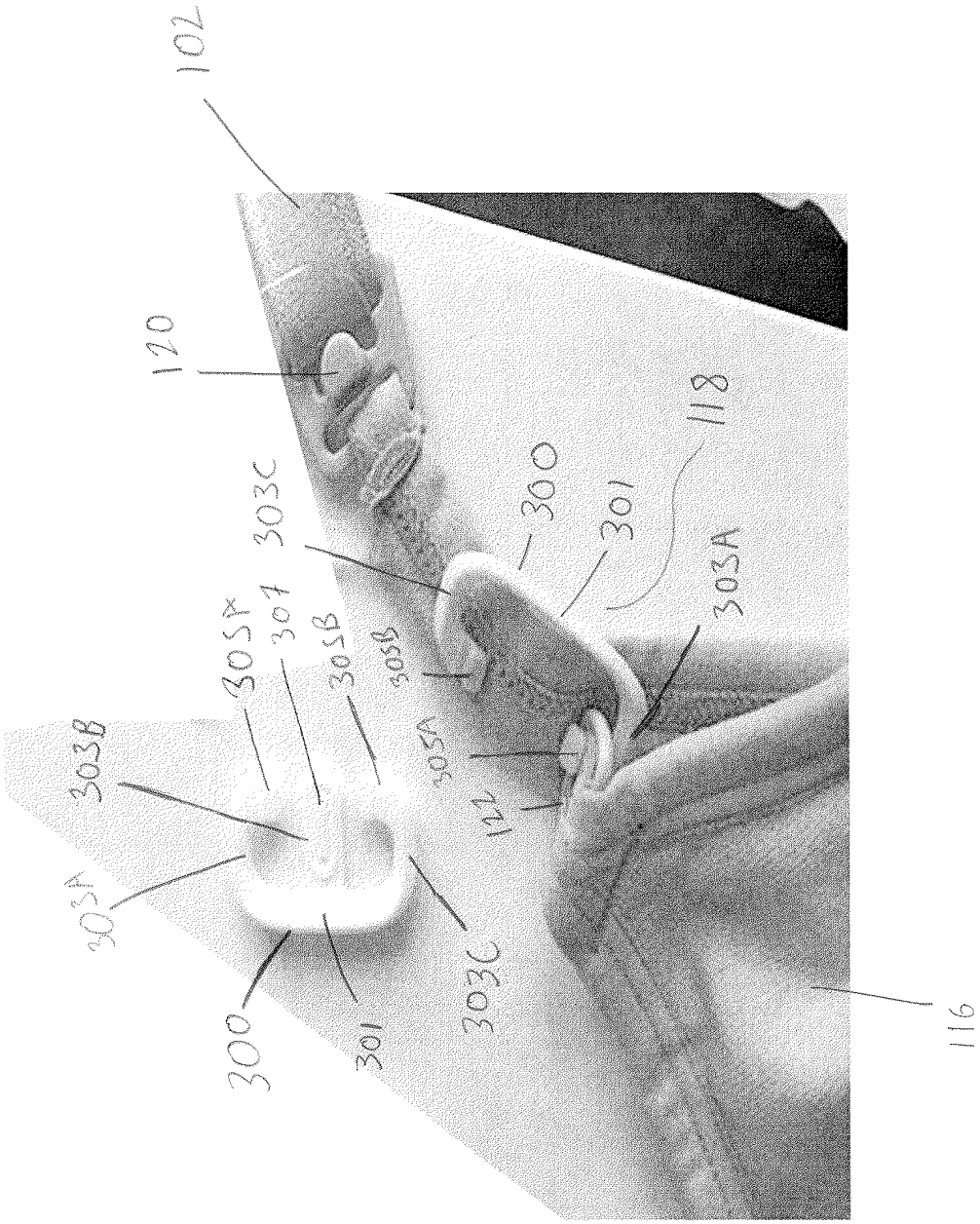
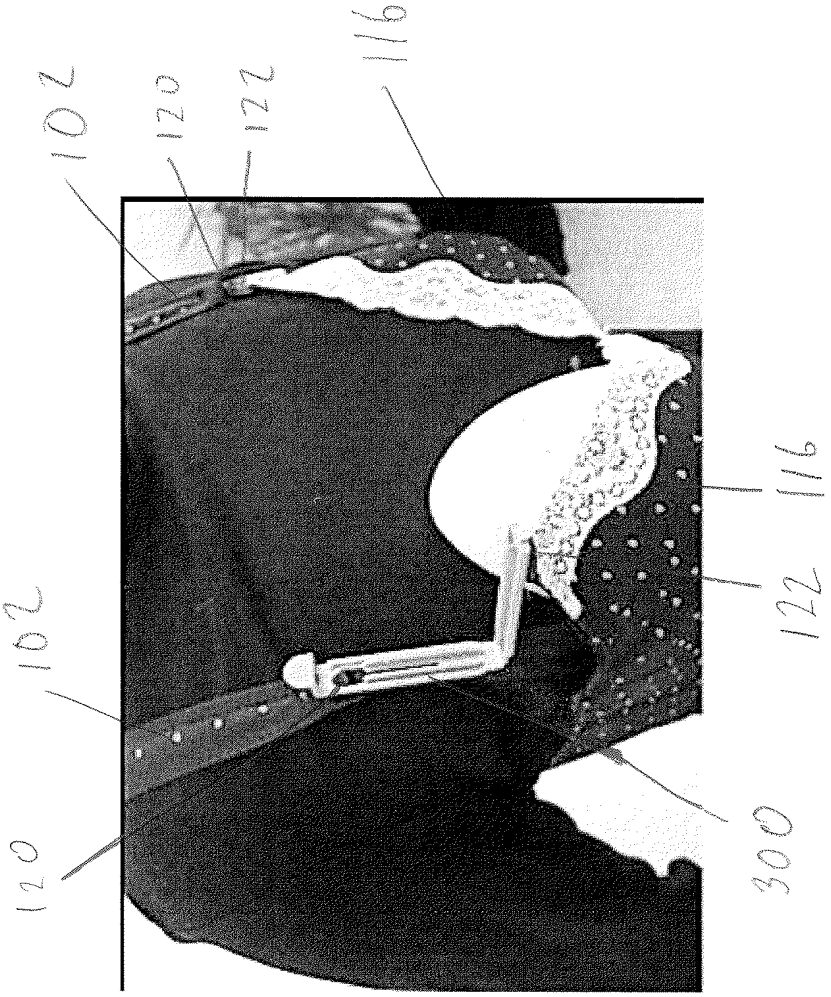

102
120
303C
300
301
118
303A
303B
305A
112
305B
301
305C
300
303A
303B
116

Fig 6

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Fig 7



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/009,547	06/15/2018	Jonathan O'TOOLE	373499.00002

CONFIRMATION NO. 5958

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

INFORMAL NOTICE

OC000000100832314

Date Mailed: 07/11/2018

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Jonathan O'TOOLE
  Adam ROLLO
  Andrew CARR

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/ngfissha/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/009,547

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 =	* 10	x 50 =	500	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			200			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1485		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/009,547	06/15/2018	3763	1565	373499.00002	30	1

CONFIRMATION NO. 5958

FILING RECEIPT

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC000000100832312

Date Mailed: 07/11/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jonathan O'TOOLE, London, UNITED KINGDOM;
Adam ROLLO, London, UNITED KINGDOM;
Andrew CARR, London, UNITED KINGDOM;

Applicant(s)

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM;

Power of Attorney: None

Domestic Applications for which benefit is claimed - None.
A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
UNITED KINGDOM 1709561.3 06/15/2017 Access Code Provided
UNITED KINGDOM 1709564.7 06/15/2017 Access Code Provided
UNITED KINGDOM 1709566.2 06/15/2017 Access Code Provided
UNITED KINGDOM 1809036.5 06/01/2018 No Access Code Provided

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 07/09/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/009,547**
Projected Publication Date: 12/20/2018
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

BREAST PUMP SYSTEM

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative,

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jonathan O'TOOLE	Nonprovisional Application Number (if known):	
Title of Invention:	BREAST PUMP SYSTEM		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Mark D. Simpson/	Date 2018-06-15
Name (Print/Typed) Mark D. Simpson	Practitioner Registration Number 32942

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
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Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

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State/Province	
Postal Code	EC1N 8LE
Country i	GB

Inventor 3 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		CARR	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

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Mailing Address of Inventor:

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Address 2	63-66 Hatton Garden		
City	London	State/Province	
Postal Code	EC1N 8LE	Country [i]	GB

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	78905		
Email Address	patents@saul.com	Add Email	Remove Email

Application Information:

Title of the Invention	BREAST PUMP SYSTEM		
Attorney Docket Number	373499.00002	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	44	Suggested Figure for Publication (if any)	1

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country [i]

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	78905		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)	
1709561.3	GB	2017-06-15	1DE1	Remove
1709564.7	GB	2017-06-15	B3B5	Remove
1709566.2	GB	2017-06-15	D6F6	Remove
1809036.5	GB	2018-06-01		Remove

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	CHIARO TECHNOLOGY LIMITED		
Mailing Address Information For Applicant:			
Address 1	63-66 Hatton Garden		
Address 2			
City	London	**State/Province**	
Country	GB	Postal Code	EC1N 8LE
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
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Signature:

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NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Mark D. Simpson/			Date (YYYY-MM-DD)	2018-06-15
First Name	Mark D.	Last Name	Simpson	Registration Number	32942

Additional Signature may be generated within this form by selecting the Add button. Add

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00002
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is based on, and claims priority to, GB Application No. 1709561.3, filed June 15, 2017; GB Application No. 1709564.7, filed on June 15, 2017; GB Application No. 1709566.2, filed on June 15, 2017; and GB Application No. 1809036.5, filed on June 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a

pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is

needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being

worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as

previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

5

SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2…IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2…IRn.

By comparing the emitted radiation intensities IE1; IE2…IEn with the received radiation intensities IR1; IR2…IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2…IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6gm and may, with material and design improvements, weigh less than 6gm.

In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In

this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore

connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing,

and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

CLAIMS

1. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

2. The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. The wearable breast pump system of Claim 1, in which the piezo air-pump is positioned at or close to the base of the housing.

4. The wearable breast pump system of Claim 1, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. The wearable breast pump system of Claim 1, in which the deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of the breast shield.

8. The wearable breast pump system of Claim 1, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. The wearable breast pump system of Claim 1, in which the deformable diaphragm is a flexible generally circular diaphragm that removably sits over a diaphragm housing that is an integral part of the breast shield.

10. The wearable breast pump system of Claim 1, in which a diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. The wearable breast pump system of Claim 1, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. The wearable breast pump system of Claim 1, in which the piezo air-pump weighs less than 10gm.

13. The wearable breast pump system of Claim 1, in which, in normal operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

14. The wearable breast pump system of Claim 1, in which the piezo air-pump is fed by air that passes through an air filter.

15. The wearable breast pump system of Claim 1, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

16. The wearable breast pump system of Claim 1, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. The wearable breast pump system of Claim 1, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. The wearable breast pump system of Claim 1, in which the housing includes a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. The wearable breast pump system of Claim 1, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. The wearable breast pump system of Claim 1, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. The wearable breast pump system of Claim 1, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

22. The wearable breast pump system of Claim 1, in which the centre of gravity of the pump system is, when a milk container attached to the housing is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

23. The wearable breast pump system of Claim 1, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. The wearable breast pump system of Claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. The wearable breast pump system of Claim 1, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. The wearable breast pump system of Claim 1, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. The wearable breast pump system of Claim 1, including a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. The wearable breast pump system of Claim 1, including a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. The wearable breast pump system of Claim 1, in which the breast shield includes a nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and the system includes a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

30. The wearable breast pump system of Claim 1, including a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

ABSTRACT

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

Figure 1.

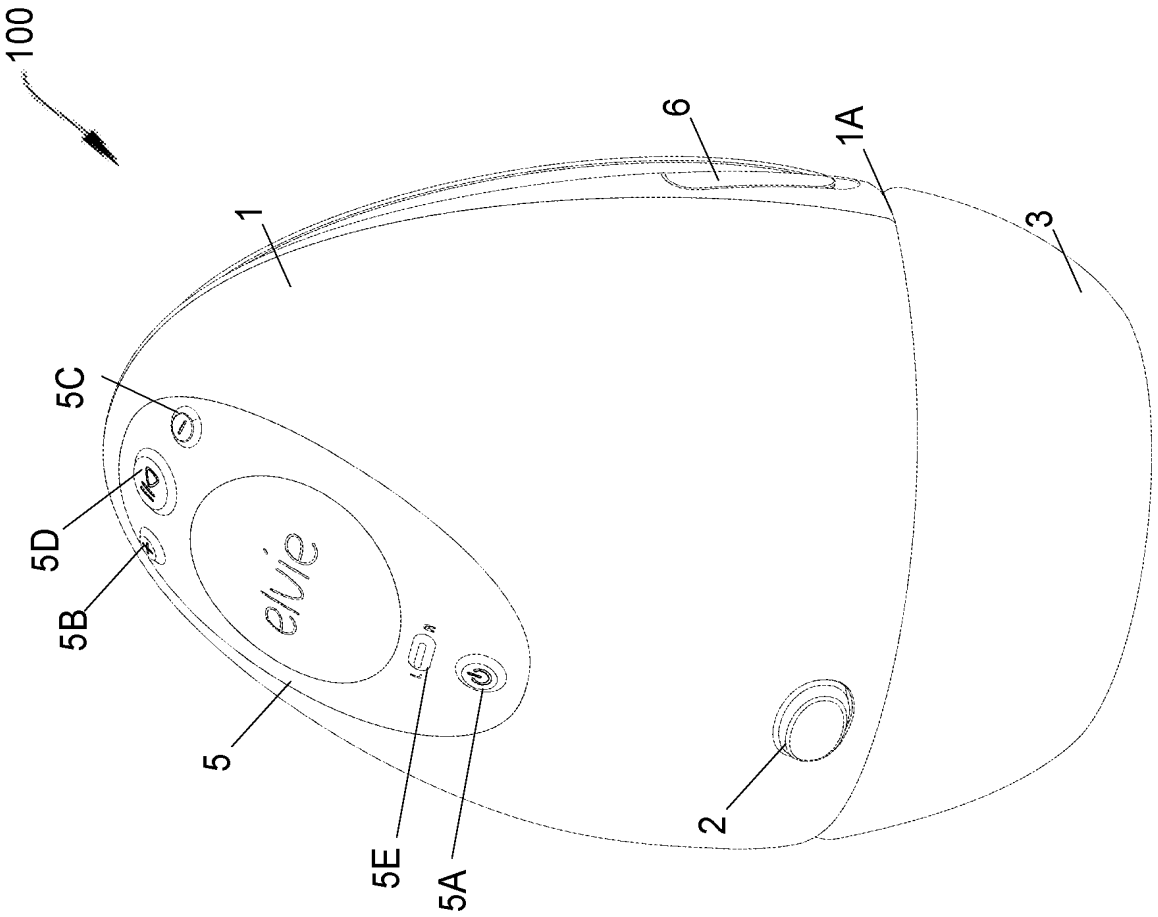


FIGURE 1

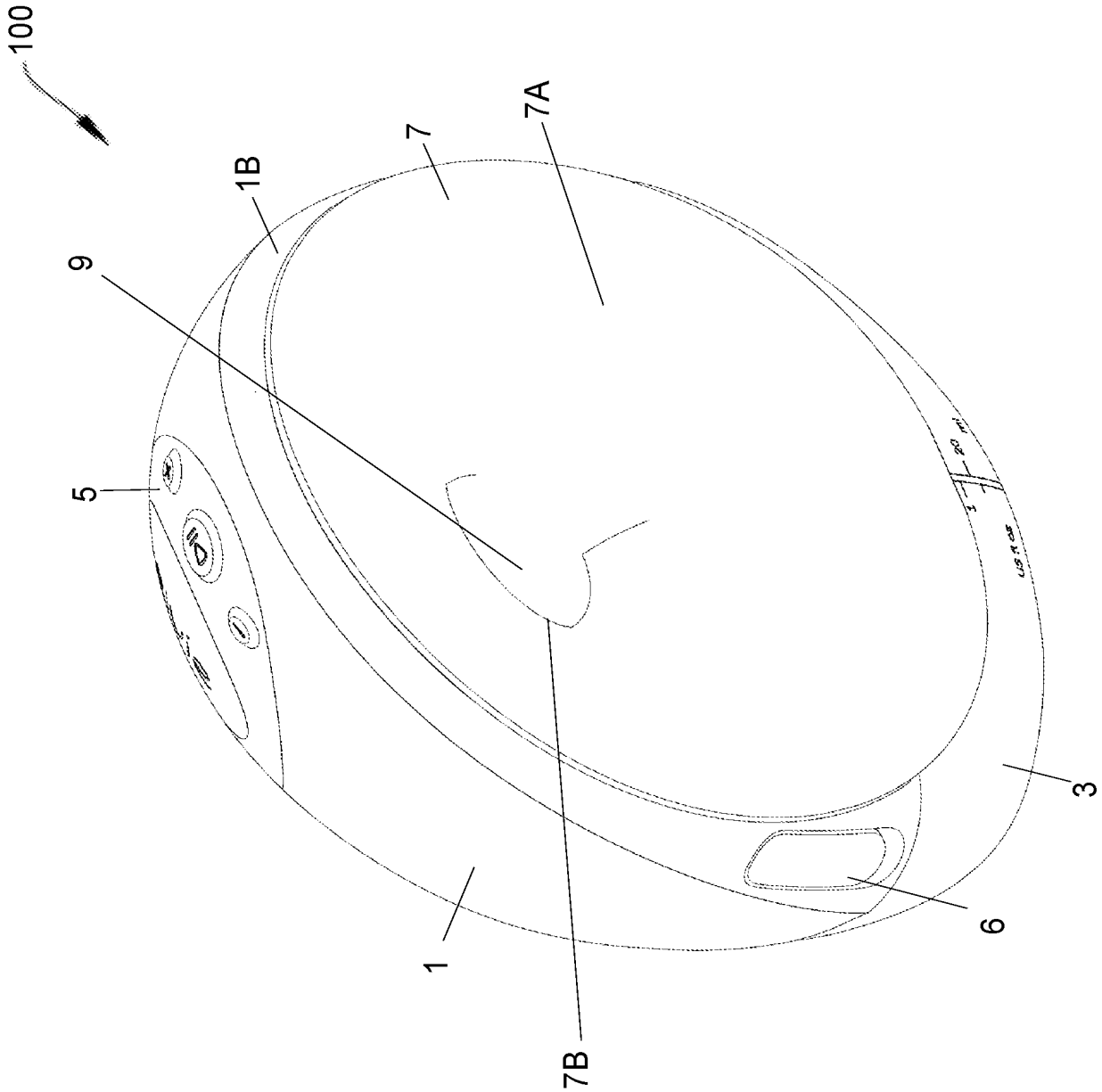


FIGURE 2

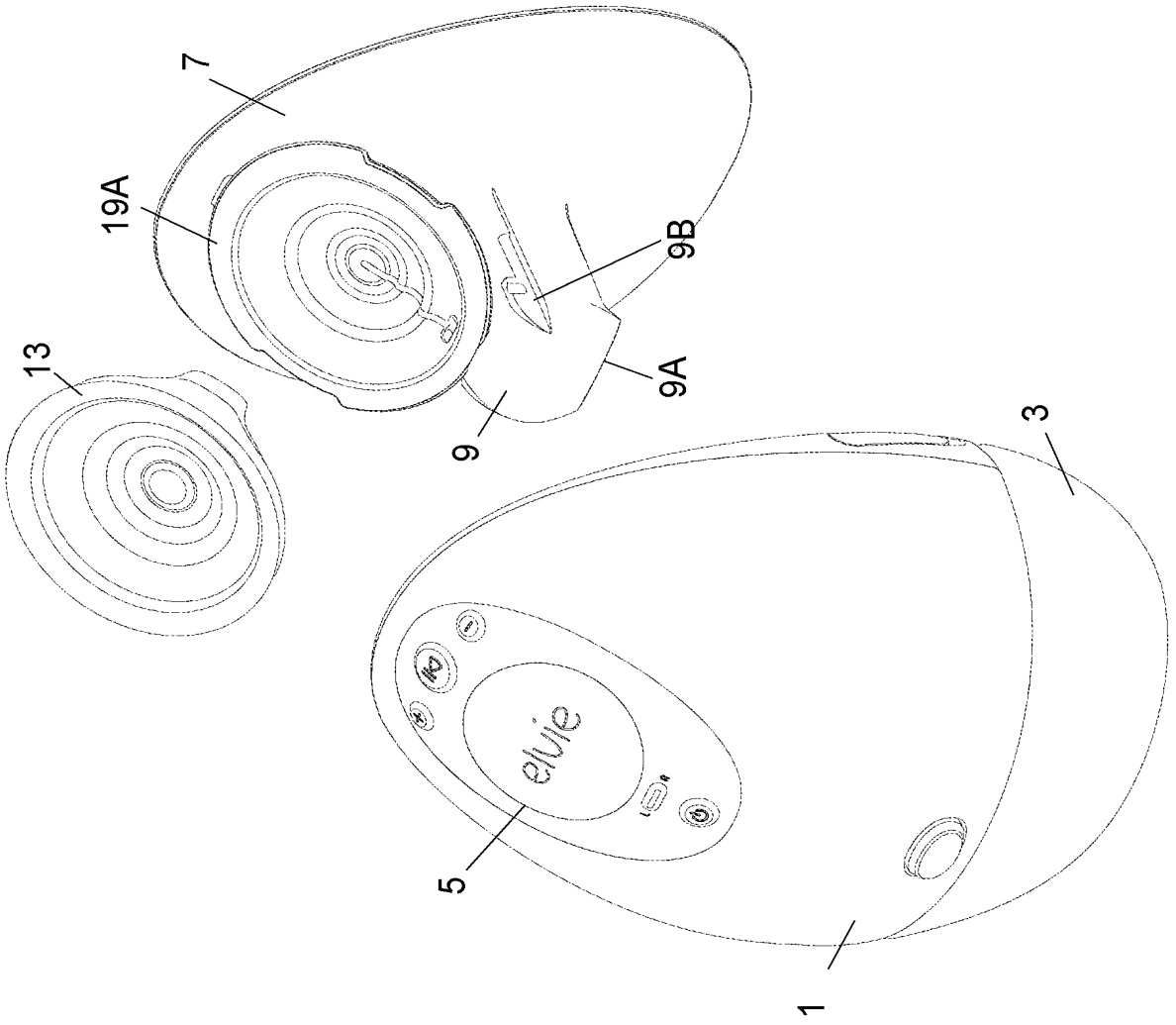


FIGURE 3

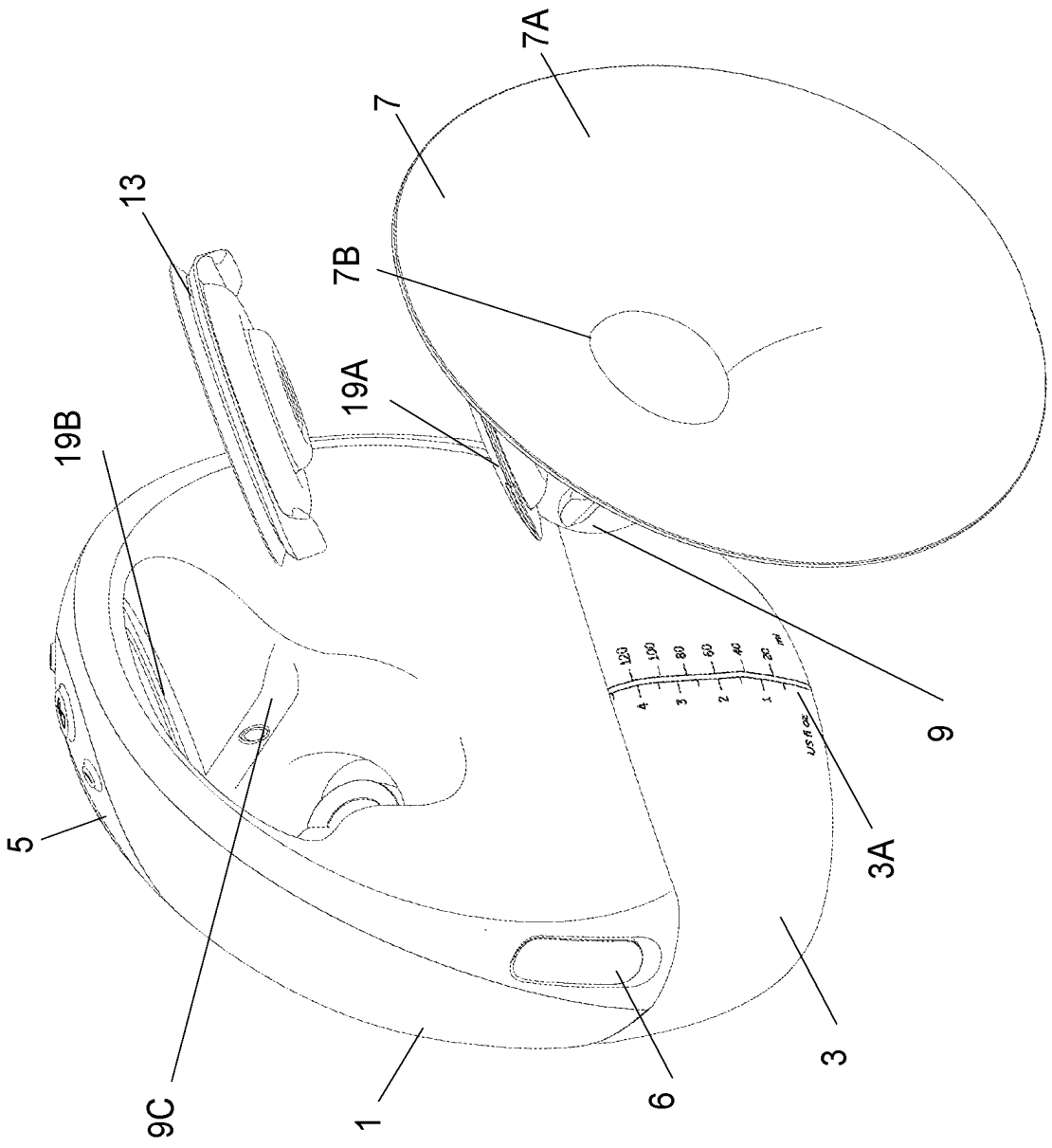


FIGURE 4

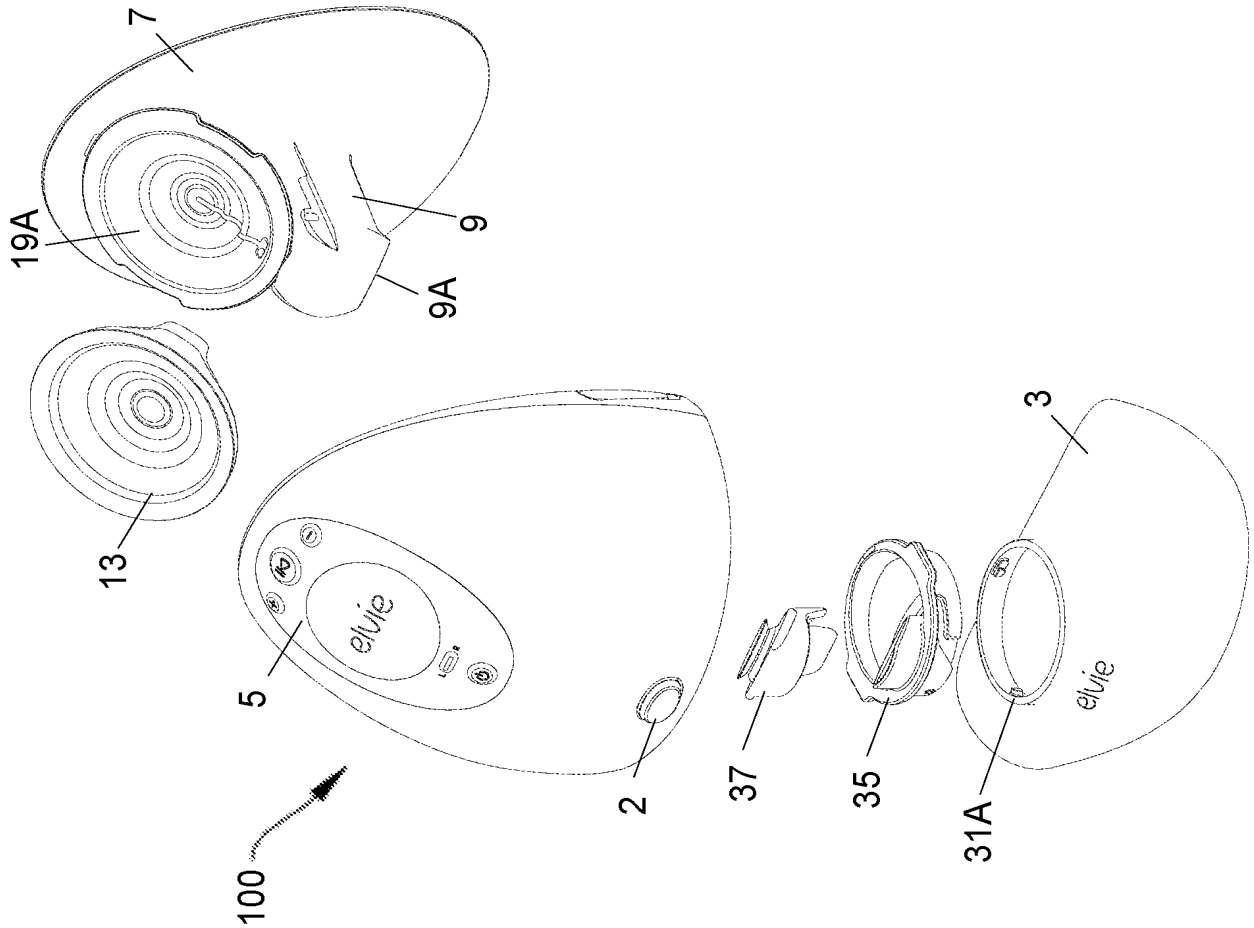


FIGURE 5

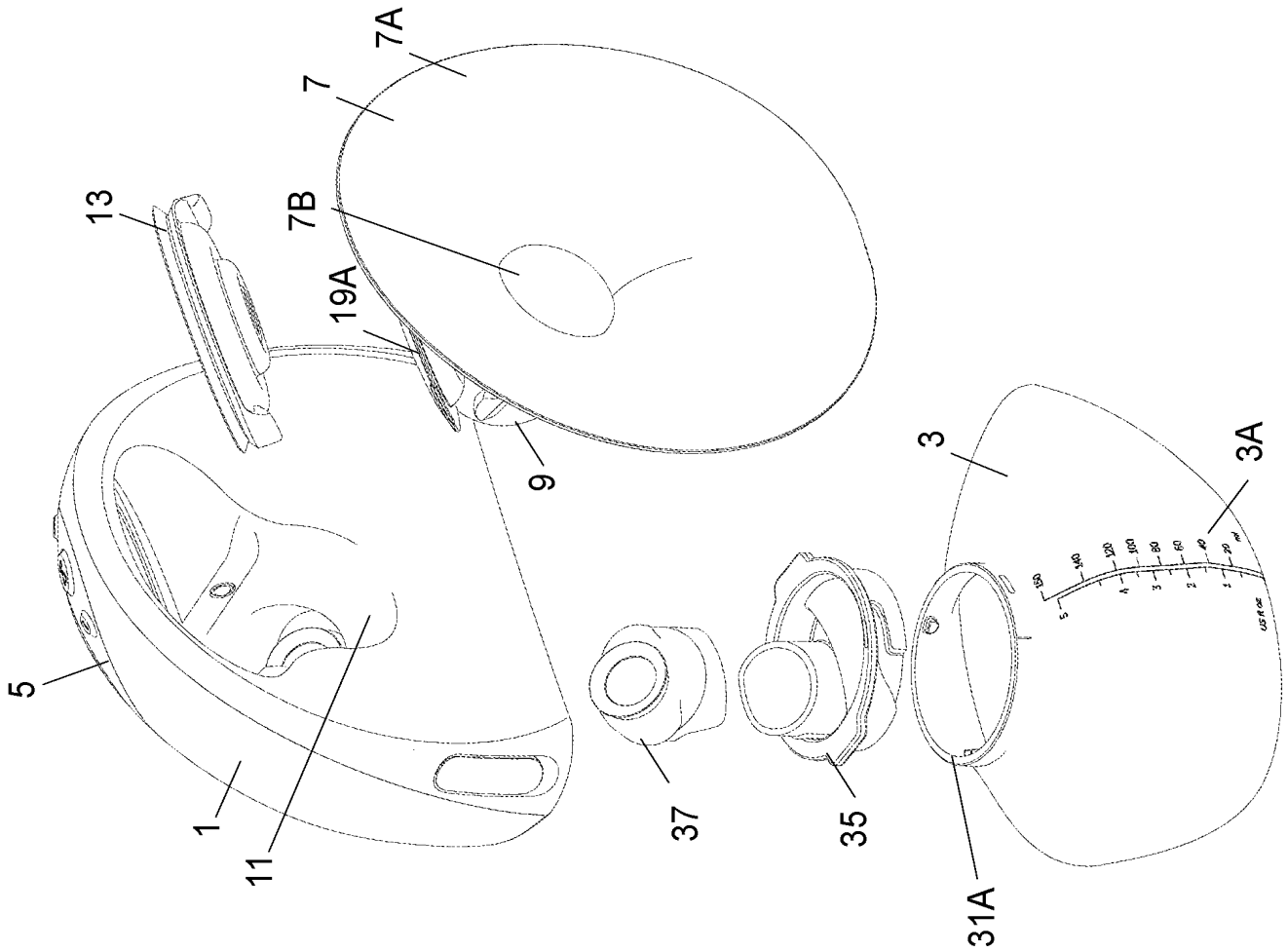


FIGURE 6

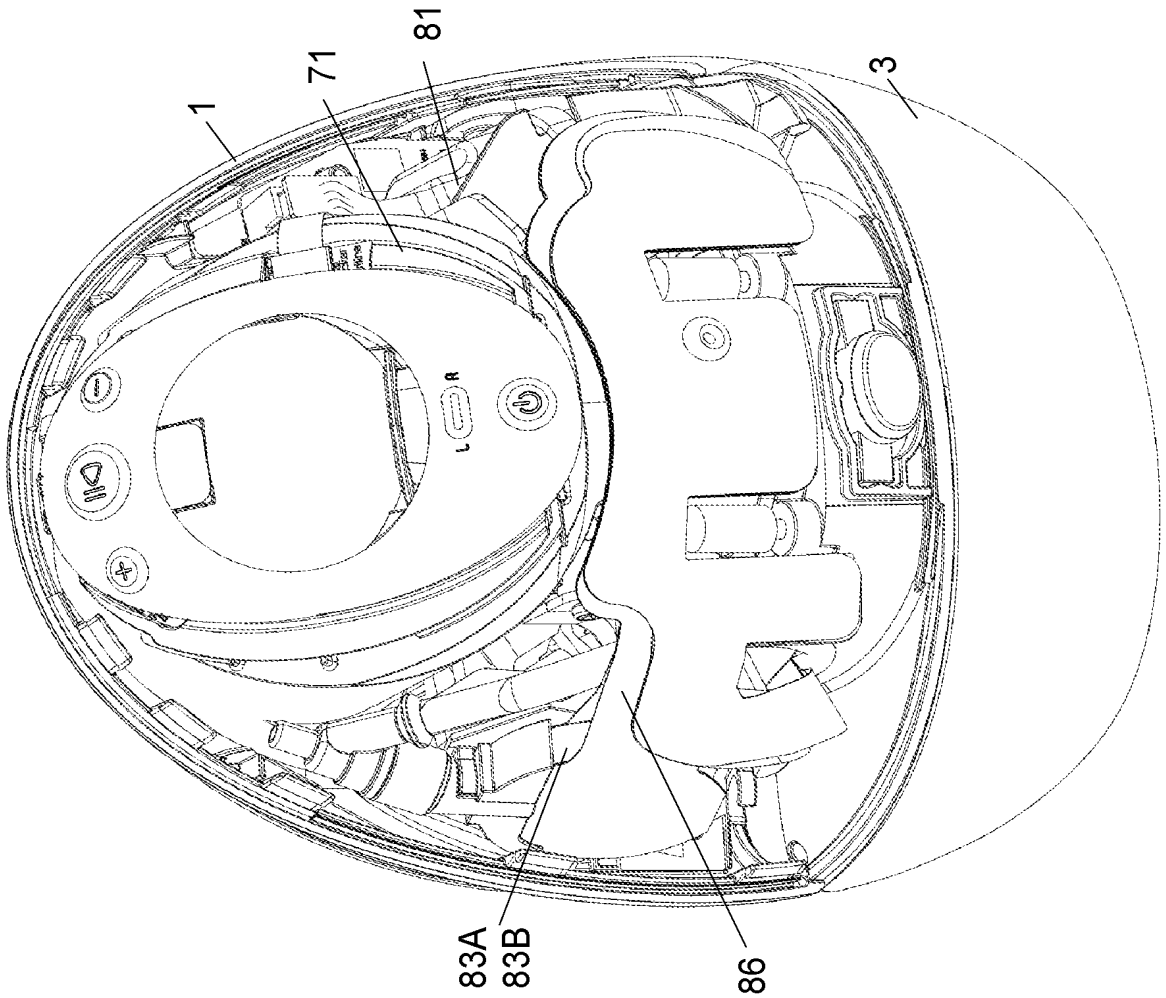


FIGURE 7

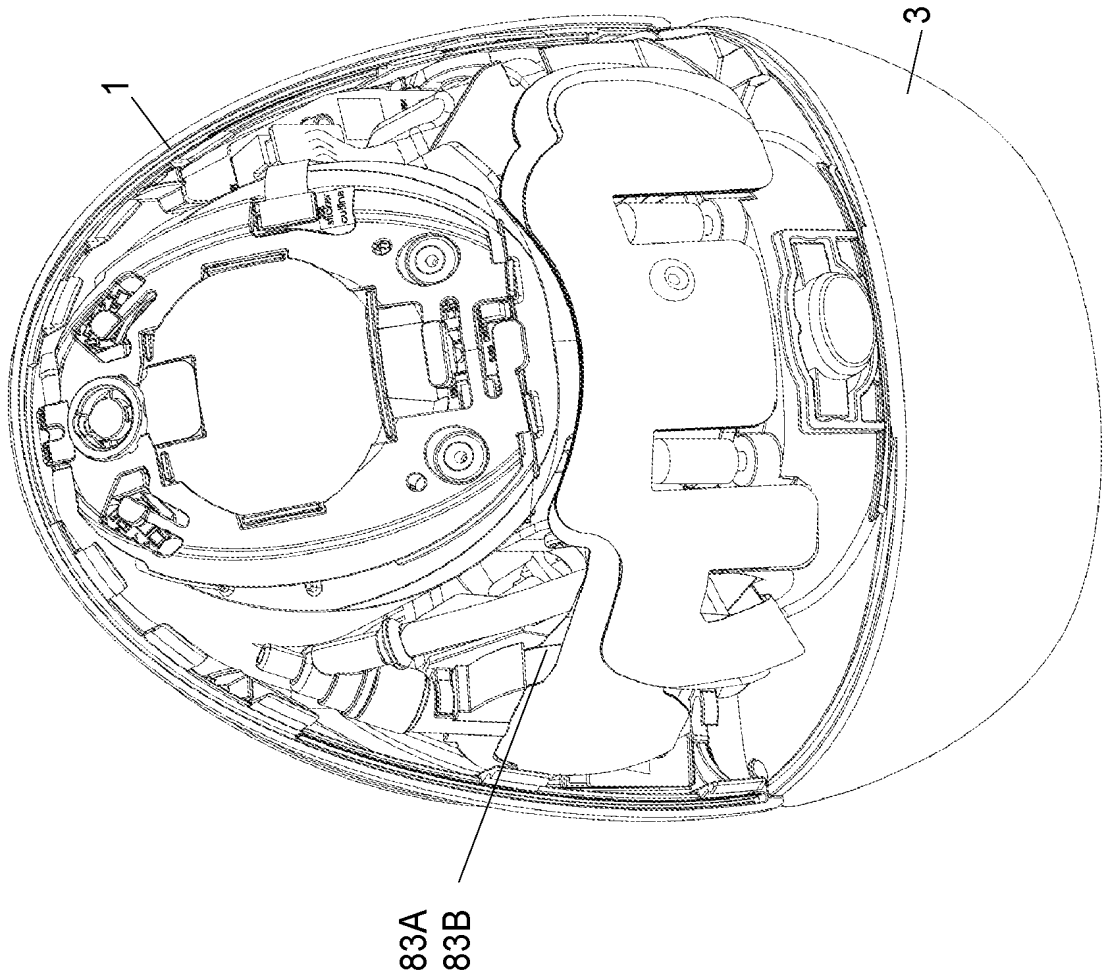


FIGURE 8

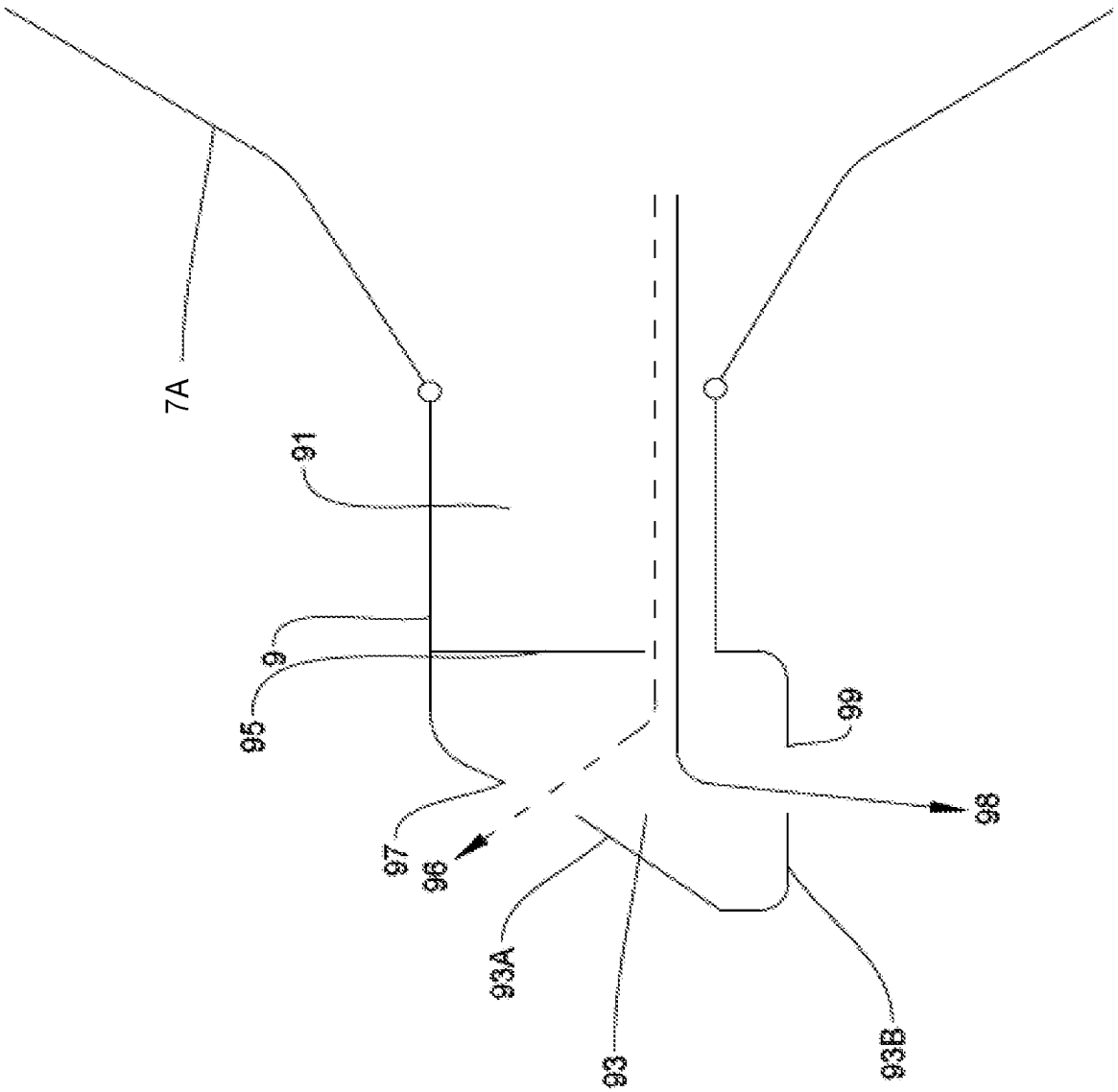


FIGURE 9

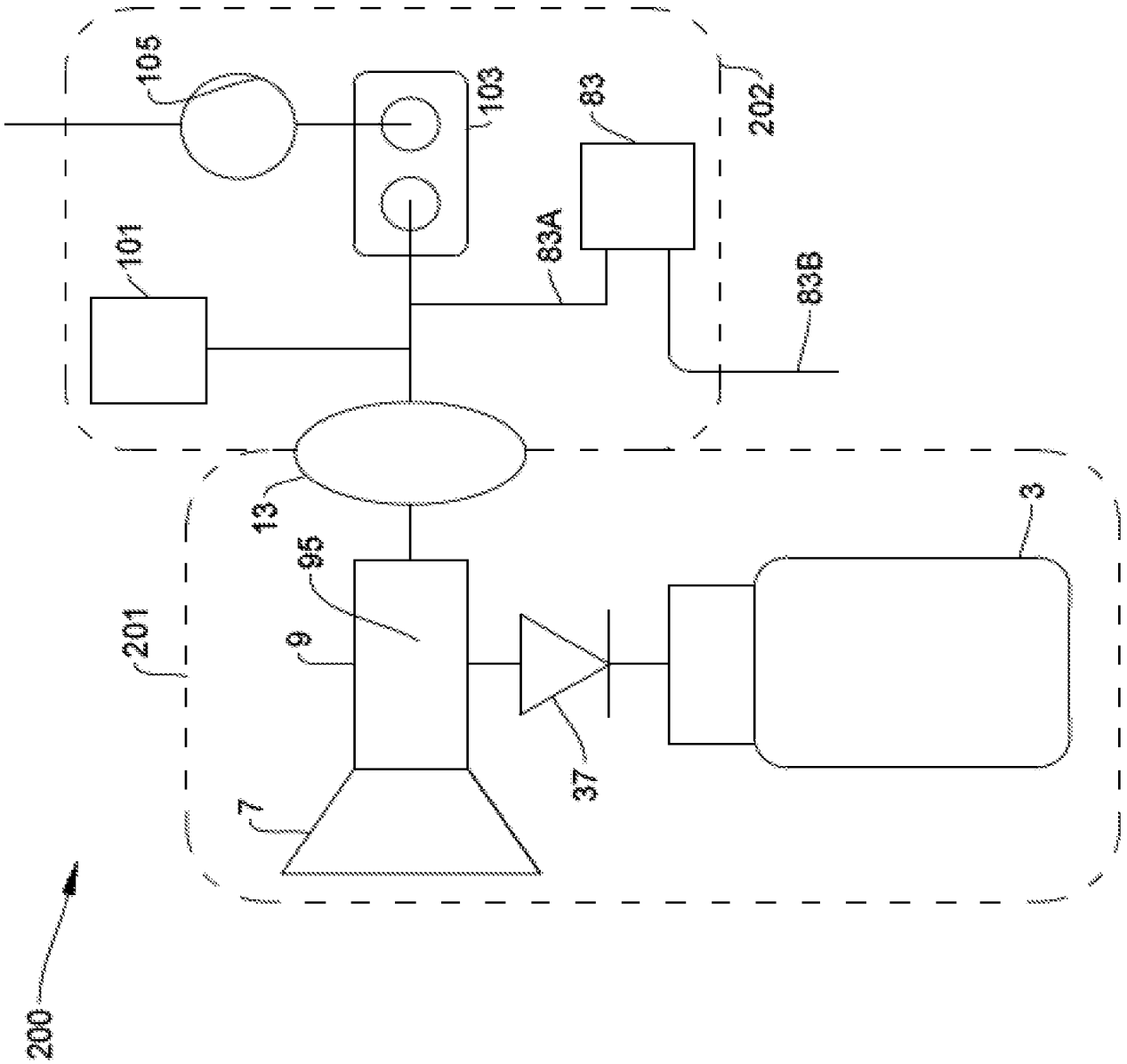


FIGURE 10

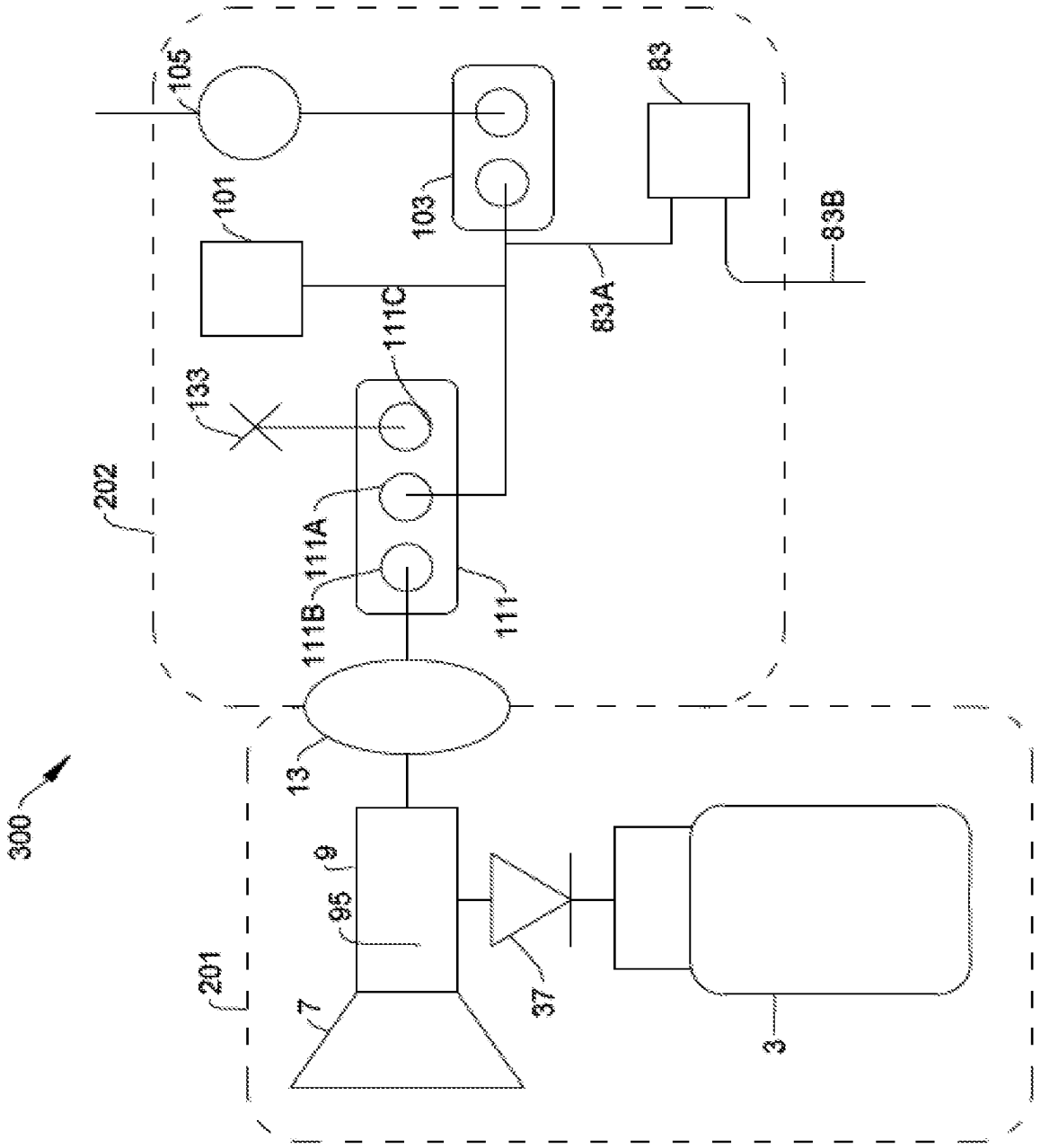

300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

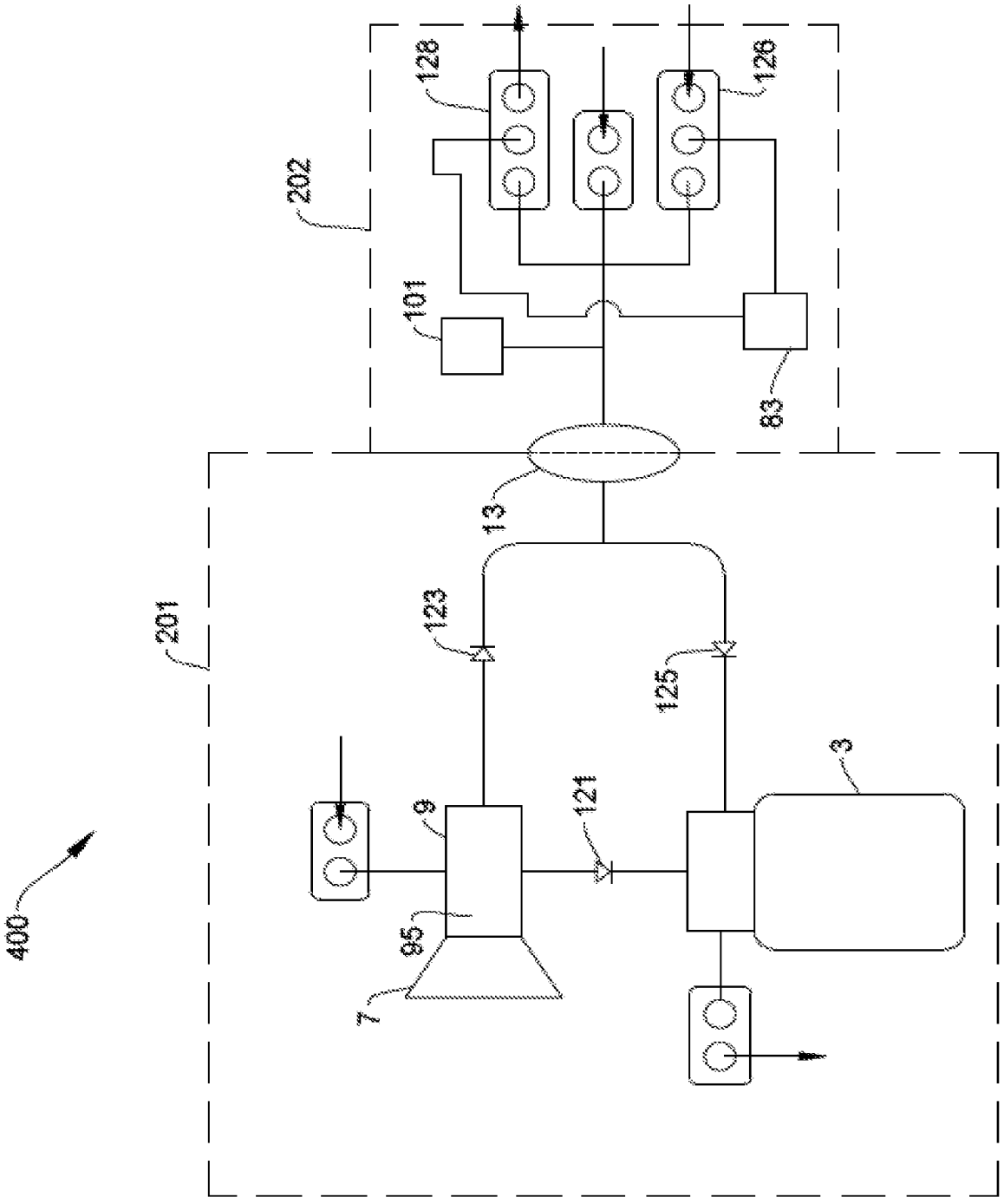


FIGURE 12

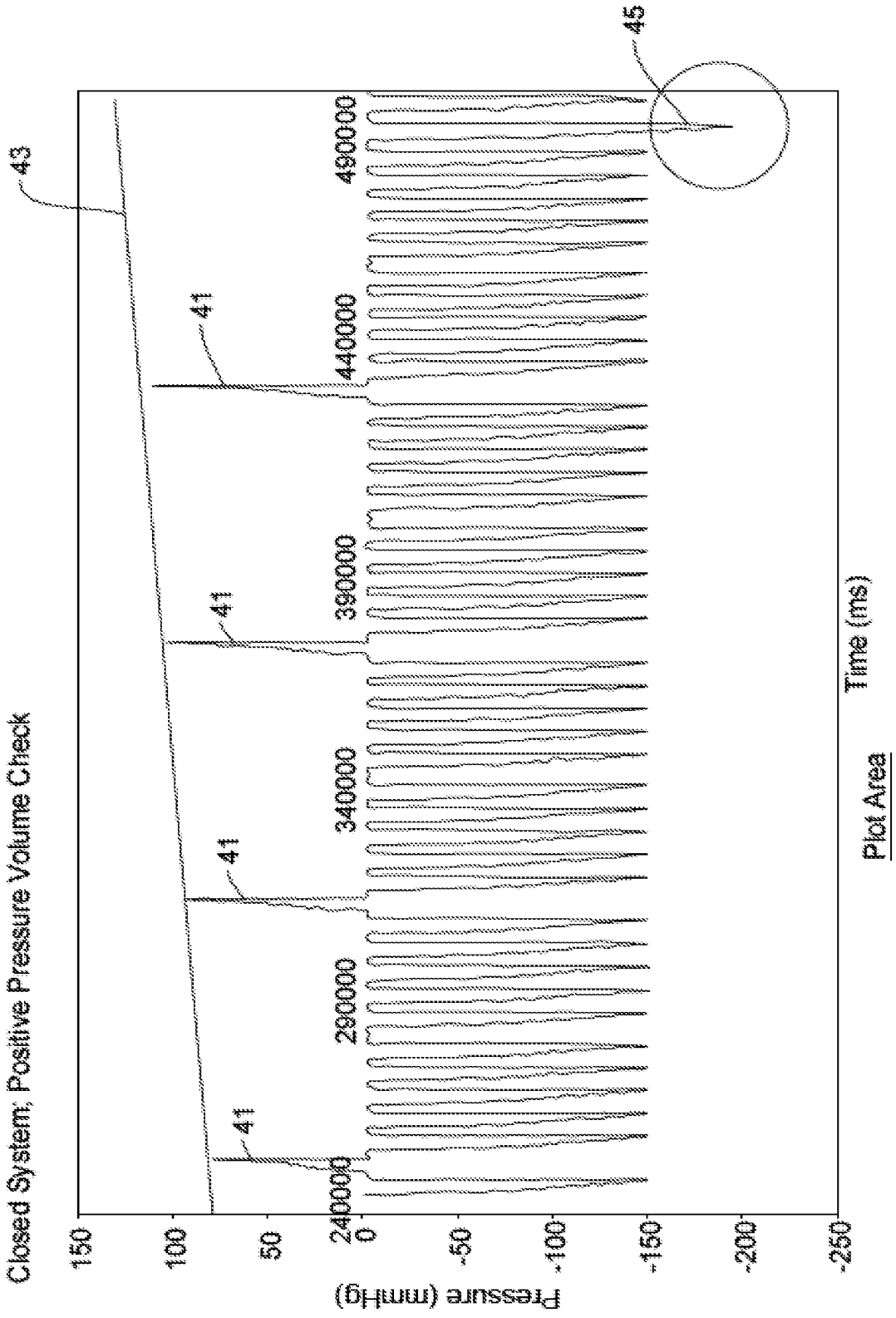

Closed System; Positive Pressure Volume Check
43
45
41
41
41
41
41
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

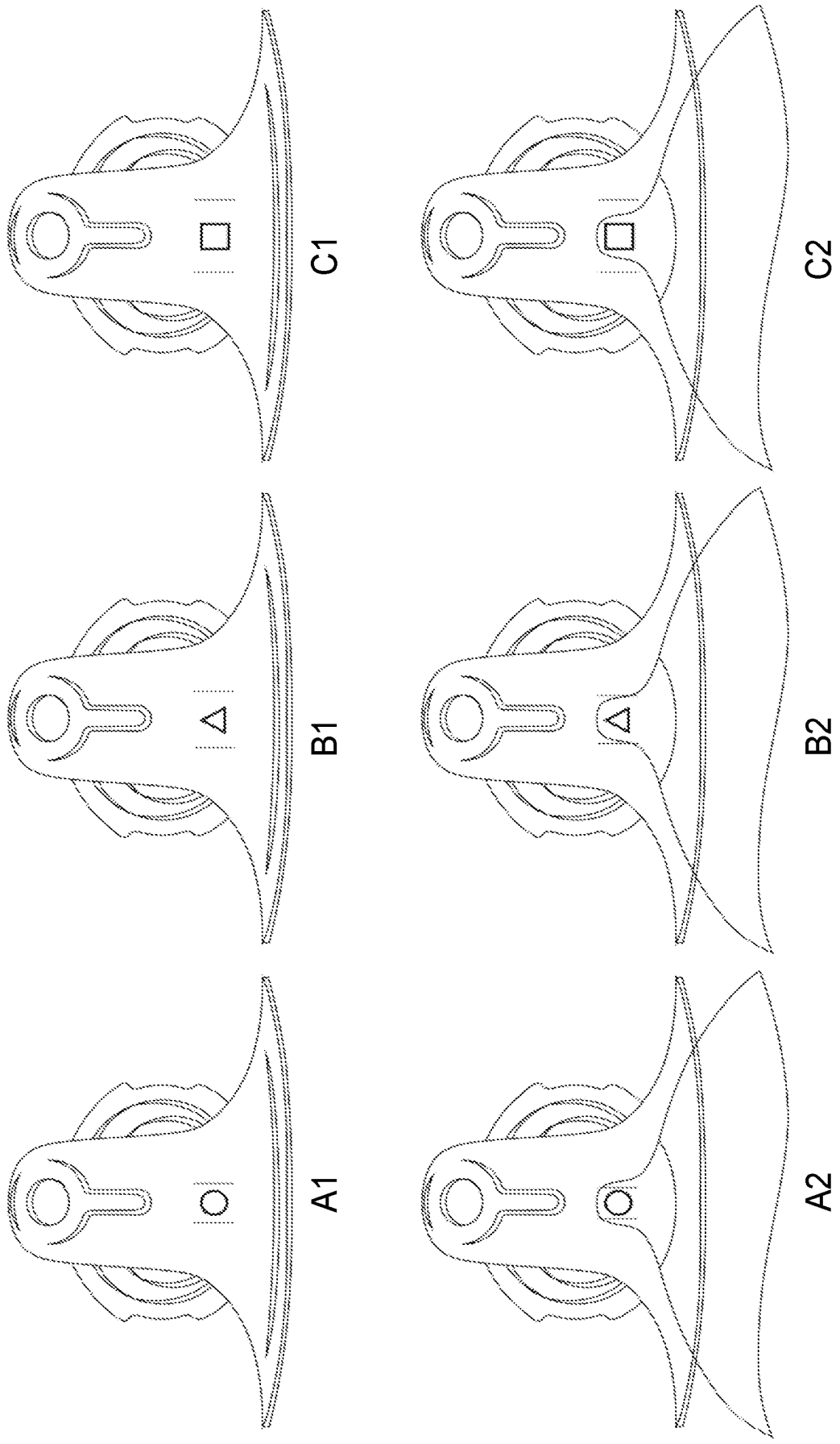


FIGURE 14

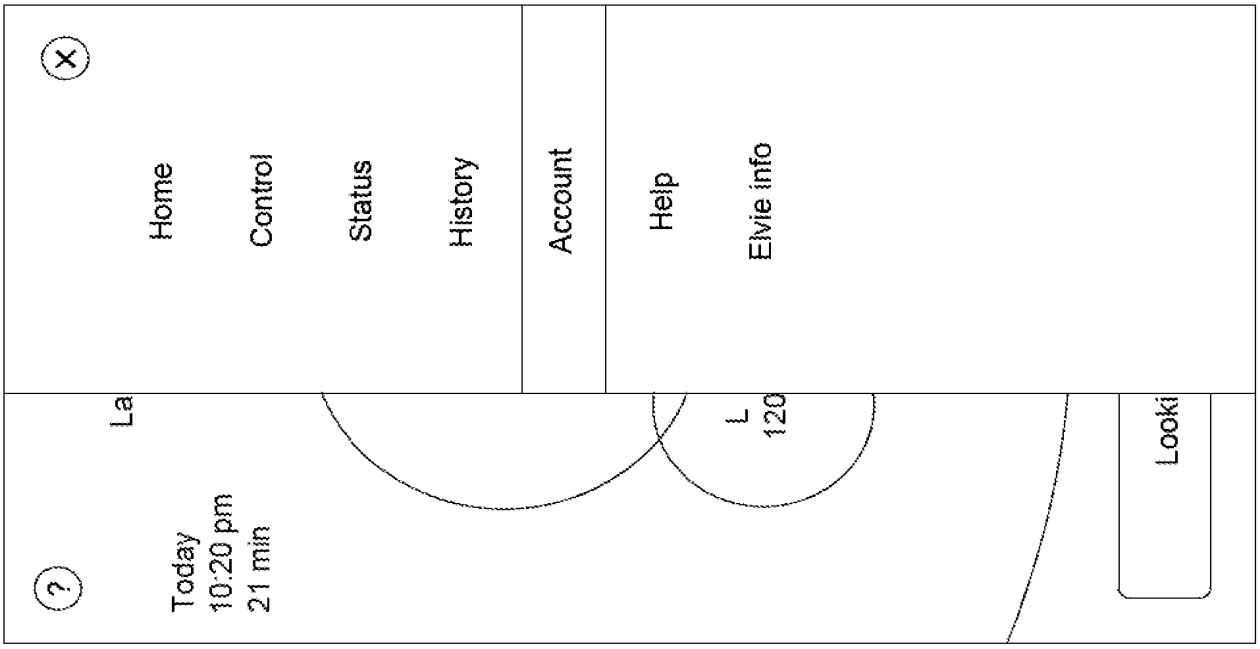

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min

FIGURE 15

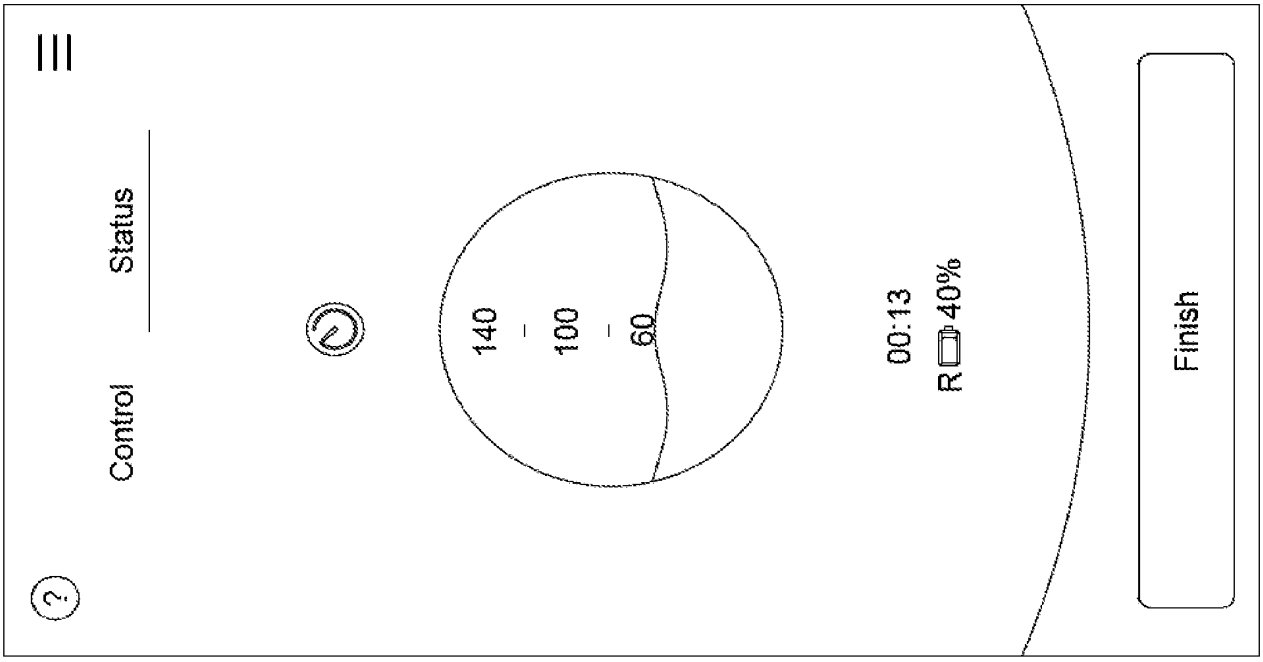
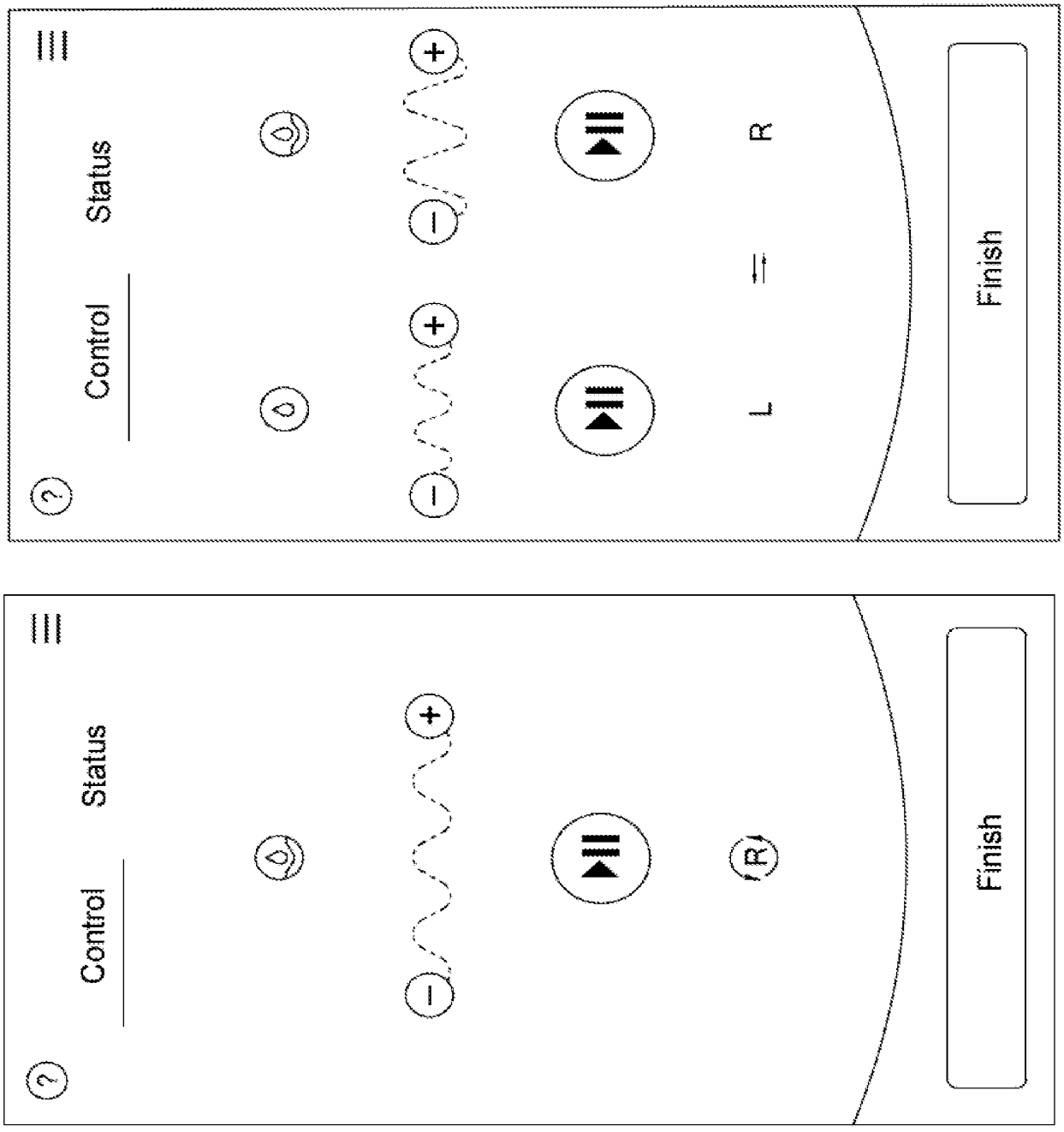


FIGURE 16



A B

FIGURE 17

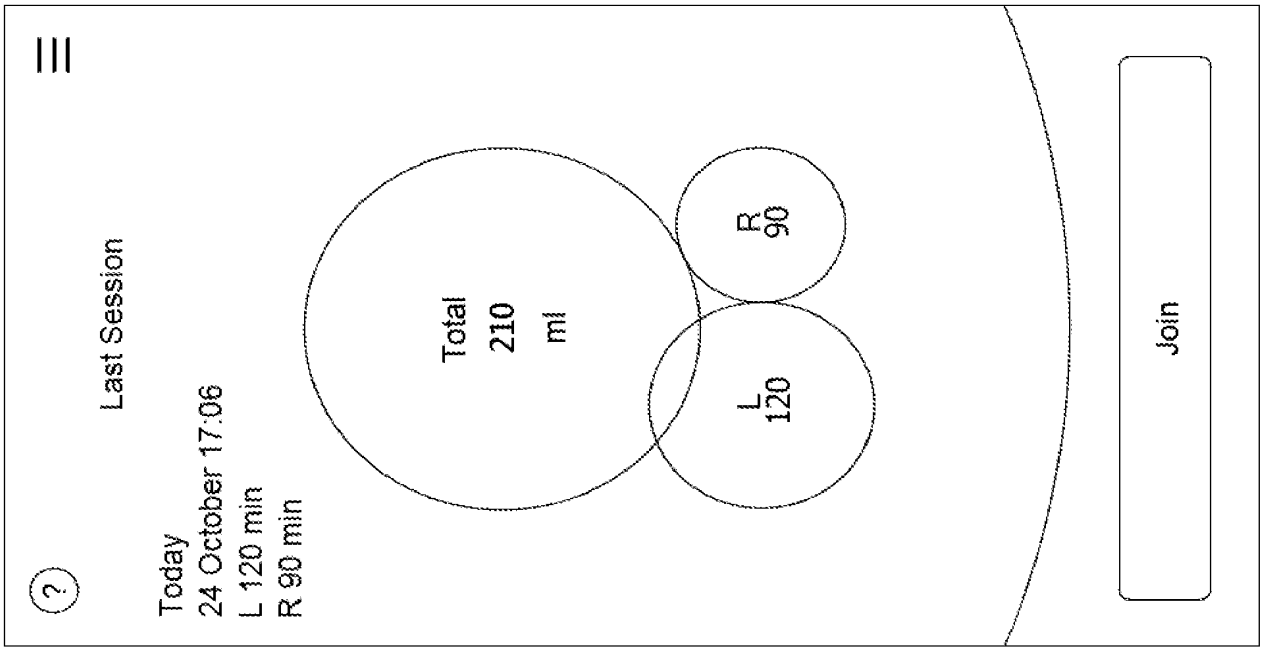

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
L
120
R
90
Join

FIGURE 18

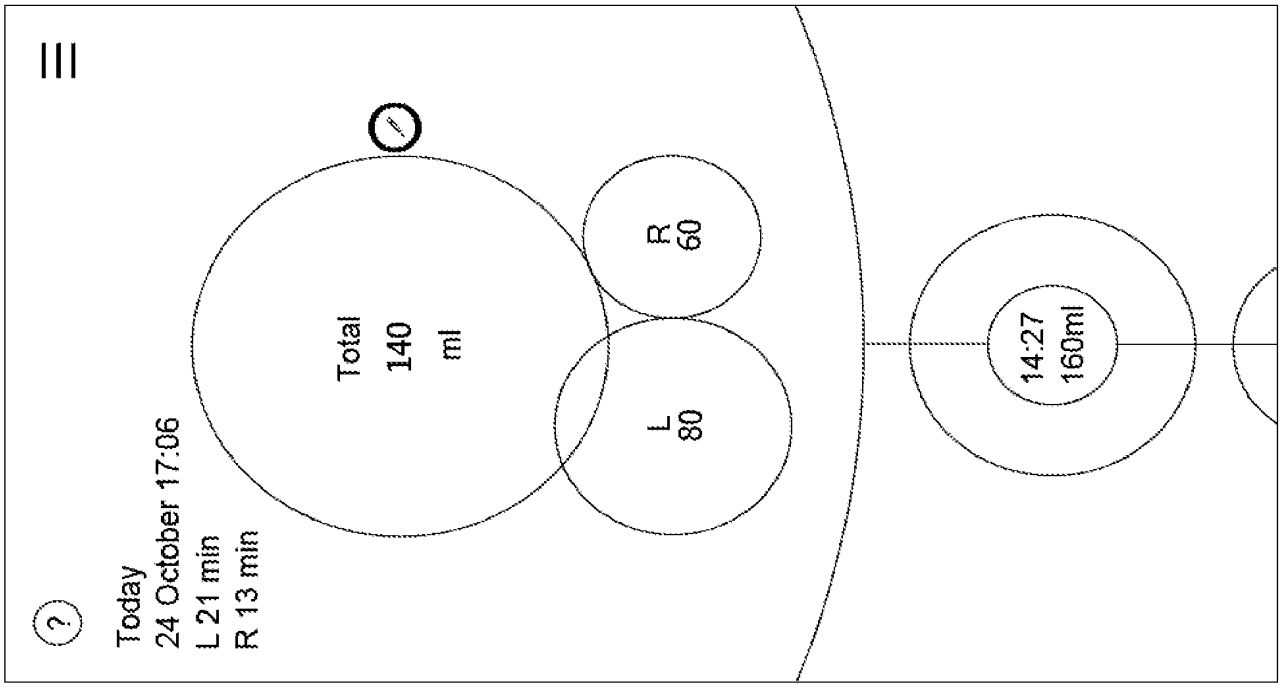

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

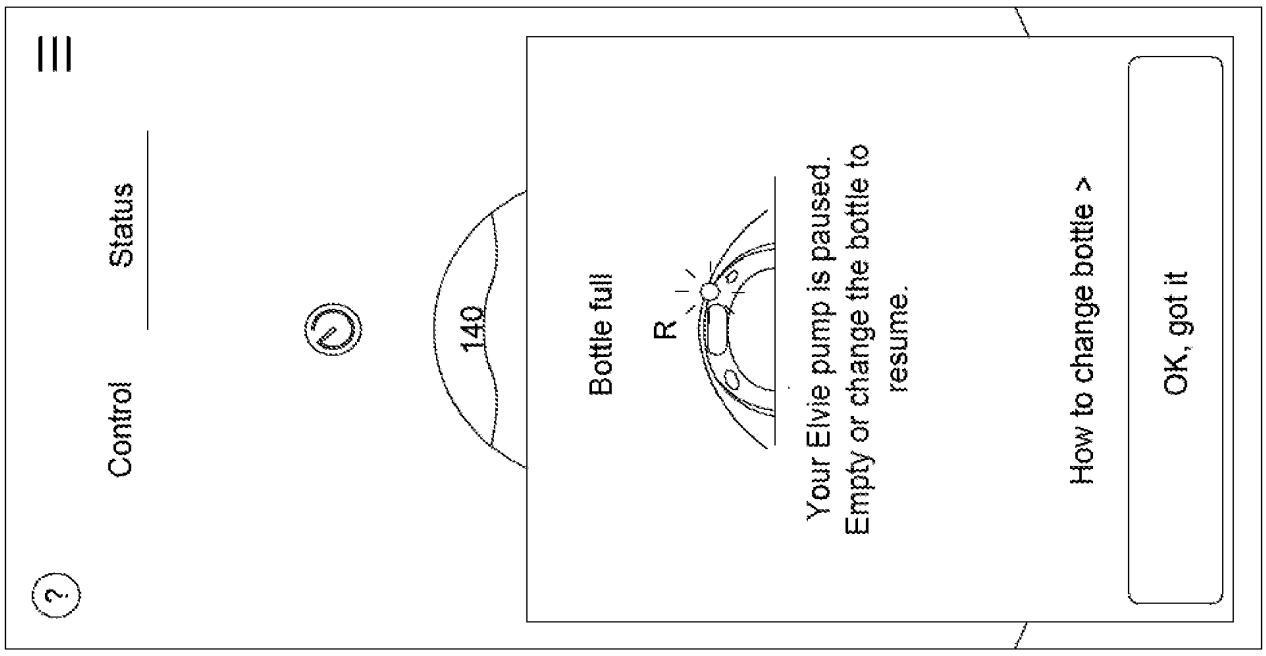

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

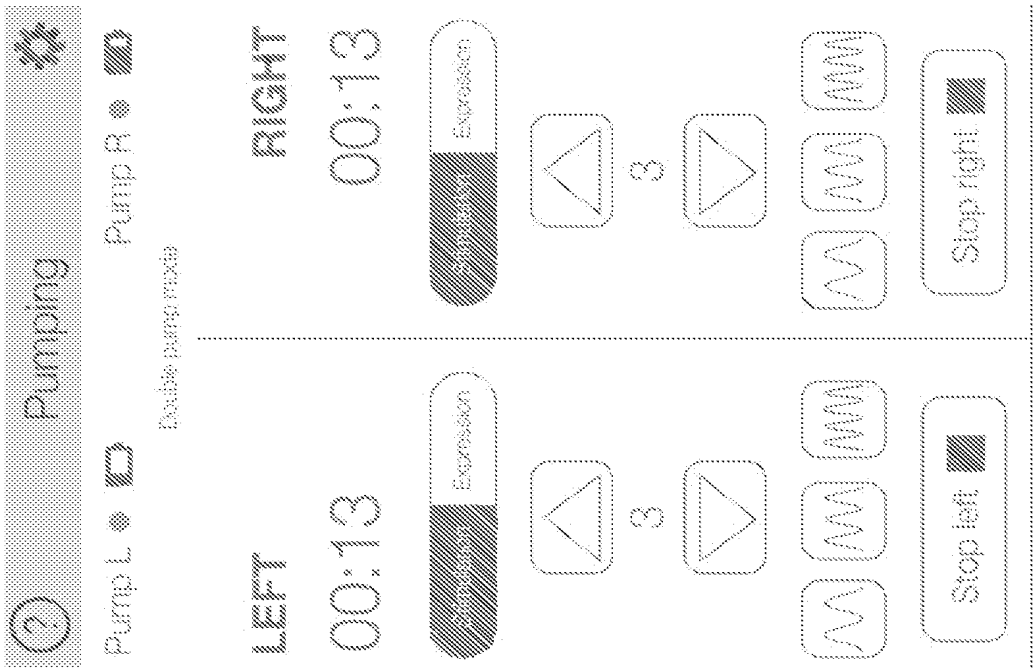

Pumping
Pump L
Pump R
Double pump mode
LEFT
00:13
Expansion
Contraction
RIGHT
00:13
Expansion
Contraction
Stop left
Stop right
Stop
Set a timer

FIGURE 21

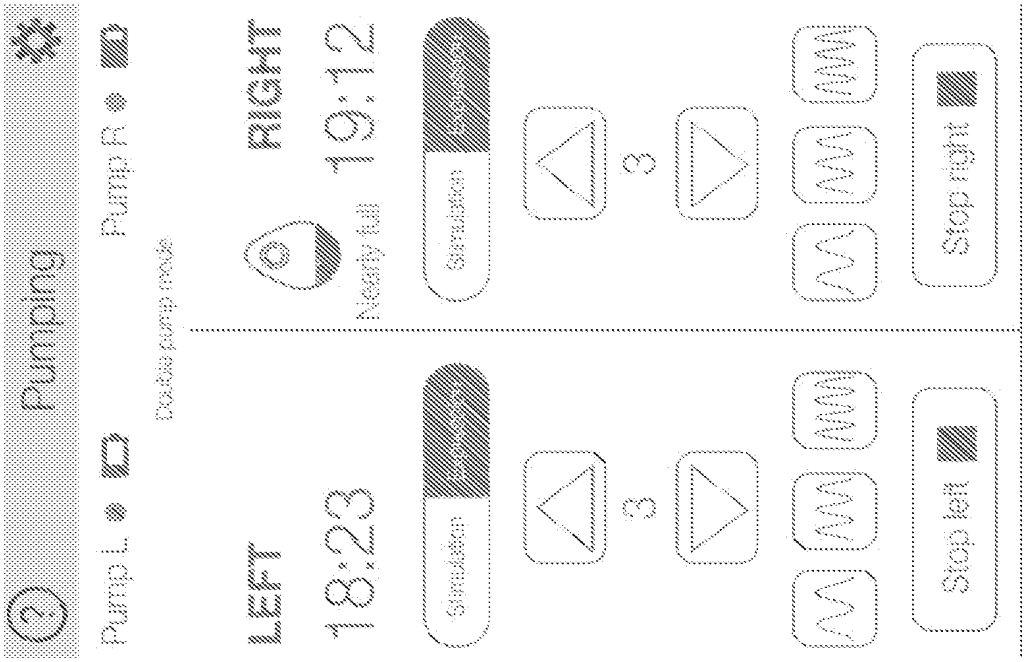

Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
Sensation
3
Stop left
RIGHT
19:12
Nearly full
Sensation
3
Stop right
Stop
Set a timer

FIGURE 22

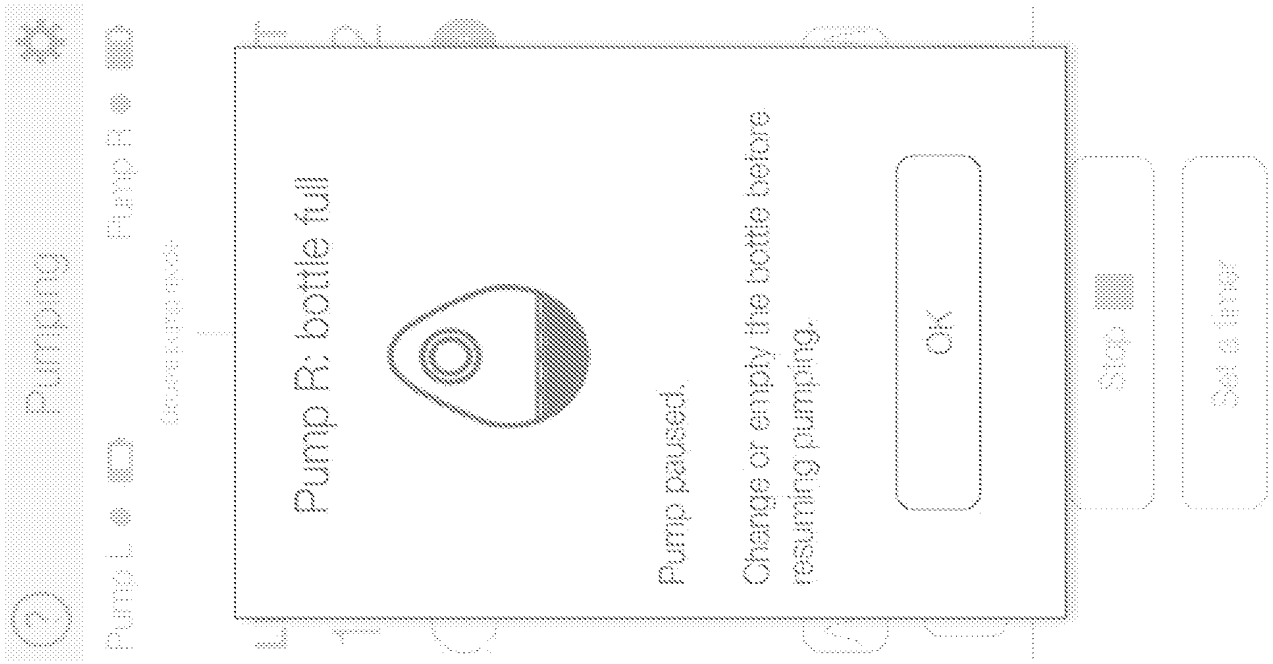

Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Orange or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23


Stopped
Pump L
Pump R
Double pump mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Tick if you emptied or changed the bottle
Resume left
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
25%
Pump R
Double pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
19mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

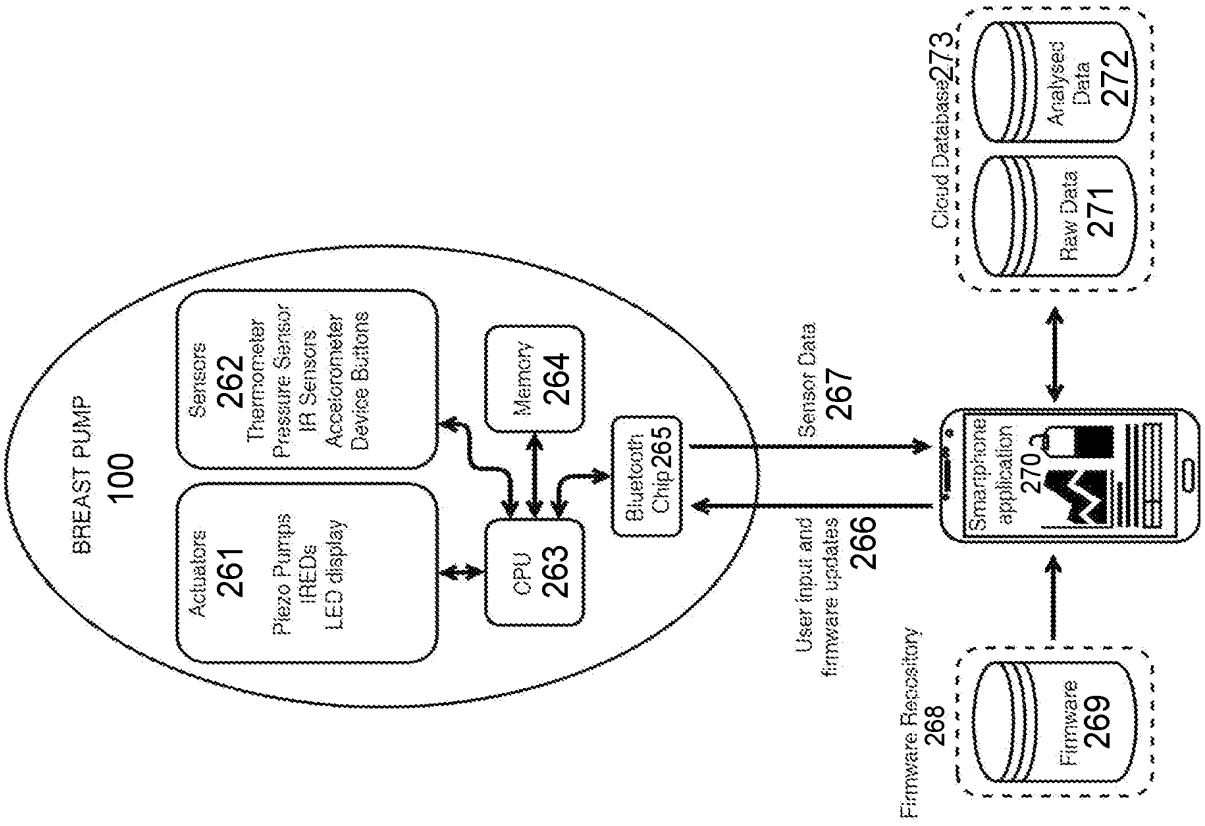

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelorometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

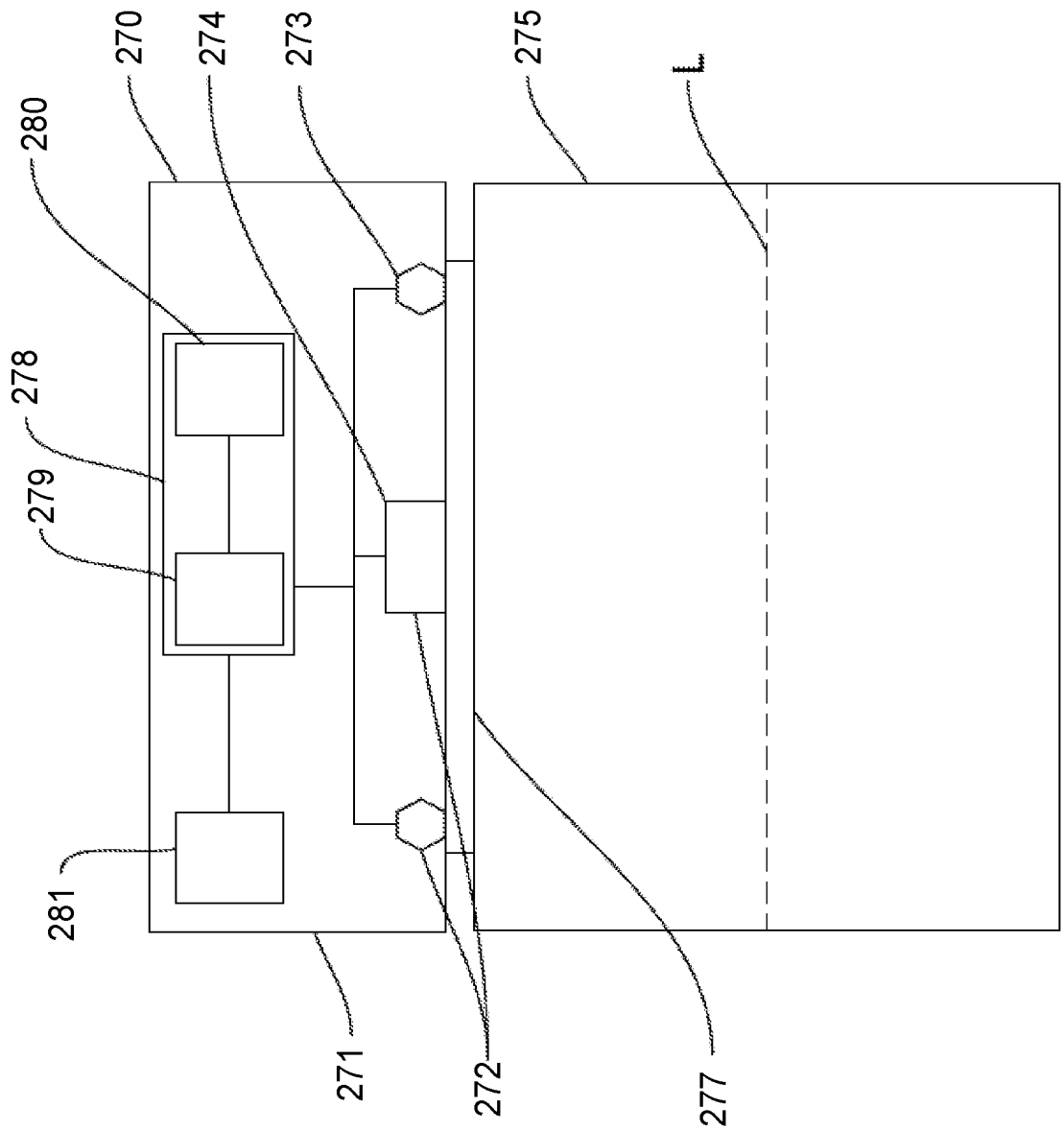


FIGURE 27

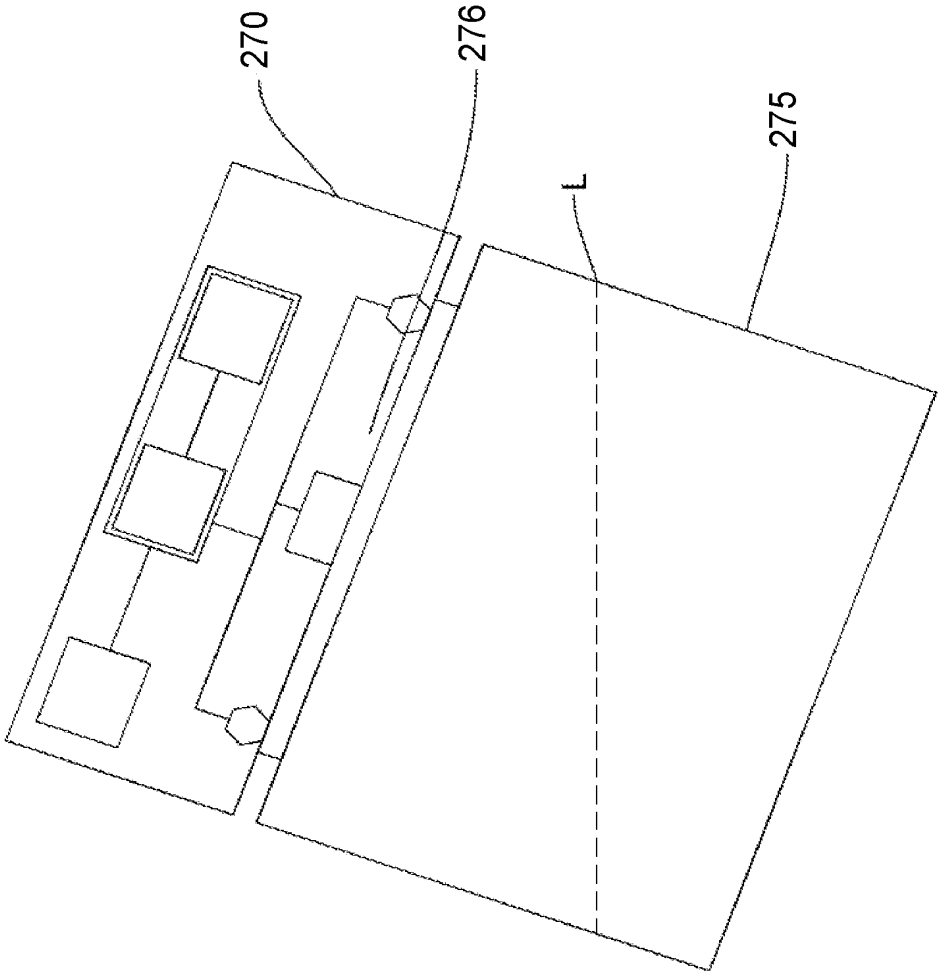


FIGURE 28

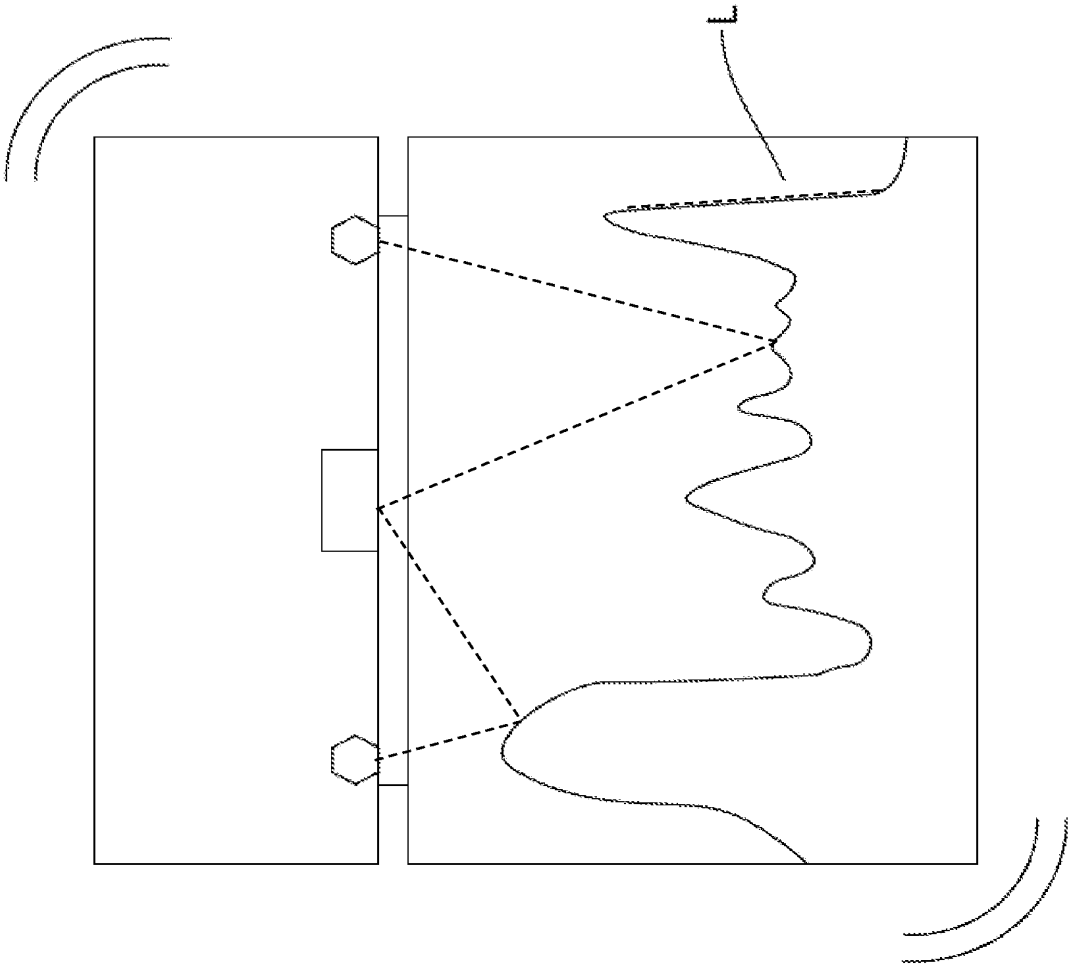


FIGURE 29

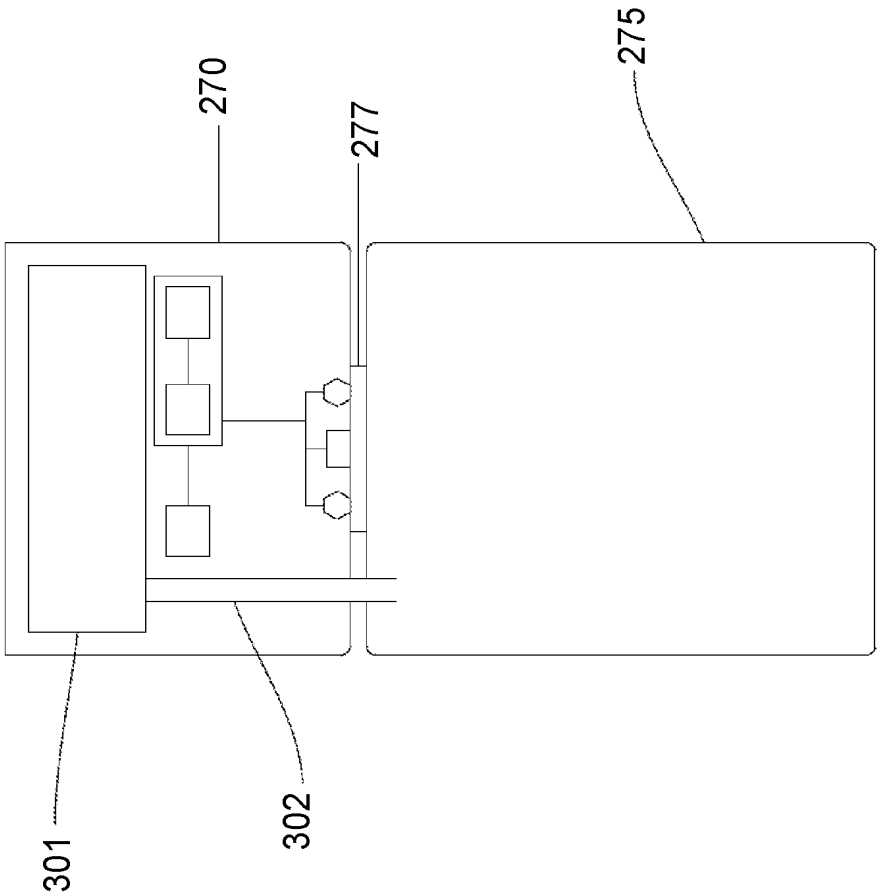


FIGURE 30

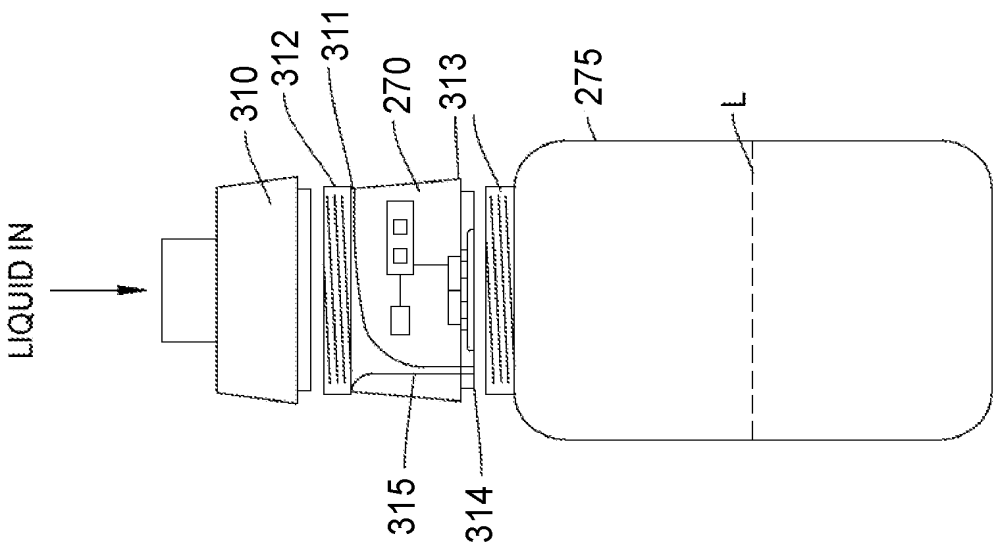


FIGURE 31

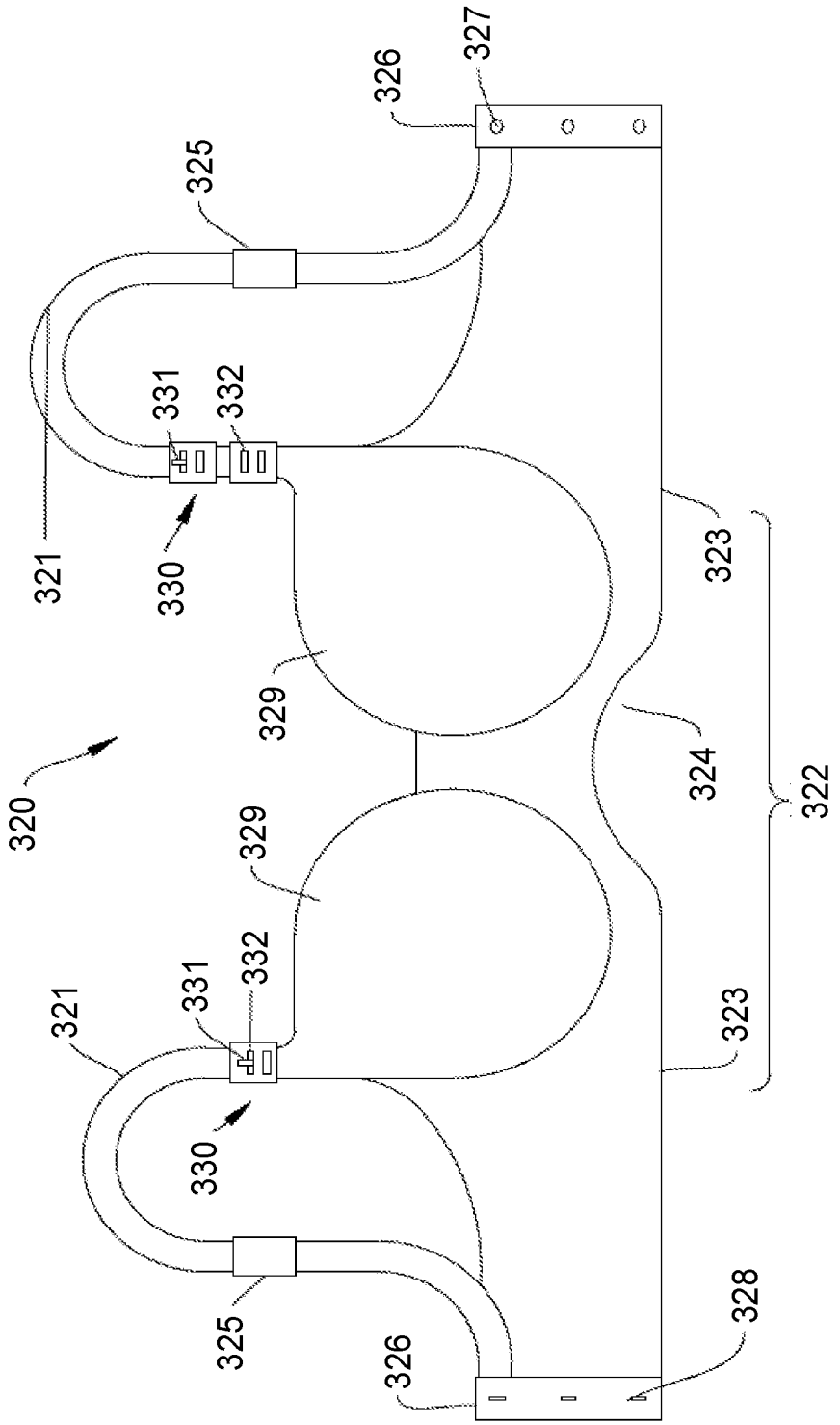


FIGURE 32

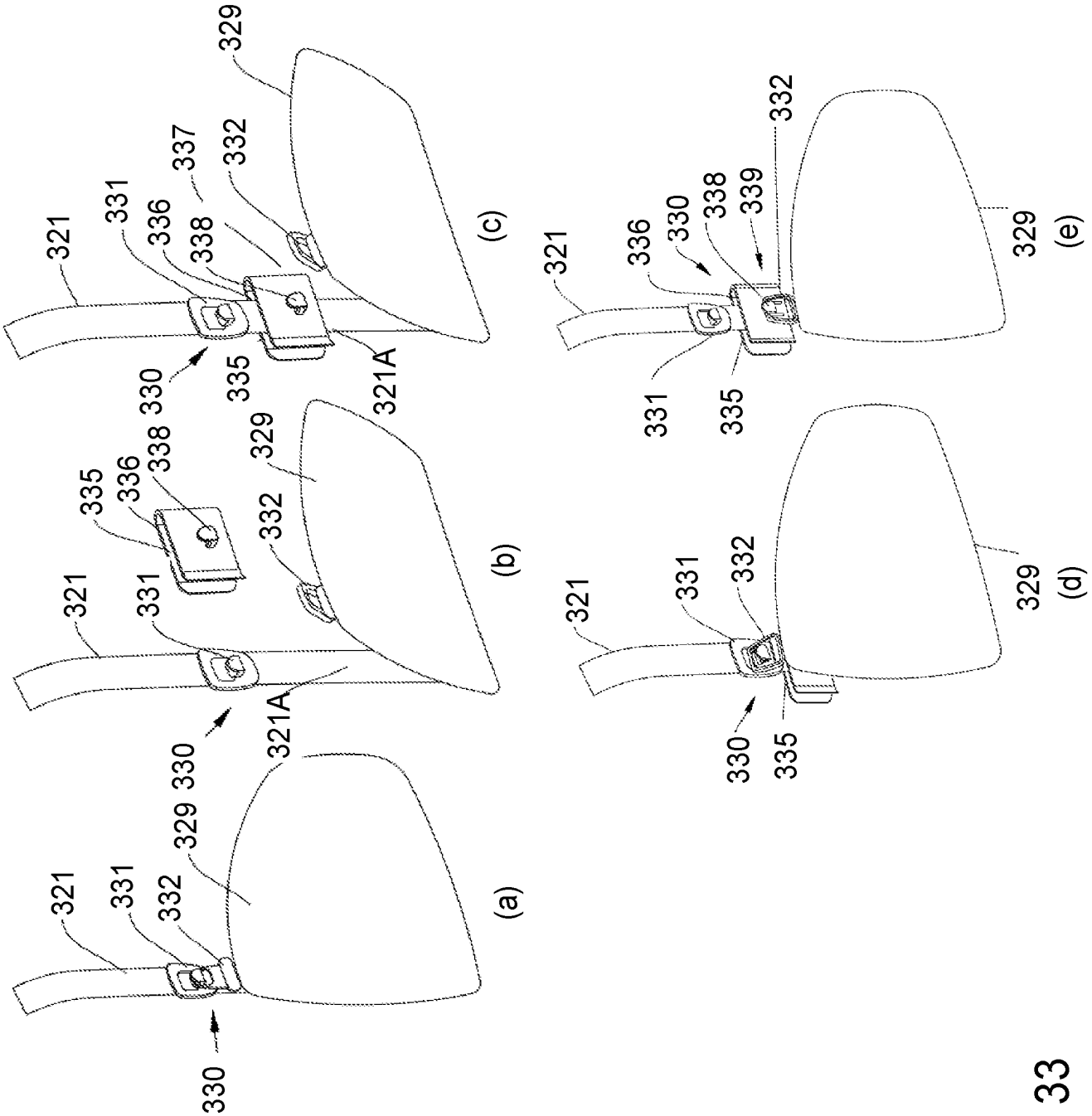

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
337
338
332
329
330
335
321A
(c)
321
331
336
330
338
339
332
329
(e)
321
331
332
329
330
335
(d)

FIGURE 33

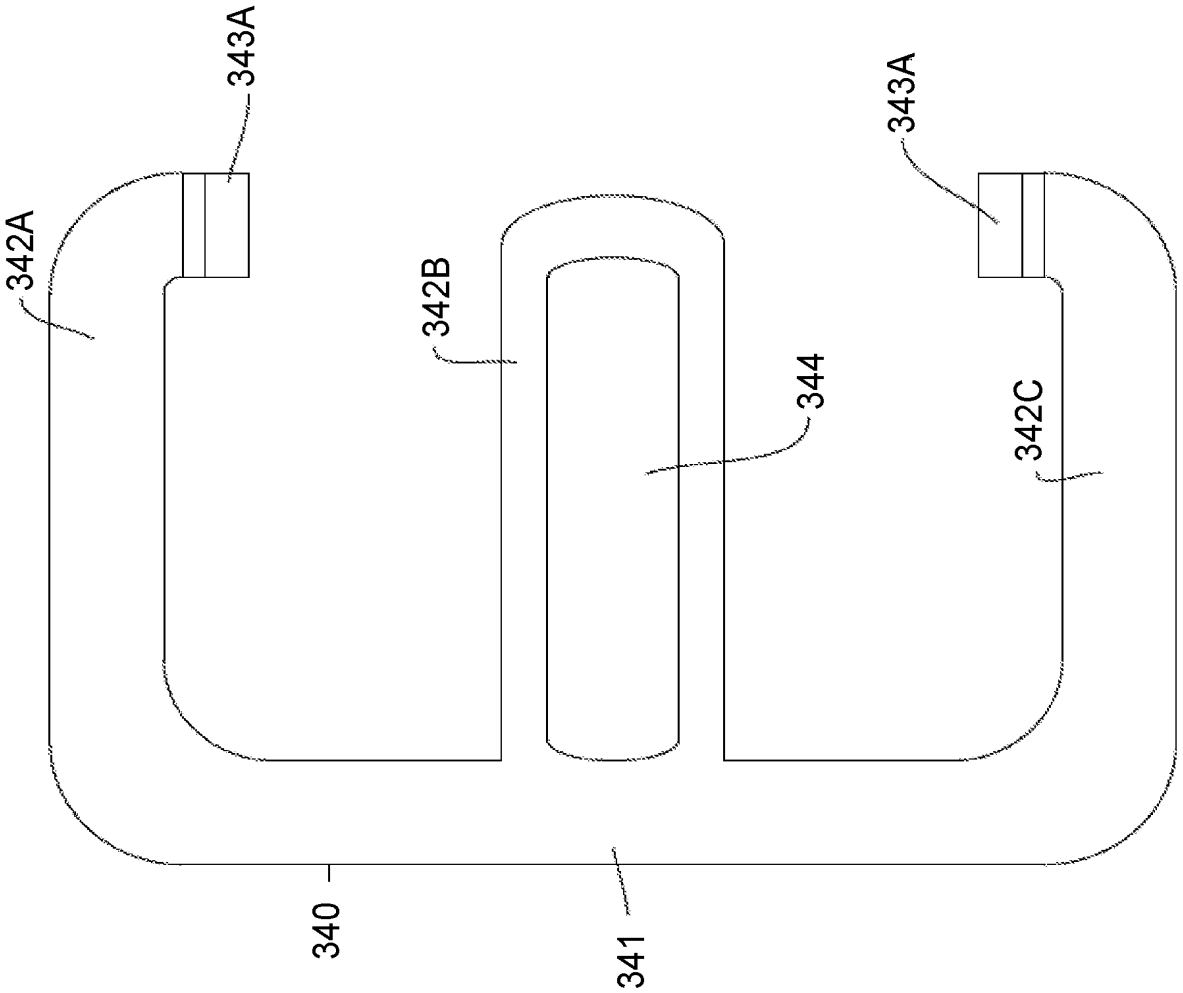


FIGURE 34

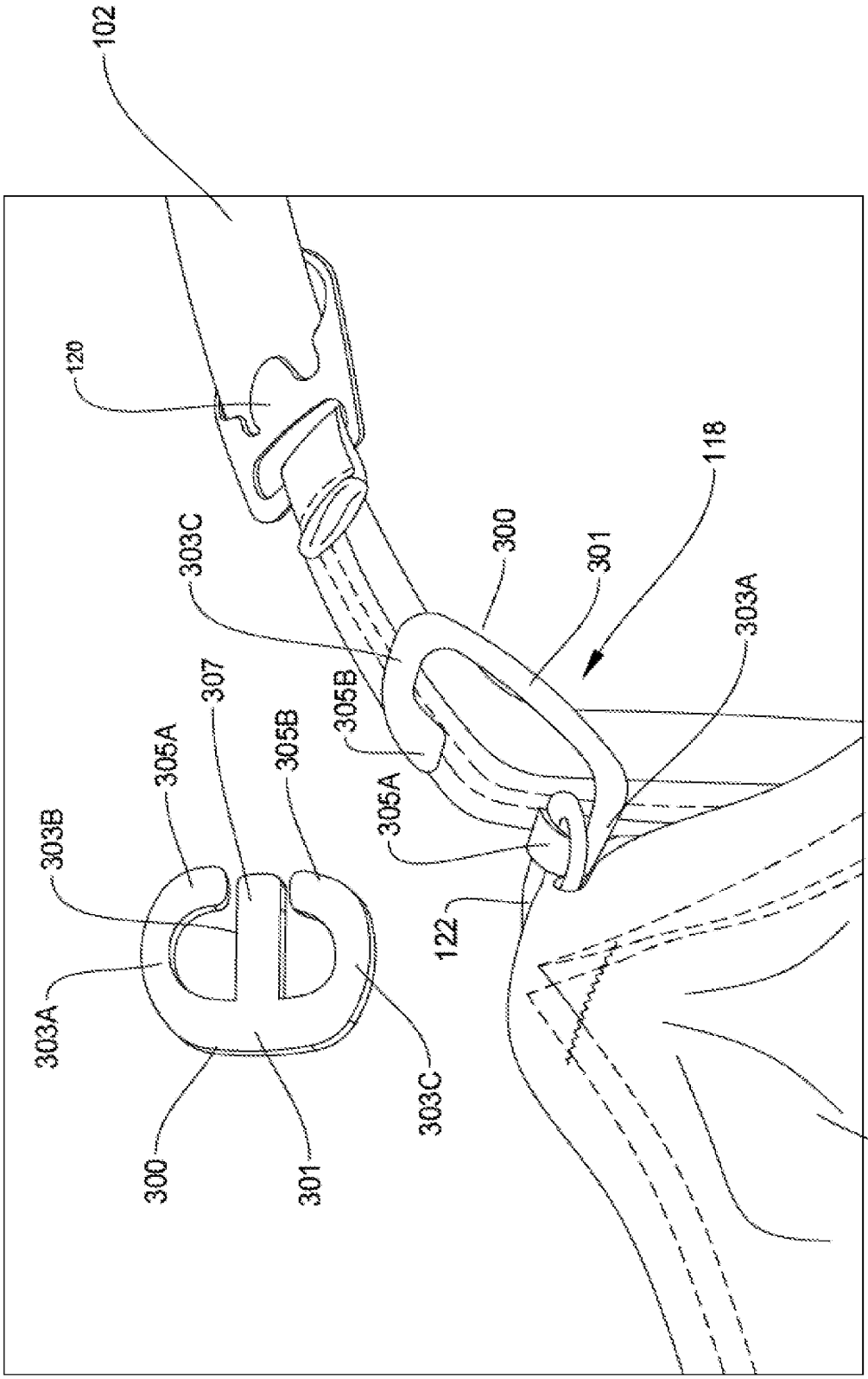

102
120
303C
300
301
118
303A
307
305B
305A
303B
305A
305B
122
303A
303C
300
301
116

FIGURE 35

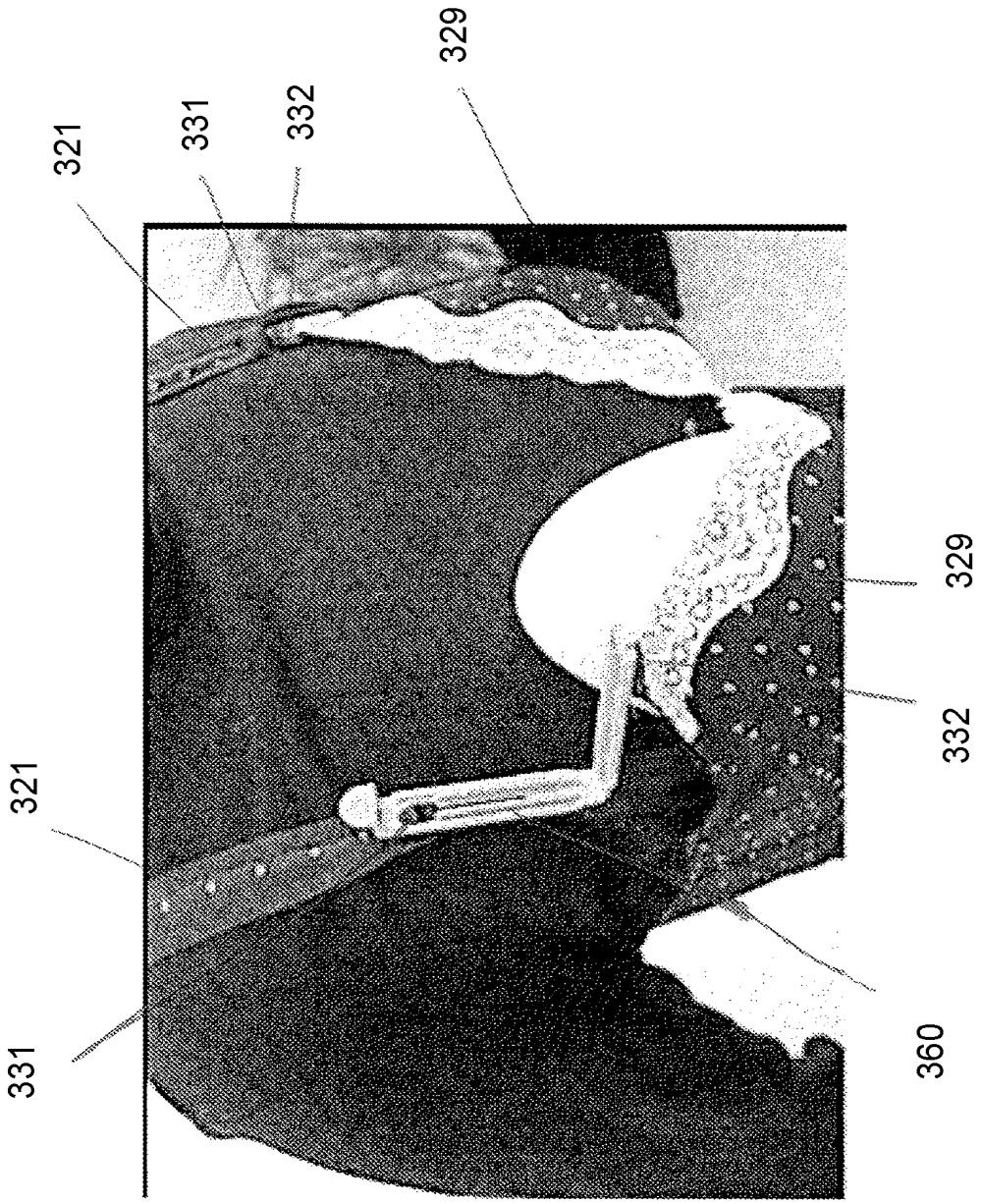


FIGURE 36

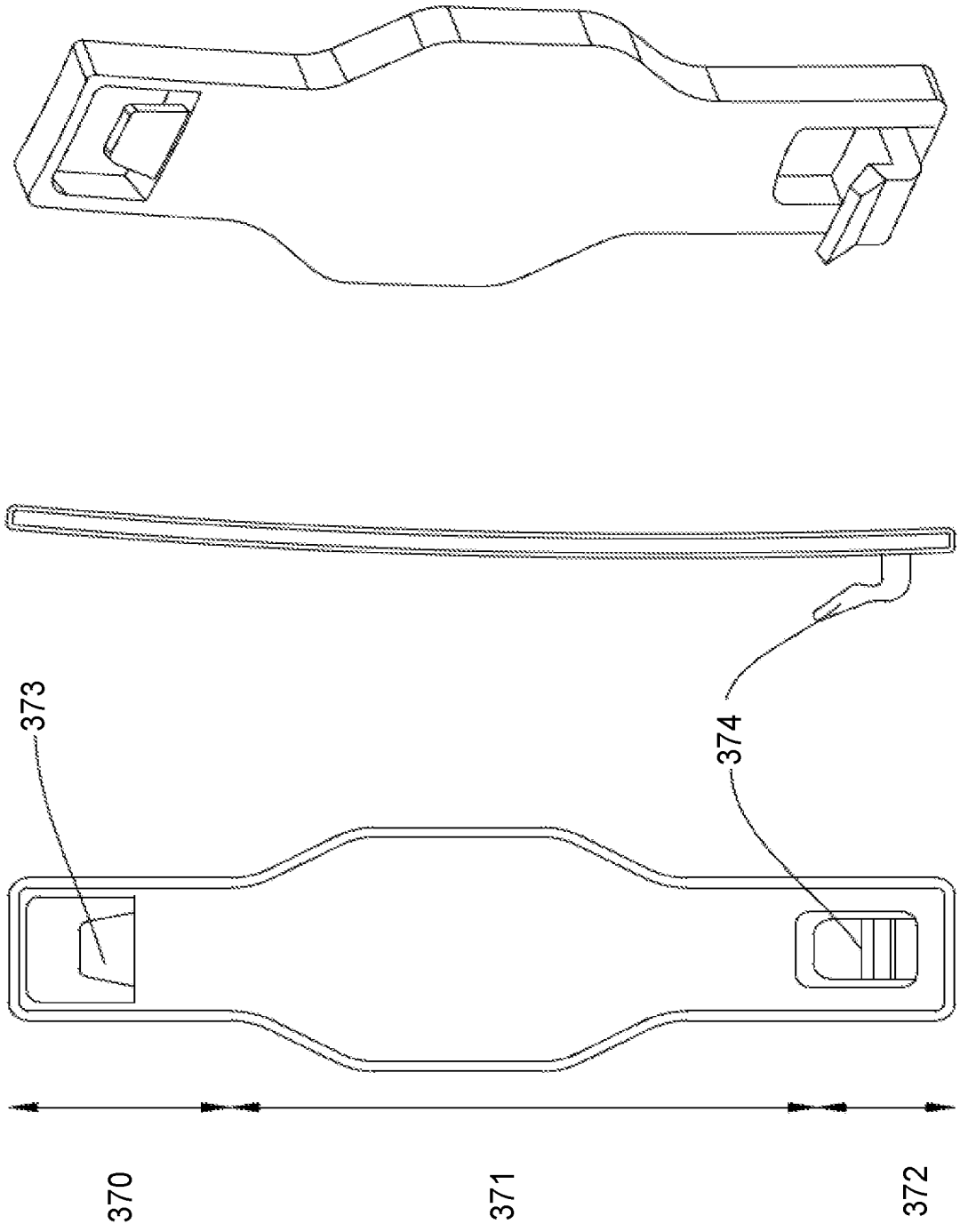


FIGURE 37

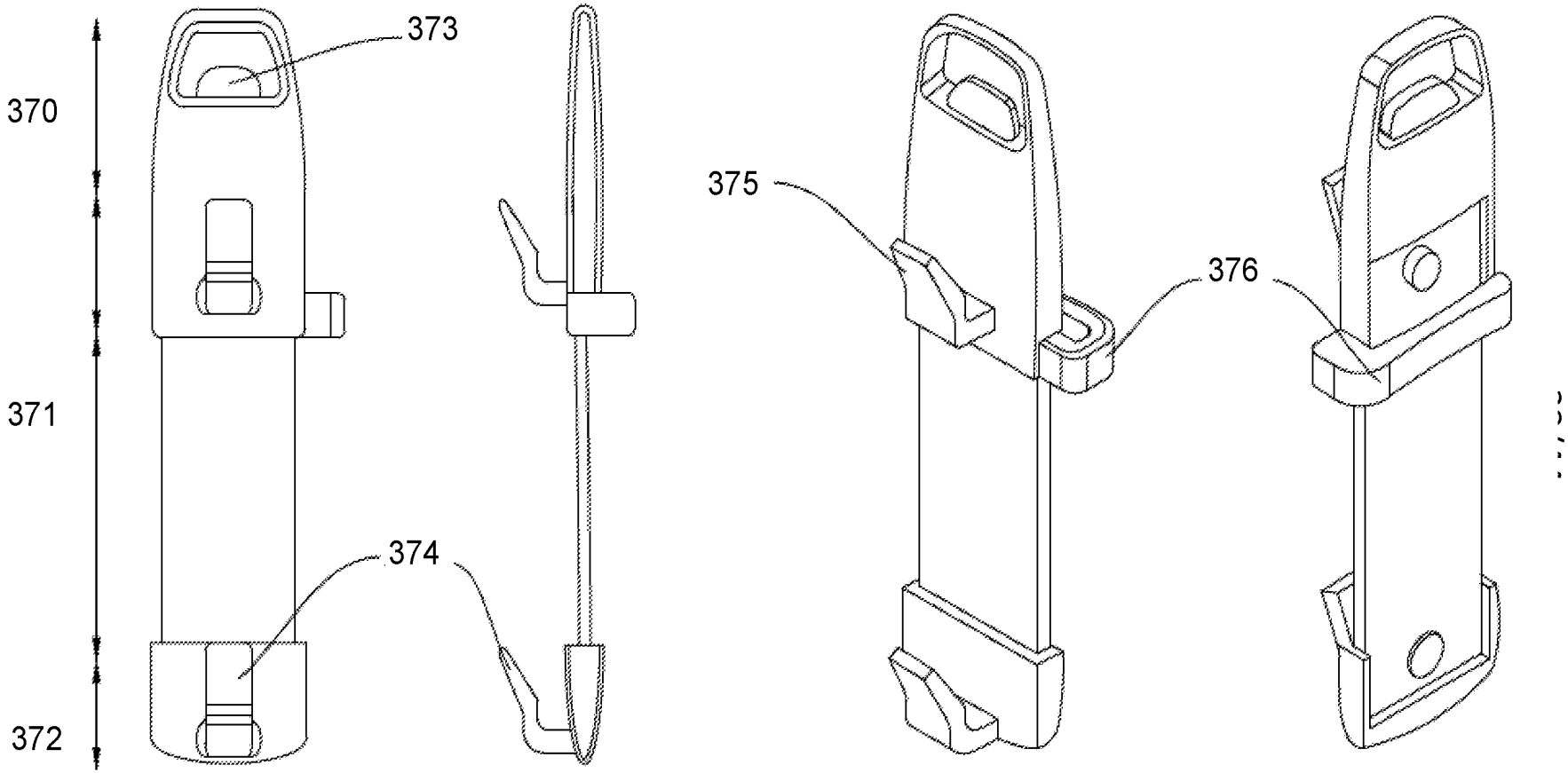


FIGURE 38

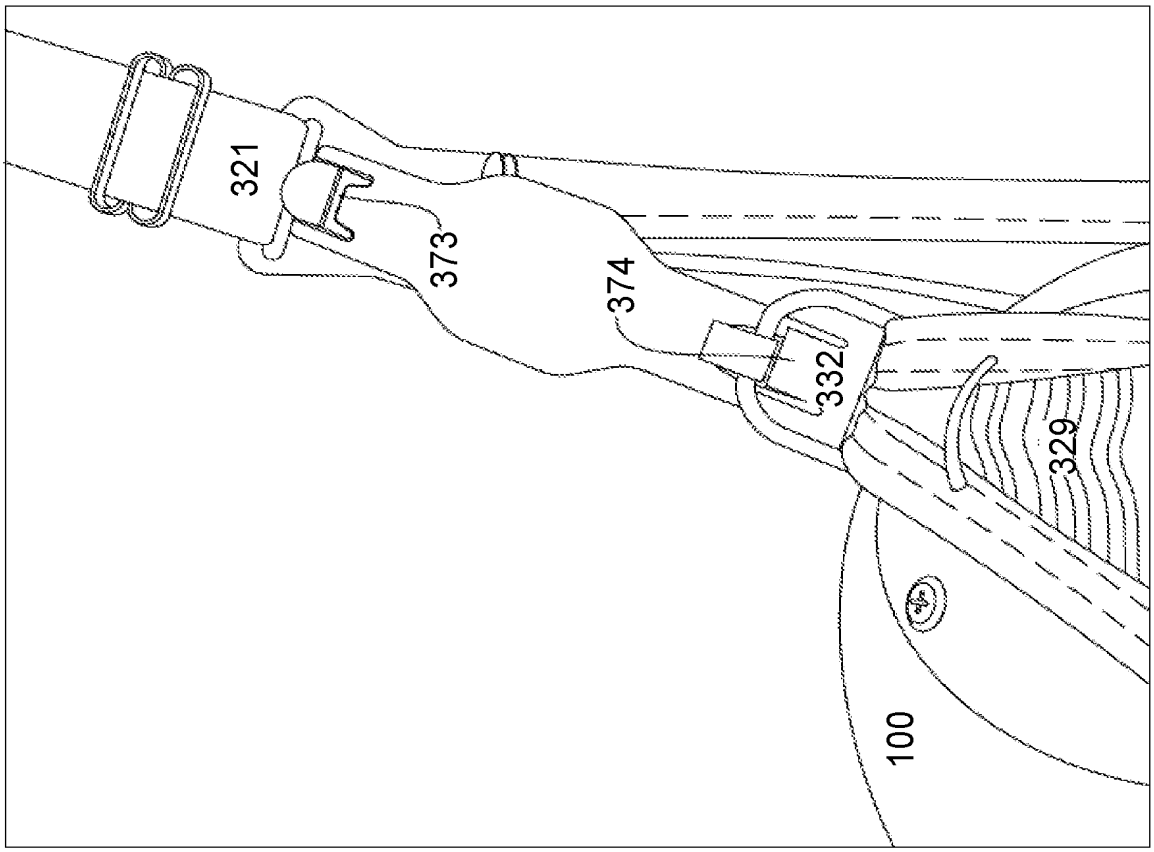


FIGURE 39

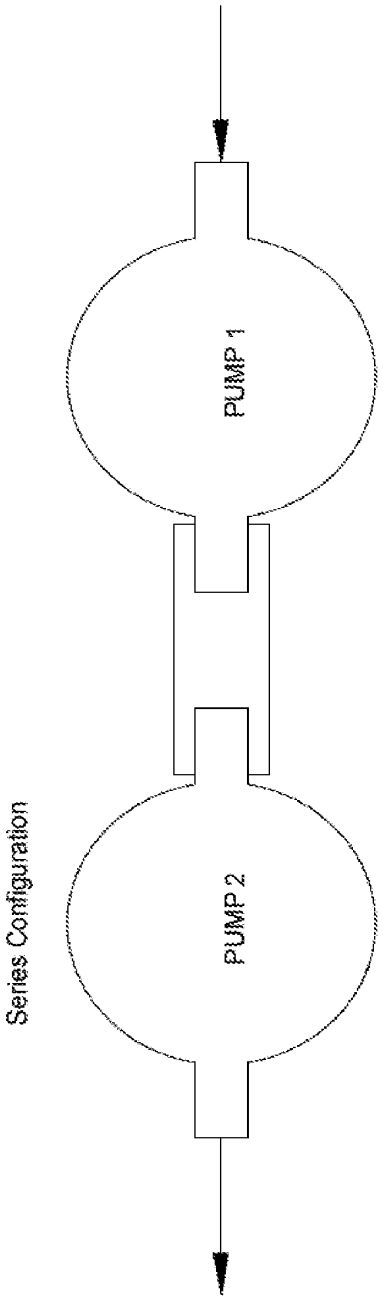


FIGURE 40

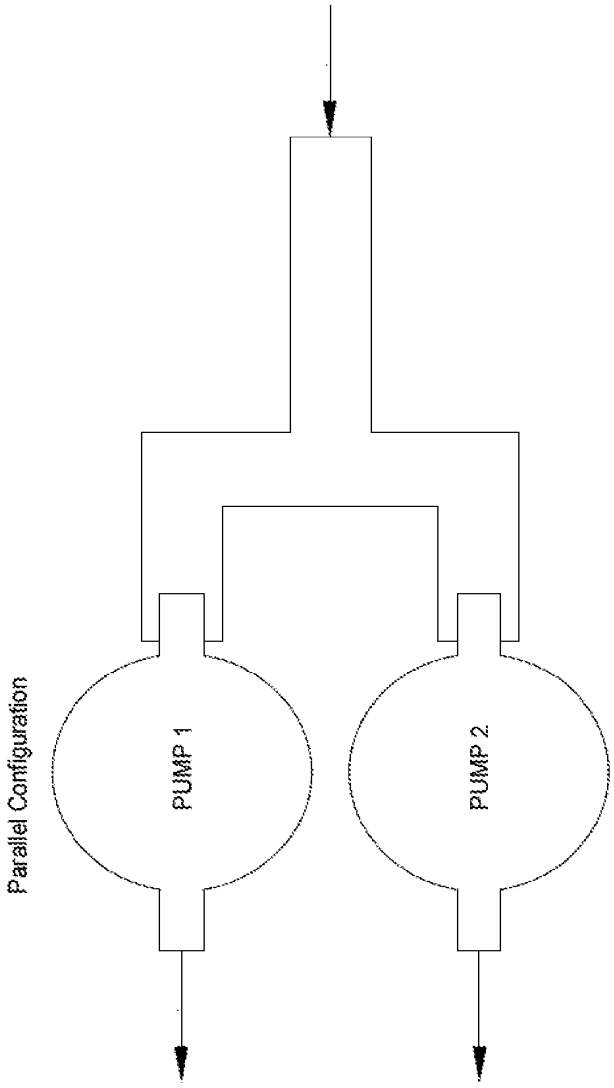


FIGURE 41

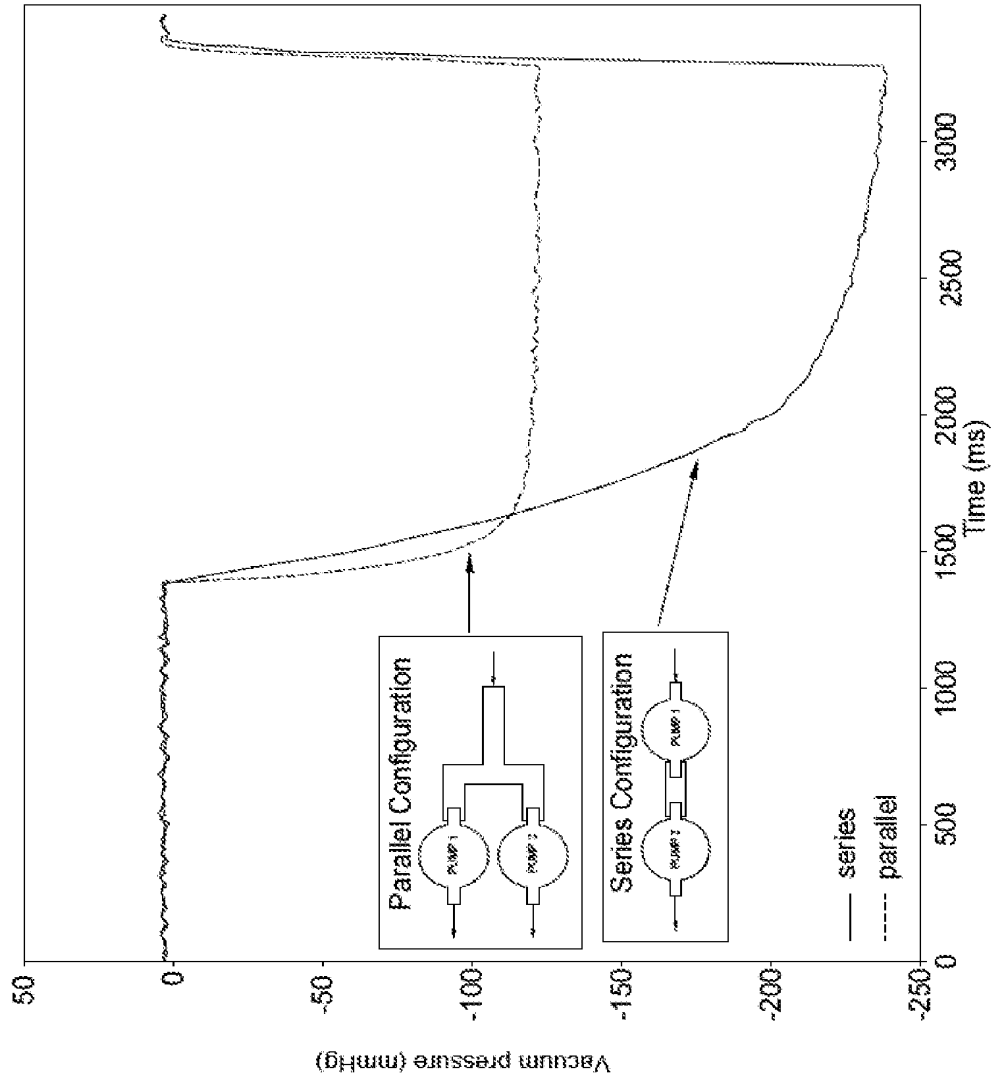

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

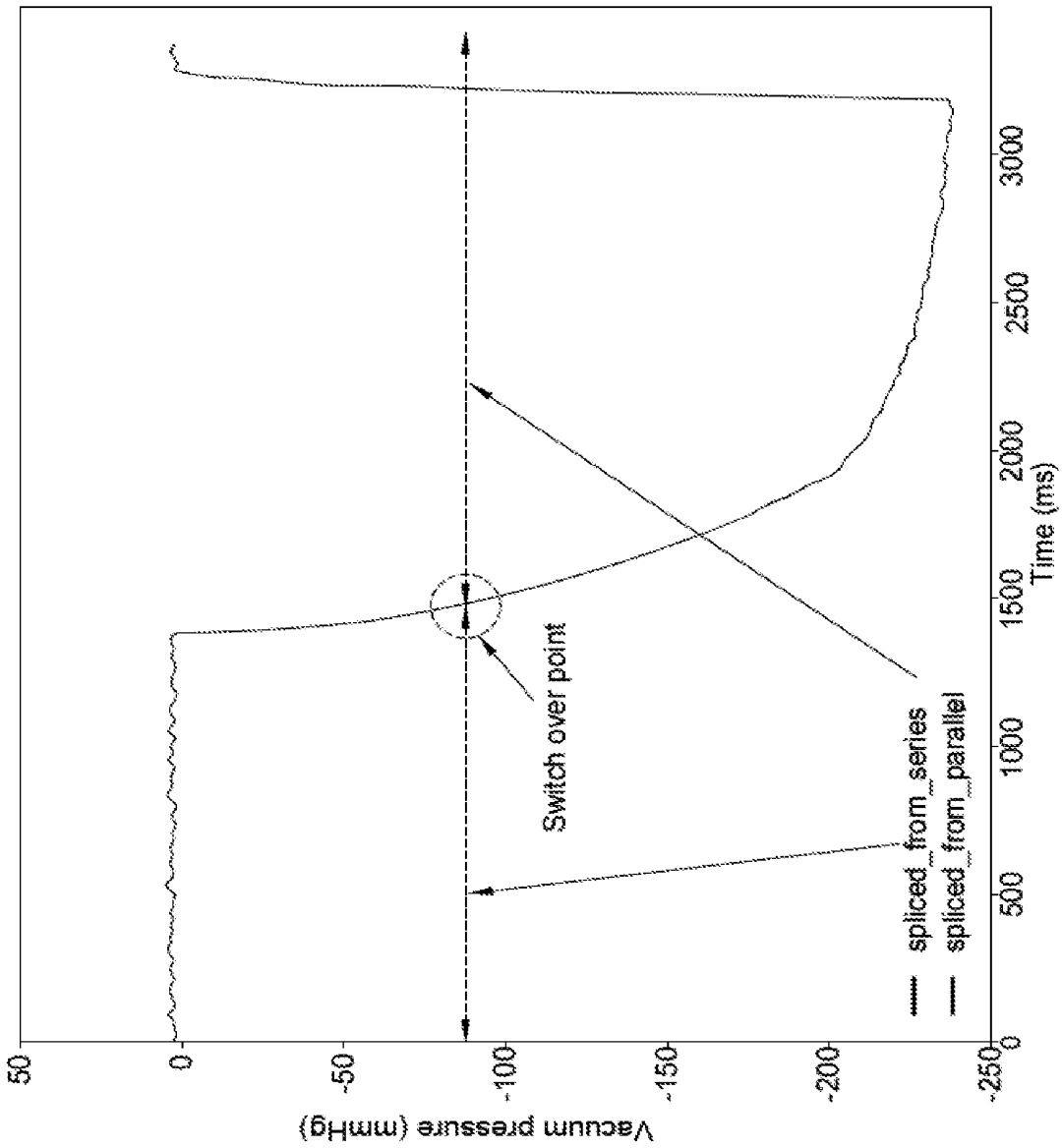

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

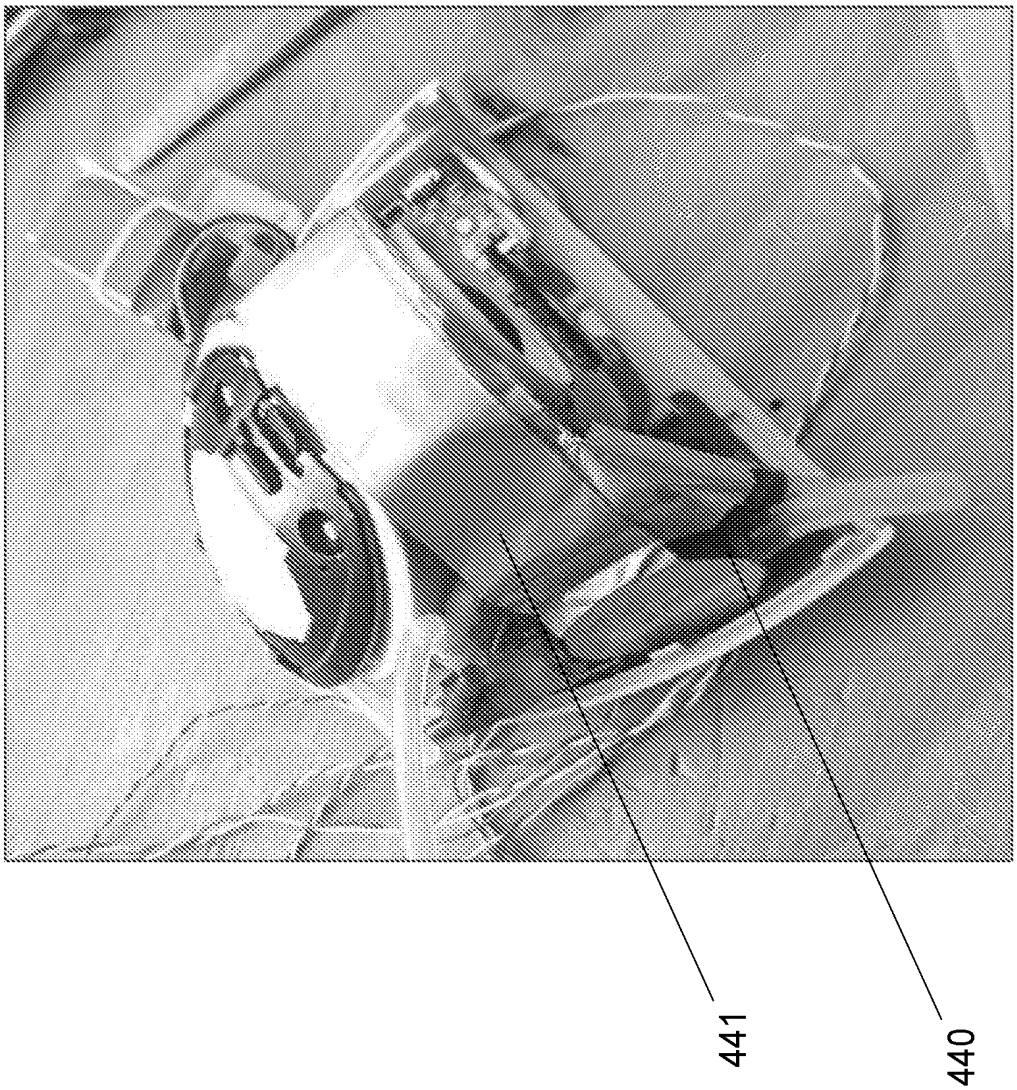


FIGURE 44

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'TOOLE
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00002

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6440100	B1	2002-08-27	Prentiss	
	2	6547756	B1	2003-04-15	Greter et al.	
	3	7201735	B2	2007-04-10	Atkin et al.	
	4	8118772	B2	2012-02-21	Dao et al.	
	5	8187227	B2	2012-05-29	Luzbetak et al.	
	6	8262606	B2	2012-09-11	Greter et al.	
	7	8282596	B2	2012-10-09	Greter et al.	
	8	8376986	B2	2013-02-19	Van Schijndel et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00002

	9	9033913	B2	2015-05-19	Khalil et al.	
	10	9173587	B2	2015-11-03	Van Schijndel et al.	
	11	2849881		1958-09-02	Anderson	
	12	5474683		1995-12-12	Bryant et al.	
	13	7048519	B2	2006-05-23	Fong et al.	
	14	7312554	B2	2007-12-25	Vogeley	
	15	4390024		1983-06-28	Williams	
	16	5973770		1999-10-26	Carter et al.	
	17	7314400	B2	2008-01-01	Fildan et al.	
	18	5941847		1999-08-24	Huber et al.	
	19	6045529		2000-04-04	Nuesch	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00002

	20	6090065		2000-07-18	Giles	
	21	6383163	B1	2002-05-07	Kelly et al.	
	22	6461324	B1	2002-10-08	Schlensog	
	23	6579258	B1	2003-06-17	Atkin et al.	
	24	6663587	B2	2003-12-16	Silver et al.	
	25	6749582	B2	2004-06-15	Britto et al.	
	26	7776008	B2	2010-08-17	Renz et al.	
	27	8057425	B1	2011-11-15	Myers et al.	
	28	8801495	B1	2014-08-12	Guindon	
	29	8926556	B2	2015-01-06	Van Eijkelenborg et al.	
	30	D548831	S	2007-08-14	Charlez	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	
	Attorney Docket Number	373499.00002

	31	9539377	B2	2017-01-10	Makower et al.	
	32	8702646	B2	2014-04-22	Garbez et al.	
	33	9345274	B1	2016-05-24	Prill	
	34	8876760	B2	2014-11-04	Bosman et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20150283311	A1	2015-10-08	Alvarez et al.	
	2	20160082166	A1	2016-03-24	Guthrie et al.	
	3	20160220743	A1	2016-08-04	Guthrie et al.	
	4	20160310650	A1	2016-10-27	Makower et al.	
	5	20170021068	A1	2017-01-26	Gaskin et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
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	Examiner Name	
	Attorney Docket Number	373499.00002

	6	20170143879	A1	2017-05-25	Okaguchi	
	7	20040074281	A1	2004-04-22	Lobdell et al.	
	8	20050219302	A1	2005-10-06	Vogeley	
	9	20070051172	A1	2007-03-08	Perinet et al.	
	10	20160000980	A1	2016-01-07	Alvarez et al.	
	11	20160082165	A1	2016-03-24	Alvarez et al.	
	12	20160151551	A1	2016-06-02	Felber	
	13	20160220745	A1	2016-08-04	Guthrie et al.	
	14	20160296681	A1	2016-10-13	Gaskin et al.	
	15	20040056641	A1	2004-03-25	Myers et al.	
	16	20040267215	A1	2004-12-30	Charlez et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
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	Examiner Name	
	Attorney Docket Number	373499.00002

	17	20060122575	A1	2006-06-08	Wakabayashi	
	18	20070051727	A1	2007-03-08	Holley, Jr.	
	19	20150217037	A1	2015-08-06	Pollen et al.	
	20	20160158424	A1	2016-06-09	Chen et al.	
	21	20160206794	A1	2016-07-21	Makower et al.	
	22	20160287767	A1	2016-10-06	Simmons et al.	
	23	20120277636	A1	2012-11-01	Blondheim et al.	
	24	20160058929	A1	2016-03-03	Nowroozi et al.	
	25	20170035951	A1	2017-02-09	Tanaka	
	26	20170220753	A1	2017-08-03	Guthrie et al.	
	27	20180021490	A1	2018-01-25	Chang et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
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	Examiner Name	
	Attorney Docket Number	373499.00002

	28	20080262420	A1	2008-10-23	Dao et al.	
	29	20140052056	A1	2014-02-20	Garbez et al.	
	30	20020193731	A1	2002-12-19	Myers et al.	
	31	20150217036	A1	2015-08-06	Pollen et al.	

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	1	1 263 487	EP	B2	2016-11-23	Medela Holding AG		
	2	1 430 918	EP	B1	2008-05-14	Medela Holding AG		
	3	2 077 868	EP	B1	2016-07-27	Medela Holding AG		
	4	2 210 628	EP	B1	2013-02-13	Medela Holding AG		
	5	2016/014469	WO	A1	2016-01-28	Exploramed NC7, LLC		

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	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
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	Examiner Name	
	Attorney Docket Number	373499.00002

	6	2016/014488	WO	A1	2016-01-28	Exploramed NC7, LLC		
	7	3311982	DE	C2	1983-10-13	Battelle Memorial Institute		
	8	197 50 620	DE	A1	1999-06-02	Siemens AG		
	9	0 503 280	EP	A2	1992-02-08	Pierburg GmbH		
	10	2016-10524	JP	A	2016-01-23			
	11	2 344 380	RU	C1	2009-01-20			
	12	94/20158	WO	A1	1994-09-15	Deka Products Limited Partnership		
	13	2005/114113	WO	A3	2005-12-01	Accu-Gauge Limited		
	14	2005/114116	WO	A1	2005-12-01	Lane et al.		
	15	2015/116749	WO	A1	2015-11-05	Murata Manufacturing Co., Ltd.		
	16	2015/174330	WO	A1	2015-11-19	Murata Manufacturing Co., Ltd.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
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	Examiner Name	
	Attorney Docket Number	373499.00002

	17	2016/002606	WO	A1	2016-01-07	Murata Manufacturing Co., Ltd.		
	18	2016/006494	WO	A1	2016-01-14	Murata Manufacturing Co., Ltd.		
	19	2016/006496	WO	A1	2016-01-14	Murata Manufacturing Co., Ltd.		
	20	2016/007560	WO	A1	2016-01-14	Naya Health, Inc.		
	21	2016/024558	WO	A1	2016-02-18	Murata Manufacturing Co., Ltd.		
	22	2016/039083	WO	A1	2016-03-17	Murata Manufacturing Co., Ltd.		
	23	2016104673	WO	A1	2016-06-30	Murata Manufacturing Co., Ltd.		
	24	2473022	GB	B	2011-12-14	Drew		
	25	2499248	GB	B	2014-04-02	Morana		
	26	2 441 367	RU	C2	2012-02-10			
	27	105288759	CN	A	2016-02-03			

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	Filing Date	
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00002

	28	1 404 393	EP	B1	2014-12-24	Medela Holding AG		
	29	2015/081459	WO	A1	2015-06-11	Chen		
	30	2015/120321	WO	A1	2015-08-13	Naia Health, Inc.		
	31	2015150225	WO	A1	2015-10-08	Koninklijke Philips N.V.		
	32	2016/164853	WO	A1	2016-10-13	Naya Health, Inc.		
	33	2017/061349	WO	A1	2017-04-13	Murata Manufacturing Co., Ltd.		
	34	2009/134271	WO	A1	2009-11-05	Dao et al.		
	35	2 436 277	EP	A1	2012-04-04	Drew		
	36	2017/139480	WO	A1	2017-08-17	Exploramed NC7, Inc.		
	37	1 586 340	EP	A2	2005-10-19	Sea Profit (Hong Kong) Limited		

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	1	GB Search Report, dated 15 November 2017, issued in priority GB Application No. GB1709561.3	
	2	GB Search Report, dated 28 November 2017, issued in priority GB Application No. GB1709566.2	
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Name/Print	Mark D. Simpson	Registration Number	32942

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(54) **Programmable breastpump**

Programmierbare Brustpumpe

Tire-lait programmable

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(30) Priority: **10.12.1999 US 170070 P**
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04017140.7 / 1 468 705
10004173.0 / 2 218 467
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10011009.7 / 2 260 885

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(56) References cited:
EP-A2- 0 330 845
DE-A1- 3 916 699
US-A- 4 564 359
US-A- 4 607 596
US-A- 4 794 915
US-A- 5 007 899
US-A- 5 571 084
US-A- 5 590 648
US-A- 5 676 525
US-A- 5 749 850
US-A- 5 776 098
US-A- 5 902 267

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Description

FIELD OF THE INVENTION

[0001] This invention relates to breastpumps for drawing breastmilk, and particularly to a motorized, such as electrically driven, breastpump.

BACKGROUND OF THE INVENTION

[0002] Breastpumps for use by nursing mothers are well known. They allow the nursing woman to express the breastmilk as necessary or convenient, and further provide collection of the breastmilkfor later use. For some mothers, breastpumps may be a necessity, such as when the child has suckling problems, or if the mother has problems with excessive or deficient milk production, or soreness, deformation or injury of the mammilla.

[0003] Manual breastpumps are commonplace, primarily because they are relatively inexpensive and easy to transport. Being manually driven, however, stroke rate and suction pressure produced can be uneven, and operating the pump can ultimately be tiring.

[0004] Electrically-driven breastpumps are also commonplace. They may be of a substantially large size of a non-portable or semi-portable type, typically including a vacuum pump which has an electric motor that plugs into standard house current. Advantages of this type of pump are ready controllability and regulation of the vacuum, and the ability to pump both breasts at once. That is, the nursing woman has both hands free to hold two breastpump shields in place for pumping of both breasts at the same time.

[0005] Battery-driven breastpumps have also been developed. These breastpumps have the advantages of controllability and regulation of the vacuum, as well as being easily carried. Such a battery-driven portable breastpump is described in U.S. 4,964,851, for example. This breastpump, sold under the name MINIELECTRIC by Medela, Inc., is lightweight and achieves good vacuum (i.e., negative pressure) regulation in preferred limits, for example, between about 100 and about 220 mmHg. The LACTINA breastpump sold by Medela, Inc. is also another type of breast pump which may be driven by battery as well as house current. It is generally disclosed in U.S. Patent No. 5,007,899.

[0006] Electrically driven motorized breastpumps have almost universally been developed with a single type of "cycle" for a given pump. That is, the driving mechanism for generating the vacuum (negative pressure) to be applied at the breast in the more sophisticated pumps is geared to a particular sequence, or curve, of negative pressure increase (i.e., increasing suction), and then release. This is often aimed at reproducing in some sense the suckling action of an infant, for instance. Breastpumping can cover a range of different conditions, however, such as where the mother's nipples are sore for some reason, there is a state of significant engorgement, some nipple stimulation may be particularly desired, let-down and relaxation may be of particular interest, it may be desired to increase milk production, and so on.

[0007] Some breastpumps provide the user with the ability to vary the amount of vacuum being applied, as well as the speed of the pumping action (i.e., number of cycles per minute). In some instances in the prior art, speed and vacuum level may influence each other, such that as speed increases so does the vacuum level. The basic "curve" remains fixed, however, and the user must adapt as best she can to making variations within that particular curve built into the machine, which typically has been generalized for the overall population of users.

[0008] US 5,571,084 is directed to a hands free lactation system wherein the vacuum magnitude and cycle frequency or cycle length of a breast pump are controlled by the outputfrom a microprocessor which includes manufacture-stored preset operating instructions. This system has exactly three settings.

[0009] DE 3916699 discloses a breast pump comprising a programmable microprocessor. The microprocessor controls in a predefined way a valve system which controls the release phase of a suction sequence.

SUMMARY OF THE INVENTION

[0010] It is an object of the invention to provide an improved breast pump. This object is achieved with the breast pump and the method according to claims 1 and 34.

[0011] It is an objective of the present invention to provide a breast pump which can be programmed to generate, among other things, a plurality of differing milk expression (extraction) sequences, or curves. To this end, the invention in one form is a breastpump comprising a breastshield having a portion within which a woman's breast is received for the expression of milk. A source of vacuum is in communication with the breastshield. There is a mechanism for operating the source of vacuum according to a first sequence, and a controller for operating the source of vacuum according to a second sequence.

[0012] The controller can have a preset program for the second sequence which is a milk letdown sequence, for example. Preferably, the breastpump has a plurality of different programs for the controller wherein each program has a different sequence.

[0013] In one embodiment of the invention, a motorized pump (e.g., compressed air, battery and/or house current) is provided with a microprocessor-based controller. Cards, with memory "chip," containing different suction curves adapted for varying conditions and objectives are included for programming the controller in this embodiment. A user selects a desired program, and that card is then read by a mechanism providing input to the controller. It should be noted that while suction curves are generally addressed in the first instance herein, the milk expression sequences may also include a positive pressure aspect. The programming could also be provided via oth-

er media, including discs, CDs, infrared data transfer, electronic feed (e.g., an Internet connection), and so forth.

[0014] A significant, and heretofore unavailable advantage realized by the present invention is the ready ability to modify the breastpump suction action to a variety of desired conditions, and provide this ability to the end-user. An attendant advantage is that, as the science of breastpumping continues to make advances, new and improved suction curves and sequences can be made available on further cards, or other progam-inputting means.

[0015] Yetanotherattendantadvantage is that the programmable pump can also record data relating to its use and operation. That data could be stored, for instance, and then retrieved as by downloading through an Internet connection, magnetic recording (disk or card), and the like. This data retrieval would be useful in medical research, for updating the pump with new data, for monitoring usage, just for some instances.

[0016] Further, a program could be made of a particular infant's suckling pattern. That program could then be used to operate the pump, and then varied over time as the infant grows.

[0017] In yet another aspect of the invention, an improved breastpump is provided which has a pre-programmed milk let-down sequence. The let-down sequence is most advantageously made available through a button or the like provided on the breastpump used to actuate the sequence.

[0018] In still another aspect of the invention, a breastpump includes an electric motor having a reduction gear system with at least first and second belts conveying motive power to a movable member of an expansible chamber device wherein a vacuum is generated. The expansible chamber device is, in one embodiment, a pair of diaphragm pumps. Each diaphragm pump has a membrane which is movable relative to a shell, each said membrane being connected to a respective drive shaft, each shaft being mounted to a respective belt for linear movement with the respective belt.

[0019] The present invention in another significant aspect has as an objective to provide a breastpump with one or more novel suction sequences which are considered to produce advantageous particularized results. Such sequences include, but are not limited to: a suction method (e.g., program or curve) for a sore nipple condition; a suction method for increased milk production; an improved suction method in general; and a method for nipple stimulation.

[0020] A method for operating a breastpump for a sore nipple condition according to the present invention comprises varying the amount of vacuum within a range of from about 20 mmHg (the least vacuum) to about 250 mmHg (the greatest vacuum) while simultaneously varying the overall suction cycle from about 25 cycles/min. at the least vacuum to about .40 cycles/min. at the greatest vacuum, such that for a lower vacuum applied there is an increase in the number of cycles. In general, this program is intended to provide a lower peak vacuum over a longer cycle.

[0021] A method for operating a breastpump which is considered to yield an increase in milk output according to the present invention comprises operating the pump at a rapid cyclical rate on the order of about 120 cycles/min., with a negative pressure in the range of about 50 to about 150 mmHg. This method further preferably includes a pause after each period of vacuum application, such as applying the vacuum for about ten seconds of vacuum, with then a two second pause.

[0022] A method for operating a breastpump according to yet another aspect of the invention comprises varying the vacuum within a range of about 100 (the least vacuum) to about 250 mmHg (the greatest vacuum), while simultaneously varying the overall suction cycle from about 47 cycles/min. at the greatest vacuum to about 78 cycles/min. at the least vacuum, such that for a lower vacuum applied there is an increase in the number of cycles, with a cycle following a curve which initially builds to a peak negative pressure, then smoothly starts a pressure increase (less negative) along an initial slope but then slows the pressure increase briefly, before continuing on essentially said initial slope for the negative pressure release.

[0023] A still further aspect of the present invention is a unique breastpump assembly having features including: a compact housing design and breastshield carrying casing; and a double-diaphragm pumping mechanism.

[0024] A prophylactic device for protecting the diaphragm from fluid (air/milk) is additionally provided. In one embodiment of this aspect of the invention, a diaphragm pump for a breastpump comprises a shell having a generally hemispherical interior shape with a flexible membrane movable within the hemispherical shape to expand and contract a volume created in a chamber defined between the membrane and the shell. A mechanism connected to the membrane, such as a puller, moves the membrane to expand and contract the volume. A port is provided in the shell through which air moves in response to expansion and contraction of the volume, such that vacuum can be communicated to a breastshield through connection to the port.

[0025] A removably mounted flexible cover is located between the shell and the membrane which isolates the membrane from fluid. The cover is removable for at least one of cleaning and disposal. To that end, the flexible membrane has a circumferential rim upon which the cover is received over the rim. The shell has an internal opening defined therein sized to encompass the rim with the cover mounted on the rim in a substantially airtight fit. The cover thereby forms a gasket between the rim and shell. A one-way valve extending through the membrane is additionally provided, allowing exhaustion of air between the membrane and cover.

[0026] Yet another significant aspect of the present invention is considered to be a manually operated control,

such as a rotary knob, which is used to simultaneously adjust the suction level as well as rate within a sequence. In this aspect of the invention, the suction "force" and "speed" are tied together in an inverse relationship. As the suction force (vacuum) is increased, for example, the rate (cycle) is decreased; as the vacuum is decreased, the cycle increases.

[0027] These and other features and advantages of the present invention will be further understood and appreciated when considered in relation to the following detailed description of embodiments of the invention, taken in conjunction with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

[0028]

FIG. 1 is a front perspective view of a breastpump assembly made in accordance with aspects of the present invention;
FIG. 2 is a side elevational view of the breastpump of FIG. 1;
FIG. 3 is a rear perspective view of the breastpump of FIG. 1;
FIG. 4 is a perspective view of the breastpump of FIG. 1 looking at the bottom;
FIG. 5 is a top view of the breastpump of FIG. 1 with a cover removed revealing diaphragm pumps;
FIG. 6 is an enlarged side view of the breastpump of FIG. 1 adjacent the bottom highlighting the program card insert slot;
FIG. 7 is a bottom perspective view of the breastpump of FIG. 1 showing battery arrangement;
FIG. 8 is a somewhat exploded assembly view of the major components of the breastpump of FIGS. 1 through 5, with a modified top cover for the diaphragm pump assembly;
FIG. 9 is a diagrammatic representation of the interaction of various components with the controller;
FIG. 10 is a schematic-type representation of a data storage and retrieval process that can be effected in accordance with the present invention;
FIGS. 11 through 14 are various methods (curves) for operating the breastpump to differing ends;
FIG. 15 is a front perspective view of another embodiment of a breastpump assembly made in accordance with aspects of the invention;
FIG. 16 is a rear perspective view of the FIG. 15 embodiment;
FIG. 17 is a somewhat exploded assembly view of the major components of yet another breastpump made in accordance with the present invention;
FIG. 18 is an enlarged front perspective view of the motor drive of the breastpump of FIG. 17;
FIG. 19 is a view similar to that of FIG. 18 but from a top perspective;
FIG. 20 is an enlarged assembly view of the diaphragm pump mechanism;
FIG. 21 (a) is a cross-sectional viewofthe assembled diaphragm pump of FIG. 20;
FIG. 21(b) is an elevational view of the assembled diaphragm pump of FIG. 20;
FIG. 21 (c) is a top view of the assembled diaphragm pump of FIG. 20;
FIG. 22 is a sectional view of the assembled breastpump of FIG. 17 taken through the middle of the breastpump along its long lateral axis (side to side) looking rearwardly;
FIG. 23 is a sectional view similar to that of FIG. 22 taken along a plane forwardly of that of FIG. 22; and
FIG. 24 is a sectional view similar to that of FIG. 22 taken along a plane behind the electric motor looking back to front.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The Breastpump Assembly

[0029] Referring to FIGS. 1 through 7 initially, a breastpump assembly of the present invention in one form has an aesthetically pleasing and compact design. The housing for the major components of the assembly is a casing 10 made of a rigid high impact plastic. As shown, it has a generally ellipsoidal cross-section along its vertical axis, yielding a pleasing smooth curving look to the casing exterior. The casing 10 is closed at its upper end by an upper housing part 11, to which is affixed a carrying handle 12.

[0030] In this first embodiment, carrying handle 12 has a pair of cradles 15 formed in opposite ends thereof. These cradles 15 are adapted to receive and support the funnel portions 16 of respective breastshields 17. These breastshields 17 (sometimes referred to themselves as breastpumps) are of the type shown and described in U.S. Patent No. 4,964,851 and 4,929,229, for instance. Further detail regarding the breastshields 17 may be obtained through reference to those patents, but will be omitted herein since the inventive features in point in this application are not contingent upon the breastshield being used, so long as it is suitable to the task of milk expression.

[0031] In general, however, the breastshields 17 have the aforementioned funnel portion 16 which communicates with conduit structure connecting to a container (bottle) 18. This particular breastshield 17 is adapted for both manual as well as motorized pumping. It has a collar 20 to which a manually-driven piston pump (not shown) is screw-threaded for attachment and use in one mode of operation. When an electrically operated vacuum pump is to be employed, there is a port provided inside of the collar 20 which is in communication with the funnel portion, and to which a tube from the vacuum pump is releasably connected to convey vacuum to the breastshield. Again, such detail is well known, and can be gleaned from the foregoing patents, among other public

sources. In operation in either mode, the widened (conical) portion of the breastshield 17 is placed on the breast for drawing vacuum within the shield, and thereby drawing milk through a pulling force applied to the breast. Milk drawn from the breast is collected in the bottle 18.

[0032] FIGS. 15 and 16 show a modified exterior for the breastpump 10' (prime numbers being used herein to refer to similar but modified parts). In this version the breastshields 17 are not cradled by the handle 12', but instead are carried in a holder 26 mounted to the back of the unit.

-The Drive Motor

[0033] Referring to FIG. 8 initially, casing 10 has a drive unit 25 mounted therein. There are, of course, any number of drives that may be used for diaphragm pumps such as those used in the instant embodiment. Indeed, the type of pump (diaphragm, piston, etc.) is not necessarily significant to certain aspects of the present invention. The driving mechanism for the breastpump shown for the embodiment in point, however, is a linear drive for the diaphragm pumps consisting of a reduction drive arrangement and a 12 V DC-motor 28.

[0034] It will be noted that the FIG. 8 embodiment is substantially the same as that of FIGS. 1 through 7, except for a modified cover for the upper housing, which here includes the rigid shells 24 for the diaphragms 34 as part of the cover 35. The diaphragm pumps 30 will be further described hereafter.

[0035] FIG. 17 shows yet another version of a breastpump of the present invention substantially the same as that of FIGS. 1 through 8, except with a modified cover 35" and shell 24"forthe diaphragm pump 30. The breastshield holder of the FIGS. 15 and 16 embodiment has also been slightly modified. It is with respect to this FIG. 17 embodiment that the majority of the interior detail of the breastpump will be further understood.

[0036] Turning now to FIGS. 18, 19 and 22 through 24 in particular, the reduction gearing contains belts 27a, 27b and 27c. Power is transferred from the shaft 29 of motor 28 to belt 27a. Belt 27a is received in a channel of wheel 51, which is mounted to the drive chassis 62 on rotatable shaft 52. Shaft 52 is fixed to rotate with wheel 51. A freewheel 53 is mounted on a shaft 54 fixed to the chassis 62 to freely rotate, and engages the outside of belt 27a, producing more surface engagement by the belt 27a with wheel 51.

[0037] Shaft 52 has a small toothed gear 55 mounted thereon. Belt 27b is toothed, and engages the gear 55. Toothed belt 27b furthermore engages a larger toothed gear 56 fixed to rotating shaft 57 (FIGS. 22 and 24). Part of gear 56 is small toothed gear portion 58. Belt 27c, which is also toothed, engages gear 58 as well as toothed gear 59. Gear 59 is fixedly mounted to rotating shaft 70. Fixed at each end of shaft 70 are small toothed gears 71 a, 71 b. Toothed belts 72a, 72b respectively engage gears 71a, 71b and freely rotating toothed gears 73a, 73b.

[0038] Diaphragm pusher (push/pull) shafts 74a, 74b are respectively clamped to belts 72a, 72b at one end. The other end engages the interior of a respective diaphragm membrane member 34 (FIG. 22, and also see FIGS. 20 and 21 (a)). Here, a screw engagement with the shafts 74a, 74b was used, with a threaded nut-like element 37 mounted in a reinforced central area of membrane 36 (again, the diaphragm pumps 30 are described in more detail below). Both of the pusher shafts 74a, 74b move in tandem as driven by respective belts 72a, 72b.

[0039] Accordingly, as motor drive shaft 29 turns, belt 27a rotates shaft 52 via wheel 51. Belt 27b is in turn thereby driven off of smaller gear 55, causing rotation of shaft 57, which in turn rotates larger gear 56 and its smaller part 58, to thereby turn shaft 70 via belt 27c which couples gear part 58 with larger gear 59. This transfers the motion via gears 71 a, 71 b to belts 72a, 72b, imparting a linear movement to the pusher shafts 74a, 74b. A forward and then backward stroke is generated, through reversal of the motor shaft 29 direction. Reduction gearing is thus obtained as desired through appropriate selection of the various gears/wheels noted above.

[0040] The location of the shafts 74a, 74b along the path of travel, as well as the length of the stroke, is measured by position sensing mechanism 78, which can be of any standard and well known variety. This sensing mechanism 78 uses a toothed wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b. Signals generated by the counter 78b are processed by the cpu of the breastpump.

[0041] A negative pressure, or vacuum, is generated in a pair of diaphragm pumps 30. Each diaphragm pump has a flexible membrane 34 mounted in the upper housing 11 assembled with a respective rigid shell 24 (and see FIGS. 20 and 21 (a) through 21 (c) described further below). The membrane and shell are in substantially airtight engagement. When the membrane 34 is pulled away from the shell 24, a vacuum is generated in the space between the shell interior and the membrane, which can be accessed through outlet port 31 formed on the shell, to which a tube 32 is connected to communicate the vacuum to a respective breastshield 17.

[0042] Power is provided either through ordinary house current via power cord 38, or electrochemical battery 39, such as a pair of 6V, 1.2Ah lead-acid type rechargeable batteries. Power cord 38 is provided on a wrap-around mount conveniently located for storage in a well in the bottom of the lower housing part 13. FIG. 7 shows wells 41 formed within the lower housing 13 through which the batteries 40 are inserted into receptacles formed within the casing 10, having covers 42 for the wells. FIG. 7 omits the detail of the wrap mount 40, for clarity.

--The Single Switch Inversely Controlling Vacuum and Rate

[0043] An on-off switch or knob 45 (and see FIG. 9) is provided on the casing, which can be rotary or pushbutton to that end. It is nonetheless rotary and push-button in this embodiment since it also acts to control the amount of vacuum being applied. As the knob 45 is rotated, a signal is generated which increases ordecreases the level of vacuum (suction force) to be applied, depending on which way the knob is turned. In this embodiment, as the suction force is increased, the cycle (rate) is decreased. That is, the rate and force are inversely related. This is considered to have a beneficial effect. The knob is pushed in for on and off:

-The Function Indicator

[0044] Additionally visible from the exterior of the casing 10 is a LCD display 48, a milk let-down button 49, and a program card slot 50 (the let-down sequence and programmable aspects will also be discussed in more detail below). Milk-let down button 49 is used to activate a pre-programmed suction sequence (embodied in components to be hereinafter described) particularly adapted for let-down and stimulate the milk ejection reflex. The slot 50 provides the interface access for programming cards used with the breastpump of this invention.

[0045] The display 48 provides visual indications of various functions of the pump. This could include, for example, the type of sequence then programmed, the level of suction force, the battery condition, and so forth.

-The Diaphragm Protective Covers

[0046] In this embodiment, the two diaphragm pumps 30 are in a well formed in the top of the casing 10. A cover 35 (also 35' and 35" (again, primed numbers being substantially similar to their un-primed counterparts)) is provided which fits over the well and is generally flush with the upper housing part 11. The outlets 31 extend through relieved areas in the cover 35, for example, for easy access in use.

[0047] It may be noted that the shells 24 are shown formed in the cover of the embodiment of FIG. 8. The FIG. 17 embodiment has the shells 24 mounted in a removable manner in the upper housing, as through a snap fit or interference engagement, such as shown in the embodiment of FIGS. 20 and 21 (a) through 21 (c), to allow easier access for cleaning or replacing the membranes of the pumping mechanism, and for cleaning the shells themselves (which are provided with grips 33 to these ends).

[0048] In the FIG. 17 embodiment, diaphragm member or membrane 34, which may be made of any suitably durable flexible and durable fluid-impervious material (to be airtight), such as silicone with a Shore A hardness in the range of 30 to 70, is molded around its perimeter to a rigid plastic collar 85. Collar 85 has a plurality of depending anchor posts 86 with outboard flanges formed thereon, which engage with the inside tip of the respective well in the upper housing part 11 within which the collar 85 is received to snap-fit the membrane 34 in place.

[0049] Prophylactic (protective) disposable/cleanable covers 36 are additionally and advantageously provided, which form-fit over the diaphragms 34 and isolate them from air and otherfluid from the breastshields. The covers 36, which can be made of the same material as the membranes but thinner, are likewise fluid-impervious.

[0050] Referring to FIGS. 20 and 21(a) through 21(c) in particular, each of the covers 36 has an upturned cuff 87 which forms an annular well around the perimeter of the cover 36. A pair of circumferential beads 88 and 89, which are slightly offset vertically from each other, are formed along the bottom area of the annular well. Uppermost bead 88 engages in an annular rim channel 90 formed along the bottom outside of shell 24', for a substantially airtight engagement between the protective cover 36 and the shell.

[0051] An interior channel 93 is formed within the interior bottom of the cover 36 by a bead 91 and shoulder 92, which each run circumferentially around the cover. This interior channel 93 is received on a slightly protruding edge or rim on the collar 85 of the membrane 34. An airtight fit is thus provided between the protective cover 36 and the membrane 34, which also serves to releasably fix the shell 24 in place over the membrane 34, and complete the diaphragm pump 30.

[0052] Note also that a one-way valve 95 is provided in the membrane 34, which communicates with the possible space that may form between the membrane 34 and overlying cover 36. This valve permits any entrapped air therebetween to be exhausted, such as if the first stroke on start-up happens to be toward the shell 24, with the protective cover 36 thereafter then following the movement of the diaphragm 34 to which it will generally be in facial engagement.

The Programmable Aspects

[0053] One significant aspect of the present invention is the ability to program the breastpump with different types of suction sequences, or cycles as they are sometimes referred to herein. With reference to FIG. 9, for instance, the breastpump utilizes a microprocessor-based system indicated at 60 which is provided user input through a plurality of "chip" cards 61. Each chip card contains one or more predetermined programs recorded on an EEPROM. For example, each card could contain a specific type of sequence along with a milk let-down sequence.

[0054] An EEPROM microcontroller of the type MB90562 may be used, for one example, or the Atmel 2-wire EEPROM chipcard microcontroller AT24C164 for another. These provide about 16K of memory, which is considered presently sufficient.

[0055] The programs (some examples of which are described hereafter) are recorded in a conventional manner, and would be provided to the mother ready to use. The programmed chip card is inserted into the slot 50 in the back of the casing 10, where it engages an interface to the microprocessor. The particular program on the selected chip card 61 is then communicated to the microprocessor 60. Microprocessor 60 is integrated with the drive unit 25 to effect operation of the drive unit in accordance with the selected program, drawing upon either the AC power source as converted via standard technology to DC (indicated at 68 in FIG. 9), or from the battery source 39. The microprocessor 60 can also control power management.

[0056] Suction force (e.g., the amount of negative pressure generated) will typically also be adjustable by the user via operation of the rotary control knob 45, as noted above. A pre-set range for the suction force will nonetheless ordinarily be provided in the program as an initial setting, for adjustment by the user thereafter via the knob 45.

[0057] One embodiment contemplated provides a milk let-down sequence (milk ejection reflex) that can be engaged without need of a chip card for the same. The milk let-down sequence (described below) is pre-programmed in the microprocessor 60, or may otherwise be wired into the circuitry in a manner to override the then-existing operating program. When the mother desires to engage this sequence, she presses the button 49, which produces and sends an electrical signal, as to the microprocessor 60. The let-down program is then effected.

[0058] It will be readily understood that a chip card 61 is but one way to program the microprocessor 60. Other input means could be used, such as more dedicated buttons like button 49, each set to actuate a given sequence pre-programmed into the microprocessor 60. A numeric pad could be provided to input a code. The programs could be provided through an electronic data link, such as a modem, or optically, or otherwise.

[0059] Data can also be recorded by the microprocessor for downloading or transfer to the chip card. Data could also be directly recorded on the chip card. For instance, it is contemplated that the suckling action of a particular child could be recorded and reduced to a sequence. That sequence could then be programmed into the pump, and the mother would then have a suckling action from the pump very reminiscent of her own child.

[0060] Referring now to FIG. 10, the chip card 61 a with breastpump operation data thereon is then read (downloaded) at a "card station" 65, shown here as a card reader 76 linked to a computer 77. The computer 77 is used to transfer the data to one of a variety of available media, such as CD, floppy disk, etc. for physical transfer to a research or data monitoring facility, here indicated at 80. The data could also simply be transferred via modem through an Internet interface.

The New Expression Methods (Cycles)

[0061] It can thus be seen that a variety of different suction cycles or sequences can now be provided with the same breastpump equipment. An example of the kind of methods that such cycle could represent comprises FIGS. 11 through 15.

[0062] FIG. 11, for instance, is what is referred to by Medela, Inc. as the "Standard Classic Program". This is a method for operating a breastpump that has been developed which is considered to provide a general optimal suction curve reminiscent of an infant's normal suckling, such as provided by the 015 "CLASSIC" breastpump sold by Medela, Inc. As indicated in the graph of FIG. 11, negative pressure is along the y-axis (in millimeters of mercury) and time (in seconds) along the x-axis. In this particular method, the cycles are fixed at about 47 per minute; the amount of suction is generally adjustable between about 100 to about 250 mmHg.

[0063] FIG. 12 illustrates what can be termed as a new "Sore Nipple Program" method. In comparison to FIG. 11, it will be seen that the lower end of the vacuum range is reduced to about 20 mmHg, and the overall suction cycle is extended in duration, i.e., from a low of about 25 cycles/min. to about 40. For a lower vacuum applied in this program, there is an increase in the numberof cycles. In general, however, there is a slower and gentler suction compared with the "CLASSIC" program of FIG. 11.

[0064] FIG. 13 shows a new method for operating a breastpump which is considered to yield an increase in milk output. This is a program that might be applied between regular pump sessions several times a day. In this method, the breastpump is operated at a rapid cyclical rate on the order of about 120 cycles/min., preferably with a pause after a period of vacuum application; here, 10 seconds of vacuum, then a 2 second pause. The negative pressure is in the range of about 50 to about 150 mmHg. Note the detail in the inset of FIG. 13 showing the rapidity and steep slopes of the vacuum application.

[0065] What has been termed a new "Superior Program" for operating a breastpump is illustrated in FIG. 14. A vacuum range of about 100 to about 250 mmHg has been chosen, with cycles ranging from about 47 to about 78 per minute. The cycle rate and the vacuum are tied, such that as, for instance, the cycles decrease, the amount of vacuum increases, i.e., there is an inverse relationship. It will be noted that this program differs from the "CLASSIC" program above in part through a sequence that initially reaches a peak negative pressure, then smoothly starts a pressure increase (less negative) along a similar (although opposite) slope to that of the negative pressure build-up, but then slows the pressure increase briefly, before continuing on essentially the initial slope for the negative pressure release. A milk let-down sequence is also incorporated in this "Superior Program," and utilizes a vacuum range of about 50 to about 150 mmHg, with cycles ranging between about 80 to about 160 per minute.

[0066] Thus, while the invention has been described herein with relation to certain embodiments and applications, those with skill in this art will recognize changes, modifications, alterations and the like which still come within the scope of the following claims.

Claims

1. A breastpump comprising:

   a breastshield (17) having a portion (16) within which a woman's breast is received for the expression of milk;
   a source of vacuum (30) in communication with said breastshield (17); and
   a controller (60) for varying the vacuum,

   characterized in that the controller (60) is programmable and that the breastpump comprises the ability for the user to modify the breastpump suction action by inputting selected programs so that the breastpump can be programmed with different types of suction sequences.

2. The breastpump according to claim 1, wherein the breastpump comprises a mechanism (45, 50, 49, 76) providing input to the controller (60), wherein the input is a program selected by the user.

3. The breastpump according to claim 1, wherein the breastpump comprises an interface (50, 76) for communicating a selected program to the controller.

4. The breastpump according to claim 1, wherein at least one sequence can differ in shape from another in more than frequency and maximum or minimum pressure.

5. The breastpump of claim 1 further comprising a plurality of different programs for said controller (60).

6. The breastpump of claim 5 wherein said programs are contained on prerecorded media (61), and said breastpump further comprises a media reader (50) which reads and inputs a program to said controller (60).

7. The breastpump of claim 6 wherein each program is recorded on a separate media (61), especially a separate card.

8. The breastpump of claim 5 wherein said programs are different sequences for varying at least one of vacuum force and vacuum cycle according to an application curve.

9. The breastpump of claim 1 further including a source of positive pressure in communication with said breastshield (17), and said programmable controller (60) further varies said positive pressure source (30).

10. The breastpump of claim 9 wherein said programs are different sequences for varying at least one of vacuum force, positive pressure force and vacuum cycle according to an application curve.

11. The breastpump of claim 1 further including a means for generating signals indicative of breastpump operating functions, and means for recording (61a) said signals for later retrieval.

12. The breastpump of claim 5 wherein said programs are recorded in said controller (60), and further including a program selection mechanism (49, 50) associated with said breastpump.

13. The breastpump of claim 1 wherein said program selection mechanism (49, 50) is at least one manually operated button (49) located on said breastpump, said button being actuable to send a signal to said controller for selection of a program.

14. The breastpump of claim 1 wherein the breastpump comprises:

   a mechanism (25) for operating said source of vacuum according to a first sequence; and
   the controller (60) for operating said source of vacuum according to a second sequence.

15. The breastpump of claim 14 wherein said controller (60) has a preset program for a milk letdown sequence.

16. The breastpump of claim 14 wherein said mechanism (25) includes an electric motor (28), said motor (28) having a reduction drive system with at least first and second belts (27a, 27b, 27c; 71a, 71b, 71c) conveying motive power to a movable member (34) of an expansible chamber device wherein a vacuum is generated.

17. The breastpump of claim 16 wherein said expansible chamber device is a diaphragm pump (30).

18. The breastpump of claim 17 wherein there are two diaphragm pumps (30), said diaphragm pumps (30) having a membrane (34) which is movable relative to a shell (24) , each said membrane (34) being connected to a respective shaft (74a, 74b), each said shaft (74a, 74b) being mounted to a respective belt (72a, 72b) for linear movement with said respective belt (72a, 72b).

19. The breastpump of claim 18 wherein said respective

shafts (74a, 74b) are driven in tandem.

20. The breastpump according to claim 1 wherein the vacuum pump (30) comprises

a chamber defined by a shell (24) and a member (34) movable relative to said shell (24);
a mechanism (74a, 74b) connected to said movable member (34) which moves said movable member (34) to expand and contract a volume defined within said chamber;
a port (31) in said shell (24) through which fluid moves in response to expansion and contraction of said volume; and
a removably mounted cover (36) between said shell (24) and said movable member (34) isolating said movable member (34) from fluid, said cover being removable for at least one of cleaning and disposal.

21. The breastpump of claim 20 wherein said cover (36) is flexible.

22. The breastpump of claim 21 wherein said movable member (34) has a circumferential rim (85), said cover (36) being received over said rim, and said shell (24) has an internal opening defined therein sized to encompass said rim (85) with said cover (36) mounted on said rim (85) in a substantially airtight fit, said cover (36) thereby forming a gasket between said rim (85) and said shell (24).

23. The breastpump of claim 21 further including a one-way valve (95) extending through said movable member (34), said valve (95) allowing exhaustion of air between said movable member (34) and said cover (36) mounted thereon.

24. The breastpump of claim 20 wherein said pump is a diaphragm pump (30), said shell (24) having a generally hemispherical interior shape, said movable member (34) being a flexible membrane.

25. The breastpump of claim 23 wherein said pump is a diaphragm pump (30), said shell (24) having a generally hemispherical interior shape, said movable member (34) being a flexible membrane.

26. The breastpump according to claim 1, the vacuum pump being a diaphragm pump (30) comprising:

a shell (24) having a generally hemispherical interior shape;
a flexible membrane (34) movable within said hemispherical shape to expand and contract a volume created in a chamber defined between said membrane (34) and shell (24);
a mechanism (74a, 74b) connected to said membrane (34) which moves said membrane (34) to expand and contract said volume;
a port (31) in said shell (24) through which air moves in response to expansion and contraction of said volume;
a removably mounted flexible cover (36) between said shell (24) and said membrane (34) which isolates said membrane (34) from fluid, said cover (36) being removable for at least one of cleaning and disposal, said flexible membrane (34) having a circumferential rim (85), said cover (36) being received over said rim (85), and said shell (24) having an internal opening defined therein sized to encompass said rim (85) with said cover (36) mounted on said rim (85) in a substantially airtight fit, said cover (36) thereby forming a gasket between said rim (85) and shell (24).

27. The breastpump of claim 26 further including a one-way valve (95) extending through said movable member (34), said valve (95) allowing exhaustion of air between said movable member (34) and said cover (36) mounted thereon.

28. The breastpump according to claim 1, comprising;

a mechanism (25) operating said vacuum source (30) to produce at least a milk letdown sequence and another sequence different from said letdown sequence.

29. The breastpump of claim 28 wherein said mechanism (25) has a motor drive.

30. The breastpump of claim 29 further including a controller (60), said controller (60) including at least two pre-programmed sequences for operating said motor drive (25), one of said sequences being a letdown sequence and another being a milk expression sequences.

31. The breastpump of claim 30 further including a sequence selecting device (49, 50), wherein said letdown sequence is selectable by an operator.

32. The breastpump according to claim 1 wherein the improvement comprises a mechanism associated with the breastpump specifically adapted to initiate a milk letdown reflex.

33. The breastpump of claims 28 to 32, wherein said mechanism operates a letdown sequence with a vacuum pressure ranging between about 50 mmHg to about 150 mmHg, and a frequency of about 80 to about 160 cycles per minute.

34. A method for operating a breastpump according to

one of claims 1 to 33, the breastpump comprising a source of vacuum (30) and a programmable controller (60) for varying the vacuum, **characterized in that** the controller (60) operates the source of vacuum (30) according to a selected program which was selected by a user and input to the controller (60), wherein the breastpump can be programmed with different types of suction sequences.

35. The method according to claim 34, wherein the suckling sequence of an infant in terms of at least suction force over time is recorded and the breastpump is programmed to operate in accordance with said recording.

36. The method according to claim 34, further comprising providing a plurality of different programs for said controller (60) for varying said vacuum in accordance with different sequences.

37. The method of claim 36 wherein said programs are provided on prerecorded media (61), and said breastpump further comprises a media reader (50), the method futher comprising the step of inputting a program through said reader (50) to said controller (60).

38. The method of claim 37 further providing each program being recorded on a separate media (61), especially on a separate card.

39. The method of claim 36 further comprising different programs having different sequences for varying at least one of vacuum force and vacuum cycle according to an application curve.

40. The method of claim 34 further including a source of positive pressure in communication with said breastshield (17), and further including the step of programming said controller (60) to vary said positive pressure source (30).

41. The method of claim 40 further comprising different programs having different sequences for varying at least one of vacuum force, positive pressure force and vacuum cycle according to an application curve.

42. The method according to claim 34 comprising varying the amount of vacuum and its cycle according to the curve of Fig. 12.

43. The method according to claim 34 comprising varying the amount of vacuum and its cycle according to the curve of Fig. 13.

44. The method according to claim 34 comprising varying the amount of vacuum and its cycle according to the curve of Fig. 14.

45. The method according to claim 34 comprising varying the amount of vacuum within a range of from about 20 mmHg (the least vacuum) to about 250 mmHg (the greatest vacuum) while simultaneously varying the overall suction cycle from about 25 cycles/min. at the greatest vacuum to about 40 cycles/min. at the least vacuum, such that for a lower vacuum applied there is an increase in the number of cycles.

46. The method according to claim 34 which is considered to yield an increase in milk output, comprising operating said pump at a rapid cyclical rate on the order of about 120 cycles/min., with a negative pressure in the range of about 50 to about 150 mmHg.

47. The method of claim 46 further including a pause after each period of vacuum application.

48. The method of claim 47 wherein said vacuum is applied for about ten seconds of vacuum, with then a two second pause.

49. The method according to claim 34 comprising varying the vacuum within a range of about 100 (the least vacuum) to about 150 mmHg (the greatest vacuum), while simultaneously varying the overall suction cycle from about 78 cycles/min. at the least vacuum to about 47 cycles/min. at the greatest vacuum, such that for a lower vacuum applied there is an increase in the number of cycles, with a cycle following a curve which initially builds to a peak negative pressure, then smoothly starts a pressure increase (less negative) along an initial slope but then slows the pressure increase briefly, before continuing on essentially said initial slope for the negative pressure release.

50. The method according to claims 45, 46, 47 comprising including a milk let-down sequence for said breastpump and additionally operating said breastpump with said milk let-down sequence.

Patentansprüche

1. Brustpumpe, aufweisend
eine Brusthaube (17) mit einem Teil (16) zur Aufnahme einer weiblichen Brust zwecks Absaugen von Milch;
eine mit der Brusthaube (17) verbundene Vakuumquelle (30); und
einen Controller (60) zur Veränderung des Unterdrucks,
dadurch gekennzeichnet, dass der Controller (60) programmierbar ist und dass die Brustpumpe dem Benützer die Möglichkeit gibt, den Saugbetrieb der Brustpumpe zu verändern, indem ausgewählte Programme eingegeben werden so dass die Brustpum-

pe mit verschiedenen Typen von Saugsequenzen programmierbar ist.

2. Brustpumpe gemäss Anspruch 1, wobei die Brustpumpe einen Mechanismus (45, 50, 49, 76) aufweist, welcher dem Controller (60) eine Eingabe gibt, wobei die Eingabe ein vom Benützer ausgewähltes Programm ist.

3. Brustpumpe gemäss Anspruch 1, wobei die Brustpumpe eine Schnittstelle (50, 76) aufweist, um das ausgewählte Programm dem Controller zu kommunizieren.

4. Brustpumpe gemäss Anspruch 1, wobei sich mindestens eine Sequenz in der Form mehr als in der Frequenz und in einem maximalen oder minimalen Druck von einer anderen unterscheiden kann.

5. Brustpumpe gemäss Anspruch 1, wobei sie ferner eine Vielzahl verschiedener Programme für diesen Controller aufweist.

6. Brustpumpe gemäss Anspruch 5, wobei diese Programme auf einem im Voraus gespeicherten Datenträger (61) enthalten sind und wobei diese Brustpumpe ferner einen Datenträgerleser (50) aufweist, welcher ein Programm liest und dem Controller (60) eingibt.

7. Brustpumpe gemäss Anspruch 6, wobei jedes Programm auf einem getrennten Datenträger (61) gespeichert ist, insbesondere auf einer separaten Karte.

8. Brustpumpe gemäss Anspruch 5, wobei diese Programme verschiedene Sequenzen sind, um mindestens den Unterdruck und/oder den Unterdruckzyklus gemäss einer Anwendungskurve zu variieren.

9. Brustpumpe gemäss Anspruch 1, wobei sie ferner eine mit der Brusthaube (17) verbundenen Überdruckquelle aufweist, und wobei dieser programmierbare Controller (60) ferner diese Überdruckquelle (30) variiert.

10. Brustpumpe gemäss Anspruch 9, wobei diese Programme verschiedene Sequenzen zur Variation von Unterdruck und/oder Überdruck und/oder Unterdruckzyklus gemäss einer Anwendungskurve sind.

11. Brustpumpe gemäss Anspruch 1, wobei sie ferner ein Mittel zur Erzeugung von Signalen aufweist, welche die Betriebsfunktionen der Brustpumpe anzeigt und Mittel zum Speichern dieser Signale für eine spätere Abfrage.

12. Brustpumpe gemäss Anspruch 5, wobei diese Programme in diesem Controller (60) gespeichert sind und wobei sie ferner einen Programmauswahlmechanismus (49, 50) aufweist, welcher dieser Brustpumpe zugeordnet ist.

13. Brustpumpe gemäss Anspruch 1, wobei dieser Programmauswahlmechanismus (49, 50) mindestens ein manuell bedienbarer Knopf (49) ist, welcher auf der Brustpumpe angeordnet ist, wobei dieser Knopf aktivierbar ist, um ein Signal zum Controller zu senden um ein Programm zu wählen.

14. Brustpumpe gemäss Anspruch 1, wobei die Brustpumpe aufweist:

einen Mechanismus (25) zum Betreiben dieser Vakuumquelle gemäss einer ersten Sequenz; und den Controller (60) zum Betreiben der Vakuumquelle gemäss einer zweiten Sequenz.

15. Brustpumpe gemäss Anspruch 14, wobei dieser Controller (60) ein voreingestelltes Programm für eine Milcheinschuss- Sequenz aufweist.

16. Brustpumpe gemäss Anspruch 14, wobei dieser Mechanismus (25) einen elektrischen Motor (28) beinhaltet, wobei dieser Motor (28) ein Reduktionsgetriebesystem aufweist mit mindestens einem ersten und einem zweiten Riemen (27a, 27b, 27c, 71a, 71b, 71c), welche Bewegungsenergie zu einem bewegbaren Teil (34) einer expandierbaren Kammereinheit führen, in welcher der Unterdruck erzeugt wird.

17. Brustpumpe gemäss Anspruch 16, wobei diese expandierbare Kammereinheit eine Membranpumpe (30) ist.

18. Brustpumpe gemäss Anspruch 17, wobei zwei Membranpumpen (30) vorhanden sind, wobei diese Membranpumpen (30) eine Membran (34) aufweisen, welche relativ zu einer Schale (24) bewegbar ist, wobei jede dieser Membrane (34) mit einem jeweiligen Schaft (74a, 74b) verbunden ist, wobei jeder dieser Schäfte (74a, 74b) mit einem jeweiligen Riemen (72a, 72b) verbunden ist für eine lineare Bewegung mit diesem jeweiligen Riemen (72a, 72b).

19. Brustpumpe gemäss Anspruch 18, wobei diese jeweiligen Schäfte (74a, 74b) im Tandem betrieben sind.

20. Brustpumpe gemäss Anspruch 1, wobei die Vakuumpumpe (30) aufweist:

eine durch die Schale (24) definierte Kammer und ein Element, welches relativ zu dieser Schale (24) bewegbar ist;
einen Mechanismus (74a, 74b), welcher mit die-

sem bewegbaren Element (34) verbunden ist und welcher dieses bewegbare Element (34) bewegt, um ein durch die Kammer definiertes Volumen zu expandieren und zu kontrahieren;
eine Öffnung (31) in dieser Schale (24), durch welche sich ein Fluid in Antwort auf die Expansion und Kontraktion dieses Volumens bewegt; und
einen zwischen dieser Schale (24) und diesem bewegbaren Element (34) lösbar angeordneten Deckel (36), welcher dieses bewegbare Element (34) vom Fluid trennt, wobei dieser Deckel mindestens zum Reinigen und/oder zur Entsorgung entfernbar ist.

21. Brustpumpe gemäss Anspruch 20, wobei dieser Deckel (36) flexibel ausgebildet ist.

22. Brustpumpe gemäss Anspruch 21, wobei dieser bewegbare Teil (34) einen umlaufenden Rand (85) aufweist, wobei dieser Deckel (36) auf diesem Rand aufgenommen ist, und wobei diese Schale (24) eine innere Öffnung aufweist, welche bemessen ist, um diesen Rand (85) mit dem darauf angeordneten Deckel (36) in einem im wesentlichen luftdichten Verschluss zu umgreifen, wobei dieser Deckel (36) eine Dichtung zwischen diesem Rand (85) und dieser Schale (24) bildet.

23. Brustpumpe gemäss Anspruch 21, wobei sie ferner ein Einwegventil (95) aufweist, welches sich durch das bewegbare Element (34) erstreckt und eine Luftentspannung zwischen diesem bewegbaren Teil (34) und diesem darauf angeordneten Deckel (36) ermöglicht.

24. Brustpumpe gemäss Anspruch 20, wobei diese Pumpe eine Membranpumpe (30) ist, wobei diese Schale (24) eine im Wesentlichen halbkugelförmige innere Form aufweist, wobei dieses bewegbare Element (34) eine flexible Membran ist.

25. Brustpumpe gemäss Anspruch 23, wobei diese Pumpe eine Membranpumpe (30) ist, wobei diese Schale (24) eine im Wesentlichen halbkugelförmige innere Form aufweist und wobei dieses bewegbare Element (34) eine flexible Membran ist.

26. Brustpumpe gemäss Anspruch 1, wobei die Vakuumpumpe eine Membranpumpe (30) ist, welche aufweist:

eine Schale (24) mit einer im Wesentlichen halbkugelförmigen inneren Form;
eine flexible Membran (34), welche innerhalb dieser halbkugelförmigen Form bewegbar ist, um ein in einer zwischen dieser Membran (34) und der Schale (24) definierten Kammer erzeugtes Volumen zu expandieren und zu kontrahieren;
einen mit dieser Membran (36) verbundenen Mechanismus (74a, 74b), welcher diese Membran (36) bewegt, um dieses Volumen zu expandieren und zu kontrahieren;
eine Öffnung (31) in dieser Schale (24), durch welche sich Luft in Antwort auf die Expansion und Kontraktion dieses Volumens bewegt;
einen zwischen dieser Schale (24) und dieser Membran (34) lösbar angeordneten Deckel (36), welcher die Membran (34) vom Fluid trennt, wobei dieser Deckel (36) mindestens zur Reinigung und/oder Entsorgung entfernbar ist,
wobei diese flexible Membran (34) einen umlaufenden Rand (85) aufweist,
wobei dieser Deckel (36) auf diesem Rand (85) aufgenommen ist, und wobei diese Schale (24) eine innere Öffnung aufweist, welche bemessen ist, um diesen Rand (85) mit dem darauf angeordneten Deckel (36) in einem im wesentlichen luftdichten Verschluss zu umgreifen, wobei dieser Deckel (36) eine Dichtung zwischen diesem Rand (85) und dieser Schale (24) bildet.

27. Brustpumpe gemäss Anspruch 26, wobei sie ferner ein Einwegventil (95) aufweist, welches sich durch das bewegbare Element (34) erstreckt und eine Luftentspannung zwischen diesem bewegbaren Teil (34) und diesem darauf angeordneten Deckel (36) ermöglicht.

28. Brustpumpe gemäss Anspruch 1, aufweisend einen Mechanismus (25), um diese Vakuumquelle (30) zu betreiben, um mindestens eine Milcheinschuss-Sequenz und eine andere, von der Milcheinschuss-Sequenz verschiedene Sequenz zu erzeugen.

29. Brustpumpe gemäss Anspruch 28, wobei dieser Mechanismus (25) ein Motorantrieb ist.

30. Brustpumpe gemäss Anspruch 29, wobei sie ferner einen Controller (60) aufweist, wobei dieser Controller (60) mindestens zwei vorprogrammierte Sequenzen zum Betrieb des Motorantriebs (25) aufweist, wobei eine dieser Sequenzen eine Einschusssequenz und eine andere Sequenz eine Milchabpump-Sequenz ist.

31. Brustpumpe gemäss Anspruch 30, wobei sie ferner eine Sequenz-Auswähleinheit (49, 50) aufweist, wobei diese Einschuss-Sequenz mittels eines Bedieners auswählbar ist.

32. Brustpumpe gemäss Anspruch 1, wobei die Verbesserung einen mit der Brustpumpe verbundenen Mechanismus aufweist, welcher speziell zur Auslösung

eines Milcheinschussreflexes geeignet ist.

33. Brustpumpe gemäss den Ansprüchen 28 bis 32, wobei dieser Mechanismus eine Einschusssequenz betreibt mit einem Unterdruck im Bereich von ungefähr 50 mmHg bis ungefähr 150 mmHg und einer Frequenz im Bereich von ungefähr 80 bis ungefähr 160 Zyklen pro Minute.

34. Verfahren zum Betreiben einer Brustpumpe gemäss einem der Ansprüche 1 bis 33, wobei die Brustpumpe eine Vakuumquelle und einen programmierbaren Controller (60) zur Veränderung des Unterdrucks aufweist, **dadurch gekennzeichnet, dass** der Controller (60) die Vakuumquelle (30) gemäss einem ausgewählten Programm betreibt, welches von einem Benützer ausgewählt wurde und in den Controller (60) eingegeben wurde, wobei die Brustpumpe mit verschiedenen Typen von Saugsequenzen programmiert werden kann.

35. Verfahren gemäss Anspruch 34, wobei die Saugsequenzen eines Säuglings in Hinsicht auf mindestens die Saugleistung in Abhängigkeit der Zeit festgehalten wird und wobei die Brustpumpe programmiert ist um in Abhängigkeit von dieser Aufzeichnung zu funktionieren.

36. Verfahren nach Anspruch 34, wobei ferner eine Vielzahl von verschiedenen Programmen für diesen Controller (60) bereitgestellt werden, um diesen Unterdruck in Abhängigkeit von verschiedenen Sequenzen zu variieren.

37. Verfahren nach Anspruch 36, wobei diese Programme auf einem vorgängig gespeicherten Datenträger (61) zur Verfügung gestellt werden und diese Brustpumpe ferner einen Datenträgerleser (50) aufweist, wobei das Verfahren ferner den Schritt aufweist, dass ein Programm mittels dieses Lesers (50) diesem Controller (60) eingegeben wird.

38. Verfahren nach Anspruch 37, wobei ferner jedes Programm auf einem separaten Datenträger (61) gespeichert ist, insbesondere auf einer separaten Karte.

39. Verfahren nach Anspruch 36, wobei ferner verschiedene Programme verschiedene Sequenzen aufweisen um mindestens den Unterdruck und/oder den Unterdruckzyklus gemäss einer Anwendungskurve zu variieren.

40. Verfahren nach Anspruch 34, wobei ferner eine Überdruckquelle mit der Brusthaube (17) verbunden ist und wobei das Verfahren ferner den Schritt aufweist, dass der Controller (60) programmiert wird um diese Überdruckquelle (30) zu variieren.

41. Verfahren nach Anspruch 40, wobei ferner verschiedene Programme verschiedene Sequenzen aufweisen um mindestens den Unterdruck und/oder den Überdruck und/oder den Unterdruckzyklus gemäss einer Anwendungskurve zu variieren.

42. Verfahren nach Anspruch 34, wobei es den Betrag des Unterdrucks und dessen Zyklus gemäss einer in Figur 12 dargestellten Kurve variiert.

43. Verfahren nach Anspruch 34, wobei es den Betrag des Unterdrucks und dessen Zyklus gemäss einer in Figur 13 dargestellten Kurve variiert.

44. Verfahren nach Anspruch 34, wobei es den Betrag des Unterdrucks und dessen Zyklus gemäss einer in Figur 14 dargestellten Kurve variiert.

45. Verfahren nach Anspruch 34, wobei der Betrag des Unterdrucks innerhalb eines Bereichs von ungefähr 20 mmHg (der geringste Unterdruck) bis ungefähr 250 mmHG (der grösste Unterdruck) variiert wird, wobei gleichzeitig ein umfassender Saugzyklus von circa 25 Zyklen/Minute beim grössten Unterdruck bis zu 40 Zyklen/Minute beim geringsten Unterdruck variiert wird, so dass für ein geringerer angelegter Unterdruck ein Anstieg in der Anzahl Zyklen vorhanden ist.

46. Verfahren nach Anspruch 34, welches erachtet wird, dass es eine Erhöhung in der erhaltenen Milchmenge bringt, wobei das Verfahren aufweist:

    betreiben einer Pumpe mit einer schnellen Zyklusrate von etwa 120 Zyklen/Minute mit einem Unterdruck im Bereich von ungefähr 50 bis ungefähr 150 mmHg.

47. Verfahren nach Anspruch 46, wobei es ferner eine Pause nach jeder Periode der Unterdruckbeaufschlagung aufweist.

48. Verfahren nach Anspruch 47, wobei dieser Unterdruck für circa 10 Sekunden angelegt wird, mit anschliessenden zwei Sekunden Pause.

49. Verfahren nach Anspruch 34, wobei der Unterdruck in einem Bereich von circa 100 (der geringste Unterdruck) bis circa 150 mmHg (der grösste Unterdruck) variiert wird, wobei gleichzeitig ein umfassender Saugzyklus von circa 78 Zyklen/Minute beim grössten Unterdruck bis zu 47 Zyklen/Minute beim geringsten Unterdruck variiert wird, so dass für ein geringerer angelegter Unterdruck ein Anstieg in der Anzahl Zyklen vorhanden ist, wobei der Zyklus einer Kurve folgt, welche anfänglich einen Höchstpunkt im Unterdruck aufweist, dann sanft einen Druckanstieg (weniger negative) entlang einer anfänglichen Stei-

gung startet, aber dann den Druckanstieg kurzzeitig verlangsamt, bevor die negative Druckentspannung im Wesentlichen entlang der anfänglichen Steigung fortgeführt wird.

50. Verfahren nach den Ansprüchen 45, 46, 47, wobei es eine Milcheinschuss-Sequenz für diese Brustpumpe beinhaltet und wobei zusätzlich diese Brustpumpe mit dieser Milcheinschuss-Sequenz betrieben wird.

Revendications

1. Tire-lait, comprenant :

une téterelle (17) ayant une portion (16) dans laquelle le sein d'une femme est reçu pour tirer du lait ;
une source de vide (30) communiquant avec ladite téterelle (17) ; et
un contrôleur (60) pour faire varier le vide,

caractérisé en ce que le contrôleur (60) est programmable et **en ce que** le tire-lait comprend la possibilité pour l'utilisateur de modifier l'action de succion du tire-lait en entrant des programmes sélectionnés, de telle sorte que le tire-lait puisse être programmé avec différentes séquences de succion.

2. Tire-lait selon la revendication 1, dans lequel le tire-lait comprend un mécanisme (45, 50, 49, 76) fournissant une entrée au contrôleur (60), l'entrée étant un programme sélectionné par l'utilisateur.

3. Tire-lait selon la revendication 1, dans lequel le tire-lait comprend une interface (50, 76) pour communiquer un programme sélectionné au contrôleur.

4. Tire-lait selon la revendication 1, dans lequel au moins une séquence peut avoir une forme différente d'une autre, pas seulement pour la fréquence et la pression maximale ou minimale.

5. Tire-lait selon la revendication 1, comprenant en outre une pluralité de programmes différents pour ledit contrôleur (60).

6. Tire-lait selon la revendication 5, dans lequel lesdits programmes sont contenus sur des supports préenregistrés (61), et ledit tire-lait comprend en outre un lecteur de support (50) qui lit et entre un programme dans ledit contrôleur (60).

7. Tire-lait selon la revendication 6, dans lequel chaque programme est enregistré sur un support séparé (61), en particulier une carte séparée.

8. Tire-lait selon la revendication 5, dans lequel lesdits programmes sont des séquences différentes pour faire varier une force de vide et/ou un cycle de vide en fonction d'une courbe d'application.

9. Tire-lait selon la revendication 1, comportant en outre une source de pression positive en communication avec ladite téterelle (17), et ledit contrôleur programmable (60) faisant en outre varier ladite source de pression positive (30).

10. Tire-lait selon la revendication 9, dans lequel lesdits programmes sont des séquences différentes pour faire varier une force de vide, une force de pression positive et/ou un cycle de vide en fonction d'une courbe d'application.

11. Tire-lait selon la revendication 1, comportant en outre un moyen pour générer des signaux indiquant des fonctions de fonctionnement du tire-lait, et des moyens pour enregistrer (61a) lesdits signaux en vue de leur obtention ultérieure.

12. Tire-lait selon la revendication 5, dans lequel lesdits programmes sont enregistrés dans ledit contrôleur (60), et comportant en outre un mécanisme de sélection de programme (49, 50) associé audit tire-lait.

13. Tire-lait selon la revendication 1, dans lequel ledit mécanisme de sélection de programme (49, 50) est au moins un bouton (49) actionné manuellement situé sur ledit tire-lait, ledit bouton pouvant être actionné pour envoyer un signal audit contrôleur en vue de sélectionner un programme.

14. Tire-lait selon la revendication 1, dans lequel le tire-lait comprend :

un mécanisme (25) pour commander ladite source de vide en fonction d'une première séquence ; et le contrôleur (60) pour commander ladite source de vide en fonction d'une deuxième séquence.

15. Tire-lait selon la revendication 14, dans lequel ledit contrôleur (60) a un programme prédéfini pour une séquence de montée du lait.

16. Tire-lait selon la revendication 14, dans lequel ledit mécanisme (25) comporte un moteur électrique (28), ledit moteur (28) ayant un système d'entraînement réducteur ayant au moins des première et deuxième courroies (27a, 27b, 27c, 71a, 71b, 71c) transmettant la puissance du moteur à un organe déplaçable (34) d'un dispositif à chambre expansible dans lequel est généré un vide.

17. Tire-lait selon la revendication 16, dans lequel ledit

dispositif à chambre expansible est une pompe à diaphragme (30).

18. Tire-lait selon la revendication 17, dans lequel il y a deux pompes à diaphragme (30), lesdites pompes à diaphragme (30) comportant une membrane (34) déplaçable par rapport à une coque (24), chaque dite membrane (34) étant connectée à un arbre respectif (74a, 74b), chaque dit arbre (74a, 74b) étant monté sur une courroie respective (72a, 72b) en vue d'un mouvement linéaire avec ladite courroie respective (72a, 72b).

19. Tire-lait selon la revendication 18, dans lequel lesdits arbres respectifs (74a, 74b) sont entraînés en tandem.

20. Tire-lait selon la revendication 1, dans lequel la pompe à vide (30) comprend
une chambre définie par une coque (24) et un organe (34) déplaçable par rapport à ladite coque (24) ;
un mécanisme (74a, 74b) connecté audit organe déplaçable (34), qui déplace ledit organe déplaçable (34) pour augmenter et réduire un volume défini dans ladite chambre ;
un orifice (31) dans ladite coque (24), à travers lequel du fluide se déplace en réponse à l'expansion et à la contraction dudit volume ; et
un couvercle (36) monté de manière amovible entre ladite coque (24) et ledit organe déplaçable (34), isolant ledit organe déplaçable (34) du fluide, ledit couvercle pouvant être enlevé pour un nettoyage et/ou une mise au rebut.

21. Tire-lait selon la revendication 20, dans lequel ledit couvercle (36) est flexible.

22. Tire-lait selon la revendication 21, dans lequel ledit organe déplaçable (34) a un bord circonférentiel (85), ledit couvercle (36) étant reçu par-dessus ledit bord, et ladite coque (24) ayant une ouverture interne définie à l'intérieur, dimensionnée de manière à renfermer ledit bord (85), ledit couvercle (36) étant monté sur ledit bord (85) dans un ajustement substantiellement étanche à l'air, ledit couvercle (36) formant ainsi une garniture étanche entre ledit bord (85) et ladite coque (24).

23. Tire-lait selon la revendication 21, comportant en outre une soupape unidirectionnelle (95) s'étendant à travers ledit organe déplaçable (34), ladite soupape (95) permettant l'échappement de l'air entre ledit organe déplaçable (34) et ledit couvercle (36) monté dessus.

24. Tire-lait selon la revendication 20, dans lequel ladite pompe est une pompe à diaphragme (30), ladite coque (24) ayant une forme intérieure généralement hémisphérique, ledit organe déplaçable (34) étant une membrane flexible.

25. Tire-lait selon la revendication 23, dans lequel ladite pompe est une pompe à diaphragme (30), ladite coque (24) ayant une forme intérieure généralement hémisphérique, ledit organe déplaçable (34) étant une membrane flexible.

26. Tire-lait selon la revendication 1, la pompe à vide étant une pompe à diaphragme (30), comprenant:

une coque (24) ayant une forme intérieure généralement hémisphérique ;
une membrane flexible (34) déplaçable à l'intérieur de ladite forme hémisphérique, afin d'augmenter et de réduire un volume créé dans une chambre définie entre ladite membrane (34) et ladite coque (24) ;
un mécanisme (74a, 74b) connecté à ladite membrane (34), qui déplace ladite membrane (34) pour augmenter et réduire ledit volume ;
un orifice (31) dans ladite coque (24), à travers lequel de l'air se déplace en réponse à l'expansion et à la contraction dudit volume ;
un couvercle flexible (36) monté de manière amovible entre ladite coque (24) et ladite membrane (34), qui isole ladite membrane (34) du fluide, ledit couvercle (36) étant amovible pour un nettoyage et/ou une mise au rebut, ladite membrane flexible (34) ayant un bord circonférentiel (85), ledit couvercle (36) étant reçu par-dessus ledit bord (85), et ladite coque (24) comportant une ouverture interne définie à l'intérieur et dimensionnée pour renfermer ledit bord (85), ledit couvercle (36) étant monté sur ledit bord (85) dans un ajustement substantiellement étanche à l'air, ledit couvercle (36) pour ainsi former une garniture étanche entre ledit bord (85) et ladite coque (24).

27. Tire-lait selon la revendication 26, comportant en outre une soupape unidirectionnelle (95) s'étendant à travers ledit organe déplaçable (34), ladite soupape (95) permettant l'échappement de l'air entre ledit organe déplaçable (34) et ledit couvercle (36) monté dessus.

28. Tire-lait selon la revendication 1, comprenant :

un mécanisme (25) actionnant ladite source de vide (30) pour produire au moins une séquence de montée du lait et une autre séquence différente de ladite séquence de montée du lait.

29. Tire-lait selon la revendication 28, dans lequel ledit mécanisme (25) a un entraînement à moteur.

30. Tire-lait selon la revendication 29, comportant en outre un contrôleur (60), ledit contrôleur (60) comportant au moins deux séquences pré-programmées pour commander ledit entraînement à moteur (25), l'une desdites séquences étant une séquence de montée du lait et une autre étant une séquence d'expression de lait.

31. Tire-lait selon la revendication 30, comportant en outre un dispositif de sélection de séquence (49, 50), dans lequel ladite séquence de montée du lait peut être sélectionnée par un opérateur.

32. Tire-lait selon la revendication 1, dans lequel l'amélioration comprend un mécanisme associé au tire-lait, spécifiquement adapté pour amorcer un réflexe de montée du lait.

33. Tire-lait selon les revendications 28 à 32, dans lequel ledit mécanisme commande une séquence de montée du lait avec une pression de vide variant entre environ 50 mmHg et environ 150 mmHg, et une fréquence d'environ 80 à environ 160 cycles par minute.

34. Procédé pour faire fonctionner un tire-lait selon l'une quelconque des revendications 1 à 33, le tire-lait comprenant une source de vide (30) et un contrôleur programmable (60) pour faire varier le vide, **caractérisé en ce que** le contrôleur (60) commande la source de vide (30) en fonction d'un programme sélectionné qui a été sélectionné par un utilisateur et entré dans le contrôleur (60), le tire-lait pouvant être programmé avec différents types de séquences de succion.

35. Procédé selon la revendication 34, dans lequel la séquence de tétée d'un nourrisson en termes d'au moins une force de succion au cours du temps est enregistrée et le tire-lait est programmé de manière à fonctionner en fonction dudit enregistrement.

36. Procédé selon la revendication 34, comprenant en outre la fourniture d'une pluralité de programmes différents pour ledit contrôleur (60) en vue de faire varier ledit vide en fonction de séquences différentes.

37. Procédé selon la revendication 36, dans lequel lesdits programmes sont fournis sur des supports pré-enregistrés (61), et ledit tire-lait comprend en outre un lecteur de support (50), le procédé comprenant en outre l'étape consistant à entrer un programme par le biais dudit lecteur (50) dans ledit contrôleur (60).

38. Procédé selon la revendication 37, fournissant en outre chaque programme enregistré sur un support séparé (61), en particulier sur une carte séparée.

39. Procédé selon la revendication 36, comprenant en outre différents programmes ayant différentes séquences pour faire varier au moins une force de vide ou un cycle de vide en fonction d'une courbe d'application.

40. Procédé selon la revendication 34, comportant en outre une source de pression positive en communication avec ladite téterelle (17), et comportant en outre l'étape consistant à programmer ledit contrôleur (60) pour faire varier ladite source de pression positive (30).

41. Procédé selon la revendication 40, comprenant en outre différents programmes ayant différentes séquences pour faire varier une force de vide, une force de pression positive et/ou un cycle de vide en fonction d'une courbe d'application.

42. Procédé selon la revendication 34, comprenant l'étape consistant à faire varier la quantité de vide et son cycle en fonction de la courbe de la figure 12.

43. Procédé selon la revendication 34, comprenant l'étape consistant à faire varier la quantité de vide et son cycle en fonction de la courbe de la figure 13.

44. Procédé selon la revendication 34, comprenant l'étape consistant à faire varier la quantité de vide et son cycle en fonction de la courbe de la figure 14.

45. Procédé selon la revendication 34, comprenant l'étape consistant à faire varier la quantité de vide dans une plage d'environ 20 mmHg (le vide le moins poussé) à environ 250 mmHg (le vide le plus poussé), tout en faisant varier simultanément le cycle de succion global d'environ 25 cycles/min au vide le plus poussé jusqu'à environ 40 cycles/min au vide le moins poussé, de telle sorte que pour un plus faible vide appliqué, il se produise une augmentation du nombre de cycles.

46. Procédé selon la revendication 34, considéré pour produire une augmentation de la production de lait, comprenant la commande de ladite pompe à un taux cyclique rapide de l'ordre d'environ 120 cycles/min, avec une pression négative de l'ordre d'environ 50 à environ 150 mmHg.

47. Procédé selon la revendication 46, comportant en outre une pause après chaque période d'application de vide.

48. Procédé selon la revendication 47, dans lequel ledit vide est appliqué pendant environ dix secondes de vide, avec ensuite une pause de deux secondes.

49. Procédé selon la revendication 34, comprenant l'éta-

pe consistant à faire varier le vide dans une plage d'environ 100 (le vide le moins poussé) à environ 150 mmHg (le vide le plus poussé), tout en faisant varier simultanément le cycle de succion global d'environ 78 cycles/min au vide le moins poussé à environ 47 cycles/min au vide le plus poussé, de telle sorte que pour un plus faible vide appliqué, il se produise une augmentation du nombre de cycles, avec un cycle suivant une courbe qui augmente initialement jusqu'à un pic de pression négative, puis commence doucement une augmentation de pression (moins négative) le long d'une pente initiale mais ralentit ensuite brièvement l'augmentation de pression, avant de continuer essentiellement sur ladite pente initiale pour la libération de la pression négative.

50. Procédé selon les revendications 45, 46, 47, comprenant l'étape consistant à inclure une séquence de montée du lait pour ledit tire-lait et à faire fonctionner en outre ledit tire-lait avec ladite séquence de montée du lait.

FIG. 1

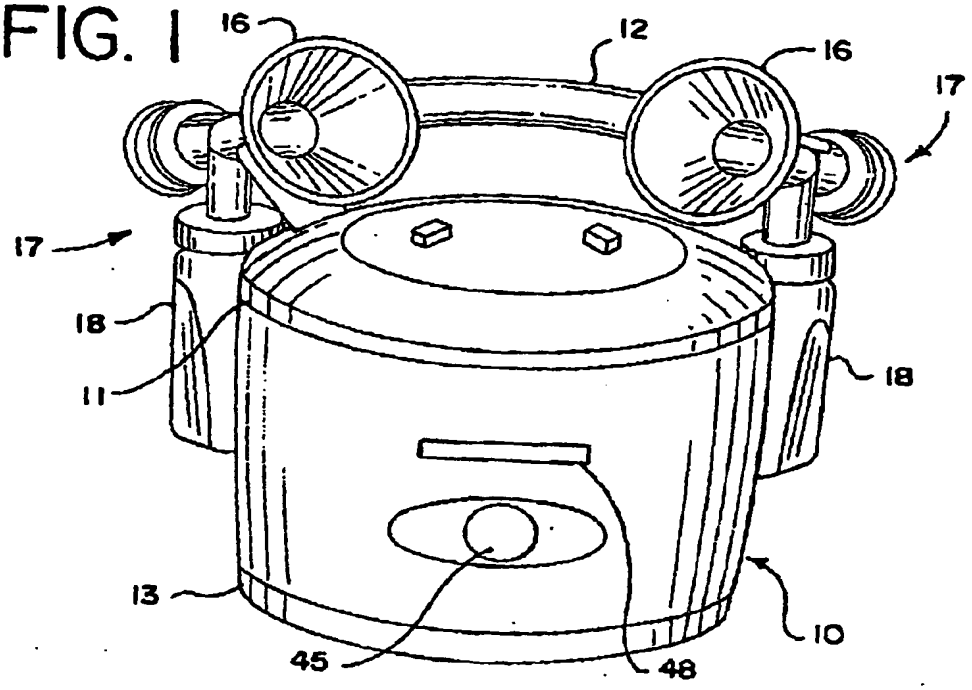


FIG. 2

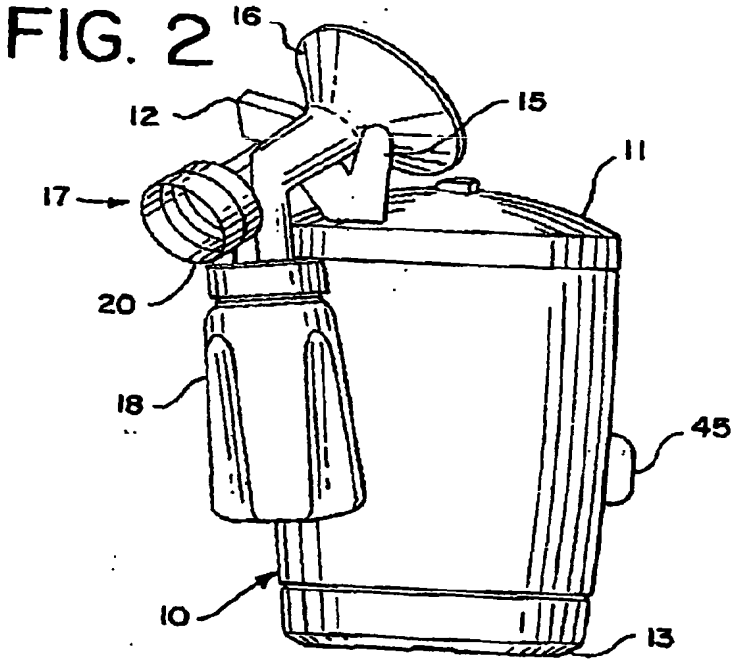


FIG. 3

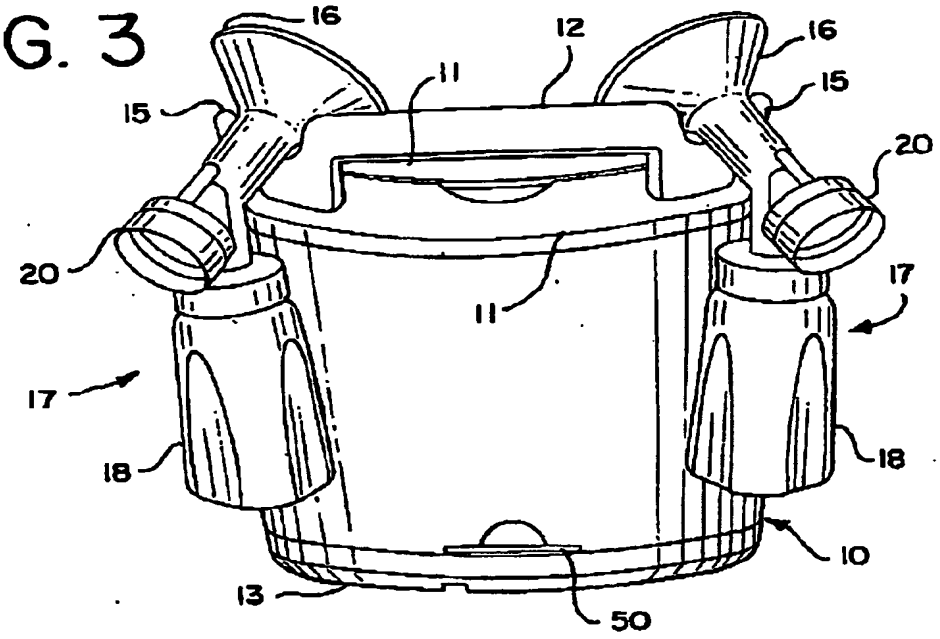

16
12
16
11
15
15
20
20
11
17
17
18
18
10
13
50

FIG. 4

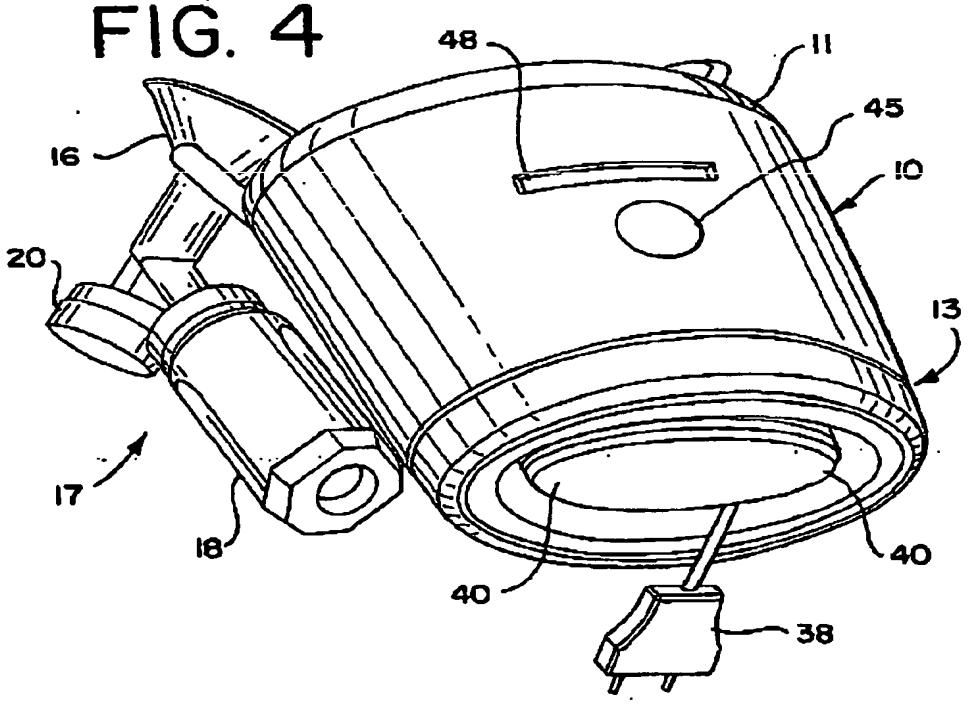

48
11
45
16
10
20
13
17
18
40
40
38

FIG. 5

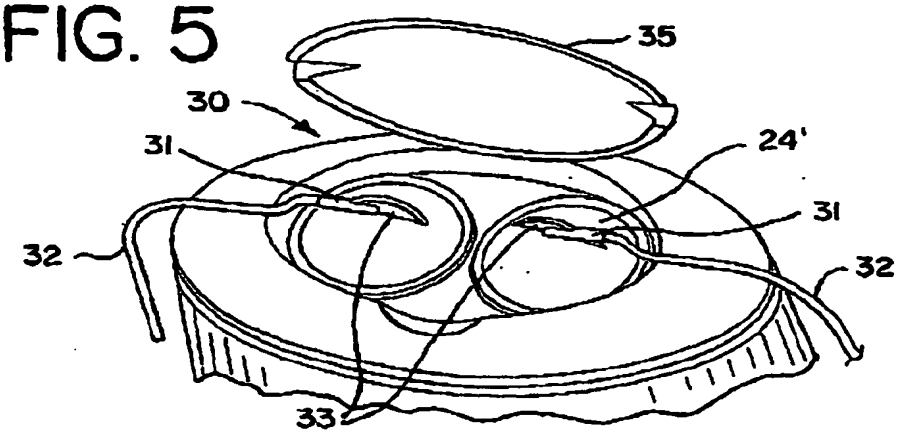


FIG. 6

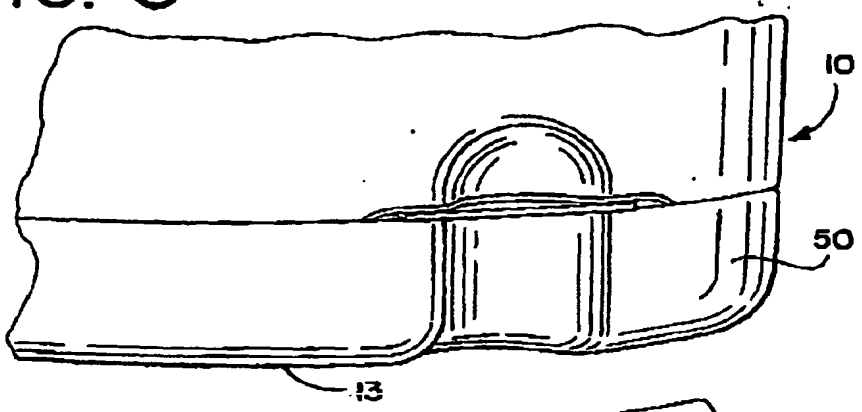


FIG. 7

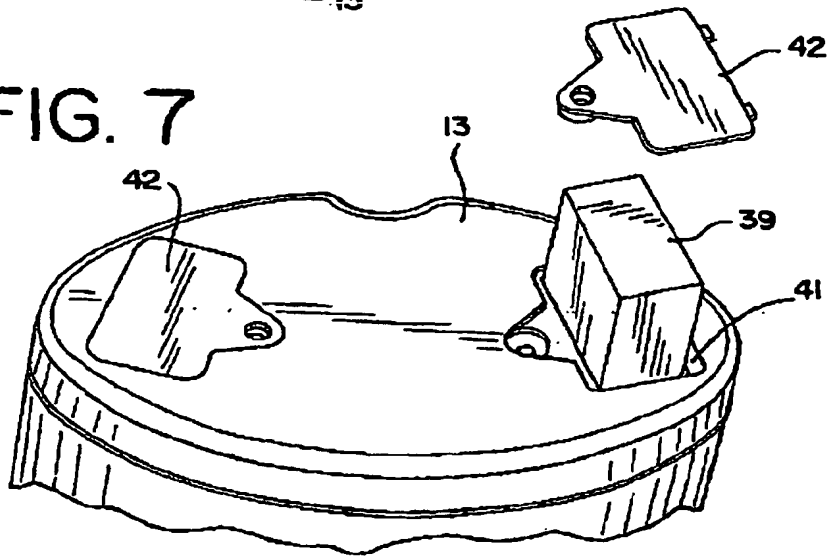


FIG. 8

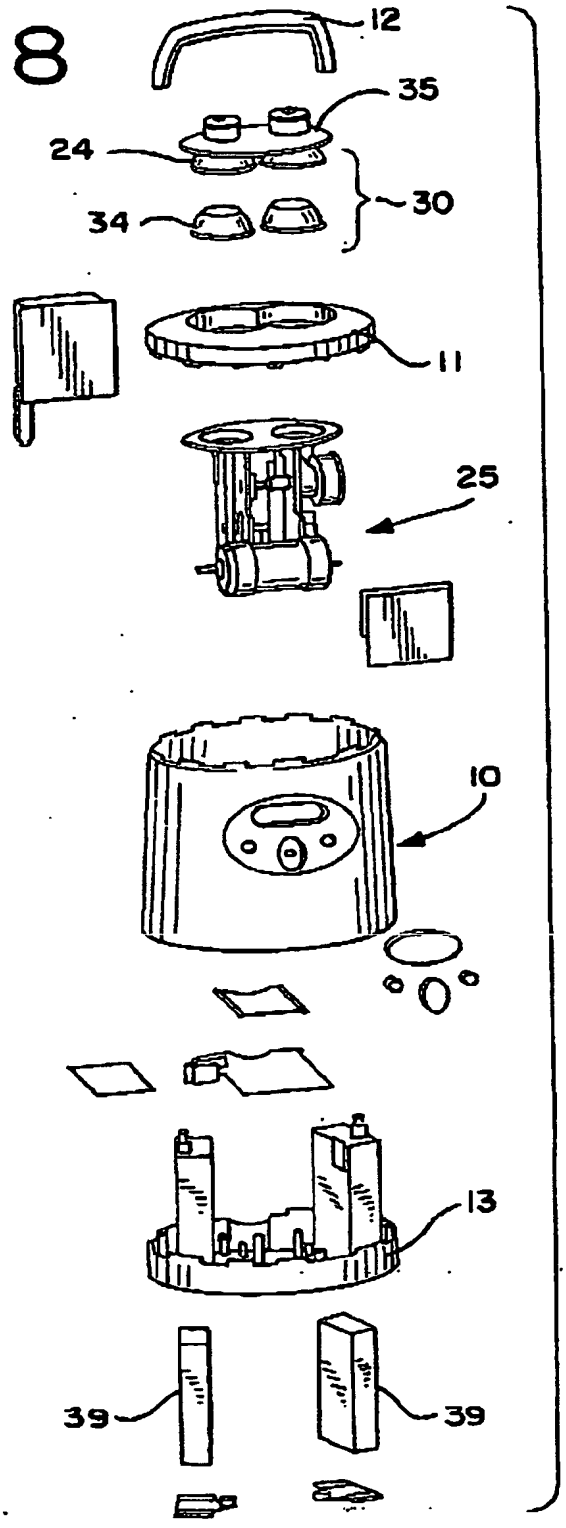


FIG. 9

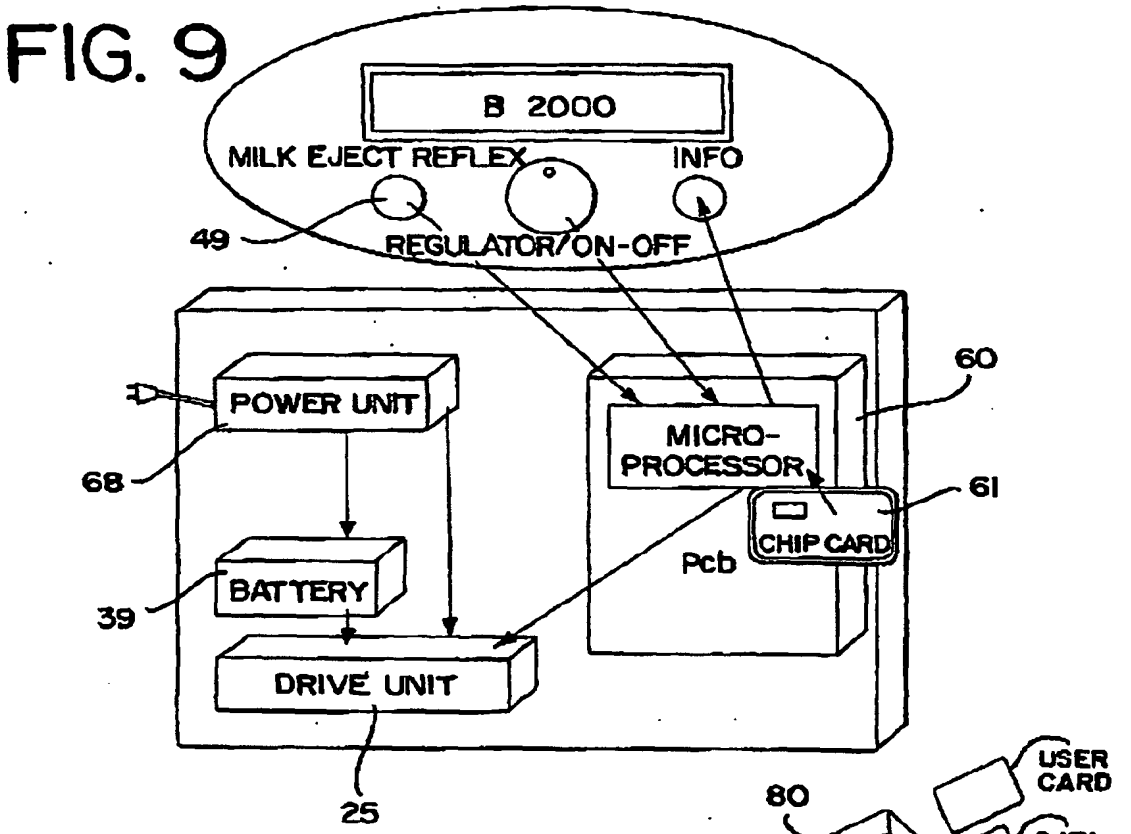

B 2000
MILK EJECT REFLEX
INFO
49
REGULATOR/ON-OFF
60
POWER UNIT
MICRO-
PROCESSOR
68
61
CHIP CARD
Pcb
BATTERY
39
DRIVE UNIT
25

FIG. 10

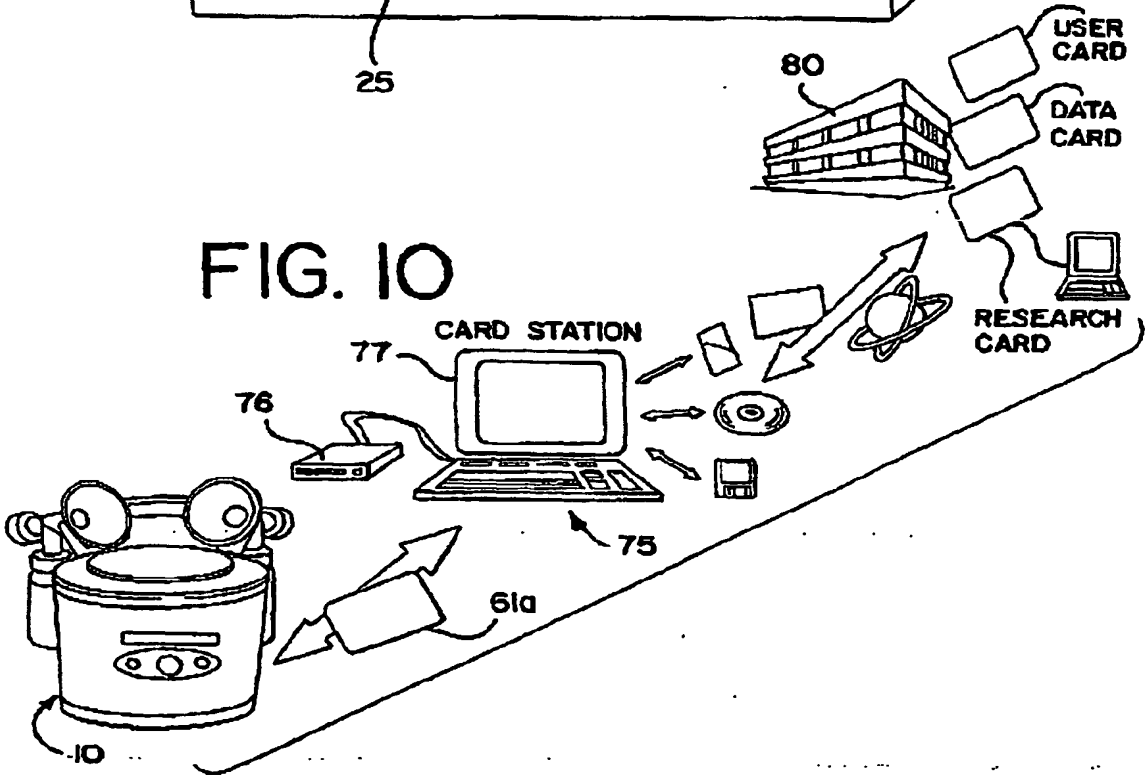
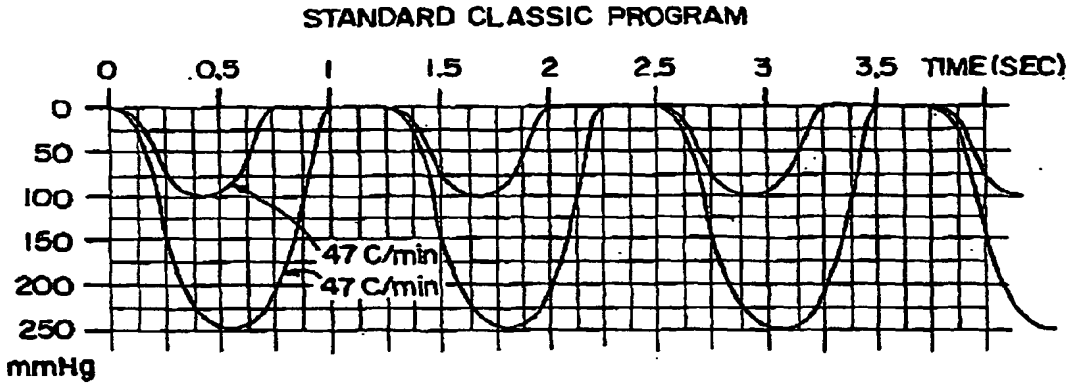
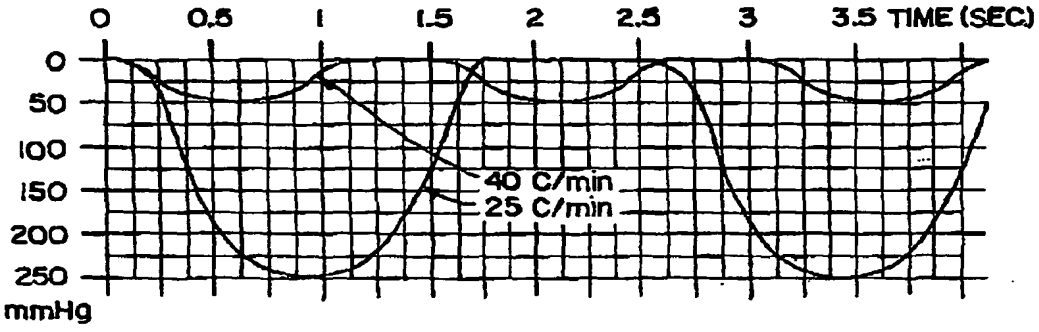

80
USER
CARD
DATA
CARD
RESEARCH
CARD
CARD STATION
77
76
75
61a
10

FIG. 11



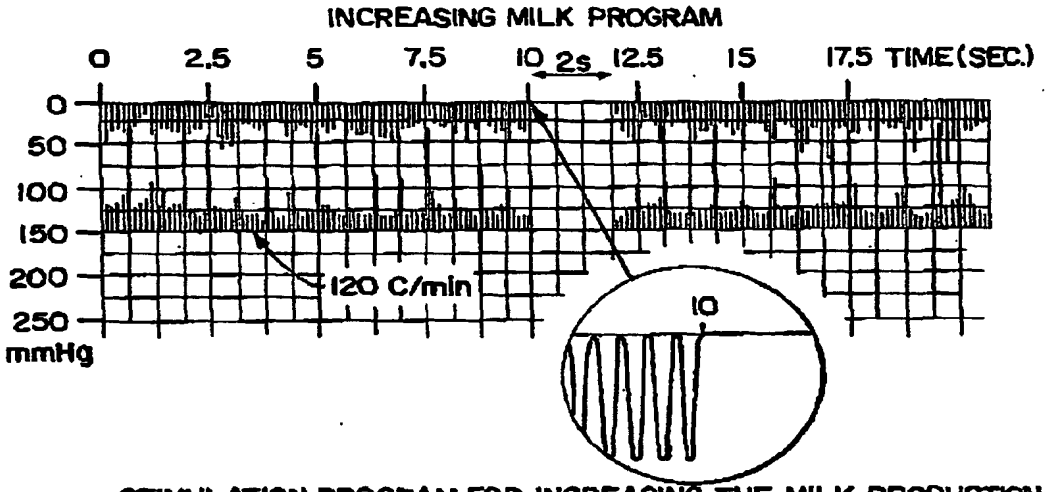
SUCTION CURVES AND CYCLES EQUAL TO CLASSIC
VACUUM RANGE: 100 - 250 mmHg
CYCLES: 47/min (NOT ADJUSTABLE)

FIG. 12



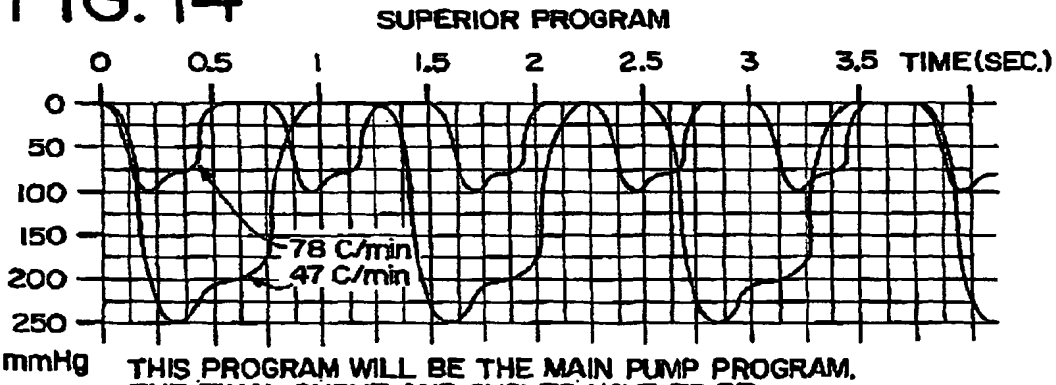
EXTREMELY GENTLE AND SLOW SUCTION
DECREASED VACUUM YIELDS GENTLER AND SLOWER SUCTION
VACUUM RANGE: 20 - 250
CYCLES: 25 - 40/min (CONTROLLED BY VACUUM LEVEL)

FIG. 13



STIMULATION PROGRAM FOR INCREASING THE MILK PRODUCTION
IT IS USED BETWEEN THE PUMP SESSIONS A FEW TIMES A DAY
VACUUM RANGE: 50-150mmHg
CYCLES: 120/min

FIG. 14



THIS PROGRAM WILL BE THE MAIN PUMP PROGRAM.
THE FINAL CURVE AND CYCLES HAVE TO BE
EVALUATED BY RESEARCHING.
VACUUM RANGE: 100-250 mmHg
CYCLES: 47-78/min AUTOMATICALLY

THIS PROGRAM CONTAINS ALSO THE MILK LET DOWN PROGRAM
VACUUM RANGE: 50-150mmHg
CYCLES: 120-150/min

FIG. 15

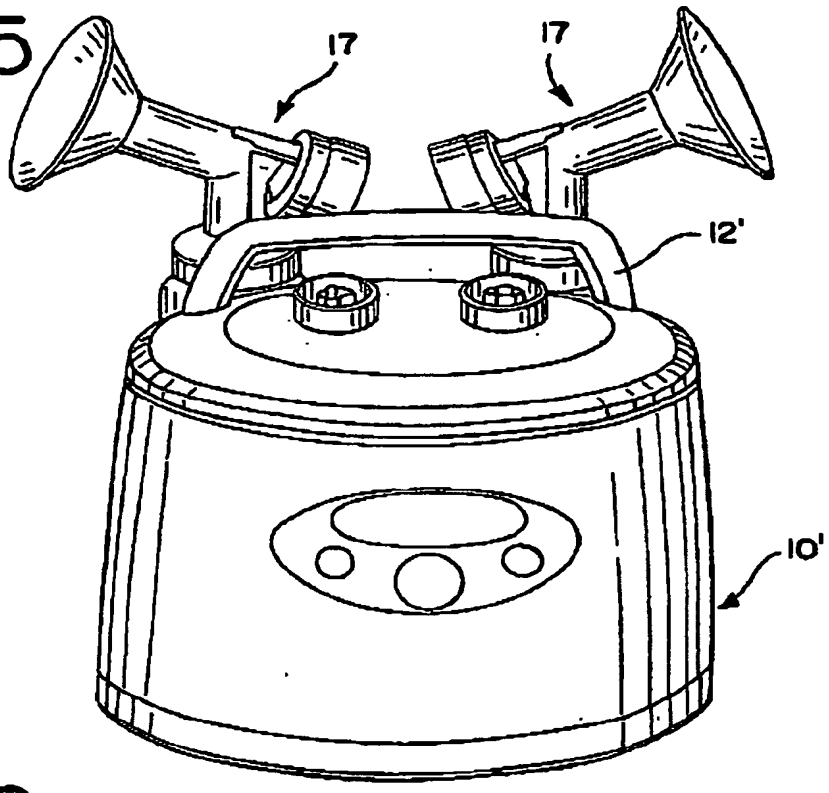


FIG. 16

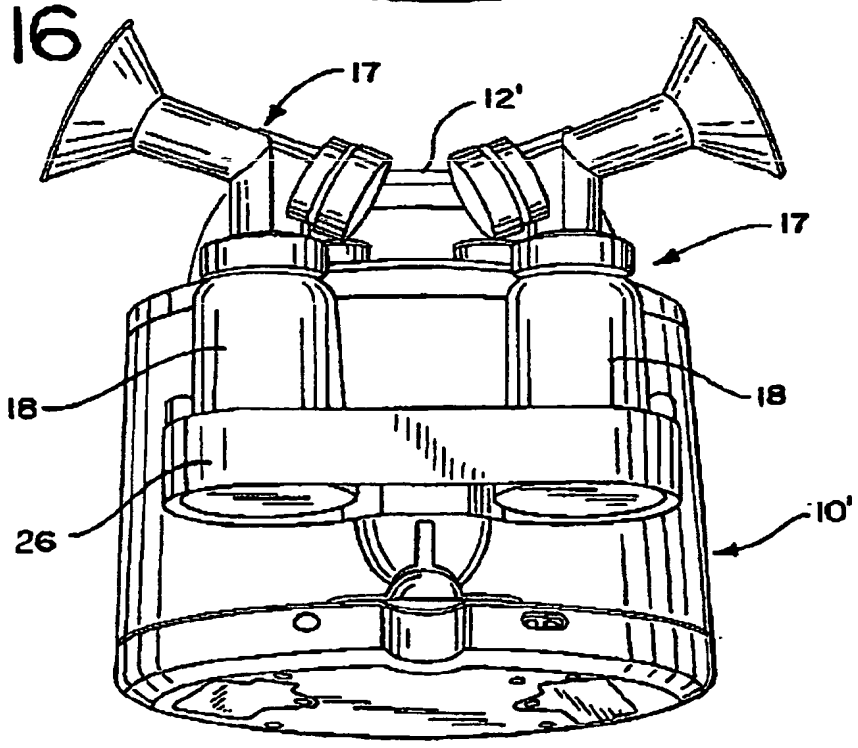


FIG. 17

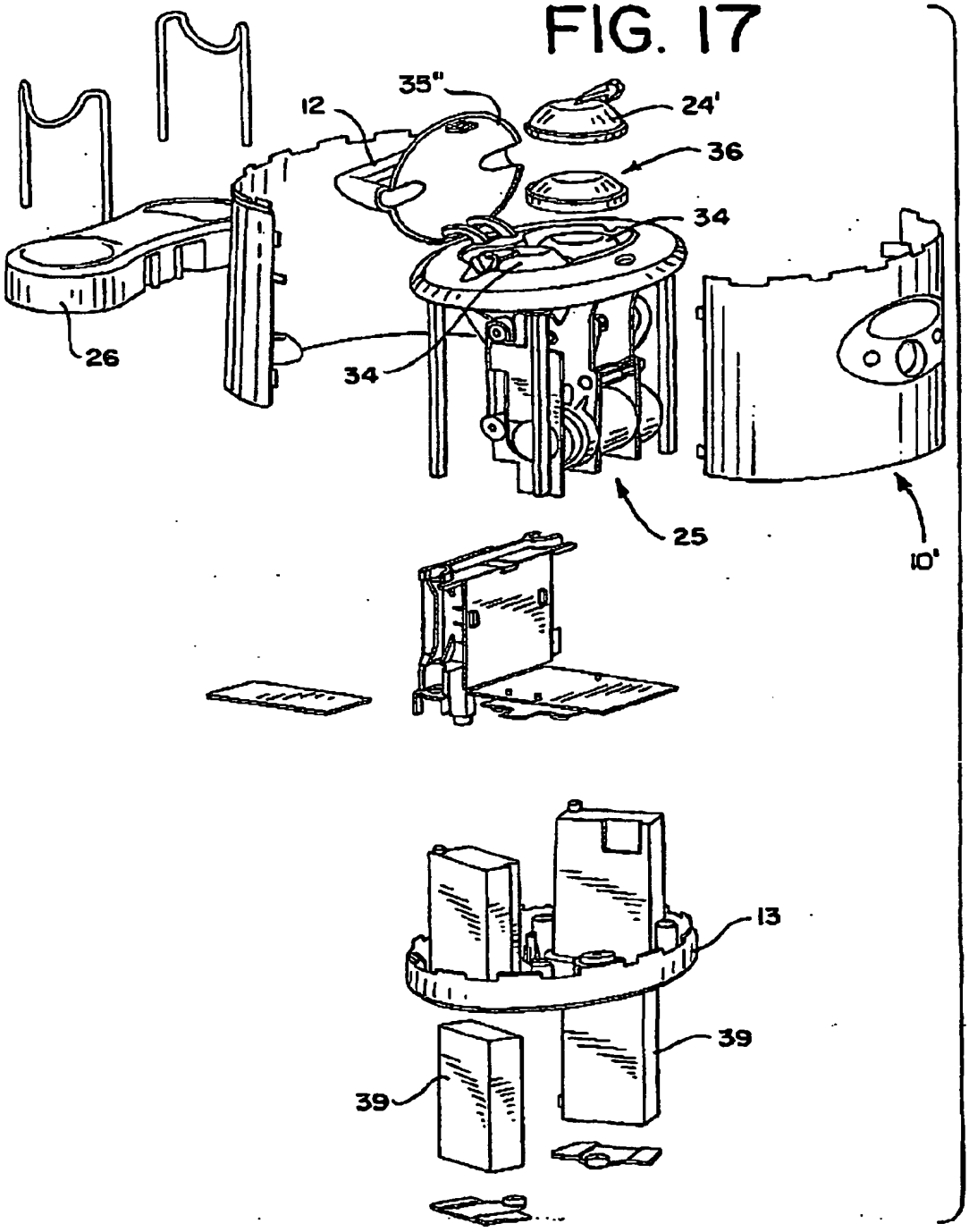


FIG. 19

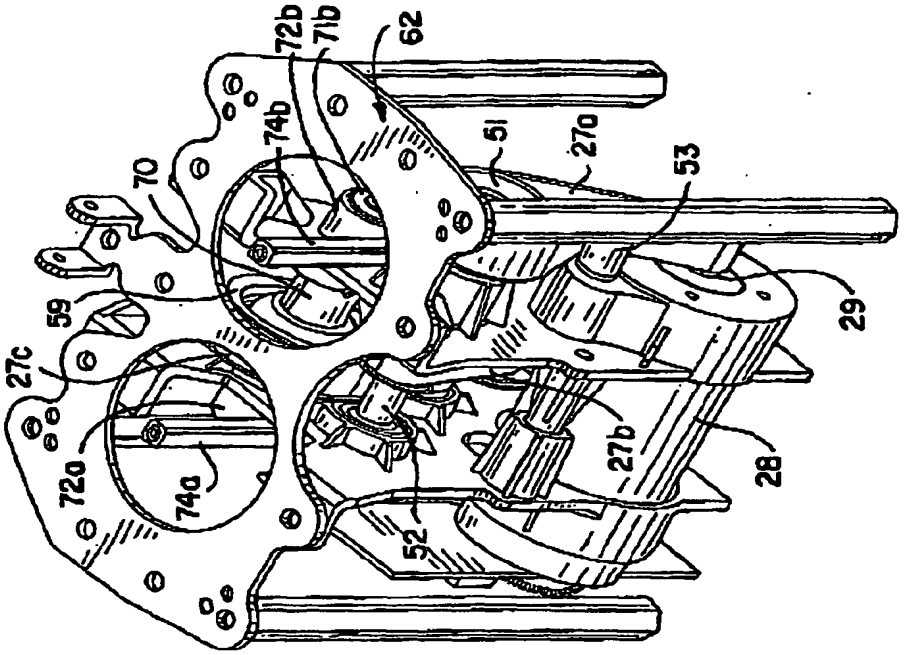

72b
71b
62
74b
70
51
27a
53
59
29
27c
72a
74a
27b
28
52

FIG. 18

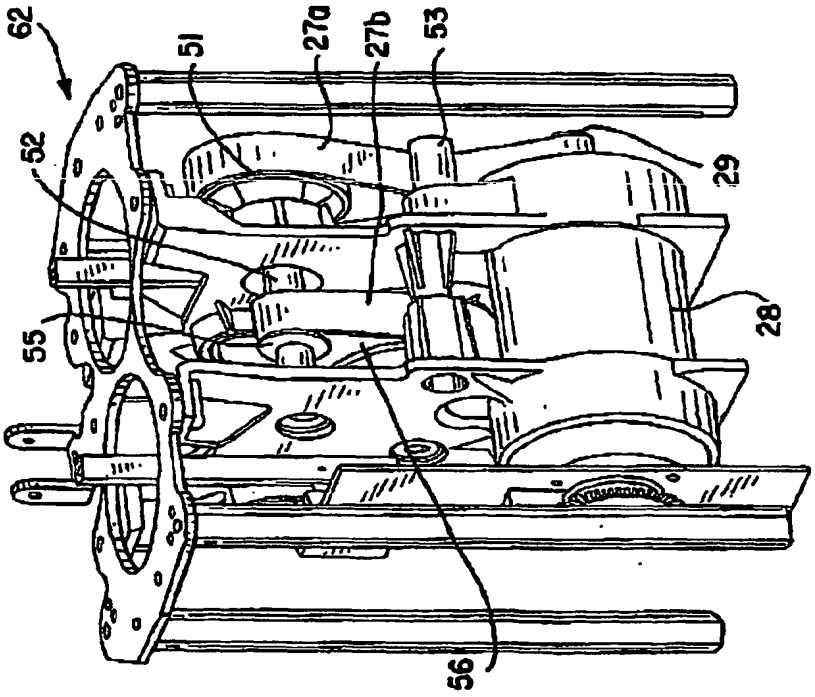

62
51
27a
27b
53
52
29
55
28
56

FIG. 20

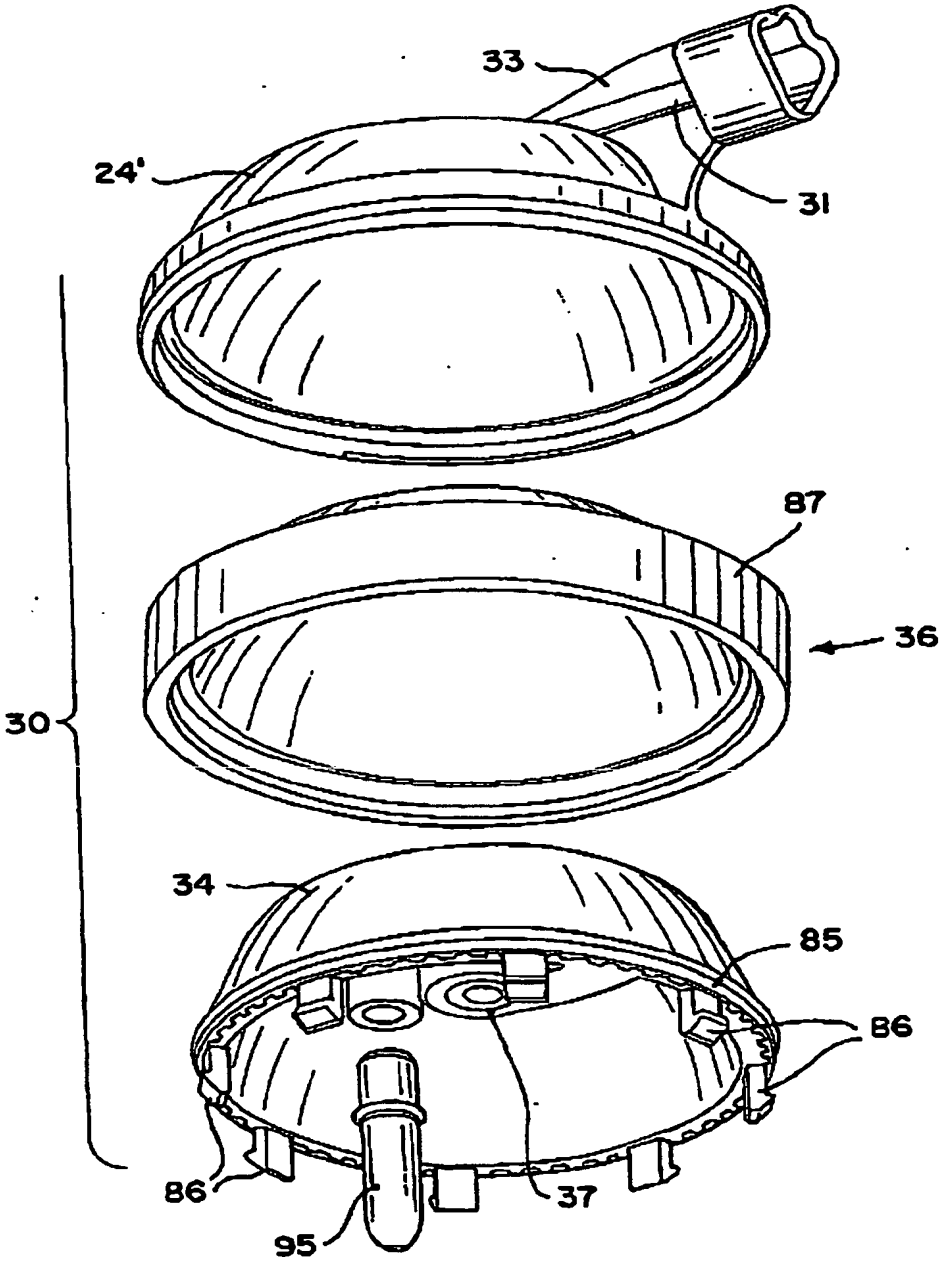


FIG. 21a

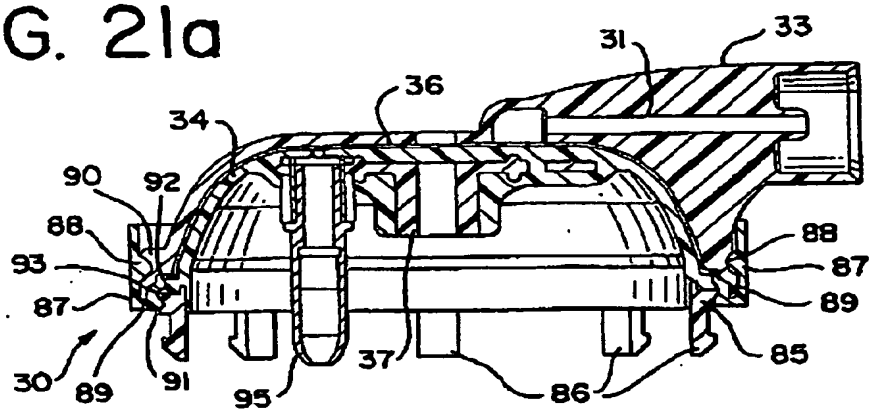


FIG. 21b

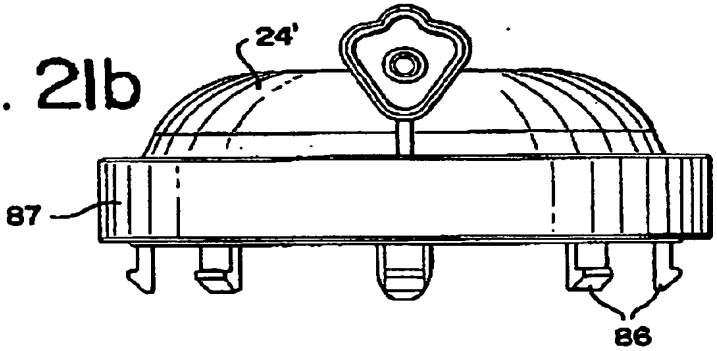


FIG. 21c

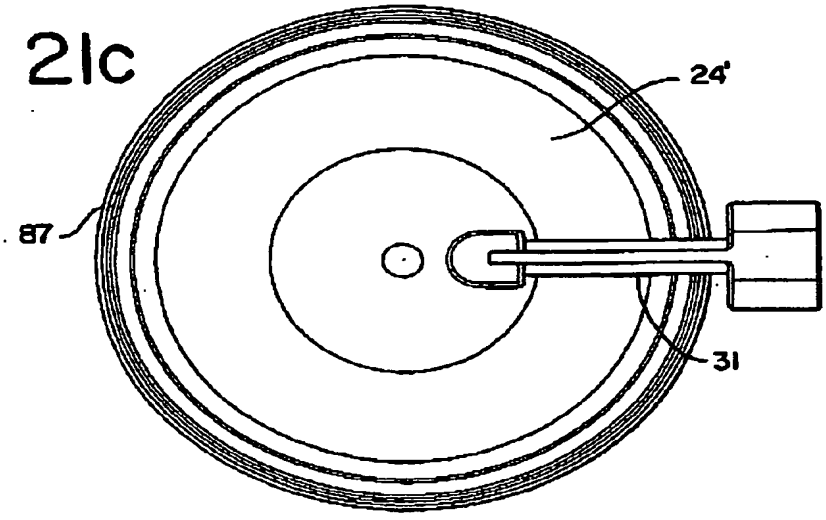


FIG. 22

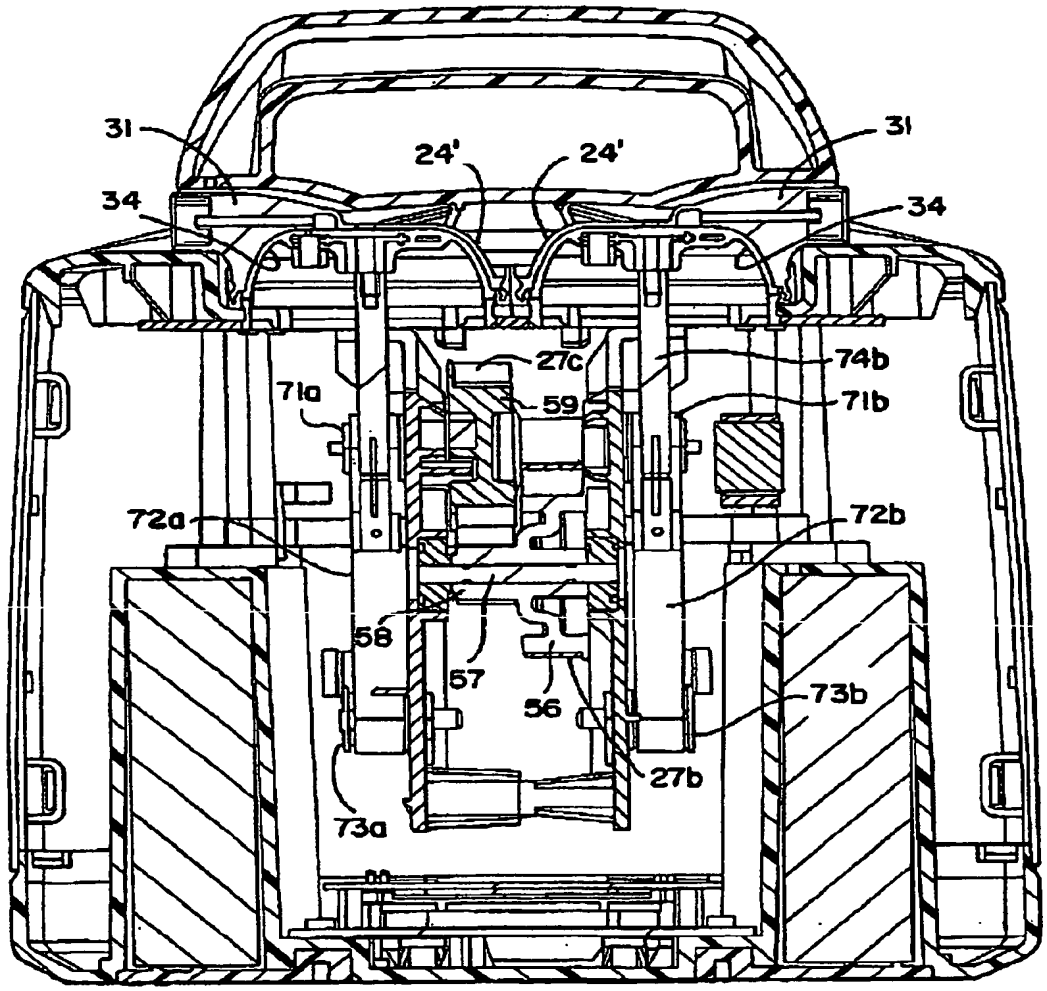


FIG. 23

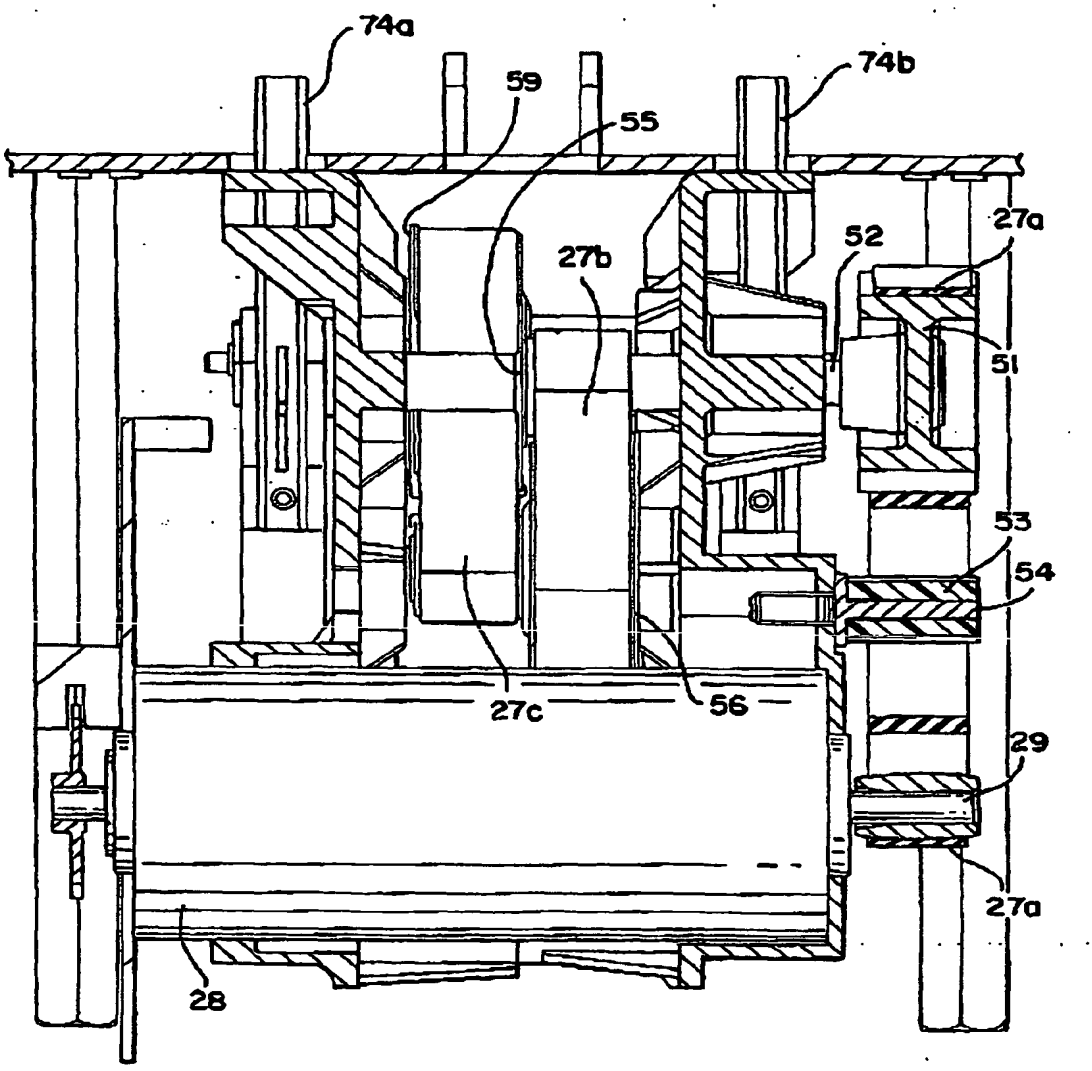
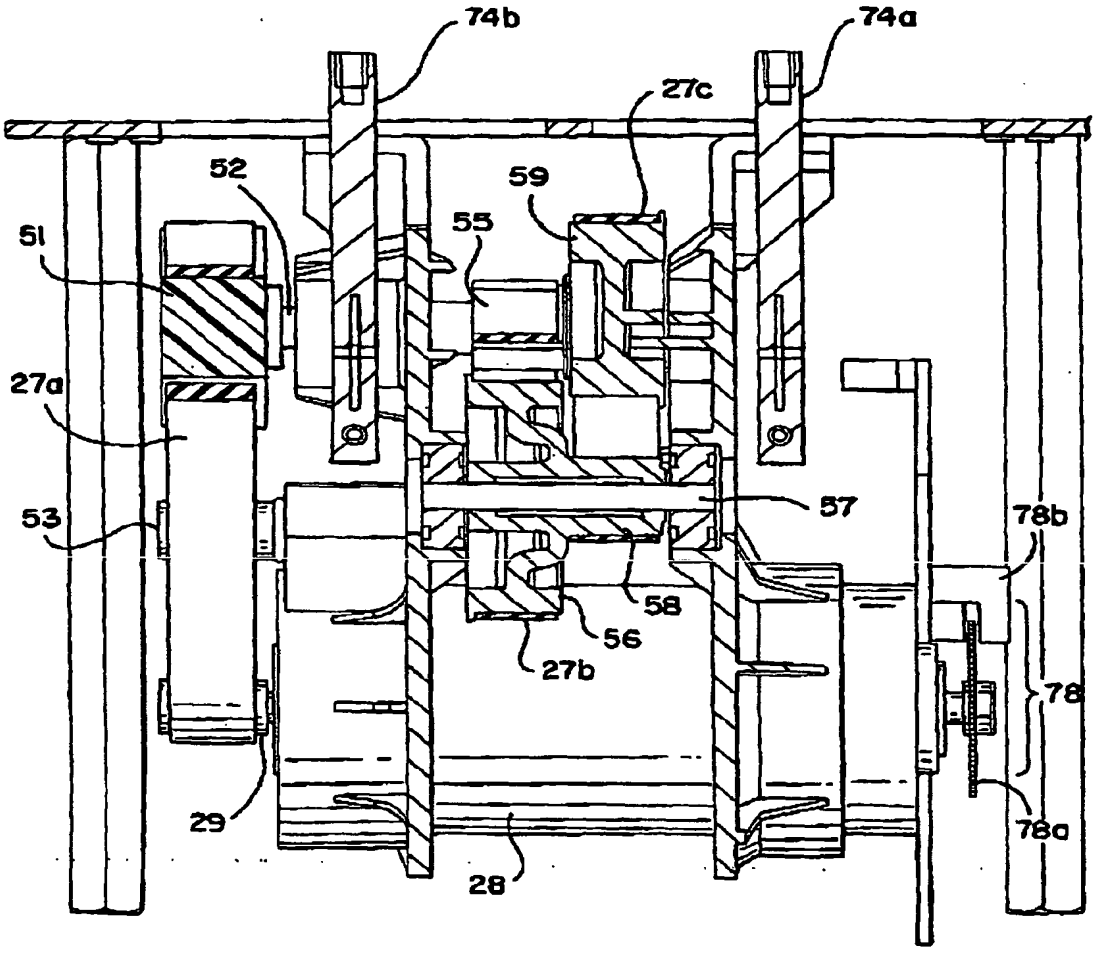


FIG. 24



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 4964851 A **[0005] [0030]**
- US 5007899 A **[0005]**
- US 5571084 A **[0008]**
- DE 3916699 **[0009]**
- US 4929229 A **[0030]**

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 430 918 B1

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A61M 1/06 *(2006.01)* ***A61B 5/00*** *(2006.01)*

(21) Application number: **03405885.9**

(22) Date of filing: **11.12.2003**

(54) Use of a breast pump

Verwendung einer Brustpumpe

Utilisation d'une pompe à lait

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR

(30) Priority: **20.12.2002 CH 21882002**
27.03.2003 US 401138
17.07.2003 US 621490

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23.06.2004 Bulletin 2004/26

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(56) References cited:
EP-A- 0 116 186
WO-A-01/47577
WO-A-01/74149
WO-A-03/028616
CA-A- 2 340 851
US-A- 5 827 191

- **HARTMANN PETER AND CREGAN MARK: "Lactogenesis and the effects of insulin-dependent diabetes mellitus and prematurity" 2 April 2001 (2001-04-02) , AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES XP002270836 * page 3017S, right-hand column, line 21 - line 36 ***
- **DALY S E J ET AL: "Degree of breast emptying explains change in the fat content, but not fatty acid composition, of human milk" EXPERIMENTAL PHYSIOLOGY, XP008030117**

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EP 1 430 918 B1

Printed by Jouve, 75001 PARIS (FR)

Description

Technical field

[0001] The invention relates to a system and to a process for detecting a milk surge in a mother's breast and to the use of a breast pump for detecting a milk surge.

Prior Art

[0002] The human breast has mammary glands which form balloon-like structures, so-called alveoli. The alveoli are connected to one another via milk ducts which lead to the nipple. The alveoli are enclosed by myoepithelial cells which contract under the influence of oxytocin. A sphincter at the end of the nipple, however, prevents the breast milk from flowing out.

[0003] If a baby then begins to suck at the breast, this is detected by mechanicoreceptors in the breast and a corresponding signal is transmitted to the mother's brain. Influenced by emotions, experiences and other external influences, the signal passes to the hypophysis which thus releases oxytocin.

[0004] The contraction of the myoepithelial cells triggered as a result leads to the alveoli deflating, as a result of which the milk ducts are widened. If the nipple sphincter is then opened by pressure, heat or other external factors, the milk can flow out. This contraction is referred to as the milk surge.

[0005] The prior art discloses breast pumps which are likewise able to express milk from the mother's breast. In particular WO 01/47577 discloses a milk pump which imitates the sucking rhythm of a baby and thus allows milk to be expressed from the breast in as natural a manner as possible.

[0006] EP 0'116'186 discloses a manually operated breast pump with a collecting cylinder. The amount of milk in the cylinder can be visually determined by means of a scale.

[0007] Breast-feeding a baby, however, is not always straightforward. The causes of problems may stem from the baby or the mother or from both. It is often difficult, however, to determine the causes precisely. Expressing milk by means of a breast pump can also be problematic for some mothers. For the manufacturers of breast pumps, it is thus important to understand breast-feeding as precisely as possible and to utilize this knowledge in the design of breast pumps. It has been found that essential information for analyzing breast-feeding problems and for optimizing breast pumps may be derived from the mother's milk surge.

[0008] Hartmann Peter and Cregan Mark: "Lactogenesis and the effects of insulin-dependent diabetes mellitus and prematurity", 2 April 2001 (2001-04-02), American Society for nutritional sciences, discusses the initiation of lactation by the mother. This initiation has to be synchronized to the delivery of the infant, permitting the newborn to change from continuous nourishment from the umbilical cord to comparable life support from its mother's breast. They therefore watch the change in concentration of lactose from birth to 7 days postpartum .

[0009] It is another aspect of breast-feeding, that the volume of milk consumed by a baby is determined in order to make sure, that the baby is well fed. The simplest, however also a not very efficient way to do so is to weigh the baby before and after the feeding session.

[0010] US 5'827'191 therefore discloses a method for monitoring a volume of milk during breast feeding, the method utilizing an elastic nipple shaped cover applied over a nipple area of a woman's breast. The cover has holes positioned above the nipple area for passage of milk to the baby's mouth. A micro measurement volume sensor is located in a space between the nipple and the elastic cover holes to measure the volume of milk flowing therethrough.

[0011] WO 01/54488 also discloses an apparatus for determining the amount of human milk supplied to a feeding baby during a breast-feeding session. A flowmeter is used to measure the milk supply.

[0012] WO 01/47577 discloses a programmable pump that can record data relating to its use and operation.

Description of the invention

[0013] It is an object of the invention to provide a system and a process which allows a milk surge to be detected in a straightforward manner.

[0014] This object is achieved by a system and a process having the features of patent claims 1 and 9, respectively.

[0015] It is another object of the invention to provide a system and a process which allows taking samples for milk analysis and/or individual use without interfering with a determination of the milk quantity.

[0016] This object is achieved by a system and a process having the features of patent claims 7 and 13, respectively.

[0017] In the process according to the invention, the milk is expressed into at least one collecting container and the quantity of milk expressed is determined as a function of time. If a milk surge takes place, then the quantity of milk detected increases abruptly. It is thus easy to detect the milk surge.

[0018] The quantity of milk is preferably weighed. However, other determining methods, for example volume measurements, are also possible.

[0019] The change in the quantity of milk over time is preferably directly determined or calculated. This allows the point in time and also the intensity of the milk surge to better be detected.

[0020] The measurement results and measurement curves obtained in this way can be evaluated, and it is possible to draw conclusions about the behavior of the corresponding test individual in response to various external and internal influences. Application areas for the system and process according to the invention are, for

example, research, in order to obtain knowledge about the breast-feeding behavior of babies and mothers. They may also be used, however, in hospitals or for advising mothers, in order to resolve breast-feeding or expressing problems. The results may also be used in product development, for the purpose of optimizing breast pumps.

[0021] In a variant of the process, the milk is collected in several containers, wherein the quantity of milk expressed is still determined as a function of time. If the quantity of milk is determined by weighing, the containers are preferably placed on the same balance. This enables splitting of milk collection whilst not interfering with the continuous collection of weight data. Since the milk collection is split, the milk samples can be individually analyzed and/or used.

[0022] Further advantageous variants and embodiments can be gathered from the dependent patent claims.

Brief description of the drawing

[0023] The subject matter of the invention is explained hereinbelow with reference to preferred exemplary embodiments illustrated in the attached drawing, in which:

Figure 1 shows a schematic illustration of the system according to the invention;

Figure 2 shows a measurement curve obtained by means of the process according to the invention and a calculated first derivative of the measurement curve;

Figure 3 shows a schematic illustration of the system according to a second embodiment of the invention and

Figure 4 shows a schematic illustration of the system according to a third embodiment of the invention.

Methods of implementing the invention

[0024] The system of the invention according to Figure 1 has a breast pump 1, with at least one breast shield 10 for expressing the milk from a human breast, at least one collecting container 2, for receiving the milk expressed, and a unit with a measuring means 3 and an evaluating means 4, by means of which a quantity of milk received in the collecting container 2 is determined as a function of time.

[0025] The measuring means 3 serves for determining the weight or the change in weight of the breast milk located in the collecting container 2. In this preferred exemplary embodiment, this measuring means 3 is a balance, preferably an electromechanical balance with a bearing surface 30, on which the collecting container 2 is arranged.

[0026] The balance 3 is electronically connected to the evaluating means 4, which is preferably a computing system, in particular a computer, in order to transmit the measured values from the balance 3 to the computer 4. It is also possible, however, for the computer 4 and balance 3 to be integrated in a single machine. The measured values may be transmitted at defined time intervals or in a continuous manner.

[0027] In the evaluating means 4, the measured values and/or the change therein are illustrated as a function of time. Figure 2 illustrates a corresponding measurement curve M and the derivative A thereof as a function of time. The y-axis shows the time in minutes, and the x-axis shows the mass in grams. The ovals O in figure 2 indicate the point in time of a milk surge. As can be seen, the flow of milk increases during a milk surge; the measurement curve M rises more rapidly. In the derivative A, the milk surges appear in the form of peaks and are thus even easier to make out. It can also be seen from the two curves M, A that the milk surge need not always have the same intensity. These curves can be evaluated and the results used for a variety of different purposes mentioned above.

[0028] Figure 1 illustrates a table-top model of a breast pump. This means that the pumping unit is arranged in a housing 11 and is connected, by means of a negative-pressure tube 12, to the breast shield 10, in order for the negative pressure which is necessary for the flow of milk to be achieved therein. The breast shield 10 is connected to the collecting container 2 via a connecting tube 13, with the result that the breast milk can pass through this tube 13 into the container 2, for example a glass or a bottle. This apparatus has the advantage that the mother can move about during the test without falsifying the measurement result.

[0029] It is also possible, however, to use a breast pump in which the collecting container 2 is arranged on the breast shield 10. Here the important factor is for it to be possible to detect the behavior of the flow of milk over time.

[0030] Figure 3 shows a second embodiment of the invention. Instead of one single collecting container 2, several containers 2', 2'', 2''' are used. The containers 2', 2'', 2''' can have the same or different volumes. The number of containers 2', 2'', 2''' depends on the kind of analysis to be made. The three containers shown in figure 3 are therefore only an example. Preferably the containers 2', 2'', 2''' are all connected to the same measuring means 3, which can be any of the measuring means mentioned above. In the example shown in figure 3, the measuring means 3 is again a balance, so that the containers 2', 2'', 2''' are placed on this balance 3.

[0031] The connecting tube 13 is preferably coupled with first moving means 14 for moving the tube 13 from a first to a second of said containers 2', 2'', 2'''. The tube 13 is moved to the next container 2', 2'', 2''' after a predetermined event. It is preferably moved automatically, the means being preferably controlled by the evaluating

means 4. It is also possible to connect the evaluation means and the moving means to a separate, but common control means. This event is preferably a time period passed, so that the connecting tube 13 is moved after a set time point. The time point can always be the same or it can change depending on the container to be filled. The event can also be a predetermined quantity of milk collected in one of the containers 2', 2'', 2''' or it can be something else.

[0032] The milk collected in the several containers 2', 2'', 2''' can be analyzed and also used individually. For example, as milk is removed from the breast the fat content of the milk increases and this system allows to track that increase.

[0033] This technique is extremely beneficial for mothers of premature infants for whom the energy density of milk is very important. The fat is responsible for approximately 50% of the energy in milk therefore, collecting the milk in fractions will provide volumes of milk with different energy densities. These can then be used individually or certain fractions can even be mixed to provide milk of specific energy density - an energy density best suited to the infant's needs.

[0034] Figure 4 shows third embodiment of the inventive system. Here, the measuring means 3, i.e. in this case the balance, is moved by second moving means 15 in order to fill the different containers 2', 2'', 2'''. This moving means 15, which can for example be a motor-driven moving table, where the balance is being placed on, is preferably connected to the evaluation and control means 4.

List of designations

[0035]

1	Breast pump
10	Breast shield
11	Housing
12	Negative-pressure tube
13	Connecting tube
14	moving means
15	second means
2	Collecting container
2'	Collecting container
2''	Collecting container
2'''	Collecting container
3	Measuring means
30	Bearing surface
4	Evaluating means
M	Measurement curve
A	Derivative
O	Oval

Claims

1. A system for detecting a milk surge in a mother's breast, the system having a breast pump (1) with a breast shield (10) for expressing milk from the breast, at least one collecting container (2), for receiving the milk expressed, and a unit (3,4) by means of which a quantity of milk received in the at least one collecting container (2) is determined as a function of time while the milk is expressed, wherein the unit (3,4) has a measuring means (3), for measuring the quantity of milk located in the at least one collecting container (2), and an evaluating means (4) by means of which the quantity of milk measured is evaluated as a function of time.

2. The system as claimed in claim 1, wherein the measuring means (3) is a balance.

3. The system as claimed in claim 2, wherein the balance (30) is an electromechanical balance with a bearing surface for the at least one collecting container (2).

4. The system as claimed in claim 1, wherein the evaluating means (4) is a computing system, in particular a computer.

5. The system as claimed in claim 1, wherein the at least one collecting container (2) is connected to the breast shield(10) via a connecting tube (13).

6. The system as claimed in claim 1, wherein the system comprises several collecting containers (2,2', 2" , 2"') being connected with said unit (3,4) for determining the quantity of milk

7. The system as claimed in claim 6 and claim 2, wherein said collecting containers (2, 2', 2 " , 2"') are arranged on said balance.

8. The system as claimed in claim 6 and claim 5, wherein the system comprises moving means (14) for moving said connecting tube (13) from one of said collecting containers to another of said collecting containers (2, 2', 2'', 2''').

9. A process for detecting a milk surge in a mother's breast, milk being expressed from the breast into at least one collecting container (2), and the quantity of milk expressed being determined as a function of time while the milk is expressed, wherein a unit (3,4) determines a quantity of milk received in at least one collecting container (2) as a function of time while the milk is expressed, and wherein the unit (3,4) has a measuring means (3), for measuring the quantity of milk located in the at least one collecting container (2), and an evaluating means (4) by means of which

the quantity of milk measured is evaluated as a function of time.

10. The process as claimed in claim 9, wherein the weight of the quantity of milk expressed is determined as a function of time.

11. The process as claimed in claim 9, wherein the change in weight of the quantity of milk expressed is determined as a function of time.

12. The process as claimed in claim 9, wherein, in order to express the milk, use is made of a breast pump (1) with a breast shield (10), and wherein the milk expressed is directed from the breast shield (10) into the at least one collecting container (2) via a connecting tube (13).

13. The process as claimed in claim 9, wherein the milk is collected in several collecting containers (2, 2', 2" , 2' ' '), wherein the collecting containers (2, 2' , 2' ' , 2"'), are filled one after the other dependent on a predetermined event.

14. The process as claimed in claim 13, wherein the predetermined event is the arrival of a set time point.

15. Use of a breast pump(1) according to any of claims 1 - 8 for detecting a milk surge in a mother's breast, milk being expressed from the breast into at least one collecting container (2) by means of the breast pump (1), and the quantity of milk expressed being determined as a function of time while the milk is expressed.

Patentansprüche

1. System zur Detektion eines Milcheinschusses in einer Mutterbrust, wobei das System eine Brustpumpe (1) mit einer Absaughaube (10) zur Absaugung von Milch aus der Brust, mindestens einen Auffangbehälter (2) zur Aufnahme der abgesaugten Milch sowie eine Einheit (3, 4) zur Bestimmung einer in dem mindestens einen Auffangbehälter (2) aufgenommenen Milchmenge als eine Funktion der Zeit während die Milch abgesaugt wird, wobei die Einheit (3, 4) ein Messmittel (3) zur Messung der Milchmenge, die sich in dem mindestens einen Auffangbehälter (2) befindet, aufweist, und ein Auswertemittel (4) zur Auswertung der gemessenen Milchmenge als eine Funktion der Zeit.

2. System nach Anspruch 1, wobei das Messmittel (3) eine Waage ist.

3. System nach Anspruch 2, wobei die Waage (3) eine elektromechanische Waage mit einer Auflagefläche (30) für den mindestens einen Auffangbehälter (2) ist.

4. System nach Anspruch 1, wobei das Auswertemittel (4) ein Rechnersystem, insbesondere ein Computer, ist.

5. System nach Anspruch 1, wobei der mindestens eine Auffangbehälter (2) über einen Verbindungsschlauch (13) mit der Absaughaube (10) verbunden ist.

6. System nach Anspruch 1, wobei das System mehrere Auffangbehälter (2, 2', 2" , 2"') aufweist, welche mit der besagten Einheit (3, 4) zur Bestimmung der Milchmenge verbunden sind.

7. System nach Anspruch 6 und Anspruch 2, wobei die besagten Auffangbehälter (2, 2', 2", 2"') auf der besagten Waage angeordnet sind.

8. System nach Anspruch 6 und Anspruch 5, wobei das System ein Bewegungsmittel (14) aufweist, um den besagten Verbindungsschlauch (13) von einem der besagten Auffangbehälter zu einem anderen der besagten Auffangbehälter (2, 2' , 2" , 2"') zu bewegen.

9. Verfahren zur Detektion eines Milcheinschusses in einer Mutterbrust, wobei Milch aus der Brust in mindestens einen Auffangbehälter (2) abgesaugt wird und wobei die abgesaugte Milchmenge als eine Funktion der Zeit bestimmt wird, wobei eine Einheit (3, 4) eine Milchmenge, die in mindestens einem Auffangbehälter (2) aufgenommen wird, als eine Funktion der Zeit bestimmt wird, und wobei die Einheit (3, 4) ein Messmittel (3) zur Messung der Milchmenge, die sich in dem mindestens einen Auffangbehälter (2) befindet, und ein Auswertemittel (4), mittels dessen die gemessene Milchmenge als eine Funktion der Zeit ausgewertet wird, aufweist.

10. Verfahren nach Anspruch 9, wobei das Gewicht der abgesaugten Milchmenge als eine Funktion der Zeit bestimmt wird.

11. Verfahren nach Anspruch 9, wobei die Gewichtsveränderung der abgesaugten Milchmenge als eine Funktion der Zeit bestimmt wird.

12. Verfahren nach Anspruch 9, wobei zur Absaugung der Milch eine Brustpumpe (1) mit einer Absaughaube (10) verwendet wird und dass die abgesaugte Milch über einen Verbindungsschlauch (13) von der Absaughaube (10) in den mindestens einen Auffangbehälter (2) geleitet wird.

13. Verfahren nach Anspruch 9, wobei die Milch in mehreren Auffangbehältern (2, 2', 2" , 2" ') gesammelt

wird, wobei die Auffangbehälter (2, 2', 2" , 2" ') abhängig von einem vorbestimmten Ereignis einer nach dem anderen aufgefüllt werden.

14. Verfahren nach Anspruch 13, wobei das vorbestimmte Ereignis das Erreichen eines vorprogrammierten Zeitpunktes ist.

15. Verwendung einer Brustpumpe (1) nach einem der Ansprüche 1-8 zur Detektion eines Milcheinschusses in einer Mutterbrust, wobei mittels der Brustpumpe (1) Milch aus der Brust in mindestens einen Auffangbehälter (2) hinein abgesaugt wird und wobei die abgesaugte Milchmenge als eine Funktion der Zeit bestimmt wird, während die Milch abgesaugt wird.

Revendications

1. Système pour détecter un afflux de lait dans le sein d'une mère, le système ayant un tire-lait (1) avec un coussin protecteur (10) pour tirer du lait d'un sein, au moins un récipient collecteur (2) pour recevoir le lait tiré, et une unité (3, 4) au moyen de laquelle une certaine quantité de lait reçue dans l'au moins un récipient collecteur (2) est déterminée en fonction du temps pris pour tirer le lait, l'unité (3, 4) ayant un moyen de mesure (3) pour mesurer la quantité de lait se trouvant dans l'au moins un récipient collecteur (2), et un moyen d'évaluation (4) au moyen duquel la quantité de lait mesurée est évaluée en fonction du temps.

2. Système selon la revendication 1, dans lequel le moyen de mesure (3) est une balance.

3. Système selon la revendication 2, dans lequel la balance (30) est une balance électromécanique, avec une surface de support pour l'au moins un récipient collecteur (2).

4. Système selon la revendication 1, dans lequel le moyen d'évaluation (4) est un système informatique, en particulier un ordinateur.

5. Système selon la revendication 1, dans lequel l'au moins un récipient collecteur (2) est connecté au coussin protecteur (10) par le biais d'un tube de connexion (13).

6. Système selon la revendication 1, dans lequel le système comprend plusieurs récipients collecteurs (2, 2', 2", 2"') connectés à ladite unité (3, 4) pour déterminer la quantité de lait.

7. Système selon la revendication 6 et la revendication 2, dans lequel lesdits récipients collecteurs (2, 2', 2", 2"') sont arrangés sur ladite balance.

8. Système selon la revendication 6 et la revendication 5, dans lequel le système comprend des moyens de déplacement (14) pour déplacer ledit tube de connexion (13) d'un desdits récipients collecteurs à un autre desdits récipients collecteurs (2, 2', 2", 2"').

9. Procédé pour détecter un afflux de lait dans le sein d'une mère, du lait étant tiré du sein dans au moins un récipient collecteur (2), et la quantité de lait tirée étant déterminée en fonction du temps pendant lequel le lait est tiré, dans lequel une unité (3, 4) détermine une certaine quantité de lait reçue dans au moins un récipient collecteur (2) en fonction du temps pris pour tirer le lait, et dans lequel l'unité (3, 4) a un moyen de mesure (3) pour mesurer la quantité de lait se trouvant dans l'au moins un récipient collecteur (2), et un moyen d'évaluation (4) au moyen duquel la quantité de lait mesurée est évaluée en fonction du temps.

10. Procédé selon la revendication 9, dans lequel le poids de la quantité de lait tirée est déterminé en fonction du temps.

11. Procédé selon la revendication 9, dans lequel le changement de poids de la quantité de lait tirée est déterminé en fonction du temps.

12. Procédé selon la revendication 9, dans lequel, afin de tirer du lait, on utilise un tire-lait (1) avec un coussin protecteur (10), et dans lequel le lait tiré est dirigé depuis le coussin protecteur (10) dans l'au moins un récipient collecteur (2) par le biais d'un tube de connexion (13).

13. Procédé selon la revendication 9, dans lequel le lait est recueilli dans différents récipients collecteurs (2, 2', 2", 2"'), les récipients collecteurs (2, 2', 2", 2"') étant remplis les uns après les autres en fonction d'un événement prédéterminé.

14. Procédé selon la revendication 13, dans lequel l'événement prédéterminé est l'arrivée d'un instant donné.

15. Utilisation d'un tire-lait (1) selon l'une quelconque des revendications 1 à 8, pour détecter un afflux de lait dans le sein d'une mère, du lait étant tiré du sein dans au moins un récipient collecteur (2) au moyen du tire-lait (1), et la quantité de lait tirée étant déterminée en fonction du temps pris pour tirer le lait.

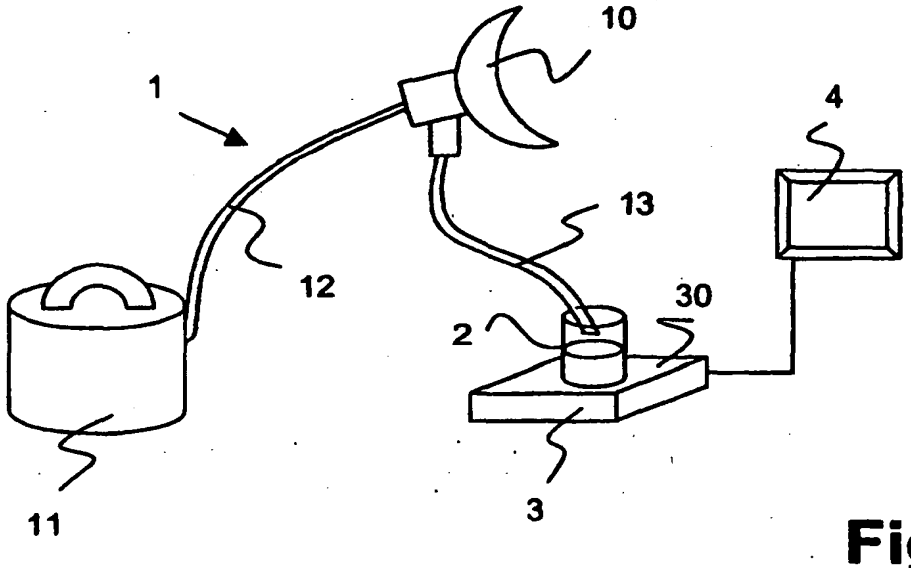


Fig. 1

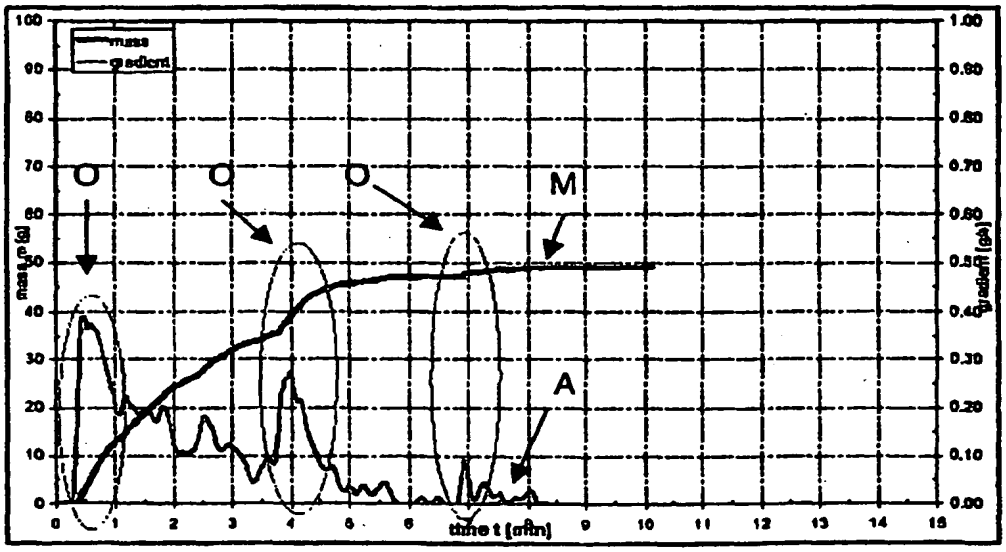


Fig. 2

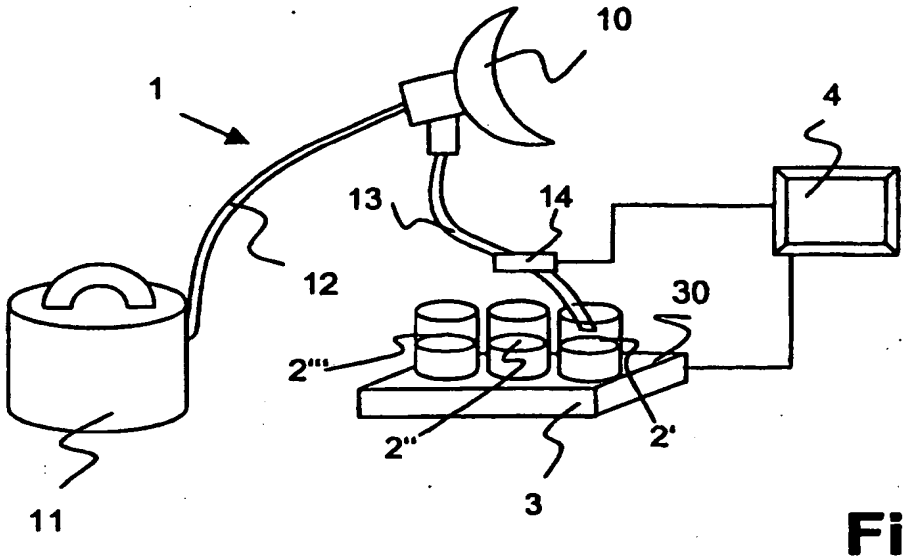


Fig. 3

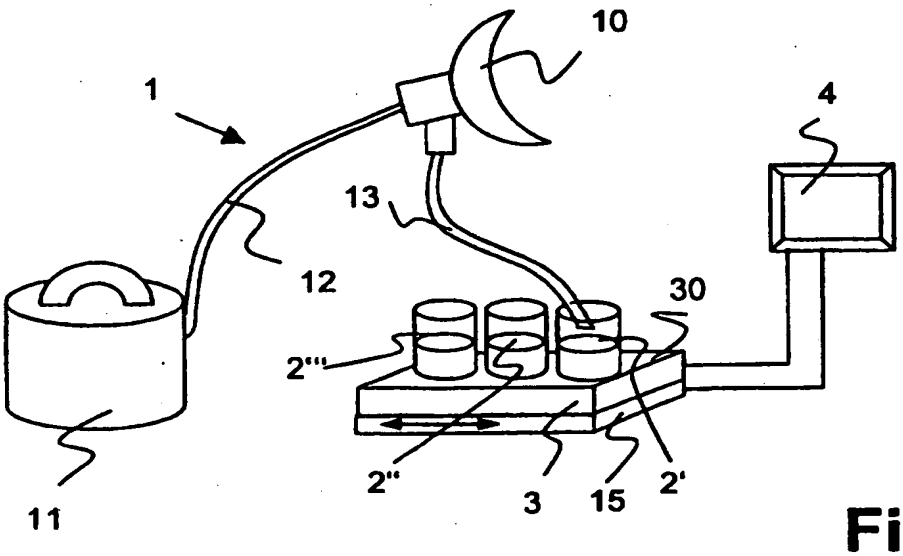


Fig. 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 0147577 A **[0005] [0012]**
- EP 0116186 A **[0006]**
- WO 0154488 A **[0011]**

Non-patent literature cited in the description

- **HARTMANN PETER ; CREGAN MARK.** Lactogenesis and the effects of insulin-dependent diabetes mellitus and prematurity. American Society for nutritional sciences, 02 April 2001 **[0008]**

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(54) **SELF-RETURNING CONTAMINATION BARRIER**

SELBSTZURÜCKKEHRENDE KONTAMINATIONSBARRIERE

BARRIÈRE ANTI-CONTAMINATION À RETOUR AUTOMATIQUE

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(56) References cited:
GB-A- 759 051
US-A1- 2004 087 898
US-A1- 2005 154 349
US-B1- 6 461 324
US-B1- 6 461 324

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EP 2 077 868 B1

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Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to contamination barriers for pumps, and more particularly to a breastpump assembly including an improved barrier to prevent milk from entering and possibly contaminating a pumping mechanism for the breastpump.

BACKGROUND OF THE INVENTION

[0002] Breastpumps are well known, and generally comprise a hood or shield that fits over the breast, a vacuum pump connected to the hood for generating an intermittent vacuum (or negative pressure) within the breastshield, and a receptacle for expressed milk. Negative pressure is pressure below atmospheric pressure. The intermittent suction action of the vacuum pump serves to pull on the breast and nipple and thereby express milk. The expressed milk typically flows from the hood, through a conduit structure and into a collection container, such as a baby bottle, for storage and later use.

[0003] Breastpumps can be manually or electrically operated. With manually operated pumps, the pumping action is done by reciprocating a piston or lever by hand, or compressing a flexible bulb, as shown in Medela's U.S. Publication No. 2004/0039330. With electrically operated pumps, the pumping action generated by a motor driven pump and typically conveyed by an air hose, or air line, that connects to the breastshield assembly.

[0004] In most instances, the pressure applied at the breast is a negative pressure (suction). That negative pressure is typically applied to the interior of the breastshield in a singular fashion, that is, without any kind of differential vacuum application over the breastshield as a whole. This has ordinarily been done through a cyclic pattern, e.g., intermittent suction. Breastpumps of this kind, which only pull and release suction, are known as simple pumps.

[0005] There are also breastpumps that apply a vacuum pressure and a positive pressure, typically applied to the interior of the breastshield, known as complex pumps. Typically, a vacuum pump that generates a positive pressure, (pressure above atmospheric pressure,) assists in forcing the expressed milk through a valve and into the collection container. A breastpump of the foregoing type is shown in U.S. Patent No. 4,857,051 to Larsson.

[0006] Positive pressure opens the valve, often used with breastpumps, to assist in movement of the breast milk through the conduit structure and into the bottle. During pumping, the expelled milk will ultimately be separated from the air drawn back and forth in the air hose, and to and from the breastshield. Some breastpumps use gravity and geometry, such as a splashguard, to separate the milk and air (air being the working fluid), but these breastpumps are often difficult to clean, and the orientation of the breastshield in use may be thereby limited. Other breastpumps use a filter, for example a hydrophobic filter, to prevent milk from entering the air hose and/or pump. That filter can become saturated, shutting down pumping; it must also be cleaned and even periodically replaced. The objective of these efforts is to isolate parts of the breastpump from milk or other liquids/bacteriological material that would constitute a contaminant, or foul the works (such as milk finding its way to the pump mechanism). In institutional settings, for another example, it is desirable to have a pump that can be transferred between mothers, yet the pump mechanism remains isolated from one mother to the next.

[0007] Some conventional electric breastpumps also use a moveable, sometimes collapsible, membrane or barrier, that separates the breastshield (including valve) from the pumping mechanism. During operation, two pressures are realized: a first pressure on the vacuum side of the membrane, or pump vacuum, and a second pressure on the breastshield side of the membrane, or breastshield vacuum. The vacuum pump communicates a negative pressure to the membrane via the air hose, such that the first pressure is greater than the second pressure, or in similar terms, the pump vacuum is greater than the breastshield vacuum. This differential vacuum causes the membrane to collapse or move. A problem with some conventional breastpumps of this type is that the membrane may not return to an initial state or position, i.e., it may end up locking or buckling.

[0008] This type of breastpump generally requires a positive pressure from the breastshield side of the membrane to push the membrane past a lock or buckle point in order to return the membrane to the non-collapsed state during a breastpump cycle. A breastpump of the foregoing type is shown in U.S. Patent No. 5,941,847 to Huber. A typical issue with these types of pumps is that leakages, evaporation, expulsion of milk and breast extension hysteresis do not ensure that the membrane returns fully to its initial non-collapsed state without the assistance of a positive pressure.

[0009] Further relevant prior art breastpump assemblies are for instance disclosed in documents US6461324 B1 and US2004/0087898 A1.

[0010] Some conventional manual breastpumps also include a collapsible or movable membrane that has a significant energy loss in "transferring" vacuum from one side to the other. The mechanical coefficient across the barrier membrane needs dramatic improvement.

[0011] Accordingly, a breastpump that reduces or eliminates contamination in the upstream pump air line and pump by isolating the pressure source from the expressed milk is desired to protect the user and prevent damage to the pump mechanism. A much more energy efficient pump system that uses a movable membrane/barrier for vacuum communication is also highly desirable.

SUMMARY OF THE INVENTION

[0012] This object is achieved with a breastpump assembly according to claim 1.

[0013] The present invention, in perhaps one of its broadest expressions, comprises a barrier for a pump or a pumping system, that separates parts of the pump while transferring a pressure change across the barrier. When a pressure, as from a vacuum source, is applied to the barrier, the barrier achieves a distended state and when the vacuum is released, as by a return to atmospheric pressure, the barrier has a natural bias that returns it to an initial "pre-loaded" state. This advantageously can actually yield a slight positive pressure from the system and the breastshield side or the downstream side of the barrier (relative to the upstream vacuum source). "Bias" is used herein to describe the pre-set tendency of the barrier to try and return to this initial state.

[0014] In a preferred embodiment of the invention a self-returning barrier is provided such that a source of positive pressure from the pump is not required to return the barrier to its initial state from a distended state during a breastpump cycle, and further that the mechanical transfer of vacuum across the barrier is highly efficient. The force required to distend the barrier of the present invention is determined by material construction, breastshield size, breast size, and the vacuum level of the pump; but in any of these systems, displacement of the barrier to a distended state requires that the pump vacuum is greater than the breastshield vacuum, i.e., there is energy lost in the mechanical transfer of vacuum from one side of the barrier to the other. The present invention achieves a highly efficient mechanical transfer.

[0015] The geometry of the inventive barrier acts as a spring in a preferred form. The barrier geometry maintains a low spring rate. A sufficient spring force designed into the barrier returns the barrier to the initial state, and further can assist in the expulsion of milk through a valve and into a collection container.

[0016] According to the invention a barrier is provided with a pre-loaded residual force when assembled. That is, the barrier is compressed along a central axis in the assembled state. The barrier is thus pre-loaded, i.e., biased when in this assembled state.

[0017] In an embodiment of the invention, a self-returning barrier is provided that returns to an initial state from a distended state in a brief time frame, i.e., 150 milliseconds or less, without assistance from the pump to thereby further, minimize energy expenditure on the breastpump system.

[0018] Preferably, the barrier isolates parts of the pump, as from contaminants or the like that could otherwise pass.

[0019] In an embodiment of the invention, a self-returning barrier is provided that collapses uniformly as well as returns to an initial state uniformly. The barrier of the present invention thereby eliminates the need to apply force to move through non-uniform states, such as in a lock or buckle condition of the prior art. The barrier of the present invention includes a corrugated geometry to prevent it from locking up or buckling. In one form this geometry comprises one or more undulations in the barrier that are generally concentric on a convex surface.

[0020] During collapse or achievement of a distended state, the barrier of the present invention in a preferred form never locks or buckles, even during circumstances when the pump vacuum remains less than the breastshield vacuum or when the pump vacuum is equal to the breastshield vacuum. Likewise, the barrier of the present invention never locks or buckles during return from a distended state to an initial state, even during the circumstances when the vacuum pressure is greater than the breastshield vacuum or the vacuums are equal.

[0021] In a preferred embodiment of the invention a self-returning barrier is provided that works with manually operated as well as electrically operated breastpumps. Furthermore, a self-returning barrier is provided that may function with complex electrical pumps providing a negative pressure and a positive pressure, and also with a simple pump providing only negative pressure (and a vent to atmosphere).

[0022] In particular, the barrier of the present invention does not require assistance from the vacuum pump, such as the positive force of air, for the barrier to return to its initial state during a breastpump cycle. The geometric and material construction of the barrier itself returns the barrier to its initial state after a suction phase.

[0023] In a broad embodiment, the present invention is a movable barrier for separating parts of a pump, as to prevent contamination that includes an initial state wherein the barrier is assembled as to possess a pre-load. When a vacuum source is applied to the barrier, the barrier achieves a distended state, and when the vacuum source is released, the barrier incrementally self-returns to an initial state.

[0024] The present invention, with application to a breastpump assembly, has a breastshield, a conduit structure and a collection container (bottle). A resilient barrier is assembled in a pre-loaded condition in a housing, which is located in an air pressure line, typically a vacuum line. When a vacuum is applied, the barrier achieves a distended state, and when the vacuum is released, the barrier utilizes the pre-load as a spring action to assist in transforming to its initial pre-load state.

[0025] In one embodiment, a breastpump assembly has a contamination barrier located in a vacuum line between a vacuum pump and a breastshield. A housing has a breastshield side and a vacuum side, also referred to herein as vacuum pump side, separated and isolated from one another by the barrier. The barrier is assembled within the housing in an initial pre-loaded state such that said barrier has a bias toward the breastshield side when no vacuum is applied. When vacuum is applied, the barrier achieves a distended state, and when the vacuum is released, the barrier returns to the initial state.

[0026] In one embodiment, the barrier has a generally

convex shape at least in part as presented by a convex barrier side, and is assembled within the foregoing housing so that the bias presses the convex barrier side against an internal breastshield side sidewall of the housing in the initial state. The convex barrier side has at least one undulation formed in its surface generally concentric with the center of the convexity of the barrier. In a most preferred form, the internal breastshield side sidewall has a shape that generally conforms to that of the convex barrier side, such that the barrier and the breastshield side sidewall substantially mate when in facial engagement (in the initial pre-load state or condition).

[0027] In the foregoing embodiment, the barrier becomes inverted under vacuum, and forms another generally convex shape when distended under vacuum, at least in part, as presented by the now inside-out barrier side in the distended state. A vacuum side sidewall has in this most preferred form, a shape that generally conforms to that of the distended barrier side, such that the barrier and the vacuum side sidewall substantially mate when in facial engagement.

[0028] In one embodiment of the invention, the barrier has a plurality of generally concentric undulations designed to provide bending moments for the barrier tending to return from a distended state to an initial state. This is contrasted with stretching of a barrier of the prior art, rather than bending.

[0029] In one embodiment of the invention a breastpump assembly is provided which isolates parts of the pump in a vacuum line from contamination, such as between a breastshield and a vacuum source in communication with the breastshield via the vacuum line. The vacuum line is in communication with a housing that has a breastshield side and vacuum side. A resilient barrier having a form with a first surface that is, at least in part, generally domelike with an unassembled dome height as measured from a base of the dome to the first surface. The resilient barrier is assembled in the housing in a manner to separate and thereby isolate the breastshield housing side and vacuum housing side in an initial state with a pre-loaded condition for the barrier. The pre-loaded condition of the barrier has an assembled dome height that is less than the unassembled dome height.

[0030] Furthermore, the vacuum realized on the breastshield side follows a generally one to one relationship with the vacuum applied on the vacuum side, after an initial level of vacuum is realized on the vacuum pump side to overcome the pre-load condition. The initial level of vacuum to overcome the pre-load condition can be about 4 to 15 mmHg (negative) in one form of the invention. This yields a highly efficient vacuum transfer across the barrier. The foregoing embodiment can further include a milk conduit structure which conveys milk from the breastshield to a container via a catch chamber and a one-way valve between the catch chamber and the container. The barrier, upon returning to an initial state with a predetermined minimum amount of milk in the catch chamber, generates an increased pressure in the catch chamber relative to the container so as to open the valve and release milk to travel into the container.

[0031] These, together with other objects and advantages will be further understood in the details of the construction and operation of the invention as more fully hereinafter described, reference being had to the accompanying drawings, forming a part hereof, wherein like numerals refer to like parts throughout, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

[0032]

FIG. 1A is a perspective view of a contamination barrier in a free state according to the present invention;
FIG. 1B is a perspective view of the barrier of FIG. 1A from the other side;
FIG. 2 is a side view of the contamination barrier of FIG. 1;
FIG. 3A is a front side perspective view of a breastpump assembly according to the present invention;
FIG. 3B is the breastpump of FIG. 3A from the back side;
FIG. 4 is an exploded perspective view from the front side of the breastpump assembly of FIGS. 3A and 3B according to the present invention (without the bottle);
FIG. 5 is an exploded perspective view from the back side of the breastpump assembly of FIG. 4;
FIG. 6A is a side view of the contamination barrier of FIG. 2 in a pre-loaded state according to the present invention;
FIG. 6B is a side view similar to that of FIG. 6A with the barrier distended;
FIG. 7A is a side sectional view of the breastpump assembly of FIGS. 3A and 3B;
FIG. 7B is a sectional view of the breastpump assembly of FIG. 7A.
FIG. 8 is an enlarged sectional view similar to that of FIG. 7B in one phase;
FIG. 9 is a sectional view similar to that of FIG. 8 in another phase; and
FIG. 10 is a comparison chart of performance (curves) of various membranes.

DETAILED DESCRIPTION OF AN EMBODIMENT OF THE INVENTION

[0033] Although the embodiments of the present invention described herein are directed to breastpump assembly systems, which is the particular environment that the invention finds its origin, it is contemplated that the present disclosure has various other applications, such as any pump system that requires a barrier to prevent contamination, or that may benefit from a movable membrane that is very efficient in transmitting pressure changes from a volume (or working fluid) on one side to a volume (or working fluid) on the other side. The invention is

however defined by the scope of independent claim 1.

[0034] The barrier of the present invention works with simple manually operated breastpumps that may provide only suction (and a vent to atmosphere), as well as more complex pumps, such as motorized pumps, and pumps providing both suction and a positive pressure. Thus, while described in particular respects with a source of vacuum, the pressure source could also be a positive pressure moving the barrier.

[0035] FIGS. 1A and 1B illustrate a self-returning contamination barrier 100 in a "free" state according to the present invention; that is, unassembled, and as it may be molded. The barrier includes an inner surface 102, and outer surface 104. As shown, the outer surface 104 includes three concentric circular panels 106, 108, 110, although any number of panels and any concentric shape are contemplated. The panels 106, 108, 110 are amalgamated, or joined, via sidewalls 112. Sidewall 112a joins center panel 106 to intermediate panel 108. Sidewall 112b joins intermediate panel 108 to exterior panel 110. Exterior panel 110 is amalgamated (joined) with a rim 114 via sidewall 112c. As shown, and discussed in more detail hereafter, a valve 101 formed integral with barrier 100, but it is contemplated that the valve 101 could be separate and apart from the barrier 100.

[0036] The self-returning contamination barrier 100 is made of a resilient material, such as an elastomer, or any plastic and rubber combination that permits the barrier to function as a spring, described more fully below. The preferred embodiment is constructed of liquid injection molded silicone (LIMS), such as LIM 6050 that available from General Electric (GE).

[0037] The barrier 100 is assembled with a breastpump protection to eliminate contamination in the pump air line. FIGS. 3A and 3B illustrate a breastpump assembly 200. The assembly 200 includes a detachable breastshield 202. The breastshield 202 engages with a breast to form a seal to ensure suction to the breast, while maintaining comfortability. The front housing 204, also referred to herein as first housing, front side, or breastshield side, includes an interface or base part 205 and bottle collar 208. Breastshield 202 is detachably connected to the interface 205 of front housing 204 (although it could be made integral therewith). A collection container or bottle 210 is attached to the collar 208 of the front housing 204. The rear housing 206, also referred to herein as second housing, back side, or vacuum side, includes a port 212 to connect to an electrically operated pump, otherwise referred to as the vacuum source.

[0038] FIG. 4 and FIG. 5 illustrate an exploded view of the breastpump assembly 200 according to the present invention. The rear housing 206 includes an interior rearwall surface 402 and an exterior surface 404. The front housing 204 includes an interior frontwall surface 502, and an exterior surface 504. As assembled, the barrier 100 is positioned between the interior rearwall surface 402 of the rear housing 206 and the interior frontwall surface 502 of the front housing 204.

[0039] The frontwall surface 502 most preferably has a shape that generally matches the outer surface 104 of the barrier 100 when it is in facial engagement in the initial state. The interior rearwall surface 402 most preferably has a shape that generally matches the inner surface 102 of the barrier 100 in a distended (inverted) state, described more fully below. The rim 114 forms a seal between the interior surface 502 of the front housing part 204 and the interior surface 402 of the rear housing part 206.

[0040] Once assembled within the housing, the barrier 100 separates and isolates the breastshield side of the housing 204 and the vacuum side of the housing 206. The barrier 100 is assembled in a pre-loaded initial state, also referred to herein as a first or initial position, or state, and maintains a concave shape as viewed from the vacuum side or a convex shape as viewed form the breastshield side, between the housing parts 204, 206, as shown in FIG. 6A. In this first position, the barrier 100 is biased toward the breastshield side of the housing 204.

[0041] As can be seen from FIG. 6A, the center panel 106 and sidewall 112a are substantially aligned with intermediate panel 108 in the pre-loaded state, i.e., when assembled. In addition, sidewalls 112b, 112c in a compressed configuration in the pre-loaded state, in comparison to the free state (FIG. 2). Looking at this another way, the barrier 100 has a dome-like shape, with a central axis. In the free state of FIG. 2, the height of the dome, as taken along this axis from rim 114 to the front surface of the convex side (panel 106), is h_1. In the pre-load state of FIG. 6A, the dome is compressed to a height of h_2, where h_2 is less than h_1. The pre-loaded state assists in the functionality (spring action) of the barrier 100 during operation, described more fully below.

[0042] With reference to FIGS. 7A and 7B, the breastshield 202 connects to the interface (collar or shield base) 205 of the front housing 204. When milk is expressed from the breast of a nursing mother, the milk thereby flows from the breastshield 202 through a liquid conduit 702 portion to a collecting or catch chamber 704, and then to the collection container 210 (here, a bottle). At the outlet of the collection chamber 704 there is provided a valve 101 which closes the collection chamber 704, leading to bottle 210. Valve 101 in this instance is shown integrated with barrier 100, but again, it is contemplated that the valve 101 could be separate and apart from the barrier 100. This system is not dependent on this type of valve, in any event.

[0043] When a vacuum or negative pressure is applied to the breastshield 202 from a well known type of suction device 706, which may be manually operated or motor driven, the valve 101 closes the collection chamber 704, and a negative pressure is applied to the interior of the breastshield 202. Milk is collected within the collection chamber 704. When the negative pressure is released, the valve 101 opens to pass milk expressed into the breastshield 202 and thence to the collection chamber 704, to flow into the bottle 210. As noted, the valve mech-

anism may be of many types, for example a duckbill type.

[0044] The vacuum or suction device 706 here is a house-current driven vacuum pump using a tube, or air line 708 to convey the vacuum, although it is contemplated that the vacuum device 706 may be a manually operated piston pump, or a battery operated diaphragm pump. The invention herein is, however, not limited to any particular kind of vacuum device.

[0045] The vacuum source 706 connects via air line tube 708 to a port 212 formed on the rear housing 206. The port 212 extends through surface 402 and communicates with the interior of the rear housing 206. There is an interior surface 502 of the front housing 204, against which the barrier 100 is initially positioned, as shown in FIG. 7B. The breastshield side of the housing 204 has an aperture 207 that extends into the conduit structure communicating with interior space 209 within the connecting collar 208. The vacuum in the rear housing 206 is thereby communicated to the breastshield 202 by movement of the barrier away from the front wall surface 502, which in turn draws air through aperture 207 from space 209 and within the breastshield 202. The above describes a vacuum conduit structure which conveys the vacuum from the source 706 to the breastshield 202.

[0046] As stated, just before the vacuum source is applied, the barrier 100 is in facial engagement with the interior frontwall surface 502 of the front housing 204. The frontwall surface 502 has a shape that generally matches the outer surface 104 of the barrier 100 in this initial state. This matching engagement, which could also be less exact for substantially matching engagement, provides the smallest amount of "dead" volume on the breastshield side. It should be appreciated that the invention provides a very efficient vacuum transfer mechanism, which will use less energy and therefore extend the useful life of a battery-operated pump.

[0047] The breastpump assembly 200 of the present invention operates through a breastpump cycle of suction, air line release, and milk release. FIGS. 8 and 9 illustrate the breastpump in the first phase, or suction phase. During operation, two pressures are realized on each side (breastshield side and vacuum side) of the barrier 100: a first pressure A on the vacuum side of the barrier 100, otherwise referred to herein as pump vacuum, and a second pressure B on the breastshield side of the barrier 100, otherwise referred to herein as breastshield vacuum. The pump 706 communicates a negative pressure to the barrier 100 via the air line 708 such that the first pressure A is at least initially greater (more negative) than the second pressure B, yielding what is known as a differential vacuum. This differential vacuum ultimately causes the barrier 100 to reach a distended state. The pump 706 draws a negative pressure (relative to atmosphere), which pulls the barrier 100 back into a second position, or distended state (see FIG. 8). The now inverted barrier 100 is in facial engagement with interior rearwall surface 402 of the rear housing 206 in the full distended state. The rearwall surface 402 has a shape that generally matches the inner surface 102 of the barrier 100 in this distended state.

[0048] As shown in FIG. 6B, when a vacuum is applied to the inner surface 102 of the barrier 100, the barrier 100 essentially turns inside out, such that an initial convex shape (FIGS. 2 and 6A) is transformed to an inverted convex shape (FIG. 6B). The center panel 106' is displaced from intermediate panel 108' via sidewall 112a', while the intermediate panel 108' is displaced from the exterior panel 110' via 112b' and the exterior panel 110' is displaced from the rim 114 via sidewall 112c'. Sidewalls 112a', 112b', 112c' are substantially lengthened in the distended state 900 in comparison to both the free state (FIG. 2) and the initial state (FIG. 6A).

[0049] As the barrier transforms to and from a distended state and an initial state, the exact position of barrier between the front housing 204 and rear housing 206 is determined by the difference between the first pressure A on the vacuum side of the barrier and the second pressure B on the breastshield side, i.e., differential vacuum. In addition to a first pressure and second pressure, the barrier 100 defines a first volume on the vacuum side and a second volume on the breastshield side. It should be noted that as the barrier moves, the first volume and second volume (in addition to the first pressure and second pressure) change respectively.

[0050] In the collection chamber release phase, vacuum is released, typically by release to atmospheric pressure into the air line 708. The breastpump enters the air line release phase where energy stored (pre-load) in the barrier 100 causes the barrier 100 to return to its initial state (FIGS. 6A and 9). The second pressure B returns to atmospheric level if no milk has been added to the collection chamber 704. If no milk, or air from leakage around the breast, has been added to the collection chamber 704, the valve 101 does not open and the breastpump cycle repeats until milk is collected in the collection chamber 704. If milk is present, however, the air volume in the breastshield side will have been reduced by the milk volume. The barrier 100 pre-load then creates an overpressure (relative to the container) within the collection chamber 704, opening the valve 101. That is, as the barrier 100 transforms from the distended state, the differential vacuum reverses wherein the first pressure A decreases and the second pressure B increases. With a pressure equal or greater than atmospheric pressure within the collection chamber 704, milk in the pathway can flow through valve 101 from the collection chamber 704 into the collection container 210, i.e., milk release phase. The barrier 100 utilizes its pre-load during displacement to pneumatically apply a pressure to the milk thus opening the valve 101 and releasing the milk into the collection container 210. As the milk is released, the pressure applied by the barrier 100 decreases to the pre-load represented by the initial state of the barrier. After the milk is released, the valve 101 closes. The vacuum system then repeats the phases again through this cycle, beginning with the suction phase.

[0051] It will be noted that the invention may be adapted so that the barrier does not return completely to the initial state. This might be in a situation where minimum vacuum level is to be maintained in the breastshield during pumping. The tendency of the barrier nonetheless causes it to move toward that initial state, if not achieving it.

[0052] FIG. 10 is a comparison chart of performance (curves) of various contamination barriers. As indicated in the graph of FIG. 10, pressure drop across the barrier, or differential pressure, is indicated along the y-axis (in millimeters of mercury) and vacuum side suction (in millimeters of mercury) is along the x-axis. The graph indicates values based on one pumping cycle drawn up to -250mmHg. The pressure drop is the difference between the pressure on the breastshield side of the barrier and the pressure on the pump side of the barrier.

[0053] The FREESYTLE curve was made with an embodiment of the invention. As indicated, it had a pre-load of 4 mmHg, i.e., it required that amount of vacuum before the barrier began to move. PURELY YOURS, ISIS IQ DUO and EMBRACE are commercial products. They are assembled without a pre-load. As can by seen in FIG. 10, FREESYLE, which incorporates the advantages of the present invention, had the most consistent pressure drop across the barrier for the entire vacuum range. This illustrates an excellent mechanical transfer, and a reduced amount of energy required on the breastpump system, when a barrier contemplated by the present invention is implemented. The FREESYTLE barrier is most efficient in that the energy loss is minimal once the preload is overcome.

[0054] It is understood that there may be many shapes, sizes, and configurations of the barrier that will fall within the scope of the invention, which is defined by the claims. The use of the terms dome,
concave and convex does not limit the invention to a round barrier. Any shape, e.g., non-round barrier is contemplated with material thickness and shape varying with respect to distance and angle from the center of the barrier to achieve the spring action discussed herein. It is seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense. It is also to be understood that the following claims are intended to cover all of the generic as well as specific features of the invention herein described, and all statements of the scope of the invention that, as a matter of language, might be said to fall therebetween.

[0055] While the present invention has been described with reference to a particular embodiment, those skilled in the art will recognize that many changes may be made thereto without departing from the scope of the present invention. Each of these embodiments and variants thereof is contemplated as falling with the scope of the claimed invention, as set forth in the following claims.

Claims

1. A breastpump assembly (200), comprising:

   a breastshield (202),
   a vacuum source in communication with said breastshield (202) via a vacuum line,
   a housing having a breastshield side (204) and a vacuum side (206), said housing being adjacent to said breastshield (202); and
   a resilient barrier (100), **characterised in that** the resilient barrier (100) is assembled in an initial pre-loaded state between said breastshield side (204) and said vacuum side (206) of said housing so as to separate said housing sides and resulting in a bias of the barrier (100) towards the breastshield side (204) of the housing, wherein said barrier (100) achieves a distended state in response to an applied vacuum from said vacuum source and said barrier (100) returns to said initial state upon release of said applied vacuum.

2. The breastpump assembly of Claim 1 further comprising
   a mechanism modulating said source of vacuum and a vacuum conduit structure which conveys a vacuum from said source to said breastshield (202),
   wherein the resilient barrier (100) is located in said vacuum conduit structure in close proximity to said breastshield (202), said barrier (100) being mounted within the housing, said barrier (100) having an outer surface (104) and an inner surface (102) forming at least in part a convex shape made to give said barrier (100) a bias toward said convex shape when returning from the distended state to said pre-loaded state, said housing having a breastshield side internal sidewall (502) that generally conforms to said barrier convex shape on said outer surface (104) of said barrier (100), said barrier (100) being mounted in said housing in a manner where said outer surface (104) of said convex shape is closer to said breastshield side internal sidewall (502) of said housing than a free state as molded of said barrier (100) would otherwise allow, such that said bias presses said barrier (100) against said internal sidewall (502) for the initial preloaded state of said barrier (100).

3. The breastpump assembly of Claim 2 wherein said barrier (100) has at least one undulation formed generally radially spaced from and concentric about the center of said barrier (100),
   said breastshield side internal sidewall (502) of said housing having a surface shape that generally

matches said barrier convex shape on said outer surface (104) of said barrier (100) such that said barrier (100) substantially mates with said breastshield side internal sidewall surface in facial engagement in said initial pre-loaded state.

4. The breastpump assembly of Claim 3 wherein said vacuum side (206) includes a rearwall surface (402) having a shape that generally matches said barrier shape in said distended position wherein said barrier (100) has been moved by application of said vacuum from said source from said rest position and has become deformed in said distended state , such that said deformed barrier (100) substantially mates with said rearwall surface (402) of said vacuum side (206) in facial engagement in said distended state.

5. The breastpump assembly of Claim 1, wherein the breastpump isolates parts of the pump in a vacuum line from contamination, wherein the vacuum source is in communication with said breastshield (202) via said vacuum line,
wherein said housing is in communication with said vacuum line; and
wherein the resilient barrier (100) has a form with a first surface that is at least in part generally domelike and has an unassembled dome height as measured from a base for said dome to said first surface, said resilient barrier (100) being assembled in said housing in a manner to separate and thereby isolate said housing sides from one another and in the initial state with the pre-loaded condition wherein said barrier (100) has an assembled dome height that is less than said unassembled dome height.

6. The breastpump assembly of Claim 5 wherein said first surface of said barrier (100) abuts an internal sidewall (502) of said breastshield side (204) of said housing in said initial state.

7. The breastpump assembly of Claim 6 wherein said barrier (100) has a second surface on an opposite side to said first surface, wherein said second surface of said barrier (100) abuts an internal sidewall (502) of said vacuum side (206) of said housing in said distended state.

8. The breastpump assembly of Claim 7 wherein said barrier (100) has a generally convex shape and least one undulation formed generally radially spaced from and concentric about a center of said barrier (100), said breastshield side internal sidewall (502) of said housing having a surface shape that generally matches the shape of said barrier first surface such that said barrier (100) in said pre-loaded condition substantially mates with said breastshield side internal sidewall surface in facial engagement, said vacuum side internal sidewall (502) of said housing having a surface shape that generally matches the shape of said barrier (100) in said distended state wherein said barrier (100) has become inverted through movement from said initial state to said distended state, such that said inverted barrier (100) substantially mates with said vacuum side internal sidewall surface in facial engagement in said distended state.

9. The breastpump assembly of Claim 8 wherein said barrier (100) is made of a resilient material which in combination with said barrier shape causes said barrier (100) to return from said distended state to said initial state on its own upon the release of said vacuum.

10. The breastpump assembly of Claim 5 wherein the vacuum realized on said breastshield side (204) follows a generally one to one relationship with the vacuum applied on said vacuum side (206) after an initial level of vacuum is realized on said vacuum side (206) to overcome said pre-load condition.

11. The breastpump assembly of Claim 10 wherein said initial level of vacuum to overcome said pre-load condition is about 4 mmHg.

12. The breastpump assembly of Claim 11 further including a milk conduit structure which conveys milk from the breastshield (202) to a container via a catch chamber and a one-way valve between said catch chamber and said container, said barrier (100) upon returning to said initial state with a predetermined minimum amount of milk in said catch chamber generates an increased pressure in said catch chamber relative to said container so as to open said valve and release milk to travel into said container.

13. The breastpump assembly of Claim 5, wherein said barrier (100) has a formed shape of convexity in a demounted condition, and when mounted within said housing said barrier (100) cannot reach said formed shape of convexity in said initial state, such that said barrier (100) is pressed against an internal sidewall (502) of said breastshield side (204) in said initial state.

Revendications

1. Ensemble tire-lait (200) comprenant :

une téterelle (202),
une source de vide en communication avec ladite téterelle (202) par l'intermédiaire d'une canalisation à vide,
un boîtier comportant un côté téterelle (204) et un côté à dépression (206), ledit boîtier étant

adjacent à ladite téterelle (202) ; et
une barrière élastique (100), **caractérisé en ce que** la barrière élastique (100) est montée dans un état initial pré-chargé entre ledit côté téterelle (204) et ledit côté à dépression (206) dudit boîtier de façon à séparer lesdits côtés de boîtier et entraînant une sollicitation de la barrière (100) vers le côté téterelle (204) du boîtier,

dans lequel ladite barrière (100) atteint un état dilaté en réaction à un vide appliqué à partir de ladite source de vide et ladite barrière (100) revient audit état initial lorsqu'on relâche ledit vide appliqué.

2. Ensemble tire-lait selon la revendication 1, comprenant en outre :

un mécanisme de modulation de ladite source de vide et
une structure de conduit de vide qui transmet le vide de ladite source à ladite téterelle (202),

dans lequel la barrière élastique (100) est située dans ladite structure de conduit de vide à proximité immédiate de ladite téterelle (202), ladite barrière (100) étant montée à l'intérieur du boîtier, ladite barrière (100) comportant une surface extérieure (104) et une surface intérieure (102) constituant au moins en partie une forme convexe faite pour donner à ladite barrière (100) une sollicitation vers ladite forme convexe quand elle revient de l'état dilaté audit état pré-chargé, ledit boîtier comportant une paroi latérale interne (502) côté téterelle qui correspond dans l'ensemble à ladite forme convexe de barrière sur ladite surface extérieure (104) de ladite barrière (100), ladite barrière (100) étant montée dans ledit boîtier d'une manière où ladite surface extérieure (104) avec ladite forme convexe est plus proche de ladite paroi latérale interne (502) côté téterelle dudit boîtier que ne le permettrait autrement un état libre, tel que moulé, de ladite barrière (100), de telle sorte que ladite sollicitation appuie ladite barrière (100) contre ladite paroi latérale interne (502) pour l'état initial pré-chargé de ladite barrière (100).

3. Ensemble tire-lait selon la revendication 2, dans lequel ladite barrière (100) comporte au moins une ondulation constituée dans l'ensemble en étant radialement espacée du centre de ladite barrière (100) et centrée sur celui-ci,
ladite paroi latérale interne (502) côté téterelle dudit boîtier présentant une forme de surface qui va dans l'ensemble avec ladite forme convexe de barrière sur ladite surface extérieure (104) de ladite barrière (100) de telle sorte que ladite barrière (100) se conjugue sensiblement avec ladite surface de paroi latérale interne côté téterelle dans une entrée en contact facial dans ledit état initial pré-chargé.

4. Ensemble tire-lait selon la revendication 3, dans lequel ledit côté à dépression (206) comprend une surface (402) de paroi arrière présentant une forme qui va dans l'ensemble avec ladite forme de barrière dans ladite position dilatée dans laquelle ladite barrière (100) a été déplacée de ladite position de repos par application de ladite dépression provenant de ladite source et s'est déformée dans ledit état dilaté, de telle sorte que ladite barrière (100) déformée se conjugue sensiblement avec ladite surface (402) de paroi arrière dudit côté à dépression (206) en contact facial dans ledit état dilaté.

5. Ensemble tire-lait selon la revendication 1, dans lequel le tire-lait isole de la contamination les pièces de la pompe dans une canalisation à vide, dans lequel la source de vide en communication avec ladite téterelle (202) par l'intermédiaire de ladite canalisation à vide,
dans lequel ledit boîtier est en communication avec ladite canalisation à vide, et
dans lequel la barrière élastique (100) présente une forme ayant une première surface qui est au moins en partie dans l'ensemble en forme de dôme et a une hauteur de dôme non assemblé telle que mesurée d'une base pour ledit dôme à ladite première surface, ladite barrière élastique (100) étant montée dans ledit boîtier de manière à séparer et de ce fait isoler l'un de l'autre lesdits côtés de boîtier et dans l'état initial de situation pré-chargée dans lequel ladite barrière (100) a une hauteur de dôme assemblé qui est inférieure à ladite hauteur de dôme non assemblé.

6. Ensemble tire-lait selon la revendication 5, dans lequel ladite première surface de ladite barrière (100) vient buter contre une paroi latérale interne (502) dudit côté téterelle (204) dudit boîtier dans ledit état initial.

7. Ensemble tire-lait selon la revendication 6, dans lequel ladite barrière (100) comporte une seconde surface sur le côté opposé à ladite première surface, dans lequel ladite seconde surface de ladite barrière (100) vient buter contre ladite paroi latérale interne (502) dudit côté à dépression (206) dudit boîtier dans ledit état dilaté.

8. Ensemble tire-lait selon la revendication 7, dans lequel ladite barrière (100) a une forme dans l'ensemble convexe et comporte au moins une ondulation constituée dans l'ensemble en étant radialement espacée du centre de ladite barrière (100) et centrée sur celui-ci, ladite paroi latérale interne (502) côté téterelle dudit boîtier présentant une forme de surface qui va dans l'ensemble avec la forme de ladite première surface de barrière de telle sorte que ladite barrière (100), dans ladite situation pré-chargée, se

conjugue sensiblement avec ladite surface de paroi latérale interne côté téterelle dans une entrée en contact facial, ladite paroi latérale interne (502) du côté à dépression dudit boîtier présentant une forme de surface qui va dans l'ensemble avec la forme de ladite barrière (100) dans ledit état dilaté dans lequel ladite barrière (100) s'est retournée en se déplaçant dudit état initial audit état dilaté, de telle sorte que ladite barrière (100) retournée se conjugue sensiblement avec ladite surface de paroi latérale interne du côté à dépression dans une entrée en contact facial dans ledit état dilaté.

9. Ensemble tire-lait selon la revendication 8, dans lequel ladite barrière (100) est faite d'une matière élastique qui, en combinaison avec ladite forme de barrière, fait revenir toute seule ladite barrière (100) dudit état dilaté audit état initial lorsqu'on relâche ledit vide.

10. Ensemble tire-lait selon la revendication 5, dans lequel le vide réalisé sur le côté téterelle (204) suit un rapport dans l'ensemble de un pour un avec le vide appliqué sur ledit côté à dépression (206) après qu'on ait réalisé un niveau initial de vide sur ledit côté à dépression (206) pour surmonter ladite situation pré-chargée.

11. Ensemble tire-lait selon la revendication 10, dans lequel ledit niveau initial de vide pour surmonter ladite situation pré-chargée est d'environ 4 mm de Hg.

12. Ensemble tire-lait selon la revendication 11, comprenant en outre une structure de conduit de lait qui transporte le lait de la téterelle (202) à un récipient par une chambre collectrice et une valve de non-retour entre la chambre collectrice et ledit récipient, ladite barrière (100), en revenant audit état initial avec une quantité minimale prédéterminée de lait dans ladite chambre collectrice, crée une pression accrue dans ladite chambre collectrice par rapport audit récipient de façon à ouvrir ladite valve et permettre au lait d'entrer dans ledit récipient.

13. Ensemble tire-lait selon la revendication 5, dans lequel ladite barrière (100) présente une forme convexe par construction quand elle est démontée et, quand elle est montée dans ledit boîtier, ladite barrière (100) ne peut pas atteindre ladite forme convexe par construction dans ledit état initial, de telle sorte que ladite barrière (100) vient buter contre une paroi latérale interne (502) dudit côté téterelle (204) dans ledit état initial.

Patentansprüche

1. Eine Brustpumpenanordnung (200), aufweisend:

eine Brusthaube (202),
eine Vakuumquelle, welche mittels einer Vakuumleitung mit der Brusthaube (202) in Verbindung steht,
ein Gehäuse mit einer Brusthaubenseite (204) und einer Vakuumseite (206),
wobei das Gehäuse an die Brusthaube (202) anschliesst; und
eine elastische Barriere (100), **dadurch gekennzeichnet,**

dass die elastische Barriere (100) in einem anfänglichen vorgespannten Zustand zwischen der Brusthaubenseite (204) und der Vakuumseite (206) des Gehäuses angeordnet ist, um die Gehäuseseiten voneinander zu trennen und in einer Vorspannung der Barriere (100) gegenüber der Brusthaubenseite (204) des Gehäuses resultierend, wobei die Barriere (100), als Reaktion auf ein von der Vakuumquelle angelegtes Vakuum, einen ausgedehnten Zustand erreicht und wobei die Barriere (100) in den anfänglichen Zustand zurückkehrt, wenn das angelegte Vakuum aufgehoben wird.

2. Die Brustpumpenanordnung gemäss Anspruch 1, weiter aufweisend einen Mechanismus, welcher die Vakuumquelle moduliert und
eine Vakuum-Leitungsstruktur, welche ein Vakuum von der Vakuumquelle zur Brusthaube (202) leitet,
wobei die elastische Barriere (100) in der Vakuum-Leitungsstruktur in unmittelbarer Nähe zur Brusthaube (202) angeordnet ist, wobei die Barriere (100) im Gehäuse angebracht ist, wobei die Barriere (100) eine äussere Oberfläche (104) und eine innere Oberfläche (102) aufweist, welche zumindest teilweise eine konvexe Form bilden, welche der Barriere (100) eine Vorspannung gegenüber der konvexen Form geben, wenn sie vom ausgedehnten Zustand in den vorgespannten Zustand zurückkehrt, wobei das Gehäuse eine brusthaubenseitige innere Seitenwand (502) hat, welche im Wesentlichen der konvexen Form an der äusseren Oberfläche (104) der Barriere (100) entspricht, wobei die Barriere (100) in einer Art und Weise im Gehäuse angebracht ist, in welcher die äussere Oberfläche (104) der konvexen Form näher zur brusthaubenseitigen inneren Seitenwand (502) des Gehäuses ist als es ein freier Zustand der Barriere (100), wie ausgeformt, anderweitig erlauben würde, sodass die Vorspannung die Barriere (100) für den anfänglichen vorgespannten Zustand der Barriere (100) gegen die innere Seitenwand (502) drückt.

3. Die Brustpumpenanordnung gemäss Anspruch 2, wobei die Barriere (100) mindestens eine Wellenform aufweist, welche radial beabstanded und konzentrisch um das Zentrum der Barriere (100) ausgebildet ist,

wobei die brusthaubenseitige innere Seitenwand (502) des Gehäuses eine Oberflächenform hat, welche im Wesentlichen der konvexen Form an der äusseren Oberfläche (104) der Barriere (100) entspricht, sodass die Barriere (100) in diesem anfänglichen vorgespannten Zustand im Wesentlichen mit der brusthaubenseitigen inneren Seitenwand im stirnseitigen Eingriff zusammenpasst.

4. Die Brustpumpenanordnung gemäss Anspruch 3, wobei die Vakuumseite (206) eine Rückwandoberfläche (402) beinhaltet, welche eine Form hat, welche im Wesentlichen mit der Barrierenform in der ausgedehnten Position zusammenpasst, wobei die Barriere (100) durch Anwendung des Vakuums der Quelle aus der Ruheposition herausbewegt und in die ausgedehnte Position verformt wurde, sodass die verformte Barriere (100) im ausgedehnten Zustand im Wesentlichen mit der Rückwandoberfläche (402) der Vakuumseite (206) im stirnseitigen Eingriff zusammenpasst.

5. Die Brustpumpenanordnung gemäss Anspruch 1, wobei die Brustpumpe Teile der Pumpe in einer Vakuumleitung vor Kontaminierung isoliert, wobei die Vakuumquelle mit der Brusthaube (202) mittels der Vakuumleitung verbunden ist,
wobei das Gehäuse mit der Vakuumleitung verbunden ist, und
wobei die elastische Barriere (100) eine Form mit einer ersten Oberfläche hat, welche zumindest teilweise domförmig ist, und welche eine nicht zusammengesetzte Domhöhe, gemessen von einer Basis für den Dom zur ersten Oberfläche, hat, wobei die elastische Barriere (100) im Gehäuse in einer Art und Weise angeordnet ist, um die Gehäuseseiten voneinander zu trennen und dadurch zu isolieren, und im anfänglichen Zustand mit dem vorgespannten Zustand, wobei die Barriere (100) im zusammengesetzten Zustand eine Domhöhe aufweist, welche geringer ist als die Domhöhe im nicht-zusammengesetzten Zustand.

6. Die Brustpumpenanordnung gemäss Anspruch 5, wobei die erste Oberfläche der Barriere an einer inneren Seitenwand (502) der Brustpumpenseite (204) des Gehäuses im anfänglichen Zustand anliegt.

7. Die Brustpumpenanordnung gemäss Anspruch 6, wobei die Barriere (100) eine zweite Oberfläche aufweist, welche der ersten Oberfläche gegenüber liegt, wobei die zweite Oberfläche der Barriere (100) an einer inneren Seitenwand (502) der Vakuumseite (206) des Gehäuses im ausgedehnten Zustand anliegt.

8. Die Brustpumpenanordnung gemäss Anspruch 7, wobei die Barriere (100) im Wesentlichen eine konvexe Form aufweist und mindestens eine Wellenform aufweist, welche radial beabstanded und konzentrisch um das Zentrum der Barriere (100) ausgebildet ist, wobei die brusthaubenseitige innere Seitenwand (502) des Gehäuses eine Oberflächenform hat, welche im Wesentlichen mit der Form der ersten Barrierenoberfläche zusammenpasst, derart, dass die Barriere unter dem vorgespannten Zustand im Wesentlichen mit der brusthaubenseitigen inneren Seitenwandoberfläche im stirnseitigen Eingriff zusammenpasst, wobei die vakuumseitige innere Seitenwand (502) des Gehäuses eine Oberflächenform hat, welche im Wesentlichen mit der Form der Barriere (100) im ausgedehnten Zustand zusammenpasst, wobei sich die Barriere durch die Bewegung vom anfänglichen Zustand in den ausgedehnten Zustand invertiert, sodass die invertierte Barriere (100) im Wesentlichen mit der vakuumseitigen inneren Seitenwandoberfläche im stirnseitigen Eingriff im ausgedehnten Zustand zusammenpasst.

9. Die Brustpumpenanordnung gemäss Anspruch 8, wobei die Barriere (100) aus einem elastischen Material besteht, welches zusammen mit der Barrierenform bewirkt, dass die Barriere (100) vom ausgedehnten Zustand selbstständig in den anfänglichen Zustand zurückkehrt, sobald das Vakuum aufgehoben wird.

10. Die Brustpumpenanordnung gemäss Anspruch 5, wobei das auf der Brusthaubenseite (204) realisierte Vakuum im Wesentlichen einer eins zu eins Beziehung mit dem auf der Vakuumseite (206) angelegten Vakuum folgt, nachdem ein anfänglicher Vakuumlevel der Vakuumseite (206) realisiert ist, um den vorgespannten Zustand zu überwinden.

11. Die Brustpumpenanordnung gemäss Anspruch 10, wobei der anfängliche Vakuumlevel zur Überwindung des vorgespannten Zustands etwa 4 mmHg ist.

12. Die Brustpumpenanordnung gemäss Anspruch 11 weiter beinhaltend eine Milch-Leitungsstruktur, welche Milch von der Brusthaube (202) via eine Auffangkammer zu einem Behälter führt, und ein zwischen der Auffangkammer und dem Behälter angeordnetes Einwegventil, wobei die Barriere (100) bei der Rückkehr in den anfänglichen Zustand mit einer vorbestimmten minimalen Menge von Milch in der Auffangkammer einen erhöhten Druck in der Auffangkammer relativ zum Behälter erzeugt, um so das Ventil zu öffnen und Milch zur Leitung in den Behälter freizugeben.

13. Die Brustpumpenanordnung gemäss Anspruch 5, wobei die Barriere (100) eine geformte Form von Konvexität im demontierten Zustand hat, und wenn

sie im Gehäuse angebracht ist, kann die Barriere (100) nicht die geformte Form von Konvexität im anfänglichen Zustand erreichen, sodass die Barriere (100) gegen eine innere Seitenwand (502) der Brusthaubenseite (204) im anfänglichen Zustand gepresst ist.

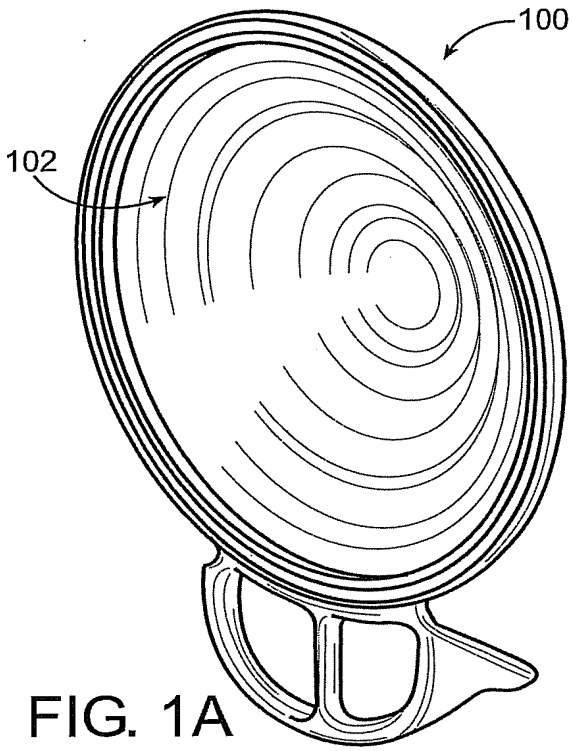


FIG. 1A

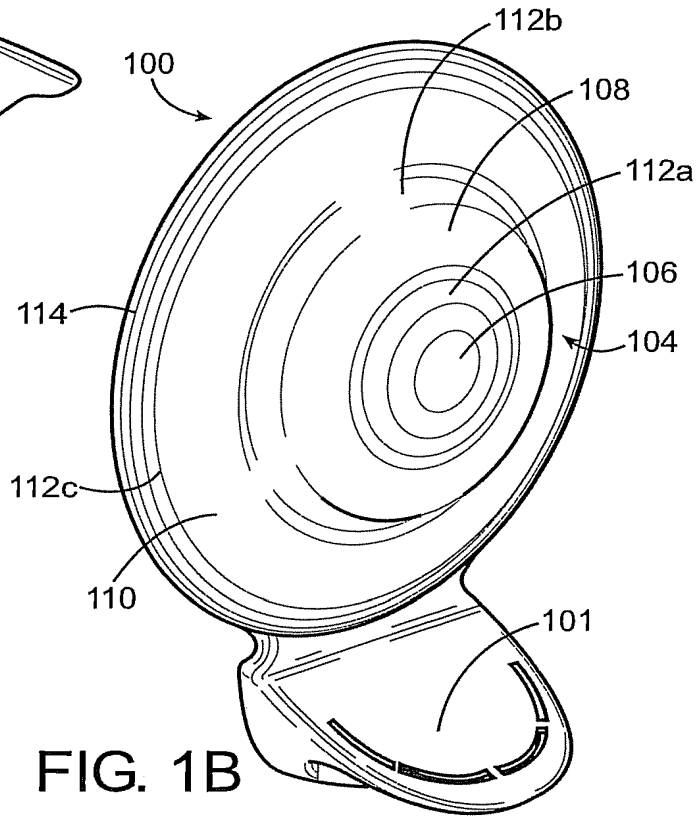


FIG. 1B

Free / As Molded

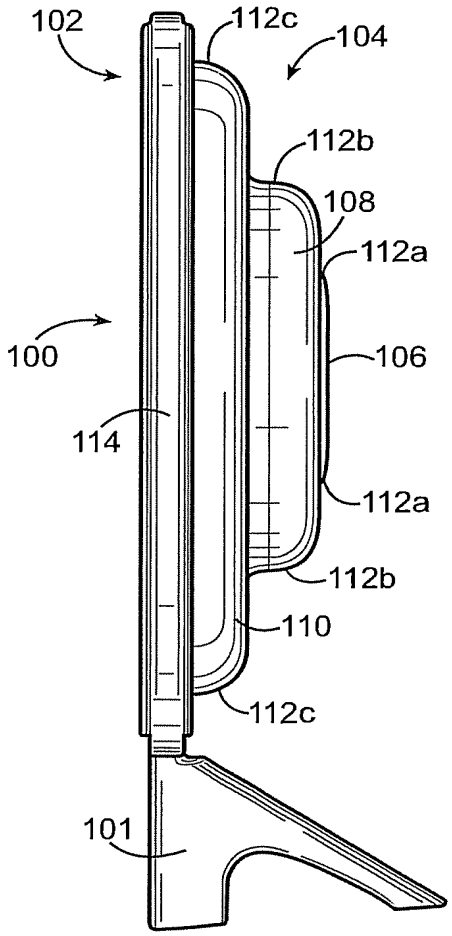


FIG. 2

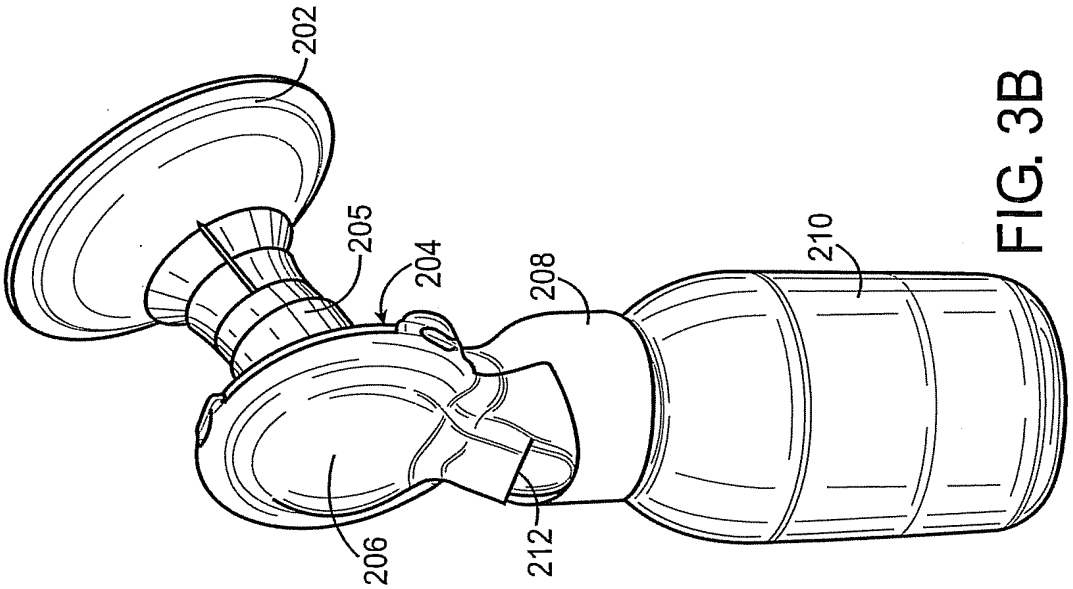


FIG. 3B

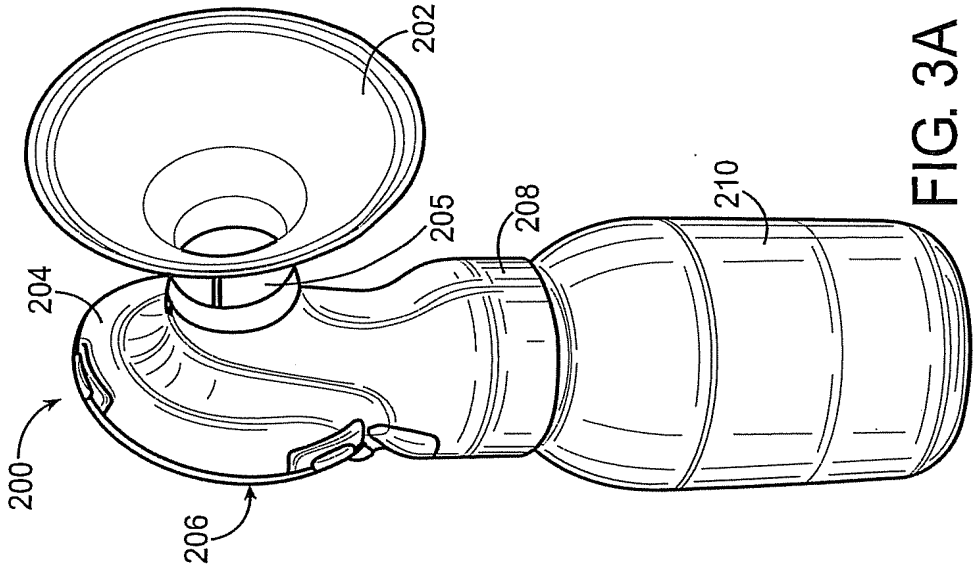


FIG. 3A

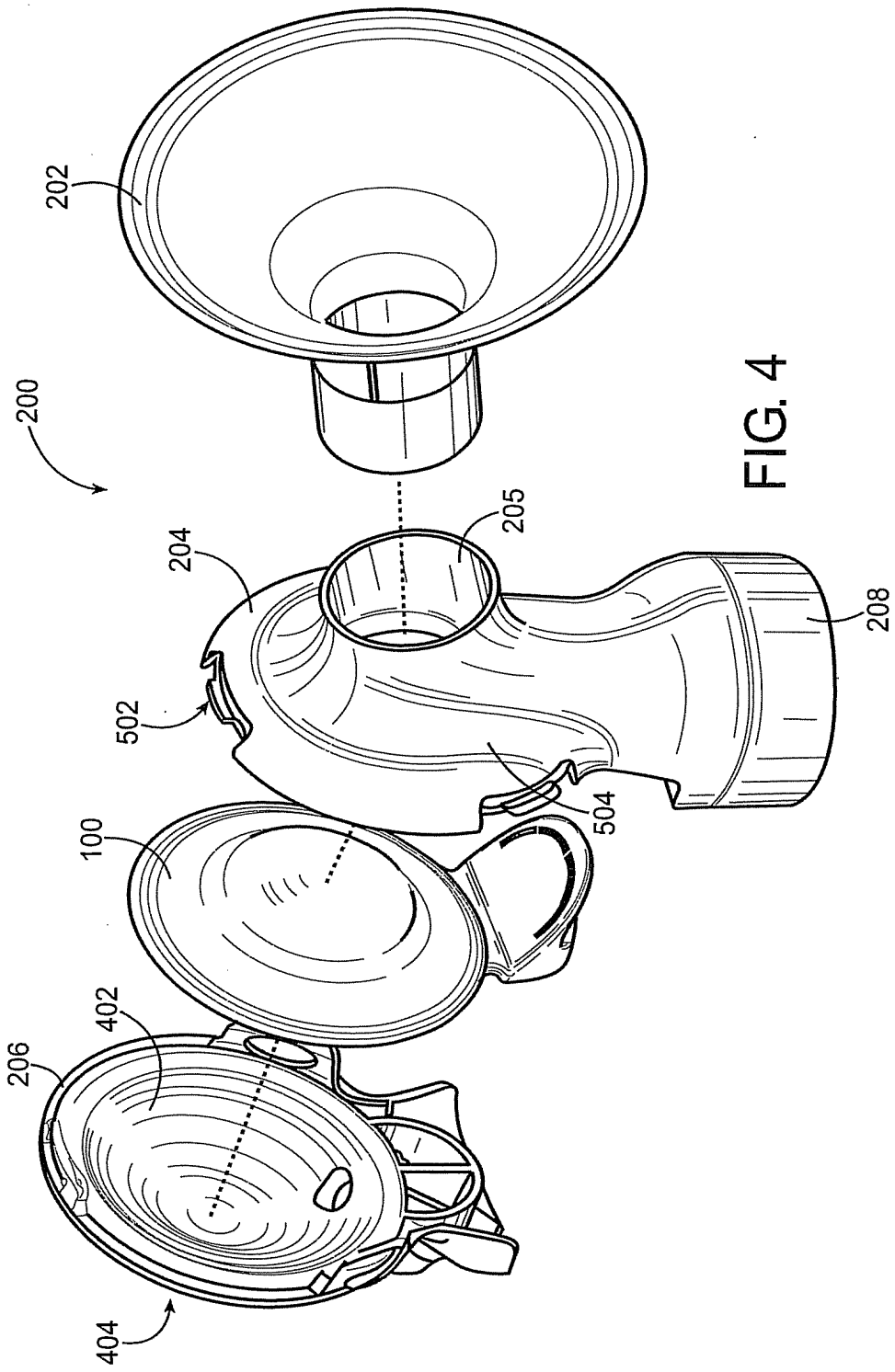


FIG. 4

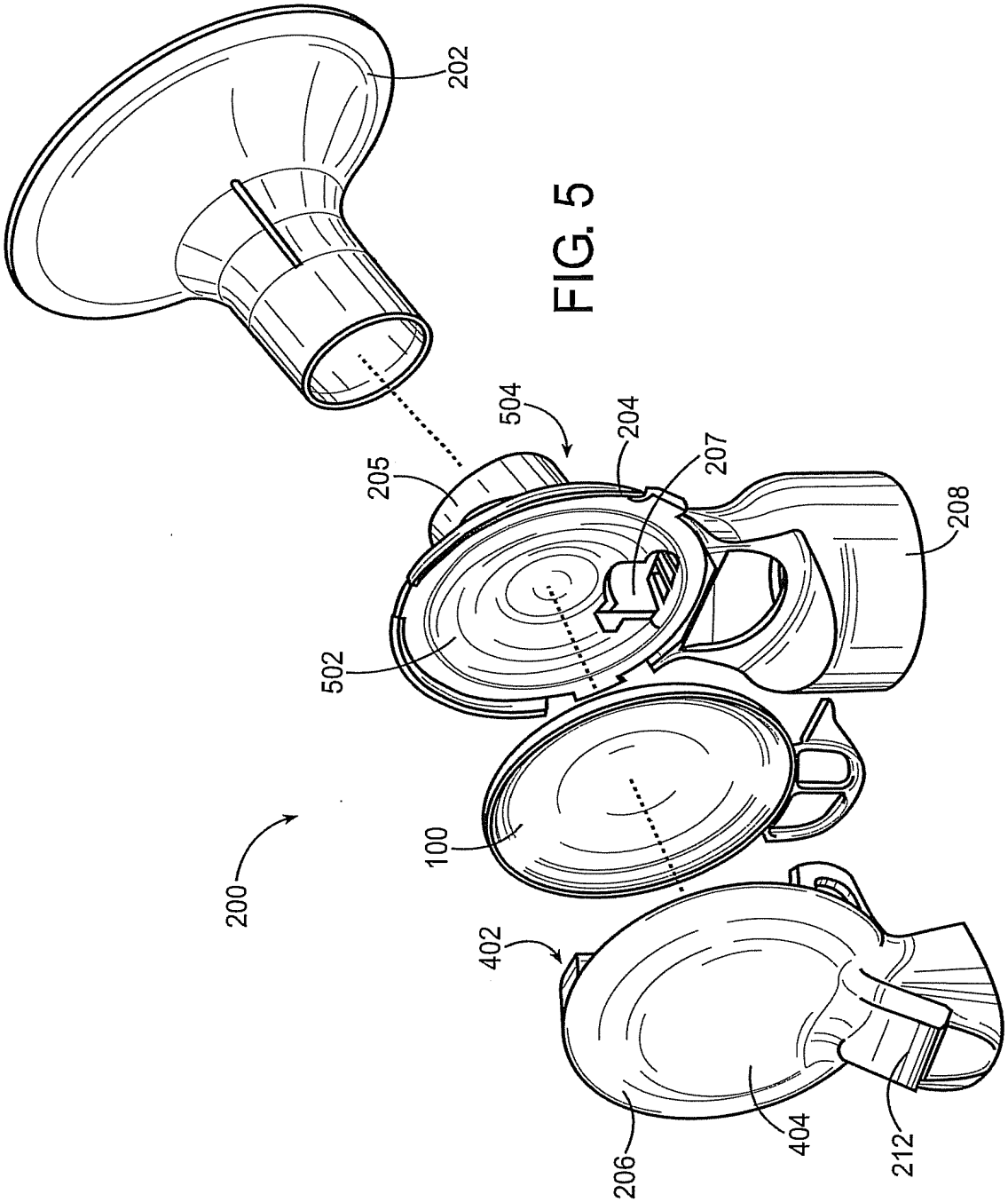


FIG. 5

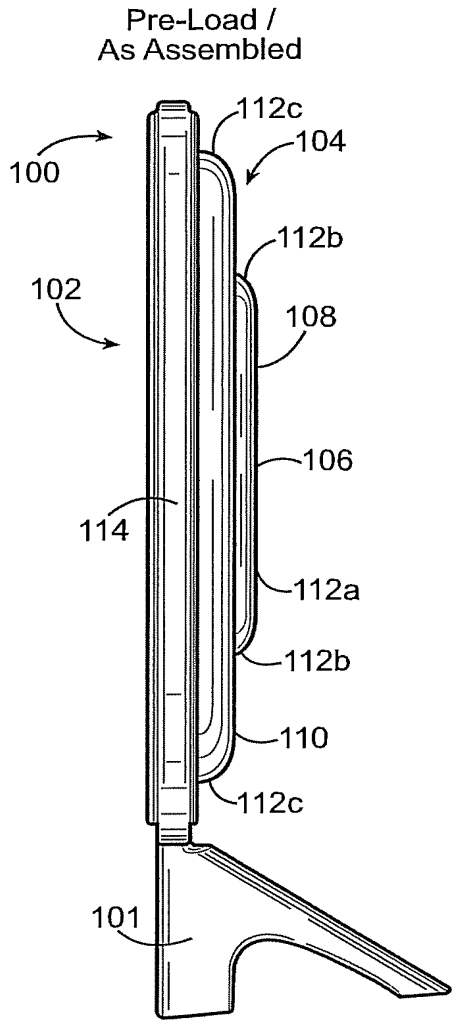

Pre-Load /
As Assembled
100
102
112c
104
112b
108
106
114
112a
112b
110
112c
101

FIG. 6A

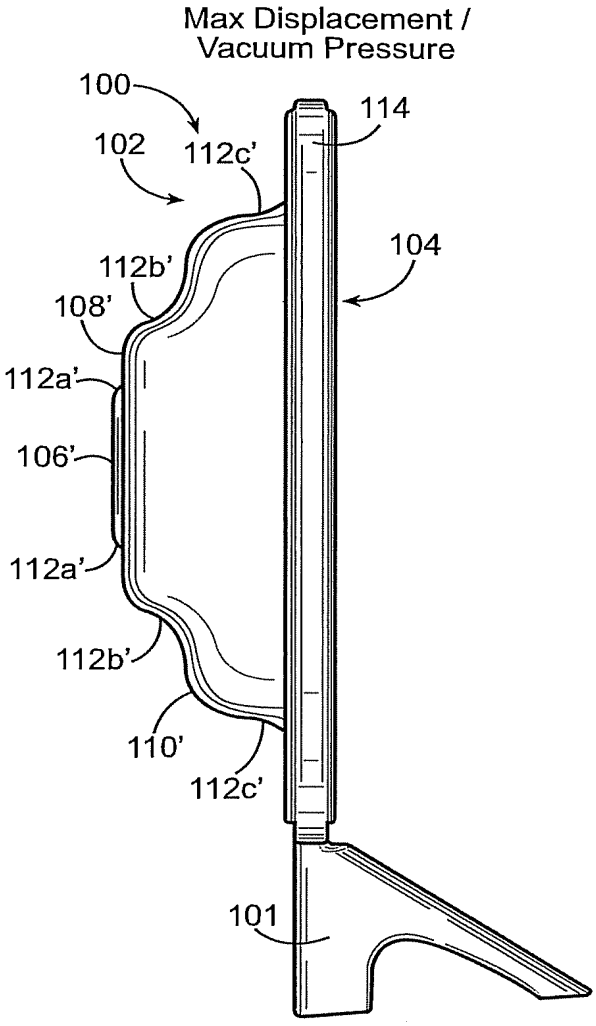

Max Displacement /
Vacuum Pressure
100
102
112c'
114
104
112b'
108'
112a'
106'
112a'
112b'
110'
112c'
101

FIG. 6B

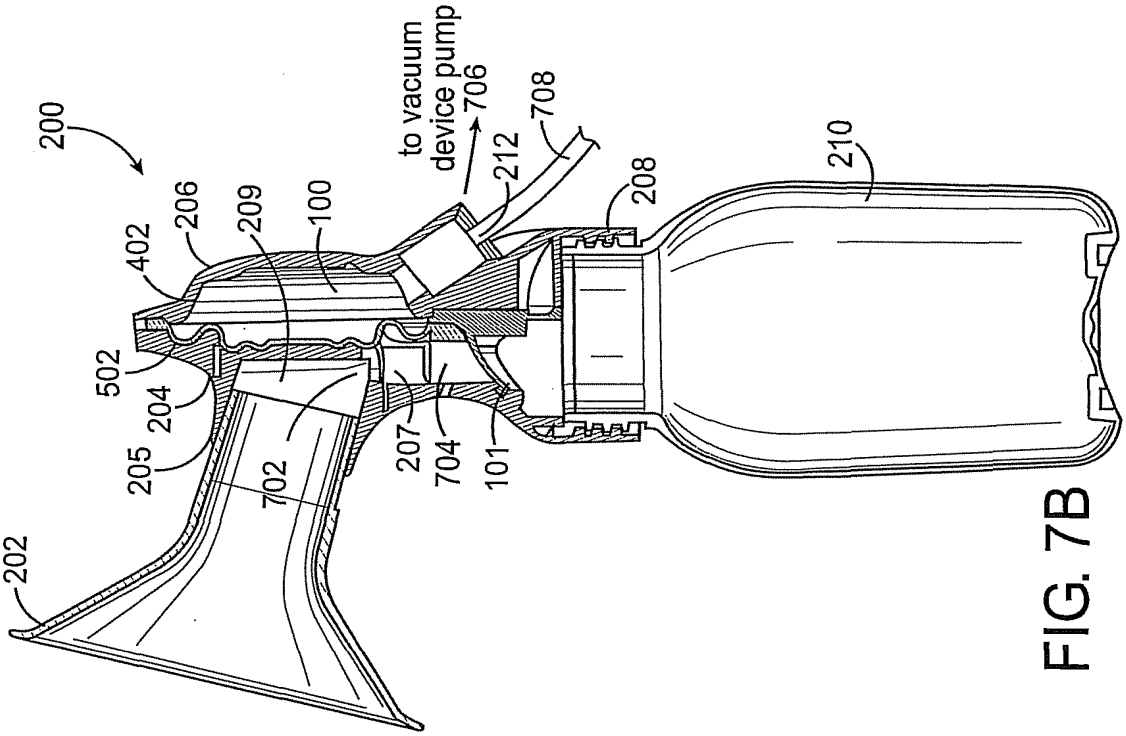

200
206
209
100
402
502
204
205
202
702
207
704
101
to vacuum device pump
706
708
212
208
210

FIG. 7B

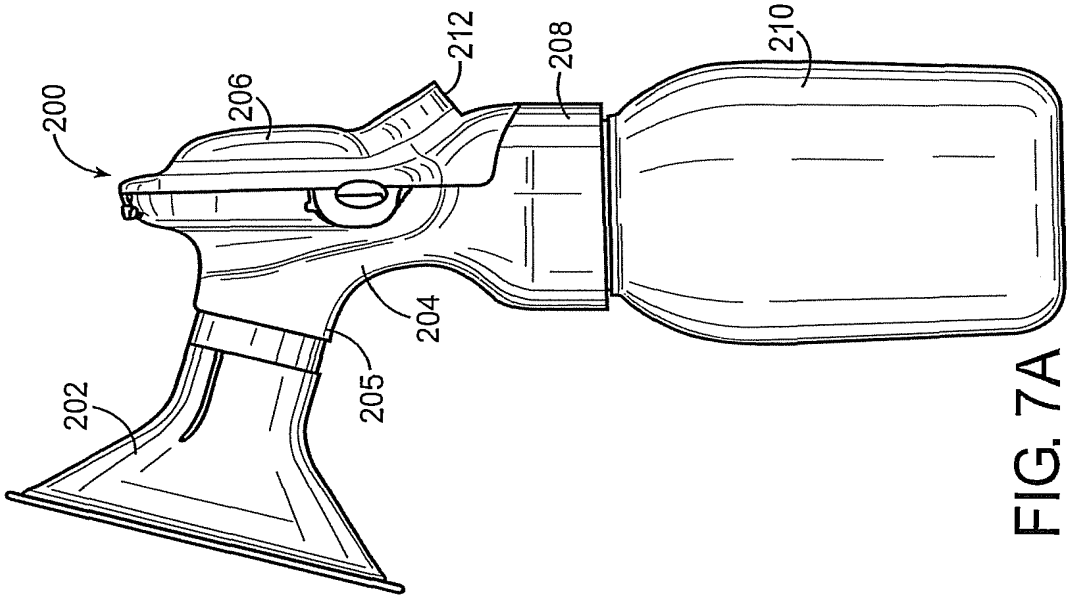

200
206
212
208
210
204
205
202

FIG. 7A

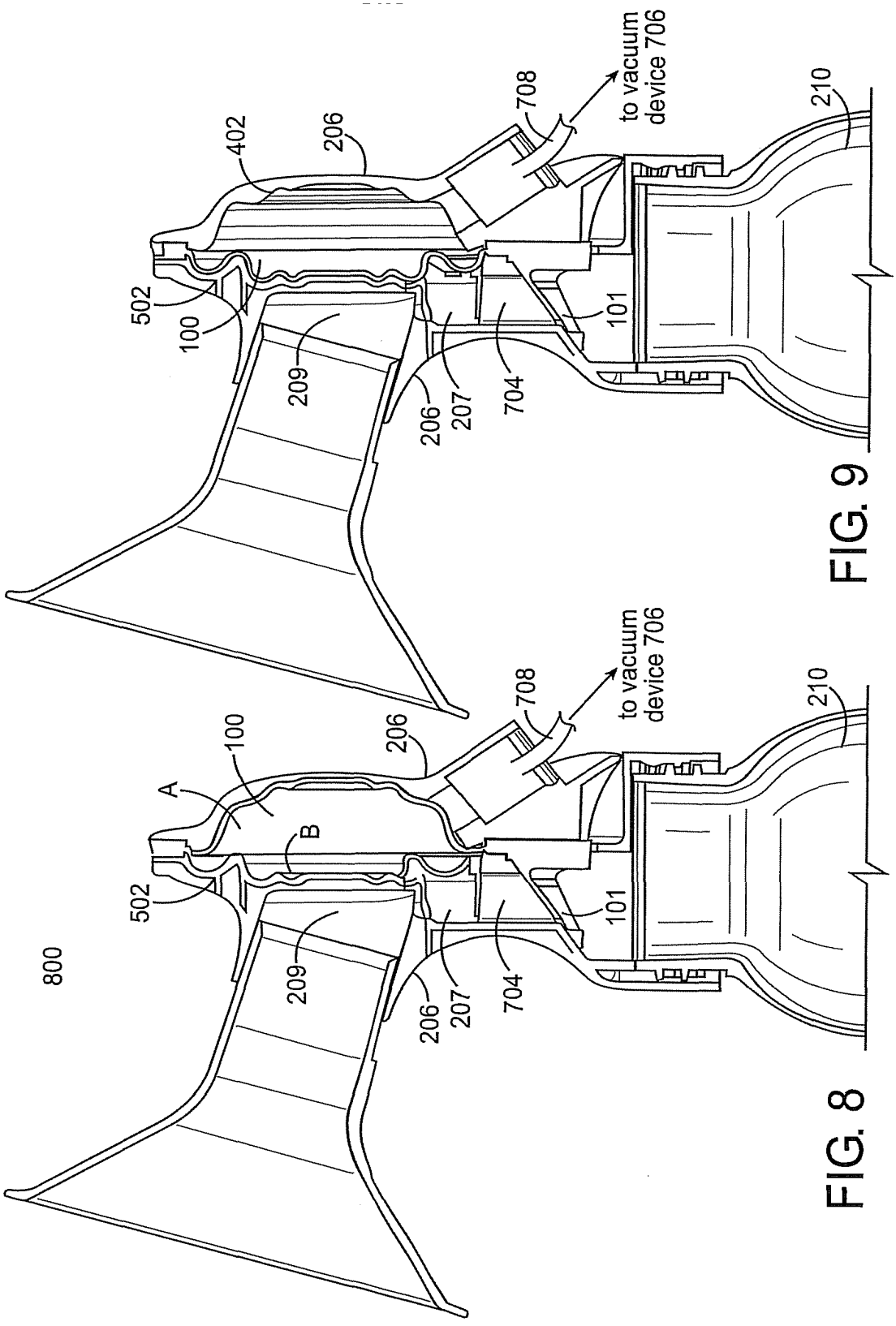

800
A
B
100
502
209
206
207
704
708
to vacuum device 706
101
210

FIG. 8

402
206
502
100
209
206
207
704
708
to vacuum device 706
101
210

FIG. 9

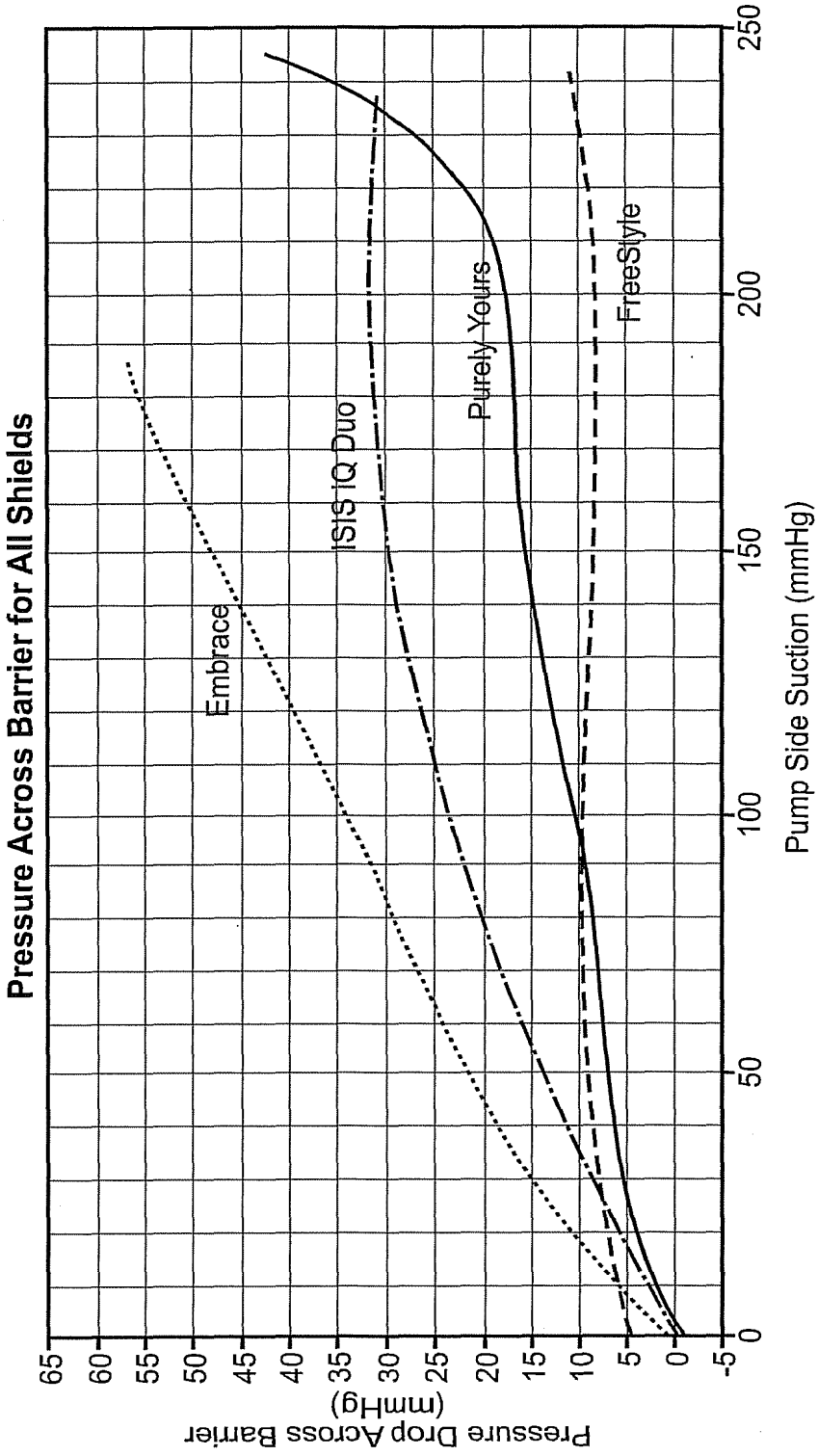

Pressure Across Barrier for All Shields
Pressure Drop Across Barrier (mmHg)
65
60
55
50
45
40
35
30
25
20
15
10
5
0
-5
0
50
100
150
200
250
Pump Side Suction (mmHg)
Embrace
ISIS iQ Duo
Purely Yours
FreeStyle

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20040039330 A **[0003]**
- US 4857051 A, Larsson **[0005]**
- US 5941847 A, Huber **[0008]**
- US 6461324 B1 **[0009]**
- US 20040087898 A1 **[0009]**

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(54) **Breastpump**

Brustpumpe

Tire-lait

(84) Designated Contracting States:
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30.12.1999 US 476076

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00993020.7 / 1 263 487

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(56) References cited:
WO-A1-98/22160 **WO-A1-99/51882**
US-A- 4 794 915 **US-A- 5 571 084**
US-A- 5 810 772

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EP 2 210 628 B1

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Description

FIELD OF THE INVENTION

[0001] This invention relates to breastpumps for drawing breastmilk, and particularly to a motorized, such as electrically driven, breastpump.

BACKGROUND OF THE INVENTION

[0002] US 5 571 084 discloses a breastpump with a controller comprising a keypad for user input.

[0003] US 4 794 915 discloses a suction sequence of a real infant.

[0004] Breastpumps for use by nursing mothers are well known. They allow the nursing woman to express the breastmilk as necessary or convenient, and further provide collection of the breastmilk for later use. For some mothers, breastpumps may be a necessity, such as when the child has suckling problems, or if the mother has problems with excessive or deficient milk production, or soreness, deformation or injury of the mammilla.

[0005] Manual breastpumps are commonplace, primarily because they are relatively inexpensive and easy to transport. Being manually driven, however, stroke rate and suction pressure produced can be uneven, and operating the pump can ultimately be tiring.

[0006] Electrically-driven breastpumps are also commonplace. They may be of a substantially large size of a non-portable or semi-portable type, typically including a vacuum pump which has an electric motor that plugs into standard house current. Advantages of this type of pump are ready controllability and regulation of the vacuum, and the ability to pump both breasts at once. That is, the nursing woman has both hands free to hold two breastpump shields in place for pumping of both breasts at the same time.

[0007] Battery-driven breastpumps have also been developed. These breastpumps have the advantages of controllability and regulation of the vacuum, as well as being easily carried. Such a battery-driven portable breastpump is described in U.S. 4,964,851, for example. This breastpump, sold under the name MINIELECTRIC by Medela, Inc., is lightweight and achieves good vacuum (i.e., negative pressure) regulation in preferred limits, for example, between about 100 and about 220 mmHg. The LACTINA breastpump sold by Medela, Inc. is also another type of breast pump which may be driven by battery as well as house current. It is generally disclosed in U.S. Patent No. 5,007,899.

[0008] Electrically driven motorized breastpumps have almost universally been developed with a single type of "cycle" for a given pump. That is, the driving mechanism for generating the vacuum (negative pressure) to be applied at the breast in the more sophisticated pumps is geared to a particular sequence, or curve, of negative pressure increase (i.e., increasing suction), and then release. This is often aimed at reproducing in some sense the suckling action of an infant, for instance. Breastpumping can cover a range of different conditions, however, such as where the mother's nipples are sore for some reason, there is a state of significant engorgement, some nipple stimulation may be particularly desired, let-down and relaxation may be of particular interest, it may be desired to increase milk production, and so on.

[0009] Some breastpumps provides the user with the ability to vary the amount of vacuum being applied, as well as the speed of the pumping action (i.e., number of cycles per minute). In some instances in the prior art, speed and vacuum level may influence each other, such that as speed increases so does the vacuum level. The basic "curve" remains fixed, however, and the user must adapt as best she can to making variations within that particular curve built into the machine, which typically has been generalized for the overall population of users.

SUMMARY OF THE INVENTION

SUMMARY OF THE INVENTION

[0010] It is an object of the invention to provide an improved breastpump. This object is achieved with a breastpump according to claim 1. To this end, the invention in one form is a breastpump comprising a breastshield having a portion within which a woman's breast is received for the expression of milk. A source of vacuum is in communication with the breastshield. There is a mechanism for operating the source of vacuum according to a first sequence, and a controller for operating the source of vacuum according to a second sequence.

[0011] The controller can have a preset program for the second sequence which is a milk letdown sequence, for example. Preferably, the breastpump has a plurality of different programs for the controller wherein each program has a different sequence.

[0012] In a preferred embodiment, the breastpump can be programmed to generate, among other things, a plurality of differing milk expression (extraction) sequences, or curves. In one embodiment of the invention, a motorized pump (e.g., compressed air, battery and/or house current) is provided with a microprocessor-based controller. Cards, with memory "chips", containing different suction curves adapted for varying conditions and objectives are included for programming the controller in this embodiment. A user selects a desired program, and that card is then read by a mechanism providing input to the controller. It should be noted that while suction curves are generally addressed in the first instance herein, the milk expression sequences may also include a positive pressure aspect. The programming could also be provided via other media, including discs, CDs, infrared data transfer, electronic feed (e.g., an Internet connection), and so forth.

[0013] In one example, there exists the ready ability to modify the breastpump suction action to a variety of desired conditions, and provide this ability to the end-user.

An attendant advantage is that, as the science of breastpumping continues to make advances, new and improved suction curves and sequences can be made available on further cards, or other program-inputting means.

[0014] Yet another attendant advantage is that the programmable pump can also record data relating to its use and operation. That data could be stored, for instance, and then retrieved as by downloading through an Internet connection, magnetic recording (disk or card), and the like. This data retrieval would be useful in medical research, for updating the pump with new data, for monitoring usage, just for some instances.

[0015] Further, a program could be made of a particular infant's suckling pattern. That program could then be used to operate the pump, and then varied over time as the infant grows.

[0016] In one example, the breastpump has a pre-programmed milk let-down sequence. The let-down sequence is most advantageously made available through a button or the like provided on the breastpump used to actuate the sequence.

[0017] The breastpump preferably includes an electric motor having a reduction gear system with at least first and second belts conveying motive power to a movable member of an expansible chamber device wherein a vacuum is generated. The expansible chamber device is, in one embodiment, a pair of diaphragm pumps. Each diaphragm pump has a membrane which is movable relative to a shell, each said membrane being connected to a respective drive shaft, each shaft being mounted to a respective belt for linear movement with the respective belt.

[0018] In one example, the breastpump has one or more novel suction sequences which are considered to produce advantageous particularized results. Such sequences include, but are not limited to: a suction method (e.g., program or curve) for a sore nipple condition; a suction method for increased milk production; an improved suction method in general; and a method for nipple stimulation.

[0019] In one axample, there is a method for operating a breastpump for a sore nipple condition comprising varying the amount of vacuum within a range of from about 20 mmHg (the least vacuum) to about 250 mmHg (the greatest vacuum) while simultaneously varying the overall suction cycle from about 25 cycles/min. at the least vacuum to about 40 cycles/min. at the greatest vacuum, such that for a lower vacuum applied there is an increase in the number of cycles. In general, this program is intended to provide a lower peak vacuum over a longer cycle.

[0020] In one example, there is a method for operating a breastpump which is considered to yield an increase in milk output comprising operating the pump at a rapid cyclical rate on the order of about 120 cycles/min., with a negative pressure in the range of about 50 to about 150 mmHg. This method further preferably includes a pause after each period of vacuum application, such as applying the vacuum for about ten seconds of vacuum, with then a two second pause.

[0021] In one example, there is a method for operating a breastpump comprising varying the vacuum within a range of about 100 (the least vacuum) to about 250 mmHg (the greatest vacuum), while simultaneously varying the overall suction cycle from about 47 cycles/min. at the greatest vacuum to about 78 cycles/min. at the least vacuum, such that for a lower vacuum applied there is an increase in the number of cycles, with a cycle following a curve which initially builds to a peak negative pressure, then smoothly starts a pressure increase (less negative) along an initial slope but then slows the pressure increase briefly, before continuing on essentially said initial slope for the negative pressure release.

[0022] In one example, there is a breastpump assembly having features including: a compact housing design and breastshield carrying casing; and a double-diaphragm pumping mechanism.

[0023] A prophylactic device for protecting the diaphragm from fluid (air/milk) is additionally provided. In one example, a diaphragms pump for a breastpump comprises a shell having a generally hemispherical interior shape with a flexible membrane movable within the hemispherical shape to expand and contract a volume created in a chamber defined between the membrane and the shell. A mechanism connected to the membrane, such as a pullet, moves the membrane to expand and contract the volume. A port is provided in the shell through which air moves in response to expansion and contraction of the volume, such that vacuum can be communicated to a breastshield through connection to the port.

[0024] A removably mounted flexible cover is located between the shell and the membrane which isolates the membrane from fluid. The cover is removable for at least one of cleaning and disposal. To that end, the flexible membrane has a circumferential rim upon which the cover is received over the rim. The shell has an internal opening defined therein sized to encompass the rim with the cover mounted on the rim in a substantially airtight fit. The cover thereby forms a gasket between the rim and shell. A ono-way valve extending through the membrane is additionally provided, allowing exhaustion of air between the membrane and cover.

[0025] In one example, there is a manually operated control such as a rotary knob, which is used to simultaneously adjust the suction level as well as rate within a sequence. The suction "force" and "speed" are tied together in an inverse relationship. As the suction force (vacuum) is increased, for example, the rate (cycle) is decreased; as the vacuum is decreased, the cycle increases.

[0026] These and other features and advantages of the present invention will be further understood and appreciated when considered in relation to the following detailed description of embodiments of the invention, taken in conjunction with the drawings, in which:

BRIEF DESCRIPTTON OF THE DRAWINGS

[0027]

FIG. 1 is a front perspective view of a breastpump assembly made in accordance with aspects of the present invention;
FIG. 2 is a side elevational view of the breastpump of FIG. 1;
FIG. 3 is a rear perspective view of the breastpump of FIG.1;
FIG. 4 is a perspective view of the breastpump of FIG. 1 looking at the bottom;
FIG. 5 is a top view of the breastpump of FIG. 1 with a cover removed revealing diaphragm pumps;
FIG. 6 is an enlarged side view of the breastpump of FIG. 1 adjacent the bottom highlighting the program card insert slot;
FIG. 7 is a bottom perspective view of the breastpump of FIG. 1 showing battery arrangement;
FIG. 8 is a somewhat exploded assembly view of the major components of the breastpump of FIGS. 1 through 5, with a modified top cover for the diaphragm pump assembly;
FIG. 9 is a diagrammatic representation of the interaction of various components with the controller;
FIG. 10 is a schematic-type representation of a data storage and retrieval process ;
FIGS. 11 through 14 are various methods (curves) for operating the breastpump to differing ends;
FIG. 15 is a front perspective view of another embodiment of a breastpump assembly ;
FIG.16 is a rear perspective view of the FIG.15 embodiment;
FIG. 17 is a somewhat exploded assembly view of the major components of yet another breastpump ;
FIG. 18 is an enlarged front perspective view of the motor drive of the breastpump of FIG. 17;
FIG.19 is a view similar to that of FIG. 18 but from a top perspective;
FIG. 20 is an enlarged assembly view of the diaphragm pump mechanism;
FIG. 21(a) is a cross-sectional view of the assembled diaphragm pump of FIG. 20;
FIG. 21(b) is an elevational view of the assembled diaphragm pump of FIG. 20;
FIG. 21(c) is a top view of the assembled diaphragm pump of FIG. 20;
FIG. 22 is a sectional view of the assembled breastpump of FIG. 17 taken through the middle of the breastpump along its long lateral axis (side to side) looking rearwardly;
FIG. 23 is a sectional view similar to that of FIG. 22 taken along a plane forwardly of that of FIG. 22; and
FIG. 24 is a sectional view similar to that of FIG. 22 taken along a plane behind the electric motor looking back to front.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The Breastpump Assembly

[0028] Referring to FIGS. 1 through 7 initially, a breastpump assembly of the present invention in one form has an aesthetically pleasing and compact design. The housing for the major components of the assembly is a casing 10 made of a rigid high impact plastic. As shown, it has a generally ellipsoidal cross-section along its vertical axis, yielding a pleasing smooth curving look to the casing exterior. The casing 10 is closed at its upper end by an upper housing part 11, to which is affixed a carrying handle 12.

[0029] In this first embodiment, carrying handle 12 has a pair of cradles 15 formed in opposite ends thereof. These cradles 15 are adapted to receive and support the funnel portions 16 of respective breastshields 17. These breastshields 17 (sometimes referred to themselves as breastpumps) are of the type shown and described in U.S. Patent No. 4,964,851 and 4,929,229, for instance. Further detail regarding the breastshields 17 may be obtained through reference to those patents, but will be omitted herein since the inventive features in point in this application are not contingent upon the breastshield being used, so long as it is suitable to the task of milk expression.

[0030] In general, however, the breastshields 17 have the aforementioned funnel portion 16 which communicates with conduit structure connecting to a container (bottle) 18. This particular breastshield 17 is adapted for both manual as well as motorized pumping. It has a collar 20 to which a manually-driven piston pump (not shown) is screw-threaded for attachment and use in one mode of operation. When an electrically operated vacuum pump is to be employed, there is a port provided inside of the collar 20 which is in communication with the funnel portion, and to which a tube from the vacuum pump is releasably connected to convey vacuum to the breastshield. Again, such detail is well known, and can be gleaned from the foregoing patents, among other public sources. In operation in either mode, the widened (conical) portion of the breastshield 17 is placed on the breast for drawing vacuum within the shield, and thereby drawing milk through a pulling force applied to the breast. Milk drawn from the breast is collected in the bottle 18.

[0031] FIGS. 1 and 16 show a modified exterior for the breastpump 10' (prime numbers being used herein to refer to similar but modified parts). In this version the breastshields 17 are not cradled by the handle 12', but instead are carried in a holder 26 mounted to the back of the unit.

-The Drive Motor

[0032] Referring to FIG. 8 initially, casing 10 has a drive unit 25 mounted therein. There are, of course, any

number of drives that may be used for diaphragm pumps such as those used in the instant embodiment. Indeed, the type of pump (diaphragm, piston, etc.) is not necessarily significant to certain aspects of the present invention. The driving mechanism for the breastpump shown for the embodiment in point, however, is a linear drive for the diaphragm pumps consisting of a reduction drive arrangement and a 12 V DC-motor 28.

[0033] It will be noted that the FIG. 8 embodiment is substantially the same as that of FIGS. 1 through 7, except for a modified cover for the upper housing, which here includes the rigid shells 24 for the diaphragms 34 as part of the cover 35. The diaphragm pumps 30 will be further described hereafter.

[0034] FIG. 17 shows yet another version of a breastpump of the present invention substantially the same as that of FIGS. 1 through 8, except with a modified cover 35" and shell 24" for the diaphragm pump 30. The breastshield holder of the FIGS. 15 and 16 embodiment has also been slightly modified. It is with respect to this FIG. 17 embodiment that the majority of the interior detail of the breastpump will be further understood.

[0035] Turning now to FIGS. 18, 19 and 22 through 24 in particular, the reduction gearing contains belts 27a, 27b and 27c. Power is transferred from the shaft 29 of motor 28 to belt 27a. Belt 27a is received in a channel of wheel 51, which is mounted to the drive chassis 62 on rotatable shaft 52. Shaft 52 is fixed to rotate with wheel 51. A freewheel 53 is mounted on a shaft 54 fixed to the chassis 62 to freely rotate, and engages the outside of belt 27a, producing more surface engagement by the belt 27a with wheel 51.

[0036] Shaft 52 has a small toothed gear 55 mounted thereon. Belt 27b is toothed, and engages the gear 55. Toothed belt 27b furthermore engages a larger toothed gear 56 fixed to rotating shaft 57 (FIGS. 22 and 24). Part of gear 56 is small toothed gear portion 58. Belt 27c, which is also toothed, engages gear 58 as well as toothed gear 59. Gear 59 is fixedly mounted to rotating shaft 70. Fixed at each end of shaft 70 are small toothed gears 71a, 71b. Toothed belts 72a, 72b respectively engage gears 71a, 71b and freely rotating toothed gears 73a, 73b.

[0037] Diaphragm pusher (push/pull) shafts 74a, 74b are respectively clamped to belts 72a, 72b at one end. The other end engages the interior of a respective diaphragm membrane member 34 (FIG. 22, and also see FIGS. 20 and 21(a)). Here, a screw engagement with the shafts 74a, 74b was used, with a threaded nut-like element 37 mounted in a reinforced central area of membrane 36 (again, the diaphragm pumps 30 are described in more detail below). Both of the pusher shafts 74a, 74b move in tandem as driven by respective belts 72a, 72b.

[0038] Accordingly, as motor drive shaft 29 turns, belt 27a rotates shaft 52 via wheel 51. Belt 27b is in turn thereby driven off of smaller gear 55, causing rotation of shaft 57, which in turn rotates larger gear 56 and its smaller part 58, to thereby turn shaft 70 via belt 27c which couples gear part 58 with larger gear 59. This transfers the motion via gears 71a, 71b to belts 72a, 72b, imparting a linear movement to the pusher shafts 74a, 74b. A forward and then backward stroke is generated, through reversal of the motor shaft 29 direction. Reduction gearing is thus obtained as desired through appropriate selection of the various gears/wheels noted above.

[0039] The location of the shafts 74a, 74b along the path of travel, as well as the length of the stroke, is measured by position sensing mechanism 78, which can be of any standard and well known variety. This sensing mechanism 78 uses a toothed wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b. Signals generated by the counter 78b are processed by the cpu of the breastpump.

[0040] A negative pressure, or vacuum, is generated in a pair of diaphragm pumps 30. Each diaphragm pump has a flexible membrane 34 mounted in the upper housing 11 assembled with a respective rigid shell 24 (and see FIGS. 20 and 21(a) through 21(c) described further below). The membrane and shell are in substantially airtight engagement. When the membrane 34 is pulled away from the shell 24, a vacuum is generated in the space between the shell interior and the membrane, which can be accessed through outlet port 31 formed on the shell, to which a tube 32 is connected to communicate the vacuum to a respective breastshield 17.

[0041] Power is provided either through ordinary house current via power cord 38, or electrochemical battery 39, such as a pair of 6V, 12Ah lead-acid type rechargeable batteries. Power cord 38 is provided on a wrap-around mount conveniently located for storage in a well in the bottom of the lower housing part 13. FIG. 7 shows wells 41 formed within the lower housing 13 through which the batteries 40 are inserted into receptacles formed within the casing 10, having covers 42 for the wells. FIG. 7 omits the detail of the wrap mount 40, for clarity.

-The Single Switch Inversely Controlling Vacuum and Rate

[0042] An on-off switch or knob 45 (and see FIG. 9) is provided on the casing, which can be rotary or push-button to that end. It is nonetheless rotary and push-button in this embodiment since it also acts to control the amount of vacuum being applied. As the knob 45 is rotated, a signal is generated which increases or decreases the level of vacuum (suction force) to be applied, depending on which way the knob is turned. In this embodiment, as the suction force is increased, the cycle (rate) is decreased. That is, the rate and force are inversely related. This is considered to have a beneficial effect. The knob is pushed in for on and off.

-The Function Indicator

[0043] Additionally visible from the exterior of the cas-

ing 10 is a LCD display 48, a milk let-down button 49, and a program card slot 50 (the let-down sequence and programmable aspects will also be discussed in more detail below). Milk-let down button 49 is used to activate a pre-programmed suction sequence (embodied in components to be hereinafter described) particularly adapted for let-down and stimulate the milk ejection reflex. The slot 50 provides the interface access for programming cards used with the breastpump of this invention.

[0044] The display 48 provides visual indications of various functions of the pump. This could include, for example, the type of sequence then programmed, the level of suction force, the battery condition, and so forth.

-The Diaphragm Protective Covers

[0045] In this embodiment, the two diaphragm pumps 30 are in a well formed in the top of the casing 10. A cover 35 (also 35' and 35" (again, primed numbers being substantially similar to their un-primed counterparts)) is provided which fits over the well and is generally flush with the upper housing part 11. The outlets 31 extend through relieved areas in the cover 35, for example, for easy access in use.

[0046] It may be noted that the shells 24 are shown formed in the cover of the embodiment of FIG. 8. The FIG. 17 embodiment has the shells 24 moulted in a removable manner in the upper housing, as through a snap fit or interference engagement, such as shown in the embodiment of FIGS. 20 and 21(a) through 21(c), to allow easier access for cleaning or replacing the membranes of the pumping mechanism, and for cleaning the shells themselves (which are provided with grips 33 to these ends).

[0047] In the FIG. 17 embodiment, diaphragm member or membrane 34, which may be made of any suitably durable flexible and durable fluid-impervioas material (to be airtight), such as silicone with a Shore A hardness in the range of 30 to 70, is molded around its perimeter to a rigid plastic collar 85. Collar 85 has a plurality of depending anchor posts 86 with outboard flanges formed thereon, which engage with the inside lip of the respective well in the upper housing part 11 within which the collar 85 is received to snap-fit the membrane 34 in place.

[0048] Prophylactic (protective) disposable/cleana.ble covers 36 are additionally and advantageously provided, which form-fit over the diaphragms 34 and isolate them from air and other fluid from the breastshields. The covers 36, which can be made of the same material as the membranes but thinner, are likewise fluid-impervious.

[0049] Referring to FIGS. 20 and 21(a) through 21(c) in particular, each of the covers 36 has an upturned cuff 87 which forms an annular well around the perimeter of the cover 36. A pair of circumferential beads 88 and 89, which are slightly offset vertically from each other, are formed along the bottom area of the annular well. Uppermost bead 88 engages in an annular rim channel 90 formed along the bottom outside of shell 24', for a substantially airtight engagement between the protective cover 36 and the shelL

[0050] An interior channel 93 is formed within the interior bottom of the cover 36 by a bead 91 and shoulder 92, which each run circumferentially around the cover. This interior channel 93 is received on a slightly protruding edge or rim on the collar 85 of the membrane 34. An airtight fit is thus provided between the protective cover 36 and the membrane 34, which also serves to releasably fix the shell 24 in place over the membrane 34, and complete the diaphragm pump 30.

[0051] Note also that a one-way valve 95 is provided in the membrane 34, which communicates with the possible space that may form between the membrane 34 and overlying cover 36. This valve permits any entrapped air therebetween to be exhausted, such as if the first stroke on start-up happens to be toward the shell 24, with the protective cover 36 thereafter then following the movement of the diaphragm 34 to which it will generally be in facial engagement.

The Programmable Aspects

[0052] In one example, there exists the ability to program the breastpump with different types of suction sequences, or cycles as they are sometimes referred to herein. With reference to FIG. 9, for instance, the breastpump utilizes a microprocessor-based system indicated at 60 which is provided user input through a plurality of "chip" cards 61. Each chip card contains one or more predetermined programs recorded on an EEPROM. For example, each card could contain a specific type of sequence along with a milk let-down sequence.

[0053] An EEPROM microcontroller of the type MB90562 may be used, for one example, or the Atmel 2-wire EEPROM chipcard microcontroller AT24C164 for another. These provide about 16K of memory, which is considered presently sufficient.

[0054] The programs (some examples of which are described hereafter) are recorded in a conventional manner, and would be provided to the mother ready to use. The programmed chip card is inserted into the slot 50 in the back of the casing 10, where it engages an interface to the microprocessor. The particular program on the selected chip card 61 is then communicated to the microprocessor 60. Microprocessor 60 is integrated with the drive unit 25 to effect operation of the drive unit in accordance with the selected program, drawing upon either the AC power source as converted via standard technology to DC (indicated at 68 in FIG. 9), or from the battery source 39. The microprocessor 60 can also control power management.

[0055] Suction force (e.g., the amount of negative pressure generated) will typically also be adjustable by the user via operation of the rotary control knob 45, as noted above. A pre-set range for the suction force will nonetheless ordinarily be provided in the program as an initial setting for adjustment by the user thereafter via the knob

45.

[0056] One embodiment contemplated provides a milk let-down sequence (milk ejection reflex) that can be engaged without need of a chip card for the same. The milk let-down sequence (described below) is pre-progtammed in the microprocessor 60, or may otherwise be wired into the circuitry in a manner to override the then-existing operating program. When the mother desires to engage this sequence, she presses the button 49, which produces and sends an electrical signal, as to the microprocessor 60. The let-down program is then effected.

[0057] It will be readily understood that a chip card 61 is but one way to program the microprocessor 60. Other input means could be used, such as more dedicated buttons like button 49, each set to actuate a given sequence pre-programmed into the microprocessor 60. A numeric pad could be provided to input a code. The programs could be provided through an electronic data link, such as a modem, or optically, or otherwise.

[0058] Data can also be recorded by the microprocessor for downloading or transfer to the chip card. Data could also be directly recorded on the chip card. For instance, it is contemplated that the suckling action of a particular child could be recorded and reduced to a sequence. That sequence could then be programmed into the pump, and the mother would then have a suckling action from the pump very reminiscent of her own child.

[0059] Referring now to FIG. 10, the chip card 61a with breastpump operation data thereon is then read (downloaded) at a "card station" 65, shown here as a card reader 76 linked to a computer 77. The computer 77 is used to transfer the data to one of a variety of available media, such as CD, floppy disk, etc. for physical transfer to a research or data monitoring facility, here indicated at 80. The data could also simply be transferred via modem through an Internet interface.

The New Expression Methods (Cycles)

[0060] It can thus be seen that a variety of different suction cycles or sequences can now be provided with the same breastpump equipment. An example of the kind of methods that such cycle could represent comprises FIGS. 11 through 15.

[0061] FIG. 11, for instance, is what is referred to by Medela, Inc. as the "Standard Classic Program". This is a method for operating a breastpump that has been developed which is considered to provide a general optimal suction curve reminiscent of an infant's normal suckling, such as provided by the 015 "CLASSIC" breastpump sold by Medela, Inc. As indicated in the graph of FIG. 11, negative pressure is along the y-axis (in millimeters of memory) and time (in seconds) along the x-axis. In this particular method, the cycles are fixed at about 47 per minute; the amount of suction is generally adjustable between about 100 to about 250 mmHg.

[0062] FIG. 12 illustrates what can be termed as a new "Sore Nipple Program" method. In comparison to FIG. 11, it will be seen that the lower end of the vacuum range is reduced to about 20 mmHg, and the overall suction cycle is extended in duration, i.e., from a low of about 25 cycles/min. to about 40. For a lower vacuum applied in this program, there is an increase in the number of cycles. In general, however, there is a slower and gentler suction compared with the "CLASSIC" program of FIG. 11.

[0063] FIG. 13 shows a new method for operating a breastpump which is considered to yield an increase in milk output. This is a program that might be applied between regular pump sessions several times a day. In this method, the breastpump is operated at a rapid cyclical rate on the order of about 120 cycles/mim., preferably with a pause after a period of vacuum application; here, 10 seconds of vacuum, then a 2 second pause. The negative pressure is in the range of about 50 to about 150 mmHg. Note the detail in the inset of FIG. 13 showing the rapidity and steep slopes of the vacuum application.

[0064] What has been termed a new "Superior Program" for operating a breastpump is illustrated in FIG. 14. A vacuum range of about 100 to about 250 mmHg has been chosen, with cycles ranging from about 47 to about 78 per minute. The cycle rate and the vacuum are tied, such that as, for instance, the cycles decrease, the amount of vacuum increases, i.e., there is an inverse relationship. It will be noted that this program differs from the "CLASSIC" program above in part through a sequence tat initially reaches a peak negative pressure, then smoothly starts a pressure increase (less negative) along a similar (although opposite) slopes to that of the negative pressure build-up, but then slows the pressure increase briefly, before continuing on essentially the initial slope for the negative pressure release. A milk let-down sequence is also incorporated in this "Superior Program," and utilizes a vacuum range of about 50 to about 150 mmHg, with cycles ranging between about 80 to about 160 per minute.

[0065] Thus, while the invention has been described herein with relation to certain embodiments and applications, those with skill in this art will recognize changes, modifications, alterations and the like which still come within the spirit of the inventive concept, and such are intended to be included within the scope of the invention as expressed in the following claims.

Claims

1. A breastpump comprising:

a breastshield, having a portion within which a woman's breast is received for the expression of milk;
a source of vacuum in communication with said breastshield;
a mechanism for operating said source of vacuum according to a first sequence; and
a controller for operating said source of vacuum

according to a second sequence,

characterized in that at least one of said sequences initially reaches a peak negative pressure, then smoothly starts a pressure increase along a similar and opposite slop that of the negative pressure build-up and then slows the pressure increase briefly, before continuing on essentially the initial slope for the negative pressure release as illustrated in Figure 14.

2. The breastpump of claim 1 wherein said controller has a preset program for said second sequence which is a milk letdown sequence.

3. The breastpump of claim 2 further comprising a plurality of different programs for said controller wherein each program has a different sequence.

4. The breastpump of either claim 1 or 3 wherein the breastpump comprises an expansible chamber device which is a diaphragm pump.

5. The breastpump of claim 4 wherein there are two diaphragm pumps, said diaphragm pumps having a membrane which is movable relative to a shell.

6. The breastpump of claim 5 wherein said diaphragm pumps are driven in tandem.

7. The breastpump of claim 3, the breastpump having a mechanism for manipulating the breast to express milk therefrom, wherein the improvement comprises a programmable controller for said mechanism.

8. The breastpump of claim 7 further comprising a plurality of different programs for said controller.

9. The breastpump of one of claims 3 or 8 wherein said programs are different sequences for varying vacuum force and vacuum cycle according to an application curve.

10. The breastpump of claim 1 wherein the mechanism operates said source of vacuum to produce at least a milk letdown sequence and another sequence different from said letdown sequence.

11. The breastpump of claim 10 wherein said mechanism has a motor drive and said breastpump further including a controller, said controller including or receiving at least one preprogrammed sequence being a letdown sequence.

12. The breastpump of claim 11 further including a sequence selecting device wherein said letdown sequence is selectable by a program selection mechanism.

13. The breastpump of claims 10 to 12 wherein said mechanism operates a letdown sequence with a vacuum pressure in a range of about 50 mmHg to about 150 mmHg, and a frequency of about 80 to about 160 cycles per minute.

14. The breastpump of either claim 1 or 4, wherein said mechanism includes an electric motor, that motor having a reduction drive system with at least first and second belts conveying motive power to a movable member of an expansible chamber device wherein a vacuum is generated.

15. The breastpump of claim 5, wherein each said membrane being connected to a respective shaft, each said shaft being mounted to a respective belt for linear movement with said respective belt.

Patentansprüche

1. Brustpumpe, aufweisend:

eine Brusthaube mit einem Teil zur Aufnahme einer weiblichen Brust zwecks Absaugen von Milch;
eine mit der Brusthaube verbundene Vakuumquelle;
einen Mechanismus zum Betreiben dieser Vakuumquelle gemäss einer ersten Sequenz; und
einen Controller zum Betreiben dieser Vakuumquelle gemäss einer zweiten Sequenz,

dadurch gekennzeichnet, dass mindestens eine dieser Sequenzen anfangs einen Spitzenwert im Unterdruck erreicht, dann sanft einen Druckanstieg beginnt entlang einer ähnlichen und entgegengesetzten Steigung zu der des Unterdruckaufbaus und dann den Druckanstieg kurzzeitig verlangsamt, bevor sie auf der im wesentlichen anfänglichen Steigung für die Druckentlastung fortfährt, wie in Figur 14 bildlich dargestellt.

2. Brustpumpe gemäss Anspruch 1, wobei dieser Controller ein voreingestelltes Programm für diese zweite Sequenz aufweist, welche eine Milcheinschuss-Sequenz ist.

3. Brustpumpe gemäss Anspruch 2, wobei sie ferner eine Vielzahl verschiedener Programme für diesen Controller aufweist, wobei jedes Programm eine unterschiedliche Sequenz hat.

4. Brustpumpe gemäss einem der Ansprüche 1 oder 3, wobei die Brustpumpe eine expandierbare Kammereinheit aufweist, welche eine Membranpumpe ist.

5. Brustpumpe gemäss Anspruch 4, wobei zwei Membranpumpen vorhanden sind, wobei diese Membranpumpen eine Membran aufweisen, welche relativ zu einer Schale bewegbar ist.

6. Brustpumpe gemäss Anspruch 5, wobei diese Membranpumpen im Tandem betrieben werden.

7. Brustpumpe gemäss Anspruch 3, wobei die Brustpumpe einen Mechanismus zum Manipulieren der Brust aufweist, um Milch abzupumpen, wobei die Verbesserung einen programmierbaren Controller für diesen Mechanismus aufweist.

8. Brustpumpe gemäss Anspruch 7, wobei sie ferner eine Vielzahl verschiedener Programme für diesen Controller aufweist.

9. Brustpumpe gemäss einem der Ansprüche 3 oder 8, wobei diese Programme verschiedene Sequenzen sind, um die Stärke des Unterdrucks und den Unterdruckzyklus gemäss einer Anwendungskurve zu variieren.

10. Brustpumpe gemäss Anspruch 1, wobei der Mechanismus diese Vakuumquelle betreibt, um mindestens eine Milcheinschuss-Sequenz und eine andere, von dieser Milcheinschuss-Sequenz verschiedene Sequenz zu erzeugen.

11. Brustpumpe gemäss Anspruch 10, wobei dieser Mechanismus einen Motorantrieb aufweist und diese Brustpumpe ferner einen Controller aufweist, wobei dieser Controller mindestens eine vorprogrammierte Milcheinschuss-Sequenz aufweist oder empfängt.

12. Brustpumpe gemäss Anspruch 11, wobei sie ferner eine Sequenz-Auswähleinheit aufweist, wobei diese Einschuss-Sequenz durch einen Programm-Auswahl-Mechanismus auswählbar ist.

13. Brustpumpe gemäss den Ansprüchen 10 bis 12, wobei dieser Mechanismus eine Einschusssequenz betreibt mit einem Unterdruck in einem Bereich von ungefähr 50 mmHg bis ungefähr 150 mmHg, und einer Frequenz von ungefähr 80 bis ungefähr 160 Zyklen pro Minute.

14. Brustpumpe gemäss einem der Ansprüche 1 oder 4, wobei dieser Mechanismus einen elektrischen Motor aufweist, wobei dieser Motor ein Reduktionsgetriebesystem aufweist mit mindestens einem ersten und einem zweiten Riemen, welche Bewegungsenergie zu einem bewegbaren Teil einer expandierbaren Kammereinheit führen, in welcher ein Unterdruck erzeugt wird.

15. Brustpumpe gemäss Anspruch 5, wobei jede dieser Membrane mit einem jeweiligen Schaft verbunden ist, wobei jeder dieser Schäfte mit einem jeweiligen Riemen verbunden ist für eine lineare Bewegung mit diesem jeweiligen Riemen.

Revendications

1. Tire-lait, comprenant :

   une téterelle ayant une partie dans laquelle le sein d'une femme est reçu pour tirer du lait ;
   une source de vide en communication avec ladite téterelle;
   un mécanisme pour opérer ladite source de vide en fonction d'une première séquence ; et
   un contrôleur pour opérer ladite source de vide en fonction d'une deuxième séquence, **caractérisé en ce qu'**au moins l'une desdites séquences atteint initialement un pic de pression négative, puis amorce doucement une augmentation de pression le long d'une pente similaire et opposée à celle de l'augmentation de pression négative, et puis ralentit l'augmentation de pression brièvement avant de continuer essentiellement sur la pente initiale pour la libération de la pression négative comme illustré dans la figure 14.

2. Tire-lait selon la revendication 1, dans lequel ledit contrôleur a un programme prédéfini pour ladite seconde séquence qui est une séquence d'éjection du lait.

3. Tire-lait selon la revendication 2, comprenant en outre une pluralité de programmes différents pour ledit contrôleur dans lequel chaque programme a une séquence différente.

4. Tire-lait selon quelconque une des revendications 1 ou 3, dans lequel ledit tire-lait a un dispositif à chambre expansible qui est une pompe à diaphragme.

5. Tire-lait selon la revendication 4, dans lequel il y a deux pompes à diaphragme, lesdites pompes à diaphragme comportant une membrane qui est déplaçable par rapport à une coque.

6. Tire-lait selon la revendication 5, dans lequel lesdites pompes à diaphragme sont entraînées en tandem.

7. Tire-lait selon la revendication 3, le tire-lait ayant un mécanisme pour manipuler le sein pour en tirer du lait, dans lequel l'amélioration comprenant un contrôleur programmable pour ledit mécanisme.

8. Tire-lait selon la revendication 7, comprenant en outre une pluralité de programmes différents pour

ledit contrôleur.

9. Tire-lait selon quelconque une des revendications 3 ou 8, dans lequel lesdits programmes sont des séquences différentes pour faire varier la force de vide et le cycle de vide selon une courbe d'application.

10. Tire-lait selon la revendication 1, dans lequel le mécanisme commande ladite source de vide pour produire au moins une séquence de montée du lait et une autre séquence différente de ladite séquence de montée du lait.

11. Tire-lait selon la revendication 10, dans lequel ledit mécanisme a un entraînement à moteur et ledit tire-lait comportant en outre un contrôleur, ledit contrôleur comportant ou recevant au moins une séquence pré-programmée étant une séquence de montée du lait.

12. Tire-lait selon la revendication 11, comportant en outre un dispositif de sélection de séquence, dans lequel ladite séquence de montée du lait peut être sélectionnée par un mécanisme de sélection de programme.

13. Tire-lait selon les revendications 10 à 12, dans lequel ledit mécanisme commande une séquence de montée du lait avec une pression de vide dans une plage d'environ 50 mmHg à environ 150 mmHg, et une fréquence d'environ 80 à environ 160 cycles par minute.

14. Tire-lait selon quelconque une des revendications 1 ou 4, dans lequel ledit mécanisme comporte un moteur électrique, ce moteur ayant un système d'entraînement réducteur avec au moins des première et deuxième courroies transmettant la puissance du moteur à un élément déplaçable d'un dispositif à chambre expansible dans lequel est généré un vide.

15. Tire-lait selon la revendication 5, dans lequel chaque dite membrane est connectée à un arbre respectif, chaque dit arbre étant monté sur une courroie respective en vue d'un mouvement linéaire avec ladite courroie respective.

FIG. 1

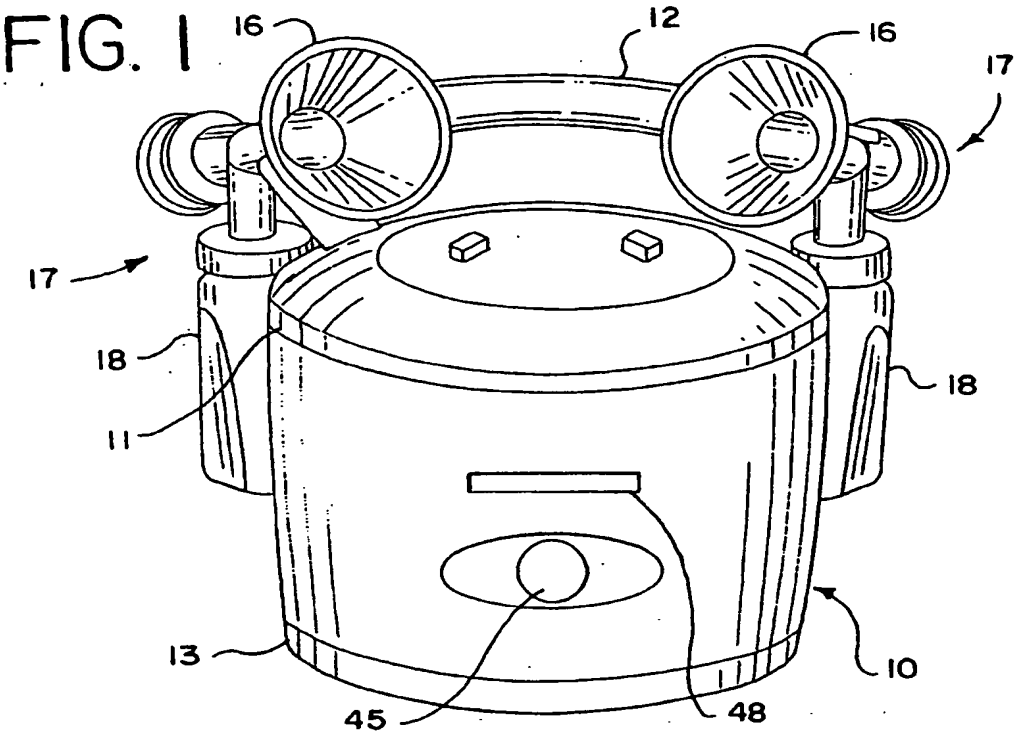


FIG. 2

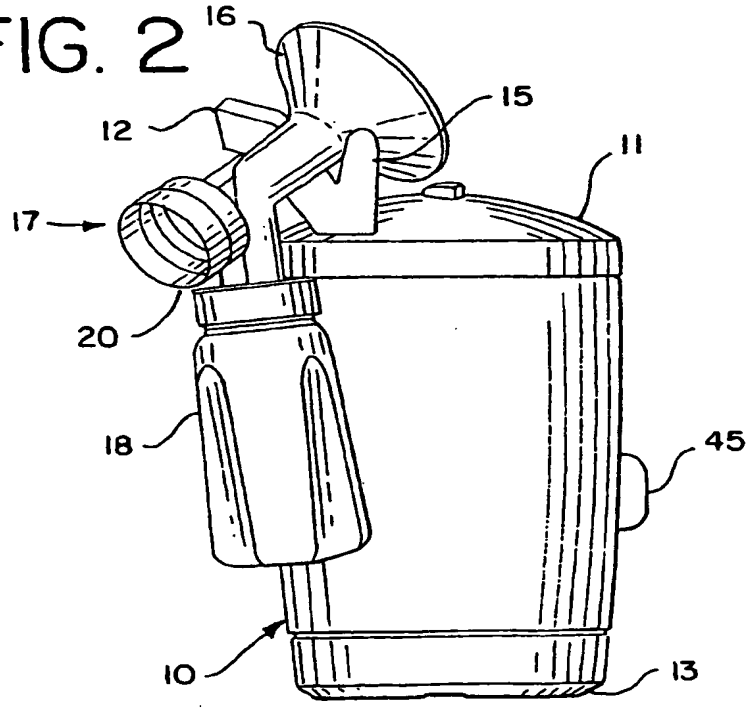


FIG. 3

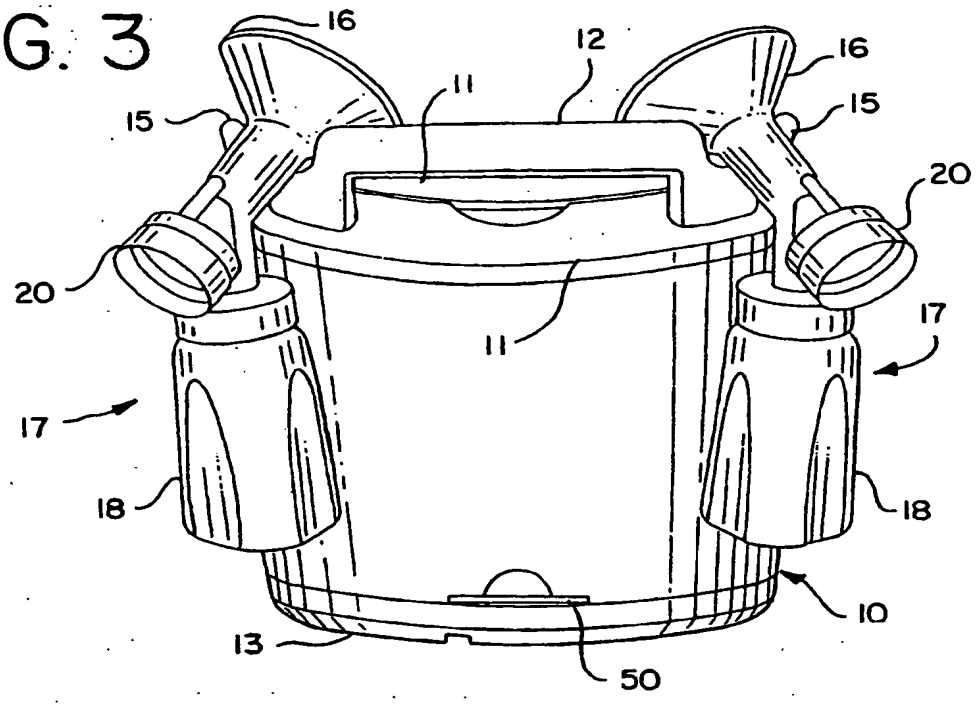

16
12
16
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13
50

FIG. 4

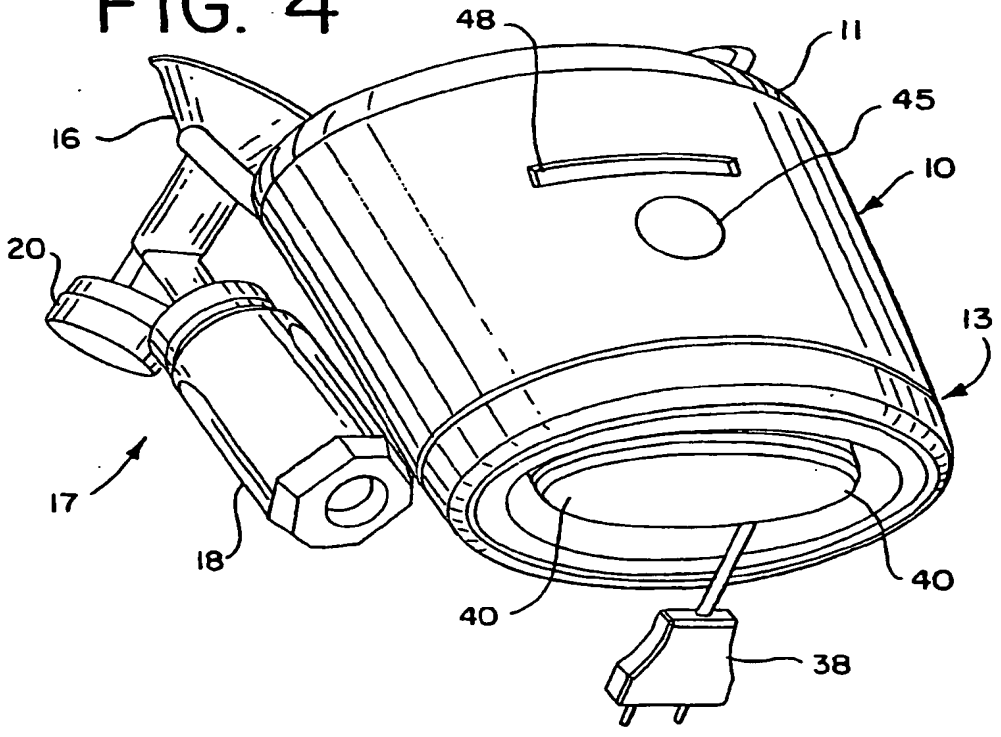

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16
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18
40
40
38

FIG. 5

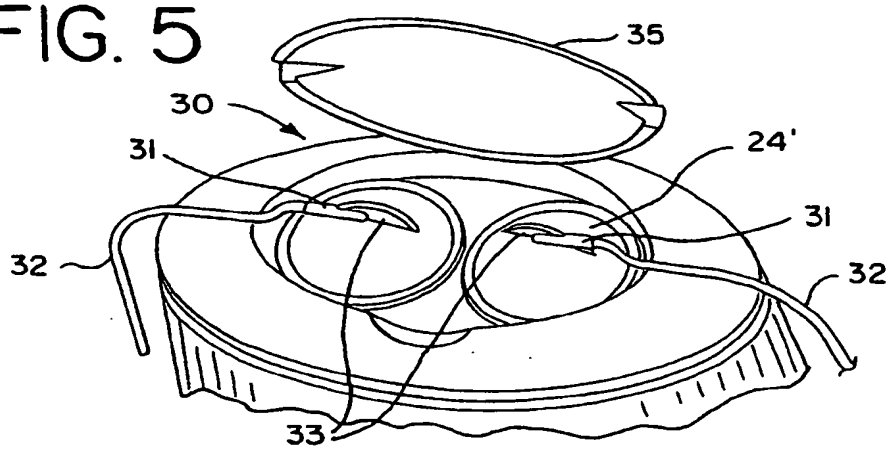


FIG. 6

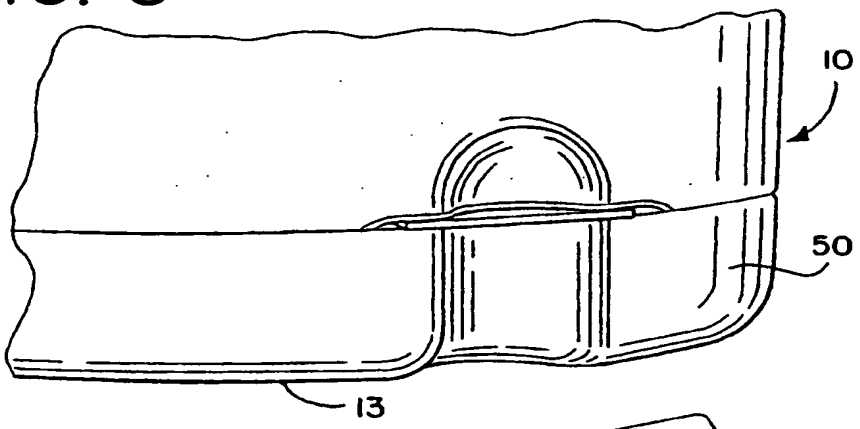


FIG. 7

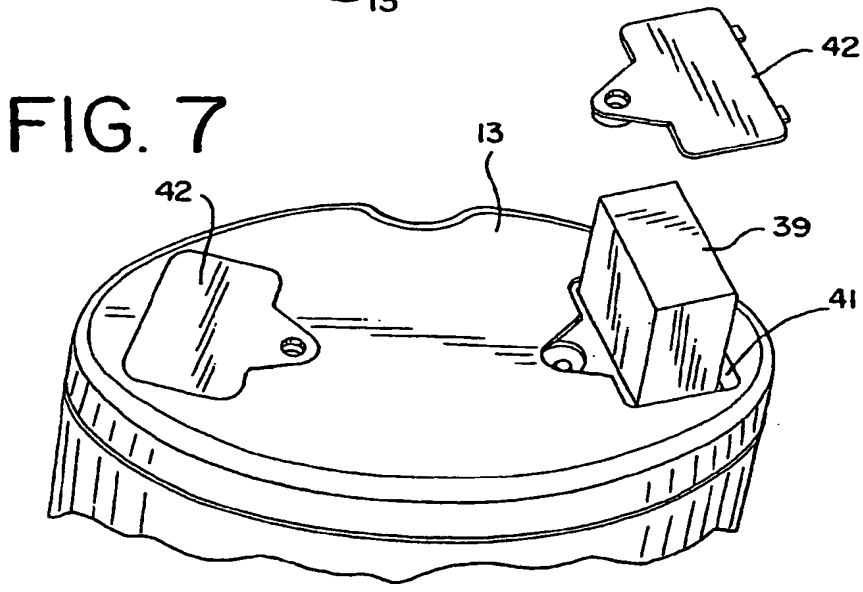


FIG. 8

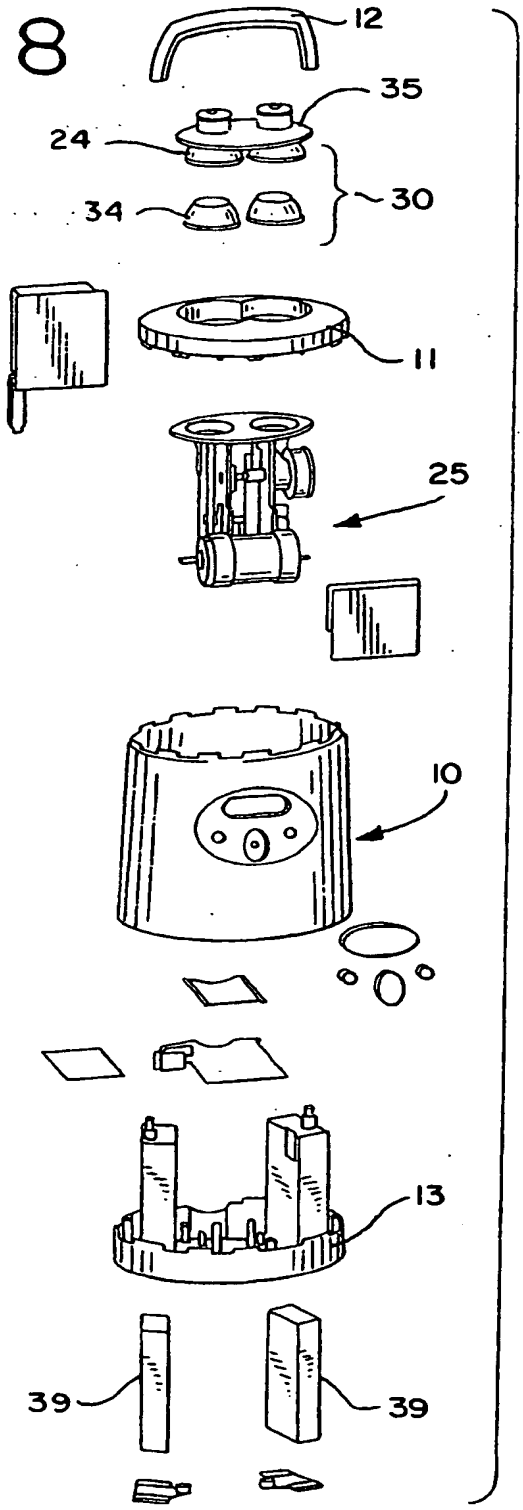


FIG. 9

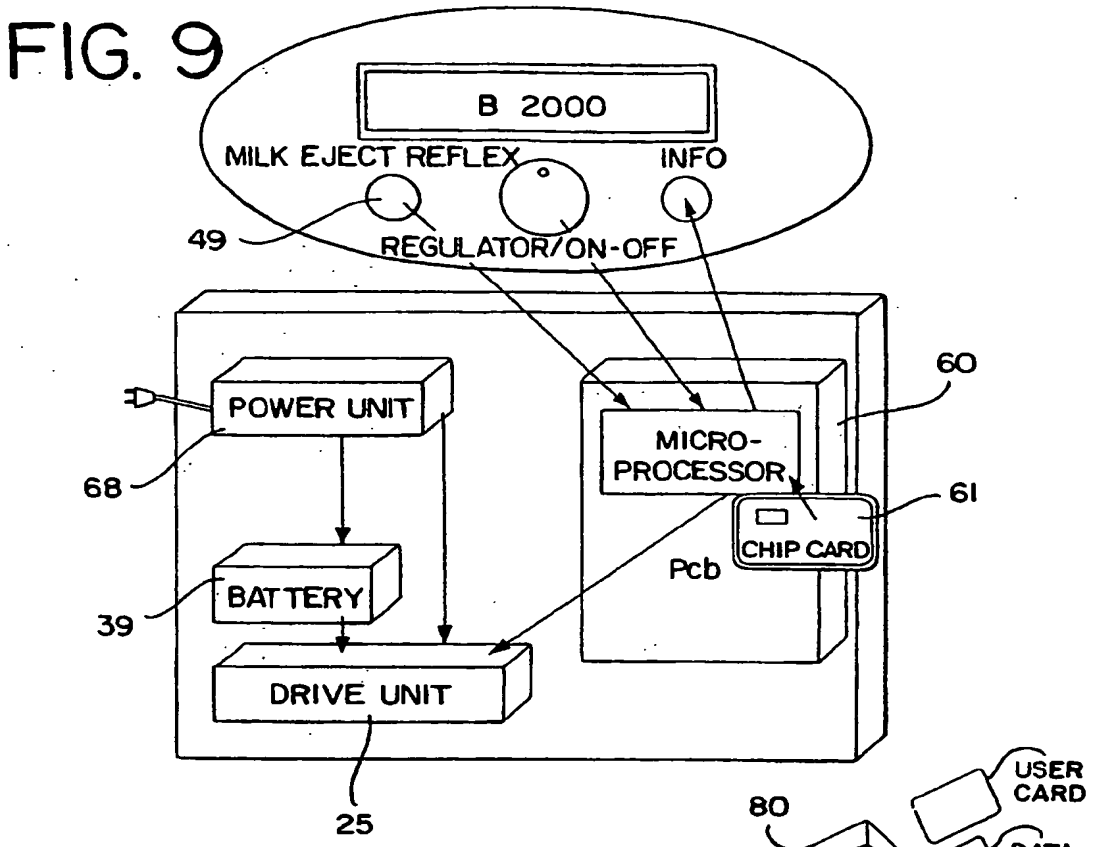

B 2000
MILK EJECT REFLEX
INFO
49
REGULATOR/ON-OFF
60
POWER UNIT
MICRO-
PROCESSOR
68
61
CHIP CARD
Pcb
BATTERY
39
DRIVE UNIT
25

FIG. 10

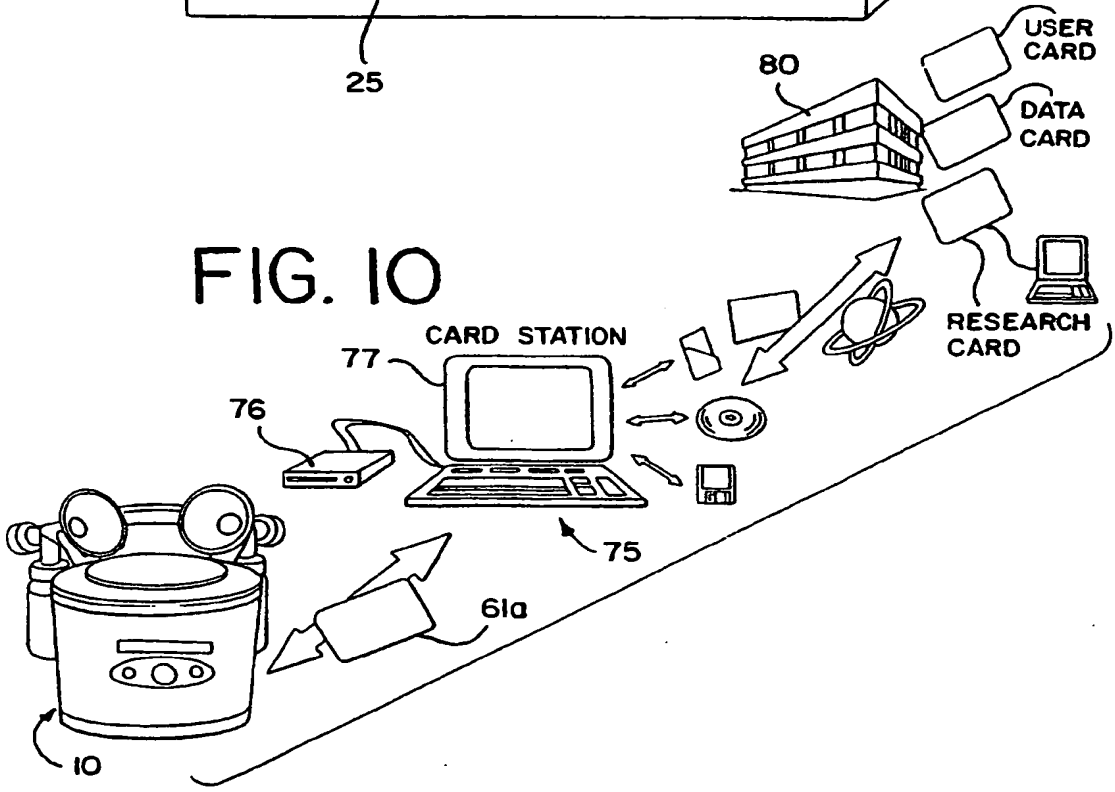
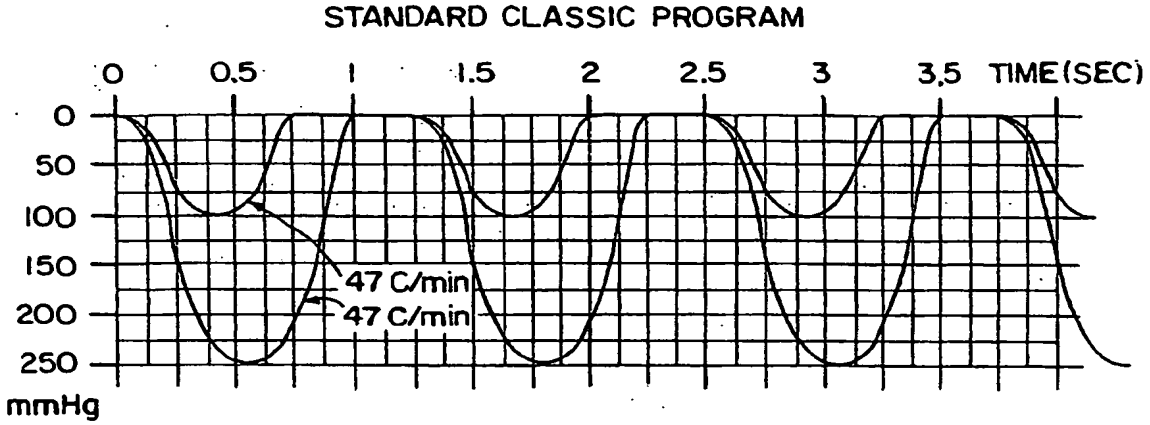
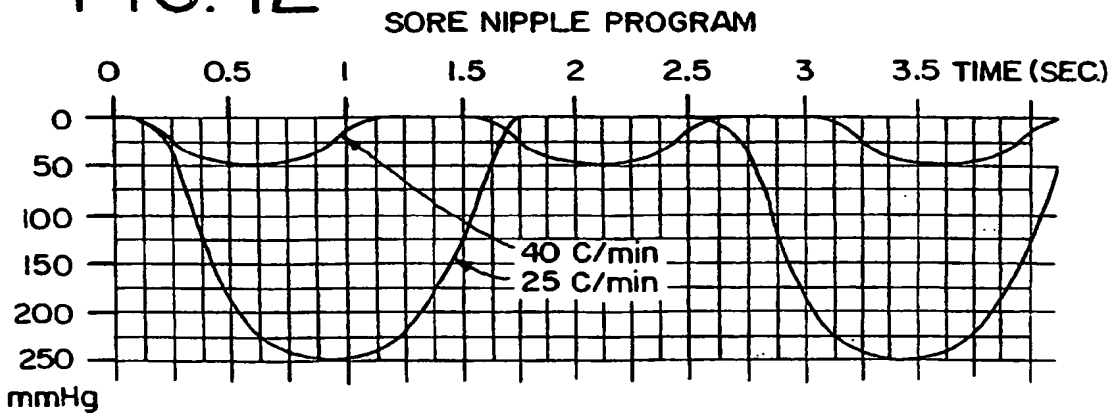

USER
CARD
80
DATA
CARD
RESEARCH
CARD
CARD STATION
77
76
75
61a
10

FIG. 11



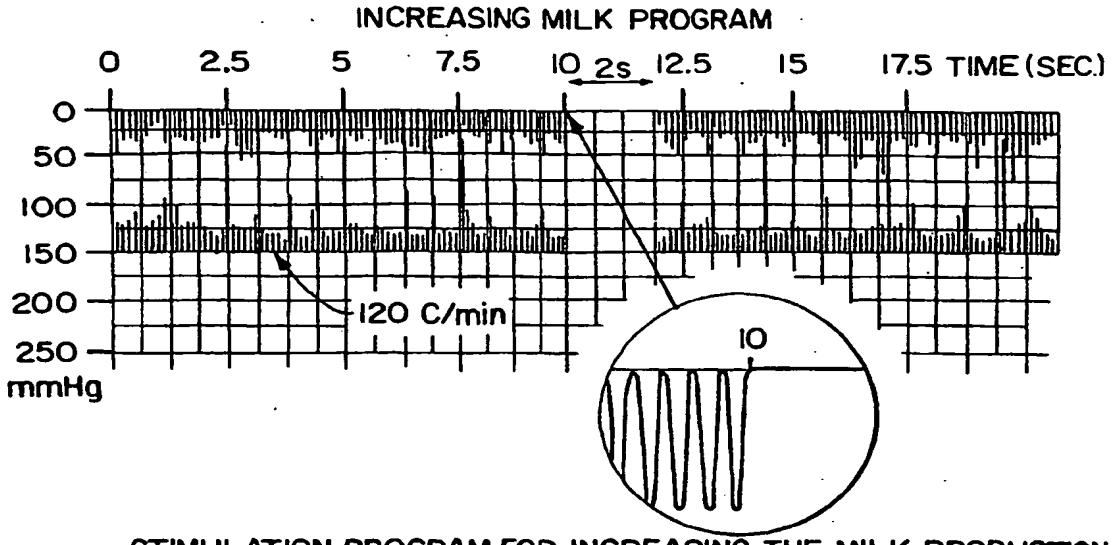
SUCTION CURVES AND CYCLES EQUAL TO CLASSIC
VACUUM RANGE: 100 - 250mmHg
CYCLES: 47/min (NOT ADJUSTABLE)

FIG. 12



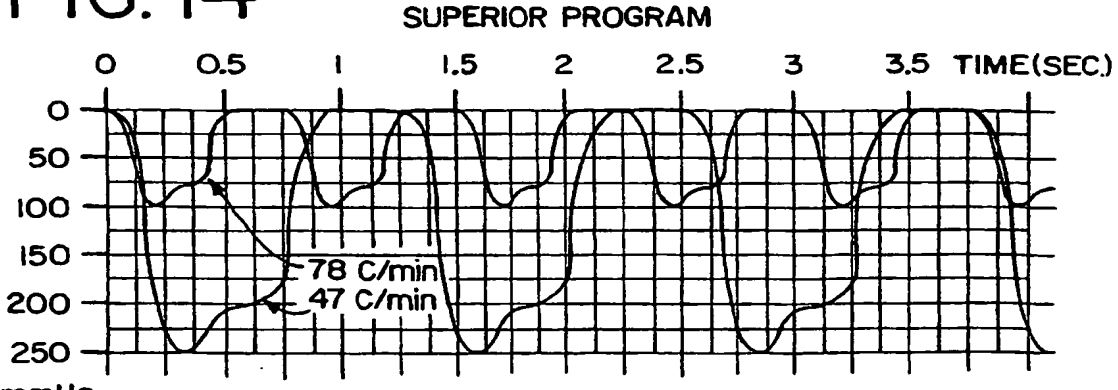
EXTREMELY GENTLE AND SLOW SUCTION
DECREASED VACUUM YIELDS GENTLER AND SLOWER SUCTION
VACUUM RANGE: 20 - 250
CYCLES: 25 - 40/min (CONTROLLED BY VACUUM LEVEL)

FIG. 13



STIMULATION PROGRAM FOR INCREASING THE MILK PRODUCTION
IT IS USED BETWEEN THE PUMP SESSIONS A FEW TIMES A DAY
VACUUM RANGE: 50-150 mmHg
CYCLES: 120/min

FIG. 14



THIS PROGRAM WILL BE THE MAIN PUMP PROGRAM.
THE FINAL CURVE AND CYCLES HAVE TO BE
EVALUATED BY RESEARCHING.
VACUUM RANGE: 100-250 mmHg
CYCLES: 47-78/min AUTOMATICALLY

THIS PROGRAM CONTAINS ALSO THE MILK LET DOWN PROGRAM
VACUUM RANGE: 50-150 mmHg
CYCLES: 120-150/min

FIG. 15

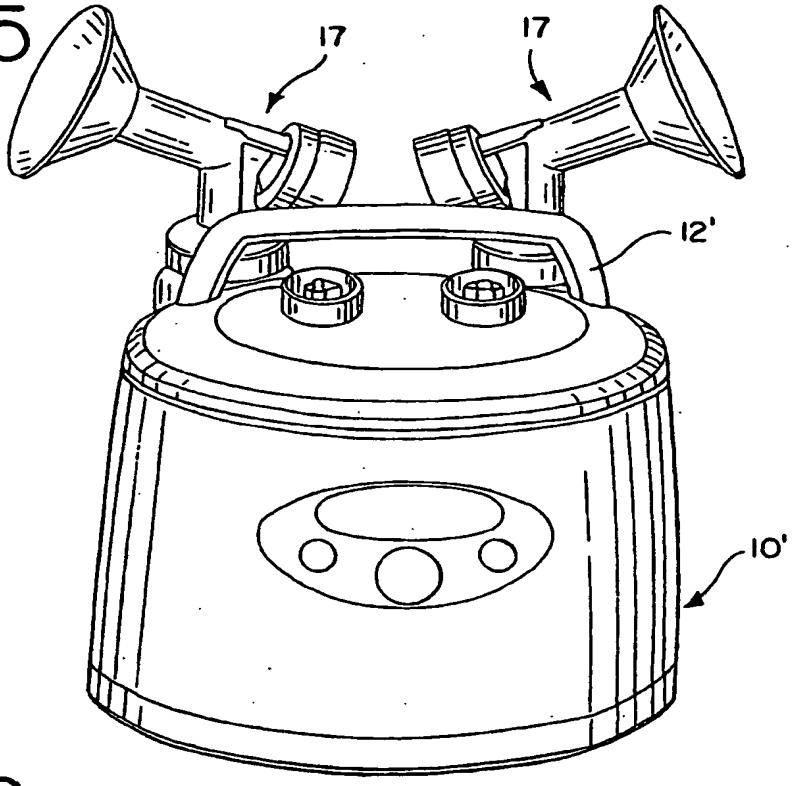


FIG. 16

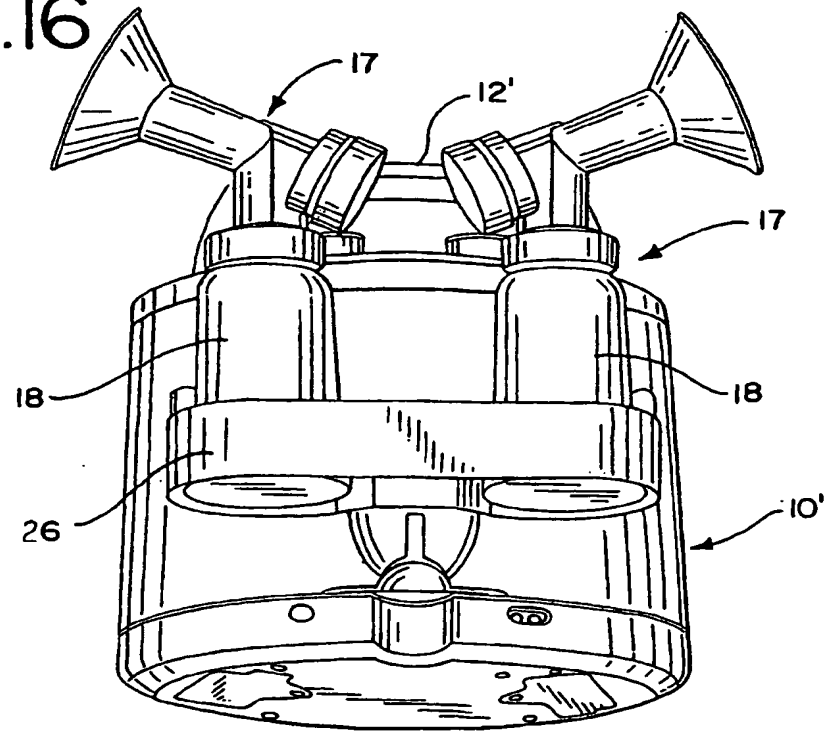


FIG. 17

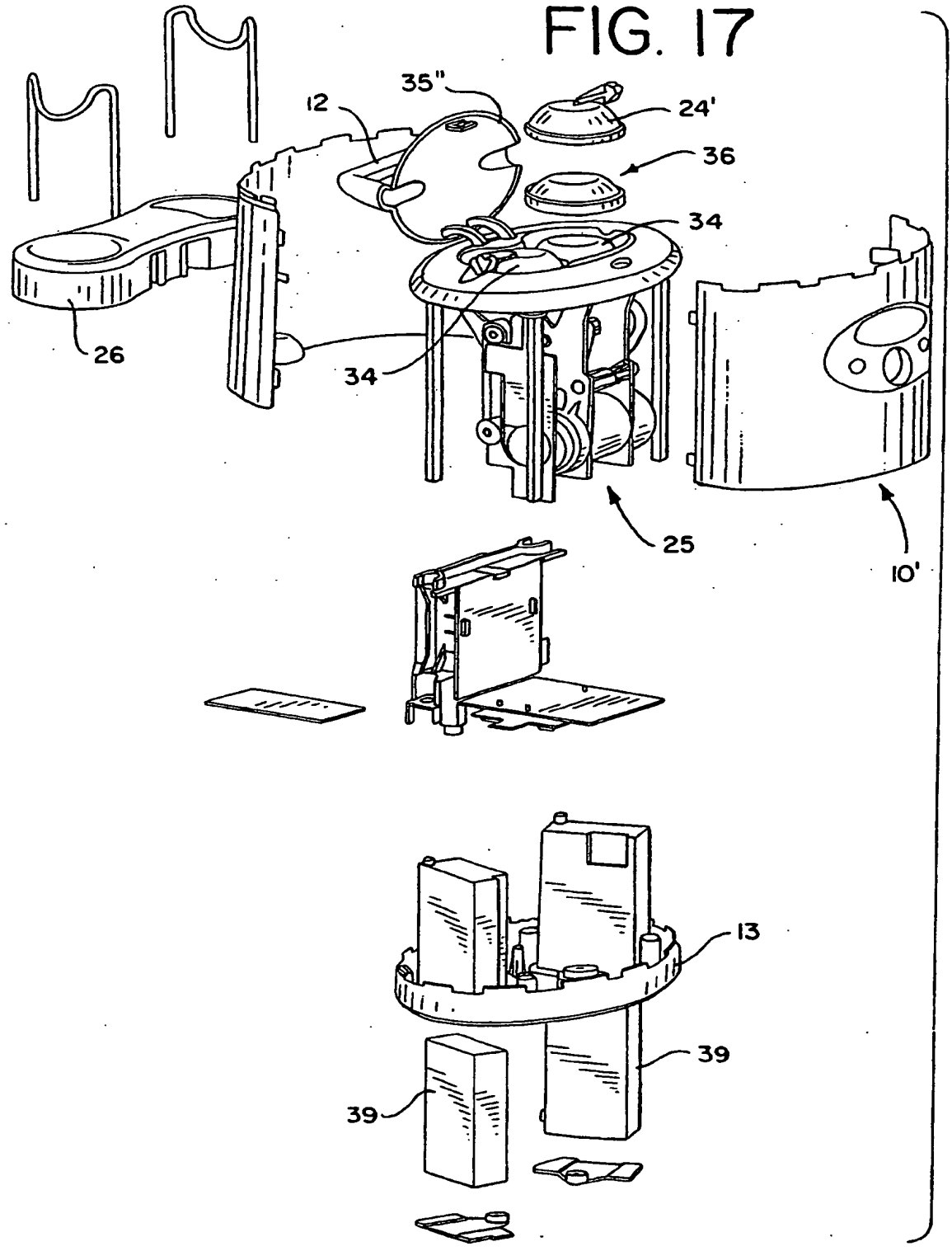


FIG. 19

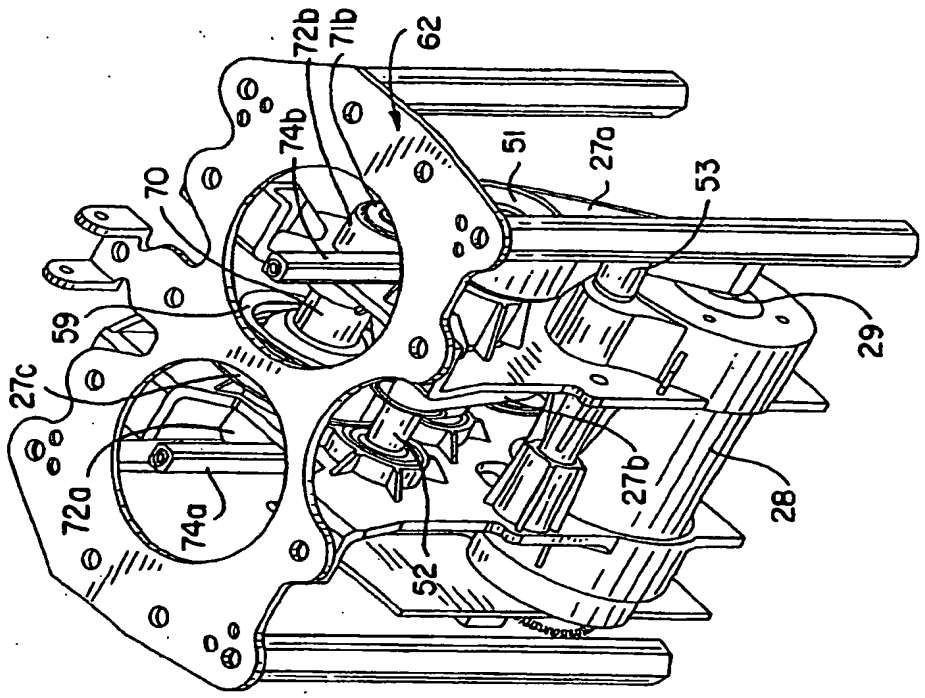

72b
71b
62
74b
70
51
27a
53
59
29
27c
72a
74a
27b
28
52

FIG. 18

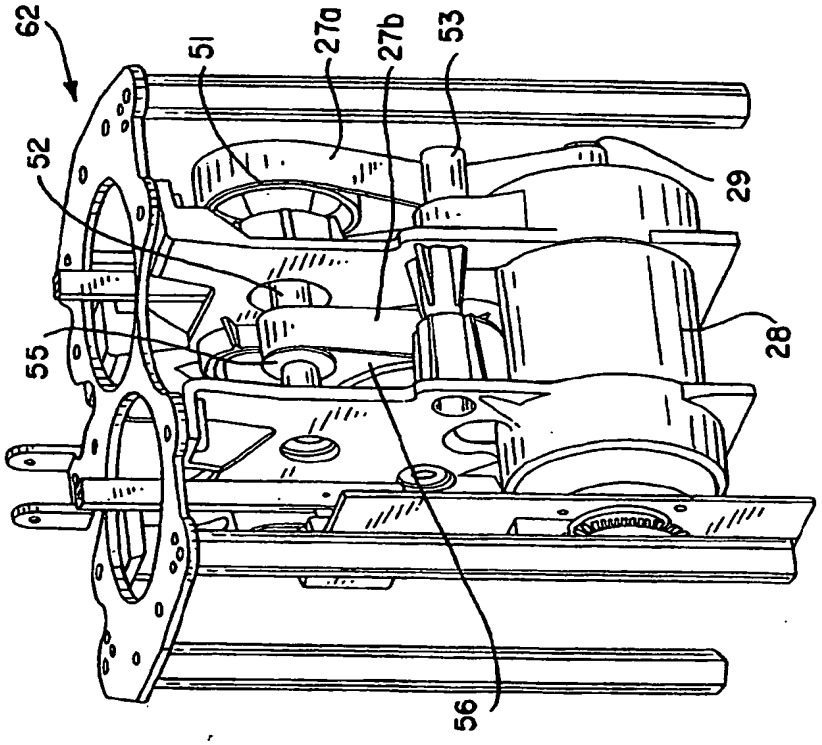

62
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27a
27b
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28
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FIG. 20

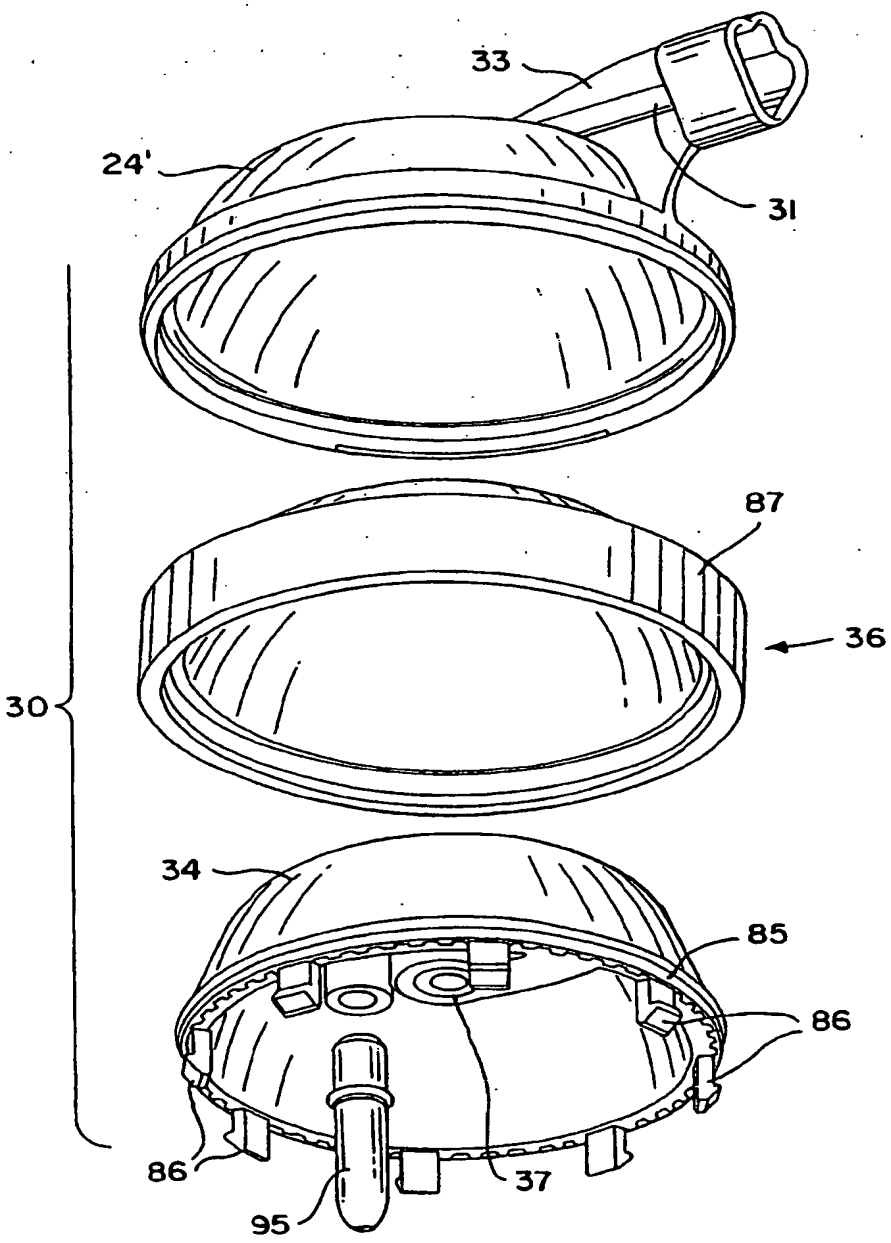


FIG. 21a

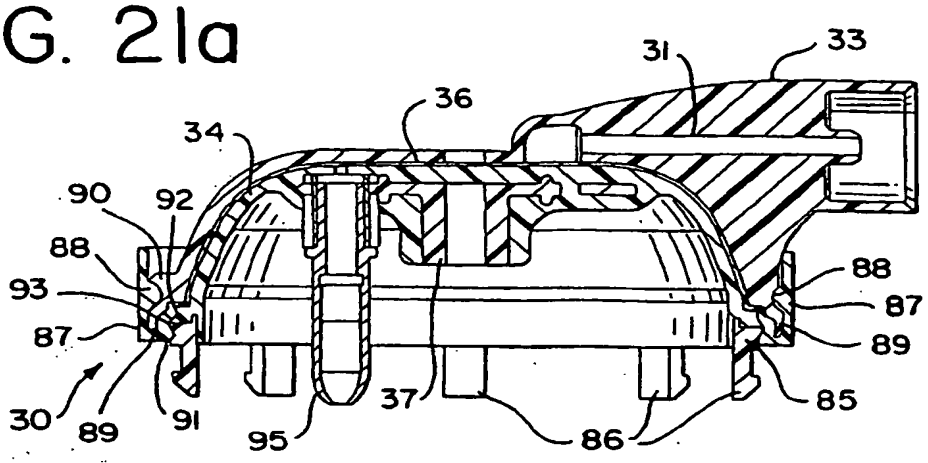


FIG. 21b

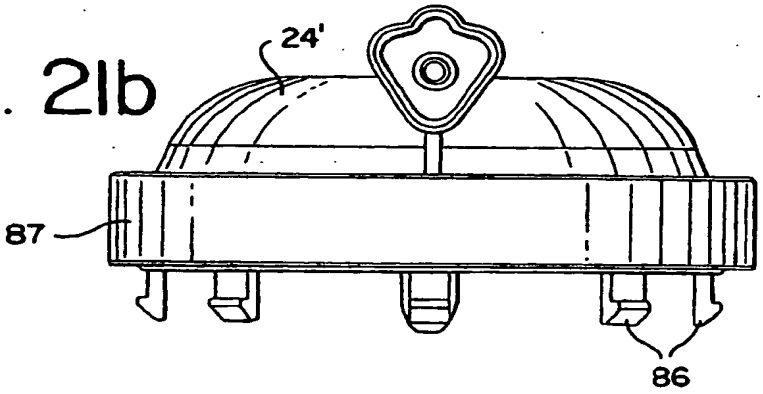


FIG. 21c

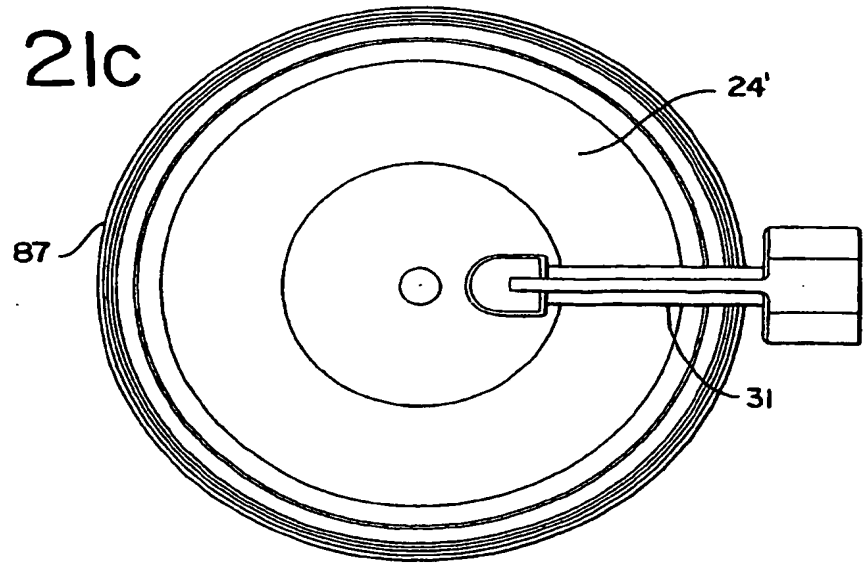


FIG. 22

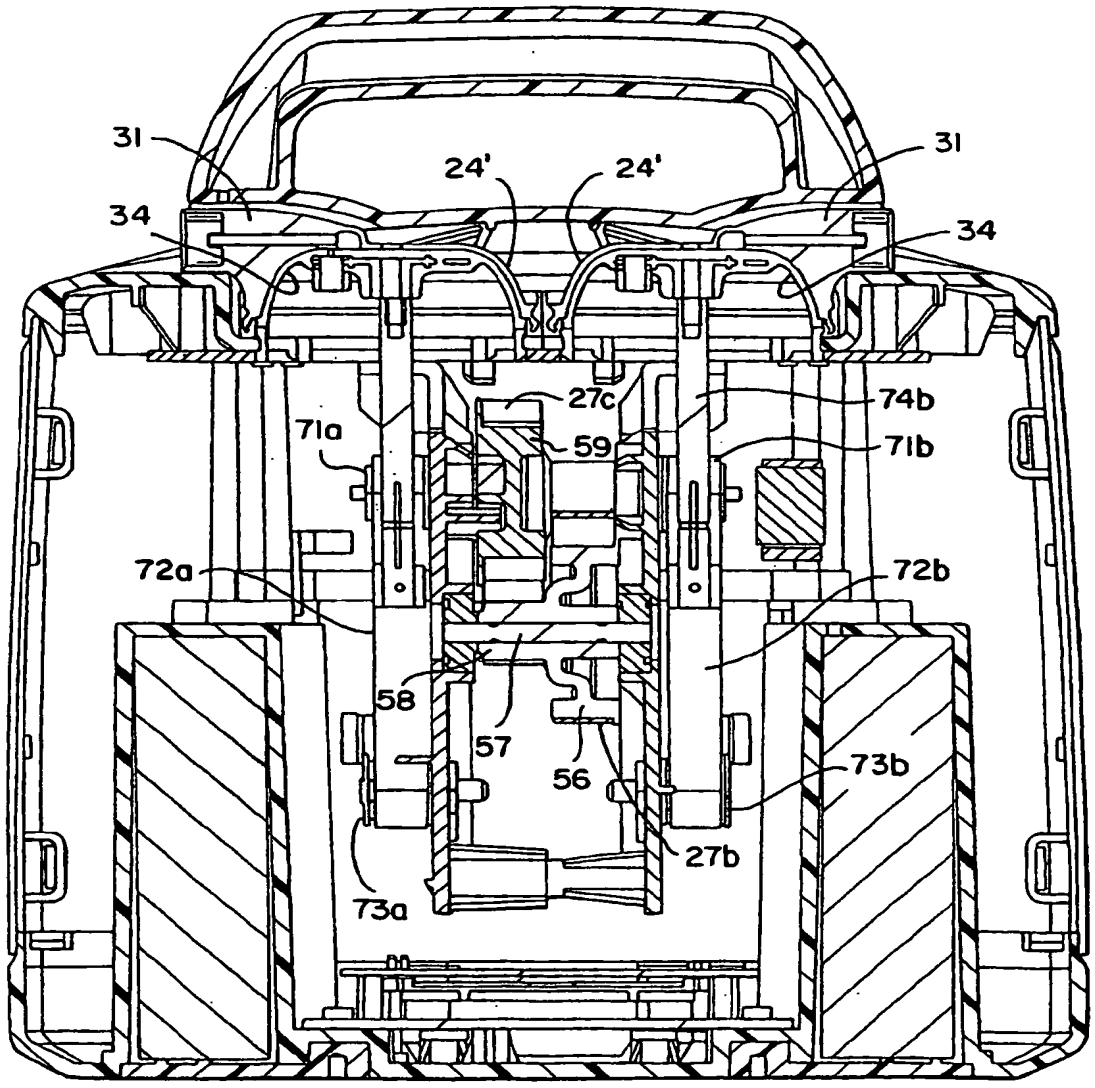


FIG. 23

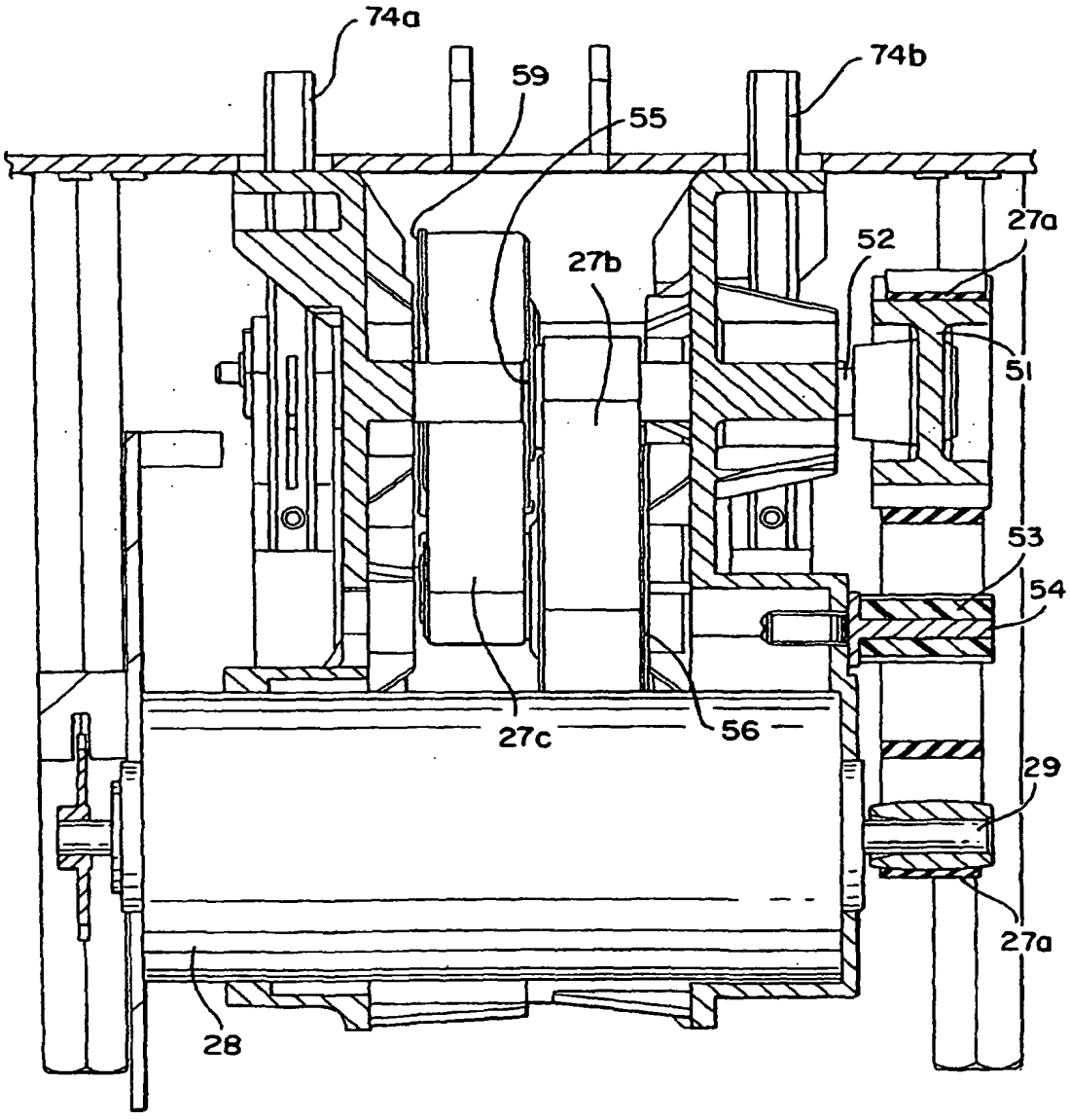
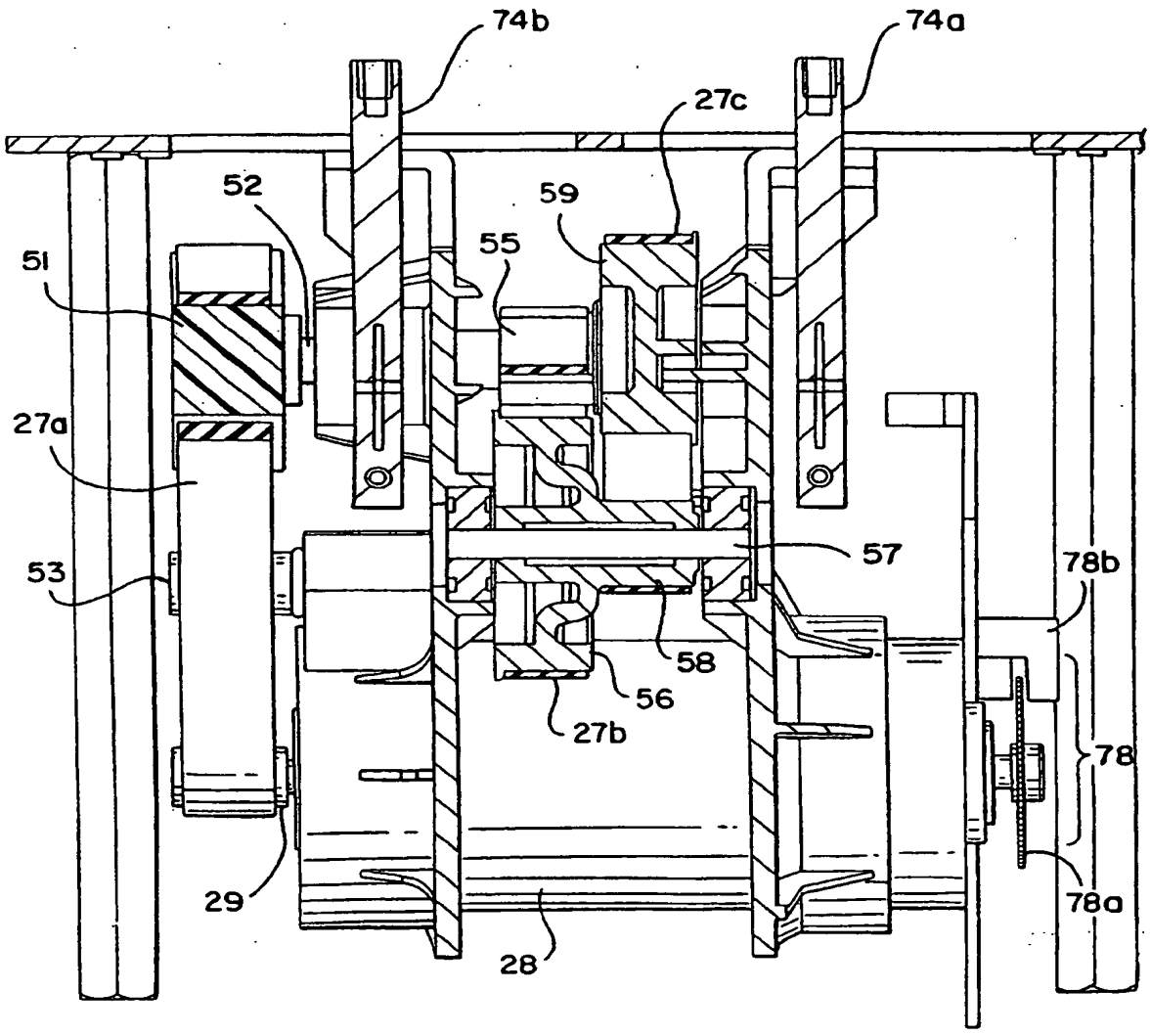


FIG. 24



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5571084 A **[0002]**
- US 4794915 A **[0003]**
- US 4964851 A **[0007] [0029]**
- US 5007899 A **[0007]**
- US 4929229 A **[0029]**

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(74) Agent: **HANLEY, John**; 2570W. El Camino Real, Suite 310, Mountain View, CA 94040 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: BREAST PUMP SYSTEM AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

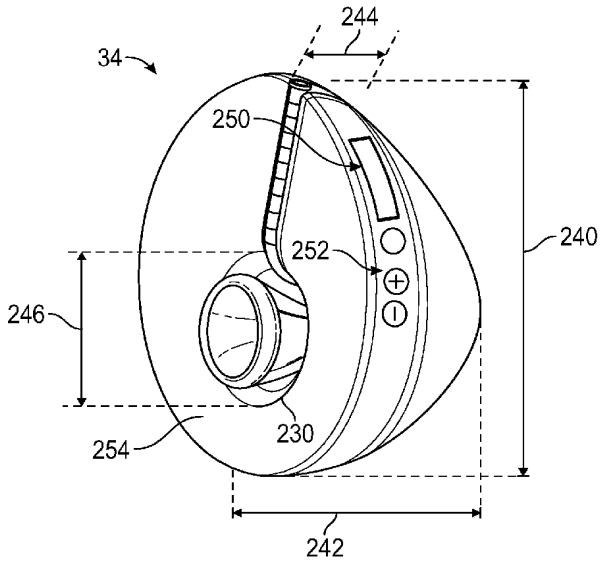


FIG. 6

WO 2016/014469 A1

BREAST PUMP SYSTEM AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to a portable, hands-free, discrete, self-powered and energy efficient breast pump system and method for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be painful to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. Many of the breast pumps available are clearly visible to an observer when the mother is using it, and many also expose the breast of the mother during use.

[0004] There is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump system that is easy to use and is discrete by not exposing the breast of the user and being invisible or nearly unnoticeable when worn.

SUMMARY OF THE DISCLOSURE

[0005] Briefly and in general terms, the present disclosure is directed towards breast pump systems and methods. The system includes breast contacting structure, a collection container and structure that extracts milk from a breast and delivers the milk to the container. The method involves extracting milk from a breast and delivering the milk to the collection container.

[0006] In one approach, a method of pumping milk from a breast involves forming a seal between a breast pump system and the breast, and pumping milk expressed from the breast through a conduit. A driving force may also be included and created by expansion of the conduit that was previously compressed to generate suction that drives expression of milk from a breast. The driving force may also be generated by pulling on the conduit that was previously compressed. Expulsion of expressed milk can be achieved by the application of a relative positive pressure to a portion of the conduit. In one particular aspect, suction applied to the breast for expression of milk involves a first suction level, and during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.

[0007] In various of the disclosed embodiments, the system defines a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers.

[0008] The disclosed method can alternatively or additionally involve one or more of providing a substantially liquid tight path between a breast through a conduit, compressing a portion of the conduit and reducing compression where returning the conduit to an uncompressed state generates suction sufficient to extract milk from a breast. Pumping can also involve compressing a second portion of conduit to generate pressure. A one-way valve between the conduit and a storage can be provided to

prevent backflow of milk and air.

[0009] A pump device can be placed in contact with a breast and connected to a storage container. Each of the pump device and storage container can be sized and shaped to be received within a user's bra. In one approach, the storage container is positioned between the pumping structure of the device and a user's bra. In other approaches, the storage container is configured about pumping structure, or can be positioned between pumping structure and the user's breast. Pumping of milk from a breast can occur without creating a change in a total mass and volume of the breast, pump device and storage container. The storage container can be one or more of flexible, or positioned around the breast. A driving mechanism can also be defined by a roller configured to maintain fluid connection between proximal and distal portions of conduit. The driving mechanism can alternatively include a single compression driver and first and second one-way valves in the conduit on opposite sides of a region that the compression driver is configured to compress. The system can include first and second drivers, where the first driver compresses a first region of conduit and the second driver compresses a second region of conduit. The first and second drivers can be configured to intermittently compress and release compression of regions of the conduit. The driving mechanism may also have its movements coordinated to create pressures sufficient to drive extracted milk. A first driver can be configured to seal a region of the conduit when milk is pumped, and sufficient pressure can be created in certain embodiments to pump milk against gravity.

[0010] A controller can be included in certain of the disclosed embodiments. The controller can be one or more of electrically connected to the pump, or configured to supply power for movements of driving mechanisms, and a battery electrically connected thereto. A pressure sensor can be further included to sense pressure within a breast adapter and in certain embodiments, the pressure sensor can be in electronic communication with the controller. Moreover, in certain approaches, the controller can adaptively control movements of drivers with input from a feedback loop established with a pressure or other sensor. The controller can further be programmable to changed control settings.

[0011] The system can be configured to generate a suction force in the range of about -60mm Hg, or in a range of about -120mm Hg to about -450mm Hg, or in a range of about -60mm Hg to about -180mm Hg, or in a range of about -60mm Hg to about -220mm Hg, or in a range of about -200mm Hg to about -450mm Hg, or in a range of about -380mm Hg to about -420mm Hg, or in a range of about -180mm Hg to about -400mm Hg, or in a range of about -180mm Hg to about -220mm Hg, or in the range of about -40mm Hg to about -70mm Hg, or in the range of about -50mm Hg to abou-60mm Hg.

[0012] A breast adapter or pump system generally can include at least one vibration element configured to apply vibration to the breast, and/or at least one heating element to apply heat to the breast. The breast adapter and conduit can be integrally formed as a unit or can define separate pieces. The breast adapter and conduit can further be configured to be removable from the pump system and replaceable. A housing can be further provided and can contain the driving mechanism and controller. The housing also can include manually operated controls for input to the controller, and additionally or alternatively, a display that is readable by the user.

[0013] In one or more embodiments, the storage container is detachable from the system. There can be a plurality of drivers having different shapes and sizes or lengths. A lower surface of a driver can be V-shaped in cross-section. A driver can be attached to a breast adapter and configured to expand the breast adapter. The breast adapter can further comprise a first flange and a second flange, wherein a gap is formed between the flanges that prevents milk spillage. In another aspect, insertion of the breast into the adapter and against the second flange deflects the second flange toward the first flange. Also, in certain embodiments, suction collapses the gap between first and second flanges.

[0014] In certain approaches, milk extraction is halted while milk is pumped to the storage container. Moreover, suction can be cycled to stimulate milk letdown and initiate extraction during letdown. After a predetermined time or after calculating an estimate of a predetermined volume of milk having been extracted, the breast can be sealed off at a predetermined suction level. The system can be configured such that a

pumping mechanism is positioned less than 2.5cm from a nipple of a breast, or less than 2.0cm from the nipple or less than or equal to 1.0cm from the nipple. Pumping can further or alternatively be accomplished without any mechanical motion of the breast or nipple. Also, pumping can be carried out by a pumping mechanism that is external to the conduit and not in fluid communication with the conduit.

[0015] Certain approaches or embodiments of the system or method can involve outputting at least one of operational and/or sensed parameters, and modifying at least one operational setting based upon the operational or sensed parameters. The system or method can further perform in real-time, or as a feedback loop. An operational setting can be one or more of suction level setting, suction waveform definition, extraction phase time, threshold milk volume estimate per extraction phase expulsion, pressure, rest phase time, heating temperatures, heating times, vibration frequency and vibration times. The system can also be configured to upload operational or sensed parameters from an external computer to a cloud server.

[0016] Suction can be maintained at a minimum during an entire milk pumping session or suction can be intermittent where suction is reduced to zero at least once over the duration of a milk pumping session. Further, the suction level can be monitored and a determination can be made when at least a minimum suction level has not been maintained and the system can be shut down. Indicators can be provided to indicate ceasing of pumping and/or to indicate when the device is to be removed from the breast. A non-contact pressure sensor is also contemplated to be incorporated into one or more of the disclosed embodiments or methods. In one approach, the sensor can define a magnetic proximity sensor.

[0017] These and other features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the specification as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Fig. 1 is an illustration of a breast pump system according to an embodiment of the present disclosure.

[0019] Fig. 2 is a partial view of the system of Fig. 1 showing only a portion of the breast adapter.

[0020] Fig. 3 is a partial, schematic illustration of the system of Fig. 1 showing the pumping region.

[0021] Figs. 4A-4F illustrate the interaction between compression elements and resilient tubing, and a pumping sequence according to an embodiment of the present disclosure.

[0022] Figs. 5A-5C illustrate operation of a system having only one compression element according to an embodiment of the present disclosure.

[0023] Fig. 6 illustrates a main body/housing of a breast pump system, without a container having been attached or the tube and adapter having been attached, to illustrate dimensions of the components shown, according to an embodiment of the present disclosure.

[0024] Fig. 7A illustrates a breast adapter/tube configured and dimensioned to be attached to the embodiment of the main body/housing of a breast pump system shown in Fig. 6, according to an embodiment of the present disclosure.

[0025] Fig. 7B illustrates a breast adapter/tube configured and dimensioned to be attached to the embodiment of the main body/housing of a breast pump system shown in Fig. 6, according to another embodiment of the present disclosure.

[0026] Fig. 7C illustrates a perpendicular relationship between a longitudinal axis of the teat and the breast adapter according to an embodiment of the present disclosure.

[0027] Fig. 7D illustrates an acute angular relationship between a longitudinal axis of the teat and the breast adapter according to an embodiment of the present disclosure.

[0028] Figs. 8A and 8B are schematic, front and side illustrations, respectively, of a breast pump system showing placement and routing of the tube, according to an embodiment of the present disclosure.

[0029] Fig. 9 is a schematic, side illustration of one example of a system having varying dimensions along the length of the tube, and optionally, varying materials from which the various portions of the tube are made, according to an embodiment of the present disclosure.

[0030] Fig. 10 illustrates a series of events that may be carried out in operating a system according to an embodiment of the present disclosure, when carrying out a milk extraction process from the breast.

[0031] Fig. 11 illustrates events that may be carried out in a control process for extracting milk according to an embodiment of the present disclosure.

[0032] Fig. 12 schematically illustrates various sections of the tube extending from the breast to the proximal end of the tube, according to an embodiment of the present disclosure.

[0033] Figs. 13A-13B show partial views of a system that employs a second compression element according to another embodiment of the present disclosure.

[0034] Figs. 13C-13E show partial views of a system that employs a second compression element according to another embodiment of the present disclosure.

[0035] Fig. 13F shows a partial view of a system that employs a second compression element according to another embodiment of the present disclosure.

[0036] Fig. 14 shows a partial view of a system that employs a second compression element according to another embodiment of the present disclosure.

[0037] Fig. 15 shows a partial view of a system that employs a first compression element according to another embodiment of the present disclosure.

[0038] Fig. 16A shows a partial view of a system, according to another embodiment of the present disclosure, in which one or both of the compression elements are attached to the tube.

[0039] Fig. 16B illustrates one way in which the tube can be configured for attachment to one or both of the compression elements, according to an embodiment of the present disclosure.

[0040] Fig. 16C is a partial cross-sectional illustration of the first compression element attached to the tube, according to the embodiment described with regard to Fig. 16B.

[0041] Fig. 17A is a partial view of a system employing another embodiment of compression element, according to an embodiment of the present disclosure.

[0042] Fig. 17B is a cross-sectional view of the compression element in Fig. 17A.

[0043] Fig. 17C is a cross-sectional illustration of a compression element and tube being received in a channel formed with a substantially planar or flat anvil surface, according to an embodiment of the present disclosure.

[0044] Fig. 17D shows a cross-sectional view of a compression element and tube being receive in a channel, wherein the anvil surface of the channel is substantially V-shaped in cross-section and the compression element has a compression surface that is substantially V-shaped, according to an embodiment of the present disclosure.

[0045] Fig. 17E shows a cross-sectional view of a compression element and tube being receive in a channel, wherein the anvil surface of the channel is concave in cross-section and the compression element has a compression surface that is convex, according to an embodiment of the present disclosure.

[0046] Fig. 18 is an isolated illustration of a milk collection/storage container according to an embodiment of the present disclosure.

[0047] Fig. 19 illustrates the connection features of the tube and container that allow for easy and rapid attachment and detachment of the container to and from the tube, according to an embodiment of the present disclosure.

[0048] Fig. 20 illustrates a container having been capped off upon removal from the system, according to an embodiment of the present disclosure.

[0049] Fig. 21 illustrates a feeding nipple attached to a container according to an embodiment of the present disclosure.

[0050] Fig. 22 shows a bottle that the container with the nipple attached thereto inserted therein to provide a more structural implement that is more easily used for feeding a baby, according to an embodiment of the present disclosure.

[0051] Fig. 23 is an exploded view of an alternative arrangement for installing a container in a bottle and providing it with a feeding nipple, according to another embodiment of the present disclosure.

[0052] Fig. 24 is an illustration of a system installed on a breast around the nipple and supported by a bra in which the system is received, according to an embodiment of the present disclosure.

[0053] Fig. 25 illustrates a milk collection container according to another embodiment of the present disclosure.

[0054] Fig. 26 illustrates alternative locations for placement of a container, according to various embodiment of the present disclosure.

[0055] Fig. 27A illustrates a breast pump system using a doughnut-shaped collection container according to an embodiment of the present disclosure.

[0056] Fig. 27B is a side view of the system of Fig. 27A shown mounted on a breast.

[0057] Fig. 28A illustrates a doughnut-shaped container having baffles intermediate of the inner and outer surfaces of the doughnut shape, according to an embodiment of the present disclosure.

[0058] Fig. 28B is a side view of Fig. 28A, showing a cross-sectional view of the container.

[0059] Fig. 28C illustrates a view with a container that does not have baffles, containing the same volume of milk as the container with baffles in Fig. 28B.

[0060] Fig. 28D is an illustration of a container showing baffles arranged in a waffle pattern to control the even distribution of the volume of milk as it is received, according to an embodiment of the present disclosure.

[0061] Fig. 28E is a side view of a main body to illustrate the dimensions of the main body, according to an embodiment of the present disclosure.

[0062] Fig. 28F is an illustration of the container of Fig. 28D mounted on the main body of Fig. 28E, according to an embodiment of the present disclosure.

[0063] Fig. 29A illustrates a container that fits around the main body of the system and the areola of the breast, according to an embodiment of the present disclosure.

[0064] Fig. 29B illustrates a variant of a container in which the one way valve is located on the outside of the annular container, according to an embodiment of the present disclosure.

[0065] Fig. 29C shows the one way valve and connecting portion of the container of Fig. 28B having been folded upwardly along a baffle line to join the one-way valve to the tube of system, according to an embodiment of the present disclosure.

[0066] Fig. 29D shows a container having been folded for more compact storage, according to an embodiment of the present disclosure.

[0067] Fig. 30 shows a milk collection container that is ring-shaped to encircle the breast, according to an embodiment of the present disclosure.

[0068] Fig. 31A shows a breast adapter that includes a rigid portion where the nipple is inserted, and a flexible, resilient portion, according to an embodiment of the present disclosure.

[0069] Fig. 31B illustrates four different locations where the breast can be alternatively compressed and allowed to expand by using four massage drivers, according to an embodiment of the present disclosure.

[0070] Fig. 32A illustrates a breast adapter provided with vibration drivers according to an embodiment of the present disclosure.

[0071] Fig. 32B is a rear view (open end) of breast adapter showing vibration drivers such as motors or piezoelectric devices mounted on the breast adapter, according to an embodiment of the present disclosure.

[0072] Fig. 32C illustrates a handheld vibration driver that is operable independently of a breast pump system, according to an embodiment of the present disclosure.

[0073] Fig. 33 illustrates a breast adapter provided with heating elements according to an embodiment of the present disclosure.

[0074] Fig. 34 schematically illustrates a breast adapter having a suction zone which is flexible and forms a seal with the breast when suction is applied, while a rigid portion receives the nipple and areola of the breast, according to an embodiment of the present disclosure.

[0075] Figs. 35A and 35B are back end, schematic illustrations of a breast adapter showing that the suction zone can be applied in a continuous ring or intermittently, according to various embodiments of the present disclosure.

[0076] Fig. 36 schematically illustrates an arrangement in which a first, relatively lower suction/vacuum level is constantly applied by a breast adapter though a suction zone to maintain a seal with the breast, according to an embodiment of the present disclosure.

[0077] Fig. 37A illustrates a flexible spring provided in a container to maintain an open channel within the container, according to an embodiment of the present disclosure.

[0078] Fig. 37B illustrates a flexible porous tube provided in a container to maintain an open channel within the container, according to an embodiment of the present disclosure.

[0079] Fig. 38 shows a breast adapter in which the upper half (or other upper portion) of the adapter has different mechanical properties and/or composition than the lower half (or other lower portion) of the breast adapter, according to an embodiment of the present disclosure.

[0080] Fig. 39A illustrates a system employing a flexible breast adapter connected to a tube which is supplied by suction/vacuum by a pump, according to an embodiment of the present disclosure.

[0081] Figs. 39B-39C illustrate that application of squeezing action by the breast adapter to squeeze the breast causes the tube to temporarily collapse (see Fig. 39B) which causes a pressure change at the nipple, and, upon release of the compression forces against the breast, the tube reopens (see Fig. 39C), according to an embodiment of the present disclosure.

[0082] Fig. 40 illustrates a breast pump system in which the pumping region 30 and container are suspended on a lanyard worn by the user, according to an embodiment of the present disclosure.

[0083] Fig. 41 illustrates an embodiment in which, in addition to the suction/vacuum created by withdrawing a compression element away from the tube, the compression element is also mechanically linked to a portion of the breast adapter surrounding the nipple, according to an embodiment of the present disclosure.

[0084] Fig. 42 is an exploded view showing where the tube of the system connects to the main body, according to an embodiment of the present disclosure.

[0085] Fig. 43 is an exploded illustration of a breast pump system showing a pressure sensor placed at a proximal end portion of the breast adapter, according to an embodiment of the present disclosure.

[0086] Figs. 44A-44B illustrate operation of a pressure sensor to detect pressure within a breast pump system, according to an embodiment of the present disclosure.

[0087] Fig. 45A illustrates a pressure sensor that can be used in a breast pump system according to another embodiment of the present disclosure.

[0088] Figs. 45B-45C illustrate additional views of the pressure sensor of Fig. 45A and its operation.

[0089] Fig. 46 is a schematic representation of a pump region that may be used in any of the breast pump systems described herein, according to another embodiment of the present disclosure.

[0090] Fig. 47 is a schematic representation of transfer of data wirelessly from a controller of the system to a smartphone, according to an embodiment of the present disclosure.

[0091] Fig. 48 illustrates configuration of the connection between the container and tube of the system for monitoring to ensure that the connection remains throughout an extraction and expulsion session, so that milk is not lost or wasted, according to an embodiment of the present disclosure.

[0092] Fig. 49 illustrates that the motors of the system may be provided with heat sensors and/or motion sensors to provide feedback to the controller as to the operating temperatures of the motors and/or movement and/or rate of movement of the motors, according to an embodiment of the present disclosure.

[0093] Fig. 50 illustrates a pressure relief member placed in the breast adapter, and also shows alternative, or additional locations for pressure relief members, according to an embodiment of the present disclosure.

[0094] Fig. 51 shows a longitudinal sectional view of a breast adapter that may be used in any of the breast pump systems described herein, according to another embodiment of the present disclosure.

[0095] Fig. 52A shows a longitudinal sectional view of a breast adapter that that may be used in any of the breast pump systems described herein, and which is a variation of the breast adapter shown in Fig. 51.

[0096] Fig. 52B is a rear perspective view of the breast adapter and tube of Fig. 52A.

[0097] Fig. 52C illustrates that when the breast is engaged with the system, the lip of the system is deflected further inwardly by the breast contact, thereby reducing or eliminating the gap and driving milk from the gap towards the nipple housing/nipple receiving cavity, according to an embodiment of the present disclosure.

[0098] Fig. 53A is a front, exploded view illustrating a breast adapter and tube, main housing 34 and milk container 60 according to an embodiment of the present disclosure.

[0099] Fig. 53B is a rear, exploded view of the components illustrated in Fig. 53A.

[00100] Fig. 53C is a front, perspective view illustrating the breast adapter and tube of Fig. 53A having been installed in the main body.

[00101] Fig. 53D is a rear, perspective view of the components shown in Fig. 53C.

[00102] Fig. 53E illustrates a front, perspective view after attaching the container to the main body of the embodiment illustrated in Figs. 53A-53D.

[00103] Fig. 53F is a rear, perspective view of the system shown in Fig. 53E.

[00104] Fig. 53G illustrates a breast pump system using a full ring-shaped container, according to another embodiment of the present disclosure.

[00105] Fig. 54 illustrates an assembly of the breast adapter and tube in the main body according to another embodiment of the present disclosure.

[00106] Figs. 55A-55E illustrate the interaction between compression elements and resilient tubing, and a pumping sequence, according to another embodiment of the present disclosure.

[00107] Fig. 56 illustrates a flow sensor provided in a breast pump system to enable the user to check in real time how much milk has been pumped, according to another embodiment of the present disclosure.

[00108] Fig. 57 illustrates a breast pump system provided with an indicator light, according to an embodiment of the present disclosure.

[00109] Fig. 58A is a front, exploded view of a breast pump system according to another embodiment of the present disclosure.

[00110] Fig. 58B is a front view illustrating the breast adapter and tube having been installed in the main body.

[00111] Fig. 58C illustrates the process of attaching the container to the system.

[00112] Fig. 58D illustrates the assembled system, with the container having been connected and fitted over the main body to conform to the contour thereof.

[00113] Fig. 58E shows the system of Figs. 58A-58D with the container having been partially filled with milk.

[00114] Fig. 59A is a front, exploded view of a breast pump system according to another embodiment of the present disclosure.

[00115] Fig. 59B is a front view illustrating the assembled system, with the container having been connected and fitted over the main body to conform to the contour thereof.

[00116] Fig. 59C is a rear, exploded view of the system of Figs. 59A-59B.

[00117] Fig. 59D is a partially exploded rear view of the system of Fig. 59A, showing the breast adapter and tube having been installed in the main body.

[00118] Fig. 59E illustrates the process of attaching the container to the tube and main body.

[00119] Fig 59F is a rear, perspective view of the system of Fig. 59A after having been assembled.

[00120] Fig. 59G is a rear view of the system of Fig. 59F after having collected milk in the container.

[00121] Fig. 60 illustrates a pressure (vacuum) release feature that may be provided on any of the systems described herein, according to an embodiment of the present disclosure.

[00122] Fig. 61 is a longitudinal sectional view of a breast adapter and a portion of a tube illustrating a pressure relief valve according to an embodiment of the present disclosure.

[00123] Fig. 62 illustrates a main body of the system having a see through window to ensure proper placement of the nipple, according to an embodiment of the present disclosure.

[00124] Fig. 63 illustrates a main body that can be at least partially peeled away which maintaining a seal of the breast adapter against the breast, according to an embodiment of the present disclosure.

[00125] Fig. 64 illustrates a pair of breast pump systems that can be installed on both breasts of a user, according to an embodiment of the present disclosure.

[00126] Fig. 65 illustrates a pair of breast pump systems installed on the breasts of a user and supported by a bra, according to an embodiment of the present disclosure.

[00127] Fig. 66 illustrates the user of Fig. 65 using the breast pump systems while in a supine position, according to an embodiment of the present disclosure.

[00128] Fig. 67 illustrates the user of Fig. 65, with a blouse worn over the breast pump systems, using the breast pump systems while working at a work station, according to an embodiment of the present disclosure.

[00129] Fig. 68 shows the user of Fig. 67, with the blouse shown partially in phantom to better shown the underlying breast pump systems and bra, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

[00130] Before the present systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[00131] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[00132] Unless defined otherwise, all technical and scientific terms used herein

have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[00133] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a valve" includes a plurality of such valves and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[00134] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. The dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[00135] Fig. 1 is an illustration of a breast pump system 100 according to an embodiment of the present disclosure. System 100 includes a breast adapter 10, a pumping region 30 within a main body 34, a one-way valve 50 and a milk storage container 60.

[00136] Fig. 2 is a partial view of the system 100 showing only a portion of the breast adapter 10. Breast adapter 10 includes a compliant region 12 made of silicone or other compliant, biocompatible material, such as, but not limited to polyurethane and/or polyether block amides (PEBAX) to provide a soft interface with the breast and also provide a seal around the areola and nipple of the breast. An inner housing 14 is configured and dimensioned to surround the nipple of the breast. Inner housing 14 can be rigid, semi-rigid or compliant. Preferably the breast adapter 10 is compliant and made from silicone or polyethylene terephthalate (PET), although other materials and combinations of materials could be used, including, but not limited to polyurethanes, polyethylene, high density polyethylene (HDPE), low density polyethylene (LDPE), polyamides, polyethylene terephthalate (PET) and/or PEBAX, For the embodiments where there is compliance, inner housing 14 is capable of iteratively opening and closing during extraction of milk from the

breast using system 100, thereby simulating a feeding cycle similar to the sequence of the tongue against the nipple when a baby is suckling.

[00137] An open segment 16 within the housing of breast adapter 10 is configured and dimensioned to allow for at least some clearance and space in front of the nipple to permit milk to exit the nipple even when the nipple is pulled forward by suction. The open section 16 terminates with a U-turn to double back to form an acute angle to minimize the overall height/profile of the system 100 away from the breast.

[00138] Fig. 3 is a partial, schematic illustration of system 100 showing the pumping region 30. A resilient tube 32 is in fluid communication with and extends proximally from the proximal end of breast adapter 10. Preferably, resilient tube 32 is integral with breast adapter 10 as shown in Fig. 1. Two active compression elements 36, 38 are operable to compress and allow decompression of the resilient tube 32 at compressible regions 40 and 42, respectively. Although the preferred embodiment uses two active compression elements as shown, alternative embodiments could have three or more active compression elements. Resilient tube 32 is preferably made of silicone, but could alternatively be made from other thermoplastic elastomers exhibiting the desired performance characteristics described herein, including, but not limited to polyurethanes and/or PEBAX. Different regions of tube 32 may be of different materials/material properties. The regions can all be molded of same material, overmolded, glued or otherwise attached, constructed, etc. In at least one embodiment, the compressible regions may have different properties from other non "active" regions – such as those non active regions being rigid (e.g., downstream of the pumping region and/or other non-active regions) to improve pumping efficiency by reducing energy losses due to expansion and contraction of regions not intended to be active. The non-active regions can be made of different materials from the active regions or otherwise reinforced. The various regions can also be other shapes than circular in cross-section. The material(s) from which the compression regions 40, 42 of tube 32 are made can be the same as that of the flange and nipple housing of breast adapter 10, only differing optionally by thickness, they could be assembled out of different materials and fused or glued together, or could be insert molded together. Further alternatively, the material(s) from which the compression regions 40, 42 are made can differ from one

another. A factor in the choice of material and material thickness and length is the response time required to expand the compression regions 40, 42 from a target compressed shape/state to an original, unbiased rebound configuration (e.g., return to a full cylindrical shape in the embodiments where tube 32 is cylindrical), force required to compress to the desired target compressed shape, radial force (pressure drop) achieved when allowing the tube 32 to self-expand, volume within the inside diameter of the tube 32 regions 40 and 42, compatibility with the materials for the remainder of the breast adapter10 (nipple housing), resiliency to maintain its material properties through multiple wash, aging and use cycles, surface and depth characteristics such as material transparency, clarity and texture/feel against the skin, visual appearance, mechanical durability, tear resistance, shape memory, soft/hardness, biocompatibility, non-reactivity and free of leachables, heat/cold resistance, etc.

[00139] Examples of tubes 32 include, but are not limited to: silicone tubing, such as used in peristaltic pumps, both platinum-cured and peroxide-cured silicone tubes. Dimensions can range greatly in inside diameter and wall thickness, but preferred embodiments can have an inside diameter of 3/16 in., ¼ in. or 5/16 in. Walls may also range to impact properties, with preferred embodiments likely in the 1/16 in. to 1/8 in. range. Inside diameters and wall thicknesses can be varied, as needed, with ensuing appropriate lengths of tubing 32. Further alternatively, pumping regions 40, 42 do not need to be in the shape of a cylindrical tube, or even a tube at all, but can be any volume shape that can be changed/compressed. For example, the cross-section could be oval, square, trapezoid, etc. as needed to fit the device space. Examples of tube inside diameters, wall thicknesses and hardness include, but are not limited to: .188" ID, .063" wall, Durometer 50 shore A; .250" ID, .063" wall, Durometer 50 shore A; .313"ID, .063" wall, Durometer 59 shore A; and .313" ID, .094" wall, Durometer 59 shore A.

[00140] As shown, the compression elements 36, 38 comprise pistons, but alternative features could be used to accomplish the same function, such as lever arms, screw drives, clamps, cams, pincers, rollers, magnets, electro-magnets, linear drives, solenoids, gears, stepper motors, or other features, respectively. The compression surfaces of the compression elements 36, 38 may be formed as flat paddles to allow complete crushing of the tube 32 without residual volume. Alternatively, one or both compression surfaces may

be formed with a "V-shaped" edge aligned axially with the tubing 32 to allow less force to compress tubing 32 to the same distance of compression, relative to a flat surface paddle. Further alternatively, or additionally, one or both compression surfaces may be formed with a cross edge (perpendicular) to axis of tubing. This provides a relatively small surface area allowing less force to completely seal tubing 32 at the location of the cross edge. However this also provides a relatively minor volume change/pressure change capability.

[00141] One or both compression surfaces may be formed as roller paddles having curved surfaces so that the compression action is not simply straight into the tubing 32. The roller paddle surface can roll on the tubing 32 to seal and move in a given direction. Dual action of the roller can be provided, so that, initially the roller comes down in compression against the tube 32 and seals the tube 32, which may be capable of being performed with relatively low force. Secondarily, the roller paddle can roll the compression surface in a predetermined direction along the length of the tube 32 and squeeze a volume of milk or air or combination in a given direction. This can be useful to maximize both increase and decrease in pressure changes and fluid movement.

[00142] Also, although the preferred embodiments described herein power the compression elements 36, 38, using electrical power supplied by one or more batteries, alternatively, they could be powered by AC electricity by plugging the system in using an AC power cord, compressed gas, spring loaded power (which may offer ways to "hand crank" to power w/o electricity), gas or suction from a remote source such as a traditional breast pump uses, etc.

[00143] Each compression element 36, 38 is operatively connected to a driver 44, 46, respectively, for independent but coordinated driving and retraction of the compression elements 36, 38. When electrically-powered drivers are used, a battery 48 is electrically connected to the drivers 44, 46 and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38. Optionally, a controller 52 may be electrically connected to the drivers 44, 46 and may be configured to modify the operation of the compression elements 36, 38 based on input received from an optional pressure sensor 54 (or multiple pressure sensors) that may be placed at least one location to assess the pumping function and maintain an acceptable

pumping negative pressure profile for a wide variety of milk expression volumes. As shown, pressure sensor 54 is placed in the inner housing 14 to measure the negative pressure within the inner housing, which is the environment that the nipple is in. Alternatively or additionally, one or more pressure sensors could be placed in tube 32 upstream of compression driver 36, in between the locations of compression drivers 36 and 38 and/or downstream of compression driver 38. Further alternatively or additionally, a pressure sensor could be placed in tube 32 near, but upstream of one-way valve 50. The pressure sensor 54 (and/or flow sensor or any other sensor employed) – may be inserted into the tube 32, but is preferably designed in such a fashion such that it produces a signal that correlates to a pressure (or flow) but may not necessarily itself be in contact with the fluid and/or gas generating the pressure or flow. This arrangement that does not directly contact the milk (interior of the tube 32) is preferred to simplify cleaning of the tube 32/breast adapter 10 or to make it cost feasible to provide the breast adapter 10/32 as a disposable unit.

[00144] Sensor 54 is preferred to be a pressure sensor but could also be a flow, temperature, proximity, motion sensor or other sensor capable of providing information usable to monitor the safety or function of the pump mechanism of system 100. Preferably sensor 54 is located nearby where the tip of the nipple 3 is located to determine actual pressure being exposed to the breast 2/nipple 3, but other sensors 54 may be located within the system 100, for example, near where the one-way valve 50 is located, and can be used to monitor other features such as bag or expulsion pressure or flow rate. With at least one sensor 54 present, by monitoring either flow or pressure directly or indirectly and also taking into account the cycles and actual positions of the compression elements 36, 38 over time, it is possible to derive/calculate approximately the volume of milk produced during a pumping session as well as understand the flow-rate at any particular time in a pumping session. The accuracy of this measurement is greatest when there is no leak of air around the breast 2 and also when there is negligible air within the tube 32, after elimination by a few cycles of the pumping mechanism.

[00145] In one system set-up, an ideal minimum suction value of a cycle is preset and a maximum suction value of a cycle is preset. Maximum suction is achieved by the opening of one or more of the compression regions 40, 42. The greater the

opening/release (assuming the tubing 32 has capacity), the greater the suction. A maximum suction for the system is achieved when both compression regions are completely released from the tubing 32, but preferably the system 100 is designed such that the operating region would not include that state to allow for flexibility in suction capacity. The minimum suction is the target minimum suction at the breast 2 at each suction cycle. When this suction is achieved, the most proximal compression region 40 to the breast 2 is closed/sealed and the milk expressed during the previous cycle is expulsed by the second compression element 38 from the second region 42 through the one-way valve 50 into the storage container 60. The timing of the proximal compression is set by a combination of milk expression rate within a specified maximum suction achieved by the tube 32 and the relaxation rate and state of the expansion of the tube 32. Thus milk expression sets the pace for the pump cycle at a targeted minimum suction, whereas the degree of compression at the various compression regions are set by maximum desired suction pressure and duration as well as milk volume capacity within the system. Thus, in at least one embodiment, a user can optimally set maximum peak pump pressure and maximum valley pump pressure and the remainder of parameters within the system would automatically adjust themselves based on milk expression rate and other fixed parameters within the system.

[00146] Controller 52 can also be pre-programmed for control of an operating sequence for driving and retracting the compression members. Preferably, controller 52 is configured to drive and retract the compression members 36, 38 via an active feedback loop, to adjust the positions of the compression members 36, 38 as needed to establish the desired negative pressure (i.e., suction) profile for optimizing milk extractions. If a controller 52 is not used, the drivers 44, 46 can be synchronized to run so that the compression drivers 36, 38 are operated in a desired coordinated manner. For example, one or more pumps can be operated in a predetermined manner without using pressure feedback. Alternatively, a different form of feedback may be employed, such as mentioned above. Even without any feedback, one or more compression elements may be operated in a predetermined sequence to create vacuums. There may be pressure relief valves so that the vacuum level the nipple experiences does not get too high into a harmful zone. Further optionally, pressure sensor 54 can be used to detect pressure changes indicative of milk volume expressed to calculate an

approximation of milk volume extracted.

[00147] A one-way valve 50 such as a duckbill valve or other type of one-way valve is provided at the end of tube 32 where it enters the milk collection/storage container 60. Valve 50 prevents back flow of milk into the tube 32, as well as preventing air from entering the proximal end of the tube and thereby maintains the suction (vacuum) level in the tube 32. In an alternative embodiment, a pressure relief valve can be provided in the breast adapter 10 near the nipple 3. The pressure relief valve can be configured to release at vacuums greater than a predetermined amount, (e.g., vacuums less than -220mm Hg). The one-way valve 50 can be configured and designed such that it allow fluid to flow through it only when the vacuum pressure is less than some threshold (e.g., pressures greater than or equal to -60mmHg). The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from tube 32 and decreasing when the compression elements compress the tube 32, but typically should not increase the vacuum to greater than the predetermined maximum vacuum (e.g., not less than -220mm Hg). As the compression elements 36, 38 compress the tube 32, the pressure in the system 100 goes up and reaches the crack pressure of -60mmHg, that opens the one-way valve 50. The compression elements 36, 38 continue compressing tube 32, pumping fluid (milk) through the one-way valve 50 and into the collection container 60 until the compression elements 36, 38 bottom out. As the compression elements 36, 38 reverse direction and pull away from the tube 32, they start the cycle again.

[00148] Figs. 4A-4F illustrate the interaction between compression elements 36, 38 and resilient tubing 32 and a pumping sequence according to an embodiment of the present disclosure. The resilient tube 32 has a lumen 56 configured and dimensioned to deliver milk from the breast through the one-way valve 50 and into the milk collection/storage container 60. As illustrated, tube 32 is cylindrical and lumen 56 is circular in cross-section, but in other embodiments, the lumen 56 could be oval or other cross-sectional shape. Likewise, tube 32 could have an oval or other cross-sectional shape. The cross-sectional shapes of the lumen 56 and tube 32 are typically the same, but need not be. In one preferred embodiment, the suction (vacuum) established by the system is established solely by the resilient, "spring-back" action of the tubing 32. Tubing 32 is designed and

configured to establish a maximum suction/vacuum in the range of less than -60mm Hg, preferably in the range of -120mm Hg to -450mm Hg, more preferably in the range of -180mm Hg to -400mm Hg when rebounding from the closed configuration shown in Fig. 4B to a fully rebounded position as illustrated in Fig. 4A. Tubing 32 is designed so that the rebound of the regions 40, 42 creates a suction vacuum in the tube 32 sufficient to ensure that the system 100 achieves vacuum around the nipple 3, so that any losses in the system 100 are taken into account. The vacuum achieved at the breast nipple 3 should achieve a maximum suction of at least up to 300mmHg suction (-300mm Hg pressure). Initially upon installation of system 100 to the breast 2, it may take several cycles of the compression elements 36, 38 before the vacuum reaches its maximum vacuum. In another embodiment the achievement of maximum suction may be as high as 450mm Hg suction (-450mm Hg pressure).

[00149] In at least one embodiment, the maximum suction/vacuum capable of being established by tube 32 is in the range of -180mm Hg to -220mm Hg, preferably about -200mm Hg. This provides a built-in fail safe to ensure that the suction/vacuum never exceeds a desired maximum operating range of -180mm Hg to -220mm Hg, preferably about -200mm Hg, as this is all that can be attained by the system. In another embodiment, the maximum suction/vacuum capability of the tube 32 is greater than a desired maximum operating suction/vacuum. For example, the maximum suction/vacuum capability could be in the range of -220mm Hg to -400 mm Hg. This greater capability provides an advantage in that, over time, should the tube 32 lose some of its elasticity/resilience performance, then the maximum operating suction/vacuum can still be achieved, due to the overdesign of the maximum suction/vacuum capability of the tube 32.

[00150] The elasticity/resilience properties of the tube 32 and inner housing 14 may be identical, for ease of manufacturing and keeping down costs of production. Alternatively, the elastic/resilience properties of the tube 32 may be different downstream of the compression members 36, 38, relative to the elastic resilience properties of the tube 32 in locations 40, 42. For example, the tube 32 downstream of locations 40, 42 may be more resilient than the tubing portions 40, 42, less resilient than tubing portions 40, 42 or even rigid. As noted above, the inner housing 14 may be resilient, semi-rigid or rigid. In at least

one embodiment, the inner housing 14, tubing portions 40, 42 and tube 32 downstream of portions 40, 42 are all integral, made of the same material, and have the same elastic/resilience properties. In other embodiments, inner housing 14 may be more elastic, less elastic or equal in elasticity to regions 40, 42 and may be more elastic, less elastic or equal in elasticity to the elasticity of the tube 32 downstream of the regions 40, 42. The tube 32 may be itself resilient but the tube 32 may optionally also include embedded resilient members (like a coil or braid) which would enhance the resiliency or strength of tube 32.

[00151] The present disclosure is designed to emulate the application of forces applied by a baby suckling from the breast to extract milk. During breastfeeding the baby's tongue is applied to the nipple/areola region of the breast. During suckling the baby draws the tongue down and slightly backwardly to create a suction/vacuum to start drawing milk into the baby's mouth. The soft palate of the baby gets pulled against the back of the tongue thereby sealing off a suction/vacuum chamber forward of this contact, into which the milk drawn by the suction/vacuum. After an amount of milk is received into the baby's mouth, the baby swallows. Once the tongue re-contacts the hard palate, this releases the maxim suction against the breast and opens a passage to allow milk to be transferred into the pharynx and then esophagus. During swallowing, as the tongue moves up and seals against the hard palate, it creates a driving force to move the milk down the soft palate and into the esophagus. After swallowing the cycle is repeated by again drawing the tongue down and slightly backwardly. During the entire cycle, the baby maintains negative pressure (suction/vacuum) on the nipple/breast. The present disclosure provides the first compression element 36 to function like the baby's tongue and hard palate, to establish the constant suction against the breast, by sealing of the tubing in region 40. The second compression element 38 functions like the swallowing/soft palate function. In this way, milk ducts are not overly collapsed during a rest or lower suction pressure phase but rather the ducts are allowed to fill like when a baby is latched to a breast. This re-filling allows for more efficiency in milk extraction more similar to a baby than conventional pump devices.

[00152] Fig. 4A shows the compression elements 36, 38 in a non-contact configuration (alternatively could be in contact, while not substantially compressing or deforming the tube 32) allowing the resilient tube to assume its full, un-deformed

configuration. In this configuration, the cross-sectional area of lumen 56 is equal in the regions 40 and 42 to the cross-section area of lumen 56 in locations adjacent to 40 and 42 in the embodiment shown. In other embodiments, the cross-sectional area of lumen 56 in the regions 40 and 42 could be unequal to the cross-sectional area of lumen 56 in locations adjacent to 40 and 42. Further alternatively, the cross-sectional areas in the regions 40 and 42 could be unequal to one another. Fig. 4B illustrates the configuration of the compression elements 36, 38 in an initial state. The initial state is the state that the pumping region is placed in when attaching the system to the breast. Once a seal has been formed by the compliant region 12 with the breast and the system has been properly placed, it can be turned on to begin a milk extraction process.

[00153] An initial suction/vacuum/suction is created by retracting compression element 36 (which is the compression mechanism nearer the breast) which allows the resilient tubing to spring back toward its initial shape to create a local suction/vacuum in the open segment 16 of the tubing and the inner housing 14 sealed against the breast. As the resilient tubing expands toward its un-deformed configuration, it creates a suction/vacuum in the lumen 56. Fig. 4C shows the compression element 36 having been fully retracted to establish the initial suction. Preferably, the tube 32 and the length 37 of compression member 36 are designed to establish a suction/vacuum by retracting element 36 as described, which is at the low end of a range considered to be sufficient for extracting milk. For example, tube 32 as shown in Fig. 4C could be configured to establish -120mm Hg of suction/vacuum or -180mm Hg suction/vacuum or some other suction/vacuum level less than -60mm Hg to around -220mm Hg. The suction/vacuum that is created is sufficient to draw milk from the breast and into the lumen 56 in a location distal of, as well as underneath the compression element 36. As the resilient tube 32 is now a closed system, the suction/vacuum is maintained with the lumen 56. The second compression member 38 can be withdrawn to further increase the suction/vacuum if desired, for example to accommodate the increase in pressure (less vacuum) as milk enters the system 100 from the breast 2. The member 38 can retract further in the direction away from tube 32 to compensate.

[00154] After a predetermined time or upon sensing a predetermined flow or volume of milk extracted, the milk is then passed through the tube 32 and valve 50 and into

the container 60. Fig. 4D illustrates the second compression element 38 is starting to be retracted. At the same time the first compression element 36 is advanced to compress the tube 32 in region 40. The movements of 36 and 38 are coordinated to achieve and maintain a predetermined minimum suction/vacuum level, typically in the range of -40mm Hg to -70mm Hg, more typically -50mm Hg to -60mm Hg. The time of closure of the first compression element 36 may be pre-determined or the time for activation of closure of the first compression element 36 may be determined based on an algorithm that includes the pressure in the system 100, the mode in which the system 100 is operating (e.g., letdown phase, extraction phase or expulsion phase, etc.) and/or other data such as milk expression rate, and timing of the second compression element 38. As the first compression element 36 is advanced to close the first region 40, the second compression element 38 continues to be retracted to allow the second region 42 to continue opening, maintaining the desired minimum suction/vacuum profile throughout until the first region 40 is closed fully leaving a desired residual suction/pressure (at the minimum suction/vacuum level) against the breast. This action drives the milk proximally through the lumen 56 (driving to the left in Fig. 4D) as the suction is maintained. This is accomplished by retracting the compression element 38 at the same time that compression element 36 is extended to begin compressing the region 40. As the region 42 expands and the region 40 compresses, this drives the milk towards the one way valve 50. Thus, the second compression element 38 functions like the swallowing/soft palate of the infant and the one-way valve functions like the soft palate as it closes against the rear of the tongue during the peak suction phase to prevent backflow in the system. Fig. 4E shows compression element 36 fully compressing region 40, thereby functioning as a closed valve, maintaining the suction against the breast. Compression element 38 has been fully retracted, as the milk has been pushed into the location of region 42 and distally thereof. As noted previously, compression elements 36, 38 are not limited to the embodiments shown. As one alternative example, compression elements 36, 38 may function like clamps or pliers, each having two pads that squeeze together, compressing regions 40, 42 therebetween. Fig. 4F shows the compression element 38 again being extended, while the compression element 36 remains in the closed valve position. The compression of region 42 by element 38 can begin as soon as the region 40 is fully closed

off by element 36 to seal off the region surrounding the breast. The compression by element 38 drives the milk out of region 42 and further downstream toward the one-way valve 50. When the compression element 38 reaches the fully closed (compressed) position, as shown in Fig. 4B, the cycle repeats, and the cycle of movements illustrated in Figs. 4B-4F continues over the course of a milk extraction session.

[00155] The system 100 is capable of functioning successfully with the pumping tube 32 in any relationship/orientation, relative to the nipple, but it is preferred to location the compression regions 40, 42 and compression elements 36, 38 higher than the nipple 3 when the systems 100 is attached to the breast 2. In this arrangement, bubbles of air that may be fed through the tube 32 early in the pumping cycle so that the tube 32 is eventually mostly filled with milk, from the nipple 3 all the way to the one-way valve 50. The benefit of this is that the system 100 then becomes very energy efficient, as it approaches a fully hydraulic system. Since milk is essentially incompressible, the value of having a system 100 that does not have a substantial amount of air allows for suction pressure to be communicated sustainably within the system in a relatively uniform fashion with much less losses of energy into the fluid itself.

[00156] As noted, the pump mechanism requires independent, coordinated compression/release of two adjacent sections of resilient tube 32 to perform the extraction and delivery of the milk from the breast to the collection container 60. Although two drivers 44, 46 are shown in the embodiment of Fig. 3, alternatively, both compression elements could be driven by a single driver to move in a coordinated manner. However, two independently operating drivers are preferred, as they can be controlled more flexibly to vary the coordination between movements of the two compression elements 36, 38, if needed. The system 100 is capable of maintaining a negative pressure against the breast at all times similar to a normal breastfeeding baby.

[00157] In an embodiment which employs one or more pressure sensors 54 and controller 52, the pressure at the location(s) of the one or more sensors 54 can be monitored throughout the milk extraction process. During the opening of region 40 as described above with regard to Fig. 4C, the pressure is monitored until a desired milk extraction suction/vacuum level is achieved. In this case, the tubing 32 and compression element 36

dimensions can be designed to achieve a greater suction/vacuum than the low end of the range of suction/vacuum considered to be effective for extracting milk, for example, to achieve a suction/vacuum in the range of -180mm Hg to -450mm Hg. In this case, the feedback from the pressure sensor 54 to controller 52 lets the controller know when the desired suction/vacuum has been achieved and the controller 52 can control the driver 44 to halt the retraction of the compression element 36 at a position less than fully retracted, and thus still partially compressing the region 40, when the desired suction/vacuum level has been reached. Additionally or alternatively, in cases where full retraction of element 36 does not achieve a desired suction/vacuum level, element 38 can be retracted by an amount that brings the suction/vacuum level up to the desired suction/vacuum level.

[00158] The relative positions of the compression elements 36, 38 correlate to the volumes of the tube in regions 40 and 42 as long as the compression elements 36, 38 are in contact with the tube 32. Thus, by knowing the total volume of the remainder of the tube 32 and breast adapter 10 making up the suction/vacuum space, it is possible to estimate the volume of milk pumped by the system, once the tube 32 distal of the pumping region 30 has been filled with milk and the extraction phase begins, by calculating the volumes of regions 40 and 42 over the course of extraction and expulsion. Alternatively, additional information, such as provided by monitoring pressure changes at the breast 2; speed and direction of compression elements 36, 38;and/or force and/or pressure data history to the present time, may be used to calculate an estimate of volume pumped. Further optionally, a flow sensor or optical sensor may be employed to provide an estimate of volume and/or measurement of the extent of filling of tube 32 in a predefined region of the tube 32 to help in estimating the volume of milk pumped. By assuming the amount of fluid in the system 100 (tube 32 filled) and then knowing the pressure curve representing the pressure contained within the system 100 over time, any changes in pressure can take into account compression element 36, 38 position, speed and direction and then estimate the impact due to milk flow from the breast 2.

[00159] Figs. 5A-5C illustrate operation of a system 100 having only one compression element 38 according to an embodiment of the present disclosure. In this embodiment, first and second one-way valves 50', 50" are provided adjacent opposite end of

the compression region 42 of the tube 32 where the tube is compressed by compression element 38. Fig. 5A shows the initial configuration of the system when it is first applied to the breast 2. After a seal of the system 100 to the breast 2 is accomplished in any of the manners described previously, and letdown has occurred, pumping of expressed milk can be performed by compressing region 42 with compression element 38 as illustrated in Fig. 5B. As the pressure increases due to the compression of region 42, milk is driven through one-way valve 50' as indicated by the leftward directed arrow in Fig. 5B. At the same time, one-way valve 50" prevents backward flow of the milk and maintains vacuum against the breast 2. In Fig. 5C, as compression element 38 is retracted away from tube 32, tube 32 resiliently expands to increase vacuum (drop the pressure) in tube 32. This closes the one-way valve 50' and opens the one-way valve 50" to extract milk from the breast 2 and into the region 42. Extraction and pumping of milk can be continued by cycling between the phases shown in Figs. 5B and 5C.

[00160] In order to prevent vacuum of against the breast from becoming too strong (limit pressure from going too low), the compression element 38 may be controlled by slow control of driver 46. If no flow of milk is detected, the driver 46 may be controlled to stop the pumping operation. Alternatively, the driver 46 may be controlled to pump for a predetermined amount of time past the detection of no flow, in order to further stimulate the nipple3/breast 2 which may signal or condition the breast 2 to increase milk production. The system 100 can be provided with a relief valve 502 in or adjacent to the breast adapter 10. The relief valve 502 may be set to open when a predetermined maximum vacuum level has been reached, e.g., -200mm Hg, -220mm Hg or the like. This is typically the maximum vacuum level that is intended to be applied for expressing milk from the breast 2. The relief valve may be independent of the operation of the one-way valve 50" as shown, or alternatively, may be configured to squeeze or vibrate the one-way valve 50" so as to close it to prevent the vacuum against the breast 2 from exceeding the maximum predetermined vacuum. Once the one-way valve is overcome by the vibration or squeezing, the vacuum against the breast is prevented from exceeding the maximum vacuum.

[00161] Breast milk container 60 is preferably a flexible bag that is fitted over the main body/housing 34 in a collapsed state so that it does not take up any significant

volume until milk is received therein, but closely follows the contours of the housing 34, so as to be received in a bra 130 and between the bra and housing, without enlarging the overall size of the system 100 as received in the bra. As stated, the container is also contemplated to be placed within the housing adjacent or about pumping structure, or alternatively, between pumping structure and the user's breast. The one-way valve is connected to the proximal end of the tube 32 (having been positioned in the channel 232) to complete the assembly of the system 100 to the condition shown in Fig. 1. Disassembly can be just as easily performed by reversing the order of the assembly description above.

[00162] Fig. 6 illustrates a main body/housing 34 of system 100, without a container 60 having been attached or the tube 32 and adapter 10 having been attached, to illustrate dimensions of the components shown, according to an embodiment of the present disclosure. It is noted here that the present disclosure is not limited to the dimensions disclosed with regard to Fig. 6, but may be varied, as this is only one specific embodiment of the disclosure. Any or all of the dimensions may be increased or decreased as needed, for example to adapt to different breast sizes, etc. The outside diameter 240 of the system housing 34 in Fig. 6 is 9cm. The total thickness 242 of the device housing 34 (and thus the entire system 100 when container 60 is in the collapsed configuration) in Fig. 6 is 4cm. The opening 244 at which the proximal end of tubing 32 is attached to the one-way valve has a diameter of about 13mm. The receptacle 230 for housing the breast adapter 10 has a diameter 246 of 4.5cm. Also shown is a display 250 which can be outputted to by controller 52, for example, to indicate if an air leak develops, what the current suction/pressure reading in the adapter 10 tube 32 is, approximate value of milk volume having been expressed, approximate flow rate of milk, pressure waveforms, phases of feeding timing, rest programming, heating applied to breast, vibration applied to breast, etc. The display can also indicate when the system is on and when it is off, duration time of a pumping session; time of day, date, count down times, speed or frequency of pumping cycles, strength of vacuum, etc. The display can be backlit to facilitating reading it in the dark. Additionally, controls 252 are provided to allow different modes of operation by the user, including, but not limited to: power up; on/off state indication; increases or decreases applied to various modes such as pumping cycle frequency, vacuum strength; selection of pumping program

versions; timer, etc. The controls are conveniently located along an exterior surface of the device for easy access by a user. Alternatively, display 250 could consist only of a light, such as an indicator light. Further alternatively, a light may be provided underneath one or more of the controls 252 or where the milk tube 32 exits the main body 34. Such lights disclosed could be configured to illuminate in different colors to indicate various modes or information or may also flash. Additionally or alternatively, an audio feature such as a speaker and amplifier may be provided to produce one or a variety of sounds to alert the user to various modes, end of pumping session, time, various pressure thresholds being reached, etc. When display 250 is used to communicate volume of milk being pumped, duration of the pumping cycle, which mode the pump is in, or read out the pressure for min/max which could be settable by the user.

[00163] It is further noted that the receptacle 230 (for housing the breast adapter 10 and thus receiving the nipple) is not centered in the housing 34, but is positioned so that its center is below the center of the housing 34. This causes the system 100 to not be centered around the nipple of the breast, but to ride in a higher position, relative to the breast, so as to better conform to the anatomy of the user, and be less noticeable when worn in a bra 130. Additionally, the inner surface 254 is not flat, but is tapered. From the edge/periphery of the inner surface 254 to the inner nipple housing 230 the inner surface is tapered to form a cup shape. As the breast adapter 10 is placed against the breast 2, it is ideally concave to allow it to receive the breast 2 comfortably and provide a smooth surface to create an effective suction seal. Thus, surface 254 tapers slightly to conform to the breast 2, to still further make wearing of the system 100 less noticeable. There may be a slight bulge in the taper to to provide a better sealing zone against/around the breast 2.

[00164] Fig. 7 illustrates a breast adapter10/tube 32 configured and dimensioned to be attached to the embodiment of the main body/housing 34 of system 100 shown in Fig. 6. As with Fig. 6, it is noted here that the present disclosure is not limited to the dimensions disclosed with regard to Fig. 7 but may be varied, as this is only one specific embodiment of the disclosure. The outside diameter 256 of the breast adapter 10 at its opening in 4cm. The inside diameter 258 of the breast adapter 10 in the region when the nipple is received is 20mm as shown. The breast adapter necks down 260 at a location designed to minimize the

distance that it is located beyond the extent that the nipple is stretched when it is formed into a teat under maximum suction/vacuum applied by the system 100. It is noted that the neck down region 260 is optional and is not included in many of the embodiments. If present, neck down region 260 is provided to create a light seal against the nipple/teat 3. Alternatively, a smooth wall of the breast adapter 10/tubing 32 is provided along the side to allow the nipple/teat 3 to move freely, as shown in Fig. 7B. The assemblies as shown in Figs. 7A-7B (as well as the remainder of the system 100) is designed so that the interface or opening of the breast adapter 10A is substantially perpendicular to the longitudinal axis 2L of the breast 2 and nipple 3 as it is formed into a teat by the system 100. Alternatively, the breast adapter 10 may be configured so that the longitudinal axis 2L forms an acute angle with the opening surface or the breast adapter/back surface of the system 100, as illustrated in Fig. 7D. Such a configuration can reduce the thickness, or distance which the system 100 extends from the breast.

[00165] The distance between the necked down region 260, or smooth region 260' that transitions to the tube 32 is preferably in the range of about 1mm to 5mm. The inside diameter 262 of the tube 32 where it integrates with the breast adapter 10 proximally of the neck region 260 is 20mm in these embodiments. The tubing 32 then tapers down to an inside diameter of 6mm in the regions to be compressed and proximal of these regions, all the way to the proximal end of the tube 32. The opening 244 of the main body 34 has an inside diameter of about 13mm and is configured and dimensioned to accommodate tube 32 with some extra clearance, to allow the extension 62 (male embodiment) to overlap the tube 32. The breast adapter 10/tube 32 unit is configured to be removed from the system 100, as shown, for cleaning after use, and then reattachment in housing 34. The regions 40, 42 snap fit (or friction fit) between portions of the compression elements 38, 36 into groove or channel 430 upon attachment of breast adapter 10/tube 32 to the housing 34, see Fig. 42, so that regions 42, 40 can be compressed without impinging on the breast adapter portion 10.

[00166] Figs. 8A and 8B are schematic, front and side illustrations, respectively, of a breast pump system 100 showing placement and routing of tube 32 according to an embodiment of the present disclosure. In this embodiment, the distal end portion of tube 32 that integrates with the breast adapter that receives the nipple 3 of the breast is positioned

below the nipple 3 so that it forms a milk collection well 32W to facilitate filling and priming of the pump region 40. Once milk enters tube 32 and into pump zone 40, the tube 32 can be routed in any direction. In the embodiment shown, the tube bends up and around the housing 34 to a location at the top of the housing 34 where it can be attached to container 60 with one-way valve therebetween. As noted, different routing schemes for routing the tube 32 may be used, such as routing to the side of the housing rather than to the top, or routing horizontally from the well 32W to the side of the housing 34 and then up and around to the top of the housing 34, or routing past the pumping regions shown in Fig. 8A and then back down to the bottom of the housing 34.

[00167] In some embodiments, it may be desirable to change dimensions and/or materials of the tube 32 along the length thereof. Fig. 9 is a schematic side illustration of one example of a system 100 having varying dimensions along the length of the tube 32, and optionally, varying materials from which the various portions of the tube 32 are made. Further optionally, the thickness of the wall of the tube 32 may vary along the length thereof to change resilience performance/compliance characteristics, whether the varying sections are of the same material or of different materials, as well as whether one or more sections are reinforced with braids, coils or the like to increase stiffness. In this embodiment, the well region 32W has the smallest diameter or cross-sectional dimension of any of the regions of the tubing, so as to minimize the volume of milk that needs to be collected in the pre-pump region of the tubing 32 before milk starts entering the pumping regions 40, 42 to be pumped. The pumping regions 40, 42 of the tube have the largest diameter, to allow more pressure change per length of tubing 32 to be generated, as a longer compression stroke by the activators 36, 38 is allowed. Downstream (proximal) of the regions 40, 42, the tube may be formed of a relatively more rigid material than that portion forming the regions 40, 42, in order to reduce the compliance and increase the flow of milk form the regions 40, 42 to the container 60. Additionally, or optionally, the portion of tube 32 downstream of region 42 may be formed to have a smaller diameter than the portions 40, 42.

[00168] Fig. 10 illustrates a series of events that may be carried out in operating a system according to the present disclosure when carrying out a milk extraction process from the breast. At event 502, the system is attached to the breast, which includes sealing

the compliant region 12 of the breast adapter 10 to form a substantially airtight (the system can overcome and accommodate small air leaks) and substantially liquid-tight seal therewith to minimize or eliminate leakage of breast milk. There are different embodiments for accomplishing this task. A most basic and preferred embodiment is to form the seal by suction/vacuum alone. This can be accomplished by actuating a system actuator 82 (see Fig. 1) to power up the system and begin generating suction/vacuum. Actuator 82 may power up the controller 52 when present, or power up the drivers 44, 46 to run a predetermined routine when a controller 52 is not present. The establishment of the seal can be accomplished by retracting the first compression element 36 in a manner as described when going from the orientation shown in Fig. 4B to that of Fig. 4C. If a seal does not establish with the first retraction of element 36, then the element 36 can be cycled between the positions shown in Figs. 4C and 4B until an adequate seal has been achieved. During cycling, as the element 36 compresses, this drives air out between the breast and the compliant region 12, and during each retraction of element 36, static suction (vacuum) is increasing built up, thereby increasing suction/vacuum within the breast adapter 10 and tube 32 with each cycle. In embodiments where a pressure sensor 54 and controller 52 are employed, the controller 52 can cycle the element 36 until a predetermined level of suction/vacuum has been achieved, which establishes that a sufficient seal has been formed. Advantageously, this cycling of the element 36 also facilitates let down of the breast milk, readying it to be extracted.

[00169] In an alternative embodiment, the seal may be established by a tacky or adhesive surface 84 may optionally be provided on an inner surface of compliant region 12 (see Fig. 2). The tacky surface may be provided by application of an adhesive, such as the type of adhesive used for stoma bags used for colostomy patients, or other effective and biocompatible adhesive or tacking agent. The sealing of the compliant region 12 against the breast may be established via the tacky surface 84 alone (or with a surface treated with a material that gets tack when heated by the body temperature of the breast 2 as it contacts the breast), or together with establishment of suction/vacuum as described in the previous embodiment. Further, optional application of pressure and/or heat may further facilitate sealing of the tacky region against the breast. In another embodiment, which may be used together with any of the previous embodiments, or by itself, the breast adapter 10 is

configured to be compressed, once applied to the breast and then released. The breast adapter 10 then resiliently returns to its original configuration, thus establishing a suction/vacuum and sealing the compliant region 12 to the breast, much in the same way that a suction cup is stuck to a flat surface. In addition, the system may be handheld against the breast until sufficient suction/vacuum is established to generate the seal. Further optionally, the system may be supported in a bra configured to hold the system during its operation.

[00170] At event 504, the system establishes a suction/vacuum level sufficient to extract milk from the breast. This is accomplished by controlling movements of the compression element 36 and optionally controlling movements of compression element 38 in coordination with movements of compression element 36. An initial vacuum/suction is created by retracting compression element 36 (which is the compression mechanism nearer the breast) to create a local suction/vacuum against the breast. As the resilient tubing expands toward its un-deformed configuration, it creates a suction/vacuum in the lumen 56. Fig. 4C shows the compression element 36 having been fully retracted to establish the initial suction. Preferably, the tube 32 and the length 37 of compression member 36 are designed to establish a suction/vacuum by retracting element 36 as described, which is at the low end of a range considered to be sufficient for extracting milk. For example, tube 32 as shown in Fig. 4C could be configured to establish -120mm Hg of suction/vacuum or -180mm Hg suction/vacuum or some other suction/vacuum level less than -60mm Hg to around -220mm Hg. The suction/vacuum that is created is sufficient to draw milk from the breast and into the lumen 56 in a location distal of, as well as underneath the compression element 36. As the resilient tube 32 is now a closed system, the suction/vacuum is maintained with the lumen 56. The second compression member 38 can be withdrawn to further increase the suction/vacuum if desired. In embodiments where controller 52 and pressure sensor 54 are employed, feedback from the pressure sensor to the controller can indicate whether the suction/vacuum is sufficient to establish milk flow from the breast, as the pressure sensed will drop once milk enters the system. If the feedback loop between the controller establishes that extraction of milk has not yet begun, then the controller 52 can incrementally control retraction of the compression member 38 until sufficient suction/vacuum is established to cause milk to start to be extracted, as confirmed by the pressure-controller

feedback loop. This control of the second compression member 38 can be subsequent to the fully retraction of the first compression member 36 or can be carried out during the retraction of the first compression member. Further alternatively, the first compression member may not be fully retracted, but some combination of partial retractions of the members 36, 38 can be established to achieve the desired suction/vacuum level. In instances where the predetermined suction/vacuum level that the tube 32 is designed to established upon full retraction of the compression element 36 alone is not sufficient to extract milk for a particular user, the controller can be programmed by the user to initially establish a suction/vacuum greater than that predetermined suction/vacuum level, so that the controller will automatically operate the compression elements 36, 38 initially to establish this greater suction/vacuum level, irrespective of pressure sensor feedback. The pressure-controller feedback loop can then still be used to adjust suction/vacuum as needed to extract milk.

[00171] Once the milk extraction has begun, the suction/vacuum is maintained at event 506 for a predetermined time, or until a predetermined volume of milk has been extracted, or when a predetermined minimum pressure has been achieved to indicate that a predetermined volume of milk has been expressed into the system 100. By continually measuring the pressure in the system (preferably, but not necessarily, in the vicinity of the nipple), an estimate of the volume of milk extracted can be calculated by the controller 52. As milk enters the suction/vacuum space, the pressure drops. The volume of milk received in the suction/vacuum space is proportional to the pressure drop and therefore the volume of milk can be estimated by knowing the pressure drop. This is also dependent however, upon ensuring that the seal between the system and the breast has not been broken and that no other air leaks have developed. As an air leak will register in the system as a continuous, somewhat constant pressure change toward zero, it can be readily distinguished from the changes in vacuum measured by receipt of milk into the suction/vacuum space, as these changes are less continuous and will continue to increase the pressure (reduce vacuum/suction), rather than remain relatively constant.

[00172] After the predetermined time has expired, or, more preferably, in embodiments where the volume of milk extracted is estimated, the milk is moved proximally from the region 42 at event 508, while sealing off the suction/vacuum space distal of the

region 42, using compression element 36, while maintaining a constant suction/vacuum pressure on the breast/nipple that is less than the extraction suction/vacuum, as described above. This can be accomplished by compressing the tube 32 with element 36 while simultaneously retracting compression element 38 to maintain the desired suction/vacuum level until the seal is formed by element 36, as described above with regard to Figs. 4D-4E. The rate at which the elements 36 and 38 are extended and retracted, respectively, and the amount of retraction of element 38 are dynamically adjusted depending upon the variables of the system, including the volume of milk present and the suction/vacuum level used during the extraction phase.

[00173] Once the compression element 36 has sealed off the tube 32 at region 40, the compression element 38 is immediately controlled to expel the milk from region 42 during the expulsion phase, by moving the milk proximally of the region 2. This is accomplished by extending the compression element 38, from whatever position it ended up in during event 506, to the fully compressed position to close off the tubing and drive the milk proximally from the region 42. This motion of the compression element 38 generates a positive pressure driving force, which is advantageous in that the milk can be pumped through the valve 50 and into the container 60 regardless of the orientation of the components, even directly against gravity. At this stage, the compression elements 36, 38 are positioned as shown in Fig. 4B and the processing returns to event 504 to carry out another cycle of milk extraction.

[00174] Fig. 11 illustrates events that may be carried out in a control process for extracting milk according to an embodiment of the present disclosure. At event 602 the compliant region 12 of breast adapter 10 is contacted to the breast such that the tube 32 is properly aligned with the nipple of the breast and a seal is established, in any of the manners already previously described. At event 604, suction/vacuum is generated in the breast adapter, which facilitates the sealing of event 602 if not already firmly established and establishes suction/vacuum to be used in milk extraction. The suction/vacuum pressure is continually monitored by the controller 52, either continuously or intermittently. At event 606, if a sufficient suction/vacuum has been achieved to establish the seal. An initial seal can be established by a vacuum that can be maintained in the pressure range of -1mm Hg to -

60mm Hg, when the system 100 is supported by a bra 130. In practice, the system can be programmed with a threshold seal vacuum level confirming that a seal has been established, wherein the threshold seal vacuum level is in the range of -20mm Hg to -60mm Hg. In one particular embodiment, the threshold seal vacuum level is -40mm Hg. Of course, it is understood that vacuum pressures of less than -60mm Hg are also sufficient to establish the seal. If there are no leaks and a sufficient suction/vacuum (predetermined suction/vacuum level) has been established, then processing proceeds to event 608. If the pressure reading indicates that there is a leak or that a sufficient suction/vacuum level has not been otherwise established, then suction/vacuum is continued to be generated at event 604. This can be accomplished by cycling the compression element 36 in a manner as descried above. Additionally, if the pressure reading indicates an air leak, the user may readjust the interface between the compliant region 12 and the breast, which may optionally include adding an adhesive and/or holding or pushing the system 100 against the breast 2 until sufficient sealing vacuum has been established. The cycling from events 606 to 604 continues until sufficient suction/vacuum has been created to establish the seal.

[00175] At event 608 the suction/vacuum is adjusted to a predetermined extraction suction/vacuum level, which is greater that the residual suction/vacuum level that is applied to the breast at times when milk is not being extracted. This predetermined extraction suction/vacuum level can be any of those previously described above, and is established by controlling movements of the compression element 36 and optionally 38, as described above. The pressure continues to be monitored by the controller 52 in a manner as described above.

[00176] At event 610, if the pressure drops and the pressure drop is characteristic of receiving milk into the suction/vacuum space and that a seal has been maintained, then processing goes to event 618. If the pressure has not dropped in a manner to indicate receipt of milk in the suction/vacuum space, then at event 612 it is determined whether the pressure has dropped characteristically to indicate an air leak. If an air leak is indicated, then the user may be prompted, via an audible signal, or a message, such as on display 250, vibration of the system, automatic shutoff of the system, a signal or message sent to an external device such as a smartphone, or an indicator light, and the user can

readjust the compliant region 12 contact with the breast to eliminate the air leak. Such adjustment may include any or all of: applying hand pressure on the system against the breast; rotating or otherwise repositioning the compliant region 12; removing the compliant region 12 from contact with the breast, applying adhesive to the compliant region 12 and reestablishing contact between the compliant region and the breast. Once the adjustment of the contact has been completed, the system returns to event 604. Distinguishing between an air leak and milk extraction is not necessarily important, as the system 100 is capable of adapting even if a consistent air leak is present. In the operating suction range, air leaks will be unusual and if such a leak exists it will be a big leak, such as when the system 100 is temporarily removed from the breast 2, and this will result in a much more rapid pressure rise than that due to milk extraction.

[00177] Referring back to event 618, if the pressure has dropped sufficiently so that the estimation of milk volume collected equals or exceeds a predetermined volume (e.g., a volume in the range of .02 to .064 oz., typically about .032 oz., then the system is controlled to change from the extraction phase to the expulsion phase at event 622 and the milk is expulsed downstream (proximally) of the regions 40 and 42 in an manner as already described. After expulsion has been completed, processing returns to event 608 to carry out another extraction phase of the cycle. The cycle can be continued for a predetermined time, or until a predetermined volume of milk has been estimated to have been extracted, or for a predetermined number of cycles, or for any combination of these endpoints, where the first endpoint reach will discontinue the cycling. Such decision is determined at event 624. Once the condition (predetermined time, predetermined volume of milk and/or predetermined number of cycles) has been met, the system shuts down at event 626. For example, for a typical pumping session in which 150ml of milk is extracted and pumped, if the session last fifteen minutes, the system 100 pumps 10ml of milk per minute. A baby suckling the breast 2 typically suckles about 30 times a minute. To replicate this, the system 100 cycles about thirty times a minute, with each stroke of the system 100 passing on average about .33ml. (.33ml/cycle). Thus the volume capability of the pumping system 100 is configured to accommodate at least about .33ml within each compression region (probably a bit more to allow for variation amongst women) but generally around that amount. As there is some

natural "dead volume" between the nipple 3 and the first compression region 40, and then a desirable small amount of dead space between the last compressor 38 and the one way valve 50, this volume should also be compensated for in the volume capability of the system 100.

[00178] The present advantage provides extremely good control over the suction/vacuum pressure waveforms established by the system against the breast. In particular, the generation of suction/vacuum by the element 36 is closely adjacent the breast itself, so there is very little loss in the transmission of suction/vacuum pressure from the element 36 to the breast. In existing systems, suction/vacuum pumps are located at a much greater distance from the breast and pressure head losses of up to 200mm Hg have been measured from pump to breast, in some instances. The distance 92 (see Fig. 12) between the compression element 36 and the end of the nipple when drawn into the open section 16 by suction/vacuum to form a teat 2' is minimized to maximize the responsiveness of the application of suction/vacuum to the breast. Additionally, the minimization of distance 92 helps to reduce the total amount of distance that the system extends from the breast when worn. When the teat 2' is maximally extended, the distance 92 may be in the range of about 0.5mm to about 3mm, typically about 1mm to 2mm.

[00179] The distance 94 (length of the compression member 36) is related to the amount of suction/vacuum to be achieved by moving the element from the position shown in Fig. 4B to the position shown in Fig. 4A. The length/distance of compression member may vary, depending upon the amount of suction and displacement desired by this component. For example, length/distance 94 may be a value within the range of 0.2 cm to 6 cm, typically about 2cm. The distance 96 between the elements 36 and 38 should be minimized so as to minimize the dead space between the compression elements, as element 38 does not drive the contents in this space proximally, and it must be moved in the succeeding cycle. Thus, the larger the distance 96 is, the less efficient the expulsion phase is. The distance 96 can be a value in the range of 0mm to 5mm, preferably as close to 0mm as can be achieved. The distance 98 (length of the second compression element 38) is designed so as to provide ample reserve suction/vacuum generation capability, so that the suction/vacuum pressure on the breast 2 can be dynamically adjusted to accommodate for a variety of different variables that occur when using by the same user, as well as across uses by different users including,

but not limited to: vary rates of milk extracted, various amount of total volume of milk extracted (ranging from about 0ml to 240ml, typically about 76 ml milk per breast 2 per extraction session), amount of suction/vacuum needed to extract milk, etc. For example, length/distance 98 may be a value within the range of 0.2 cm to 6 cm, typically about 2cm. The distance 102 between the proximal end of the second compression element 38 and the one-way valve 50 should also be minimized to reduce the volume of milk between the pumping mechanism and the valve 50, which does not get pumped out of the tube 32 until one or more successive cycles. In one example, distance 102 was a length holding a volume of milk when full of about .25ml to 3ml, typically about 1ml.

[00180] Figs. 13A-13B show partial views of system 100 that employs a second compression element 38 according to another embodiment of the present disclosure. In this embodiment, the compression effector 38A is rotationally mounted relative to driver 38B via joint 104. As the compression element is advanced against the tube 32, the mechanism 104 rotates the compression effector 38A relative to the drive 38A (clockwise, as shown in Fig. 13B) so that the distal end portion of the compression effector 38A advances more than the proximal end portion as it rotates, as shown in phantom in Fig. 13A. At a predetermined distance (such as when the distal end portion of 38A seals off the tube 32, or at some other predetermined distance less than the distance required for sealing), the mechanism 104 reverse rotates the compression effector 38A (counterclockwise, as shown in Fig. 13B) to advance the proximal end portion of the compression effector 38A further against the tube 32. These actions provide a better force vector for expulsing the milk toward the one-way valve (in the direction of arrow 106), as compared to a compression element 38 having a compression effector 38 that does not rotate.

[00181] Figs. 13C – 13E show another rotational compression element 38 according to an embodiment of the present disclosure. In this embodiment, compression effector 38A and an upper portion of shaft 38B are relatively rigid, while a lower portion of the shaft, where it joins the compression effector 38A is elastic and forms the joint 104. As the compression element 38 advances toward tube 32, the lower portion of the compression effector 38A contacts the tube 32 first. As the compression element 38 continues its advance and begins compressing tube 32, the equal and opposite force pushing against the

compression effector 38A by tube 32 deflects the joint 104 by the lever arm provided by the lower portion of the compression effector 38A applied against the joint. This causes rotation of the compression effector 38A (in the counterclockwise direction shown in Fig. 13D, increasing the angle 910). This rotation can continue until the compression effector becomes perpendicular to the shaft 38B and aligned with the tube 32, with angle 910 forming a right angle, as shown in Fig. 13E, depending upon the distance by which the compression element 38 is advanced against the tube 32. Upon retraction of element 38 away from the tube, joint 104 resiliently returns to its unbiased configuration as shown in Fig. 13C. Fig. 38F shows still another embodiment of compression element 38 configured to perform in the same manner as the embodiment of Fig. 13C, but where the elastic joint 104 has been replaced by a pin joint 104 and biasing member 910 interconnecting a portion of the compression effector 38A to the shaft 38B above the pin joint 104 so as to bias the compression effector 38A at a non-perpendicular orientation relative to the shaft 38B.

[00182] Fig. 14 shows a partial view of system 100 that employs a second compression element 38 according to another embodiment of the present disclosure. In this embodiment, the compression effector 38A is segmented to provide independently operable segments 38A that can be advance and retracted individually. Although four segments are shown in Fig. 14, more or fewer could be employed to operate in a similar manner to that described. Segments 38A are slidably mounted to driver 38B via a telescoping shaft 108 that is spring-loaded by biasing member 110 to bias the positions of the segments 38A relative to the driver 38B as shown in solid lines in Fig. 14. As the compression element 38 is advanced against the tube 32, cam 108 rotates relative to the driver (clockwise, as shown in Fig. 14) thereby contacting the distal most segment first and extending it from the driver 38A so that it extends into the tube 32 further than the other segments 38A. Upon further advancement of driver 38A and rotation of cam 108 the next-distal most segment 38A is contacted by cam 108 causing it to extend from the driver 38A. The process can continue until all segments have been extended like the distal most one shown in Fig. 14 to fully closes off the space 42. Upon retraction of the driver 38B, cam 108 reverse rotates and biasing member retracts the segments 38A relative to driver 38B to the positions shown in solid lines in Fig. 14 as they lose contact with the cam 108. Alternatively, the cam 108 can

be designed to customize the final profile of the segments 38A when the driver 38B is fully extended, so as to arrange the amounts of extension of each individual segment 38A from the driver 38B by the distances desired. Further alternatively, the compression element 38 can be designed so that the driver does not need to advance at all, but instead extends and retracts the segments 38A though rotation and counter-rotation of the cam 108 and retraction forces provided by the biasing member 110.

[00183] Fig. 15 shows a partial view of system 100 that employs a first compression element 36 according to another embodiment of the present disclosure. This embodiment of compression element 36 can be combined with any of the embodiments of compression element 38 described herein. In this embodiment, the compression effector 36A of compression element 36 is minimized, so that length 94 is in the range of about 1 to 4 mm, preferably about 1 to 2 mm, so that it is effective to seal off the tubing 32 (as described with regard to Fig. 4B), but operates in concert with compression element 38 to establish sufficient suction/vacuum for extracting milk. By minimizing the length 94, less force is required to seal off the tube 32, as compared to the force necessary to seal the tube using the compression element 36 in the embodiment of Fig. 14, for example, resulting in a savings of energy, which can lead to a smaller driver 44 being used, a smaller battery 48 due to the lower energy requirements, and/or longer operational time before the system 100 needs to be recharged or plugged in to an AC power source (in embodiments where this is possible). Response times of the system 100 may also be faster. The time required for the compression element 36 and the tube 32 to completely seal or release may be shorter. Also, there is less volume that is moved on the final close during feedback, so if the sealing element 36 is near closing and waiting for the pressure feedback controlling the larger compression element 38 to establish the desired pressure before closing, the smaller profile corresponds with less volume change on that final seal motion. Therefore the sealing can be more precisely and accurately controlled

[00184] Fig. 16A shows a partial view of system 100 according to another embodiment of the present disclosure, in which one or both of compression elements 36 and 38 are attached to the tube 32. The compression elements are attached to the tube 32 at 38C along a portion or all of the surface of each of the compression elements that contacts the

tube 32. The attachment may be by adhesive, welding and/or mechanical means such as banding, containment between jaws of a clamp formed by a compression actuator, screwing and sealing, bolting and sealing, or the like. The attachment provides the system with the capability of generating suction/vacuum by actively driving the portions 40, 42 of the tube. Thus, the suction/vacuum can be generated by a combination of forces provided by the elasticity of the tube sections 40, 42 and the driving forces applied by compression elements 36 and 38 or by the forces applied by compression elements 36 and 38 alone. One advantage that this arrangement may provide is that the response time of the tube 32 return to an uncompressed state could potentially be sped up by rapid movement control of the compression elements 36, 38.

[00185] Figs. 16B illustrates one way in which tube 32 can be configured for attachment to one or both of compression elements 36, 38, according to an embodiment of the present disclosure. In this embodiment, a tab 320 is integral with tube 32 and extends radially therefrom to be connected to a compression element 36, 38. Tab 320 may be made of the same material as tube 32 and integrally molded therewith, or may be laminated to tube 32, or otherwise integrated therewith. Optionally, tab 320 may be reinforced by a reinforcing layer 322, such as a fibrous mesh or other layer of material that is tougher than the material making up the tab. The reinforcing layer may be laminated inside of the tab material or provided as a backing layer. Openings 324 are provided to facilitate connection of the compression element 36, 38 to tab 322. Openings 322 may be optionally reinforced by rings or grommets 326 integrally joined in the openings by molding, welding adhesive or other expedient. Fig. 16C is a partial cross-sectional illustration of compression element 36 attached to tubing 32 according to the embodiment described with regard to Fig. 16B. A pin or rod 324 passes through opening 324 and connects to compression element 36 at both ends. In an arrangement where a compression element 36, 38 connects to tubing 32, the actuation of the compression element 36, 38 can assist in tube 32 expansion, thereby increasing the speed at which the tube 32 rebounds from a compressed configuration and/or increasing force applied by expansion of the tube 32.

[00186] Fig. 17A is a partial view of a system employing another embodiment of compression element 36. In this embodiment a small protrusion 36D extends across the

width of the compression effector 36A so that it is sufficient to span the width of the tube 32 and seal it off when the compression element 36 is fully extended. Because the length 114 of the protrusion is very small, for example, in the range of about 1 to 4 mm, preferably 1 to 2 mm, there is much less force required to be applied to the compression element 36 to seal off the tube as compared to sealing off the whole length of the compression effector 36A, like what occurs in the embodiment of Fig. 14. Likewise, the depth 116 by which the protrusion 36D need not be great, in the range of 1 to 10 mm (with the maximum equal to the outside diameter or height in non-circular cross-section embodiments) of the tube 32, preferably 1 to 3 mm. Of course the length of the protrusion 36D is not limited to the preferred values described, as any length short of the entire length of the compression effector 36A could be employed, but the shorter the length, the greater the energy savings. Likewise the depth 116 could vary from the ranges supplied, but as the depth increases, the volume displaced by the remainder of the compression effector will consequently decrease, so there will be a tradeoff between energy saved and volume displaced, that being an inverse relationship.

[00187] Fig. 17B is a cross-sectional view of the compression element 36 taken along line 12B-12B in Fig. 17A. This view shows that the remainder of the contact surface 36E (excluding the protrusion 36D) is contoured to further reduce energy expenditure while retaining substantial ability to displace volume. In this embodiment, the cross-sectional shape of the contour 36E is substantially V-shaped or U-shaped, so that the ridgeline 36F that runs longitudinally of the compression effector 36A, preferably, but not necessarily midway of the width of the compression effector 36A and aligned with the longitudinal axis of the effector 36A. The ridgeline 26F contacts the tube 32 first and presses into it, and, with increasing compression, more and more of the contoured surface contacts and compresses the tube. However, none of the contoured surface 36E seals off the tube, as that function is provided solely by the protrusion 36D.

[00188] In the embodiments discussed thus far, the compression elements 36, 38 compress the tube 32 against a substantially flat "anvil" surface of the channel 232 in the 34 into which the tube is installed. Fig. 17C is a cross-sectional illustration of compression element 36 with tube 232 being received in a channel 232 formed with a substantially planar

or flat anvil surface 232A. Note that the width 232W of the channel 232 is greater than the outside diameter of the uncompressed tube 32, so there is room for the compressed tube 32 to widen as it is flattened. Also, the width of the compression element 36 is greater than the outside diameter of the uncompressed tube 32, typically having a width about equal to the width of the fully compressed tube 32. Alternatively the anvil surface 232A of channel 232 may be substantially V-shaped in cross-section, as illustrated in Fig 17D and the compression element 36 (and/or 38) may have a compression surface 36S that is substantially V-shaped. This results in a relatively lower force required to be applied by the compression element 36 to completely seal off the tube 32, compared to the amount of force required to seal off the tube 32 in the embodiment shown in Fig. 17C. Still further, other non-flat anvil surfaces 232A can be provided to lessen the overall force required by the compression element 36 to seal off the tube 32. Another non-limiting example of this is illustrated in Fig. 17E, where the anvil surface 232 is concave, and the compression surface 36S is convex.

[00189] The rebound/recoil stored energy in the resilient tube 32 itself is the primary if not sole means for generating suction within the system 100 in preferred embodiments, as described above. As also described herein, one or both compression elements 36, 38 may be attached to the tube 32 to supplement the recoil force of the tube 32. The vacuum is generated by change in volume in the chamber/tube 32. As noted previously, tube 32 need not be circular in cross-section, but could be any shape chamber where volume changes (with valves) generates the vacuum. The action of the rebounding walls of the tube/chamber 32 creates the vacuum. Other means of moving the walls can be magnetic, e.g., both compression elements 36, 38 driven by various electromagnetic means to move them. Alternatively, electromagnetic members may be embedded into or attached on the tube/chamber 32 walls that can be electromagnetically driven to change positions of the walls to create the vacuum. Further alternatively, shape memory alloys (e.g., NITINOL, or the like) can be built into or on the walls such that there is a pre shape/configuration and then with current, the shape changes and affects a shape change in the tube geometry. The shape can start or be activated to compress the tube 32. Still further, any other structure/means to change the state of a material via electricity or other means can be employed so that the

change in state drives a change in geometry of the tube/chamber 32 to change volume. The system 100 is capable of maintaining a negative pressure against the breast at all times similar to a normal breastfeeding baby. The breast 2 includes ducts through which the milk is expressed. As the expression suction/vacuum level is applied to the breast, the diameter of the ducts increases due to the suction/vacuum causing the expression of milk from the ducts. As the milk is expressed from these ducts, they become substantially depleted and collapse. This is typically when the baby swallows or when a milk extraction system cycles to wait for the next extraction phase. In existing systems where the suction/vacuum is reduced to zero (atmospheric pressure) between extraction phases, the ducts contract and do not allow expression of milk, but allow some refilling of milk to occur from larger ducts upstream of the ducts that open to the surface of the nipple. In the case of the nursing baby, as well as use of the present system 100, the suction/vacuum applied to the breast between extraction phases (swallowing in the case of the baby, expulsion phase in the case of the present system) is maintained at a lower suction/vacuum pressure than the extraction suction/vacuum, but still greater than atmospheric pressure. In one non-limiting example, the extraction suction/vacuum is about -200mm Hg and the intermittent suction/vacuum applied to the breast, between extraction phases, is about -50mm Hg. This suction/vacuum applied between extraction phases is not great enough to extract milk from the nipple, but is sufficient to maintain a certain level of expansion of the radii of the ducts to allow more refilling to occur between extraction phases, while not allowing substantial extraction of milk.

[00190] The drivers 44, 46 are each stepper motors in at least one embodiment, that are controlled by controller 52. Since the compression driver 36 can be controlled to be always in either a fully open position or a fully closed (sealed) position, it can be operated by a motor-driven cam, rather than a stepper motor, since it does not need any sophisticated stepper-motor drive input. In this case, the compression driver 38 can be controlled by a stepper motor for dynamic adjustment, via a feedback loop to the controller 52 that controls the stepper motor 46 to: position the compression driver 38 to ensure the desired residual suction/vacuum is applied to the breast when compression driver 36 seals off region 40; drive the compression driver 38 to generate the appropriate pressure wave form to expulse

the milk; and drive the compression driver 38 at a controlled rate and pressure of expulsion of milk across the one-way valve 50. Alternative drivers that can be used as drivers 44, 46 include, but are not limited to: an electromagnet on one side of the compression element 36 or 38 with an iron or magnetic core on the other side of the tubing, opposite the compression element, such that when current is activated, the compression element compresses against the tube 32; cammed motors; or motors driving clamps on a linear or rotational rack and pinion drive train.

[00191] Fig. 18 is an isolated illustration of the milk collection/storage container 60. In the embodiment as shown in Fig. 18, container 60 is a flexible, hemispherically shaped bag that envelopes the main body 34 of the system when installed on the system. The one-way valve 50 is preferably provided as integral with the container 60, as shown, but could alternatively be made to be removable, or could be integrally or removably attached to tube 32. By providing the one-way valve 50 within the tubing integral to the container 60, this allows the container 60 to be immediately sealed once detached from tube 32, which avoids leakage. Container 60 is preferably a compliant bag made of a biocompatible, food grade material such as LDPE. Alternative materials that can be used include, but are not limited to: linear low density polyethylene (LLDPE), polylactic acid (PLA), polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), high density polyethylene (HDPE) or polyethylene terephthalate (PET).

[00192] The collection of milk into container 60 is performed under the positive pumping force/pressure of the pumping mechanism/region 30. Thus the system 100 does not rely on gravity for collection of milk in the container 60. This is advantageous, as it allows breast milk to be extracted and collected over even an uphill gradient, such as may occur when the user is lying down, bending over, or in environments such as a bumpy ride, as in an automobile or airplane trip. This further allows flexibility as to where the collection bag/container 60 (and the input thereto) is located relative to the nipple of the breast. For example, the container 60 could be placed near, on, above, below or on the side of the breast. In the embodiment shown in Figs. 1 and 5, the input to the container 60 is above the breast when system 100 is mounted to the breast. This facilitates easier attachment of the container 60, removal of the container 60 when full or needed to be used, and replacement of another

container 60 on the system 100.

[00193] Fig. 19 illustrates the connection features of the tube 32 and container 60 that allow for easy and rapid attachment and detachment of the container to and from the tube 32. An extension 62 of the one-way valve 50 is configured to form a snap fit, or lock via a detent 64 with a mating receptacle 66 in a proximal end portion of tube 32 to rapidly establish and gas-proof and liquid-proof seal. One or more seals such as O-ring 63 or the like can be provided at the junction to facilitate the sealing process. For example, in the detent and receptacle arrangement shown, the container 60 can be easily and rapidly attached to the tube 32 by inserting the extension 62 into the proximal end of the lumen 56 and turning the extension 62/container 60 a quarter turn. Detachment can be just as easily performed by turning a quarter turn in the opposite direction. Other quick-connect mechanisms that are capable of establishing a quick and easy liquid-tight and gas-tight connection could be substituted for those described. It is noted that the connection mechanism could alternatively be reversed, with the male portion being on the proximal end of the tube 32 and the female portion begin on the extension 62. Further alternatively, the one-way valve 50 could be integrally formed at the distal end of the tube 32 with either a male or female extension and the mating component of the connection mechanism could be integrally formed at the opening of the container 60.

[00194] Upon removal from the system 100 (as well as prior to connecting the container 60 to the system 100), the container 60 can be capped to prevent exit of fluid therefrom and also prevent air from entering the container, as illustrated in Fig. 20. Cap 68 is provided with the same mating mechanism 66 as that found at the proximal end portion of tubing 32, so that cap can be twisted a quarter turn, snap fit, or otherwise attached to extension 62 in the same way that extension 62 forms a connection with tubing 32. Still further, a feeding nipple 70 can be attached to extension 62, as shown in Fig. 21, in the same manner that tube 32 and cap 68 are attached, to form a liquid-tight and gas-tight seal with the extension, to allow feeding of a baby directly from the container 60. Thus, a container containing milk can be configured for immediately feeding a baby after removing the container 60 from the system 100. Alternatively, container 60 can be capped and stored in the refrigerator or freezer for later use.

[00195] Fig. 22 shows a bottle 72 that the container 60 with the nipple 70 attached thereto can be inserted into and contained to provide a more structural implement that is more easily used for feeding a baby. Bottle 72 includes a hollow shell 72 configured and dimensioned to receive the container 70 while allowing the nipple 70 to extend out of the open end thereof. A bottle cap 74 has an opening that allows the nipple 70 to extend therethrough and is configured and dimensioned to enclose the open end of the shell 74 when the bottle is assembled. Bottle cap 74 can be fixed to shell 74 by mating threads, bayonet fitting, snap fitting or other similar arrangement. The assembled bottle 72 as shown is ready to use for feeding a baby, or alternatively can be stored in the refrigerator or freezer for later use.

[00196] Fig. 23 is an exploded view of an alternative arrangement for installing container 60 in a bottle 72 and providing it with a feeding nipple 70. In this embodiment an insert adapter 120 is provided to adapt the container 60 to be used with a commercially available nipple 70 and bottle 72 that are currently sold and readily available. The insert adapter is provided with a valve defeat extension 122 which contains a central lumen 124 that is in fluid communication with the annulus 126 of the adapter 120. The valve defeat extension 122 is configured and dimension to be inserted through the one-way valve 50 to hold it open and allow milk to be sucked out through the valve defeat extension and nipple 70. In another embodiment, the one-way valve is removable and is removed prior to installation of the adapter 120. The top surface 128 of the adapter 120 is flat and configured to form a fluid-tight, airtight seal with the flat bottom surface of the nipple 70. The container 60 is dropped or placed into the bottle 72 after inserting the valve defeat extension 122 through the one-way valve 50. The threads 70T of the bottle are engaged by mating threads 120t at the bottom portion of the adapter and tightened to form an airtight, fluid-tight seal therebetween. A second set of threads 120W are provided on the top portion of the adapter 120 and mate with the threads 128T of the nut 128, which are tightened to physically hold the flange of the nipple 70. The under surface of the shoulder 128H compresses the flange 70F between it and the top surface of the adapter 120 to form the seal as the threads are tightened. The threads and size of the adapter 120 and nut 128) can be manufactured in various sizes and specifications for use in adapting to a variety of bottle and nipple

manufacturing standards.

[00197] Fig. 24 is an illustration of the system 100 installed on the breast 2 around the nipple 3 and supported by a bra 130 in which the system 100 is received. The flexible container 60 conforms to the curvature of the bra 130 so that the wearing of the system 100 is very discreet. Also because of the flexibility of the container 60 and the positive pumping action of the system 100, the container 60 can be in a collapsed condition prior to filling it, so that it takes up virtually no space within the bra 130. Thus, only the contour of the main body 34 of the system 100 adds any bulk to the appearance of the breast. As the container 60 beings to fill with milk, the breast 2 reduces in size by an equivalent volume of the milk expressed and therefore the outward appearance of the components supported by the bra does not significantly change.

[00198] The milk collection container 60 does not necessarily need to be hemispherically shaped as described above, but could alternatively be formed to have a different shape. Further, an array of differently size and/or shaped containers may be provided to accommodate different storage needs (containers have relatively more capacity for breast that produce and express relatively more milk), placement (different size or shape for placement between the breasts), etc. Fig. 25 illustrates a milk collection container 60a according to an embodiment of the present disclosure. Collection container 60a can be made from any of the same materials described above for making collection container 60. In this embodiment, milk collection container 60a is shaped like a conventional blood collection bag such as the type used by the red cross for blood donations, but is equipped with a one-way valve 50 and extension 62 in the same manner as container 60. Because of the positive pumping pressure capability of the system 100' (same as 100, but used with container 60'), the container can be placed between the breasts as shown in Fig. 26 and connected to tube 32 either at the top or the bottom (or any other location) of the container 60a. Also shown in Fig. 26 are alternative locations where the container 60a could be carried by the user. These include, but are not limited to: adhered to the torso just below the breasts, or carried in a holster that is attached by a belt around the waist of the user, or clipped to a belt around the waist of the user. Alternatively, container 60a could be carried in a pocket of a blouse, sweater or jacket worn by the user. Further alternatively, container 60a can be supported by

a table or other external structure if the user is to remain stationary during an extraction process. Optionally, container 60a may have an extension tube 32', which may have the same properties as tube 32 and include an extension 62 with connection mechanism for connecting to the tube 32 of the system 100'. The extension tube 32' can be particularly useful for placement of the container 60a away from the location of the breasts.

[00199] Fig. 27A illustrates system 100" which is the same as system 100 except for the use of doughnut-shaped collection container 60b. Collection container 60b can be made from any of the same materials described above for making collection container 60. Collection container 60b fits on top of the breast 2 and surrounds the main body 34 of system 100". In this way, the profile of the system 100' extends away from the body of the wearer less than system 100, as container 60b does not overlie main body 34, as is readily apparent from the side view of Fig. 27B. Alternatively, instead of forming a complete ring, the doughnut-shaped container 60b could extend only over a predefined arc, such as in the range of from about 180 degrees to 355 degrees. In this embodiment, the volume gain in the container 60b arising from collection of milk will equal the loss in volume of the breast having that volume of milk extracted, resulting in no change in the volume contained within the bra 130 of the user, so that there is no noticeable difference in the appearance of the user before and after collection of milk in the container 60.

[00200] Any of the collection containers described herein may optionally include one or more baffles or other constrictions to facilitate a more even fluid distribution to avoid unsightly bulges on the wearer that might otherwise occur in a collection container not having such restrictions, where the milk all accumulates at the lowest portion of the container due to gravity. Fig. 28A illustrates a doughnut-shaped container 60b having baffles 76 intermediate of the inner and outer surfaces of the doughnut shape. Note that container 60b is connected to tubing 34 via extension 62 at the lower portion of the container 60b in this instance. This is unrelated to the inclusion of baffles 76, but is shown as one of the alternative locations that a container can be attached to the tube 34. Baffles 76 are locations in the container 60b, where the opposing layers of the container are fused or glued together to restrict the container 60b from expanding as much as it otherwise would. Various shapes like pie wedges, waffles, etc. can be formed by the baffles 76. Further,

shapes that take into the contour/three-dimensional geometry of the main body 34 that the container 60 will conform to can be provided. Optionally, an additional layer of polymer 61 can be provided on top of the baffles 76 to help smooth out the external surface of the container 60 to improve the aesthetics of the container when worn, by smoothing out the exterior surface. Fig. 28B is a side view of Fig. 28A, showing a cross-sectional view of the container 60b. Fig. 28C illustrates a view with a container 60b that does not have baffles, containing the same volume of milk as the container 60b with baffles 76 in Fig. 28B. On comparison, it can be readily observed that most if not all of the milk has accumulated in the lower portion of the container 60b in Fig. 28C, resulting in a bulging appearance under the clothing of the wearer. In contrast, the milk is more evenly distributed in Fig. 28B and does not present an asymmetrical, unsightly bulge.

[00201] Fig. 28D is an illustration of a container 60 showing baffles 76 arranged in a waffle pattern to control the even distribution of the volume of milk as it is received. Fig. 28E is a side view of a main body 34 to illustrate the dimensions of the main body 34, according to an embodiment of the present disclosure. In this embodiment, the overall distance 280 from top to bottom of the main body 34 measures about 9cm. The distance 282 from where the main body 34 begins to taper inwardly to follow the contours of the breast 2 to the end of the taper at the bottom portion of the main body 34 measures about 7cm. The dimension of the portion that is configured to receive the nipple 3 measures about 2cm in diameter. The overall length 284 of the main body 34 measures about 4.5cm. The distance 286 between the proximal most surface of the main body 34 and the proximal bend end of the nipple receiving cavity is about 1cm. The length 284 of the nipple receiving cavity is about 3cm and the main body 34 extends distally from the distal end of the nipple receiving cavity by a distance 290 of about 0.5cm. It is noted that the foregoing dimensions are exemplary only and that any and all of these dimensions may be varied for other embodiments. Fig. 28F is an illustration of the container 60 of Fig. 28D mounted on the main body 34 of Fig. 28E. Also shown in phantom lines is a nipple 3 received in the nipple receiving cavity of the main body 34.

[00202] As noted, in order to control shape of the container and/or volume distribution of milk, container 60 may have various baffles/waffles 76. The size and/or

shape of the waffles 76 will help the container 60 conform to a curved surface. Baffles/waffles 76 can also control height or protrusion of the container locally. For example, it may be beneficial to the allow the container 60 to swell more on the top of the main body 34, in which case, less dense waffle baffling 76 will be provided at the upper portion of the container 60 as compared to that provided at the lower portion of the container 60. The bottom of the container, provided with more dense waffling 76, will minimize the swell height in the bottom portion of the container, resulting in more aesthetic, discrete changes in breast shape contour while pumping.

[00203] The container 60 can be larger than the pump housing (main body) 34, allowing a portion of the container to contact the skin of the breast 2. Also, the container 60 can be contained within the housing 34, about or adjacent pumping structure, or the container can be positioned between the pumping structure or housing and the user's breast. Further alternatively, container 60 can dual shape, cavities or compartments. Part of the container 60 may lie on top of the main body and allow collection of only a predetermined volume of milk, such as 4 oz. or some other predetermined volume. The remaining portion of the container 60 may hang below the breast 2 or to the side. This allows distribution of the milk volume to aid in discretion/aesthetics – as well as weight distribution. By keeping the extra milk volume next to the skin – there is less moment arm/weight of milk further out from the woman's chest. This can facilitate stability of the attachment of the system 100 to the breast 2 and comfort.

[00204] Alternatively, the breast pump system may allow multiple ways to collect the milk. For example, if desired for comfort or aesthetic reasons, when a user expects to express greater than 5oz milk per breast, the system 100 may allow replacement of the on pump container 60 with tubing that attaches at the same point and transfers milk to a "remote" collection vessel, such as a remote collection container worn at the waist or in a purse/bag held over the shoulder or left on a desk.

[00205] Fig. 29A illustrates a container 60c used with system 100''' that fits around the main body 34 of the system and the areola of the breast 2. In this instance, container 60c is connected to tube 34 at the bottom of the main body and one-way valve 50 is provided on the inside surface of the annular container. Fig. 29B illustrates a variant of

container 60c in which the one way valve 50 is located on the outside of the annular container. Baffles 76 are formed in the container 60c to help evenly distribute the milk, but also to facilitate folding of the container. Fig. 29C shows the one way valve and connecting portion of the container 60c having been folded upwardly along a baffle 76 line to join the one-way valve 50 to the tube 32 of system 100"'. After collecting milk in the container 6c and detaching it from the system 100"', the container 60c can be tri-folded along the other baffle 76 lines as shown in Fig. 29D, for more compact storage, such as in the refrigerator or freezer.

[00206] Fig. 30 shows another embodiment of a milk collection container 60d that is ring-shaped to encircle the breast 2 and which includes one-way valve 50. Additionally container 60d is provided with a tab or flap 78 that extends from the milk containing portion of the container 60d and that is not configured to contain any milk. Because the flap/tab 78 is separated from the milk volume containing portion, it can be written on or otherwise annotated without the potential of puncturing the milk-containing portion or otherwise contaminating the contained milk. This tab/flap 78 feature can be provided on any of the embodiments of milk collection container described herein.

[00207] Various modifications and embodiments of the breast adapter 10 can be employed in system 100 to enhance milk drawdown and extraction, improve comfort of fit, and provide other advantages. Fig. 31A shows a breast adapter that includes a rigid portion 80 where the nipple is inserted, and a flexible, resilient portion 82. Massage drivers 84 such as rollers that are driven by motor 86 to advance and retract the rollers 84 against the breast to massage it, or other mechanical equivalent, such as pumps, motor-driven lever arms or the like can provide mechanical massaging of the breast to simulate actions of a suckling baby and potentially improve milk extraction. Massage drivers 84 can be provided in more than one plane to deform the breast along more than one direction. Fig. 31B illustrates four different locations 86a, 86b, 86c, 86d where the breast 2 can be alternatively compressed and allowed to expand by using four massage drivers. These massage drivers can be actuated in many different patterns so as to effect different massage actions. More or fewer than two or four massage drivers 84 can be implemented to design various different patterns of massage.

[00208] Fig. 32A illustrates an embodiment in which the breast adapter 10B is

provided with vibration drivers 90. Vibration drivers 90 may be in the form of piezoelectric transducers that can be electrically driven by battery 48 at a desired frequency to apply vibration to the breast 2, which may help to stimulate milk letdown and/or extraction. Frequencies of vibration applied may be in the range of 100Hz to 30kHZ, typically about 250Hz.

[00209] Vibration drivers 90 may be employed on any of the breast adapter embodiments described herein. Alternatively, massage drivers 84 may be modified so at to apply vibrational frequency to the breast 2. Further alternatively, vibration drivers may be provided on a different element of the system 100 or on an additional element separate of the system 100, as opposed to providing them on the breast adapter 10. Although six vibration drivers 90 are shown in Fig. 32, more or fewer could alternatively be used (as few as one). Application of vibration to the breast 2 by vibration drivers 90 may be applied to stimulate milk down, by application of vibration for ninety second or less, for example. Additionally, the vibration applied to the breast may enhance milk flow volume and/or rate during extraction, by stimulating hormonal release and/or by the physical agitation of the breast. Vibration may also help prevent ducts in the breast from becoming clogged. Vibration can help with flow and may help prevent clogged ducts. It may also be helpful in unclogging ducts and/or increasing milk flow over that which would have been achieved without application of vibration. Vibration can also be applied to break up/facilitate flow. Various frequencies may be activated for different modes applied to achieve different ones (or combinations of) these effects. Relatively slower vibrational frequencies may be more attuned to bulk mechanical movement, while higher frequencies may actually hit resonant frequencies with smaller structures like the milk ducts. Different structures within the breast can be targeted based on frequency and amplitude of the vibrational forces applied.

[00210] Fig. 32B is a rear view (open end) of breast adapter 10 showing vibration drivers 90 such as motors or piezoelectric devices mounted on the breast adapter 10. One or more of the vibration drivers 90 can be activated at any one time, so that a pattern of activation can be run so that drivers 90 apply vibration or massaging at different times in a sequence to carry out a squeezing or massaging motion. Additionally, power and/or frequency applied to each driver 90 can be changed as desired. Fig. 32C illustrates a

handheld vibration driver 900 that is operable independently of system 100. In the embodiment shown, handheld driver 900 is a pen or other elongated implement that is configured with one or more motors or piezoelectric vibrators. Optionally, different attachments can be provided to vary the contact surface and/or shape of the distal end 902 of the implement 900 used to contact a target location 5 of the breast 2 to be vibrated or massaged. Like the embodiment of Fig. 32B, the frequency and/or power applied by implement 900 can be changed as desired by the user.

[00211] Fig. 33 illustrates an embodiment in which the breast adapter 10C is provided with heating elements 92. Heating elements 92 may be in the form of electrically resistive coils, or elements, piezoelectric transducers, or other alternative elements that can be electrically driven by battery 48 to generate heat. The heat generated is applied to the breast 2, which may help to stimulate milk letdown and/or extraction. Heating elements 92 may be employed on any of the breast adapter embodiments described herein. Heating elements 92 may be used in combination with vibration drivers 90. Although four heating elements 92 are shown in Fig. 33, more or fewer could alternatively be used (as few as one). Heating has been demonstrated in clinical studies to increase flow and speed of expression. Therefore heating elements 92 may apply heat to the breast to benefit flow increase, less clogging, less mastitis rates, etc.

[00212] The application of suction/vacuum to the breast 2 by breast adapter 10 may be varied. Fig. 34 schematically illustrates a breast adapter 10D having a suction zone 94 which is flexible and forms a seal with the breast 2 when suction is applied, while a rigid portion 96 receives the nipple and areola of the breast. Figs. 35A and 35B are back end, schematic illustrations of breast adapter 10D to show that the suction zone 94 can be applied in a continuous ring 96a or intermittently 96b. Suction to breast 2 provides more positive /additional security for attachment and sealing against the breast 2. The embodiments of Figs. 34 and 35A show rings of suction which can also function to form a seal against the breast 2. The embodiment of Fig. 35B targets suction forces against the breast 2 to ensure attachment to breast 2 so the system 100 doesn't break away and fall off, as it relies on the pumping mechanism suction cycle to maintain the seal. By intermittently applying the suction (as opposed to a continuous ring of suction), the smaller combined area where the

suction is applied requires less suction/power to be generated by the suction source to maintain the attachment.

[00213] Fig. 36 schematically illustrates an arrangement in which a first, relatively lower suction/vacuum level is constantly applied by breast adapter 10D though suction zone 96a to maintain a seal with the breast. A second, larger suction/vacuum level is intermittently applied to the space 98 surrounding the nipple 3 for extraction of milk.

[00214] Figs. 37A-37B illustrate features that may be provided in a milk collection container 60 to reduce the risk of the container not opening to receive milk due to the sides of the container sticking together, static, or some other obstructive force. In Fig. 37A, a flexible spring 370 is provided in container 60a, which keeps an open channel within the container and does not obstruct the flow, due to the loosely wound coils of the spring, and which allows the container 60a to remain flexible, as the spring 370 is flexible. In Fig. 37B, a flexible porous tube 372 provides similar functions to spring 37. Although elements 370 and 372 are shown in use in container 60a, it is noted that they can be equally as well used in any of the other embodiments of milk collection container described herein.

[00215] Fig. 38 illustrates another embodiment of breast adapter 10E in which the upper half (or other upper portion) 380 of the adapter 10E has different mechanical properties and/or composition than the lower half (or other lower portion) 382 of the breast adapter 10E. In the embodiment shown, portion 382 is flexible and portion 382 is rigid, or has less flexibility that portion 380. When used in combination with massage drivers 84, the breast 2 will be massaged at the bottom portion thereof, but not as much, or not at all along the top portion.

[00216] Fig. 39A illustrates a system employing a flexible breast adapter 10F connected to tube 32, which is supplied by suction/vacuum by pump 390. The application of squeezing action by adapter 10F to squeeze the breast 2 (whether by massage drivers 84 or other compression means) causes tube 32 to temporarily collapse (see Fig. 39B) which causes a pressure change at the nipple 3. Upon release of the compression forces against the breast 2, the tube 32 reopens (see Fig. 39C) and milk is extracted into the tube 32.

[00217] Fig. 40 illustrates a breast pump system 300 in which the pumping region 30 and container 60 are suspended on a lanyard 420 worn by the user. The length of

the lanyard 420 is adjustable, so that the user can position the pumping region 30 and container 60 lower or higher than shown, to a location that is comfortable to the user. Tubes 32 interconnect the pumping mechanism 30 with breast adapters 10, which may be provided on both breasts 2 as shown, or, alternatively, only on one breast 2.

[00218] Fig. 41 illustrates an embodiment in which, in addition to the suction/vacuum created by withdrawing compression element 36 away from tubing 32T the compression element 36 is also mechanically linked to a portion of breast adapter 10 surrounding the nipple 3. Thus, as element 36 moves away from tube 32, it also pulls on that portion of breast adapter 10, causing it to open wider and create a greater suction/vacuum around the nipple 3. As the compression element 36 compresses the tubing 32, as shown in Fig. 41, it also mechanically moves the wall of the breast adapter 10 to reduce its cross-sectional dimension.

[00219] Referring back to Fig. 2, the pressure sensor signals received by controller 52 from pressure sensor 54 can be used to plot pressure/suction (vacuum) waveforms applied by the system 100 during operation. Additionally, pressure sensor 54 signals can be used to determine when milk flow initiates, as well as the rate and/or volume of milk flow based on pressure changes resulting from milk being present in the adapter 10 and/or tube 32. Since milk is incompressible, and neglecting any losses associated with air leaks, and also assuming a majority of air has been purged from the system 100, the wall of the tube 32 as it rebounds to regain the unbiased configuration (in the absence of any milk inflow) creates a peak suction P(p) when released from the compressor element 36/38. In this state the tube 32 is deformed to have less volume within it, referred to as volume V(p). P(p) and V(p) will be maintained as a constant if there is no milk inflow. As milk inflows, the tube 32 begins to return to its natural shape. At each incremental amount of volume of milk introduced into the system 100, the suction force of the tube 32 reduces. The reduced suction level is referred to here as P(n) and the volume associated with each increment is V(n), where n equals a positive integer that starts at 1 and increases by 1 with each increment of milk received. Eventually the pressure reaches a final suction pressure P(f) that corresponds to a final full volume of V(f). Thus, via either a look-up table or by direct equation, each pressure detected can be converted to a volume. As a result, the amount of

milk passed in one cycle of the system is equal to V(f) minus V(p) which is detectable by determining P(f) and P(p). When used in detecting letdown and initial expression of milk from the breast, upon detecting the initial expression, controller 52 can control compression elements 36, 38 to change from a mode used to initiate letdown and initial extraction (which may be performed by rapid cycling of compression element 36 alone, or a combination of rapid cycling of elements 36 and 38) to an extraction mode, such as by operating elements 36, 38 to maintain a maximum predetermined suction/vacuum (e.g., -180mm HG, -200mm Hg or -220mm Hg). Upon sensing a predetermined amount of volume of milk having entered the system, the controller 54 can again change the mode of operation of elements 36, 38 to perform the expulsion phase, where element 36 seals off the breast adapter at a predetermined suction/vacuum level (e.g., -50mm Hg or -60mm Hg) and element 38 is operated to expulse the milk from region 42 under positive pressure. After the expulsion phase (when element 38 has completed its stroke), controller 54 again changes the mode of operation of elements 36, 38 to return to the extraction phase.

[00220] Cycle frequencies, amplitudes of pressure (suction/vacuum) can be controlled by controller 54 based on feedback from pressure sensor 52. These variables can be altered by the controller to optimize milk extraction, based on the estimations of milk flow and/or milk volume calculated from the pressure readings. Further, controller 52 can be programmed to end processing when milk flow senses had diminished to a predetermined flow rate, including, but not limited to a flow rate of zero, or alternatively, can be programmed to end processing at a predetermined time after a flow rate of zero has been reached. By continuing to apply suction/vacuum in an extraction phase for a predetermined time (e.g., thirty seconds, one minute, two minutes, or some other predetermined time) after flow rate has reached zero, this has the potential of stimulating the breast to increase milk production for subsequent feedings/milk extraction processes. Any of these automatic control schemes by the controller 52 can be overridden by the user, to choose different programming or operate the system 100 in manual mode via the use of controls 252.

[00221] Because the compression actuation elements 36, 38 are placed so close to the nipple 3, there is very little attenuation of the suction/vacuum waveforms generated thereby, relative to currently existing systems which typically place the suction/vacuum

pump much further from the nipple. This provides an advantage in that pressure (suction/vacuum) waveforms, such as relatively high frequency changes in suction/vacuum can be applied, which would not be possible with prior art systems, as the attenuation would render them ineffective. For example, controller 52 can be programmed to mimic a feeding baby in one instance by emulating the baby performing three quick sips or suckles on the breast, followed by a longer duration suck, and then repeating this cycle. This would involve operating the compression elements 36, 38 to apply the maximum suction/vacuum (e.g., -200mm Hg) to the breast 2/nipple 3 for a very short duration (e.g., half a second or less), followed by reducing the suction/vacuum to the minimum continuously applied suction/vacuum (e.g., -60 mm Hg), repeating this cycle two more times, then applying the maximum suction/vacuum for a more extended period (e.g., five seconds, tens seconds, fifteen seconds or more). After the extended period expires, the entire cycle could be repeated. This is only one example, as the controller 52 can be programmed to carry out any other variations of suction/vacuum cycling desired. For example, a mother could program the controller 52 to mimic the patterns of her baby when feeding, including programming the patterns of timing for pausing between sucks, how hard they suck (amount of suction/vacuum) and the frequency of sucking.

[00222] Pressure sensor 54 is preferably located in the breast adapter 10, preferably at a location near where the nipple 3 is received. Alternatively, the pressure sensor could be placed anywhere in juxtaposition with the suction/vacuum space. Further alternatively, in addition to the placement of the pressure sensor 54 in the breast adapter as illustrated in Fig. 2, one or more additional pressure sensors could be further included downstream of this location, including, but not limited to: distal of region 40, in between regions 40 and 42, proximal of region 42, but adjacent thereto, and/or distally adjacent one-way valve 50. In one embodiment, pressure sensor 54 is made as a "window" of the same material that surrounds it, so that it is sensitive to pressure changes and flexes inwardly or outwardly in response to pressure changes within the space that it is located.

[00223] Fig. 43 is an exploded illustration of system 100 according to another embodiment of the present disclosure, in which pressure sensor 54 is placed at the proximal end of the breast adapter 10 where the breast adapter 10 and tubing 32 are integrated and

form the acute angle turn so that tubing 32 extends back distally along the contour of the breast adapter 10. An opening 432, which may optionally be closed off by a visibly transparent window 434, is provided in housing 34 and configured, dimensioned and positioned to be aligned with pressure sensor 54 upon insertion of the breast adapter 10/tubing 32 unit into the housing 34 in a manner as described previously. Opening 432 (and optionally window 434) allow optical sensing of the deviations in position of sensor 54 as the sensor 54 flexes in or out as a result of pressure change in the space within the breast adapter 10/tubing 32.

[00224] Figs. 44A-44B illustrate operation of the pressure sensor 54 to detect pressure within the system. Fig. 44A shows pressure sensor 54 in an undeflected state at a known pressure. The pressure may be, for example, atmospheric pressure, or the minimum suction/vacuum level to be sustained (e.g., -60mm Hg or -50mm Hg or some other predetermined minimum suction/vacuum level), or some other known pressure. As suction/vacuum increases within the breast adapter 10, pressure sensor 54 flexes inwardly, as illustrated in Fig. 44B. The position/amount of deflection of the pressure sensor window 54 can be optically monitored by an optical monitor 440, which may include, but is not limited to: a light source, one or more fiber optic fibers, or the like. Alternatively, a metal/magnetic proximity sensor can be used, such as described with regard to Figs. 45A-45C. The amount of window deflection of the sensor 54 correlates to the pressure (suction/vacuum) within the breast adapter 10. The controller 52 receives optical signals (or electric signals converted from the optical signals of optical monitor 400), calculates the amount of deflection of sensor 54 indicated by the signals, and calculates a pressure reading from the amount of deflection calculated.

[00225] An alternative type of pressure sensor 54' that could be used is a Non-Contact DVRT®, available from Lord Microstrain Sensing Systems (Cary, North Carolina). This type of pressure sensor uses two coils 450, 452, one for sensing and the other for temperature compensation, see Fig. 45A. A metallic and/or magnetic target 454 is embedded in the material of the breast adapter 10, (or portion of tube 32, see Figs. 45B-45C) in a region 10', 32' that is relatively more flexible than the portions of the breast adapter 10/tube 32 that surround the region 10', 32', respectively. The region 10', 32' may be in any

of the locations described above with regard to sensor 54. The flexible region 10', 32' can formed as a part of the breast adapter 10/tube 32, such as by molding it to be thinner and more flexible than the surrounding areas. Alternatively, the flexible region 10', 32' can be grafted onto the breast adapter 10/tube 32, such as by forming a cutout region and then bonding (vulcanizing, or the like) a more flexible component over the cutout region. As the pressure in the breast adapter 10/tube 32 varies, the distance between the magnetic target 454 and the coils 450,452 varies, as illustrated in Fig. 45C due to the deflection of the flexible region 10', 32'. The coils 450, 452 sense displacement of the target 454. as the change in distance changes the field of inductance and results in a measurable change of either current or voltage. The change in voltage or current, is received as a signal from the sensor 54' by controller 52. The signal can be calibrated and correlated to changes in pressure within the breast adapter 10/tube 32. Signals representative of the pressure change are sent by sensor 54' to controller 52 via electrical line 456 (or, alternatively, wirelessly), where controller 52 can calculate displacement and pressure based on the signals received. Other alternative pressure sensors that could be employed include, but are not limited to: strain gauges, piezoelectric devices, or other pressure sensors currently available that can measure the pressure levels induced by the present system.

[00226] Fig. 46 is a schematic representation of a pump region 30' that may be used in any of the breast pump systems described herein, according to another embodiment of the present disclosure. Pump region 30' uses only one servo motor (or a DC motor with gearing) 44 to actuate both compression elements 36, 38. Motor 44 is mechanically connected to a drive arm 462 that rotates to drive compression elements 36, 38 alternatively. In the initial actuation of motor 44 the drive arm 462 is swept via rotation about 464 (counter-clockwise in Fig. 46) to release compression element 36 to enable tube 32 to rebound, upon complete retraction, a toggle 462 is actuated, so that the next operation of motor 44 rotates the drive arm 46 in the opposite direction (clockwise in Fig. 46) to drive the compression element 36 to compress region 40 of tube 32. The toggle 460 is again actuated at the end of this operation and the next operation of motor 44 actuates the drive arm 460 to retract compression element 38 to create the high level suction/vacuum (e.g., -200mm Hg) in the tube 32). The motor 44 controls the drive arm 460 to halt or reverse direction when the

targeted high level suction/vacuum is reached. Additionally, the entrance and exit of the drive arm into and from the zone 466 actuates toggle 460 to cause the next motion of drive arm 464 to be in the opposite direction.

[00227] The breast pump systems according to the present disclosure may optionally be designed with the capability of communicating to an external computer which may be, but is not limited to: a smartphone, a tablet computer, a laptop computer, a notebook computer or a server. Fig. 47 is a schematic representation (not to scale) of transfer of data wirelessly from controller 52 to smartphone 470. Controller 52 may include a wireless transmitter 472 that can be actuated by the user via controls 252 to send data to the external device 470 at will, as long as the external device 470 is in range of the transmitter 472. Alternatively, or additionally, a hard wire connection may be provided to send the data over the hard wire to the external device 470. Further alternatively, controller 52 can be provided with a BLUETOOTH® transmitter, so that data is automatically transmitted to the external device 470 whenever the external device 470 in in range of the BLUETOOTH® transmitter. Still further, controller 52 can be configured to automatically upload data to a server in the cloud and/or upload data to the cloud when instructed to do so by the user using controls 252. The uploaded data can then be used or shared in group studies of the data. Further, the external device 470 may be capable of downloading other customized programs for use with the breast pump system, which could be updated by crowd sourcing results from other mothers, etc. The uploaded data could also be useful for insurance companies or other entities having permission under the Affordable Care Act (and/or the user's permission) to use the data.

[00228] The external device 470 can be provided with software to customize pump functions based on data received from the controller 52, to calculate volume of milk extracted, to track expression efficiency and monitor it over time (within a single extraction session, as well as over multiple extraction sessions), keep track of inventory of previous expression sessions, dates of the sessions, and the specific containers 60 used in each individual session. This tracking can be useful for reminders to use the containers of milk 60 with a specified time, and can organize order in which the containers are to be used (e.g., first-in, first-out, or other scheme). Pump functions can be customized by varying suction

levels, altering suction waveforms (amplitude and duration of application of suction), phases of extraction or feeding times, rest programming, heating temperatures and times, vibration frequency and duration, etc. Also the battery level can be monitored and a warning provided when the battery reaches a predetermined low level of charge. The external device may also use the display 478 to display one or more photos of the mother's baby during an extraction session to increase the emotional and physical reinforcement to simulate what is provided when the baby is actually feeding.

[00229] The extraction and expulsion phases of the cycle can be repeated continuously from the beginning to ending of a extraction session. Alternatively, controller 52 can be programmed to intermittently go through a rest phase during which all suction/vacuum is removed and the breast is exposed to atmospheric pressure. In the rest phase, the breast adapter 10 can be maintained sealed against the breast 2 by the support of the system 100 by bra 130 and, optionally, with an adhesive applied to the breast adapter 10 where it contacts the breast. The rest phase can be instituted to simulate the feeding baby "taking a break" from feeding, even though the feeding session has not yet ended. Additionally, such rest phases may help prevent edema, mastitis, or other problems that might occur without them. A rest phase can be commenced after a predetermined number of extraction and expulsion phases have been carried out or after a predetermined time of carrying out extraction and expulsion phases. The rest phase may be carried out for a predetermined time (a few seconds or more) after which suction/vacuum is re-established and the extraction and expulsion phases are again carried out. Further optionally, a rest phase may be commenced upon sensing via pressure sensor 54 that milk flow has fallen below a predetermined flow rate or has fallen to zero. The rest phase can also be initiated by user at the user's discretion, as various users may want to pump for relatively longer or shorter periods between rest phases.

[00230] The connection between the container 60 and tube 32 may be monitored to ensure that the connection remains throughout an extraction and expulsion session so that milk is not lost or wasted. One way of monitoring is to make components 66 and 63 metallic (see Fig. 48) or provide tube end 56 and connector 64 with other metallic contacts that are joined to make electrically contact when container 60 is properly connected to tube 32. The

metallic connection is electrically connected to controller 52 which monitors the circuit to ensure that conductivity is maintained. If the container 60 should become dislodged or removed from the system such that conductivity is broken, the controller 52 immediately senses the disruption in conductivity and shuts down the pumping region 30.

[00231] Likewise, motors 44, 46 may be provided with heat sensor 490 and/or motion sensors 492 (e.g., tachometer or other motion sensor) to provide feedback to controller 52 as to the operating temperatures of the motors and/or movement and/or rate of movement of the motors, as illustrated in Fig. 49. This feedback can be used by the controller to shut down or slow down one or more motors if it overheats or fails to move properly when activation signals are applied.

[00232] A breast pump system according to the present disclosure may optionally be provided with a pressure relief mechanism to prevent generating too great a suction/vacuum within the system. Fig. 50 illustrates a pressure relief member 502 placed in the breast adapter 10, and also shows alternative, or additional locations for pressure relief members 502 in phantom. Pressure relief member 502 may comprises a pressure relief valve that automatically opens when a predetermined pressure that the valve is designed for is exceeded. For example, valve 502 may automatically open when the suction/vacuum pressure drops below -250mm Hg or some other predetermined suction/vacuum level. Optionally, pressure relief member 502 may be in electrical communication with controller 52, such that controller 52 could automatically activate pressure relief member based on monitoring conditions indicating that the suction/vacuum is too great, or for rapidly initiating a rest phase, or is some other problem with the system is sensed. Still further, a user can control the controller 52 manually via controls 252 to manually initiate the pressure relief valve 52. A further alternative pressure relief member 52 is a lever arm or plunger than can be electrically activated by a coil to physically break the seal between the breast adapter 10 and the breast.

[00233] Fig. 51 shows a longitudinal sectional view of a breast adapter 10' that may be used in any of the breast pump systems described herein, according to another embodiment of the present disclosure. In addition to the primary flange 510 provided for receiving a portion of the breast 2 therein, adapter 10' includes a second flange 512 that

loops or folds inwardly from the primary flange 510 and contacts the breast 2 when the breast is inserted into the system for carrying out an extraction session. Secondary flange 512 is designed to remain in contact with the breast 2 at all times during wearing of the system and preferably forms a seal with the breast. When the system has no suction/vacuum applied and up to a suction/vacuum level of the maximum suction/vacuum level applied during expulsion (e.g., 50mm Hg or 60mm Hg), a gap 514 exists between the secondary flange 514 and the primary flange 510. This is advantageous in that if the system should become disconnected from the breast 2 for any reason, any milk in the breast adapter will be captured between the flanges 510 and 512 in the gap 514, so that no milk spillage will occur. During the extraction phase, when the higher suction/vacuum is applied (e.g., -180mm Hg, -200mm Hg or -220mm Hg), the stronger suction/vacuum collapses the gap 514 and the resulting contact between the secondary flange 512 and primary flange 510 drives out any milk that may have been present in the gap 514 and into the tube 32. The collection of milk in gap 514 will occur even if the breast moves away from the flange 512 momentarily during an extraction phase, as this results in a loss of suction/vacuum and the gap 514 immediately reopens.

[00234] Figs. 52A shows a longitudinal sectional view of a breast adapter 10" that that may be used in any of the breast pump systems described herein, and which is a variation of the breast adapter 10' shown in Fig. 51. In addition to the primary flange 520 provided for receiving a portion of the breast 2 therein, adapter 10" includes a second flange 522 in the form of a flexible lip that extends radially inwardly from the primary flange 520 and contacts the breast 2 when the breast is inserted into the system for carrying out an extraction session. Fig. 52B is a rear perspective view of breast adapter 10" and tube 32 showing the surface of the flexible lip 522 in its unbiased configuration, where it extends radially inwardly and, together with flange 520, forms gap 514. Deflectable lip 522 is designed to remain in contact with the breast 2 at all times during wearing of the system and preferably forms a seal with the breast. When the breast 2 is engaged with the system, the lip 522 is deflected further inwardly by the breast contact (see Fig. 52C), thereby reducing or eliminating the gap 514 and driving milk from the gap 514 towards the nipple housing space 524. When the system breaks contact with the breast, the deflectable lip resiliently returns to

the unbiased position shown in Figs. 52A-52B and captures any excess milk left in the nipple housing space, preventing it from spilling out of the breast adapter 10".

[00235] Fig. 53A is a front, exploded view illustrating the breast adapter10 and tube 32, main housing 34 and milk container 60 according to an embodiment of the present disclosure. The main body/housing is smoothly contoured on its distal surface, so as to form a visual impression of the breast 2 when received in bra 130. A notch 530 is provided at the top of the main body 34 that is configured and dimensioned to receive the one-way valve 50 of container 60 for connection to tube 32.

[00236] Fig. 53B is a rear, exploded view of the components illustrated in Fig. 53A. This perspective better shows the contours of the main body 34, illustrating its "egg-shape" or "pear-shape" front profile. Also shown is the location of the nipple cavity 532 that is below the center of the main body 34. The proximal (rear) surface 34P of the main body 34 is concavely contoured and the breast adapter 10 follows this contour so as to cup the breast 2 as it is received and provide comfort and low profile.

[00237] Fig. 53C is a front view illustrating the breast adapter 10 and tube 32 having been installed in the main body 34. The compliant region 12 of breast adapter 10 overlies the edge of main housing 34 so that no seams or edges are present when the breast adapter is in contact with the skin of the breast 2. The proximal end of tube 32 is shown located within the notch 530, in preparation for connection of the container 60 thereto via one-way valve 50. Fig 53D is a rear view of the components shown in Fig. 53C. The smooth interface provided by the compliant region overlapping the edge of the main body 34 can be seen, and tube 32 can be seen extending up to the notch 530.

[00238] Fig. 53E illustrates a front view after attaching the container 60 to the main body 34. The container 60 in this embodiment defines a cut-out region 534 that is a spaced formed where the container is absent, such that it does not form a full ring. This cut out region 534 as shown spans about ninety degrees of the ring space, but may be as low as about forty–five degrees or as large as about one hundred thirty five degrees, or spans a region anywhere in between 45-135 degrees. The region 536 (emphasized by dotted ellipse 538 in Fig. 53E) that is not covered by the container 60 when container 60 is mounted on main body 34, better allows the container 60 to conform to the shape/contours of the main

body 34 and also provides an open area where the controls 252 and/or display 250 can be provided on the main body. Fig. 53F is a rear view of the assembly shown in Fig. 53E. Alternatively, container 60 may be provided as a full ring, as illustrated in Fig. 53G, or other container configurations, such as those described herein may be used. In Fig. 53G, container 60 is attached to main body 34 by a short tab or tubular extension 540 that interconnects tube 32 and one-way valve 50. The extension 540 positions container 60 so that a portion of main body 34 is visible on either side of the extension, so that controls 232 and/or display 230 can be positioned for viewing by the user. Extension 540 also provides an even hanging/balance to the container as it fills up with milk.

[00239] Fig. 54 illustrates an assembly of the breast adapter 10 and tube 12 in the main body 34 according to another embodiment of the present disclosure. In this embodiment, flanges 12F are provided to extend distally from the overlap of compliant region 12 on the edge of main body 34. The flanges 12F also taper distally to form a smoother transition with the breast 2 when the system 100 is mounted on the breast 2, thereby making the system 100 less visible or noticeable when worn by a user. The tapered, thin flexible flange 12F extends distally from the outer edge of the compliant region 12 that snaps around the circumference of the main body 34 of system 100. Flexible flange 12F is preferably, but not necessarily integrally formed with the compliant region 12 and breast adapter 10.

[00240] Figs. 55A-55E illustrate the interaction between compression elements 36, 38 and resilient tubing 32 and a pumping sequence according to another embodiment of the present disclosure. In this embodiment, compression element 36 comprise a short length compression effector 36A (in this case, compression effector 36A has the same length or diameter of the shaft of the compression element 36 and may optionally be simply the free end of the shaft), to reduce the amount of force necessary to function as a shut off valve by sealing the region 40. The compression element 38 in this embodiment moves horizontally (in the Figs, but could be a different direction depending upon the orientation of the system) along the length direction of the tube 32. Thus rather than moving against the tubing 32 radially inwardly or retracting away from the tubing 32, compression element 38 rolls or slides along the tube to change the suction/vacuum levels in the system.

[00241] The compression surface of the compression element 38 maintains a constant distance 550 from the anvil surface 232A of the channel 232 that the tube is positioned in. This maintains the tube 32 in an unsealed configuration, such that the tube portion that is between the compression element 38 and anvil surface 232A is maintained in a collapsed, but not sealed condition, see 552. Fig. 55A shows an orientation in which the minimum suction/vacuum (e.g., -60mmHg or -50mm Hg, or some other predetermined minimum) is maintained against the breast. The compression element 36 is fully retracted away from the tube, so that the tube is not compressed in region 40. In this phase, the majority of the tubing region 42 is compressed, but not sealed off.

[00242] To move the system to an active suction phase, where the maximum predetermined suction/vacuum is generated (e.g., -200mm Hg, -220mm Hg or some other predetermined maximum suction/vacuum level) the compression element 36 maintains it position and the compression element 38 is slid or rolled in a direction away from the breast to enable tubing region 42 to return to its uncompressed configuration and generate suction/vacuum, see Fig. 55B. The compression element 38 can be continuously controlled by controller 52 using feedback from pressure sensing the suction/vacuum space, to move toward or away from the breast in order to maintain the predetermined maximum suction/vacuum level, which can be programmed into the controller for use in the feedback loop used to maintain the maximum suction/vacuum. Movement toward the breast decreases the suction/vacuum while, conversely, movement away from the breast increases the suction/vacuum. Fig. 55C shows the compression element 38 having been returned to the position shown in Fig. 55A to re-establish the predetermined minimum suction/vacuum, in this case, -60mm Hg. The change in volume within the tubing between the distal end of compression element 38 and the breast 2 when moving from the position of element 38 in Fig. 55B to the position in Fig. 55C is the volume of milk expressed during that cycle, assuming no air leaks to the system. Thus by knowing the inside diameter of tube 32 and the relative positions of compression element 38 (as tracked by controller 52), an estimate of the volume of milk that is moved proximally of the compression element 38 can be calculated by the controller 52. Further, the calculated estimates of volume can be displayed on the system display 230, wirelessly outputted to an external computing device such as a

smartphone or other computer, and/or uploaded to the Internet, such as to a web-based cloud server..

[00243] As the predetermined minimum suction/vacuum level is reached, the compression element 36 is actuated and driven to seal off the tubing in region 40, as shown in Fig. 55D. Note that the tubing 32 in contact with element 38 is not sealed off, see 552. Once the tube 32 is sealed off by element 36 so that the minimum suction/vacuum level is maintained against the breast 2, compression element 38 is rolled or slid toward the breast (and toward element 36) to transfer the volume of milk located between the elements 36 and 38 distally of element 38 and out through one-way valve 50 into the collection container 60, as illustrated in Fig. 55E. The movement of element 38 toward element 36 generates a positive pressure in the space between elements 36 and 38 that drives the milk out through the partially opened tube 552, 32 and proximally of the element 38. After completing the expulsion phase illustrated in Fig. 55E, the compression element 36 is retracted while maintaining at least the minimum suction/vacuum level against the breast by adjusting the element 38 as needed as the cycle returns to Fig. 55A in preparation for another extraction phase.

[00244] The amount of dead space in the system, e.g., the summation of spaces 92 and 96 in Fig. 12, impacts the size and characteristics of the tubing 32 needed to generate sufficient suction/vacuum levels. A relatively larger dead space requires a relatively larger inside diameter of tube 32 and/or active tubing length (i.e., the length of tube 32 that is compressed and released to generate suction/vacuum, such as the region 42 in Figs. 55A-55E). Additionally, the dead space will change as the suction/vacuum level is increased and the nipple 3 is sucked further into the nipple reception cavity of the breast adapter 10, thereby reducing the volume of the dead space somewhat. Expression of milk decreases the active suction/vacuum level applied. This decrease in suction/vacuum can be measured to estimate the volume of milk having been expressed. Further, the pressure sensor used for suction/vacuum level measurement can be used in an active feedback loop by the controller 52 to adjust the compression element 38 (or, in other embodiments, both elements 36 and 38) to maintain the desired, predetermined maximum suction/vacuum level. The maximum suction/vacuum level that the system is capable of generating is governed by the properties

of the tube 32, including inside diameter, wall thickness, material and durometer of the tube 32. In the embodiment of Figs. 55A-55E, the tubing 34 is configured with a capacity to generate a suction/vacuum that exceeds the predetermined maximum suction/vacuum level.

[00245] When there is no flow of milk in the tube 32, the pumping region 32 may lose the ability to cycle through the full range of predetermined suction/vacuum pressures, and will maintain a lower mean suction/vacuum pressure. For example, when flow discontinues, the system may not be able to cycle up to -60mm Hg, but, instead alternates between -200mm Hg and -90mm Hg. Controller 52 can be programmed to review pressure readings from a predetermined number of previous cycles and evaluate at least one of: the pressure peaks of the waveforms of the predetermined number of previous cycles; or calculate and compare the mean suction/vacuum pressure levels of the predetermined number of previous cycles. If the pressure has not reached the predetermined minimum suction/vacuum level (e.g., -60mm Hg) during the predetermined number of previous cycles, this indicates that the milk expression and expulsion session has ended, as there is no more flow in the tube 34. When such an event is reached, the controller 52 may be programmed to automatically shut off the system 100. This routine would not be active during the letdown phase, e.g., during the first four minutes (or other predetermined time period measured from commencement) of the pumping cycle as the user is in the letdown phase and is not expressing milk. When the system automatically shuts off the controller can indicate on display 250 the pumping session has ended and/or send an alert to an external computer such as a smartphone or other device to indicate that the pumping session has ended. Additionally, the estimate volume of milk pumped during the session can be displayed on the display 250 and/or sent to an external computer.

[00246] Alternatively a flow sensor 560 may be provided in the system (see Fig. 56) to enable the user to check in real time how much milk has been pumped, as a real time real running total of milk volume can be estimated and displayed on display 250 and/or sent to be displayed on a smartphone or other external computer. The controller 52 can be programmed such that, when monitoring the flow sensor 560, it will automatically shut off the system after a predetermined time period (e.g., two minutes, four minutes, or some other predetermined time period) has passed during which there has been no milk flow.

[00247] In addition to sensing when milk expression stops or when collection vessel 60 is full, the system 100 can also auto detect when full let down occurs. The pump region 30 may start with a preprogrammed cycle that is intended to assist in letdown. This cycle is typically faster in frequency and shallower in vacuum amplitude than that of the expression cycle. The initial let down cycle may be modified by a user to fit the user's personal preferences via a "learning" or "program" mode in the controller 52 of system 100. While the system is going through its initial "letdown" cycle, it can track the pressure changes in the breast area. Once milk flows, it will affect the pressure positively. Upon such a change – with appropriate delays, checks, confirmation, the program can automatically switch to a deeper, fuller expression mode where the cycle typically slows down and pressure (vacuum) amplitude increases. Additionally, while in expression mode, the system can monitor pressure changes. Knowing compression elements 36, 38 positions, speed, power, and pressure generated (immediate, history, expected) the system can monitor and calculate milk expression flow or some corollary measure that is relative to flow. The system can then optimize its action (frequency, pressure profile, etc.) to optimize milk expression.

[00248] The controller 52 of the system 100 can optionally be programmed to "overshoot" some meaningful amount of pressure or frequency to help "push" the demand experienced by the mother and help enhance the breast's mechanism to increase supply.

[00249] By providing a tube 32 designed to create a maximum value that exceeds the predetermined maximum operating suction/vacuum, this enables the system to have enough reserve capacity so that, after the pumping region 30 has finished cycling (either because the user manually shuts it off or the cycles were stopped automatically though feedback because there was no more milk expressed), the compression elements 36, 38 have reserve travel remaining so that they can be further operated to further compress the tube 32 in order to return the suction/vacuum pressure of the system to zero so that the user doesn't feel the feeling of removing a suction cup from the breast 2, but rather the system readily detaches or falls off, without any remaining suction resisting removal. This operation to return the suction/vacuum to zero can be automatically carried out as part of the shutdown process of the system. The system 100 can be provided with an indicator, such as

an indicator light, audible indicator, or other indicator readily interpreted by the user to indicate to the user when the suction/vacuum has been removed after shutdown. Fig. 57 illustrates an embodiment of system 100 according to the present disclosure which has been provided with an indicator light 570. When the system 100 is manually shut down by the user, the indicator light changes from a green color to a red color, for example, and after a predetermined time (e.g., two seconds or some other predetermined time) the red light stays on while the system operates the pumping region 30 to return the pressure level to zero. Once the pressure returns to zero, the indicator light turns off, indicating to the user that it is okay to remove the system 100 from the breast 2.

[00250] Fig. 58A is a front, exploded view of system 100 according to another embodiment of the present disclosure, illustrating breast adapter10 and tube 32, main housing 34 and milk container 60 according to an embodiment of the present disclosure. The main body/housing is smoothly contoured on its distal surface, so as to form a visual impression of the breast 2 when received in bra 130. A notch 530 is provided at the top of the main body 34 that is configured and dimensioned to receive the one-way valve 50 of container 60 for connection to tube 32. Container 60 is provided with baffles 76 to help maintain the shape of the container 60 to conform to the main body 34 as it fills with milk.

[00251] Fig. 58B is a front view illustrating the breast adapter 10 and tube 32 having been installed in the main body 34. The compliant region 12 of breast adapter 10 overlies the edge of main housing 34 so that no seams or edges are present when the breast adapter is in contact with the skin of the breast 2. The proximal end of tube 32 is shown located within the notch 530, in preparation for connection of the container 60 thereto via one-way valve 50.

[00252] Fig 58C illustrates the process of attaching the container 60 to the system. As the extension 62 is inserted into the distal end 66 of tube 32 so that detents 64 are received in mating receptacles in the distal end 32 to connect (with optional inclusion of one or more seals such as O-rings, or the like) the container 60 and tube 32 with a liquid-tight, airtight connection, the container 60 is fitted over the main body 34, so it conforms closely to the shape of the front surface of the main body, so as to be well-concealed within a bra. Container 60 in this embodiment is not continuously concentric, but forms a cutout

region 536 (at the bottom portion of the container in this embodiment) to allow the container 60 to assume a curved concave surface to follow the convex surface of main body 24 without wrinkling or buckling. The cutout region may be wedge-shaped, as shown and span about 25 to 45 degrees of the circular shape of the container 60 when it is laid flat.

[00253] Fig. 58D illustrates the assembled system 100, with the container having been connected and fitted over the main body 34 to conform to the contour thereof. Fig. 58E shows the system 100 with the container 60 having been partially filled with milk 4. The baffles 76 are illustrated as facilitating the even distribution of milk 4 in the container 60 as the container maintains its original configuration following the contours of the front surface of main body 34.

[00254] Fig. 59A is a front, exploded view of system 100 according to another embodiment of the present disclosure, illustrating breast adapter 10 and tube 32, main housing 34 and milk container 60 according to an embodiment of the present disclosure. This embodiment is essentially the same as the embodiment of Figs. 58A-58E, except that container 60 is provided with graduation markings 590 configured to accurately measure the amount of milk collected. In the embodiment shown, the graduation markers 590 indicate 1 oz., 2 oz., 3 oz. and 4 oz., respectively. The markers 590 may, of course, be varied to indicate different volume levels, if desired.

[00255] Fig. 59B is a front view illustrating the assembled system 100, with the container 60 having been connected and fitted over the main body 34 to conform to the contour thereof. The container 60 is further shown as having been partially filled with milk 4, with the graduation markers being viewable to estimate that the volume of milk 4 collected is about three and a half ounces. The baffles 76 are illustrated as facilitating the even distribution of milk 4 in the container 60 as the container maintains its original configuration following the contours of the front surface of main body 34.

[00256] Fig. 59C is a rear, exploded view of system 100 of Figs. 59A-59B, illustrating the nipple receiving cavity 702 of breast adapter 10 that is configured to receive the nipple 3 while leaving a vacuum-suction space between the nipple 3 and the breast adapter. Also visible from this rear view is the channel 430 in main body 34 that is configured and dimensioned to receive tube 32. The graduation markers 590 on container 60

are also visible from the rear view. The exploded view of Fig. 59C illustrates how the components of the system 100 can be assembled and disassembled. In the embodiment shown, breast adapter 10 is formed integrally with tube/conduit 32 as a single unit. As noted previously, adapter 10 and tube 32 could be formed separately and then joined to form an airtight, liquid-tight connection. In addition to containing the pumping mechanism 30, housing 34 includes a receptacle 230 configured and dimension to receive the breast adapter 10 and snugly hold it in the operable position shown in Fig. 1. Housing 34 also includes a channel 232 configured and dimensioned to receive tube 32 and hold it in proper position so that it can be acted upon by compression elements 36, 38 as intended. Tube 32 can be received in channel 232 with a snap or friction fit, for example, so that it is held in alignment with the compression elements 36, 38, with the closest surface to the compression elements 36, 38 being positioned for movement under compression and resilient return to an uncompressed state, while the opposite surface is held stationary against a surface of the channel 232.

[00257] Fig. 59D is a partially exploded rear view of the system 100 of Fig. 59A, showing the breast adapter 10 and tube 32 having been installed in the main body 34. The compliant region 12 of breast adapter 10 overlies the edge of main housing 34 so that no seams or edges are present when the breast adapter is in contact with the skin of the breast 2.

[00258] Fig 59E illustrates the process of attaching the container 60 to the tube 32 and main body 34. Note that the distal end of the tube 32 is not visible from this view. As the extension 62 is inserted into the distal end 66 of tube 32 so that detents 64 are received in mating receptacles in the distal end 32 to connect (with optional inclusion of one or more seals such as O-rings, or the like) the container 60 and tube 32 with a liquid-tight, airtight connection, the container 60 is fitted over the main body 34, so it conforms closely to the shape of the front surface of the main body, so as to be well-concealed within a bra. Container 60 in this embodiment is not continuously concentric, but forms a cutout region 536 (at the bottom portion of the container in this embodiment) to allow the container 60 to assume a curved concave surface to follow the convex surface of main body 24 without wrinkling or buckling. The cutout region may be wedge-shaped, as shown and span about 25 to 45 degrees of the circular shape of the container 60 when it is laid flat.

[00259] Fig. 59F is a rear view of the system 100 of Fig. 59A after having been assembled. This rear view shows another perspective of how the container 60 closely conforms to the curvature of the front surface of the main body 34. Fig. 59G is a rear view of the system 100 of Fig. 59F after having collected milk 4 in the container 60. This rear view shows another perspective of how, even after collecting milk to near full capacity, the container 60 continues to closely conform to the curvature of the front surface of the main body 34.

[00260] Fig. 60 illustrates a valve feature that may be provided on any of the systems described herein, according to an embodiment of the present disclosure. As the compression element 38 moves from the position shown in solid lines to the position shown in phantom lines to reduce the vacuum from the high operating vacuum level for extraction (e.g., 200mm Hg or the like) to the low vacuum level (e.g., 60mm Hg or the like) to be maintained against the breast 2 during the pumping (expulsion) phase, a controlled valve may be provided in order to facilitate the flow, working together with the compression elements 36, 38. In the embodiment shown in Fig. 60, a valve mechanism 590 is provided to operate the one-way valve 50 to reduce the resistance to flow of the breast milk. In this embodiment, when the compression element 38 nears the end of its compression stroke (as shown in phantom in Fig. 60), it contacts pivot arm 592, forcing the contacted portion down and pivoting the opposite, non-contacted portion about pivot joint 592 to drive pushrod 594 upwardly. Pushrod 594 in turn pushes against lever arm 596 which rotates about pivot joint 599 forcing the free end of lever arm 596 against one-way valve to temporarily open it. The valve 50 closes when the compression element 38 retracts. The compression element 38 retracts in response to the pumping mechanism operating in its desired range of 60mm Hg to 220mm.

[00261] Fig, 61 is a longitudinal sectional view of breast adapter 10 and a portion of tube 32 illustrating a pressure relief valve according to an embodiment of the present disclosure. In this embodiment one or more channels 920 may are provided in the wall of the breast adapter 10 to provide fluid communication between an external vent 922 and a valve 924, that together, form the pressure relief valve. Valve 924 as shown is in the form of a flap that can deflect. Flap 924 has a predetermined spring constant that keeps it in

the closed configuration shown until a predetermined maximum suction value has been reached, such as -200mm Hg, -220mm Hg, or some other predetermined maximum suction level. Once the maximum suction level is exceeded, flap 924 opens to release vacuum from within the breast adapter 10 as outside air is ported through the vent 922 and channel(s) 922. Flap 924 closes automatically once the suction level drops back down to less than the predetermined maximum suction level.

[00262] Optionally, the nipple receiving portion of the main body 34 may be configured for visualization therethrough so that a user, or a second person can confirm proper placement and alignment of the nipple 3' centrally within the breast adapter 10. The breast adapter portion receiving the nipple is also made visually clear, like that of the main body, to facilitate this visualization. Milk flow may also be visible through this clear window 930, see Fig. 62. Additionally, milk flow can be observed through the tube 32 and or container 60, which are also see through.

[00263] In some embodiments, breast adapter 10 has features to prevent the breast from becoming sweaty or too hot, for example, a large portion of the non-sealing portion of the breast adapter can be a breathable fabric, have vent holes, or be made of a cooling gel. The main body 34 in some embodiments has features that also prevent the breast from becoming sweaty or too hot, for example, vent holes in the main body release heat from the main body, a cooling fan provides a flow of air to cool the main body or the breast, or has a cavity in which a replaceable cooling pack is placed.

[00264] Fig. 63 is a schematic representation of a portion of a system 100 that includes a main body 34 that can be peeled back or partially separated from the breast adapter 10 to allow the user or another person to see through the breast adapter 10, while maintaining the seal of the breast adapter 10 against the breast 2. The rear edge portion 34E of the main body may be made flexible to allow the peel back action.

[00265] The breast pump systems 100 of the present disclosure may be paired and used in parallel (or serially) when mounted to both breasts 2 of a user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base

unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. Fig. 64 is a perspective view showing a pair of breast pump systems 100, according to an embodiment of the present disclosure.

[00266] Fig. 65 shows a user wearing two breast pump systems 100 on breasts 2, the systems being supported by a bra 130. Fig. 66 shows the ability of the systems 100 to be used by the user while reclined or lying in a supine position. Fig. 67 shows the user wearing a blouse over the breast pump systems 100 and bra 130, demonstrating the degree to which the present system can be concealed, as the systems are barely noticeable, giving an elegant, natural look. Fig. 68 is the view of Fig. 67 with a portion of the blouse shown in phantom to show the systems 100 and bra 130.

[00267] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure as described herein.

CLAIMS

That which is claimed is:

1. An automated method of pumping milk from a breast, the method comprising:
forming a seal between a breast pump system and the breast;
pumping milk expressed from the breast through a conduit; and
maintaining at least a latch suction on the breast throughout a pumping session.

2. The method of any preceding claim, wherein expansion of the conduit generates suction, the suction created solely by recoil of the conduit having been previously compressed.

3. The method of any preceding claim, wherein expansion of the conduit is supplemented by driving the expansion with a driver.

4. The method of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second latch suction level is maintained against the breast, the second latch suction level being lower than the first suction level.

5. The method of any preceding claim, further comprising compressing at least one portion of the conduit and reducing compression of the at least one portion, wherein the returning of the at least one portion toward its uncompressed state generates suction sufficient to extract milk from the breast.

6. The method of any preceding claim, wherein pumping involves compressing a second portion of the conduit to generate a positive pressure.

7. The method of any preceding claim, further comprising providing a controller that control pumping to assume a desired waveform.

8. The method of any preceding claim, further comprising providing a one-way valve between the conduit and the container to prevent backflow of milk and air into the conduit.

9. The method of any preceding claim, further comprising providing a housing, wherein the storage container is positioned within the housing.

10. The method of any preceding claim, further comprising providing a housing, wherein the storage container is positioned on an external surface of the housing and against a bra of a user.

11. An automated system for controlling pumping cycles to pump milk from a breast, the system comprising:

a breast adapter configured and dimensioned to form a seal with the breast;

a storage container for storing the milk pumped from the breast; and

a conduit in fluid communication with, and interconnecting the adapter and the storage container;

wherein at least a latch suction is maintained throughout a pumping session.

12. The system of any previous claim, further comprising a driving mechanism configured to compress a region of the conduit.

13. The system of any previous claim, further comprising structure attached to the conduit to facilitate expansion of the conduit.

14. The system of any previous claim, further comprising a controller configured to control operational settings of the system.

15. The system of any previous claim, of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and

wherein, during expulsing, a second latch suction level is maintained against the breast, the second latch suction level being lower than the first suction level.

16. The system of any preceding claim, further comprising a one-way valve, the one-way valve preventing backflow of milk into the conduit.

17. The system of any preceding claim, wherein pumping involves compressing a second portion of the conduit.

18. The system of any preceding claim, wherein the driving mechanism comprises a roller configured to roll against the conduit, in directions along a length of the conduit.

19. The system of any preceding claim, wherein pumping to pump the milk against gravity.

20. The system of any preceding claim, further comprising a battery configured to supply power for operation of system.

21. The system of any preceding claim, further comprising a pressure sensor configured to sense pressure.

22. The system of any preceding claim, wherein the controller adaptively controls movements with input from a feedback loop established with a pressure sensor.

23. The system of any preceding claim, further comprising at least one vibration element configured to apply vibration to the breast.

24. The system of any preceding claim, further comprising at least one heating element configured to apply heat to the breast.

25. The system of any preceding claim, wherein the conduit includes a lower surface defining a V-shape cross-section.

26. The system of any preceding claim, wherein the milk flow is sensed and the controller automatically changes application of suction from a cycling of suction during a letdown phase to a sustained application of suction during an extraction phase.

27. The system of any preceding claim, wherein pumping is performed without application of any mechanical motion to the breast or nipple.

28. The system of any preceding claim, wherein said at least one operational setting is selected from the group consisting of: at least one suction level setting, suction waveform definition, extraction phase time, threshold milk volume estimate per extraction phase, expulsion pressure, rest phase timing, heating temperatures, heating times, vibration frequency and vibration times.

29. The system of any preceding claim, wherein at least one operational and sensed parameters from the external computer is uploaded to a cloud server.

30. The system of any preceding claim, further comprising a non-contact pressure sensor.

31. The system of any preceding claim, further comprising a storage container, wherein the storage container is positioned around the breast.

32. The system of any preceding claim, further comprising a housing and a storage container, wherein the storage container is contained within the housing.

33. The system of any preceding claim, further comprising a housing and a storage container, wherein the storage container is positioned externally of the housing and against a user's bra.

34. The system of any preceding claim, further comprising a housing, wherein the housing includes one or more transparent sections so that one can see though the housing.

35. The system of any preceding claim, wherein the system defines a natural breast profile.

36. The system of any preceding claim, wherein the conduit is conveniently removable from the system and replaceable.

37. The system of any preceding claim, further comprising control buttons conveniently located on an external surface of the system.

38. The system of any preceding claim, further comprising a controller configured to alter pumping when the user is lying down, bending over, or in environments such as a bumpy ride, as in an automobile or airplane trip.

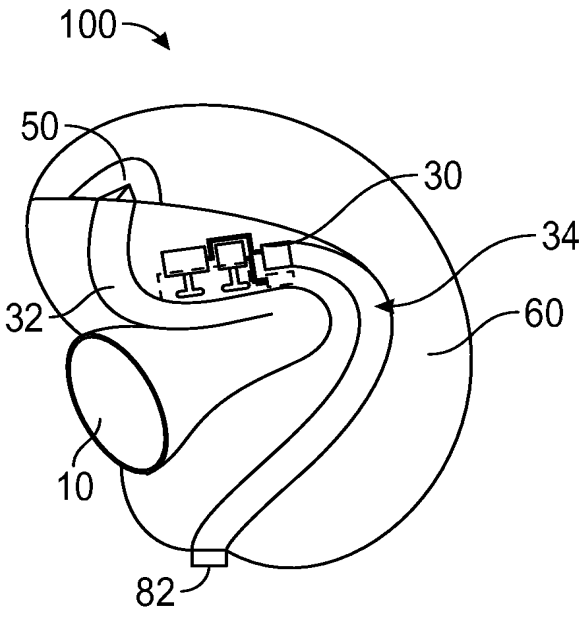


FIG. 1

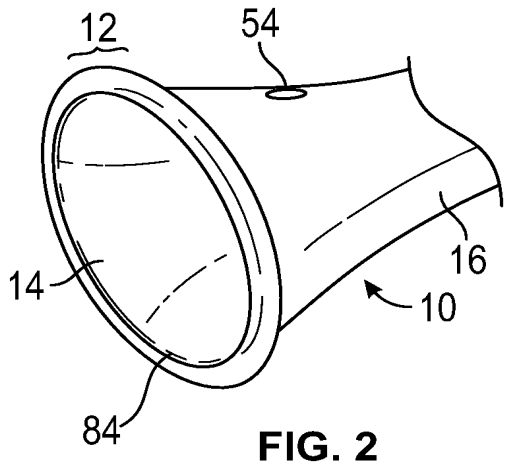


FIG. 2

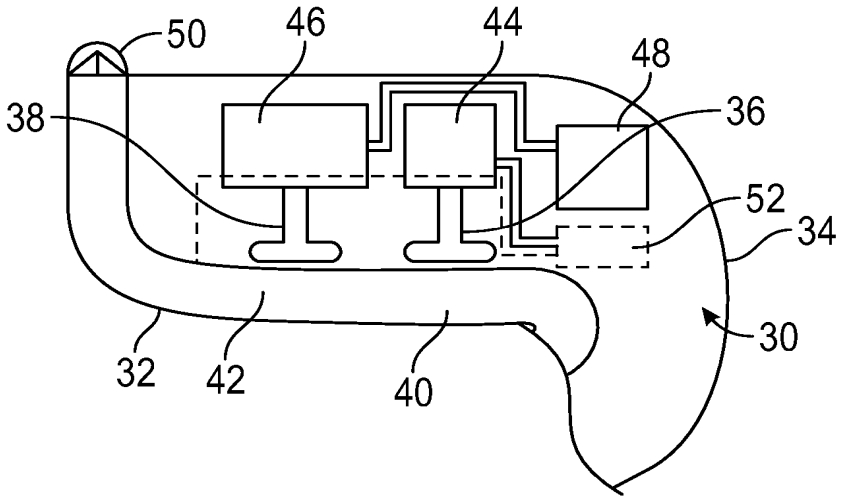


FIG. 3

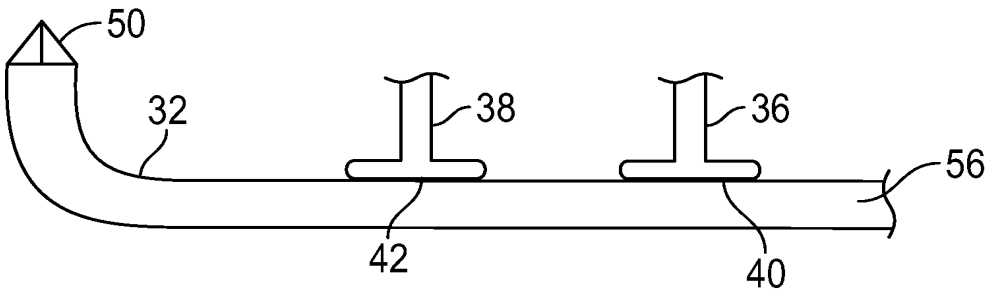


FIG. 4A

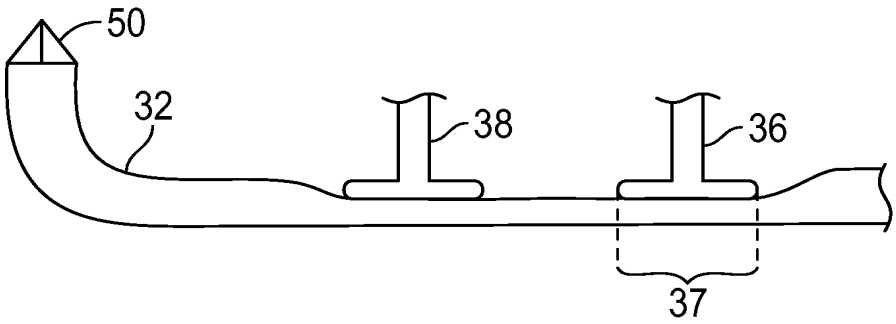


FIG. 4B

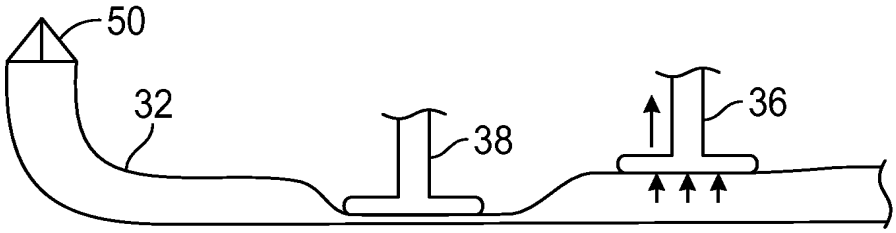


FIG. 4C

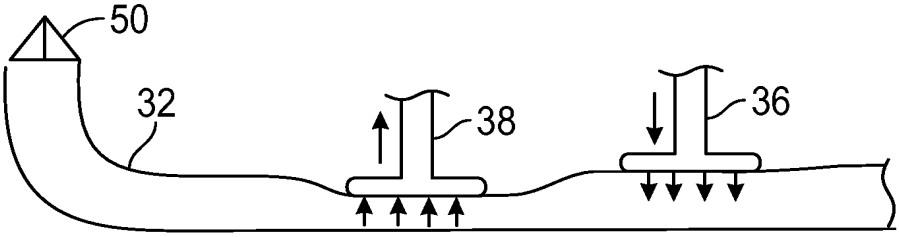


FIG. 4D

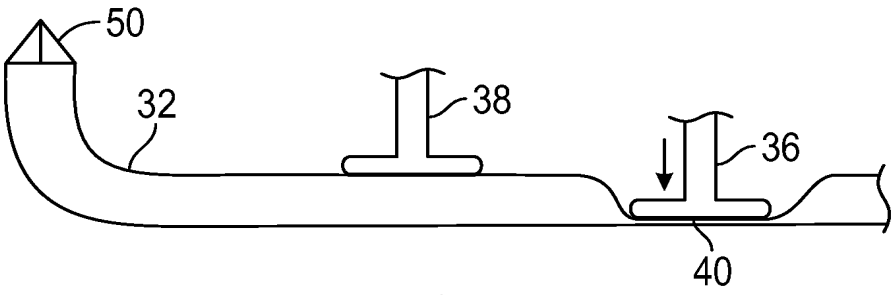


FIG. 4E

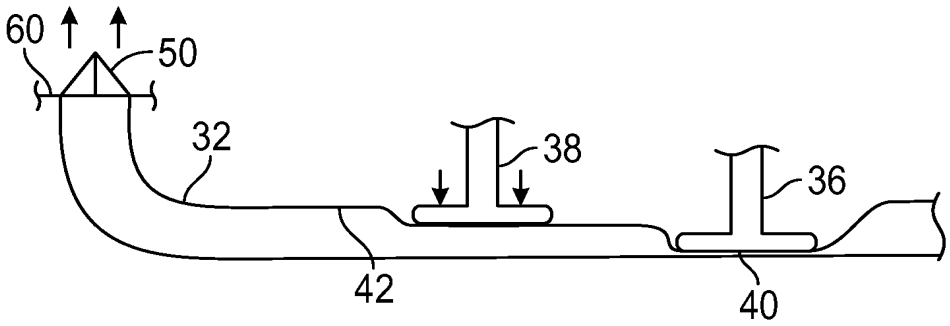


FIG. 4F

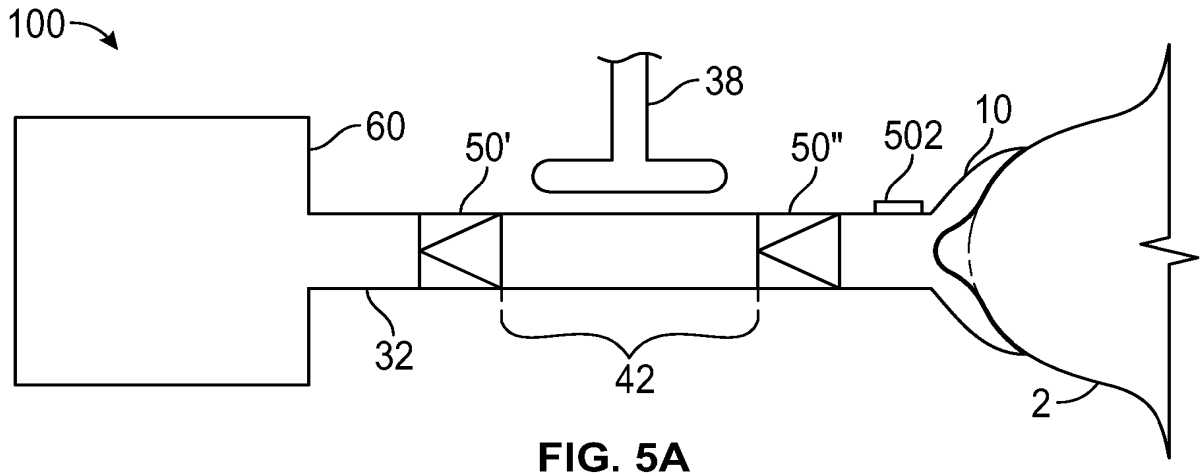


FIG. 5A

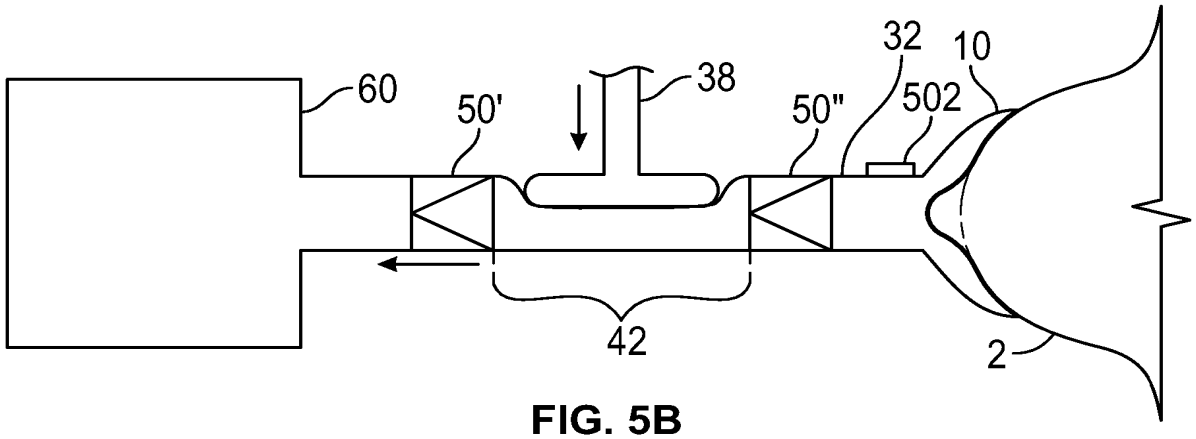


FIG. 5B

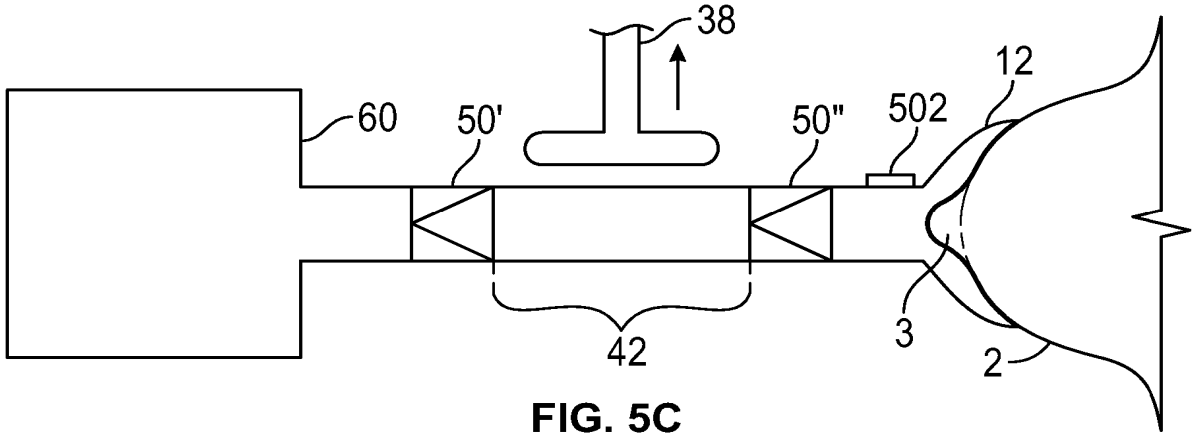


FIG. 5C

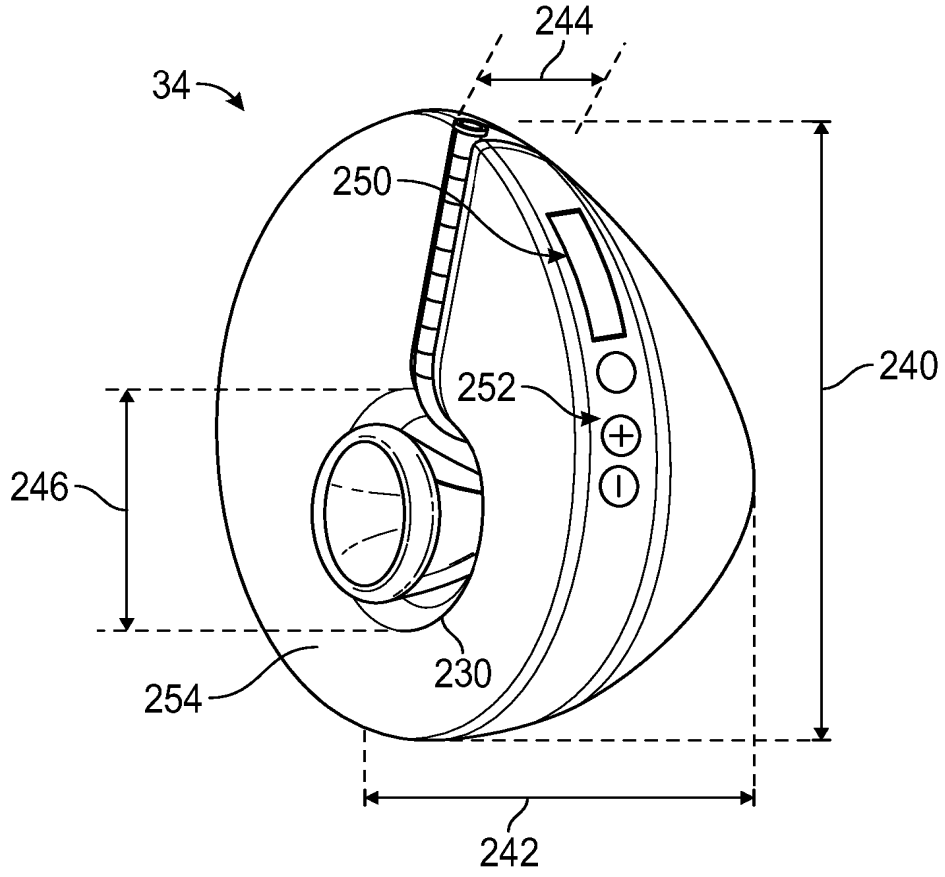


FIG. 6

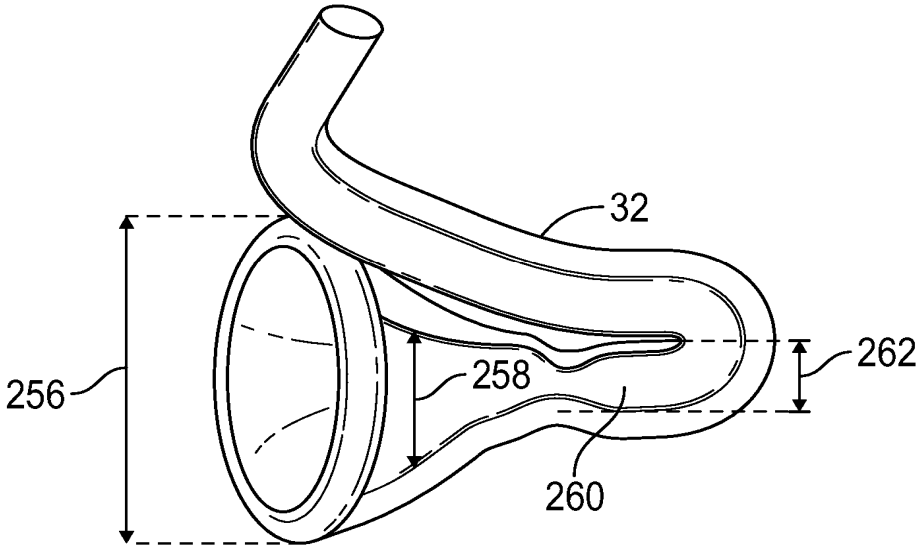


FIG. 7A

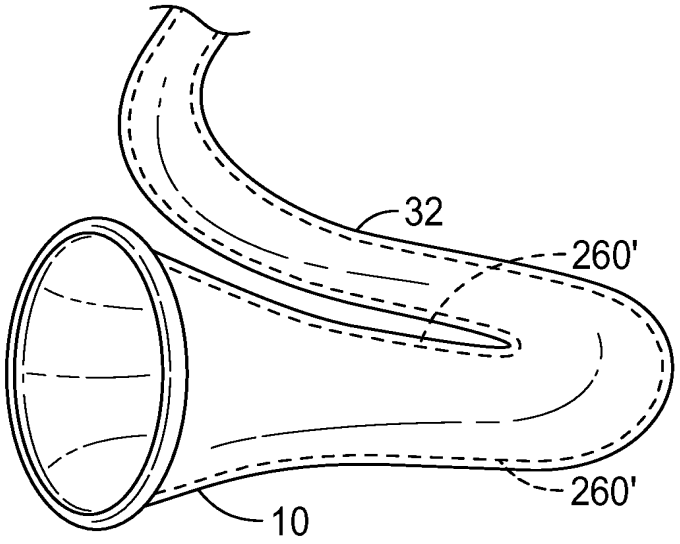


FIG. 7B

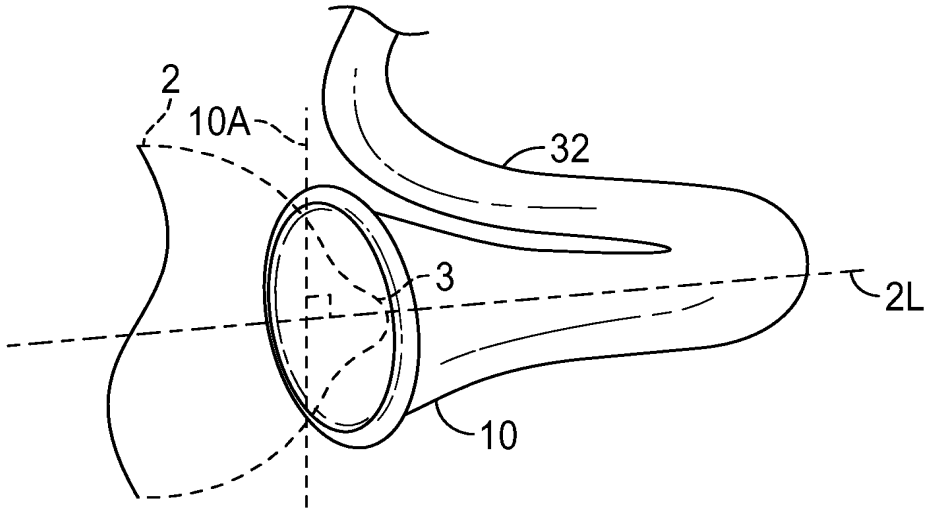


FIG. 7C

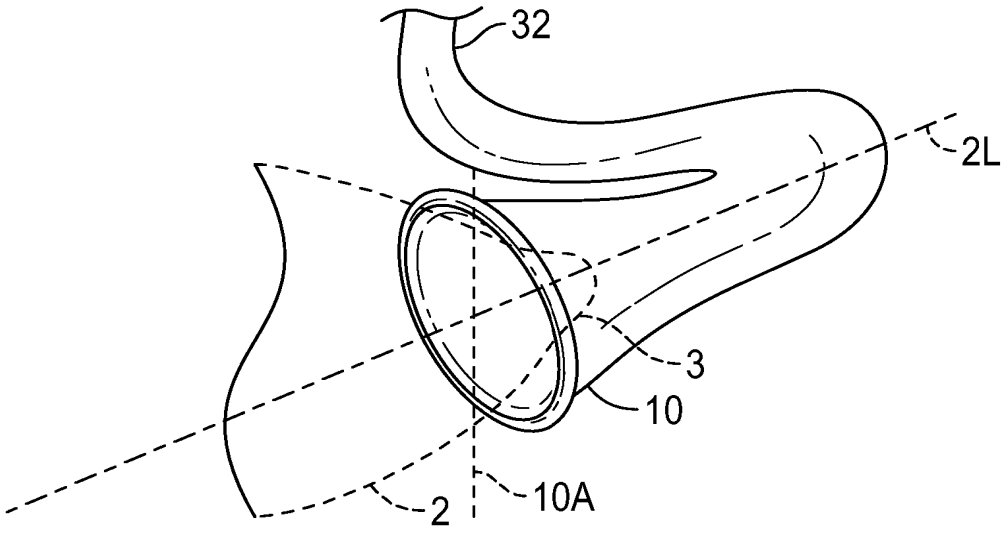


FIG. 7D

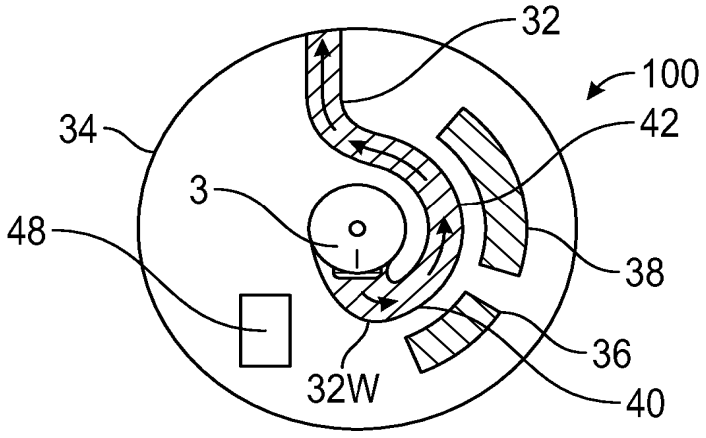


FIG. 8A

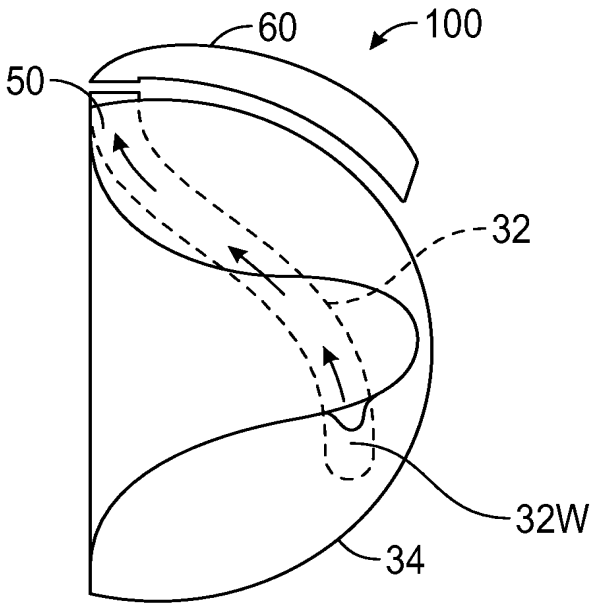


FIG. 8B

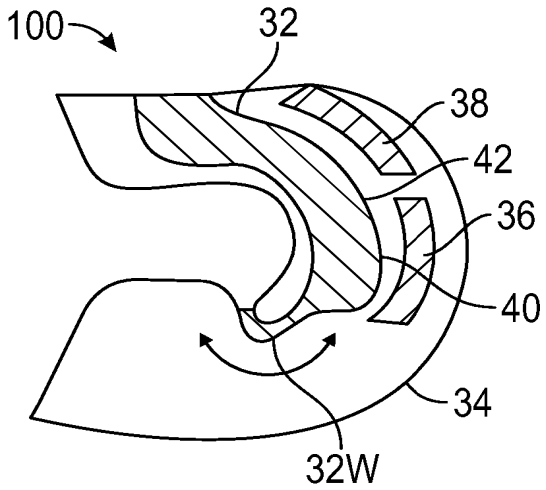


FIG. 9

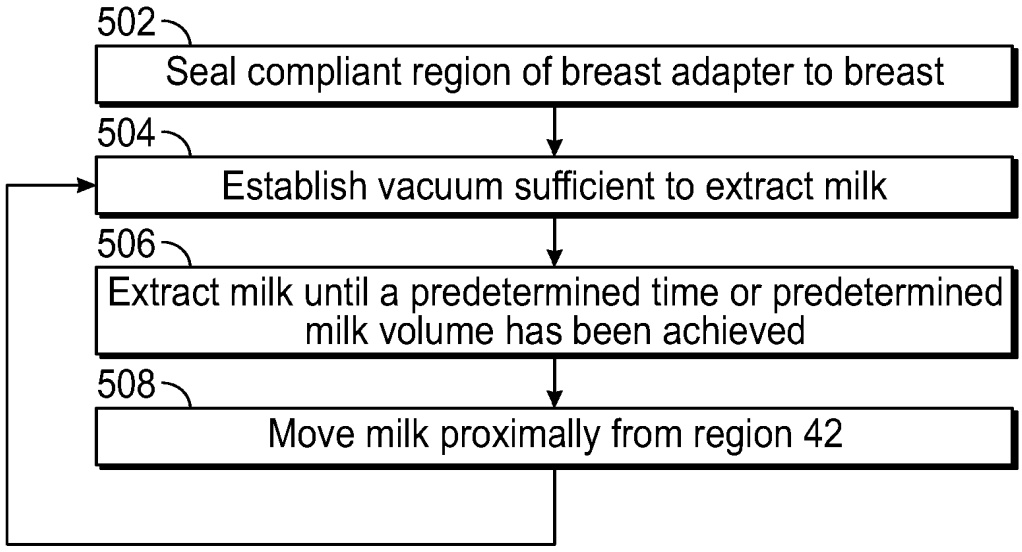


FIG. 10

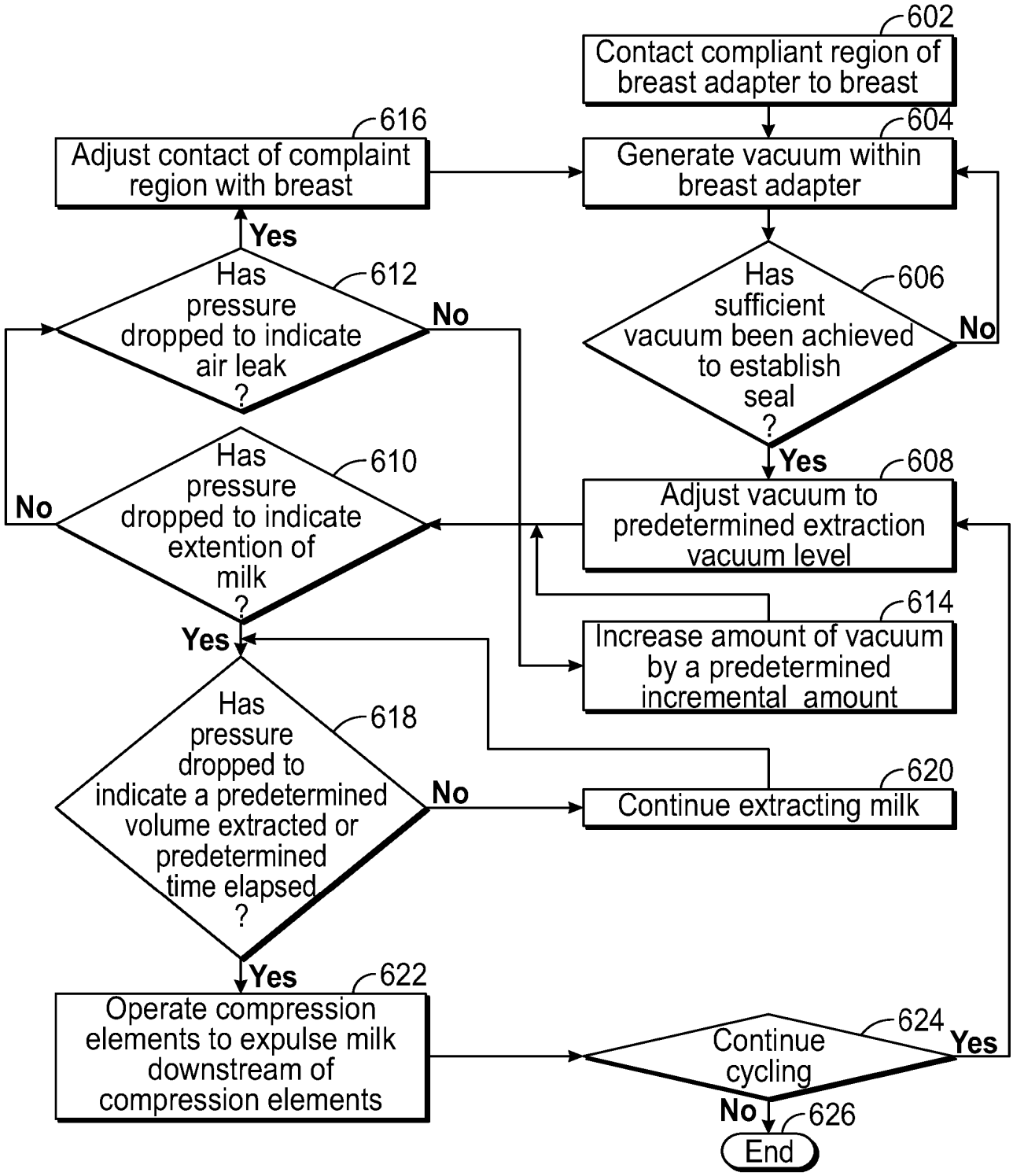

602
Contact compliant region of breast adapter to breast
604
Generate vacuum within breast adapter
606
Has sufficient vacuum been achieved to establish seal ?
No
Yes
608
Adjust vacuum to predetermined extraction vacuum level
610
Has pressure dropped to indicate extention of milk ?
No
Yes
612
Has pressure dropped to indicate air leak ?
No
Yes
616
Adjust contact of complaint region with breast
614
Increase amount of vacuum by a predetermined incremental amount
618
Has pressure dropped to indicate a predetermined volume extracted or predetermined time elapsed ?
No
Yes
620
Continue extracting milk
622
Operate compression elements to expulse milk downstream of compression elements
624
Continue cycling
Yes
No
626
End

FIG. 11

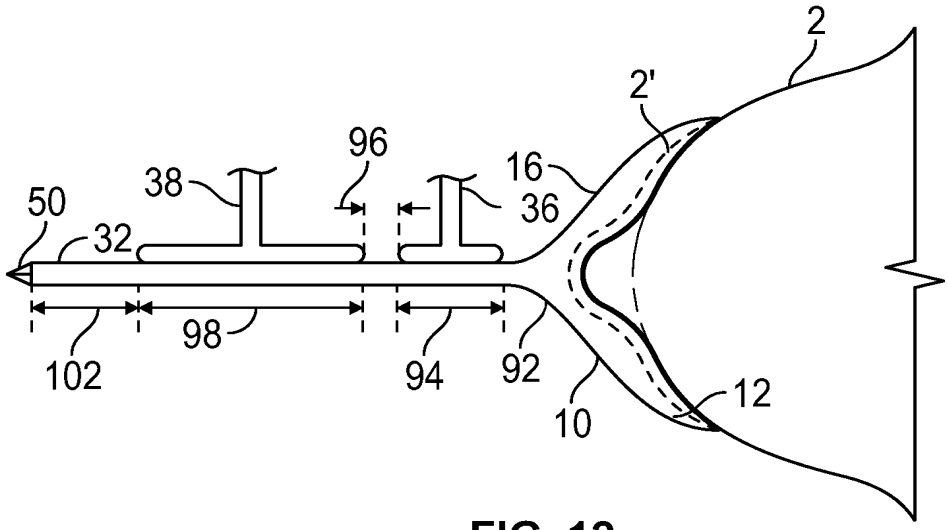


FIG. 12

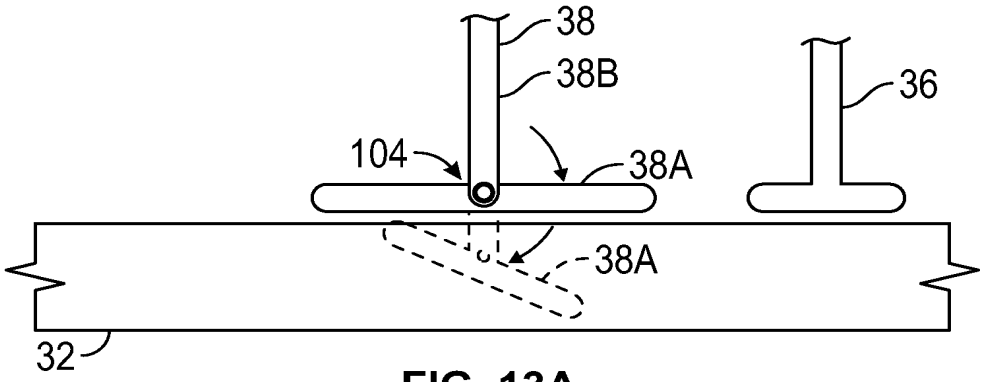


FIG. 13A

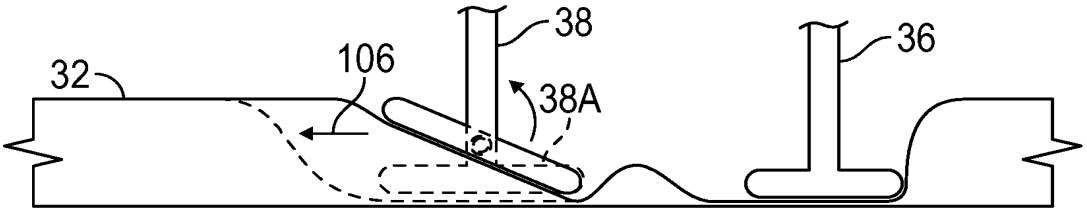


FIG. 13B

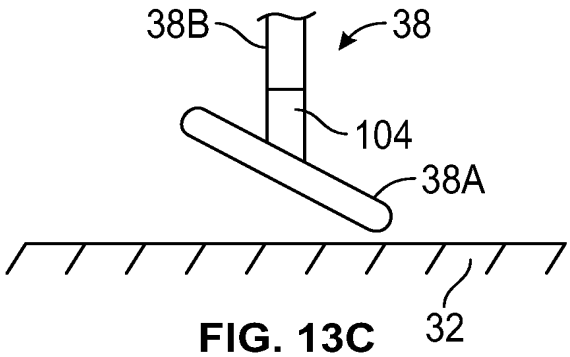


FIG. 13C

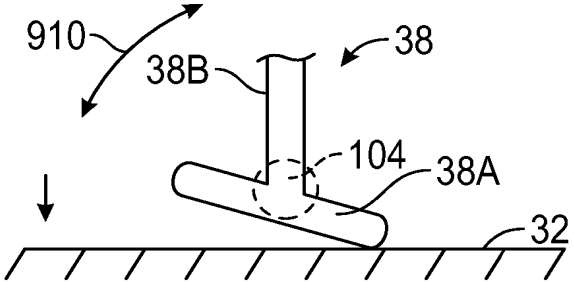


FIG. 13D

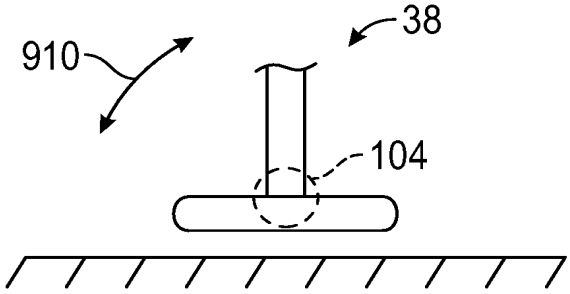


FIG. 13E

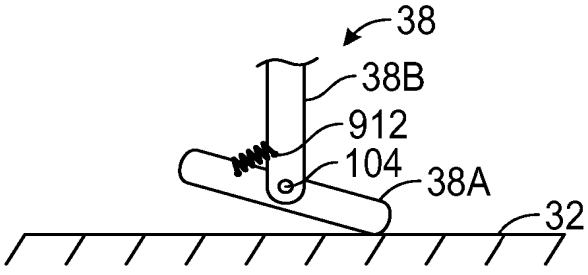


FIG. 13F

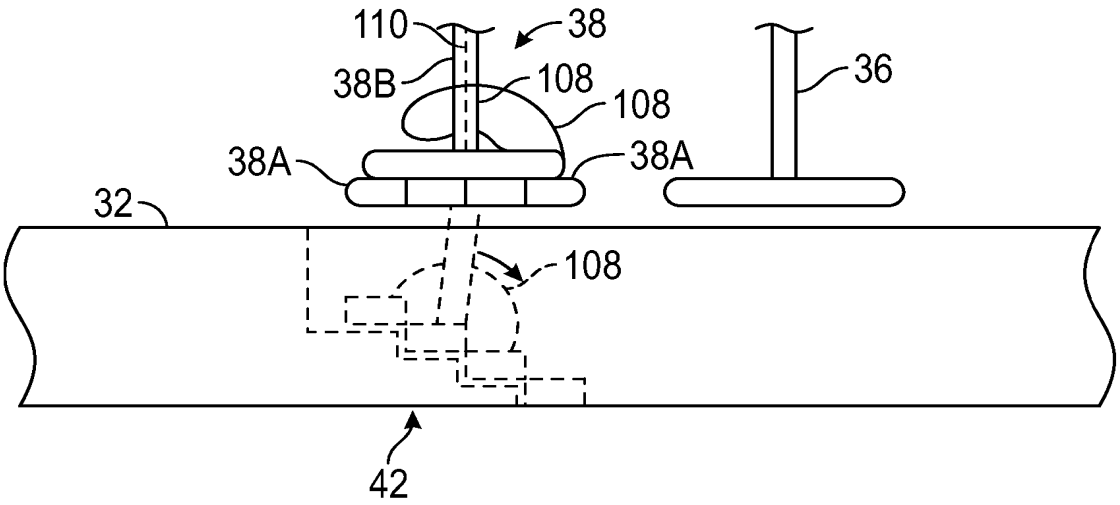


FIG. 14

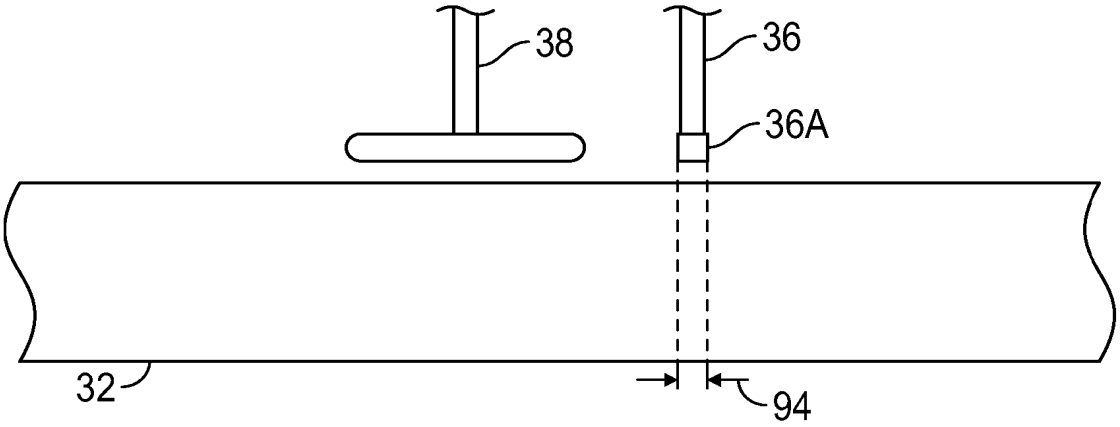


FIG. 15

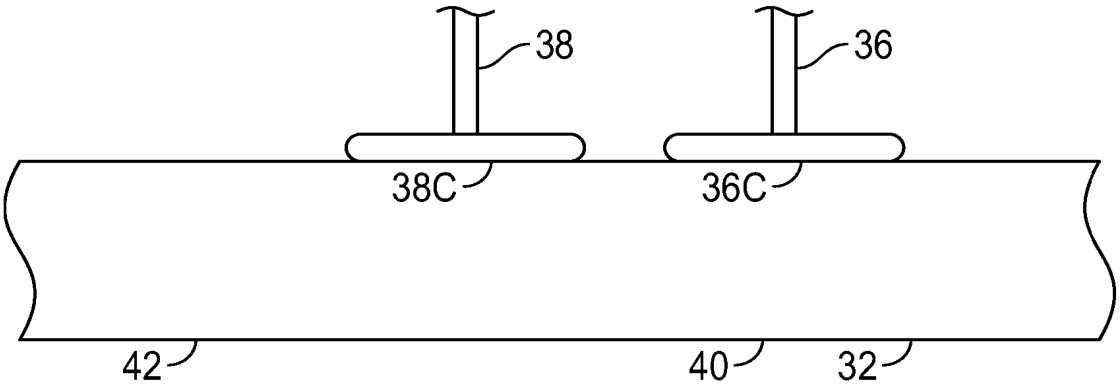


FIG. 16A

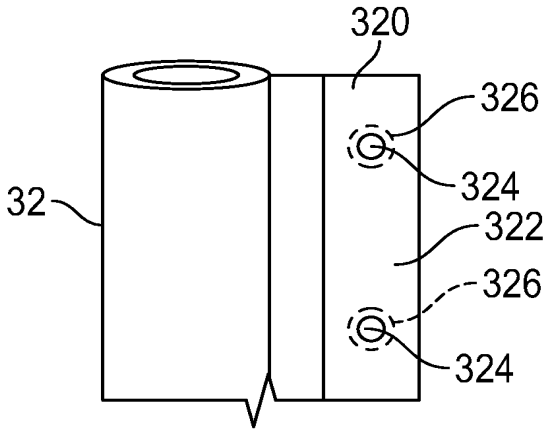


FIG. 16B

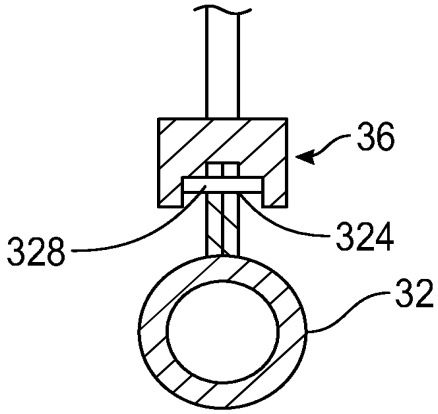


FIG. 16C

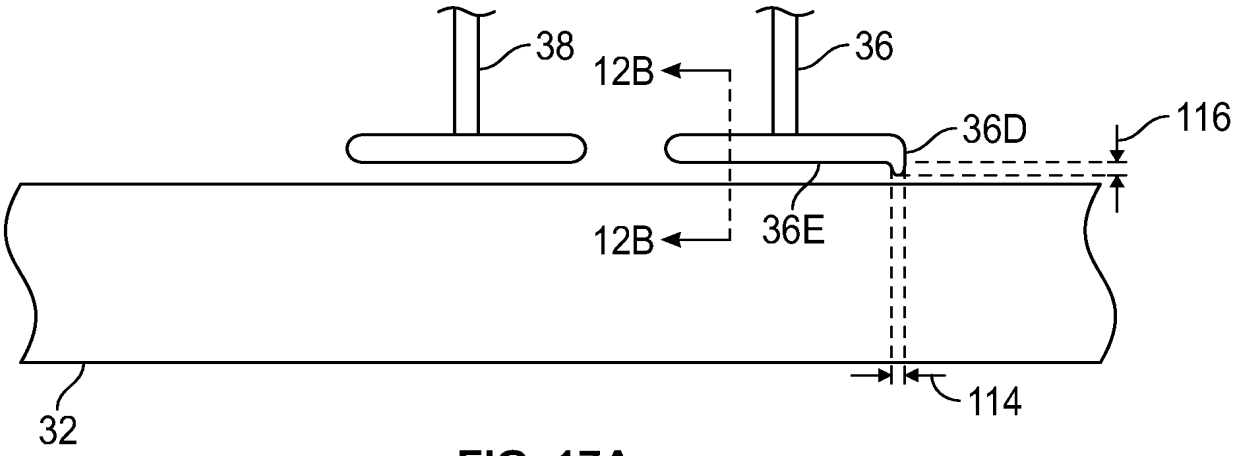


FIG. 17A

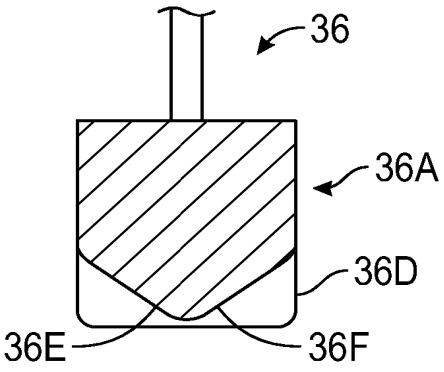


FIG. 17B

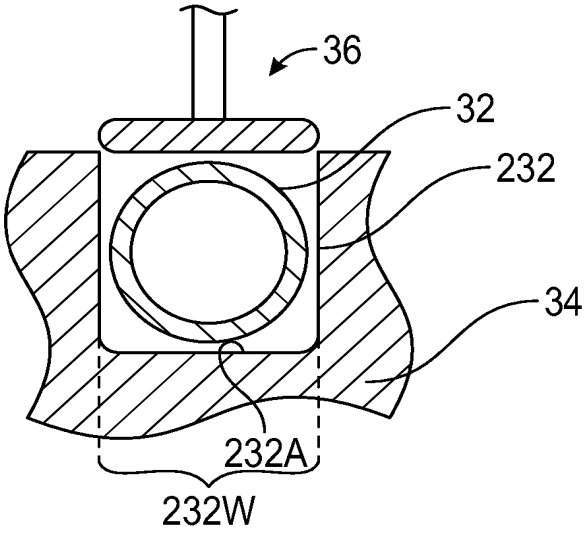


FIG. 17C

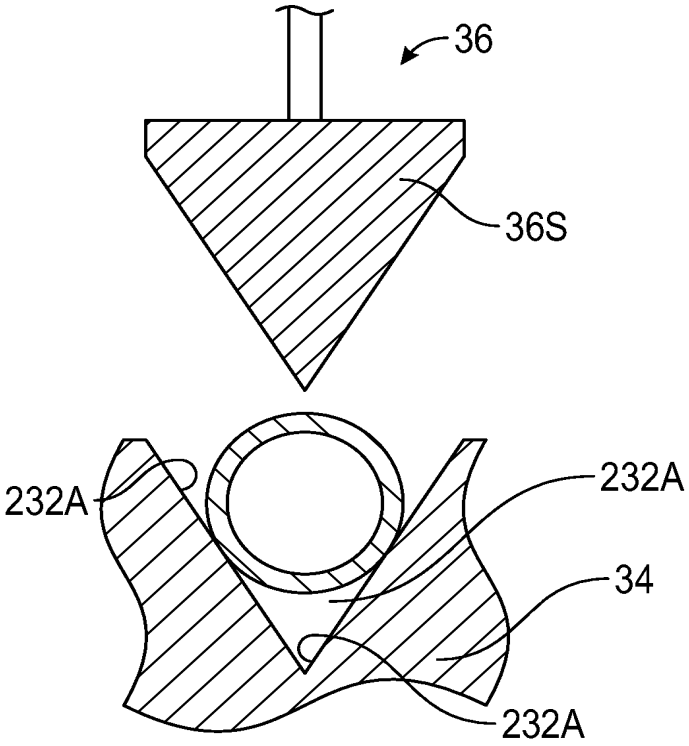


FIG. 17D

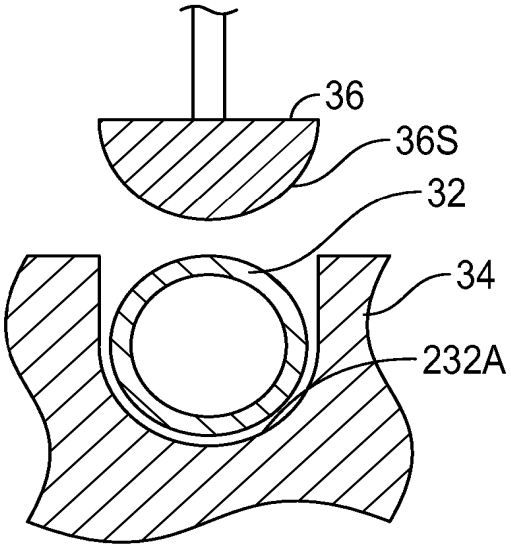


FIG. 17E

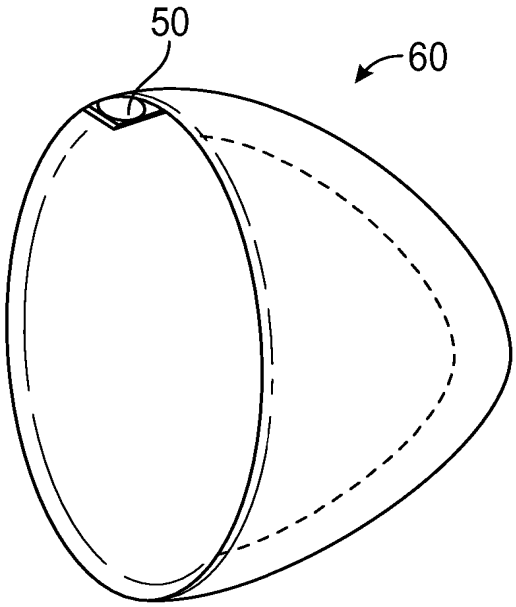


FIG. 18

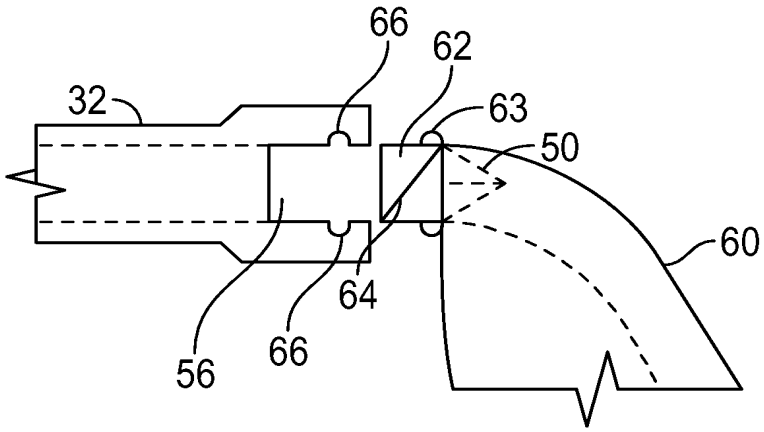


FIG. 19

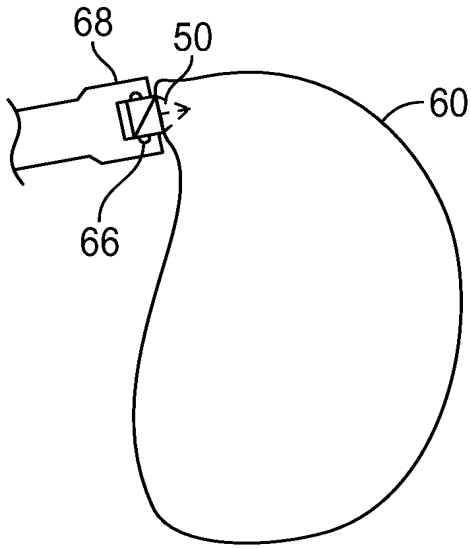


FIG. 20

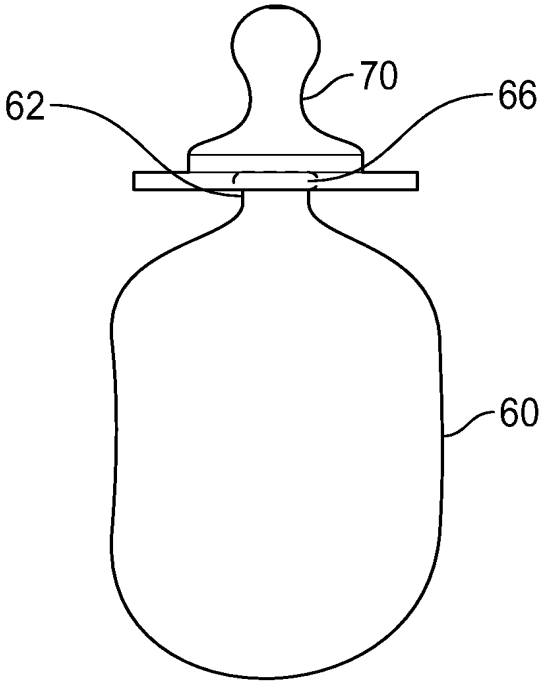


FIG. 21

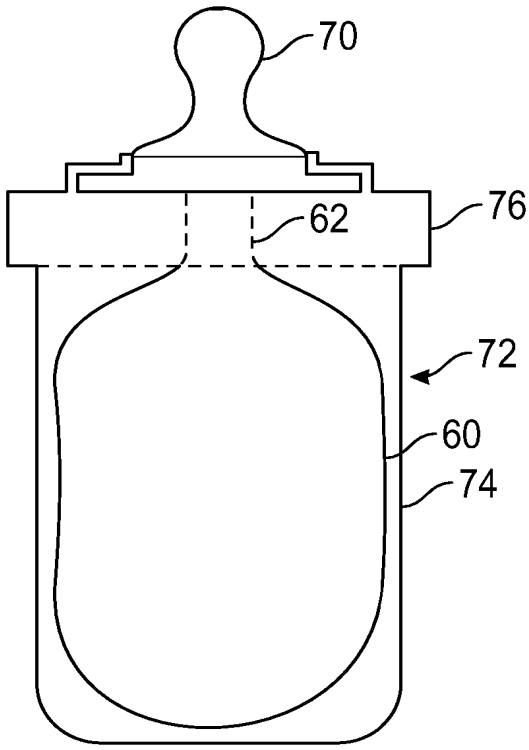


FIG. 22

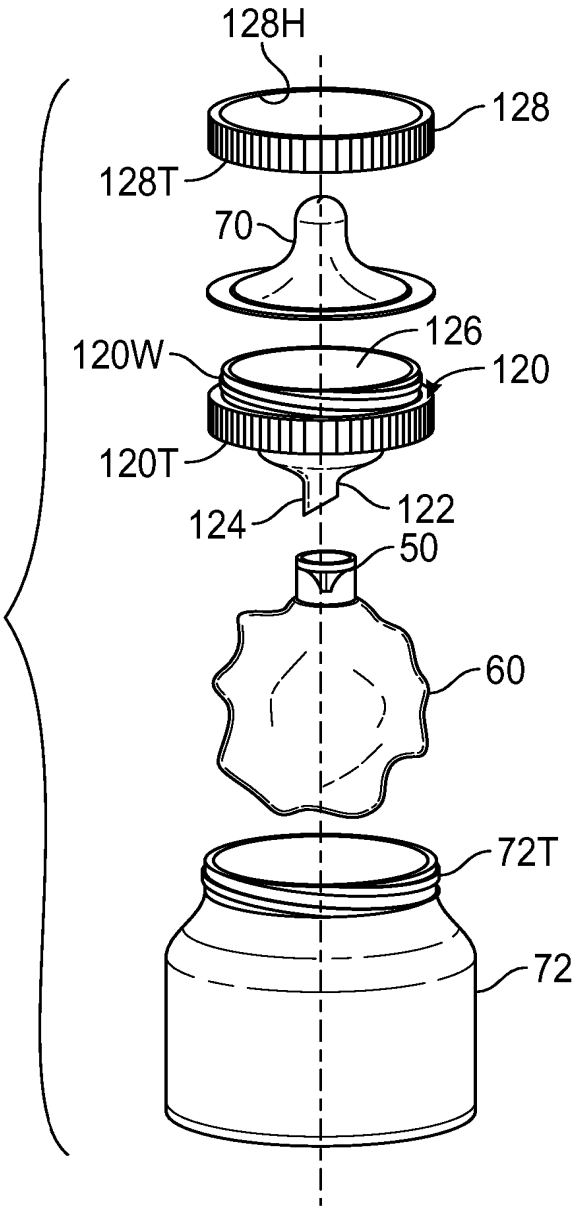

128H
128
128T
70
126
120W
120
120T
124
122
50
60
72T
72

FIG. 23

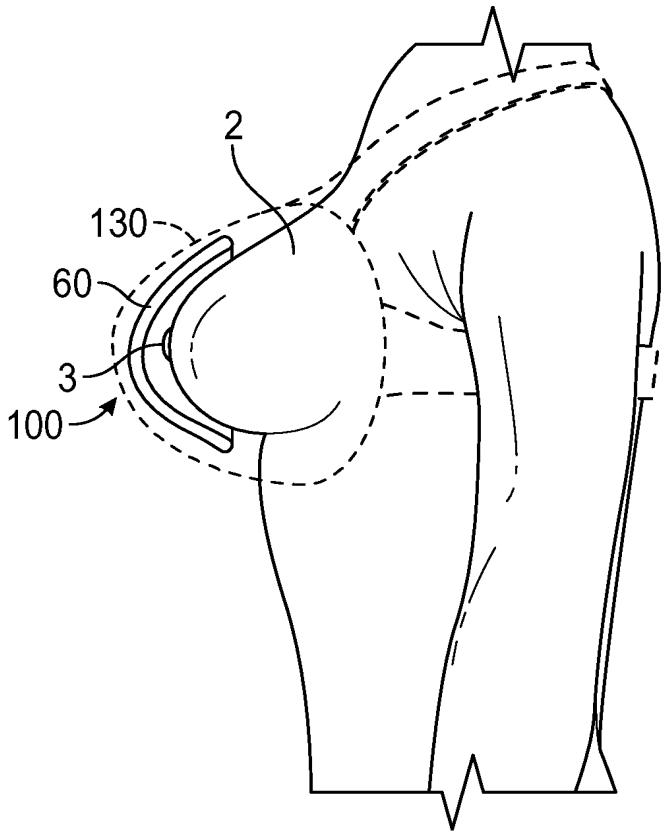

2
130
60
3
100

FIG. 24

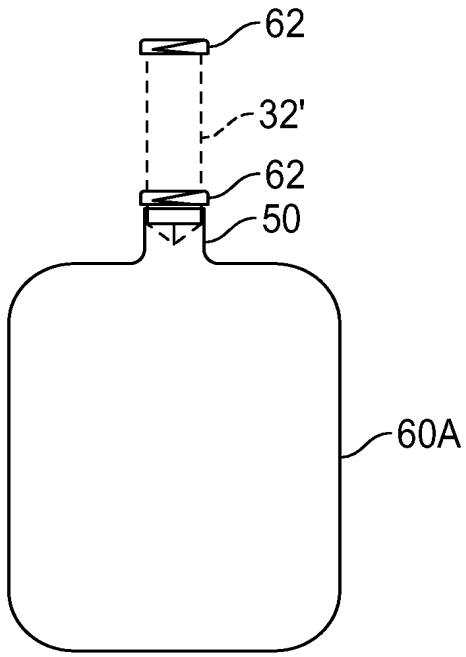


FIG. 25

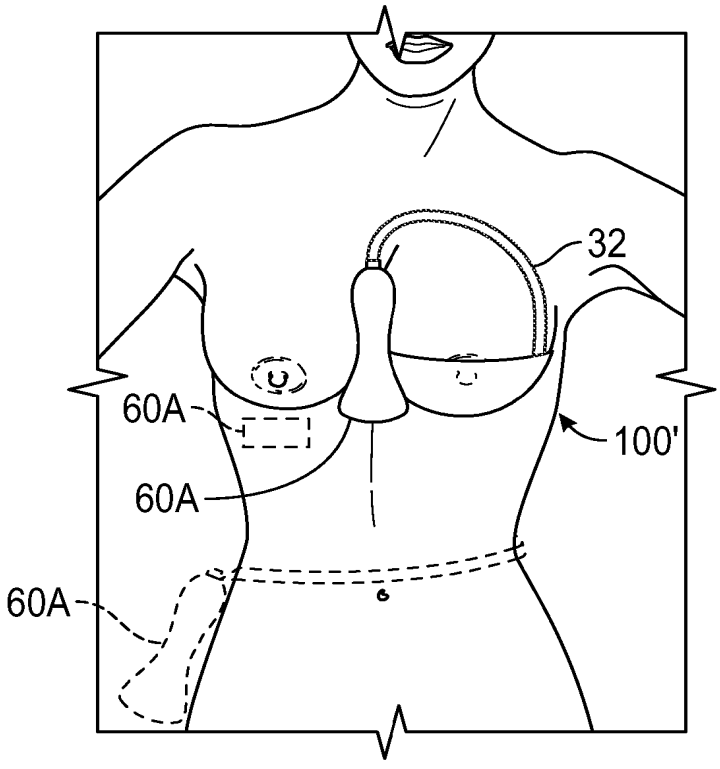


FIG. 26

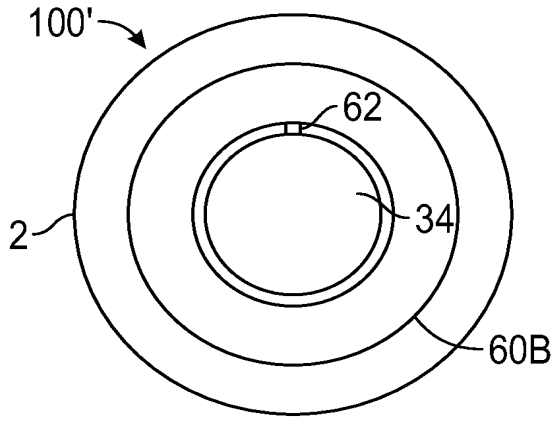


FIG. 27A

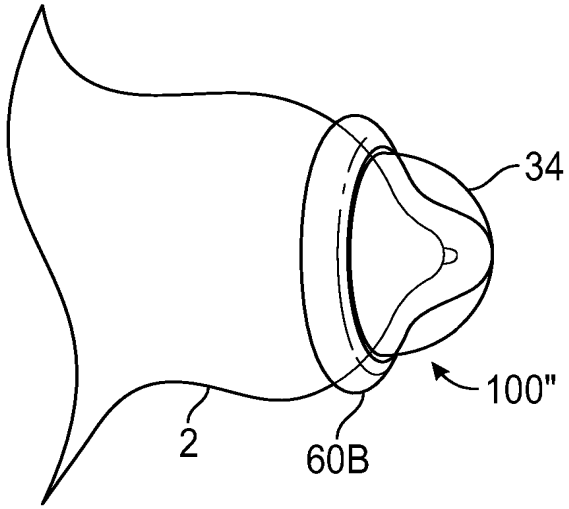


FIG. 27B

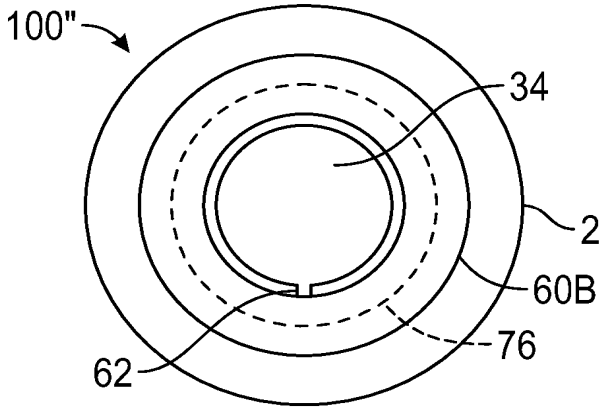


FIG. 28A

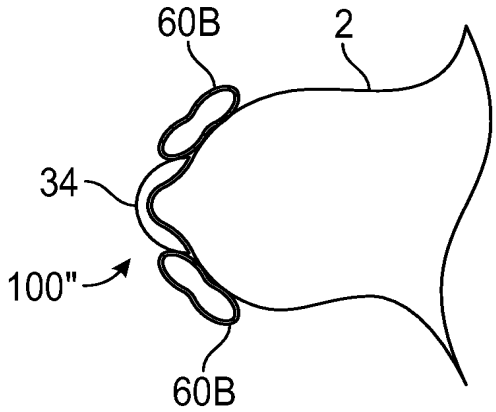


FIG. 28B

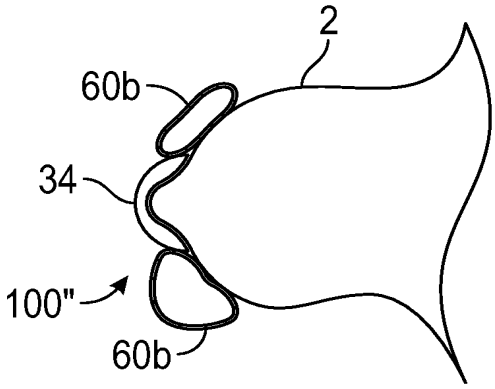


FIG. 28C

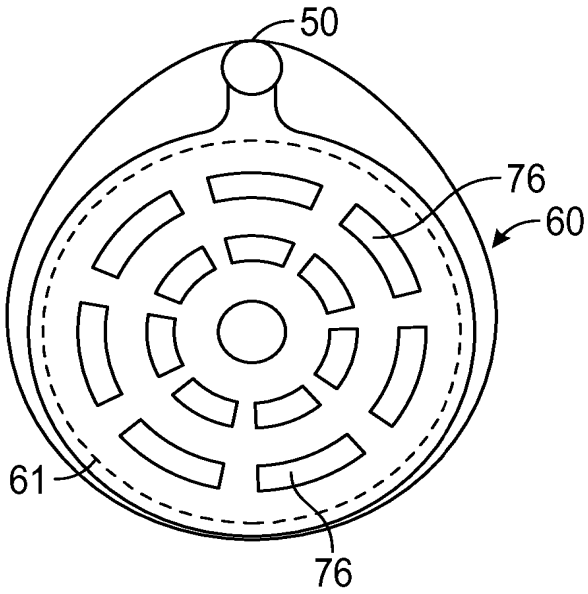


FIG. 28D

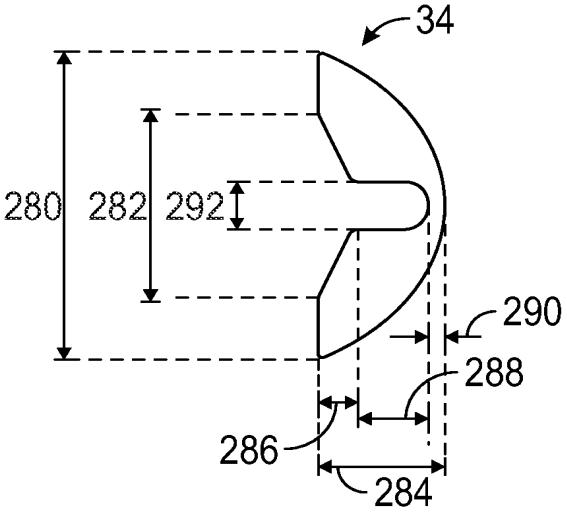


FIG. 28E

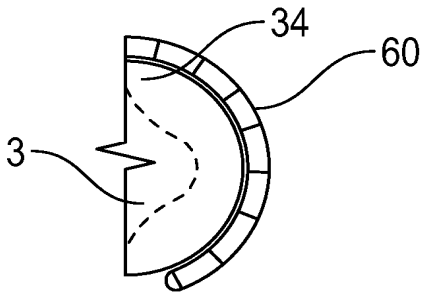


FIG. 28F

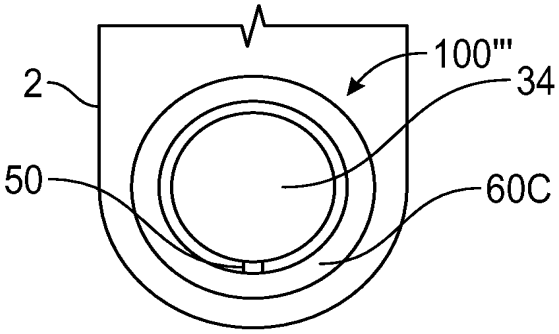


FIG. 29A

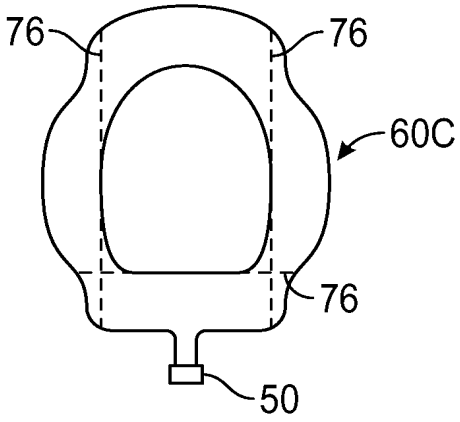


FIG. 29B

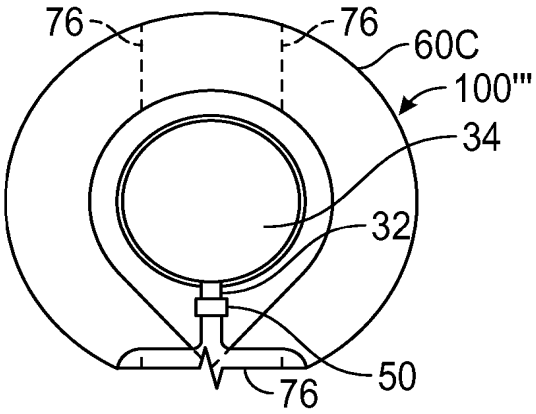


FIG. 29C

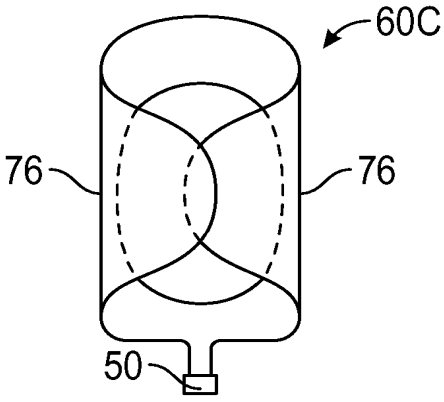


FIG. 29D

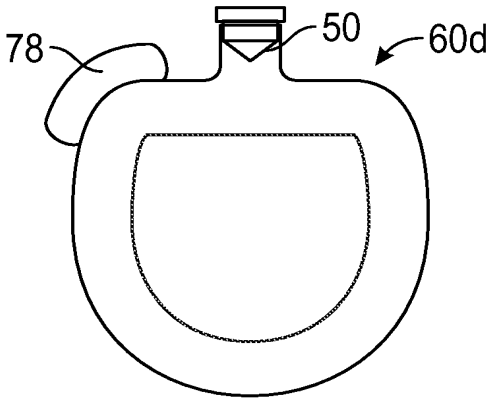


FIG. 30

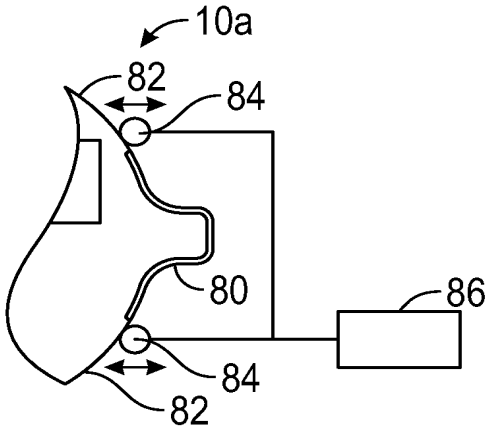


FIG. 31A

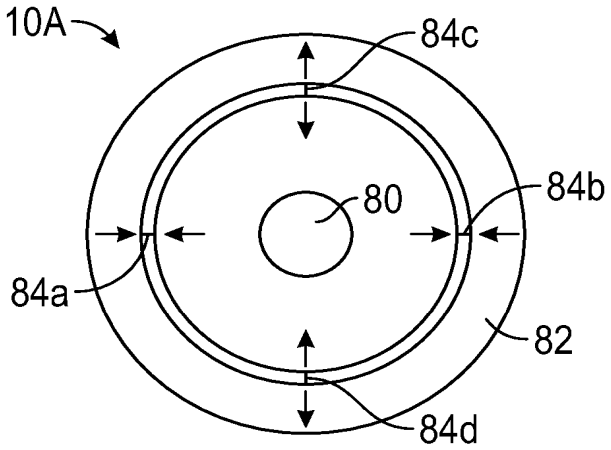


FIG. 31B

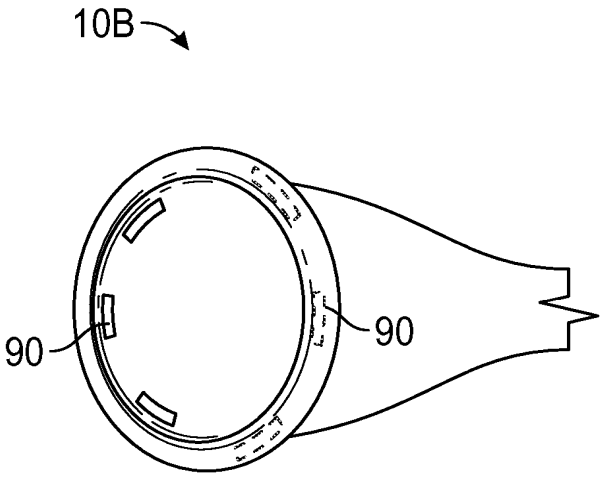


FIG. 32A

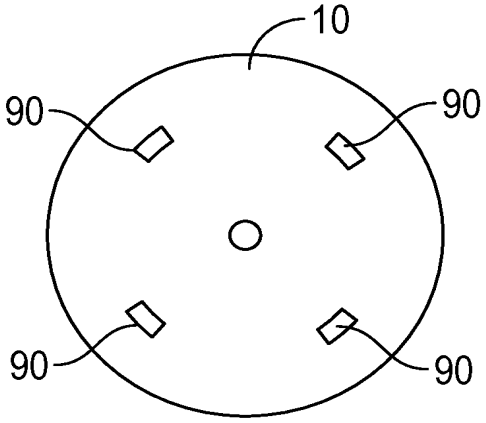


FIG. 32B

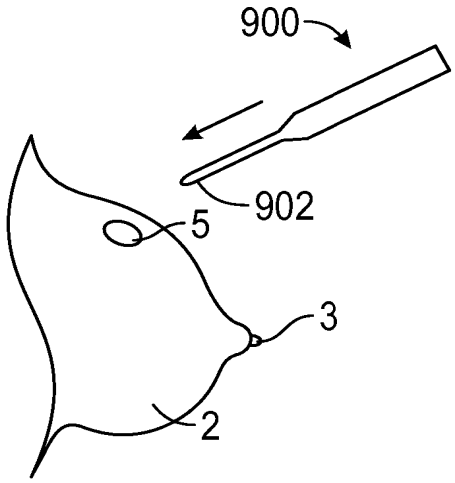


FIG. 32C

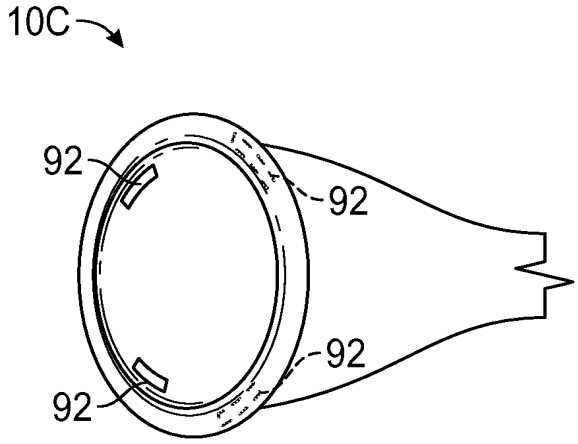


FIG. 33

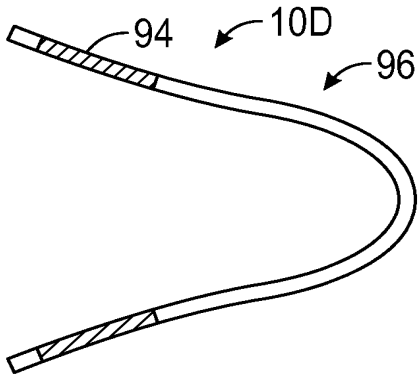


FIG. 34

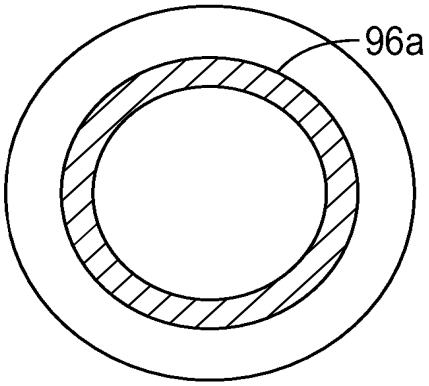


FIG. 35A

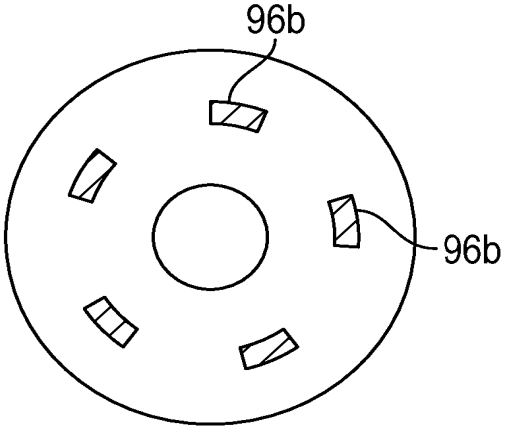


FIG. 35B

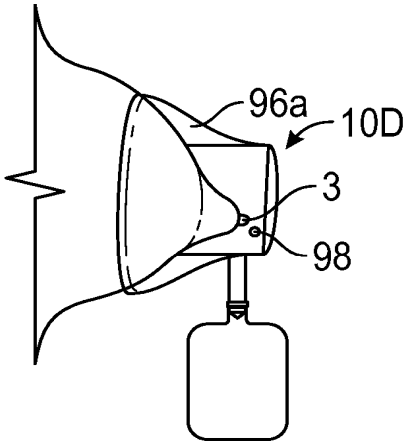


FIG. 36

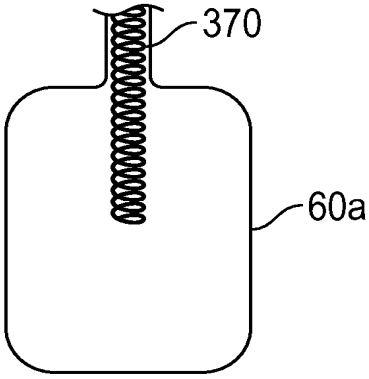


FIG. 37A

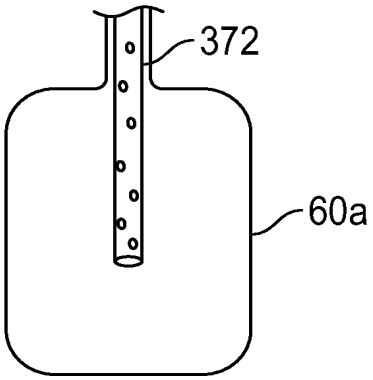


FIG. 37B

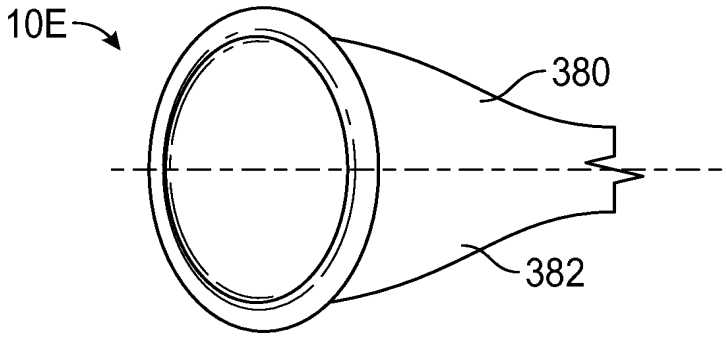


FIG. 38

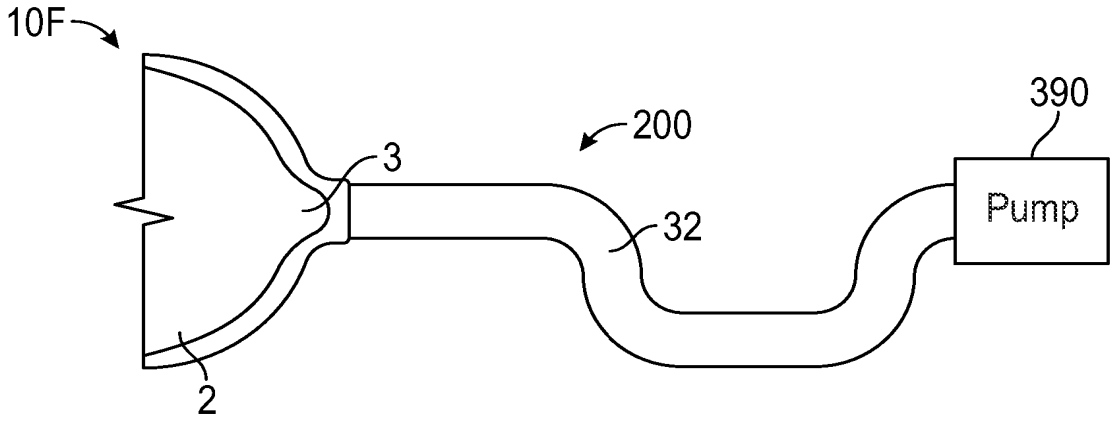


FIG. 39A

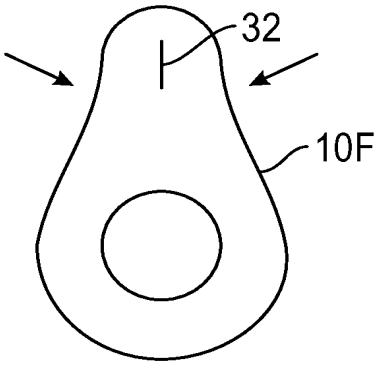


FIG. 39B

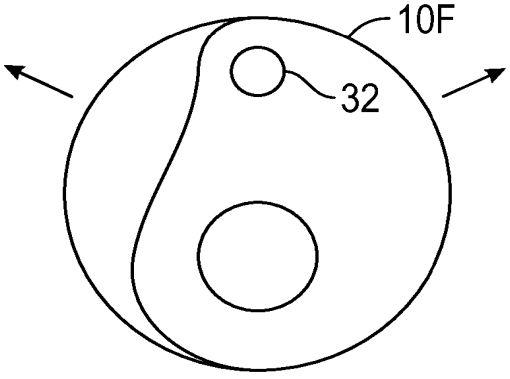


FIG. 39C

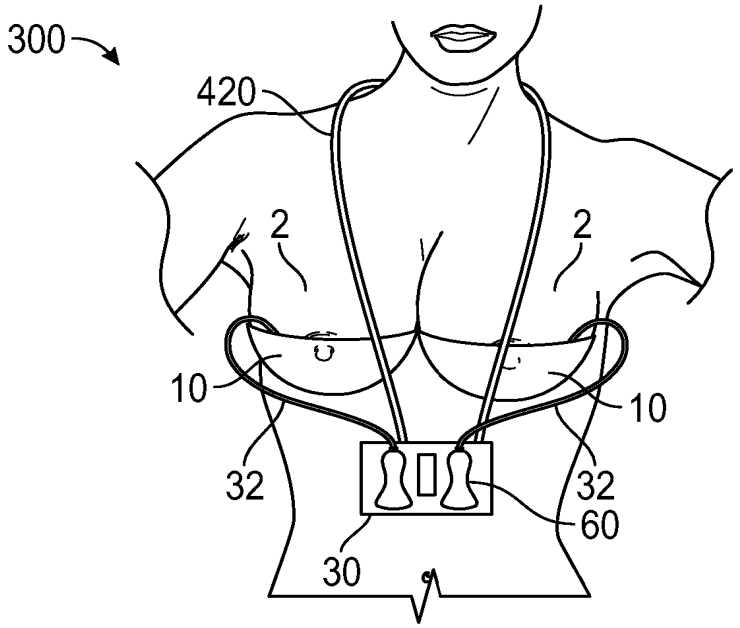


FIG. 40

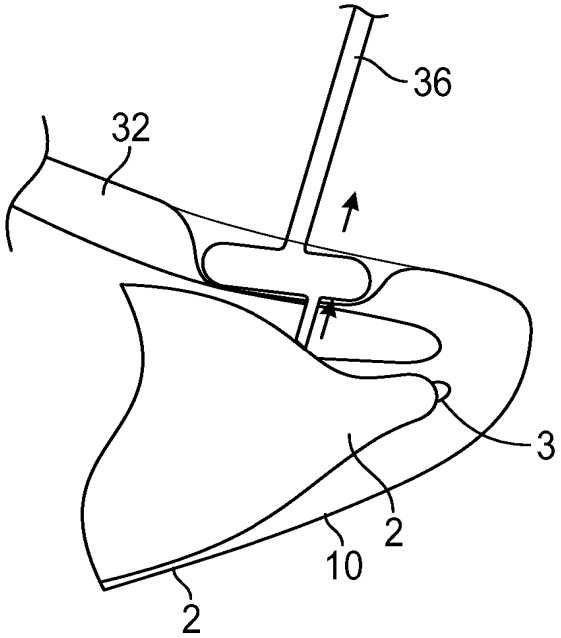


FIG. 41

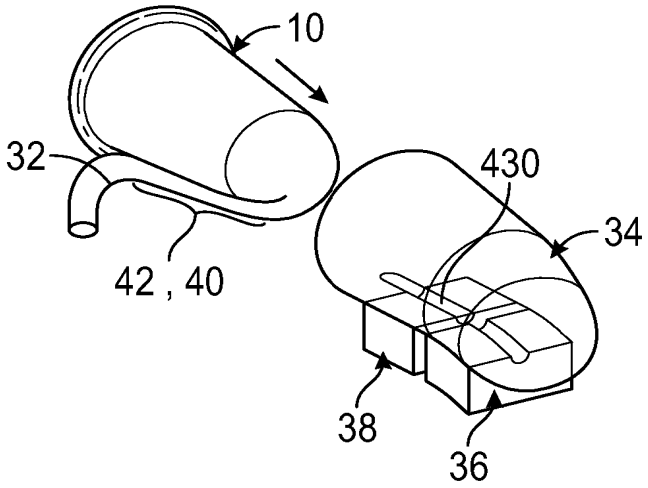

10
32
430
34
42 , 40
38
36

FIG. 42

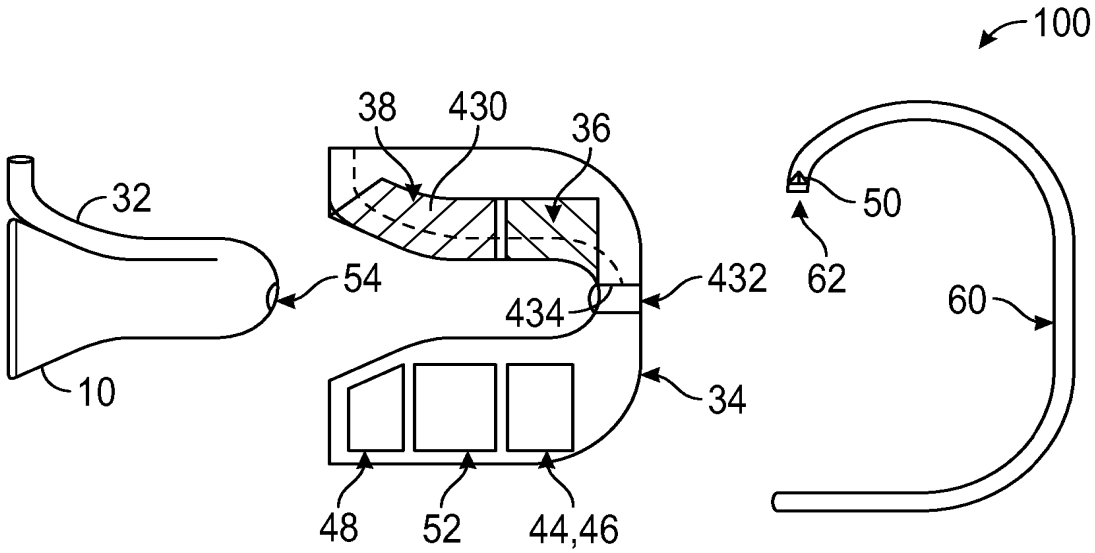

100
38
430
36
32
50
54
432
62
434
60
10
34
48
52
44,46

FIG. 43

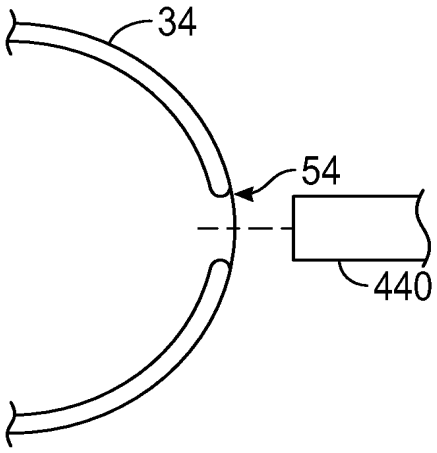


FIG. 44A

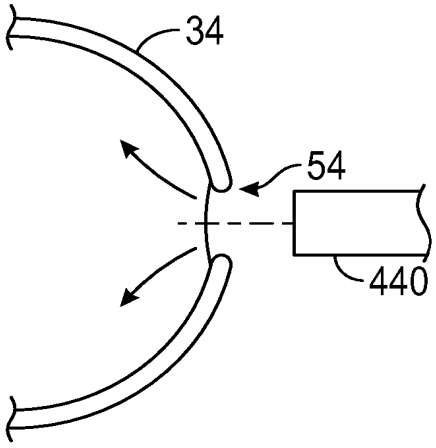


FIG. 44B

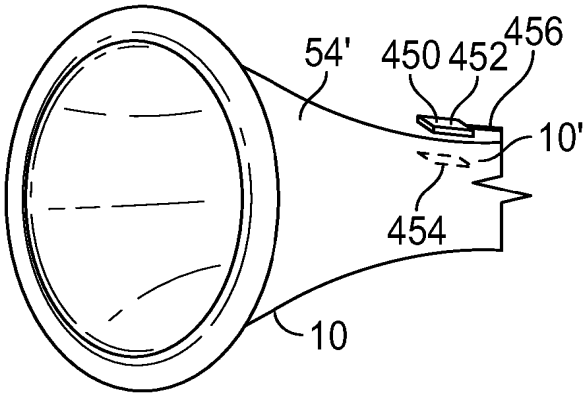


FIG. 45A

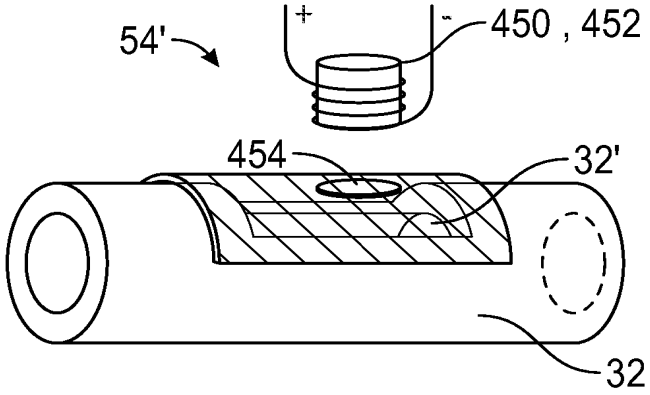


FIG. 45B

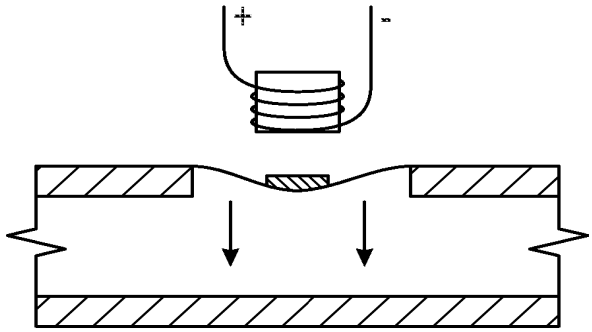


FIG. 45C

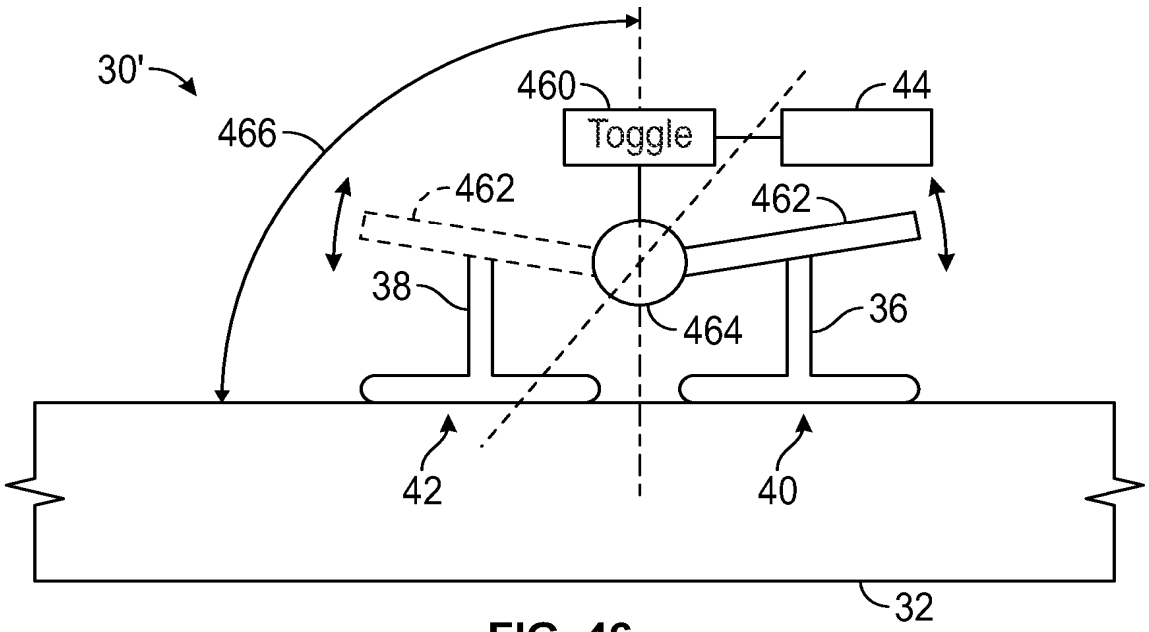


FIG. 46

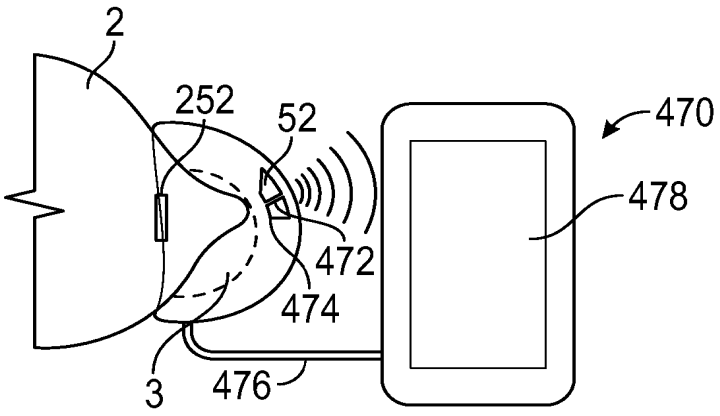


FIG. 47

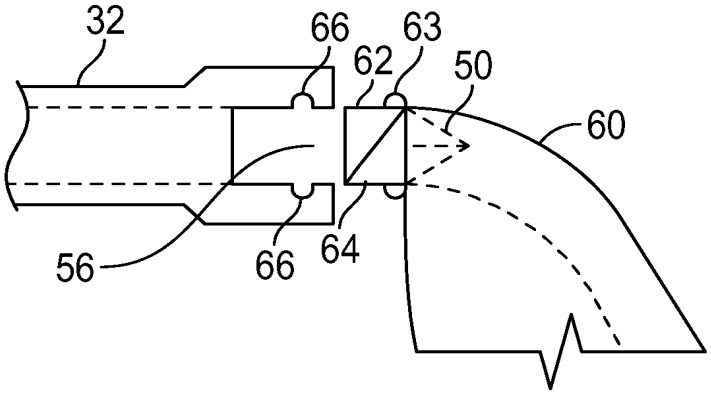


FIG. 48

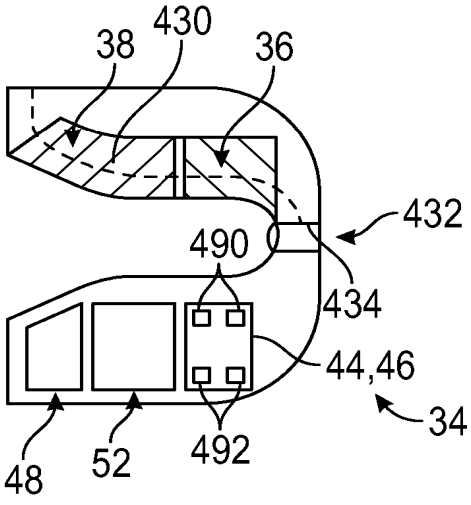


FIG. 49

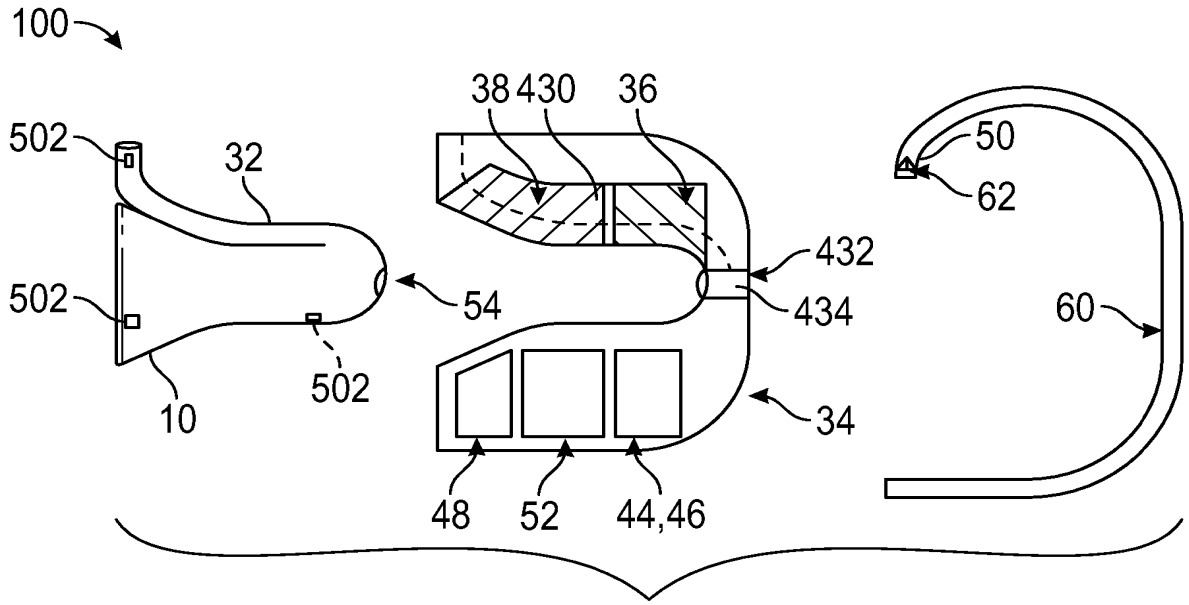

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FIG. 50

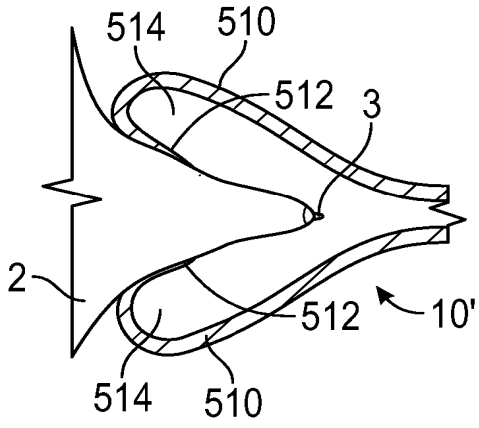

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FIG. 51

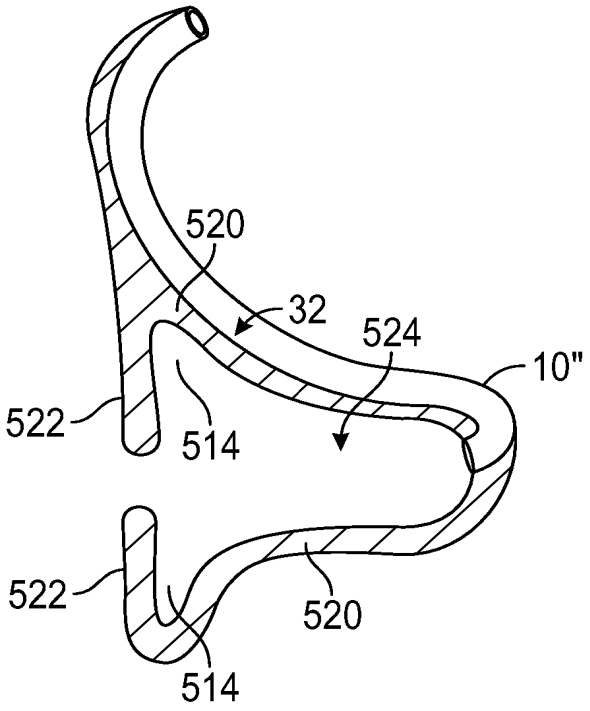


FIG. 52A

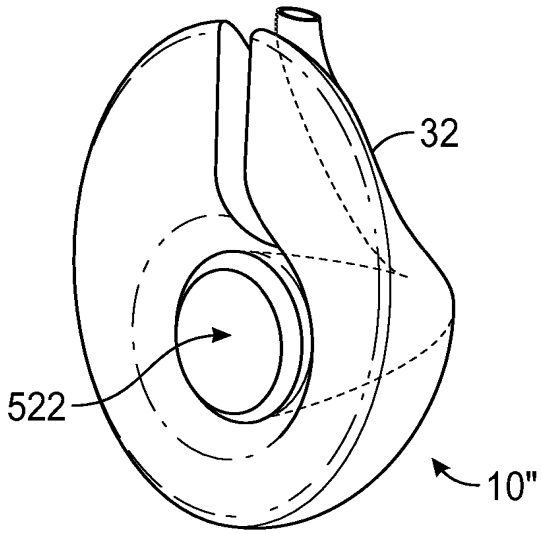


FIG. 52B

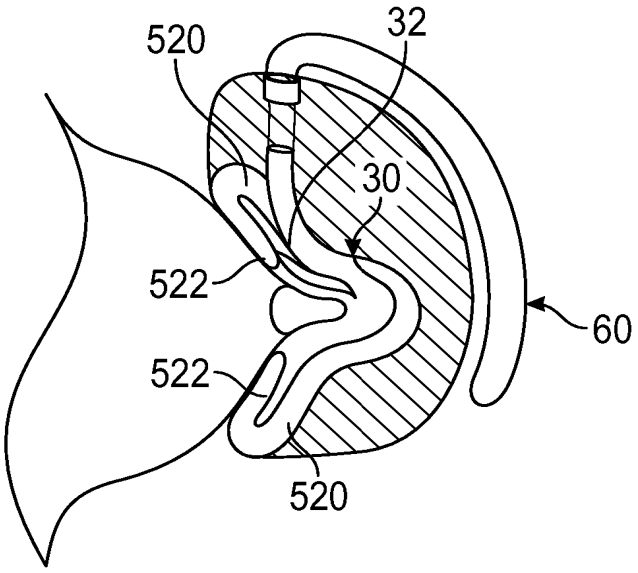


FIG. 52C

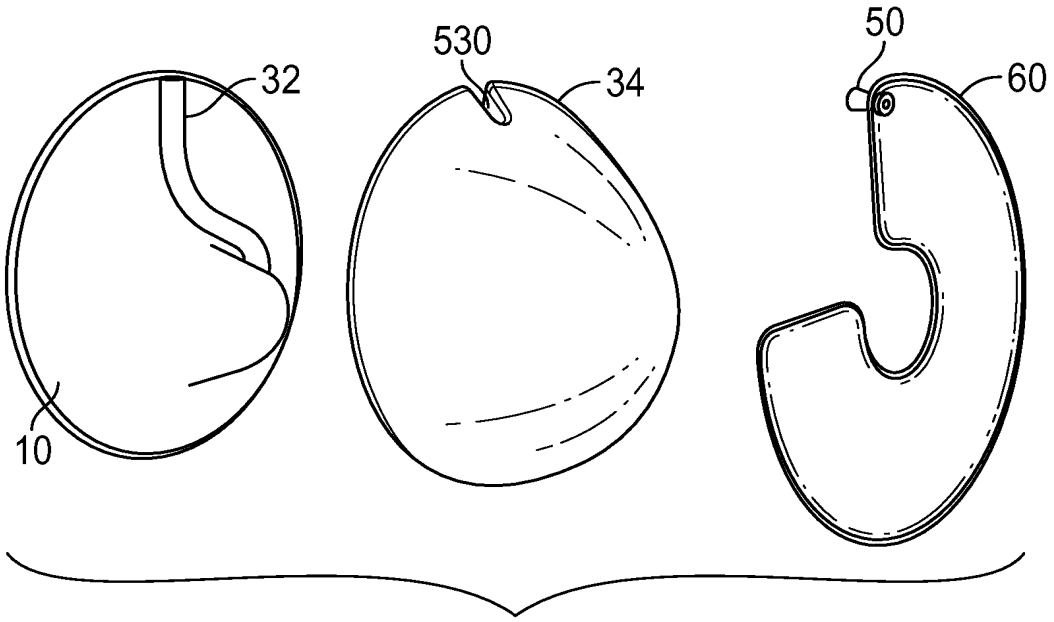


FIG. 53A

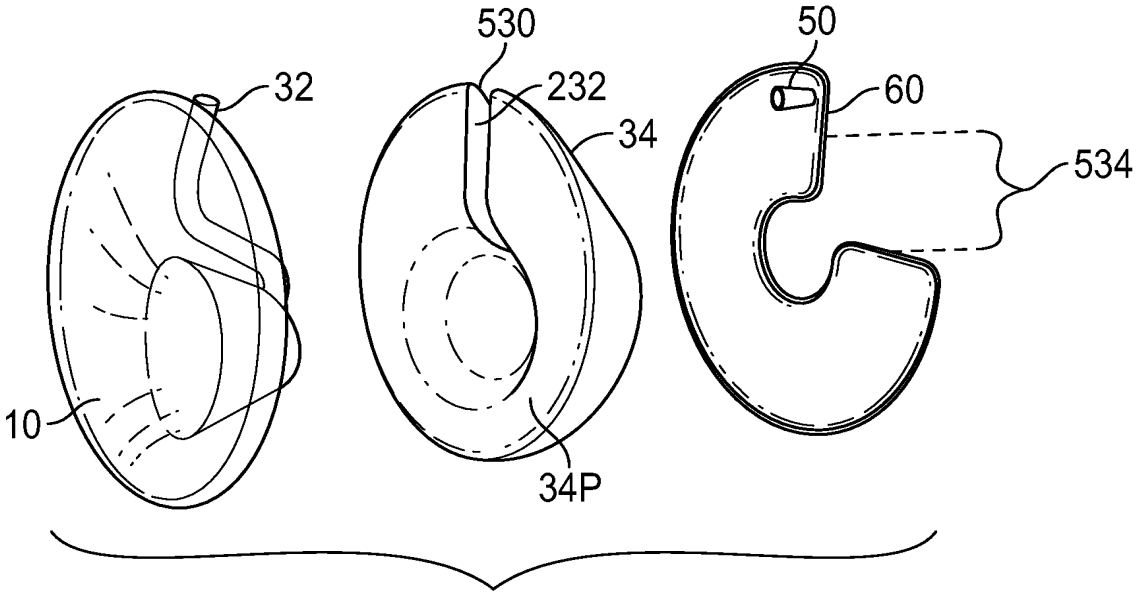


FIG. 53B

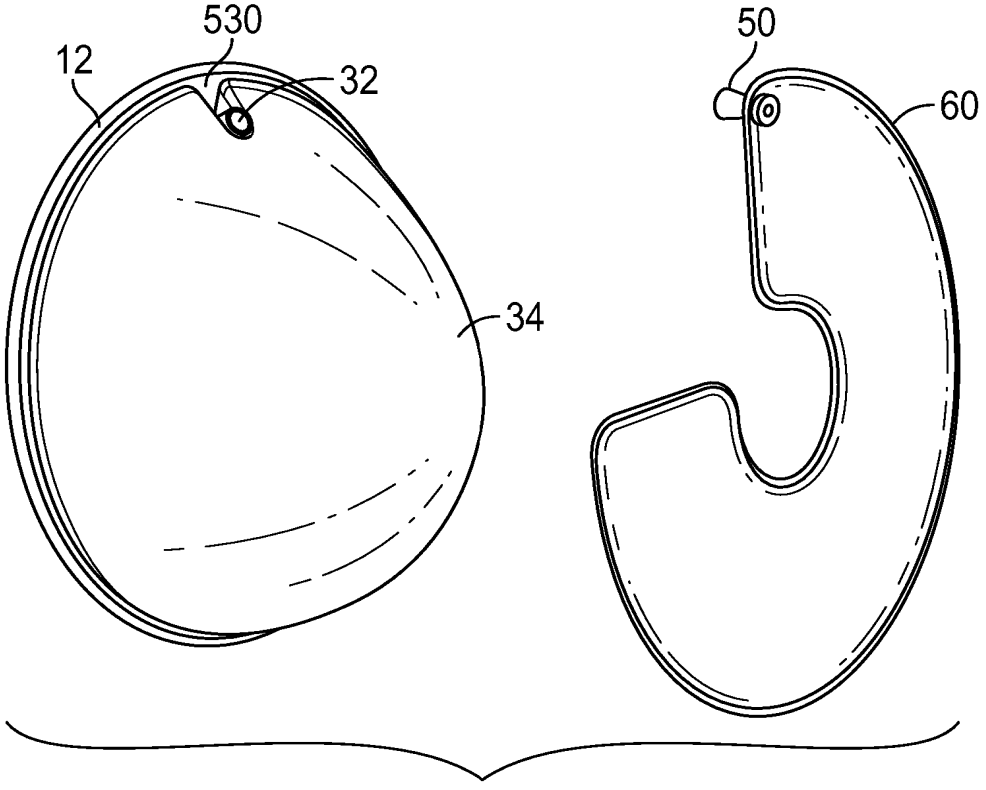


FIG. 53C

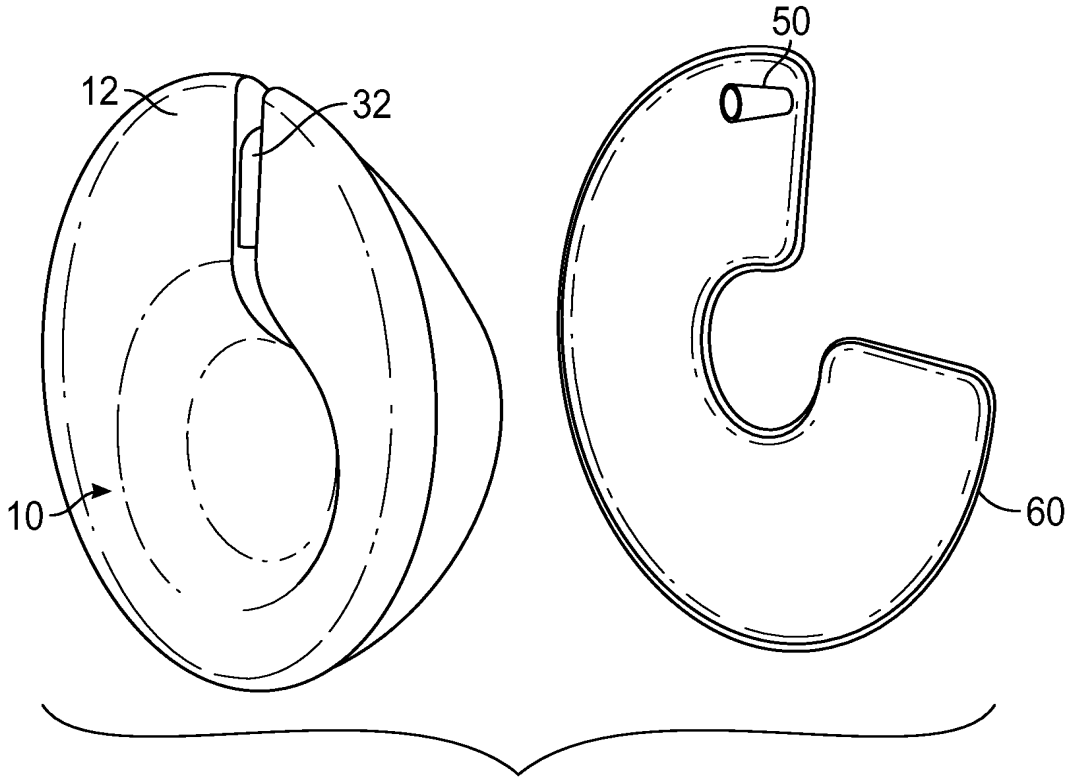


FIG. 53D

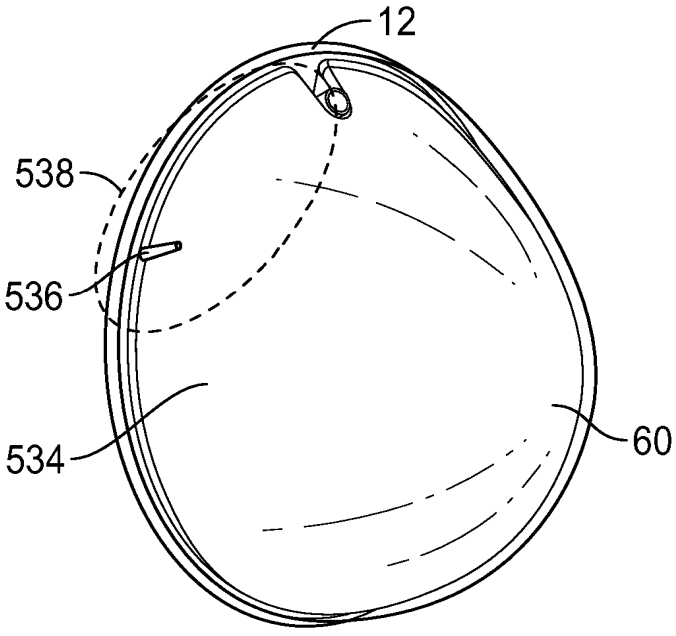


FIG. 53E

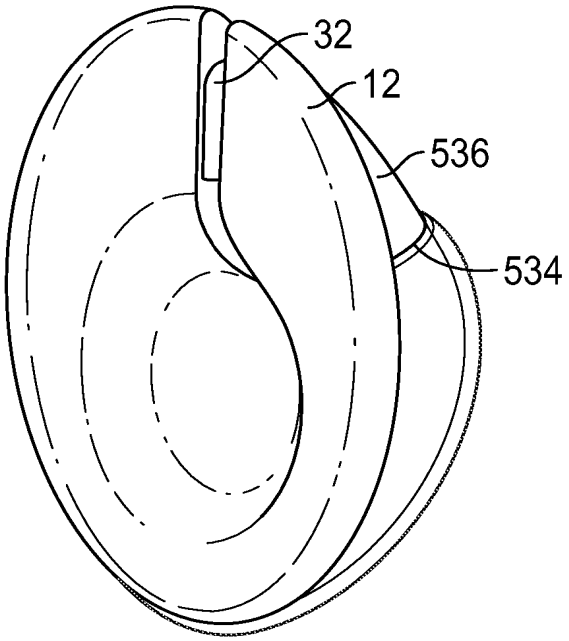


FIG. 53F

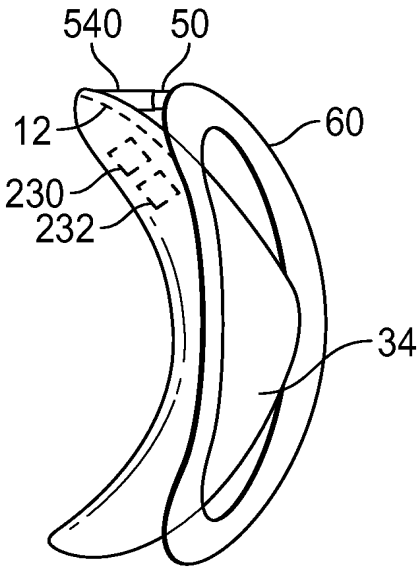


FIG. 53G

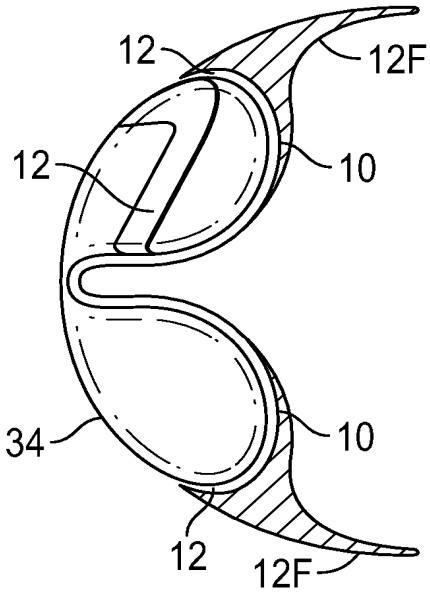


FIG. 54

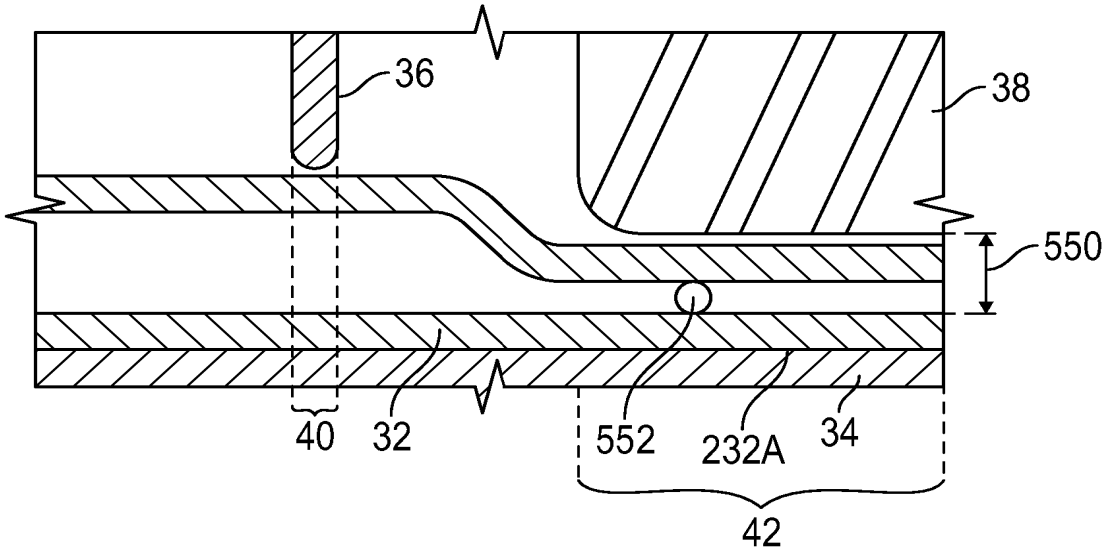


FIG. 55A

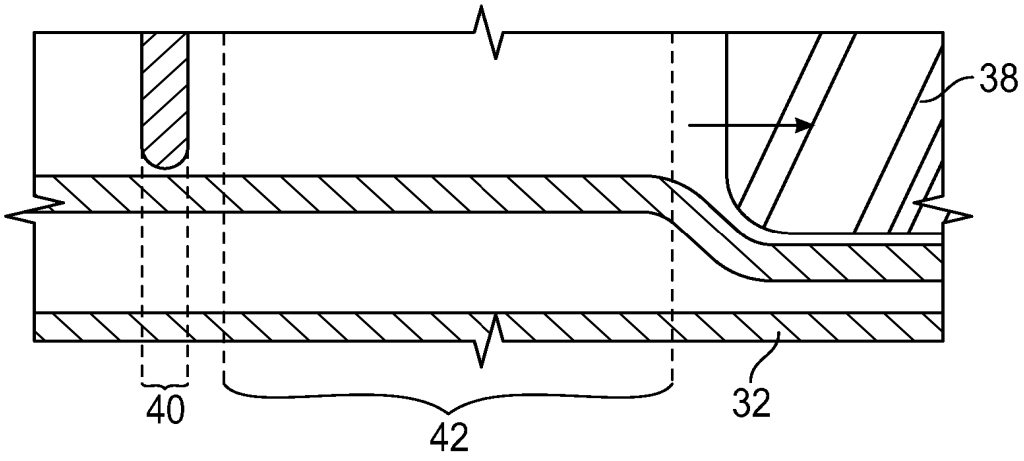


FIG. 55B

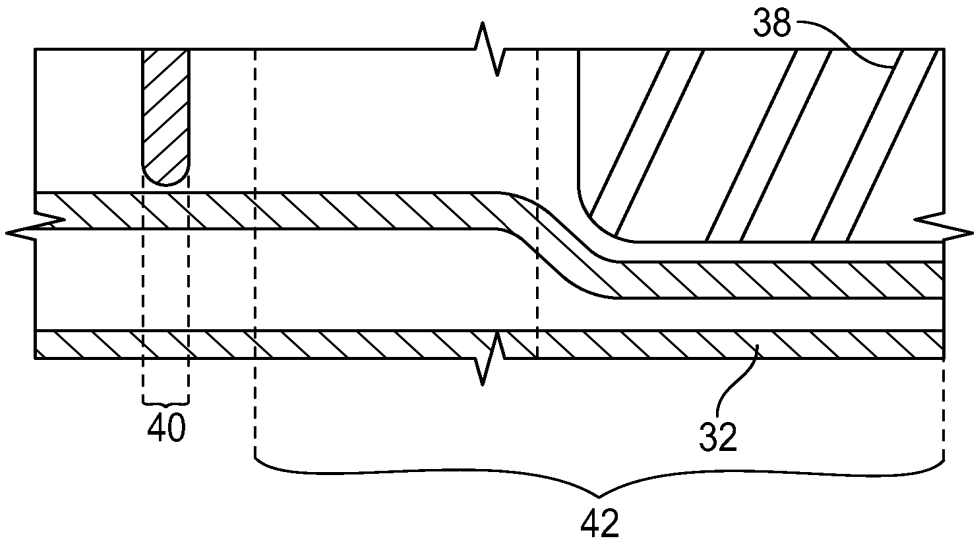


FIG. 55C

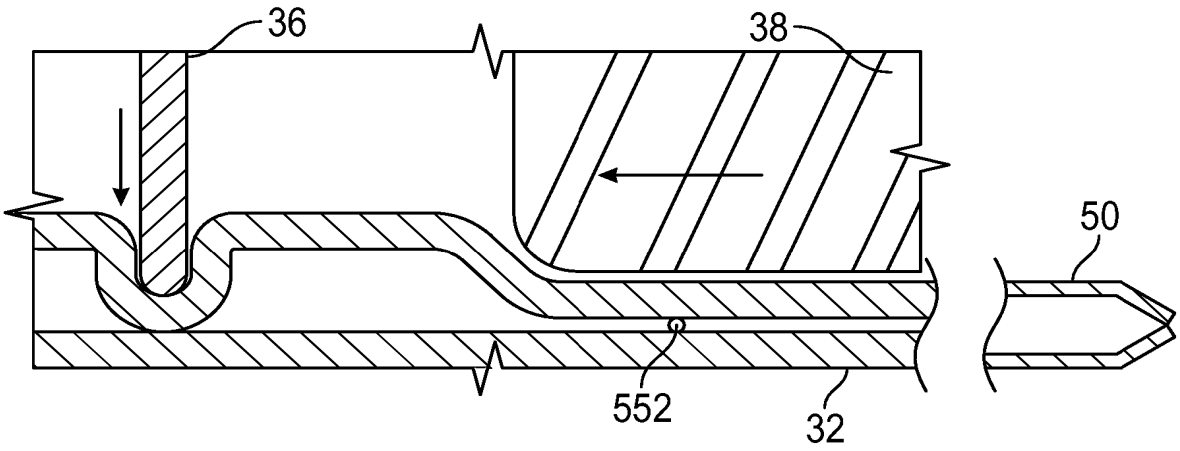


FIG. 55D

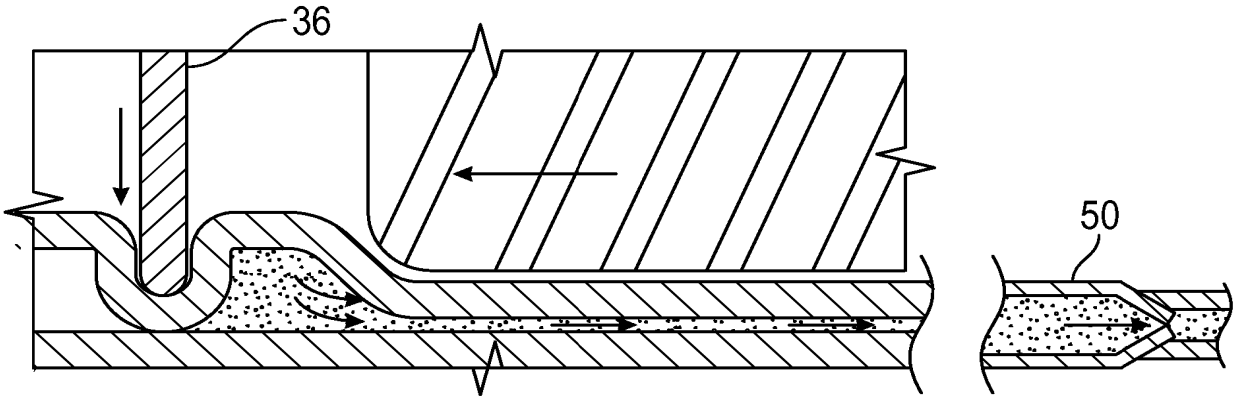


FIG. 55E

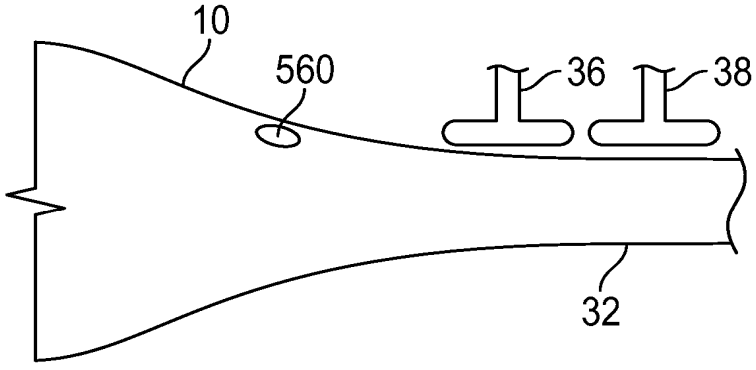


FIG. 56

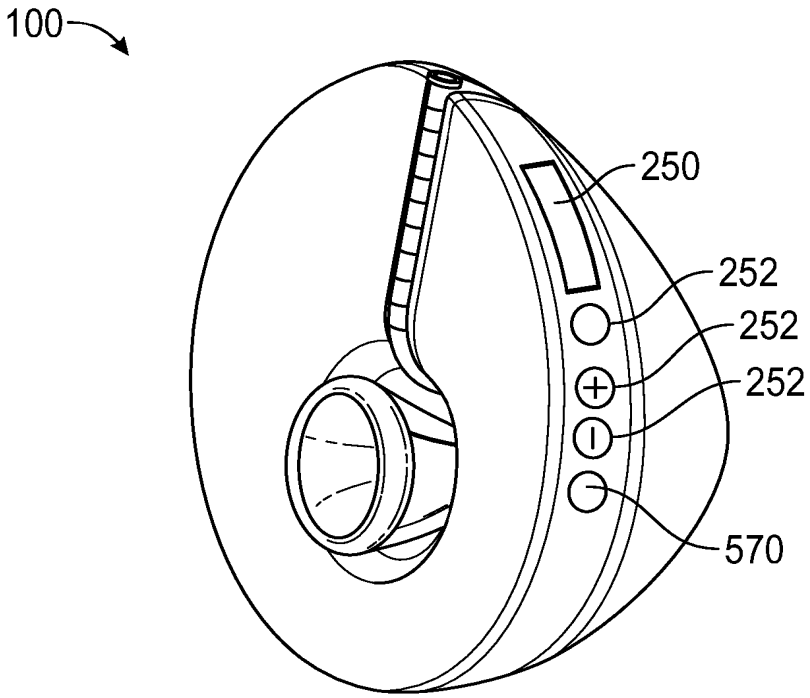


FIG. 57

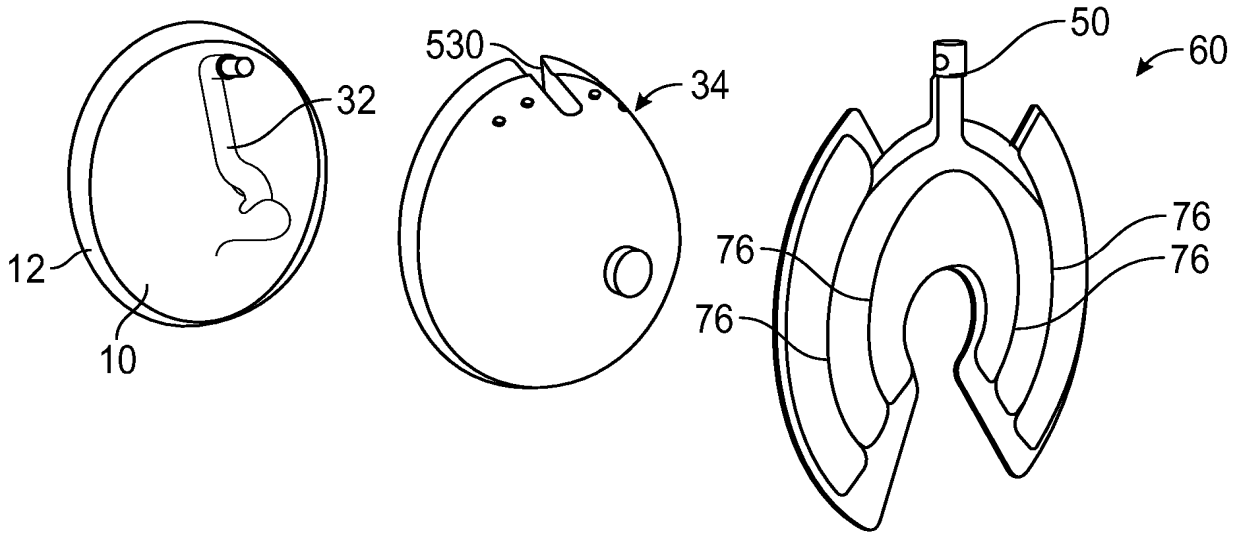


FIG. 58A

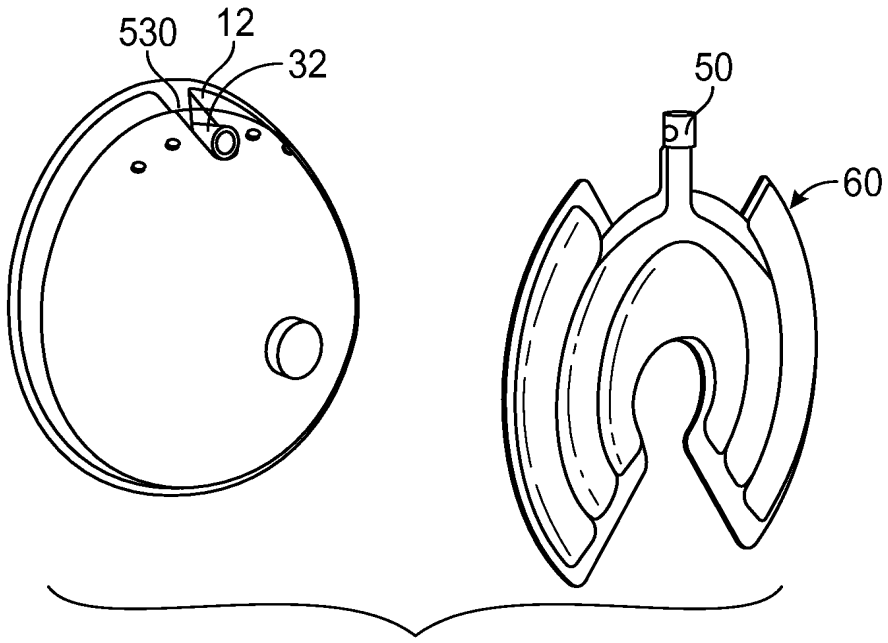


FIG. 58B

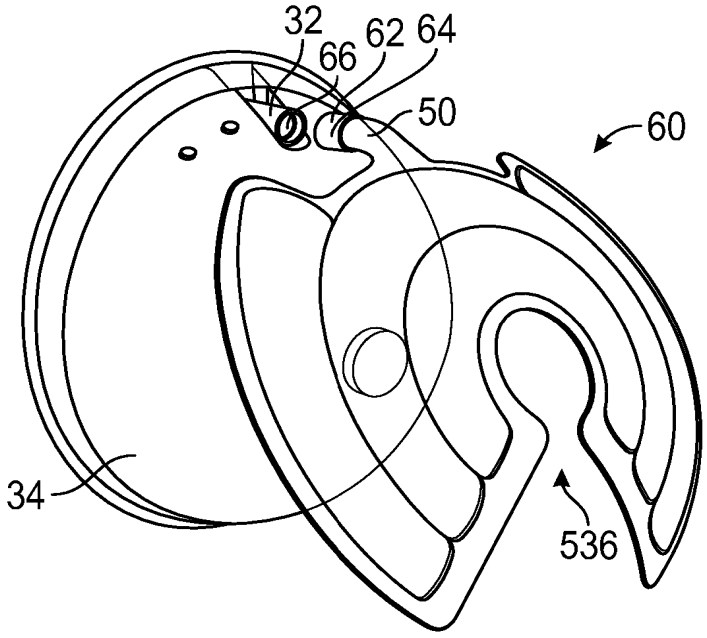


FIG. 58C

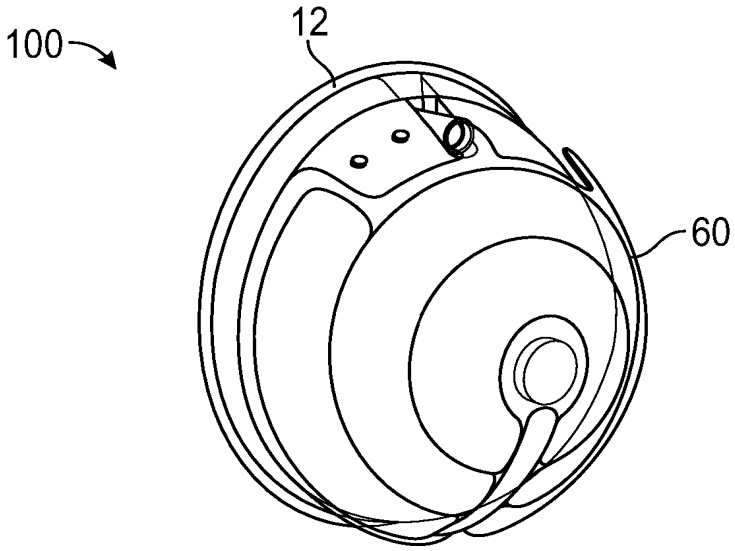


FIG. 58D

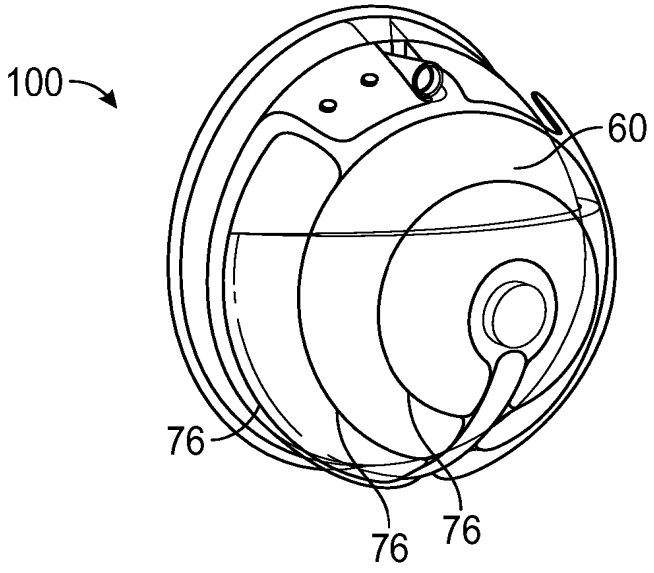


FIG. 58E

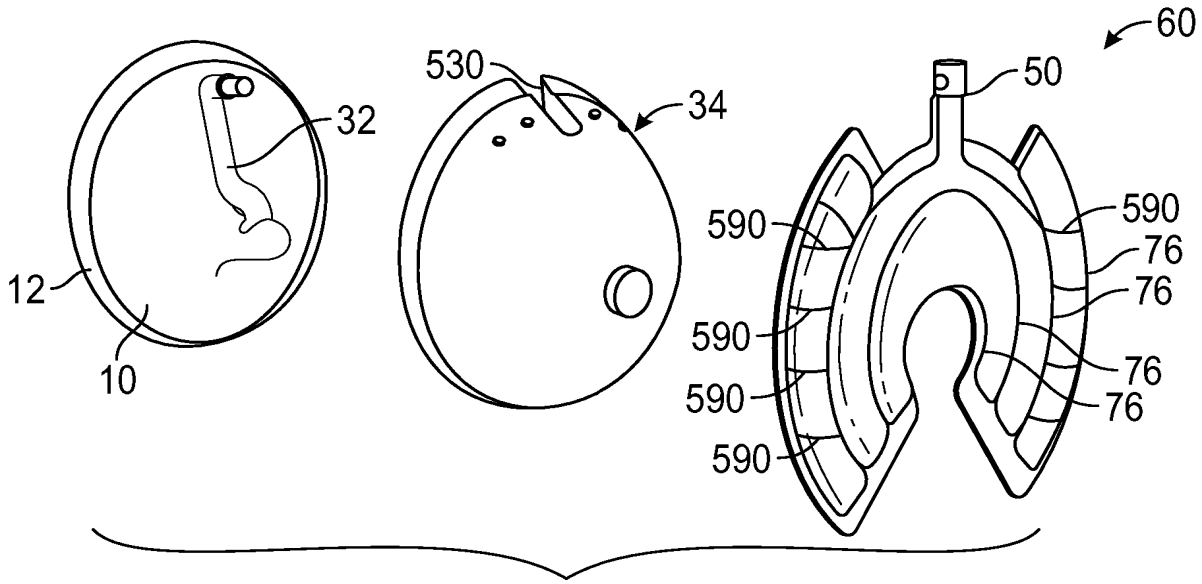


FIG. 59A

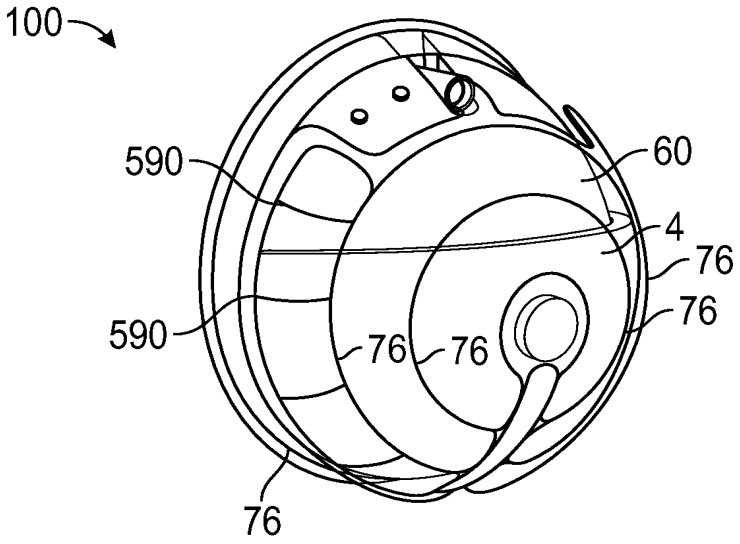


FIG. 59B

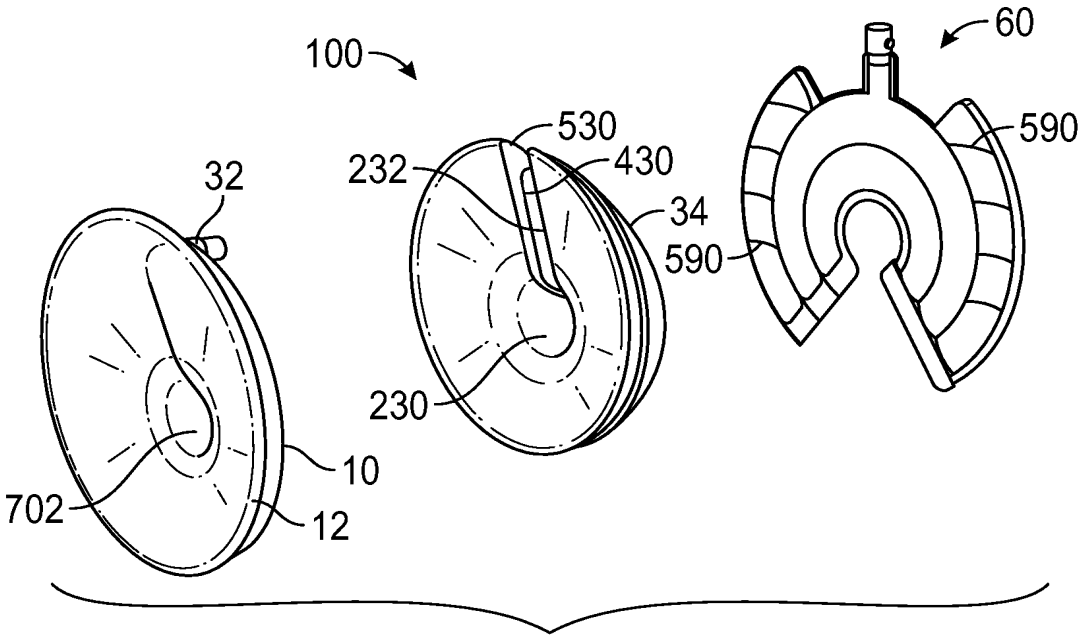


FIG. 59C

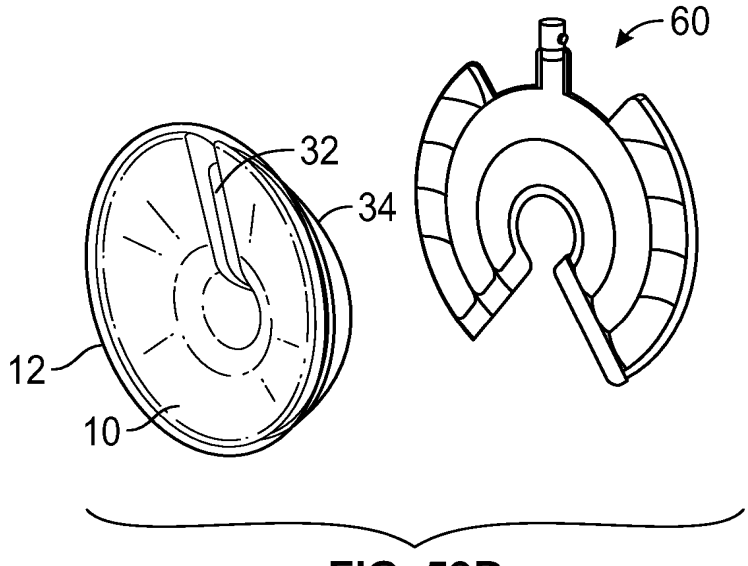


FIG. 59D

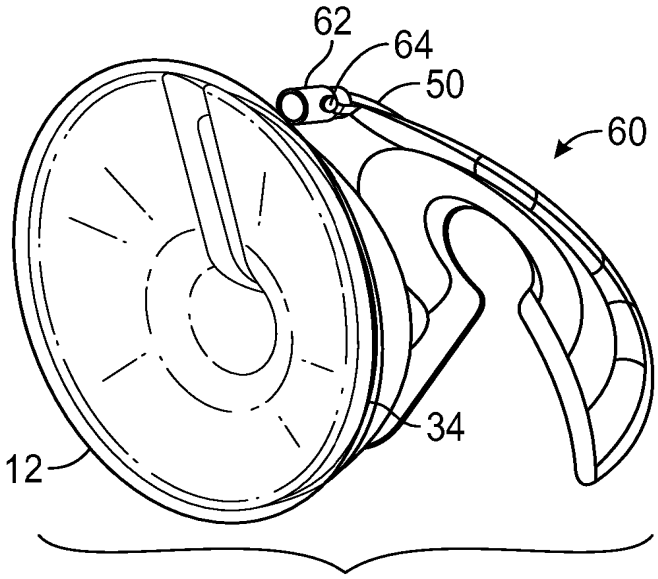


FIG. 59E

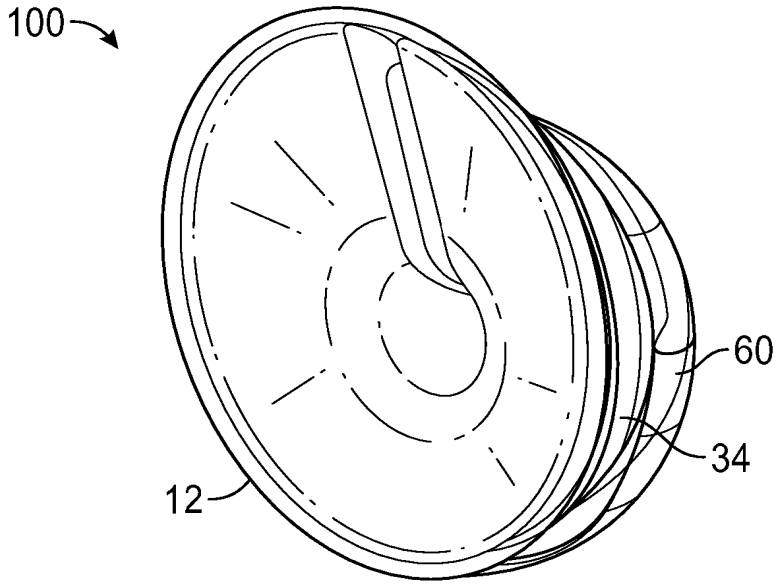


FIG. 59F

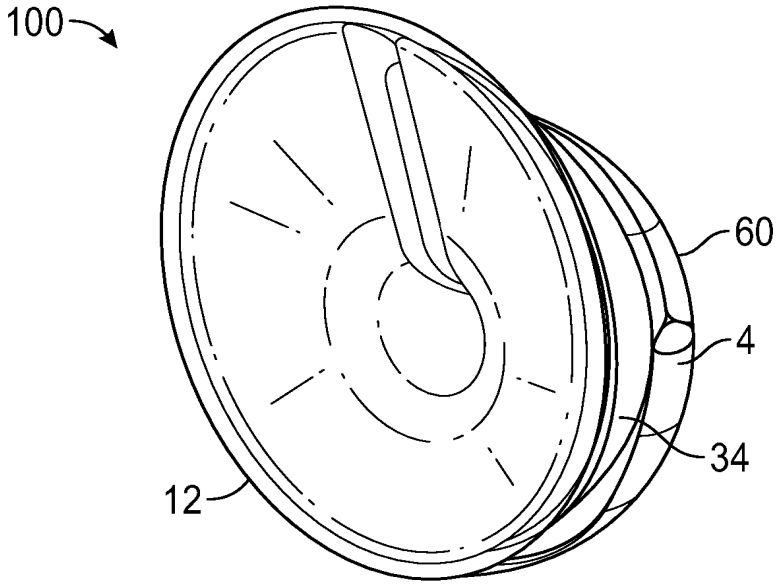


FIG. 59G

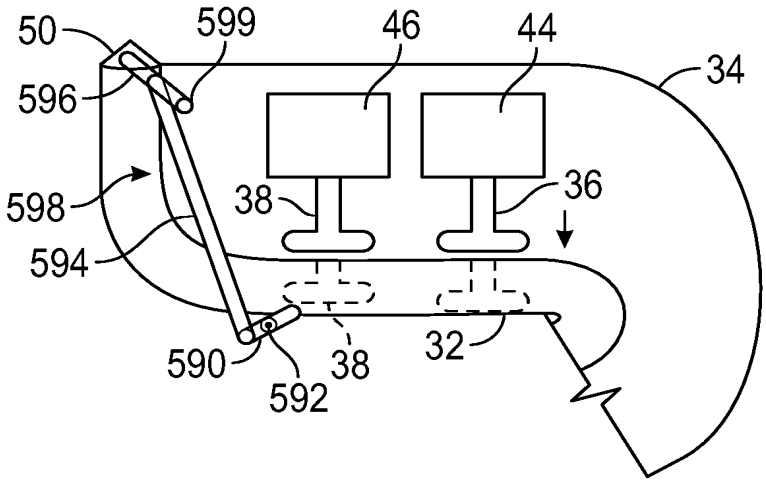


FIG. 60

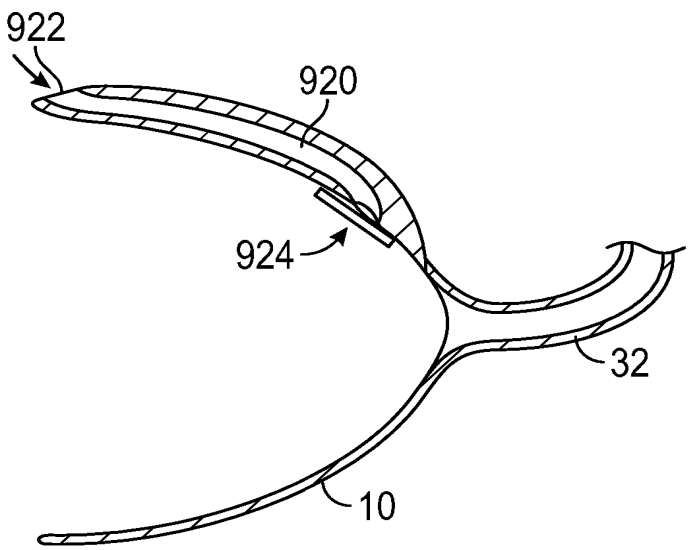


FIG. 61

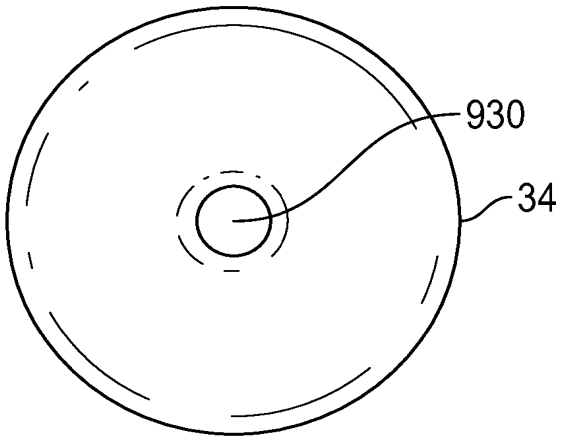


FIG. 62

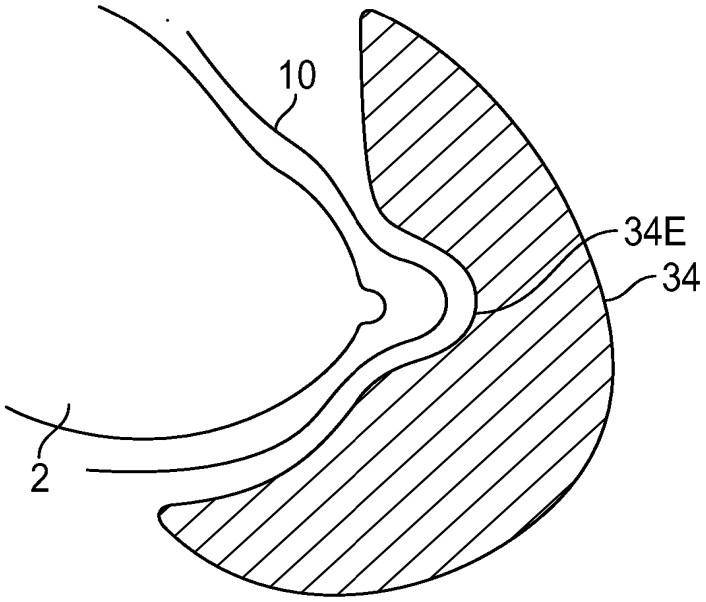


FIG. 63

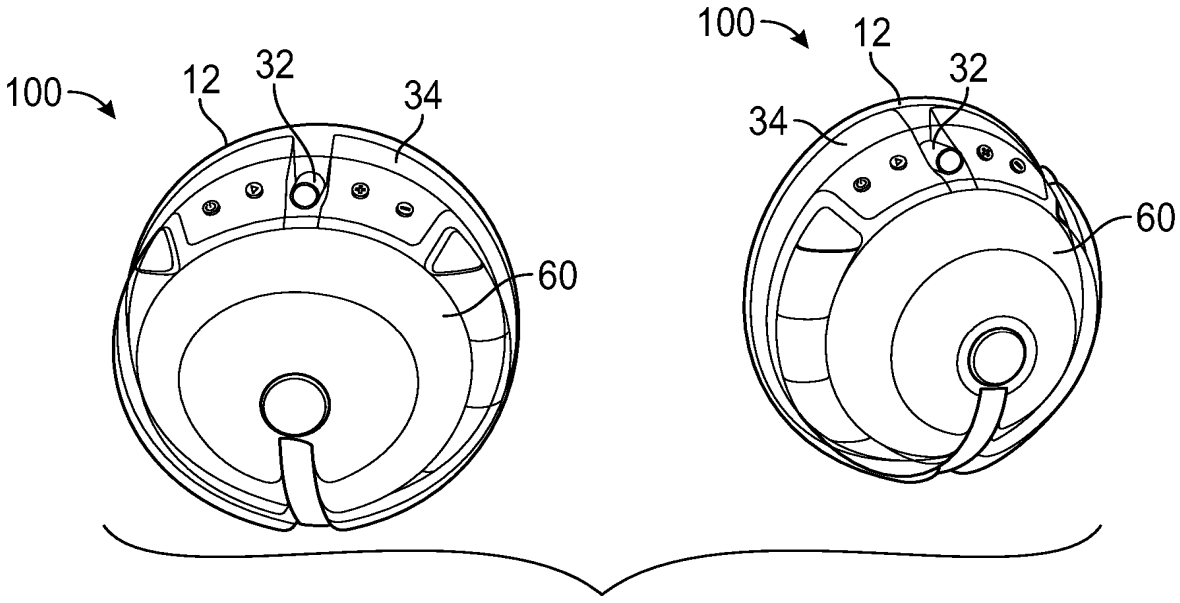


FIG. 64

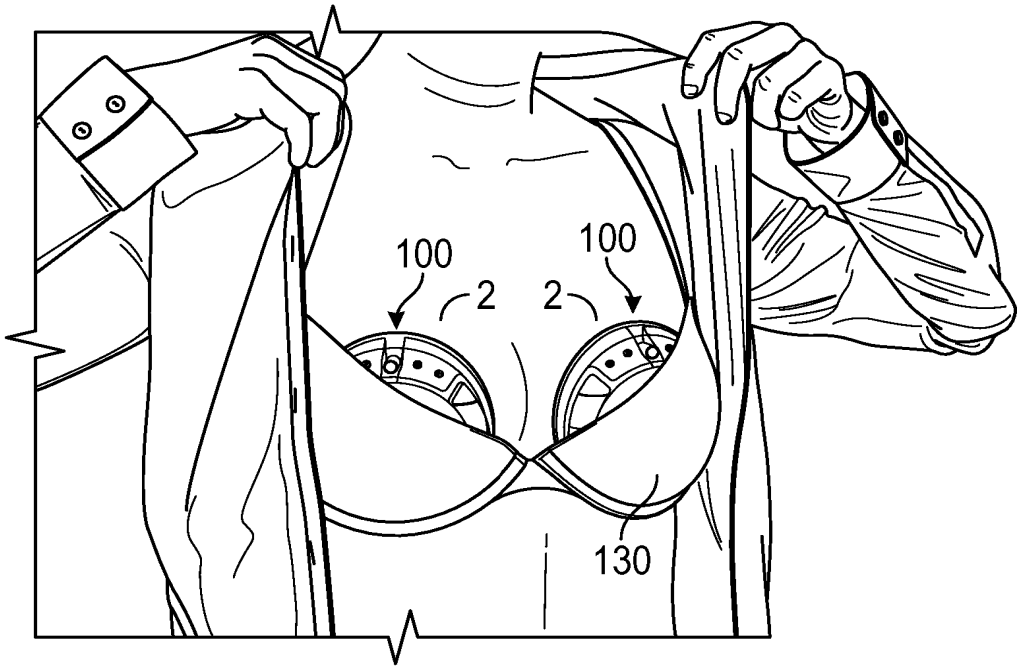


FIG. 65

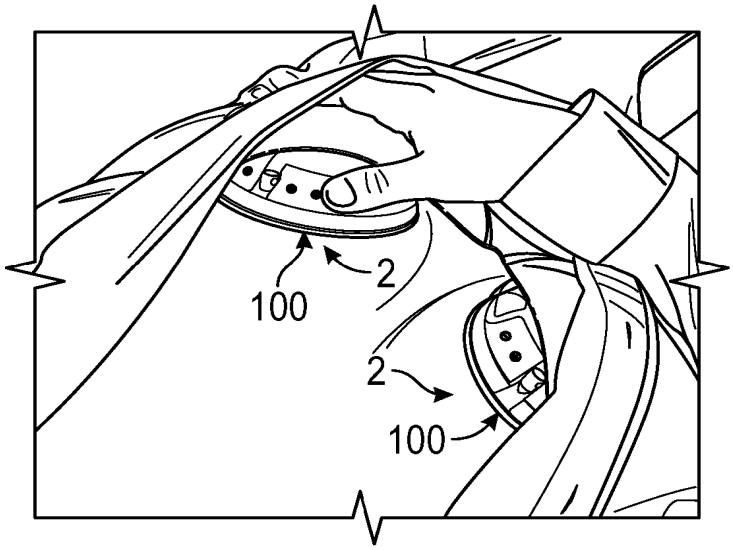


FIG. 66

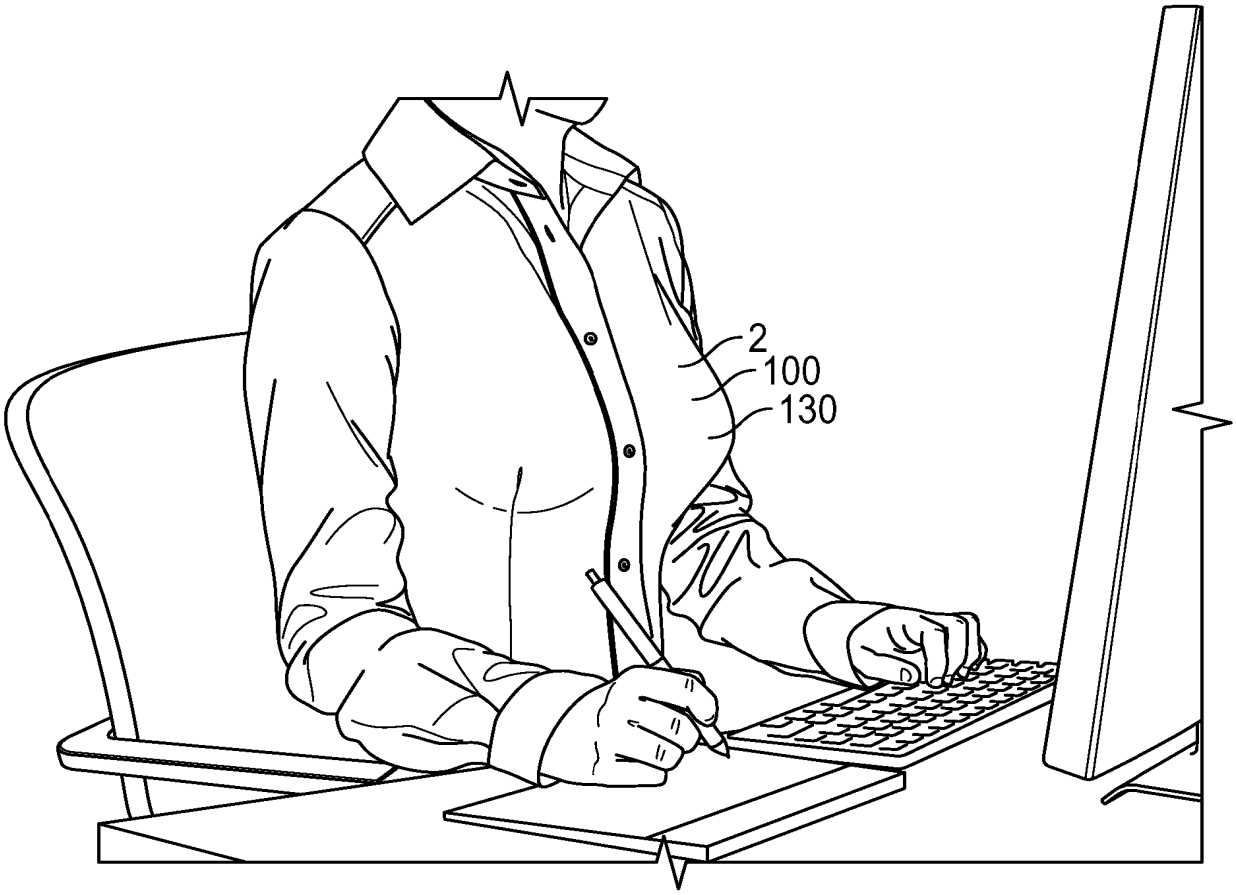


FIG. 67

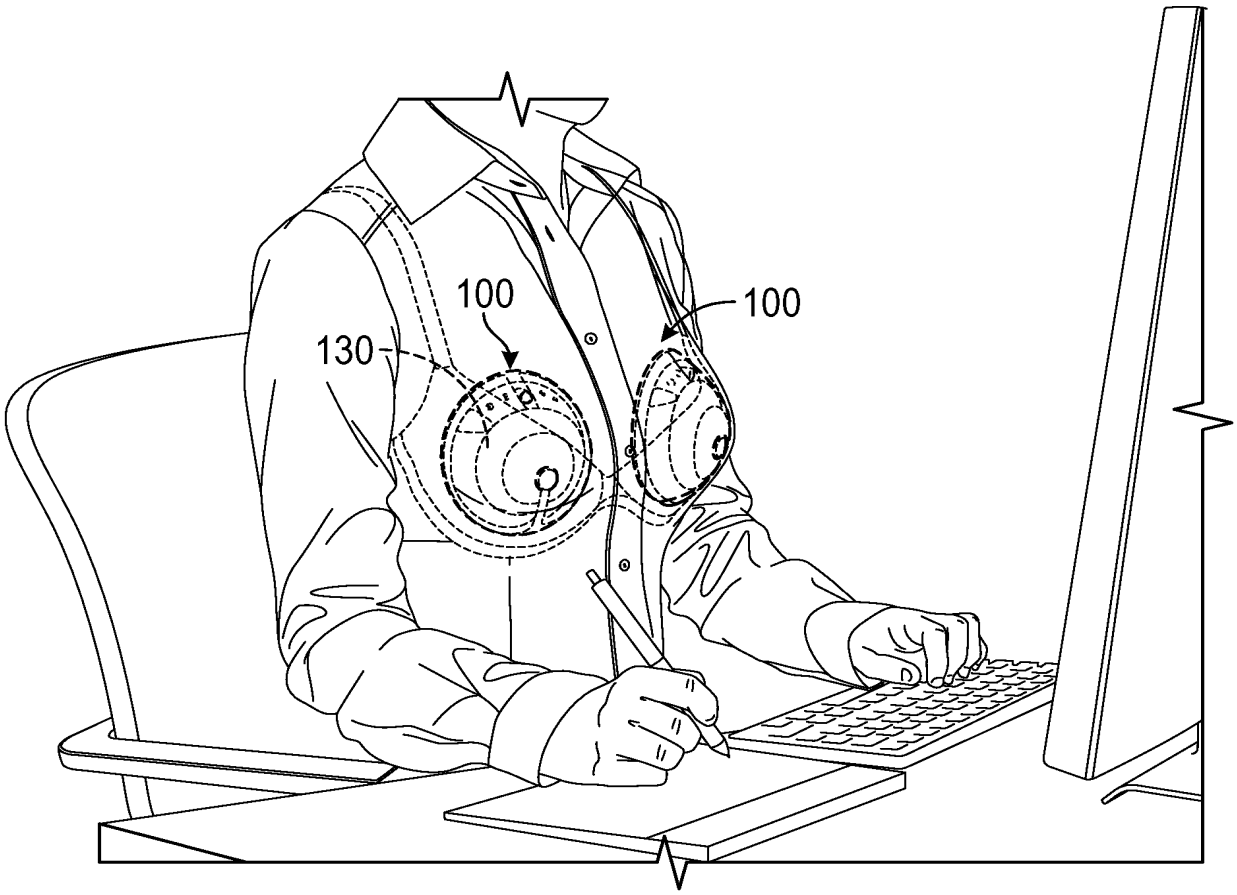


FIG. 68

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2015/041257

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), USPTO, PAJ, Esp@cenet, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8070715 B2 (MEDELA HOLDING AG) 06.12.2011, abstract, claims 1-5, 7, 18, 20, 22, 23, column 5,lines 11-39, 43-50, column 10, lines 44-50, column 11, lines 10-22, fig. 1, 3, 6, 7	1, 11
Y		2, 3, 12, 13
Y	US 4263912 (ADAMS FRANK H) 28.04.1981, abstract, column 9, lines 5-14, 20-68, column 10, lines 3-13	2, 3, 12, 13

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2015 (19.10.2015)	05 November 2015 (05.11.2015)

Name and mailing address of the ISA/RU:	Authorized officer
Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	E. Nosova Telephone No. 8 (499) 240-25-91

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041257

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 14-38
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 January 2016 (28.01.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/014488 A1

(51) **International Patent Classification**:
A61M 1/06 (2006.01)

(21) **International Application Number**:
PCT/US2015/041277

(22) **International Filing Date**:
21 July 2015 (21.07.2015)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
62/027,685 22 July 2014 (22.07.2014) US
62/053,095 19 September 2014 (19.09.2014) US

(71) **Applicant**: **EXPLORAMED NC7, LLC** [US/US]; 2570 W. El Camino Real, Suite 310, Mountain View, CA 94040 (US).

(72) **Inventors**: **MAKOWER, Joshua**; 14300 Miranda Road, Los Altos Hills, CA 94022 (US). **CHANG, John, Y.**; 354 Solana Drive, Los Altos, CA 94022 (US). **TOROSIS, Michele**; 1262 Nightingale Court, Los Altos, CA 94020 (US). **LANDRY, Michael**; 1805 Vista Lane, Austin, TX 78703 (US). **BRIGHT, Earl**; 1590 Julie Lane, Los Altos, CA 94024 (US). **CANNON, Alan, W.**; 32933 Norwalk Street, Union City, CA 94587 (US).

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) **Title**: BREAST PUMP SYSTEM AND METHODS

(57) **Abstract**: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

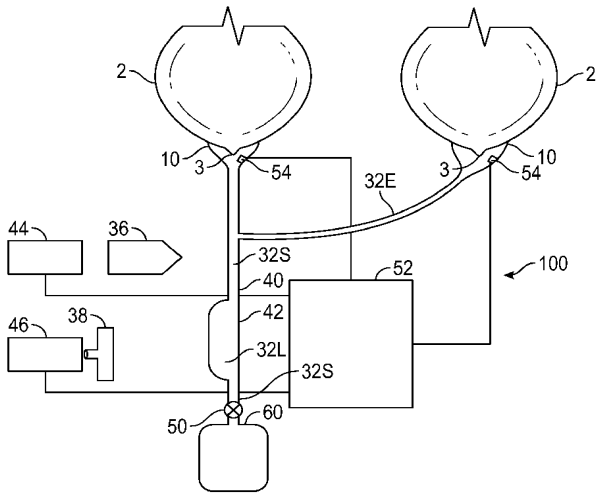


FIG. 24

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BREAST PUMP SYSTEM AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to portable, energy efficient breast pump systems and methods for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be painful to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. Many of the breast pumps available are clearly visible to an observer when the mother is using it, and many also expose the breast of the mother during use.

[0004] There is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump system that is easy to use and is discrete by not exposing the breast of the user and being invisible or nearly unnoticeable when worn.

SUMMARY OF THE DISCLOSURE

[0005] Briefly and in general terms, the present disclosure is directed towards breast pump systems and methods. The system can include breast contacting structure, a storage container and structure that facilitates transfer of extracted mild from the breast to the storage container. The method can involve pumping milk from a breast and delivering mild to the storage container. In one particular approach, a controller is further provided which controls the breast pump, and in one embodiment, controls the pumping of milk from a plurality of breast pumps.

[0006] According to one aspect of the present disclosure, a system for pumping milk from a breast can included a skin contact member configured to form a seal with the breast. The system can additionally or alternatively include one or more of a conduit in fluid communication with and connected to the skin contact member and a driving mechanism configured to compress a first region of the conduit, wherein the first region in the conduit has a first cross-sectional area, wherein a second region of the conduit has a second cross-sectional area, wherein a third region of .the conduit has a third cross-sectional area, and wherein the first cross-sectional area is larger than the second cross-sectional area and larger than the third cross-sectional area.

[0007] In various of the disclosed embodiments, the system defines a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers.

[0008] In at least one embodiment, the skin contact member, the conduit and the driving mechanism are contained within a main body that is configured to be attached to the breast and supported by a bra. The system can further include a one-way valve attached to a proximal end of the conduit and a storage container for storing the milk pumped from the breast. The system can also further include a one-way valve attached to a proximal end of the conduit and configured to attach to the storage container to place the conduit in fluid communication with the storage container.

[0009] A driving mechanism can be provided and be further configured to retract away from the first region of the conduit, and wherein a suction created by compressing the first region of the conduit and allowing the first region of the conduit to rebound is a driving force for extracting milk from the breast.

[0010] In at least one embodiment, the conduit, the driving mechanism and the controller are contained within a main body, the system further including controls on the main body that are operable by a user to select or modify at least one of: pumping mode, frequency of pumping cycle, maximum suction pressure achieved during a pumping cycle, latch suction pressure achieved during the pumping cycle, pumping force and pumping session time. The skin contact member may be incorporated in the main body, the main body being configured to be attached to the breast and supported by a bra. In at least one embodiment, the main body is connected to the skin contact member via a second conduit.

[0011] In at least one embodiment, the driving mechanism and the controller are contained within a main body, the system further including one or more of: an external computer external of the main body; the controller being configured to send signals to and receive signals from the external computer. The controller can include a wireless transmitter and wireless receiver for wirelessly sending the signal to and receiving the signals from the external computer. The external computer can also include a processor and instructions, which when executed, cause the processor to: customize pump functions based on the signals received from the controller; and send the customized pump functions to the controller. Further, the external computer includes a processor and instructions, which when executed, cause the processor to: calculate volume of milk extracted, to track expression efficiency and monitor it over time, based on the signals received from the controller. Additionally, the external computer can include a processor and instructions, which when executed, cause the processor to track of inventory of previous pumping sessions, including tracking at least one of: dates of the previous pumping sessions, volumes pumped in the previous pumping sessions, and specific tracking numbers for specific milk collection containers into which milk has been pumped in the previous pumping sessions. Alternatively or additionally, the

external computer can send the customized pump functions to the controller in real time, during a pumping session.

[0012] The main body is contemplated to include a battery electrically connected to the controller and the pumping mechanism, and the external computer includes a processor and instructions, which when executed, cause the processor to one or more of monitor remaining battery power of the battery and output a warning when the battery reaches a predetermined low level of charge. The customized pump functions include modifications to at least one of: maximum suction pressure level, latch suction pressure level, suction pressure waveform over a pumping cycle, phases of extraction or feeding times, rest times, heating temperatures and times, vibration frequency and duration, and pumping session time.

[0013] In at least one embodiment, the external computer includes a display, and a processor and instructions, which when executed, cause the processor to: display one or more photos of a user's baby during a pumping session.

[0014] In at least one embodiment, the external computer includes a processor and instructions, which when executed, cause the processor to: compile a histogram, using signals received from the controller; and display the histogram on a display of the external computer.

[0015] In at least one embodiment, the external computer is further configured to receive inputs from a user when the user uses an input feature of the external computer; wherein the external computer includes a processor and instructions, which when executed, cause the processor to produce at least one of: customized pump functions, recommendations to the user, or a histogram based on the signals received from the controller and inputs received from the user.

[0016] According to another aspect of the present disclosure, a system for pumping milk from a breast including a skin contact member to form a seal with the breast includes one or more of: a conduit in fluid communication with, the skin contact member at a first end portion of the conduit; a one-way valve connected at a second end portion of the conduit; and a driving mechanism configured to compress and release compression of at least one region of the conduit; wherein the compression and

release of the compression provide driving forces for extracting the milk from the breast and pumping the milk out of the second end portion of the conduit.

[0017] In at least one embodiment, the skin contact member comprises a proximally extending segment joining the conduit and forming a chamber between the breast and the conduit.

[0018] In at least one embodiment, the segment forming the chamber extends downwardly from a nipple of the breast when the skin contact member is sealed to the breast.

[0019] In at least one embodiment, the segment comprises an outlet located where the conduit joins the segment, the outlet located in a lower portion of segment, so that milk, when contained in the segment extends to a fluid level above the outlet.

[0020] In at least one embodiment, the skin contact member comprises a flange comprising a compliant material.

[0021] In at least one embodiment, the segment comprises a flap which covers a predetermined portion of an opening of the segment, said flap being mounted on a living hinged such that a nipple of the breast bends the flap over to open the opening when inserted into the segment, and upon withdrawing the nipple from the segment, the flap returns to a position covering said predetermined portion of said opening.

[0022] In at least one embodiment, the flange comprises a stiff region comprising a stiff material less compliant than the compliant material.

[0023] In at least one embodiment, the stiff region is formed by an insert comprising the stiff material.

[0024] In at least one embodiment, the stiff region is integral with the flange.

[0025] In at least one embodiment, the skin contact member and the conduit are integrally formed.

[0026] In at least one embodiment, the skin contact member and the conduit are formed in portions dividable along axis aligned with a flow path of the conduit; wherein the portions can be opened up along the axis to facilitate cleaning internal surfaces of the skin contact member and the conduit.

[0027] In at least one embodiment, a segment of the portions is joined by a hinge, such that upon opening the portions for cleaning, the portions remain connected to one another via the hinge.

[0028] In at least one embodiment, the portions comprise mating connectors along perimeters thereof, to facilitate attachment and detachment of the portions to and from one another.

[0029] In at least one embodiment, the perimeters form an airtight seal upon connecting the portions together.

[0030] In at least one embodiment, the system further includes rigid frames that contact perimeters of the mating portions, providing a backing to facilitate forming a seal between the perimeters of the portions.

[0031] In at least one embodiment, the conduit includes a first region, a second region and a third region, the second region being upstream of the first region and the third region being downstream of the first region; wherein the first region has a first cross-sectional area, the second region has a second cross-sectional area, and the third region of has a third cross-sectional area; and wherein the first cross-sectional area is larger than the second cross-sectional area and larger than the third cross-sectional area.

[0032] In at least one embodiment, the second region is reinforced with at least one biasing member.

[0033] In at least one embodiment, the driving mechanism comprises at least one motor.

[0034] In at least one embodiment, the driving mechanism comprises an encoder cooperating with the motor to tract a current position of the motor.

[0035] In at least one embodiment, the skin contact member, the conduit and the driving mechanism are contained within a main body that is configured to be attached to the breast and supported by a bra.

[0036] In at least one embodiment, the system further includes a flange member releasably attachable to the main body to provide an appearance of a natural breast contour when clothing is worn over the flange member attached to the main body having been attached to the breast.

[0037] In at least one embodiment, the system further includes a contouring shell configured to receive the main body therein and to provide an appearance of a natural breast contour when the skin contact member is sealed to the breast.

[0038] In at least one embodiment, the system further includes a second skin contact member configured and dimensioned to form a seal with a second breast; and a second conduit in fluid communication with the second skin contact member.

[0039] In at least one embodiment, the driving mechanism is a first driving mechanism, the system further including: a second driving mechanism configured to compress and release compression of at least one region of the second conduit; wherein the compression and release of the compression of the at least one region of the second conduit provide driving forces for extracting the milk from the second breast and pumping the milk out of the second conduit.

[0040] In at least one embodiment, the second conduit is in fluid communication with the driving mechanism.

[0041] In at least one embodiment, the system further includes a controller configured to control operations of the driving mechanism.

[0042] In at least one embodiment, the system further includes a sensor configured to sense at least one dynamically changing characteristic within the system, the sensor being configured to input signals representative of the at least one dynamically changing characteristic to the controller.

[0043] In at least one embodiment, the sensor comprises a pressure sensor.

[0044] In at least one embodiment, the controller uses inputs signals from the sensor to control operations of the driving mechanism with a negative closed loop feedback mechanism, to extract milk from the first and second breasts.

[0045] In at least one embodiment, the system further includes a first controller configured to control operations of the first driving mechanism, and a second controller configured to control operations of the second driving mechanism.

[0046] In at least one embodiment, the system further includes a first sensor configured to sense at least one dynamically changing characteristic within the system, and a second sensor configured to sense the at least one dynamically changing characteristic within the system, the first sensor being configured to input signals representative of

the at least one dynamically changing characteristic to the first controller and the second sensor being configured to input signals representative of the at least one dynamically changing characteristic to the second controller.

[0047] In at least one embodiment, the first sensor comprises a first pressure sensor and the second sensor comprises a second pressure sensor.

[0048] In at least one embodiment, the first controller uses input signals from the first sensor to control operations of the first driving mechanism with a negative closed loop feedback mechanism, to extract milk from the first breast and the second controller uses input signals from the second sensor to control operations of the second driving mechanism with a negative closed loop feedback mechanism, to extract milk from the second breast.

[0049] In at least one embodiment, the first and second controllers are configured to transmit and receive signals from one another for coordinated control of the first and second driving mechanisms.

[0050] In at least one embodiment, the system further includes one or more of an external computer comprising a processor, transmitter and receiver, the external computer configured to receive signals from the controller, calculate modified controlled parameters and send the modified control parameters to the controller, wherein upon receiving the modified control parameters, the controller modifies operation of the driving mechanism in accordance with the modified control parameters.

[0051] In at least one embodiment, the system further includes a cleaning bottle configured to input cleaning fluid into the skin contact member and the conduit for cleaning internal surfaces of the skin contact member and the conduit.

[0052] In at least one embodiment, the system further includes a cleaning implement configured to make physical contact with inner surfaces of the conduit for cleaning the conduit.

[0053] In at least one embodiment, the cleaning implement comprises a brush.

[0054] According to another aspect of the present disclosure, a method of pumping milk from a breast includes one or more of: generating suction pressure in a conduit in fluid communication with the nipple of the breast; monitoring at least one dynamic

characteristic; and modifying the suction pressure in the conduit, as a result of feedback received from the monitoring.

[0055] In at least one embodiment, the monitoring comprises monitoring pressure.

[0056] In at least one embodiment, the monitoring comprises monitoring milk flow rate.

[0057] In at least one embodiment, the method further includes automatically ceasing suction pressure generation based on feedback received from the monitoring.

[0058] In at least one embodiment, the monitoring and the modifying are performed by a controller onboard a pumping system that includes a driving mechanism that generates the suction, the method further including: transmitting data from the controller to an external computer having at least one processor.

[0059] In at least one embodiment, the method further includes instructions which, when executed by the at least one processor cause the processor to: receive data transmitted by the controller; calculate at least one result using the data as inputs; and perform at least one of transmitting the at least one result to the controller and display the at least one result on a display of the external computer.

[0060] In at least one embodiment, the monitoring and the modifying are performed by a controller onboard a pumping system that includes a driving mechanism that generates the suction, the method further including: modifying, with an external computer external of the pumping system, instructions for carrying out at least one pump function by the pumping system; and transmitting the instruction to the controller.

[0061] In at least one embodiment, the monitoring and the modifying are performed by a controller onboard a pumping system that includes a driving mechanism that generates the suction, the method further including one or more of: providing an external computer external to the system; receiving data from the controller; and performing at least one of: customizing at least one pump function, calculating volume of milk extracted, tracking expression efficiency; monitoring expression efficiency over time, tracking inventory of expressed milk, tracking dates of milk pumping sessions, and tracking specific containers used in specific pumping sessions, based on data received by the external computer from the controller.

[0062] In at least one embodiment, the at least one pump function comprises at least one of: suction levels, suction waveforms, amplitude and duration of application of suction, phases of extraction or feeding times, rest programming, heating temperatures and times, vibration frequency and duration and pumping session duration.

[0063] In at least one embodiment, the method further includes displaying at least one image of a user's baby on a display of the external computer when milk is being pumped from the breast.

[0064] According to another aspect of the present disclosure, a method of improving breast pumping includes one or more of: generating suction pressure with a breast pump to cause expression of milk from the breast; monitoring at least one dynamic characteristic created by the breast pump; sending pumping data from the breast pump to an external computer; compiling, by the external computer, data received; and providing to a user at least one output calculated from the pumping data received from the breast pump.

[0065] In at least one embodiment, the at least one output comprises recommendations to a user about future breast pumping sessions.

[0066] In at least one embodiment, the at least one output comprises a histogram compiled by the external computer.

[0067] In at least one embodiment, the method further includes one or more of: modifying, by the external computer, instructions for at least one pump function, based on data received from the breast pump; transmitting the instructions for at least one pump function having been modified to the breast pump; and operating the breast pump using the instructions for at least one pump function having been modified.

[0068] In at least one embodiment, an interactive feature is provided on the external computer, wherein the external computer prompts a user to request input from the user when a downtrend is seen in milk extraction production, as to whether the mother is weaning.

[0069] According to another aspect of the present disclosure, a method of operating a breast pump includes one or more of: attaching a skin contact member of the breast pump to the breast to form a seal therewith; selecting a pumping mode; actuating a compression member to cycle through compression and retraction strokes, according to

the pumping mode to generate suction to express milk from the breast; and automatically modifying the pumping mode based on feedback provided by a sensor in the breast pump.

[0070] In at least one embodiment, the method further includes one or more of: attaching a second skin contact member of a second breast pump to a second breast to form a seal therewith; selecting a pumping mode for the second breast pump; actuating a second compression member to cycle through compression and retraction strokes, according to the pumping mode to generate suction to express milk from the second breast; communicating data between the first and second breast pumps; and automatically modifying the pumping mode of at least one of the first and second breast pumps, based on the data communicated between the first and second breast pumps.

[0071] According to another aspect of the present disclosure, a method of facilitating breast pumping includes one or more of: a user providing personal data about at least one of the user and the user's baby into a program on a computer; sending pumping data from a breast pump during a breast pumping session to the computer; customizing a pumping mode tailored to the user based on the pumping data received from the breast pump and personal data inputted by the user; sending the customized pumping mode to the breast pump; and pumping milk from the user's breast according to instructions contained in the customized pumping mode.

[0072] These and other features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the systems and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0073] Fig. 1A is a side view of a breast pump system (without milk collection container) according to an embodiment of the present disclosure.

[0074] Fig. 1B illustrates components of the breast pump system of Fig. 1A with the exterior of the main body having been removed.

[0075] Fig 1C shows a proximal end view of Fig. 1B.

[0076] Fig. 2A is a perspective view of a skin contact member integrally formed with a conduit, according to an embodiment of the present disclosure.

[0077] Fig. 2B illustrates a skin contact portion with a downwardly sloping proximal segment, according to an embodiment of the present disclosure.

[0078] Fig. 3 shows a proximal end view of a subassembly according to an embodiment of the present disclosure.

[0079] Fig. 4 illustrates a cleaning bottle administering cleaning fluid to a skin contact member and conduit, according to an embodiment of the present disclosure.

[0080] Fig. 5 illustrates a cleaning implement according to an embodiment of the present disclosure.

[0081] Fig. 6 shows one side portion of the subassembly of Fig. 3.

[0082] Fig. 7 illustrates a flange stiffener according to an embodiment of the present disclosure.

[0083] Fig. 8 illustrates rigid frames according to an embodiment of the present disclosure.

[0084] Fig. 9A a biasing member inside a chamber according to an embodiment of the present disclosure.

[0085] Fig. 9B illustrates resilient ribs attached to a backing face of a chamber according to an embodiment of the present disclosure.

[0086] Fig. 9C illustrates compression springs installed along walls of a chamber according to according to an embodiment of the present disclosure.

[0087] Fig. 9D illustrates a compression member attached to a conduit portion, according to an embodiment of the present disclosure.

[0088] Fig. 10 illustrates a view of a compression member according to an embodiment of the present disclosure.

[0089] Fig. 11 illustrates a motor and encoder according to an embodiment of the present disclosure.

[0090] Fig. 12 is a view of a compression member according to an embodiment of the present disclosure.

[0091] Fig. 13A illustrates the use of two compression members for compressing a pumping chamber, according to an embodiment of the present disclosure.

[0092] Fig. 13B illustrates the use of one compression member for compressing a pumping chamber, according to an embodiment of the present disclosure.

[0093] Fig. 13C is a side view of the embodiment shown in Fig 13A, but shown with the external shell of the main body.

[0094] Fig. 13D is a side view of the embodiment shown in Fig 13B, but shown with the external shell of the main body.

[0095] Fig. 13E illustrates a drive train for driving two compression members with one motor, according to an embodiment of the present disclosure.

[0096] Fig. 14A illustrates a partial view of a pumping system according to an embodiment of the present disclosure.

[0097] Fig. 14B illustrates a partial view of a pumping system according to another embodiment of the present disclosure.

[0098] Figs. 15A-15C illustrate longitudinal sectional views of various sizes of external shells that can be attached to a main body of a system according to embodiment of the present disclosure.

[0099] Fig. 16A illustrates a model of a main body of a system according to an embodiment of the present disclosure.

[00100] Fig. 16B shows placement of the model on the breast of a user, according to an embodiment of the present disclosure.

[00101] Fig. 16C shows the appearance of the model and breast when supported by a bra, according to an embodiment of the present disclosure.

[00102] Fig. 16D shows the breast with the model installed, supported by bra, with a t-shirt being worn, according to an embodiment of the present disclosure.

[00103] Fig. 17A illustrates an example in which form factor of the main body does not follow the contours of the breast.

[00104] Fig. 17B illustrates that even after donning a supporting bra and outer garment, the main body mounted to the breast is still noticeable as an unnatural contour.

[00105] Fig. 18A is a cross-sectional view of a contouring flange according to an embodiment of the present disclosure.

[00106] Fig. 18B illustrates the contouring flange of Fig. 18A attached to a main body, according to an embodiment of the present disclosure.

[00107] Fig. 18C illustrates the user shown in Fig. 17B after adding the contouring flange of Fig. 18A to the main body before fitting it to the breast, according to an embodiment of the present disclosure.

[00108] Fig. 18D illustrates a contouring flange according to another embodiment of the present disclosure.

[00109] Fig. 19A illustrates a cross-sectional view of a contouring shell according to an embodiment of the present disclosure.

[00110] Fig. 19B illustrates use of a contouring shell by a user employing a system according to an embodiment of the present disclosure.

[00111] Fig. 19C shows a variant of the contouring shell of Fig. 19A.

[00112] Fig. 19D is a cross-sectional view of a contouring shell according to another embodiment of the present disclosure.

[00113] Fig. 19E is a cross-sectional view of a contouring shell according to another embodiment of the present disclosure.

[00114] Fig. 19F is a cross-sectional view of a contouring shell according to another embodiment of the present disclosure.

[00115] Fig. 20 illustrates a system wherein two devices are used together, according to an embodiment of the present disclosure.

[00116] Fig. 21 illustrates a system wherein two devices are used together, according to another embodiment of the present disclosure.

[00117] Fig. 22 illustrates a system wherein two devices are used together, according to another embodiment of the present disclosure.

[00118] Fig. 23 illustrates a system in which a pump device is attached to one of the user's breasts and a skin contact member is attached to the other breast, according to an embodiment of the present disclosure.

[00119] Fig. 24 schematically illustrates the conduit connections of the embodiment of Fig. 23 in more detail.

[00120] Fig. 25 shows a schematic circuit diagram of componentry used to control a system according to an embodiment of the present disclosure.

[00121] Fig. 26 is a perspective view of a device of the system according to an embodiment of the present disclosure.

[00122] Fig. 27 illustrates events that may be carried out in a coordinated operation of breast pumps on both breasts using a system according to an embodiment of the present disclosure.

[00123] Fig. 28 is a schematic representation of transfer of data wirelessly from a controller to a smartphone, according to an embodiment of the present disclosure.

[00124] Fig. 29 illustrates a milk collection container with a barcode or QR code, according to an embodiment of the present disclosure.

[00125] Fig. 30 illustrates a histogram displayed on an external computer, according to an embodiment of the present disclosure.

[00126] Fig. 31 schematically illustrates data inputs that are received by an app/software of an external computer, used to evaluate, track and manage breast milk expression using a system according to an embodiment of the present disclosure.

[00127] Fig. 32 illustrates a histogram displaying expected breast milk extraction volumes, according to an embodiment of the present disclosure.

[00128] Fig. 33 illustrates a breast pump system according to an embodiment of the present disclosure, in which the controller is provided in an external computer, according to an embodiment of the present disclosure.

[00129] Fig. 34 illustrates a system that includes vibration members, according to an embodiment of the present disclosure.

[00130] Fig. 35 illustrates a subassembly according to another embodiment of the present disclosure.

[00131] Fig. 36 illustrates cleaning fluid being administered to the interior surfaces of a skin contact member and conduit, according to an embodiment of the present disclosure.

[00132] Fig. 37 is a partial view of a subassembly according to another embodiment of the present disclosure.

[00133] Fig. 38 illustrates a breast pump system according to another embodiment of the present disclosure.

[00134] Fig. 39 illustrates a breast pump system according to another embodiment of the present disclosure.

[00135] Fig. 40 illustrates a breast pump system according to another embodiment of the present disclosure.

[00136] Fig. 41 illustrates one example of a pressure waveform used in one pumping mode of a system according to an embodiment of the present disclosure.

[00137] Fig. 42 illustrates a method of monitoring a baby's feeding style during breastfeeding, according to an embodiment of the present disclosure.

[00138] Fig. 43 illustrates a system including a sensor adhered to the breast of a user, according to an embodiment of the present disclosure.

[00139] Fig. 44 is a detailed view of the sensor of Fig. 44.

DETAILED DESCRIPTION OF THE DISCLOSURE

[00140] Before the present systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[00141] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[00142] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure, the

preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[00143] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a valve" includes a plurality of such valves and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[00144] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. The dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[00145] Fig. 1A is a side view of a breast pump system 100 (without milk collection container) according to an embodiment of the present disclosure. The main body 34 of system 100 is shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. Fig. 1B illustrates components of the breast pump system 100 with the exterior of the main body 34 having been removed. System 100 includes a skin contact member 10 (such as the breast flange shown in Fig. 1B, or member having a different shape, but configured to seal to the breast of a wearer and provide fluid communication with the pump) a pumping region 30 and a conduit 32. Fig. 1C shows a proximal end view of Fig. 1B, to illustrate more details of the pumping region 30.

[00146] The conduit region 32L in the embodiment of Figs. 1A-1C in not cylindrical,

but is formed as a pump chamber having a substantially oval face 32F and walls that extend substantially perpendicular thereto. The backing face 32LP, such as the backing plate 32LP shown in Fig. 2 is substantially oval in shape with a substantially flat surface the joins the walls 32W (see Fig. 9) of the chamber to seal the chamber. The conduit portions 32S are cylindrical as shown, but do not need to be tubular or circular in cross section. When tubular, the cross-sections may be oval, square, other polyhedral shape, non-symmetrical, or non-geometric shape. In one embodiment where tubing/conduit regions 32S are circular in cross section, 32S has an inside diameter of .104 inches and a wall thickness of .044 inches. Tubing 32S can have inside diameter dimensions in the range of .040 inches to .25 inches and wall thickness dimensions in the range of .006 inches to 3/32 inches. The hardness of the materials used to make tubing region 32S that is compressed by compression member 36 and compression chamber 32L (but not the backing member 32LP) can be in the range of 20 to 70 Shore A Durometer, typically in the range of 45 to 55 Shore A Durometer. However, these values may vary, depending upon the geometry of the portions 32S and 32L. Also, the material(s) used for the portions 32S, 32L is chosen for the ability to rebound against the high vacuum generated by the system. If the rebound is generated in another way, or assisted with another feature, the wall thicknesses and durometers of portions 32S and 32L can be relatively lower. Examples of assist features include, but are not limited to: ribbed reinforcement of portion 32L; attachment of compression members 36, 38 to portions 32S, 32L, respectively; and/or provision of one or more biasing members 32B such as a spring to provide or assist in providing rebound force, as illustrated in Fig. 9A, for example. One or more biasing members 32B may be incorporated into or the walls 32W and/or face 32LP of the chamber 32L. Fig. 9B illustrates resilient ribs 32B attached to the backing face 32LP of the chamber 32L. Fig. 9C illustrates compression springs 32B installed along walls 32W in between stiffened shoulders 32SH extending from face 32F and stiffened regions of conduit 32S or extensions of the still backing face 32LP. Alternatively, a single compression spring could be installed around all four walls between faces 32F, 32LP. Alternatively or additionally, one or more biasing members 32B may be positioned inside the chamber as illustrated in Fig. 9A. When positioned inside the chamber, the one or more biasing

members are made as thin as functionally possible, to limit the amount of restriction to milk flow caused thereby.

[00147] Further alternatively or in addition to use of one or more biasing members, the face 32LP may include features that can attach to the compression member 38, so that when the compression member 38 moves in a direction away from the conduit portion 32L, the face 32F is drawn by the pulling force of the compression member 38, thereby facilitating its re-expansion or rebound from the compressed configuration. Fig. 9D illustrates one embodiment of this feature, in which undercuts or notches 32U are formed in the face 32F to mate with tabs 38T formed in compression member 38. Optionally, as also shown in Fig. 9D, notches 38N can be formed in compression member 38 to mate with tabs 32T extending from face 32F to further secure the connection between the compression member 38 and face 32F. The attachment between the compression member 38 and face 32 can be readily manually separated, thereby facilitating easy removal of subassembly 35 for cleaning, replacement, etc.

[00148] Two active compression elements 36, 38 are operable to compress and allow decompression of the conduit portions 32S and 32L, respectively at compressible regions 40 and 42, respectively. Although the preferred embodiment uses two active compression elements as shown, alternative embodiments could have three or more active compression elements. Resilient conduit 32 is preferably made of silicone, but could alternatively be made from other thermoplastic elastomers exhibiting the desired performance characteristics described herein, including, but not limited to polyurethanes and/or PEBAX. Different regions of conduit 32 may be made of different materials/material properties. The regions can all be molded of the same material, overmolded, glued or otherwise attached, constructed, etc. In at least one embodiment, the compressible regions 40, 42 may have different properties from other non "active" regions – such as those non active regions being rigid (e.g., tubing 32S upstream and/or downstream of the pumping region and/or other non-active regions) to improve pumping efficiency by reducing energy losses due to expansion and contraction of regions not intended to be active. The non-active regions can be made of different materials from the active regions or otherwise reinforced. The various regions can also be other shapes than circular in cross-section. The material(s) from

which the compression regions 40, 42 of conduit 32L are made can be the same as that of the skin contact member 10, only differing optionally by thickness. Further alternatively, the material(s) from which the compression regions 40, 42 are made can differ from one another. A factor in the choice of material and material thickness and length is the response time required to expand the compression regions 40, 42 from a target compressed shape/state to an original, unbiased rebound configuration (e.g., return to a fully unbiased shape), force required to compress to the desired target compressed shape, expansile force (pressure drop) achieved when allowing the conduit portion 32L to self-expand, volume within the regions 40 and 42, compatibility with the materials for the remainder of the skin contact member10 (nipple housing), resiliency to maintain its material properties through multiple wash, aging and use cycles, surface and depth characteristics such as material transparency, clarity and texture/feel against the skin, visual appearance, mechanical durability, tear resistance, shape memory, soft/hardness, biocompatibility, non-reactivity and free of leachables, heat/cold resistance, etc.

[00149] Examples of tubes 32S include, but are not limited to: silicone tubing, such as used in peristaltic pumps, both platinum-cured and peroxide-cured silicone tubes. Dimensions can range greatly in inside diameter and wall thickness, as noted above. Walls may also range to impact properties, with preferred embodiments in the ranges noted above. Inside diameters and wall thicknesses can be varied, as needed, with ensuing appropriate lengths of tubing 32. Likewise, the dimensions, wall thicknesses and volume capacity of chamber 32L may vary, as noted above. Other factors that are considered for material choice and geometry of portions 32L and 32S include characteristics of the material for hysteresis, under the pressures (vacuum levels) experienced during use over repeated cycles, elongation, tensile strength modulus of elasticity and tear strength, etc.

[00150] In the embodiment of Fig. 1C, compression element 36 is minimized, so that length 94 is in the range of about 1 to 4 mm, preferably about 1 to 2 mm, so that it is effective to seal off the tubing 32S, but operates in concert with compression element 38 to establish sufficient suction/vacuum for extracting milk. The length 94 at the proximal end of the compression element 36 is in the range of about .25 inches to 1.0

inch, in at least one embodiment, about .75 inches, and tapers to a length 97 of about 1/16 inch to about 3/16", typically about 1/8 inch. The compression element tapers nearly to a point, but not too sharp to run the risk of cutting the tube 32S. Thus, the initial contact surface of compression element 36 against tube 32S is minimized to minimize the amount of force required to initiate collapsing of the tube 32S. Because the contact surface spans across the entire width of the tube 32S, it pinches off the tube 32S against the anvil surface 2320, thus sealing this location in an airtight, liquid-tight manner, so that the suction level experienced by the breast does not change as the compression element 38 works to change the suction level in the conduit 32 downstream of the compression member 36.

[00151] The width of compression element 36 is typically at least as great as the inside diameter/width of the conduit 32S at region 40, most typically greater than or equal to the outside diameter/width of portion 32S, but could be equal or slightly less than the inside diameter/width or less than the outside diameter/width but greater than the inside diameter/width, since the compressive action of the compression element 36 against portion 32S extends slightly past the ends of the compression element 36. By minimizing the length 94, less force is required to seal off the tube 32S, as compared to the force necessary to seal the tube 32S using a compression element 36 having a greater length. Also, the relatively smaller diameter/width of conduit portion 32S compared to cross –sectional width of conduit portion 32L allows the conduit portion 32S to be sealed with a relatively shorter throw of the compression element 36, thereby reducing power requirements of the system 100, which can lead to a smaller driver 44 being used, a smaller battery due to the lower energy requirements, and/or longer operational time before the system 100 needs to be recharged or plugged in to an AC power source (in embodiments where this is possible). Response times of the system 100 may also be faster. The time required for the compression element 36 and the conduit region 32S to completely seal at 40 or release may be shorter. Also, there is less volume that is moved on the final close during feedback, so if the sealing element 36 is near closing and waiting for the pressure feedback controlling the larger compression element 38 to establish the desired pressure before closing, the smaller profile corresponds with less volume change on that final seal motion. Therefore the

sealing can be more precisely and accurately controlled.

[00152] The compression elements 36 and 38 are driven by dedicated compression drivers 44, 46. Alternatively, compression elements 36 and 38 could be driven by a single compression driver, controlled by controller 52 to drive each of the compression elements 36, 38 in the manner desired. In a mechanical system (linkage or cable), a clutch or toggle switch can be used to engage and disengage the compression element 36 at the appropriate time. In a hydraulic or pneumatic system, an additional solenoid valve can be used to shunt power to the compression element 36. As shown, the compression elements 36, 38 comprise pistons, but alternative features could be used to accomplish the same function, such as lever arms, screw drives, clamps, cams, pincers, rollers, magnets, electro-magnets, linear drives, solenoids, gears, stepper motors, or other features, respectively. The compression surfaces of the compression elements 36, 38 may be formed as flat paddles to allow complete crushing of the regions 40, 42 without residual volume. Alternatively, one or both compression surfaces may be formed with a "V-shaped" or "U-shaped" edge (such as in the embodiment of compression member shown in Fig. 10). When so configured, the U-shaped or V-shaped edge of compression member 36 is transverse to the direction of flow through region 40 and the U-shaped or V-shaped edge of compression member 48 is aligned with the direction of flow to allow less force to compress conduit 32 to the same distance of compression, relative to a flat surface paddle.

[00153] One or both compression surfaces may be formed as roller paddles having curved surfaces so that the compression action is not simply straight into the tubing 32. The roller paddle surface can roll on the conduit 32 to seal and move in a given direction. Dual action of the roller can be provided, so that, initially the roller comes down in compression against the conduit 32 and seals the tube 32, which may be capable of being performed with relatively low force. Secondarily, the roller paddle can roll the compression surface in a predetermined direction along the length of the tube 32 and squeeze a volume of milk or air or combination in a given direction. This can be useful to maximize both increase and decrease in pressure changes and fluid movement.

[00154] Each compression element 36, 38 is operatively connected to a driver 44, 46,

respectively, for independent but coordinated driving and retraction of the compression elements 36, 38. When electrically-powered drivers are used, a battery 48 is electrically connected to the drivers 44, 46 and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38 (see Fig. 14). Battery 48 may be induction charged to allow for more water resistance of the device. In an induction-chargeable embodiment, no plug is required to charge the battery 48, but rather the device can be placed on an induction charger that optionally includes a magnet to keep the induction charger properly aligned with the battery for induction charging. For embodiments not employing induction charging, the device can be charged via plug in to an AC charger. Further optionally, a battery brick can be provided in an accessory bag, so that when the device is placed in the accessory bag, it begins charging off the larger battery contained in the "battery brick". Additionally, the battery brick can be plugged into an AC outlet to charge itself, without the need to remove the battery brick from the accessory bag. Further advantageously the battery brick can be configured to charge a pair of devices (pumps) simultaneously when both device are placed in the accessory bag.

[00155] A sensor 54 (see Figs 2 and 3, which show alternative placement locations) is used to provide feedback to the controller 52 for controlling the pumping cycles to achieve and/or maintain desired vacuum levels. In this way, milk ducts are not overly collapsed during a rest or lower suction pressure phase but rather the ducts are allowed to fill like when a baby is latched to a breast. This re-filling allows for more efficiency in milk extraction more similar to a baby than conventional pump devices. Sensor 54 is preferred to be a pressure sensor but could also be a flow, temperature, proximity, motion sensor or other sensor capable of providing information usable to monitor the safety or function of the pump mechanism of system 100. In a preferred embodiment, the pressure sensor is a non-contact type that does not come into contact with the milk. For example sensor 54 can be a thinner wall (or otherwise configured to be more flexible) than the surrounding locations, so that it flexes with changes in pressure, and the positions of the flexing thin wall can be monitored by a sensitive physical gauge (e.g., pressure sensitive resistor, strain gauge, etc.) that contacts the flexing thin wall of

an optical monitor, each of which inputs to the controller 52, so that the controller can calculate the pressure relative to the position of the thin wall. Other embodiments of non-contact sensor that can be used are disclosed in provisional application Serial No. 62/027,685, filed 07/22/2014, which is hereby incorporated herein, in its entirety, by reference thereto. Alternatively, a contact type pressure sensor 54 can be employed. Examples of contact-type pressure sensors 54 that can be employed are disclosed in provisional application Serial No. 62/050,810, filed 09/16/2014, which is hereby incorporated herein, in its entirety, by reference thereto. Upon powering up the system the controller 52 calibrates the pressure sensor 54 to atmospheric pressure, so that it is accurate regardless of the elevation at which it is being used. Preferably sensor 54 is located nearby where the tip of the nipple 3 of the breast 2 is located to determine actual pressure being exposed to the breast 2/nipple 3, but other sensors 54 may be located within the system 100, for example, near where the one-way valve 50 is located, and can be used to monitor other features such as container 60 contents or expulsion pressure or flow rate. With at least one sensor 54 present, by monitoring either flow or pressure directly or indirectly and also taking into account the cycles and actual positions of the compression elements 36, 38 over time, it is possible to derive/calculate approximately the volume of milk produced during a pumping session as well as understand the flow-rate at any particular time in a pumping session. The accuracy of this measurement is greatest when there is no leak of air around the breast 2 and also when there is negligible air within the tube 32, after elimination by a few cycles of the pumping mechanism.

[00156] A one-way valve 50 such as a duckbill valve or other type of one-way valve is provided at the end of conduit 32 (see Fig. 1B where it enters the milk collection/storage container 60) or is connected in fluid communication with another conduit 32' that can connect to a milk collection/storage container 60. Valve 50 prevents back flow of milk into the tube 32, as well as preventing air from entering the proximal end of the tube and thereby maintains the suction (vacuum) level in the conduit 32. Valve 50 can further be designed to open in the reverse direction, for safety purposes, if a predetermined maximum vacuum level is exceed in tubing 32, such as greater than 250 mm Hg vacuum (-250mm Hg pressure), for example. In at

least one embodiment, the pressure at which the valve 50 opens to allow flow into the milk collection container 60 is about 25mm Hg. In an alternative embodiment, a pressure relief valve 150 (see Fig. 1B) can optionally be provided in the system 100, such as in the skin contact member 10, or other location along conduit 32. The pressure relief valve 150 can be configured to release at vacuums greater than a predetermined amount, (e.g., vacuums greater than 250mm Hg (pressures less than -250mm Hg), or some other predetermined maximum vacuum level). If vacuum at the breast 2 were to get too strong, the pressure relief valve 150 provides a mechanical release to prevent vacuum from getting stronger. For example, the pressure relief valve may be set at -250mmHg, the prevent any suction pressure less than -250mm Hg. The pressure relief valve 150 can be in the form of a spring and ball, pin and O-ring, or other equivalent mechanical means of providing pressure relief. The one-way valve 50 can be configured and designed such that it allows fluid to flow through it only when the pressure in tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "crack pressure". The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from conduit 32 and decreasing vacuum when the compression elements compress the conduit 32 (regions 40, 42), but typically should not increase the vacuum to greater than the predetermined maximum vacuum. As the compression elements 36, 38 compress the conduit 32 (against anvil surfaces 2320, 2322, respectively, see Fig. 3C), the pressure in the system 100 goes up and reaches the minimum suction level (e.g., -60mmHg, -30mm Hg, or some other predetermined minimum suction level), at which time the compression member 36 seals off portion 32S (region 40) thereby maintaining the minimum suction against the breast 2. Continued compression of portion 32L by compression member 38 continues to increase the pressure downstream of compression member 36, until the crack pressure is reached (e.g., 25mm Hg or some other predetermined, positive crack pressure), that opens the one-way valve 50. The compression elements 36, 38 continue compressing tube 32, pumping fluid (milk) through the one-way valve 50 and into the collection container 60 until the compression element 38 reaches an end point in travel (typically before "bottoming out" against the anvil). The end point in travel of the compression element 38 against

portion 32L may be predetermined, or may be calculated on the fly by the controller 52 using feedback from pressure sensor 54 and feedback from the driver of the compression element 38, from which the controller 52 can calculate the relative position of the compression element 38 over the course of its travel. The compression member 36 remains closed throughout this process, as it is used to seal off the conduit 32 at region 40 the entire time that the compression element 38 is pumping milk out of the region 42 and into the collection container 60. As the compression elements 36, 38 reverse direction and pull away from the conduit 32, they start the cycle again.

[00157] Fig. 2A is a perspective view of the skin contact member 10 integrally formed with the conduit 32, according to an embodiment of the present disclosure. An open segment 16 within the housing of the skin contact member 10 is configured and dimensioned to allow for at least some clearance and space in front of the nipple 3 to permit milk to exit the nipple even when the nipple is pulled forward by suction. Open segment 16 is typically distinct from the main body of the flange 10 as the flange 10 tapers to meet the generally non-tapered chamber of the open segment 16. In the embodiment shown in Fig. 2, an outlet 13 is formed at or near the top of the proximal end portion of the segment 16 when the flange 10 is attached to the breast 2. This ensures that any air present between the breast 2 and the flange 10 is expelled initially, prior to pumping of milk. In an alternative embodiment, outlet 13 is formed at or near the bottom of the proximal end portion of the segment 16 when flange 10 is attached to the breast 2, as illustrated in Fig. 2B. This placement of the outlet 13 facilitates pumping milk out of the flange 10 after a breast pumping session has ended and the flange 10 has been removed from the breast 2. In addition to placing the outlet 13 at the bottom of the proximal end portion of segment 16, the embodiment in Fig. 2B provides a skin contact member 10 has a segment 16 that angles downwardly away from the nipple 3 when skin contact member 10 is attached to the breast. This orientation helps to minimize the volume of milk remaining in the skin contact member 10/segment 16 at the end of a pumping cycle, as the milk drains by gravity to the lowest level in the segment 16, where the outlet 13 is located. Also, the downwardly projecting angle of the segment and skin contact member 10 directs the nipple 3 downwardly and minimizes air/dead volume 216. Also, the teat is pulled into the skin

contact member 10 with less pressure swing and less movement so segment 16 can be designed as a relatively smaller volume, again leaving less milk 218 at the end of a pumping cycle, and with less risk of chafing or bottoming out of the nipple (teat) in the segment 16. The outlet 13 is below the level where the breast 2 contacts the skin contact member most proximally. Accordingly, this reduces the chances of spilling milk when the skin contact member 10 is removed from the breast. The descending angle of the segment 16 also permits the user to tilt back to a certain degree (such as reclining in a chair or bed) while still maintaining the level of the milk 218 below the proximal most contact between the breast 2 and the skin contact member.

[00158] Further alternatively, the outlet 13 can be formed intermediate the top and bottom of the proximal end portion of the segment 16 when flange 10 is attached to the breast 2, in any of the embodiments described. This placement facilitates some extraction of air out of the space in the flange 10, while also facilitating pumping milk out of the flange 10 when the flange has been removed from the breast 2.

[00159] The subassembly 35 shown in Fig. 2 contains the only components that come in contact with the milk of the user (other than the milk collection container). The subassembly of Fig. 2 is made to be readily removable from the system 100 for cleaning and, in a preferred embodiment, is machine washable. After cleaning the subassembly of Fig. 2 can be easily reinstalled to the system for the next pumping session. In an alternative embodiment, subassembly 35 is made as a disposable part of the system 100 that is removable and replaceable. In one embodiment, the entire subassembly 35 of Fig. 2 is made integral. In another embodiment, the subassembly 35 is made with a split casing so that first and second side portions (which may be hinged, or may be completely separable from one another) can be opened to allow easier cleaning.

[00160] Fig. 3 shows a proximal end view of a subassembly 35 that includes the split casing mentioned above. In this embodiment, a living hinge (or other hinge mechanism) 335 joins the two portions of the subassembly, even when they are separated along the juncture 337. In an alternative embodiment, hinge 335 is not present, such that the two portions can be completely separated from one another.

[00161] Fig. 4A illustrates a cleaning accessory 410 provided to facilitate cleaning of

the subassembly 35 either when the subassembly 35 is still installed within the system 100, or after having removed the subassembly 35 from the system, such as like shown in Fig. 2. In this embodiment, cleaning accessory 410 includes a squeeze bottle 412 that is compressible to force cleaning fluid under pressure through the skin attachment member 10 (chamber 16) and conduit 32, and out of the subassembly to flush and clean the interior surfaces thereof. An application tip 414 of the cleaning accessory 410 is configured with a flange shape to seal with the skin contact member 10 so that back flow of the cleaning fluid around where the application tip 414 meets the skin contact member 10 is eliminated or minimized and pressure application is enhanced. The connection tubing 416 joining the application tip 414 to the squeeze bottle 412 in fluid communication, can be angled, as shown, or extend straight out of the bottle 412.

[00162] Fig. 5 is an illustration of a cleaning accessory 510 according to another embodiment of the present disclosure. Accessory 510 can be used separately of, or in conjunction with accessory 410. Accessory 51 comprises a distal end portion comprising a bottle brush 512 sized and dimensioned to fit within the small conduit portions 32S with some compression of the bristles 512B of the brush. The shaft 514 of the accessory 510 is resiliently flexible, allowing the brush portion 512 to be advanced into the conduit 32 up to and through the large portion 32L of the conduit. Optionally, a handle 516 may be provided at the proximal end of the accessory 510 to facilitate handling and operation by the user.

[00163] Further alternatively, or in addition to use of one or both of the accessories described with regard to Figs. 4-5 and/or dishwashing and/or manual washing, the system can be provided with a wash mode in which the pumps of the system are operable to pump cleaning fluid through the chamber 16 and conduit 32 to clean the milk contacting surfaces.

[00164] Fig. 6 shows one side portion (the left side portion of the illustration of Fig. 3) of the subassembly 35 showing the internal surfaces thereof. The fluid pathway provided by the subassembly starts at the interface with the breast 2, within skin contact member 10 through segment 16, outlet 13, small conduit portion 32S, large conduit portion 32L (pump chamber, in this embodiment), proximal small conduit portion 32 and out of the subassembly, through a one-way valve (not shown in Fig. 6)

and into a milk collection container (also not shown in Fig. 6). As shown in Fig. 6, outlet 13 is provided at the top of the proximal end portion of segment 16. Alternatively, outlet 13 may be form at the bottom of the proximal end portion of segment 16, or intermediate the top and bottom of the proximal end portion of segment 16, as illustrated in phantom in Fig. 6. The volume of the internal chamber formed by the pump chamber (portion 32L) of the conduit 32 is typically in the range of about two to eight cm^3, in at least one embodiment, the volume was about four cm^3. The dimensions of the pump chamber could be any combination of dimensions that provide the volume described above. In one embodiment, 32L formed as a tubular structure had an inside diameter of about .5" (but could be within a range of about .25" to about .75") with a length set by the volume requirements. Other shapes include rectangular, oblong shape (such as an oblong tube, conical tube, etc.), or any other shape designed to fit into the form factor of the device and meet the functional requirements.

[00165] As shown in Figs. 3 and 6, the large conduit portion (pump chamber) 32L is formed so that the capacity of the chamber is all on one side of the subassembly (the side shown in Fig. 6), with a flat backing plate formed to oppose it. Alternatively, the capacity of the chamber could be formed all on the other side, or could be divided among both sides, either symmetrically or asymmetrically. By providing the capacity all on one or the other sides, this facilitates the provision of a flat backing plate that is stiffer than the remainder of the large conduit portion/pump chamber 32L. The small conduit portion 32S that is configured to be compressed by compression member 36 is formed symmetrically about both sides of the subassembly 35, but could alternatively be formed asymmetrically. Likewise, the small conduit portion 32S leading out of the large conduit portion 32L and having an exit opening 317 for delivering milk out of the subassembly 35 and into the milk collection container, is formed symmetrically about both sides of the subassembly 35, but could alternatively be formed asymmetrically. Although the tubing portions 32S are round in cross-section in the embodiment shown, they could alternatively be made to have different shapes, such as oval, trapezoidal, other polygonal shape or other non-polygonal shape, as long as the shape is open so as to provide a lumen therethrough, and functions with the mechanical characteristics desired.

[00166] All the components of the subassembly 35 are compliant and resilient, except for backing member 339 which is made stiff and relatively rigid, so as to resist deformation when compression member 38 is driven toward it. Optionally, a portion of flange 10 may be made stiffer than the compliant material of the subassembly and/or an insert 341 of stiffer material may be placed in the flange as illustrated in Fig. 7. Alternative to the placement shown in Fig. 7, the insert 341 could be configured and dimensioned to stiffen the outer rim of the flange 10, or a portion further proximal of the location shown in Fig. 7. Further alternatively, rather than an insert 341, any of these portions could be integrally formed with a stiffer material, or insert 341 could be molded within the flange 10. Further alternatively, combinations or all of the aforementioned portions could be made stiff. If a removable insert 341 is used, the present disclosure includes customizing the size and shape of an insert to the particular needs of the individual user, including size and shape of the breast, as well as user preferences regarding comfort. Further alternatively, a plurality of inserts 341 of various sizes, shapes and/or stiffnesses can be provided, among which the user can select for the desired fit and comfort. Still further alternatively, an insert 341 can be made adjustable so as to fit different sized breasts and the individual comfort requirements of the user.

[00167] For embodiments of the subassembly 35 that are separable, either with our without the hinge 335, a rigid frame 345 can be provided to fit over the borders of the left and right subassembly portions where they can snap together to form a seal upon rejoining the portions, see Fig. 8. The frames 345, see Fig 8, are made of a rigid material such as stainless steel, titanium, ABS plastic or other rigid plastic. The borders of the left and right subassembly portions that are sandwiched by the frames 345 are compliant and form an airtight, liquid tight seal between them when rejoining the subassembly portions. For example, the borders may be made of silicone, or any other compliant polymer disclosed for making the tubing 32 and skin contact member 10 in Provisional Application No. 62/050,810, which was incorporated herein, in its entirety, by reference thereto, above. Optionally, male members 347 (e.g., pushpins, barbs, male portions of snaps or other protruding extensions) may extend from frame 345 and the border that frame 345 covers, and female members 345 (e.g., openings,

female portions of snaps, nuts, etc.) that mate with male members 347 may be formed in the opposite frame and align with openings through the opposite border that the opposite frame covers. Upon pressing the two portions of the subassembly 35 together, the male members 347 pass through the openings 349 in the opposite border and frame 345 and retain the male members 347, with a force sufficient to compress the borders together to form an airtight, fluid-tight seal. The retention of the male members 347 by the female members 349 can be overcome when manually separating the portions of the subassembly 35, using manual force greater than the compressive forces applied to the borders. The suction that is generated within the subassembly 35 during use further enhances the seal between the borders. Further alternatively, the borders can be sealed and unsealed using a zipping mechanism similar to what is used in food storage bags.

[00168] Fig. 11 is a perspective view of driver 46 shown in Fig. 1C. Driver 46 includes a servo motor 46M, and a gear box 46G and an encoder 46E mounted to opposite ends of motor 46M. As motor 46M rotates, encoder 46E, which is fixed relative to the rotating motor shaft, rotates with the motor. An optical monitor 1146, such as an infrared laser or the like is beamed against the encoder 46E, such as the rotating blades of the encoder 46E cross the optical beam emitted by the optical monitor 1146 as the motor rotates. As the blades cross the beam, the beam is reflected back to a sensor 1148. By counting the reflections, the sensor 1148 and controller 52 can calculate the position of the motor 46M from a start position, and the position of the compression member 38 that it is driving, relative to a reference or starting position of the compression member. A similar arrangement is provided for the driver 44 of compression member 36.

[00169] The drive train 46T of the driver 46 includes a shaft 1042 that is received in journal bearing 1044 mounted to the frame 1030 of the main body 30. Driving rod 1047 is offset from shaft 1042 by configuration in crankshaft 1049 that is rotated (oscillated) by servo motor 46 to drive the compression member 38 toward and away from the conduit portion 32L. The driving rod 1047 engages with surfaces 1038 of compression member 38 (see Fig. 12) to drive the compression member 38 against the conduit portion 32L and, upon reverse oscillation of the motor 46, pulls away from the

surfaces 1038 to allow the conduit portion 32L to resiliently return towards its unbiased configuration. The opposite surface (back side surface, not visible in Fig. 6) forms the anvil 2232 against which the large tubing section 32L is compressed. Pins 1039 mounted in housing 30 are received in closed-ended (blind) holes 1041 in the compression member 38 to maintain the compression member 38 in alignment with the region 42 and the driving rod 1047 as it travels toward and away from the conduit region 42L. Compression members 36, 38 are preferably made of ABS plastic, glass-filled ABS plastic, polycarbonate, or other rigid plastic.

[00170] In order to reduce the overall length of the housing/main body 34, and thus the amount of distance by which the system 100 protrudes from the breast of the user, the compression chamber 32L can be made half as long (or otherwise shorter or smaller overall volume) and a second chamber 32L (which may be a duplicate, mirror image of the first, or other size) may be mounted on the opposite side of the housing as illustrated in Fig. 13A. A second compression driver 38 is configured to compress the second compression chamber 32L in the same manner as described previously. As a result, the overall length 1310 of the housing 34 (see Fig. 13C) is significantly shorter than the length 1312 of the housing 34 (see Fig. 13D) in a system employing only one compression chamber 32L, as shown in Figs. 13B and 13D. Dual chamber embodiments can be driven by two motors 46, as illustrated in Fig. 13A, or alternatively, a drive linkage, such as a cable 1314, or a mechanical linkage providing scissoring action can be connected to a single motor 46 to drive both compression members 38. Fig. 13E shows an embodiment in which a single motor 46 is configured to drive both compression members 38 against and away from conduit portion (pump chamber) 32L. A drive train connecting the motor 46 to the compression members 38 includes a camshaft 1316, cables 1314 and linkages 1318 connecting the camshaft 1316 to the cables 1314. An advantage of this arrangement employing only one motor 46 and cables 1314 is that it creates flexibility between the pump chamber 32L and the motor 46. Thus the motor 46 can be placed anywhere in the housing 34 and the power can be routed as needed around any other structures to the location of the compression members 38 and pump chamber 32L. Alternatively, instead of cables, a pneumatic or hydraulic system could be used to add flexibility between the motor and pump

chamber.

[00171] Although illustrated as being mounted on the right side of the housing 34, the driver 44 and compression member 36 could alternatively be mounted on the left side of the housing (same side as the driver 46 and compression member 38 in Fig. 1C). Because the forces required for closing the conduit section 32S with compression member 36 are less than the forces required for compressing conduit section 32L by compression member 38, a bearing is not required for mounting the free end of shaft 1052. A single cam 1054 is mounted on the shaft 1052 and is oscillated to drive against compression member 1054 to close off conduit section 32S (region 40) and, with reverse rotation, to pull away from the compression member 36 to allow conduit section 32S to reopen.

[00172] Fig. 14A illustrates an embodiment of the present disclosure showing the control board (controller) 52 mounted on the external surface of the backing plate 32LP of conduit portion 32L. Although a single control board is shown, it is noted that controller 52 may include two or more controller boards, in this or any of the other embodiments described herein. One or more batteries (off-the shelf or custom) 48 are mounted on the lower portion of the main body 34, such as below motor 44 in Fig. 14A. Fig. 14B illustrates an embodiment of the present disclosure showing controller 52 having two control boards, mounted toward the bottom of the main body. In this embodiment, batteries 48 are mounted to the sides of motors 44 and 46.

[00173] Figs. 15A-15C illustrate longitudinal sectional views of various sizes of external shells 34F that can be attached to the assembly shown in Fig. 1B to provide an enclosed main body 34 and pumping section 30 like shown in Fig. 1A. Shells 34F can be made in various sizes and shapes that can be selected to best match the size and shape of the breast 2 of the individual user. For example, a user with a bra size of 36C may select a shell size like that shown in Fig. 15A, while a user with bra size 36D may select the shell of Fig. 15B and a user with bra size 34B may select the shell 34F illustrated in Fig. 15C. The present disclosure is not limited to those shapes and sizes shown in Figs. 15A-15C, as many other sizes and shapes of shells 34F may be provided. Further, an optimized shape and size of shell 34F may be installed on the system 100 that has been optimized to fit the largest population of the user population,

with or without the capability to change out the shell 34F for a more customized size and shape.

[00174] Fig. 16A illustrates a model of the main body 34 of the system 100 with the proximal surface 34F having been contoured and sized to provide a natural appearance of the breast 2 when mounted on the breast 2, supported by a bra 130 and covered by clothing 132. Fig. 16B shows placement of the device/main body 34 on the breast 2 of the user. Fig. 16C shows the appearance of the device 34 and breast 2 when supported by bra 130. It can be observed that no unnatural looking bulges, bumps or discontinuities in the curvature of the breast are apparent. Fig. 16D shows the breast 2 with the device 34 installed, supported by bra 130, with a t-shirt being worn. The clothing (t-shirt) 132 follows a continuous, natural looking line of curvature 133 of the breast 2.

[00175] For some users, the form factor of the main body 34 as supplied may not result in the natural, uninterrupted appearance of that shown in Fig. 16D. Fig. 17A illustrates one such instance in which the form factor of the main body 34 and/or proximal surface 34F does not follow the contours of the breast 2 as naturally as in the example described in regard to Figs. 16A-16D above. Fig. 17B illustrates that even after donning a supporting bra and outer garment (e.g., t-shirt, blouse or other shirt or sweater type apparel), the existence of the main body 34 mounted to the breast is still noticeable as an unnatural contour resulting from the main body 34. In the example shown in 17B, a discontinuity, "notch" or "ledge" formation 136 is visible. The bra 130 worn by the user defines the available shape and geometry of the device (e.g., main body 34, milk collection container 60, etc.) as attached to the breast 2, even more than the breast does. In addition to, or alternative to changing out the shell 34F for a more customized size and or shape, a contouring flange 1810 may be provided to fill in the discontinuous region 136 to restore the natural contour lines and appearance of the breast 2.

[00176] Fig. 18A is a cross-sectional view of a contouring flange 1810 according to an embodiment of the present disclosure. One or more flange portions 1812 extend from the main body 1814 of the contouring flange 1810 to extend distally from the main body 34 of the device when the contouring flange 1810 is attached to the main body

34, as illustrated in Fig. 18B. In this embodiment, the contouring flange 1810 is made to snap fit over the distal perimeter of the main body 34, but alternative means of joining a contouring flange 1810 with the main body 34 could be used, such as pressure adhesives, tape, or other equivalent that can releasably attach the contouring flange 1810 to the main body 34. The contouring flange portions 1812 do not necessarily need to form an airtight seal with the contouring flange 1810 if they are formed as one or more separate pieces, in which case the contouring flange breast component 1810 would form an airtight seal with the main body 34. Alternatively, the breast component of the contouring flange 1810 and contouring flange portions 1812 can be formed integrally and form an airtight seal with the main body 34 at the juncture of the components 1810, 34. Fig. 18C illustrates the user shown in Fig. 17B after adding the contouring flange 1810 to the main body 34 before fitting it to the breast 2. It can be observed that the natural contour lines of the user's breast have been restored as the t-shirt 132 worn by the user follows the natural contour lines of the breast. The flanges 182 taper proximally to form a smooth contour with the main body 34 and also taper distally to form a smoother transition with the breast 2 when the system 100 (main body 34 plus milk collection container 60, or alternatively, main body 34 without the collection container 60, in embodiments where the milk collection container is not mounted on the main body 34) is mounted on the breast 2, thereby making the system 100 less visible or noticeable when worn by a user. The flange 1812 is preferably, but not necessarily integrally formed with the main body 1814. The contouring flange 1810 is typically made of a compliant material, such as silicone, or any of the other alternative compliant materials listed above as used for making the conduit. Alternatively, the contouring flange can be made of a different material than those used for making the conduit, such as a more breathable material, like fabric or wicking material to help with heat management.

[00177] The flanges 1812 of the contouring flange 1810 of Fig. 18A extend at least from top and bottom portions of the main body 34 when attached thereto. The flanges may extend about arcs of the top and bottom portions of the perimeter of the main body in amounts within the range from about forty five degrees to one hundred eighty degrees (in embodiments where flange 1812 completely encircles the perimeter),

typically within a range of about sixty to one hundred twenty degrees.

[00178] Further alternatively, the flange 1812 may extend only from the top portion of the main body 34, as this is typically where the non-uniformity of the appearance of the breast 2 is more evident. In these embodiments, the main body 1814 may encircle the distal perimeter of the main body 34, or alternatively, may only extend around and attach to a top portion of the perimeter. Fig. 18D illustrates a contouring flange 1810 in which the main body only extends around the top portion of the distal perimeter of the main body 34 and flange 1812 extends only over a top portion of the breast 2. All embodiments of the contouring flange 1810 may be made in a series of sizes having different lengths of flange portions 1812 for further flexibility in matching the right amount of contour correction needed.

[00179] In addition to or alternative to the various fitting and contour correction solutions discussed above, a contouring shell 1910 may be provided to make the breast contour lines of the user appear more natural when the system 100 is attached to the breast 2 and the user is wearing clothing. Fig. 19A illustrates a cross-sectional view of a contouring shell 1910 according to an embodiment of the present disclosure. Contouring shell 1910 is made of a thin-walled, supportive material that defines an outer shape by the outer contour 1912 of the shell 1910 that is shaped with the natural contour lines of a breast 2. Shell 1910 may be produced in a variety of sizes and shapes to provide more flexibility in choosing the right shape and size for each particular user. Additionally, shell 1910 can be custom-molded to match the actual shape and contours of the breast of an individual user. The material from which shell is made may be any of those used for supporting bras 130, "push-up" bras, or the like.

[00180] Fig. 19B illustrates use of a contouring shell 1910 (cross-sectional view of 1910) by a user employing a system 100 according to an embodiment of the present disclosure. The system 100 is completely contained within the shell 1910 and the shell 1910 provides the shape and contours of the natural breast 2 so that the user's shape appears natural when viewing the clothes worn by the user. Optionally, the user may place a second shell 1910 over the other breast 2, whether or not a second device 100 is placed over the other breast 2, to provide even more symmetry to the appearance of the breasts 2.

[00181] Fig. 19C shows a variant of contouring shell 1910 which is internally contoured to support the main body 34 and milk collection container 60 (when present). Contouring shell 1910 has a distal opening dimensioned and tapered to contact the breast 2 so that the outer surface of the shell follows substantially natural lines of contour of the breast 2 when worn. The internal surfaces 1912 are contoured at distal portions thereof to follow the contours of the breast 2 and then open up to a bowl 1914 that closely follows the contours of the main body 34. Thus, the bowl 1914 has a smaller radius of curvature that the radius of curvature of the portions of the inner surfaces 1912 distal to the bowl 1914 in the cross-sectional view of Fig 19C. The contouring shell 1910, which may optionally be made of fabric, which may assist in cooling, sweat management (wicking), comfort, and provide a lighter weight solution, as compared to materials of the type discussed for making the conduit 32 and skin contact member 10. Examples of fabric that may be used include, but are not limited to: silk, wicking polyester blends, etc. Another advantage to using fabric is that it is easy to wash. In any material embodiment, the contouring shell looks natural before any milk has been pumped into the container 60, all the way up until the container 60 is full of milk and after the container 60 is full of milk. Contouring shell 60 will accommodate any changes in breast shape to keep a natural contour. Some embodiments of the shell 60 will be adjustable, as being stretchable (expandable and contractible) and/or having the ability to change angle (like rolling up a tube of paper into a cone shape, whereby many different angles/cones can be made according to the way the rollup occurs). In embodiments that can change angle, a releasable fastener 1918, such as hook and loop type fastener, snaps, adhesive, or other type fastener that can be readily attached detached, is provided so as to allow the user to fix the shell in a desired shape/angle. Further alternatively, or additionally, the contouring shell may be telescoping 1920, accordioned, or otherwise have the ability to slide to accommodate changes in breast 2 shape and/or container 60 volume as milk expressed, see Fig 19F.

[00182] Fig. 19D is a cross-sectional view of a contouring shell 1910 according to another embodiment of the present disclosure, shown mounted on the breast of a user 2. In this embodiment, shell 1910 has a central opening 1916 at a proximal end thereof, through which a proximal portion of the main body 34 protrudes when the

shell 1910 is installed thereon. The proximal end portion of the shell 1910 surrounding the opening 1916 forms a friction fit with the main body 34.

[00183] Any of the embodiments of contouring shell can be made very thin and need only be strong enough to support the drapage of clothing thereover. Examples of materials that may be used include, but are not limited to: plastic films, open or closed cell foams; lace material, or other polymers, including natural fibers.

[00184] Fig. 20 illustrates an embodiment of system 100 wherein two devices are used together, one on each breast 2 of the user. The controllers 52 of the devices can be wired together, or configured to communicate wirelessly (e.g., via radio communication) so that the controller 52 on one side can adapt functionality based in part on the current functioning of the device controlled by the other controller 52. For example, the controller 52 on the left side may communicate to the controller on the right side that the left side pump is in a milk extraction phase, at which time the controller on the right side pauses pumping until receiving a communication from the left controller 52 that the left side pump has paused, so that milk extraction occurs sequentially. Alternatively, the communication may be to coordinate simultaneous operation of the system pumps on both breasts. Simultaneous operation may be with the pumps on both sides pumping in phase, or out of phase by various amounts, wherein the controllers 52 coordinate the timing of the pump cycles on both sides. Given feedback from the pressure sensor 54 to the controller 54 of each respective device, the controllers can calculate a running total volume estimate of milk extracted from each breast 2. The controllers 52 communicate with one another, so that an overall total of milk extracted from both breasts can be calculated at any time. If the pumping mode being run has a total milk extraction volume goal for example, and one of the controllers determines that, when the current milk extraction total volume has reached a certain percentage of the total goal, but one of the breasts 2 has had 75% of the overall current total extracted, then the controllers 52 might cooperate to increase milk extraction from the second breast, while slowing down the pumping of the first breast, or pausing, for example. Each controller 52 can track pressure and milk flow rate. Where it is desirable to express substantially equal volumes of milk from each breast 2, the controllers 52 can coordinate to make sure that each breast 2 expresses

substantially equivalent volumes of milk, before shutting down the system. Substantially equivalent volumes may be predesignated in the software operated by the controllers to be within a range of 45%-55% of total milk volume expressed, 48% to 52% of total milk volume expressed, 50% of total milk volume expressed, or some other predetermined percentage or range of percentages. Some breasts 2 naturally produce different volumes of milk. The system may track production and determine expected values, as the volumes between breasts may not be the same. In this case, the system can execute similar logic to reach maximum or optimized expected production volumes for each breast, even when the expected volume of one breast is different than the expected volume for the other breast.

[00185] The controllers 52 may control the respective pumping sections 30 to "take turns" slowing or pausing on pumping section 30, while controlling the other pumping section to continue pumping, and vice versa. Further, one pumping section 30 may be a "slave" to the logic of the controller 52 of the other pumping section 30, allowing both pumping sections to be controlled by one controller 52 located in one of the devices. In such an embodiment, the "slave" pumping section 30 in the slave device receives control commands from the controller 52 located in the other device (master device) in the same manner that the controller 52 provides control commands to the pumping section in the master device. Likewise, sensor 54 in the slave device provides feedback to the controller 52 in the master device in the same manner that the sensor 54 in the master device provides feedback to the controller 52 in the master device.

[00186] Fig. 21 illustrates an embodiment of system 100 wherein two devices are used together, one on each breast 2 of the user, and wherein only one of the devices includes a battery 48, which is electrically connected to both devices to power both devices. The battery is internally wired to the components of the device on the left side and a wire or cable 2012 connects the battery 48 to the components of the device on the right side.

[00187] Further alternatively, only one device may be provided with controller 52 and battery 48 to control both devices, as illustrated in Fig. 22. Although all of these examples show the master or controlling device to be on the left side, with the slave device on the right side, it would be readily apparent that the arrangements could be

reversed, such that the master device appeared on the right side and the slave device on the left. Further alternative to Fig. 22, the battery 48 could be provided in the right side device and the controller 52 could be provided in the left side device or the battery 48 could be provided in the left side device and the controller 52 could be provided in the right side device.

[00188] Fig. 23 illustrates a system 100 according to an embodiment of the present disclosure, in which a pump device is attached to one of the user's breasts 2 (user's right breast, left side of Fig. 23, but could be the opposite) and a skin contact member 10 is attached to the other breast 2. A conduit 32E which is preferably less compliant than regions 40, 42 connects the skin contact member 10 attached to the other breast 2 to the conduit 32 of the device. Fig. 24 schematically illustrates the conduit connections in more detail. The conduit 32E connects the stand-alone skin contact member 10 to the conduit 32 of the device, so that the compression members 36, 38 and drivers 44, 46 generate the pumping forces needed to extract milk from both breasts 2 simultaneously and pump the milk into a milk collection container in fluid communication with conduit 32S and one-way valve 50. Sensors 54 provided to both skin contact members 10, segments 16, or other location in the vicinity of the breasts 2, provide feedback to the controller 52. Based on pressure feedback readings from the sensors 54, and positions of the motors 46, 48 provided by feedback from encoders mounted on the motors 44, 46, controller 52 can calculate estimates of milk volume expressed from each breast 2.

[00189] Fig. 25 shows a schematic circuit diagram of componentry used to control system 100 according to an embodiment of the present disclosure. Controller 52 includes a microcontroller board 1602 (e.g., Arduino Mega 2560, or other microcontroller board of comparable functionality). A microcontroller processor 1604 is provided on board 1602 to process the control functions for reading pressure (and/or any other function being sensed, such as flow, or other function) and controlling the functions of the motors 44, 46, as well as monitoring speed, direction and positions of the motors 44,46 and compression members 36, 38. A variable resistor/potentiometer 1606 (or digital equivalent) is provided for user input to adjust the maximum vacuum achieved during a cycle of a pumping profile. The user can adjust the potentiometer

1606, by selecting pumping force with the mode selector 156 and then increasing or decreasing pumping force by pressing either the "minus" button 161 or the "plus" button 162, respectively (see Fig. 26), until the desired force is attained. Optionally, the pumping force value could be displayed on the control panel 165 and/or could be transmitted by wire or wirelessly to be displayed on the display of an external computer 60 such as a smart phone, tablet, or other external computer. A second variable resistor/potentiometer 1608 is provided for user input to control the speed of the pumping, i.e., to adjust the period of the pumping cycle. The user adjusts potentiometer 1608 using mode selector 160 to go to speed mode and then increases or decreases the speed using the buttons 161 or 163. The mode selector button 156 also enables the user to select different modes/profiles of pumping performance by the system 100. Different profiles/modes can be selected by the user by operating the mode selector 156 to select one of the modes provided in the system and then pressing the "enter" or "select" button 159 to select the mode desired. The power switch 1612 is turned on and off by operation of power switch 154 by the user to connect or disconnect the battery 48 to or from the circuits. All of the above operations that can be performed by control buttons 154, 156, 159, 161, 162 and display 165 can alternatively or additionally be performed remotely, from an external computer such as a smartphone, tablet computer or other external computer communicating with the system 100 either by wire or wirelessly.

[00190] The system 100 provides integrated sensing via sensor 54 and processing of sensed signals by controller 52. This closed control loop enables a pump that is responsive to the user's breast milk flow. Although the system 100 can target latch (minimum) and maximum suction pressure levels, either through levels predefined in a selected pumping mode, or further modified by user selection in a manner described above, the rate of "slippage" from those pressure levels once hit correlates directly to the rate of milk expression. Since the volumes of the cavities defined by the conduit 32 and skin contact member 10/segment 16 are approximately known, the volume of milk being expressed can be calculated directly from the pressure drop measured by the system via pressure sensor 52. This data may be usable to dynamically vary targeted pressure levels for latch and maximum on a cycle-by-cycle basis, vary the

suction cycle frequency and vary the rate of change of pressure between cycles. This dynamic ability to real-time adjust the pumping program is unique and heretofore unknown. Because of the dynamic adjustability, a defined "let down" mode or cycle becomes unnecessary, as the pump dynamically adjusts the cycles as the milk begins to flow. Further, by providing real time pressure feedback to the controller 52, the controller 52 can calculate rates of milk flow as noted above. If the calculated flow rate falls below a predetermined flow rate (after initial let down and after the predetermined flow rate or a second predetermined flow rate has been exceeded), then, in one example, the controller 52 can pause the pumping cycle to allow further internal flow and buildup of milk in the breast 2 for a predetermined pause time, and then resume the pumping cycle. This "refill" or "refractory" period provided by the pause may ultimately lead to greater and/or faster milk yields than by pumping continuously and not letting the breast 2 rest to refill/recover during pause times without pumping. The pumping cycle can be continued if the milk flow rate returns above the predetermined flow rate, with a pause again being initiated upon falling below the predetermined flow rate again. Further, the controller 52 may be programmed such that the falling below of the predetermined flow rate needs to be met for a predetermined consecutive number of pump cycles before the pause is commenced, or the predetermined flow rate may be an average predetermined flow rate averaged over a predetermined number of pump cycles.

[00191] Different types of pumping modes that may be stored by the controller include those examples disclosed in Application Serial No. 62/050,810, but like that application, the present disclosure is not limited to those modes. Additional modes are described below, but the present disclosure is not limited to only those modes described, as a virtually unlimited number of different pumping modes could be programmed, although of course, only a finite number of such modes will typically be stored by the system 100. A "sleep" mode or "nighttime" mode could be provided which, when selected, allows the user to select a time in the near future when the system 100 will power up and begin a pumping session. This allows the user to attach the system and go to bed, as the system will begin the pumping session at the selected time, whether the user is asleep or awake. Typically, but not necessarily, the sleep

mode may have a lower maximum suction that other selectable daytime modes, and may have a shorter session time, pumping only for a shortened time period sufficient to relieve pressure buildup in the breasts 2 which might otherwise cause discomfort and even disruption of sleep. The pumping profile of the sleep mode can be gentler than daytime modes, for example having lower maximum suction pressure and/or shorter hold periods at maximum suction pressure during the pumping cycles, with the goal being not to wake the sleeping user while the user is laying on her side or back.

[00192] Alternatively, or additionally, when in "sleep" or "nighttime" mode, the system 100 may also be able to sense when one or both breasts 2 are "full" by receiving inputs from a sensor 4310 attached to the breast 2 (see Fig. 43) of a type described in US Application Serial No. 62/050,902, filed 09/16/2014, which is hereby incorporated herein, in its entirety, by reference thereto. On embodiment of sensor 4310 (other embodiments as disclosed in Application Serial No. 62/050,902 may be used) as shown in Fig. 43 is configured to be adhered to the skin of the breast 2 and is adhered to the breast 2 as shown in Fig. 43, to detect expansion and contraction of the skin. Device 4310 includes a distal mount portion 4312, a proximal mount portion 4314 and a flexible intermediate portion 4316 that bridges the proximal 4314 and distal 4312 mount portions. The proximal mount portion 4314 has components mounted to it that measure changes in the skin that the device 4310 is adhered to. The back surfaces of the distal and proximal mount portions 4314, 4312 have an adhesive 4318 applied thereto so that the device 4310 can be adhered to the skin, while the intermediate (bridge) portion 4316 does not have any adhesive applied thereto, so that it can more freely expand and contract. There are various ways that the device 4310 can be configured. In one preferred embodiment, an elastically expandable material (silicone, or any number of elastomers) can be used for all portions 4312, 4314 and 4316, in order to render manufacturing easier and relatively less costly. Attached to or embedded within the portions 4312 and 4314 can be a reinforcing structure (e.g., a weave or non-expandable plastic or fabric), which renders the portions 4312, 4314 resistant to deformation. Additionally or alternatively to providing a reinforcing structure, the adhesive by which the portions 4312, 4314 are attached to the skin may provide or supplement the function of providing resistance to deformation.

Alternatively to making all portions 4312, 4314, 4316 of the same material, composite materials can be chosen so that the composite material provided for portions 4312, 4314 could include non-elastomeric material encased by or otherwise attached to elastomeric material, which may be the same as, or different from the elastic material used to form portion 4316. Elastomeric materials may include, but are not limited to, one or more of silicones, polyurethanes, polyether block amides (PEBAX), polyethylene terephthalates (PET), polyethylenes, high density polyethylenes (HDPE), low density polyethylenes (LDPE), polyamides and/or other biocompatible thermoplastic elastomers. Materials that can be woven as reinforcing fabrics include, but are not limited to, one or more of: polytetrafluoroethylenes (PTFE), polyesters, polypropylenes, polyethylenes, para-aramid synthetic fibers and/or other biocompatible polymers used for making woven fabric. Non-expandable, or non-elastomeric materials that may be used include, but are not limited to, at least one of: acrylonitrile butadiene styrene (ABS) plastics, polyester fiberglasses, high density polyethylenes (HDPE), high impact polystyrenes (HIPS), nylon, polybutylene terepthalates (PBT), polyethylene terephthalates (PET), polycarbonates and/or other biocompatible, thermosetting polymers or none-expandable, non-elastomeric materials. Woven fabrics used may have either elastomeric or rigid properties depending on how they are configured and could therefore be used in portions 4312, 4314 or portion 4316, depending upon configuration for elastomeric properties or rigidity properties. Adhesives that may be used to adhere the portions 4312, 4314 to the skin include, but are not limited to, at least one of: pressure sensitive adhesives of the type used in ostomy applications, containing various rubber-like organic molecules such as polybutadiene and polyisobutylene, polyacrylate pressure sensitive adhesives, silicone adhesives, soft skin adhesives (Dow Corning ®), skin friendly adhesives (Scapa Healthcare, Windsor, Connecticut), removable adhesives (an adhesive designed to stick to a substrate without edge lifting that can be removed without damage to either the label or the substrate, such as available from Avery Dennison), and/or any other adhesive successfully used for temporary adherence to the skin.

[00193] The distal and proximal mount portions 4312, 4314 are adhered to the skin at locations that initially place the bridge portion 4316 in an unbiased stated (neither

stretched nor compressed). A sensor 4320 (see Fig. 44), such as an electric resistor, strain gauge, magnet or the like is provided on proximal mount 4314 and is configured so that compression and expansion of the bridge portion 4316 applies strain/forces to the sensor 4320, which measures the amount of expansion or compression according to methods well understood in the strain measurement arts. In the embodiment shown in Figs. 43-44, a circuit 4322 is provided on proximal mount that is powered by battery 4324 and can be configured to process the output of the sensor 4320, and optionally, store the processed signals in optional memory 4326. Additionally, an antenna 4328 is electrically connected to the circuit 22, which can be used to transmit the data stored in memory 26 (or directly transmit, if memory 26 is not provided) to controller 52, which uses the stretch/contraction data to calculate an estimate of the volume of the breast 2 to which the device 4310 is adhered. Controller 52 can be programmed, when in sleep mode, to initiate pumping when the estimated breast calculated is greater than or equal to a predetermined breast volume that is considered to be "full", or sufficiently full that breast pumping is needed to relieve discomfort that would otherwise increase in the breast 2 of the sleeping user.

[00194] Fig. 27 illustrates events 2700 that may be carried out in a coordinated operation of breast pumps on both breasts 2 using a system 100 according to an embodiment of the present disclosure. After attachment of the system 100 to both breasts 2 such that a main body 34 pump is attached to a first breast and a second main body pump 34 is attached to a second breast and a pumping mode has been selected for both pumps (typically the same mode for each) the pumping session begins at event 2702 with pumping cycles being applied to both breasts. At event 2704, the controllers 2704 communicate dynamic parameters specific to the particular breast pump being controlled to each other. Dynamic parameters may include any combination of the following, but are not limited to: maximum suction pressure, latch (minimum) suction pressure, cumulative volume of milk, volume of milk expressed in most recent cycle, milk flow rate, etc.

[00195] At event 2706, each processor 52 determines whether a pumping goal for the current pumping session has been achieved. There may be multiple pumping goals, in which case all pumping goals must be achieved before ending processing at event

2708. In the simplest example, if there is only one pumping goal, the pumping goal may be any of, but not limited to: elapsed time, cumulative milk volume or minimum flow rate after first exceeding a predetermined flow rate. If the goal(s) has not yet been achieved at event 2706, then at event 2710, the controllers determine whether adjustment of one or more pumping parameters is needed to be applied to the pumping mechanisms 30 that it controls, based on the current dynamic parameters of both its pumping session, as well as the current dynamic parameters of the pumping device operating on the other breast. One or more parameters may need to be controlled, for example, if one breast has expressed more than a predetermined percentage of the current cumulative total of milk expressed, in which case, the pump for the higher producing breast may be modified to slow the pump cycle, lower the maximum suction pressure level, increase one or more pause times in the cycle, and/or make some other parameter modification. Alternatively, or in addition thereto, the controller for the pump on the lower producing breast may speed up the pump cycle, raise the maximum suction pressure level, decrease or increase one or more pause times in the cycle, and/or make some other parameter modification. If no adjustments are needed, or after one or more adjustments are made at event 2712, the next pump cycle is executed on each pump. The processing returns to event 2704 where the communication between controllers 52 is again carried out.

[00196] The breast pump systems 100 according to the present disclosure may be designed with the capability of communicating to an external computer which may be, but is not limited to: a smartphone, a tablet computer, a laptop computer, a notebook computer or a server. Fig. 28 is a schematic representation (not to scale) of transfer of data wirelessly from controller 52 to smartphone 470. Controller 52 may include a wireless transmitter 472 that can be actuated by the user via controls 156, 158, 161, 163 to send data to the external device 470 at will, as long as the external device 470 is in range of the transmitter 472. Alternatively, or additionally, a hard wire connection may be provided to send the data over the hard wire to the external device 470. Further alternatively, controller 52 can be provided with a BLUETOOTH® transmitter, so that data is automatically transmitted to the external device 470 whenever the external device 470 in in range of the BLUETOOTH® transmitter. Further, the controller 52

may be configured to automatically transmit signals to the external computer 470 whenever the external computer is in sending range of the controller 52 and the controller has any date that needs to be sent, but has not yet been sent. Likewise, automatic receiving of signals could be configured similarly. Further, the external computer 470 may be provided with an app 474 that is configured to allow the operator of the external computer 470 contact the controller and establish communications from that end. Still further, controller 52 can be configured to automatically upload data to a server in the cloud and/or upload data to the cloud when instructed to do so by the user using controls 252. The uploaded data can then be used or shared in group studies of the data. Further, the external device 470 may be capable of downloading other customized programs for use with the breast pump system, which could be updated by crowd sourcing results from other mothers, etc. The uploaded data could also be useful for insurance companies or other entities having permission under the Affordable Care Act (and/or the user's permission) to use the data.

[00197] The external device 470 can be provided with software (either in app 474, or in another program) to customize pump functions based on data received from the controller 52, to calculate volume of milk extracted, to track expression efficiency and monitor it over time (within a single extraction session, as well as over multiple extraction sessions), keep track of inventory of previous expression sessions, dates of the sessions, and the specific containers 60 used in each individual session. Fig. 29 illustrates a milk collection container 60 provided with a barcode or QR code 2910 that is scannable by the external computer 470. By scanning the barcode or QR code 2910 into the app 474, the app logs that number of the barcode or QR code in and tracks it relative to all other milk collection containers. If the scanning is done, preferably sequentially with respect to the bags, but in any other order that identifies and correlates specific milk containers 60 each to unique numbers or other identifiers (and preferably to date and time of extraction as well), the app 474 can track the ages of the milk collected and direct the user as to an order in which the containers 60 should be used for consumption by the baby. By indicating a particular bar code or QR code (or number associated therewith) to the user for the next milk collection bag that is suggested to be used for the next feeding, the user can go into the cooler and locate the

specific milk collection container 60 to be used. This provides more order and efficiency to the manner in which the extracted milk is consumed and lowers wastage by ensuring that the milk containers 60 are used in the best order. This tracking can be useful for reminders to use the containers of milk 60 with a specified time, and can organize order in which the containers are to be used (e.g., first-in, first-out, or other scheme). Pump functions can be customized by varying suction levels, altering suction waveforms (amplitude and duration of application of suction), phases of extraction or feeding times, rest programming, heating temperatures and times, vibration frequency and duration, etc. Also the battery level can be monitored and a warning provided when the battery reaches a predetermined low level of charge. The external device may also use the display 478 to display one or more photos of the mother's baby during an extraction session to increase the emotional and physical reinforcement to simulate what is provided when the baby is actually feeding.

[00198] By receiving the pumping data from the controller, the app 474 can compile histograms 476 and display them on the display of the external computer 470. In the example shown in Fig. 28, a histogram 476 of milk extraction volume is shown that plots milk volume per time, where the time scale may be in days, weeks, sequential milk extraction sessions or other unit of time, in a time sequential order, so that trends in milk volume needs of the baby can be visualized. The trend line 478 in Fig. 28 establishes the milk volume deficit 480 that needs to be supplemented to the baby in month 4. Because of the capabilities of the system 100 and control feedback loop including the controller 52 and pressure sensor 54, the data that is transmitted can be done automatically, and the milk extraction volumes can be calculated, either by the controller 52 or by the processor running the app on the external computer 4790, so the user does not need to manually enter the milk extraction volume values, time or date values, or other pump cycle data into this tracking system, as it can all be taken care of automatically.

[00199] In addition to providing data graphically, such as in histogram 476 form, or providing tabular data, the app 774 can also display recommendations based upon data received. For example, the user can input the baby's date of birth so that the app can keep track of the baby's age. Based upon the baby's age and a national trend line 484

of babies' milk consumption needs, combined with a knowledge of what percentage of total breast extractions sessions are done by pump (which may be inputted by the user), the remaining being natural sessions with the baby feeding directly, and other food, if any, including formula, cow's milk, solid food etc., that is consumed by the baby (as also inputted by the user) the app can plot the breast extraction volumes, as scaled by the percentage done by pump extraction, against the national trend line 484 of total milk volume needs per the age of the baby, and determine if the mother is pumping sufficient volumes of milk. In the example of Fig. 30, there is a deficit 480 at month 4. The app in response to this deficit, can recommend changes to the pumping routine, such as additional or different times for pumping, longer pumping sessions and/or different pumping modes to try. If it is known that the baby is supplementing with formula or starting solid food, the app can adjust accordingly the expected milk volume extraction levels, frequency of pumping expected, alert levels, etc.

[00200] Additionally, an interactive feature of the app may request input from the user when a downtrend is seen in milk extraction production, as to whether the mother is weaning. If the mother answers yes, the app can suggest a weaning pumping schedule, as a change to the current pumping routine that the mother is practicing.

[00201] Periodically the app 474 may prompt the user to provide information in the form of a questionnaire, which can be written or oral, in order to update the current status of the baby's feeding routines. Inputs for information such as whether the baby has begun supplementing with formula and how much, whether the baby has started on solid food and, if yes, how much, baby's weight, baby's length/height.

[00202] Through the buttons on the device or through a remote app in direct communication with the pump information regarding the age of the baby, the mom's goals (i.e. NICU feeding versus a 1 year old feeding) and other information could be used to vary how the pump responds to the pressure/volume feedback it receives. For a mom whose baby is in the NICU, expression will be small and may take more time – in this case a gentler cycle that continues for a much longer time with little expressed would be expected – whereas a mom with a 1 year old baby would have a much more dynamic cycle and as expression slows the pump would be programmed to shut down relatively soon after that is detected. The combination of "knowledge" of the situation

the mom is in (baby age, etc., personal goals – working mom vs. nighttime loading), plus the information gained from the sensor give the pump the ability to truly be matched to its user and learn over time.

[00203] Fig. 31 schematically illustrates where data inputs are received by the app/software 474 used to evaluate, track and manage breast milk expression using system 100. Measured inputs 488 are inputted to app 474 by the one or more controllers 52 of the system 100, either by a wired connection or (preferably) wirelessly transmitted. Measured inputs may include, but are not limited to, at least one of: length of pumping session time, time of day at which pumping session was initiated, milk volume expressed during the pumping session, pumping session frequency (e.g., how many times per day is pumping done), pressure waveforms for the pumping cycles applied, maximum suction pressure applied, latch suction pressure applied, flow rate, etc.. User-entered inputs 490 may include, but are not limited to, at least one of: baby's weight, baby's birthdate, percentage of baby feedings that result from the milk expressed by pumping (as opposed to natural, direct breastfeeding by the baby), pumping goals (e.g., build up, to increase volume per pumping session; maintenance, to keep volume per session relatively the same; weaning, to gradually decrease volume per session, baby in neonatal intensive care unit (NICU) and breast pumping is just being started by the new mother, etc.), mother's age, which "feeding" the pumping session is taking over, how many feedings per day (specified by breastfeeding or pumping session) , time of day, whether a target volume of expressed milk per breast is desired, or a target timeframe for pumping, etc.

[00204] The inputs 488, 490 are processed by the algorithms of the app 474 and information is displayed on the display 492 of the external computer 470 for reading by the user. The user can confirm the conclusions reached by the app in terms of expected milk expression outputs, breast pumping frequencies, frequency of breast pumping sessions, expected lengths of breast pumping sessions, etc., by providing feedback to such through an input capability of the external computer 470. Alternatively, the user may want to modify one or more aspects of the conclusions displayed, and can do so by inputting desired changes through the input capabilities of the external computer 470. Upon receiving such changes, the algorithms of the app 474 re-compute

conclusions based upon previous inputs that have not changed, and the new information inputted by the user. New results from the re-computations are displayed at 492 and the user can again review the results. This process can iterate until the user is satisfied with the results/suggestions display by the app 474. Changes may be made by the user in regard to any of the variables described above with regard to conclusions that have been outputted. Additionally, or alternatively, the user may need to update user-entered inputs, such as baby's weight and/or other food intake., for example.

[00205] Based upon the inputs received, one of the outputs that the app 474 can calculate and display is an expected breast volume extraction per breast pumping session, relative to the age and/or weight of the baby, relative to the age of the baby, as illustrate as 494 in Fig. 32. This expected volume may be based on previous breast extraction volumes from previous sessions, and/or national averages relative to age and/or weight. The expected volume curve may also be modified by goal inputs of the user. For example, if the user wants to increase production, the curve 494 may be somewhat steeper than it otherwise would be. Likewise, for a weaning goal, the curve 494 would have a downward slope at some time period and then continue moving downward.

[00206] The expected volume input can be sent to the controller(s) 52 either by wire or wirelessly. Given the responsive nature of the system 100, through the pressure readings feedback as described above, during a milk extraction session the system controller(s) 52 can keep track of the total volume of milk that has been expressed. As the total milk volume expressed reaches the desired volume indicated by curve 494, the controller 52 can automatically cease pumping action and end the pumping session. Likewise, if the expected total volume of expressed milk has not been achieved after the expected of a pumping session, the controller(s) can continue to pump until the expected total volume has been achieved, or for a predetermined time period e.g., one minute, two minutes, five minutes, ten minutes, or some other predetermined time period, which may be set by the app 474, or specified by the user input to the app 474) after the expected end time of the current pumping session.

[00207] In addition to expected expressed milk volume data, the external computer 470 can execute the app 474 to send information to the controller(s) 52 to instruct specific

pumping modes to use at specific times (or other thresholds, such as when a predetermined volume has been achieved, etc.) during a pumping session. The modes that are instructed for execution may also be influenced by the user's inputted goals. As one example, if the user is a new mother whose baby is in the NICU, and the mother is just beginning to try and express milk using the system 100, app 474 may instruct the controller(s) 52 to execute a more gentle pumping cycle than that used for maintenance or building goals. Additionally, in this mode, the controller(s) will not shut down the pumping operation as readily, as it will be expected that less milk will be extracted by the new mother and that it may take a longer time, with less flow. Accordingly, the more gentle cycle may be continued for a longer period before shutdown, and the milk flow threshold for shutdown will be much lower.

[00208] The software for executing the pumping modes can be uploaded from the app 474 along with the instructions resulting from processing the user-entered inputs and measured inputs. Preferably, however, the pumping modes are already contained in firmware on the controller(2) 52 so the external computer 470 (via app 474) only needs to input specific data that effects running of the particular modes, such a mode selection, mode selection times or other parameters for switching modes, expected milk expression volume, etc. It is also noted here that mode selection by the controller(s) 52, as executed according to instructions received by the app 474, can be overridden by the user at any time using the controls 153 (see Fig. 26), and any other changes, such as pump frequency, maximum suction pressure; latch suction pressure, etc., can also be manually overridden by the user with controls 153.

[00209] In addition to sending data to the controller(s) for use in operations during pumping sessions, and displaying data for use and interaction by the user, data may be sent from app 474, restricted sets of data can be sent to the user's health care provider and/or health insurance carrier (e.g., by transmission over the Internet, or other transmission means). The data that is sendable to the healthcare provider may be the same or different from the data that is sent to the health insurance carrier, as the data sent to the health insurance carrier may be more restrictive than what is sent to the healthcare provided. The data that is sendable to the healthcare provider may be restricted, such that certain data that is identified as private is not sent, or all data that is

available to the user may be sent to the healthcare provider. Information that is sendable to the health insurance provider will generally include at least data about how often the system 100 is used by the user, as the health insurance provider may require a minimum amount of use in order for the costs of the system 100 to be covered (or partially covered) by health insurance reimbursement. All or a portion of the data provided by app 474 can also be exported by a social media format for use in various other community help purposes.

[00210] Fig. 33 illustrates a breast pump system according to an embodiment of the present disclosure, in which controller 52 is provided in the external computer 470. In this embodiment, all of the control functions of controller 52, as described above, are carried out in the external computer 470, rather than in the main body 34. The real-time control and feedback is the same as in embodiments where controller 52 is located in the main body 34 of the device, but the control signals are outputted, and feedback is received by the controller at the location of the external computer, where the signals are transmitted either wirelessly (by Bluetooth, or other radio transmission or wireless transmission protocol) or, optionally, by a wire or cable connection 3300. Further optionally, in embodiments where the wired connection 3300 is provided, battery 48 can be eliminated from the main body 34 of the device, and power to operate all components of the device can be transmitted over the wire connection 3300 from external computer 470, which may be battery-powered, or connected to AC power.

[00211] An infant's supply needs as to the volume of milk that needs to be consumed per day grows as the baby grows and gets older. The breasts 2 of the mother respond to this growing need by increasing milk production as the needs increase. Currently known pumping systems do not actively take into account these growing needs, as they operate in the same manner regardless of the age and size of the baby being fed. The present disclosure offers at least one "build" mode that can be selected by a user to stimulate increasing production by the breasts 2. As the system 100 is responsive to the expression of milk during a pumping session, while pumping in a build mode, the system 100 may sense that the milk volume flow (and/or total volume expressed at a particular time) is on track for the average production to date by the mother, but, in order to stimulate increase in production, the system 100 can increase, in real-time, the

time period over which the pump holds maximum suction pressure per cycle, or the maximum suction pressure level achieved, or both, or provide other modifications to the current pumping cycle to try and achieve an even greater expression of milk. This simulates a breastfeeding baby that works harder (harder and/or longer sucks) to try and draw more milk from the mother's breast 2, or a baby that just consumes more milk from the breast 2 for a longer period of time, because of its increasing needs due to growth. As the feedback can be provided continuously or from cycle-to-cycle, the controller 52 can assess in real time which changes are being effective, if any, in increasing the amount of milk extracted, and make further modifications, or maintain successful modifications, going forward with pumping cycles.

[00212] When executing a maintenance mode, the controller 52 executes the mode as instructed by the app 474 (or user, via manual mode selection on the device) with parameters of suction and suction holding times being maintained if sufficient milk flow feedback is received, and with the pumping session ended when the expected milk expression volume has been achieved. Similarly, in weaning mode, the controller 52 executes the mode as instructed by the app 474 (or user, via manual mode selection on the device) with parameters of suction and/or suction holding times being generally less than in maintenance mode, which helps to signal the breast 2 and the mother's brain to begin reducing milk production. A maximum pump mode may be provided that is designed to extract the most volume of milk possible within a predetermined time period, for example, when the mother has only a limited amount of time to pump. In this mode, the maximum suction, latch suction, and suction hold periods are designed to maximize the milk extraction within a predefined time period, which can be inputted by the user through user inputs 490 or through controls 153. This mode may not be optimal for overall total volume of milk extracted when a more extensive time period is available, but it is optimized for the time period selected. In any of these modes, the system 100 can alter suction levels (maximum and or latch), hold times, pause times, cycle frequency, etc., based on feedback received by the controller 52.

[00213] Fig. 34 is a schematic illustration of a distal end view of a pumping device, with the subassembly 35 having been removed so as to show the channel portions 232L, 232S and 232B that the conduit portions 32L and 32S and the segment 16 fit into when

subassembly 35 is assembled into the main body 34, according to an embodiment of the present disclosure. In this embodiment, vibration members 3400 are provided in channels 3402 and configured for rapid back and forth movement (in and out of the page, as shown in Fig. 34) driven by drive trains 3404connecting the vibration members 3400 to motor 46, so that when motor 46 is operated to drive the compression member 38 back and forth, it also drives the vibration members 3400 in and out. When the system 100 is installed on the breast 2 for operation in a milk extraction session, operation of motor 46, not only drives compression member 38, but also drives vibration members 3400 to oscillate into and away from the breast 2. This vibratory contact can further facilitate milk extraction (including stimulation of the nipple 3 and areola regions of the breast 2), and can also stimulate the breast 2 and mother's brain to condition them to produce greater total milk extraction volumes for future pumping sessions. Alternatively, or additionally, the system 100 may be configured to apply heat to the breast 2 to facilitate maximization of milk volume expressed and/or to add comfort to the user.

[00214] Fig. 35 illustrates subassembly 35 according to another embodiment of the present disclosure. In this embodiment, the entrance opening to segment 16 is at least partially blocked (greater than 50% of the opening, more preferably in the range of 60 to 100%, even more preferably in the range of 75% to 100%) by gate 3500. Gate 3500 includes a living hinge 3502 configured such that, when the system is installed on the breast 2, as breast 2 contacts the skin contact member 10, nipple 3 protrudes past the gate 3500, thereby bending gate 3500 down against the lower wall of the segment 16 as illustrated in phantom in Fig. 35. Upon finishing the pumping session, as the system is removed the breast 2, the gate 3500 returns to its initial, closed orientation shown in solid lines. Thus, if there is milk remaining in segment 16 upon detachment of the system 100 from the breast 2, most if not all of this milk will be prevented from spilling out of the segment 16 by gate 3500.

[00215] Fig. 36 illustrates a method of cleaning the subassembly 35 without removing it from the system. In this embodiment, cleaning fluid, such as soapy water or other specially formulated cleaning fluid can be dumped from a container 3600 (or other source of cleaning fluid/soapy water) into the segment 16 and the pumping section 30

can be actuated to pump the cleaning fluid through the conduit 32 and out of one-way valve 50. After running the cleaning fluid/soapy water through the system 100, pure water, saline, or other rinsing agent can be pumped through the conduit 32 in the same manner. This cleaning action can be performed using any pumping mode, as desired. Alternatively, a mode designed specifically cleaning may be available for selection by the user.

[00216] Fig. 37 is a partial view of subassembly 35 according to another embodiment of the present disclosure. In this embodiment, the side walls 16W are collapsible under some predefined suction pressure greater than maximum suction operating pressures to be used during pumping. For example, walls 16W may be configured to collapse at suction pressures in the range of -240mm Hg to -250mm Hg, or -220mmHg to -240mmHg, or some other predetermined suction pressure greater than maximum operating suction pressure. In this way, the walls 16W do not collapse during the pumping session. However, when milk pumping is determined to have been completed, just prior to shutting down the pumping section 30, the controller 52 operates the pumping section 30 to gradually increase maximum suction pressures, to collapse the walls 16w down to the nipple 3, thereby sucking substantially all remaining milk out of the segment 16. Alternatively, the collapsible region of the walls 16W can be made to collapse proximally of the nipple 3, but not against the nipple 3. Next the compression member 36 maintains the tubing section 32S closed and the pumping section (motors 44, 46) is shut down and the system 100 can be removed from the breast with little risk of milk spillage, since there will be substantially no milk left distally of the compression member 36. Upon breaking the suction seal between the system 100 and the breast 2, the walls 16W resiliently return to their original, non-collapsed configurations shown in Fig. 37. Optionally, a tab 3700 or other member can be provided on the skin contact member 10, which can be manually pulled to facilitate a small break in the suction seal to make it easier to remove the system 100 from the breast 2.

[00217] Fig. 38 illustrates a breast pump system 100 according to another embodiment of the present disclosure. In this embodiment, rather than being included in a device that mounts to the breast 2, the pumping section 30, conduits 32S, 32L, battery 48,

controller 52, one way valve 50 and milk collection container 60 are all contained within a purse, satchel or other bag or container 3800 designed and dimensioned to support these components. Container 3800 can be supported by the user with a shoulder strap 3804 configured and dimensioned to be worn over the shoulder of the user, or, can alternatively be supported on an external surface 3806 such as a table, chair, desk, bed, or the like. In the embodiment shown, the skin contact members 10 are attached to the breasts 2 in the same manner as previously described embodiments, and are connected to the pumping section via conduits 32E that are less compliant than the conduit sections 32S, 32L, and are preferably made as rigid as is practical. Pressure sensor 54 is provided in or near segment 16 located at the proximal end portion of skin contact member 10. Alternatively, pressure sensors could be located on the conduit 32 in the container 3800, such as adjacent segment 40/32S. The conduits 32E can be connected to a single pumping section 30 via conduit portions 32S and 32L, or may be each connected to its own dedicated pumping section 30 and conduit portions 32S and 32L, for more individualized control over the pumping operations on each breast 2.

[00218] Fig. 39 illustrates a breast pump system 100 according to another embodiment of the present disclosure. In this embodiment, like in the embodiment of Fig 38, rather than being included in a device that mounts to the breast 2, the pumping section 30, conduits 32S, 32L, battery 48, controller 52, one way valve 50 and milk collection container 60 are all mounted on a lower section of bra 130, below the breasts 2. In the embodiment shown, the skin contact members 10 are attached to the breasts 2 in the same manner as previously described embodiments, and are connected to the pumping section via conduits 32E that are less compliant than the conduit sections 32S, 32L, and are preferably made as rigid as is practical. Pressure sensor 54 is provided in or near segment 16 located at the proximal end portion of skin contact member 10. Alternatively, pressure sensors could be located on the conduit 32 in pumping section 30, such as adjacent segment 40/32S. The conduits 32E can be connected to a single pumping section 30 via conduit portions 32S and 32L, or may be each connected to its own dedicated pumping section 30 and conduit portions 32S and 32L, for more individualized control over the pumping operations on each breast 2.

[00219] Fig. 40 illustrates a breast pump system 100 according to another embodiment of the present disclosure. In this embodiment, rather than being included in a device that mounts to the breast 2, the pumping section 30, conduits 32S, 32L, battery 48, controller 52 and one way valve 50 are all contained within a portable unit 4000 alongside a milk collection container 60. Portable unit 4000 can be readily hand carried by the user or placed in a purse, bag or other container 3800 or, can be supported on an external surface 3806 such as a table, chair, desk, bed, or the like. In the embodiment shown, the skin contact members 10 are attached to the breasts 2 in the same manner as previously described embodiments, and are connected to the pumping section via conduits 32E that are less compliant than the conduit sections 32S, 32L, and are preferably made as rigid as is practical. Pressure sensor 54 is provided in or near segment 16 located at the proximal end portion of skin contact member 10. Alternatively, pressure sensors could be located on the conduit 32 in the portable unit 4000, such as adjacent segment 40/32S. The conduits 32E can be connected to a singled pumping section 30 via conduit portions 32S and 32L, or may be each connected to its own dedicated pumping section 30 and conduit portions 32S and 32L, for more individualized control over the pumping operations on each breast 2.

[00220] The responsive nature of the present systems 100 enables the systems to maintain a desired pressure waveform over repeated pumping cycles even as the milk volume within the conduit 32 varies. Fig. 41 illustrates one example of a pressure waveform 4100 used in one pumping mode of the system according to an embodiment of the present disclosure. In this embodiment, the pressure waveform moves from a latch suction pressure of -60mm Hg to a maximum suction pressure of -200mm Hg, over a hold period 4100 during which the maximum suction pressure is maintained, and back to the latch suction pressure of -60mm Hg. As milk enters the system, the more that the conduit 32 fills up with milk, the more the suction will "bleed off" in the conduit. For example, the phantom lines 4102 and 4104 illustrate how the suction pressure becomes less than maximum suction pressure and continues to decrease (relatively higher pressure) as the milk continues to take up more and more volume of the conduit 32. The phantom lines are the result if the pumping mechanism is not responsive and just carries on with the same pumping parameters (stroke, force and

timing) with each succeeding cycle. However, by receiving feedback from sensor 54, controller 52 can modify the pumping parameters in real time, so as to maintain each cycle of the pumping cycle as it should be, i.e., following the solid lines in the waveform in Fig. 41. This can be achieved, for example, by increasing the stroke of the compression member 38 until the maximum suction level is achieved, and then modifying the position of compression member 38 as needed during the hold period 4100 to maintain the maximum suction pressure over the course of the holding period. This same type of responsivity can be applied in real time, over the extent of the entire pumping cycle so as to maintain a desired pumping profile cycle after cycle.

[00221] As the system 100 is being operated, the user has the ability to manually change operating parameters such as maximum suction pressure, latch suction pressure, hold times, pause time, etc. Controller 52 may be programmed to monitor manual changes made by the user during use, and to save these changes in memory and apply the changes automatically the next time the user uses the same pumping mode that was modified previously. Over a series of uses of any given pumping mode, the controller 52 (and/or app 474) may compare pumping results (e.g., milk extraction volume) for the various changes in pumping parameters made by the user over multiple sessions, identify those changes that produced the greatest milk extraction results, save those changes that produce the best results, and apply those changes in the next pumping session using the same pumping mode. In this way the system "learns" more efficient pumping parameters for application to a specific individual user.

[00222] Other pumping modes may be programmed in an effort to simulate an actual baby breastfeeding from the breast 2. Examples of such modes include pumping modes that don't simply repeat the same suction pressures and hold periods cycle after cycle, but vary them in ways attempted to change in the way a baby changes suckling patterns during breastfeeding. Other modes that can be provided include a mode that simulates an active, aggressive feeder and a made that simulates a sleepy, slow feeder, where the active mode could achieve a higher maximum suction level and/or longer hold periods at maximum suction level compared to a standard pumping mode (e.g., maintenance mode) and the sleepy mode could be set for lower maximum suction level and or shorter hold periods at maximum suction level compared to a standard pumping

mode such as maintenance mode. Other profiles could be provide as modes that the user could select from to attempt a breast pumping session that is most closely matched to a manner in which her baby breastfeeds, such as a frequent pauser mode, wherein pauses in the pumping action are more frequent and/or longer than those provided in a more standard mode.

[00223] Fig. 42 illustrates a method of monitoring a baby's feeding style during breastfeeding, according to an embodiment of the present disclosure. In this embodiment, a microphone 310 is adhered to or placed against the throat of the baby 5 and swallow sounds are recorded. By recording and differentiating between the sounds that vary for a swallow full of milk and a swallow empty of milk, as well as swallows having intermediate amounts somewhere in between full and empty, and the time periods between swallows, this data can be inputted to app 474 (or controller 52) and used to derive a pumping mode that cycles according to the timing of swallows performed by the baby 5 during the actual breastfeeding. Sucking sounds may also be recorded to differentiate between hold periods at maximum suction and pause periods during which only latch suction is applied to the breast when operating the system in this baby mode. Additionally, a camera 320 can optionally be provided to view the throat as the baby 5 swallows, as an aid to counting the number of swallows during the feeding session. Otherwise the number of swallows can be audibly determined using the microphone 310 (and associated amplifier and recording equipment 312, types of which are known in the art).

[00224] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure as described herein.

CLAIMS

That which is claimed is:

1. An automated method of pumping milk from a breast of a user, the method comprising:

providing a breast pump system including a closed loop control system capable of sensing and controlling suction pressure waveforms to optimize filling milk of a user during minimum suction and optimize extraction during increase suction greater than minimum suction;

forming a seal between the breast pump system and a breast;

pumping milk expressed from the breasts through a conduit; and

delivering milk to a storage container;

wherein natural physiology of producing milk is facilitated.

2. The method of any preceding claim, further comprising first and second breast pumps and coordinating the pumping of the first breast pump with the second breast pump.

3. The method of any preceding claim, wherein expansion of the conduit generates suction, wherein expansion of the conduit is supplemented by driving structure attached to the conduit.

4. The method of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level, wherein the second suction level is a latch suction which is maintained throughout a pumping session.

5. The method of any preceding claim, further comprising compressing at least one portion of the conduit and reducing compression of the at least one portion, wherein the returning of the at least one portion toward its uncompressed state generates suction sufficient to extract milk from the breast.

6. The method of any preceding claim, further comprising providing a battery and monitoring battery charge.

7. The method of any preceding claim, further comprising generating a histogram reflecting pumping action.

8. The method of any preceding claim, further comprising measuring flow rate of extracted milk.

9. The method of any preceding claim, further comprising one or more motors and tracking the position of the motors.

10. The method of any preceding claim, further comprising providing one or more controllers, the controllers operating to recommend pumping patterns.

11. An automated system for controlling pumping cycles to pump milk from a breast of a user, the system comprising:

a closed control system capable of sensing and controlling suction pressure waveforms to optimize filling milk ducts of a user during minimum suction and optimize extraction during increased suction greater than the minimum suction;

a breast adapter configured and dimensioned to form a seal with a breast;

a storage container for storing the milk pumped from the breasts; and

a conduit in fluid communication with, and interconnecting the adapter and the storage container;

wherein natural physiology of producing milk is facilitated.

12. The system of any previous claim, further comprising first and second pump systems, wherein pumping of milk from a first breast is coordinated with pumping of milk from a second breast.

13. The system of any previous claim, further comprising structure attached to the conduit to facilitate expansion of the conduit.

14. The system of any previous claim, further comprising a controller configured to generate a histogram reflecting pumping action.

15. The system of any previous claim, of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level, wherein the second suction level is a latch suction which is maintain throughout a pumping session.

16. The system of any preceding claim, further comprising a battery and a controller monitoring the battery.

17. The system of any preceding claim, further comprising a sensor that senses flow rate.

18. The system of any preceding claim, further comprising a display configured to display an image of a baby or project recorded sounds of the baby.

19. The system of any preceding claim, further comprising a motor and a sensor for tracking a position of the motor.

20. The system of any preceding claim, further comprising a controller configured to track inventory.

21. The system of any preceding claim, further comprising a controller configured to track dates of extracted milk.

22. The system of any preceding claim, further comprising a controller, wherein the controller adaptively controls one or more of maximum suction pressure level, latch suction pressure level, suction pressure waveform over a pumping cycle, phases of extraction or feeding times, rest times, heating temperatures and times, vibration frequency and duration, and pumping session time.

23. The system of any preceding claim, further comprising a controller, wherein the controller controls one or more of pumping mode; frequency of pumping cycle, maximum suction pressure achieved during a pumping cycle; latch suction pressure achieved during the pumping cycle, pumping force and pumping session time.

24. The system of any preceding claim, wherein the conduit includes a non-circular region.

25. The system of any preceding claim, wherein the conduit includes a section with opposing flat sections.

26. The system of any preceding claim, further comprising a contouring shell configured to provide an appearance of a natural breast contour when the skin contact member is sealed to the breast.

27. The system of any preceding claim, wherein the controller provides or controls one or more of a sleep mode, pumping goals, tracking of efficiency, weaning modes, growing modes, communication with health care providers, maintenance modes, and maximum pump modes.

28. The system of any preceding claim, further comprising a living gate configured to inhibit loss of milk.

29. The system of any preceding claim, wherein walls of the conduit are collapsible to suck remaining milk out of the conduit.

30. The system of any preceding claim, wherein one or more controllers control pumping to match desired waveforms.

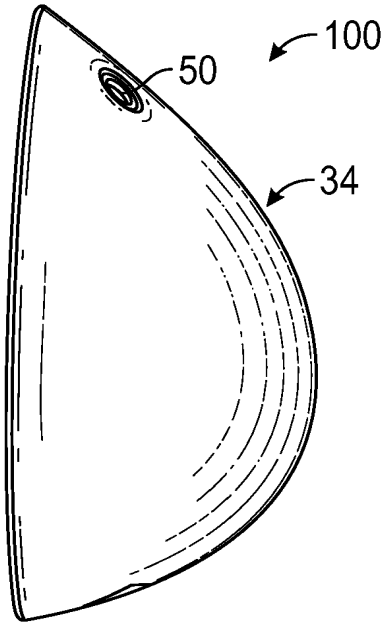

100
50
34

FIG. 1A

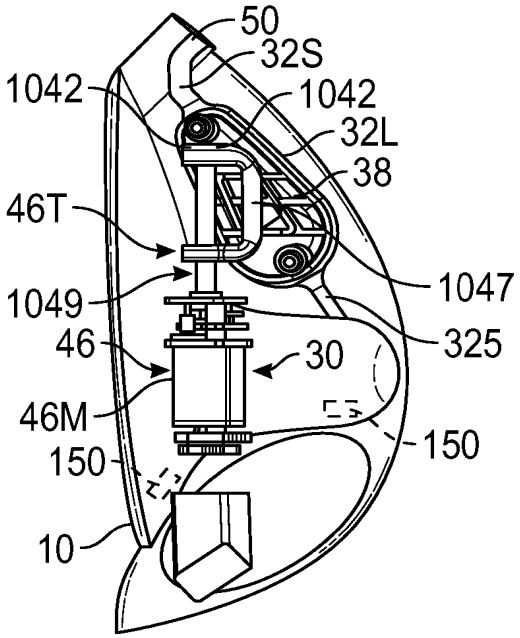

50
32S
1042
1042
32L
38
46T
1047
1049
325
46
30
46M
150
150
10

FIG. 1B

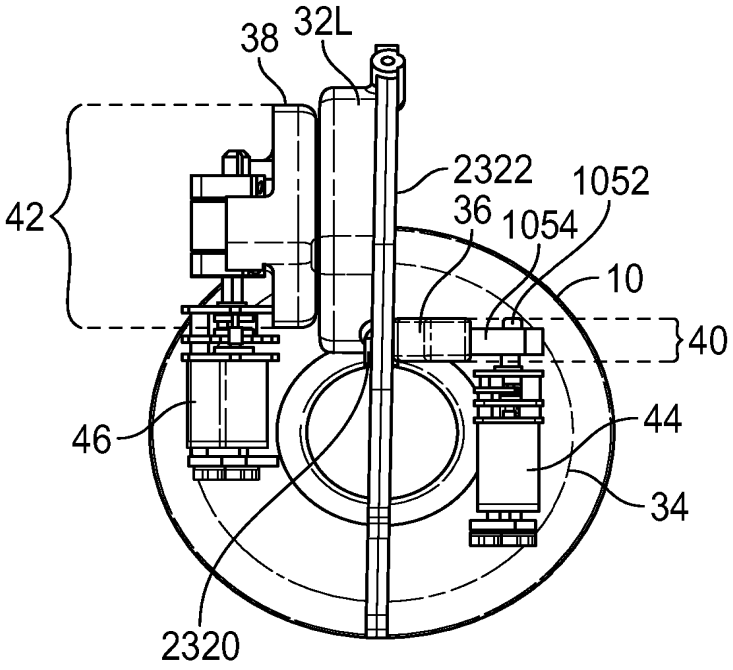

38
32L
42
2322
1052
36
1054
10
40
46
44
34
2320

FIG. 1C

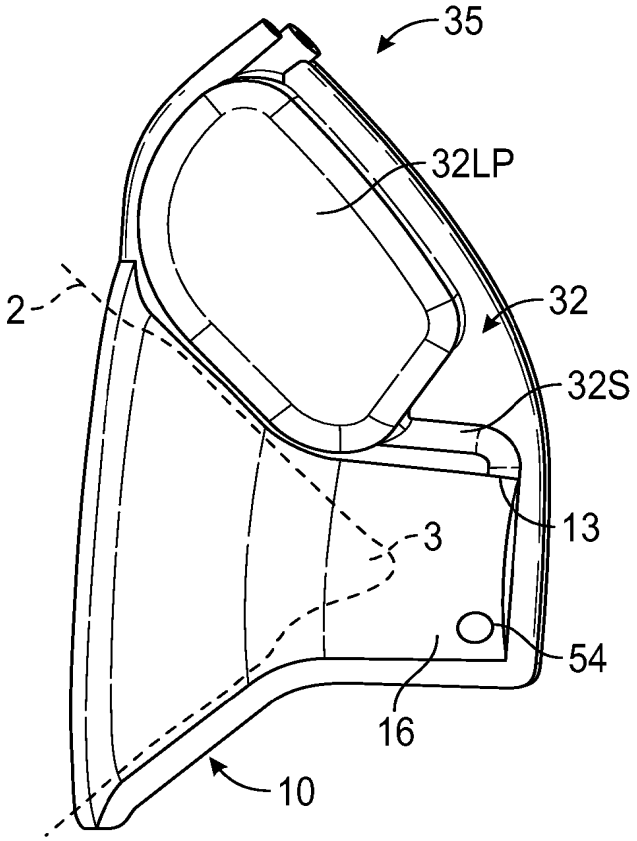

35
32LP
2
32
32S
13
3
54
16
10

FIG. 2A

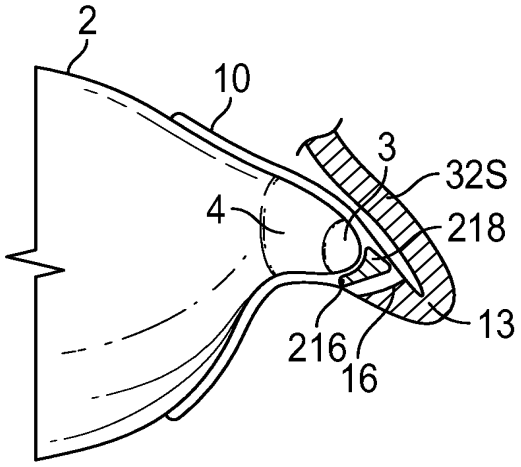


FIG. 2B

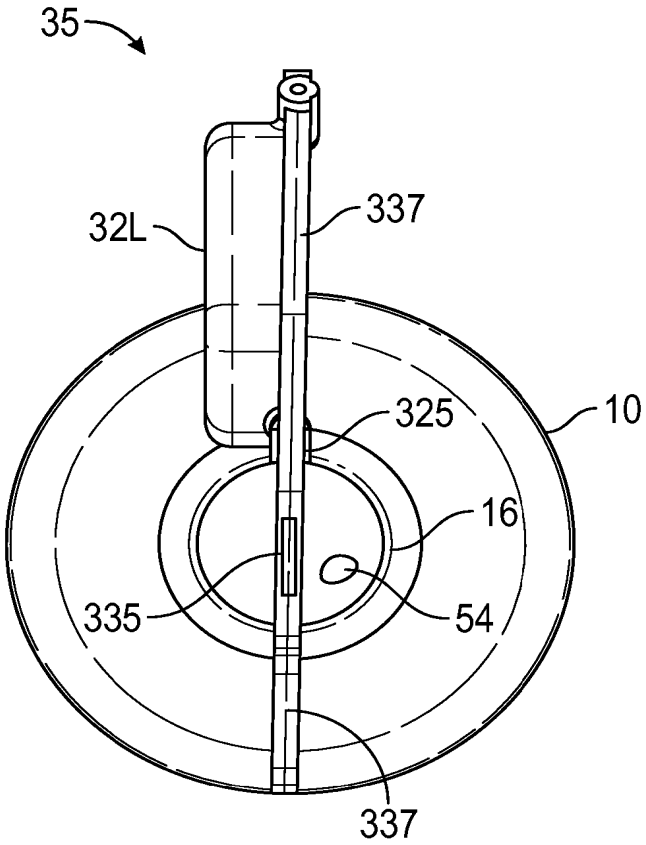


FIG. 3

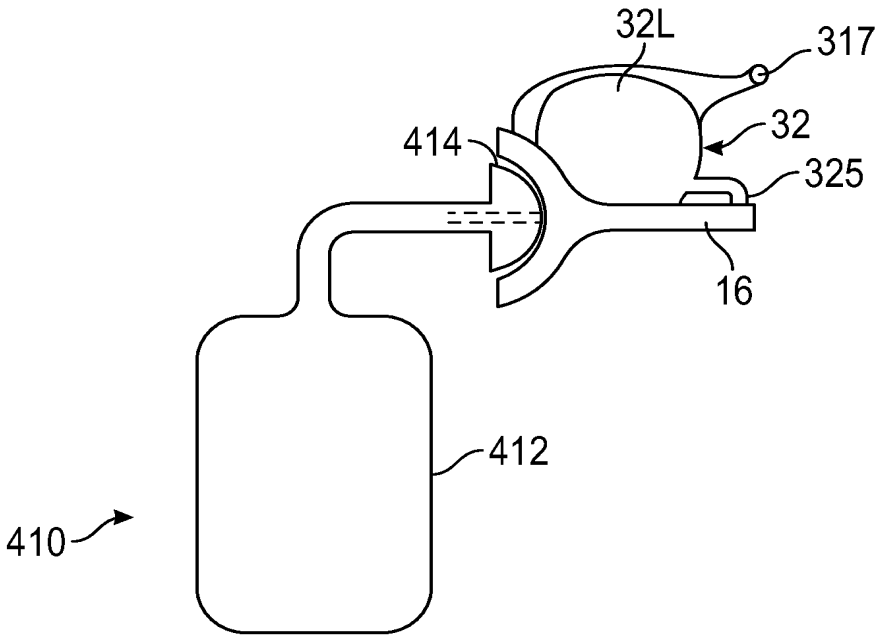


FIG. 4

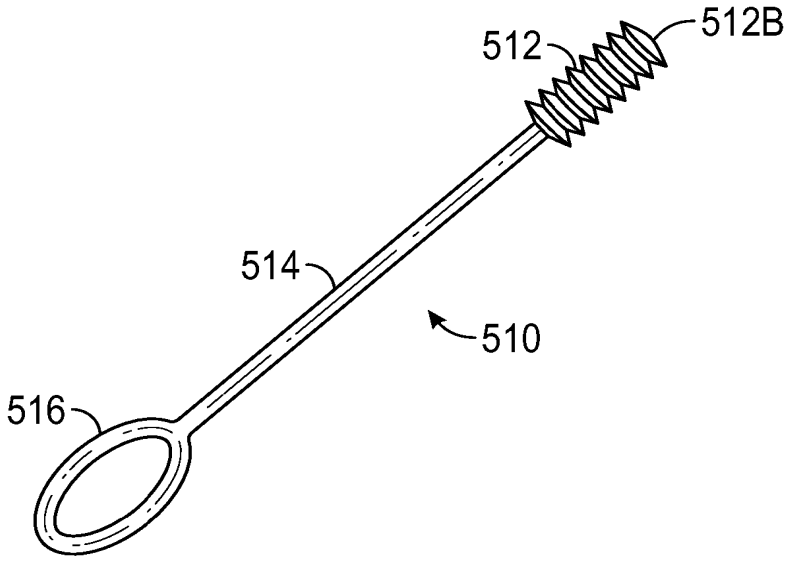


FIG. 5

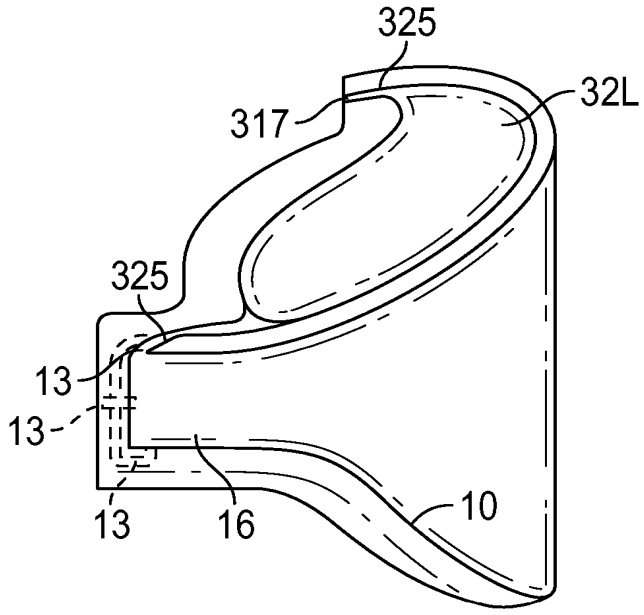


FIG. 6

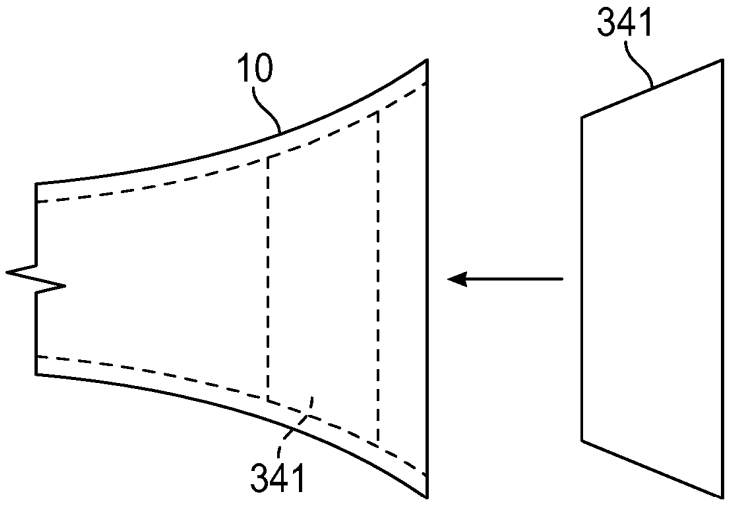


FIG. 7

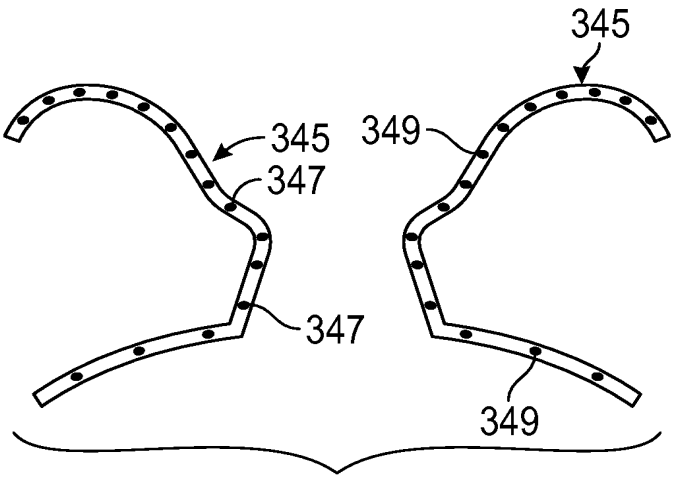


FIG. 8

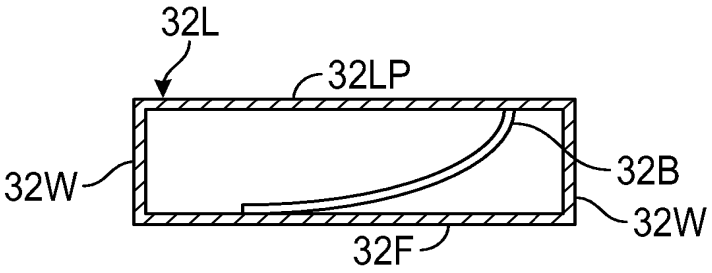


FIG. 9A

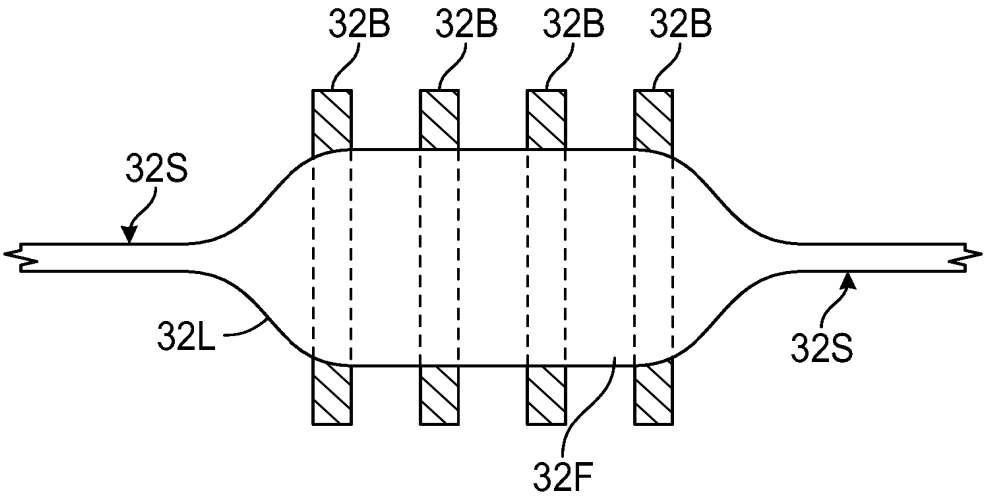


FIG. 9B

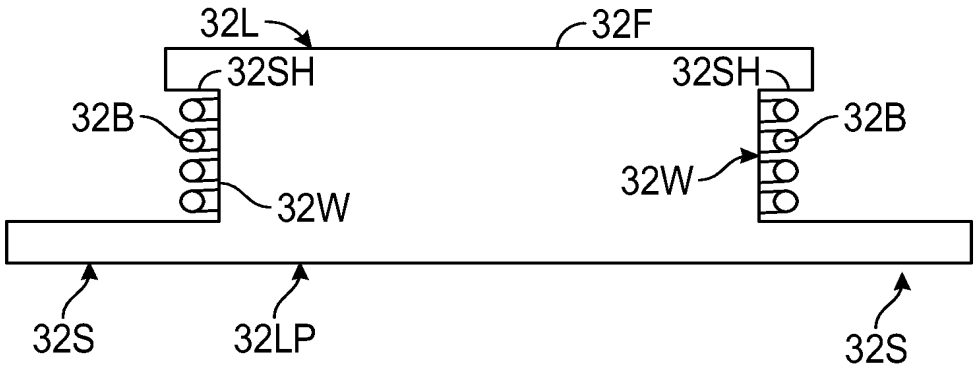


FIG. 9C

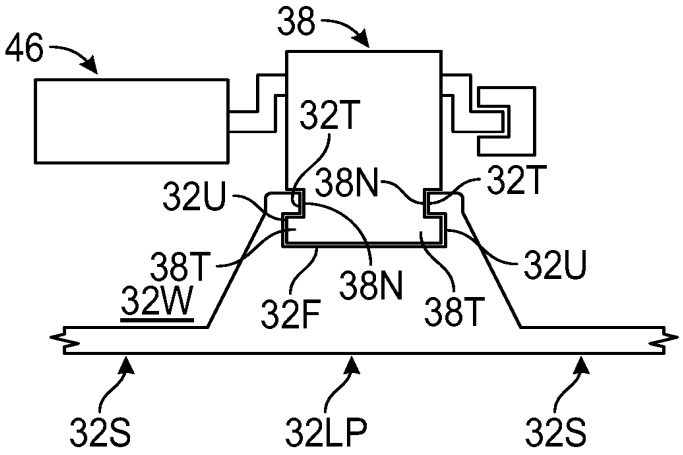


FIG. 9D

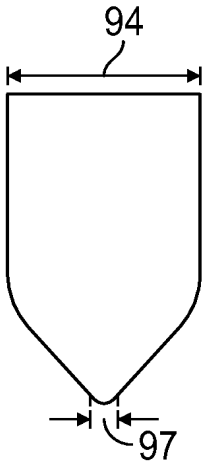


FIG. 10

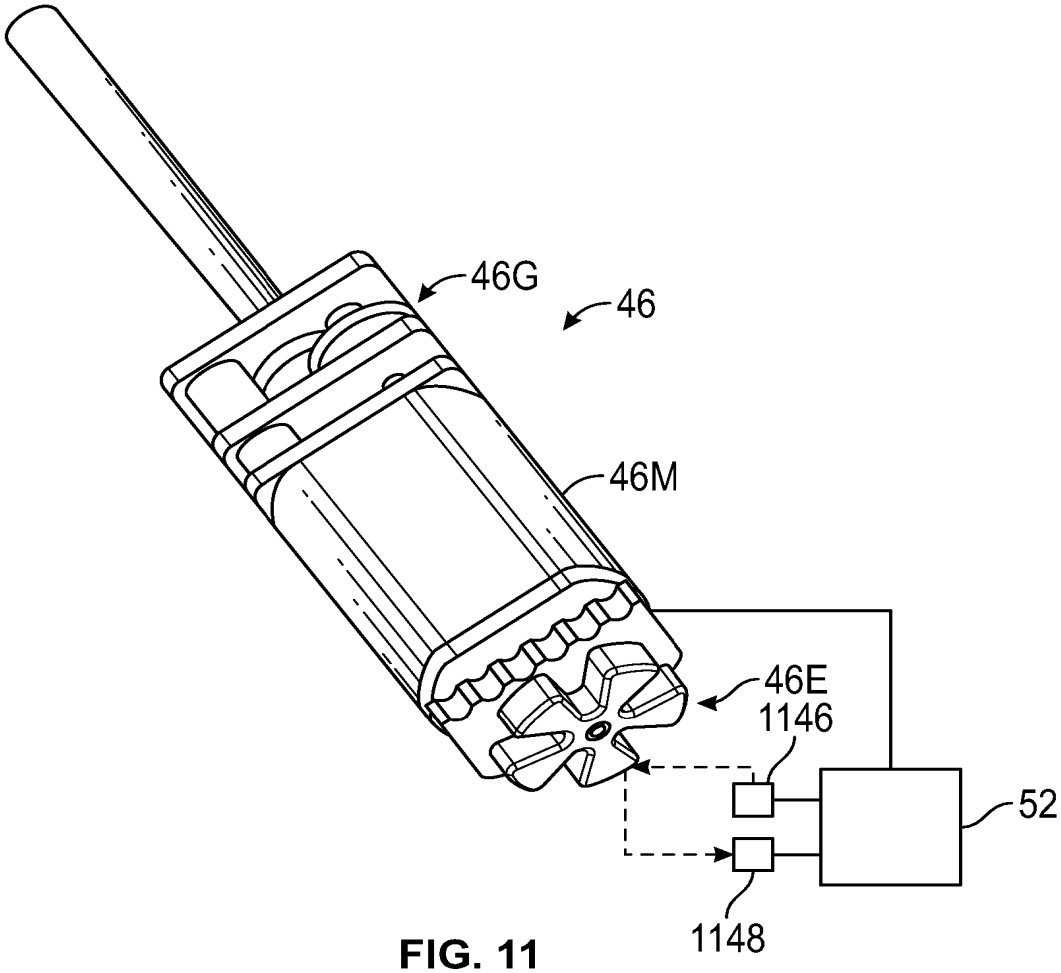


FIG. 11

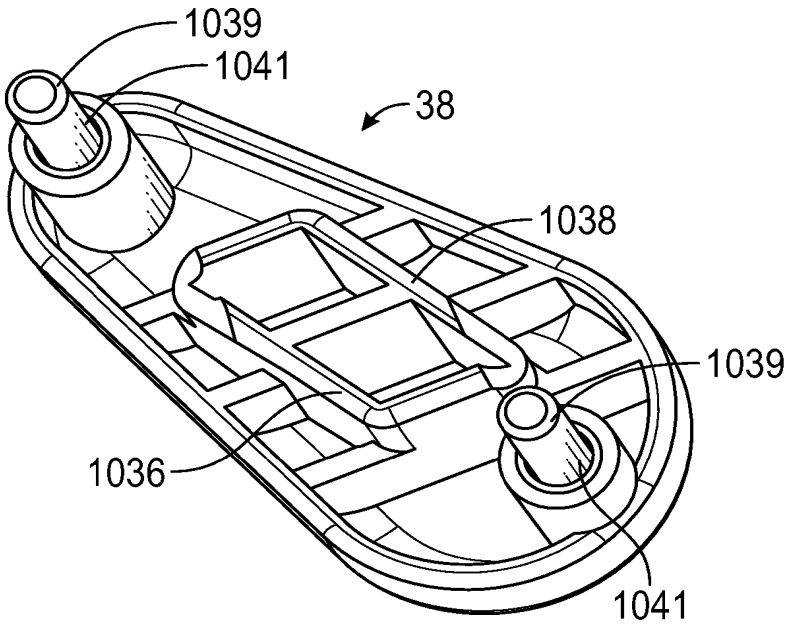


FIG. 12

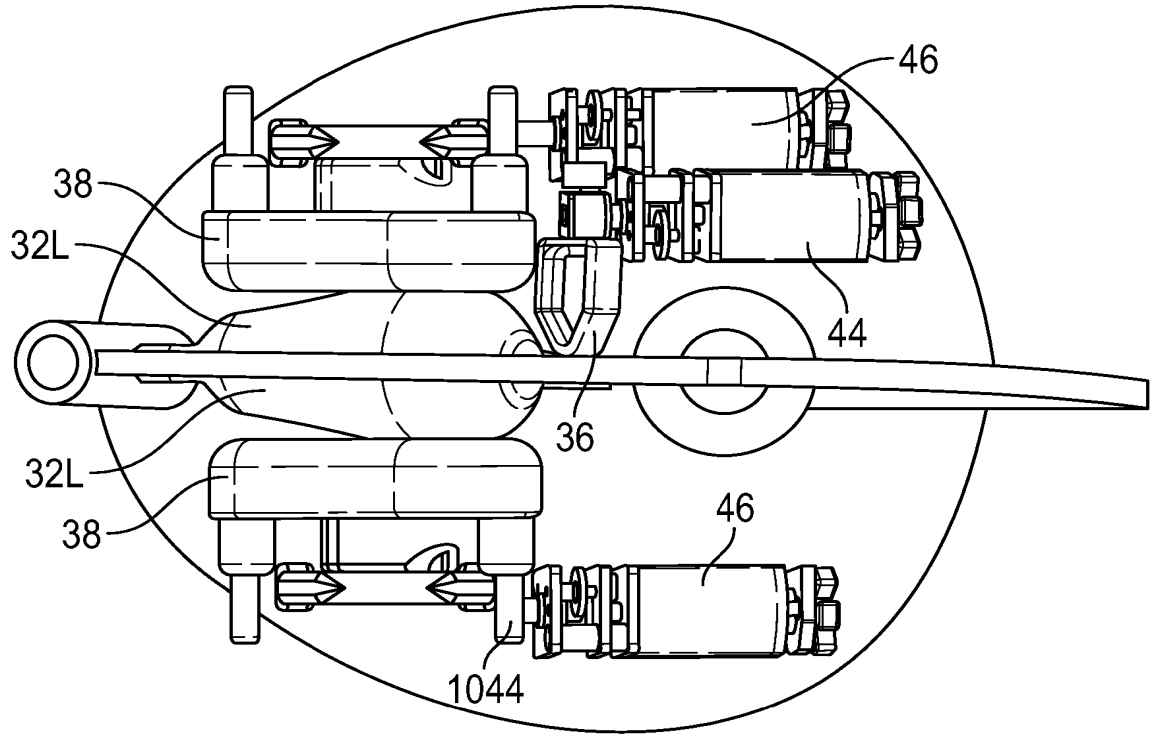


FIG. 13A

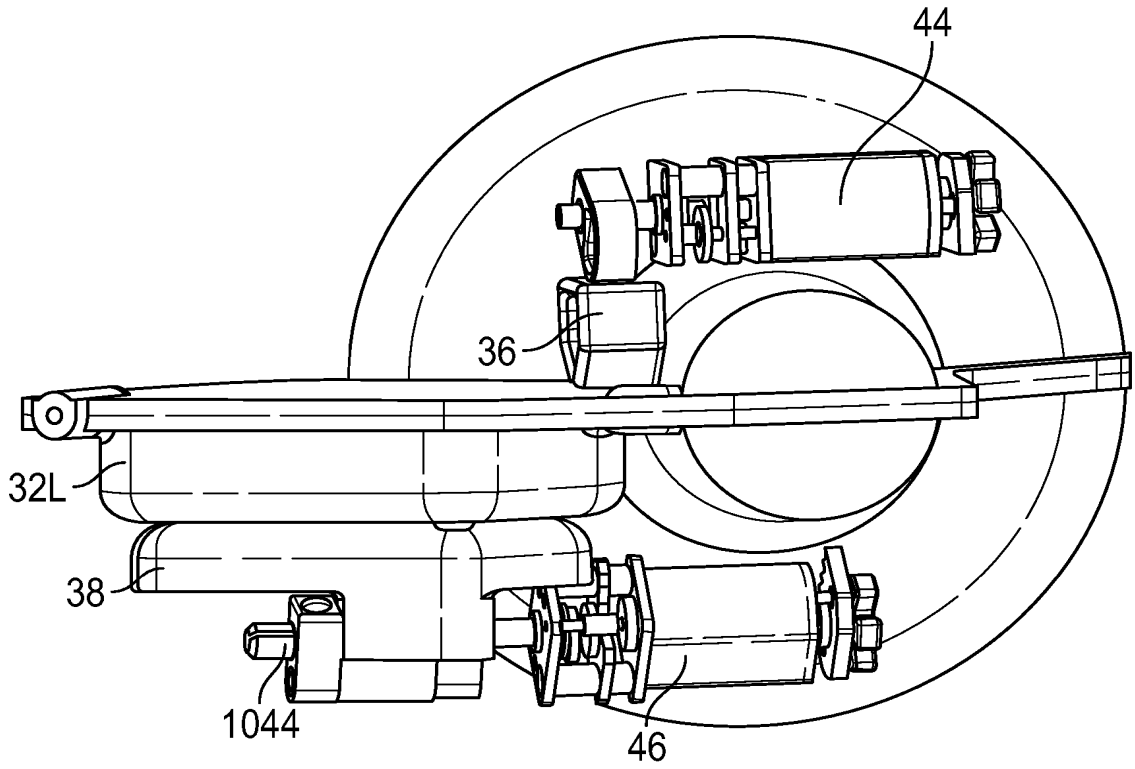


FIG. 13B

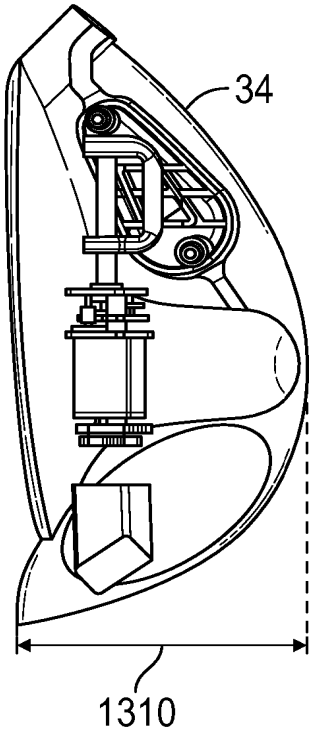


FIG. 13C

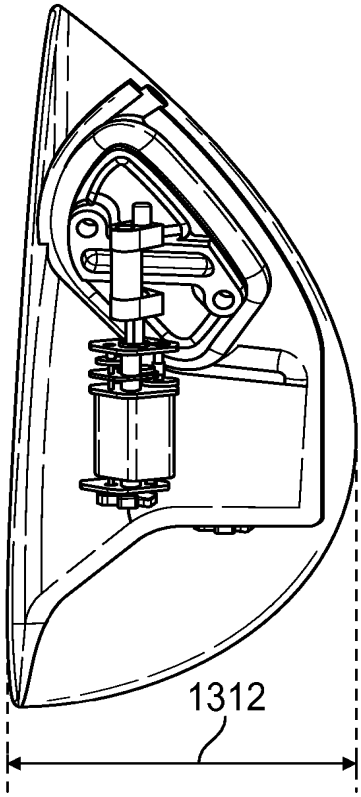


FIG. 13D

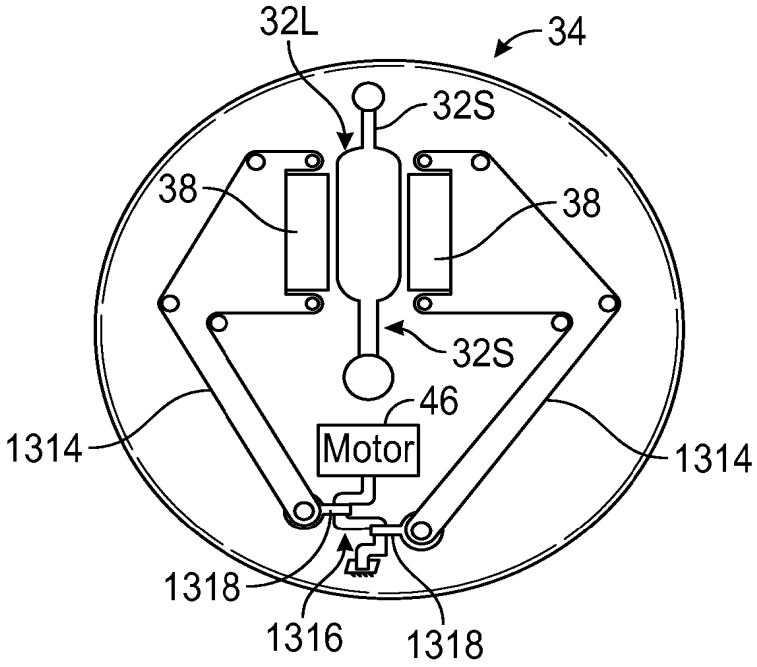


FIG. 13E

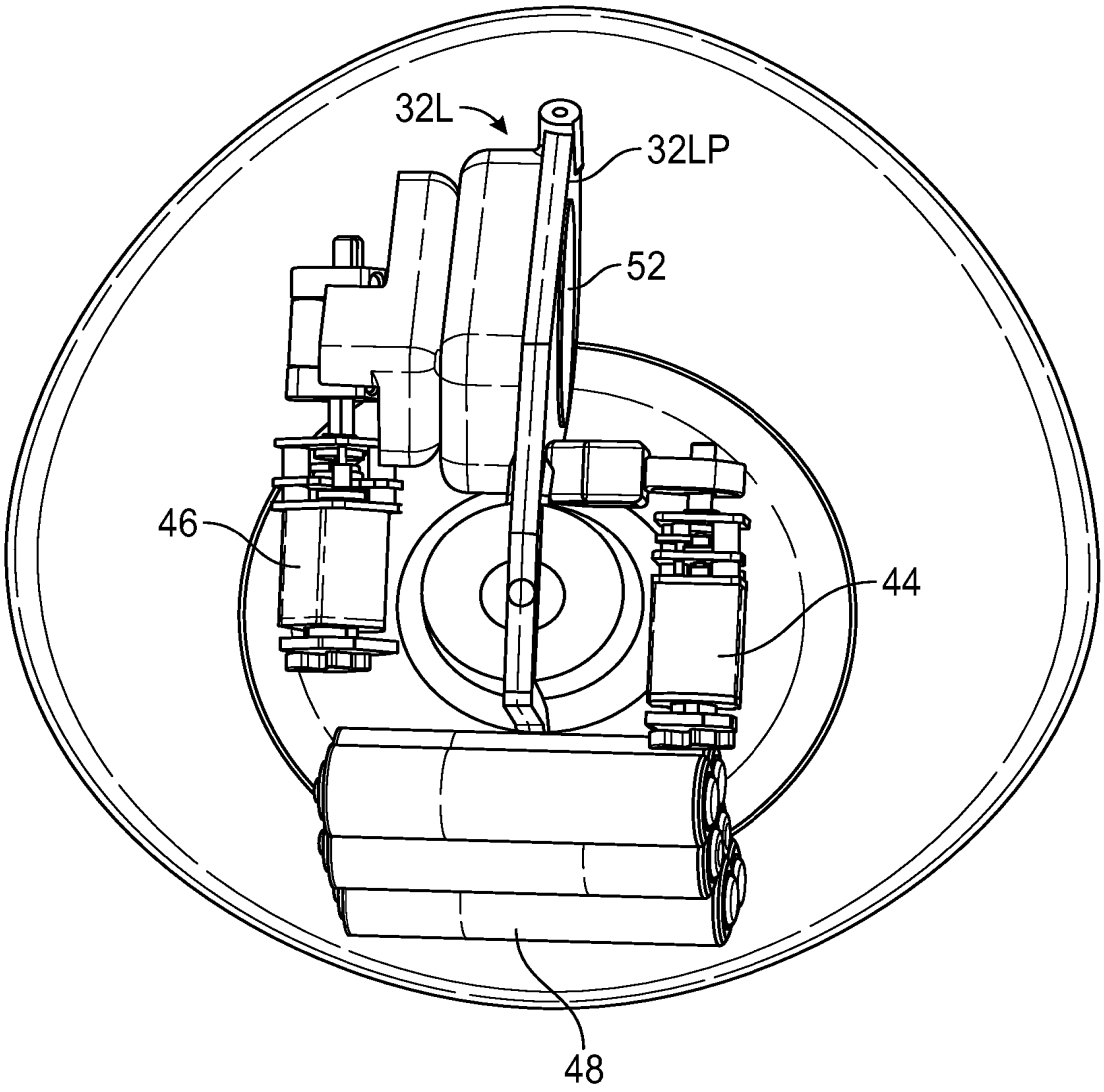


FIG. 14A

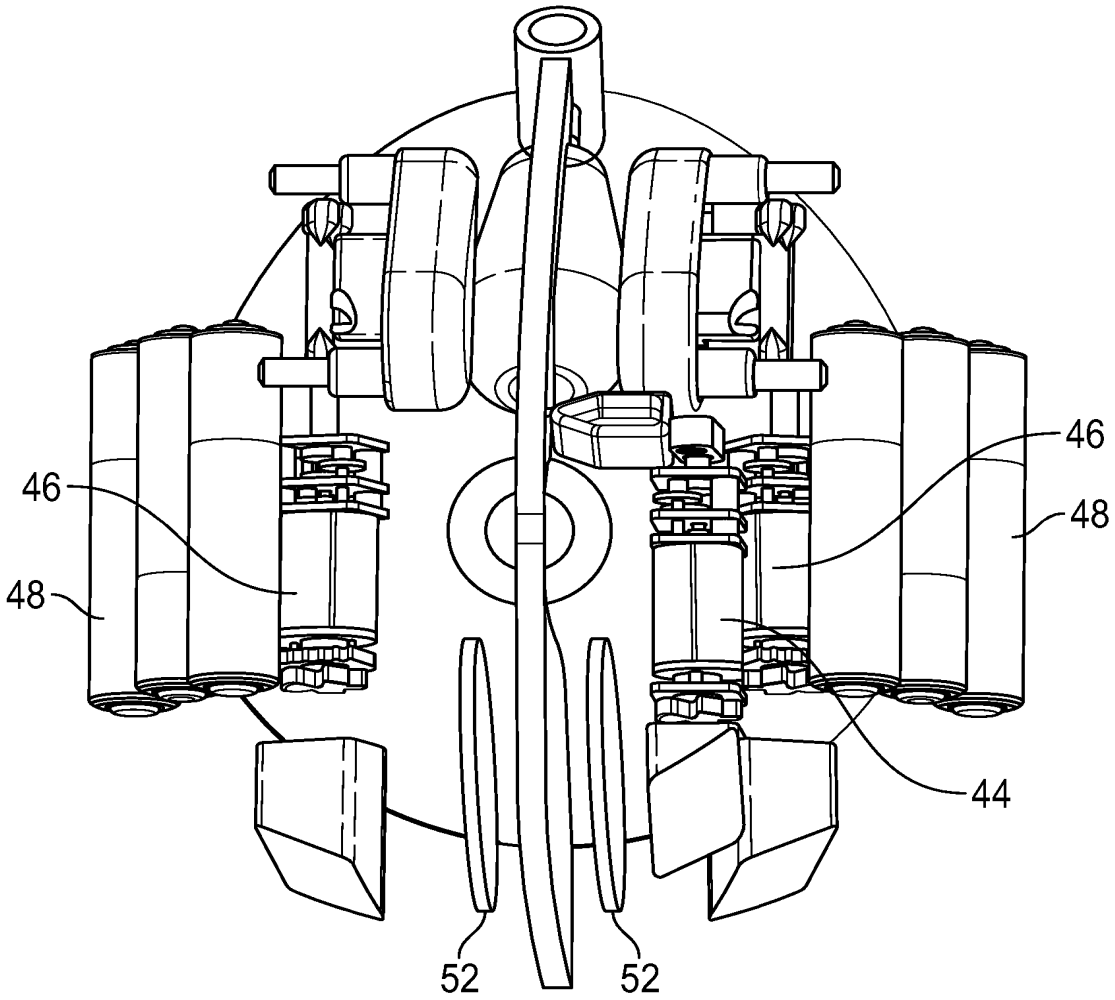


FIG. 14B

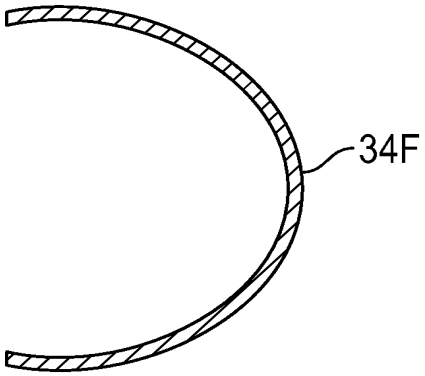


FIG. 15A

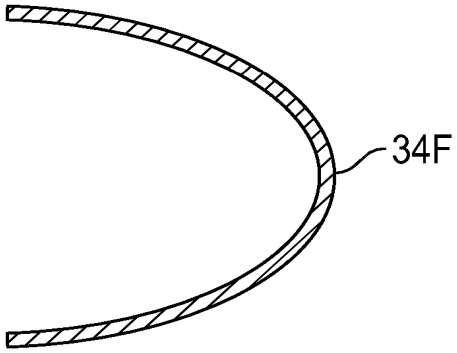


FIG. 15B

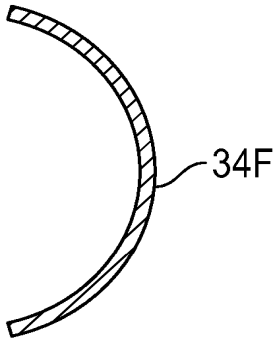


FIG. 15C

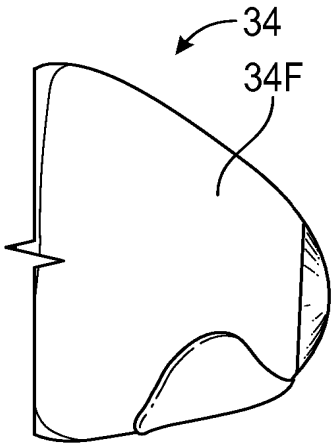


FIG. 16A

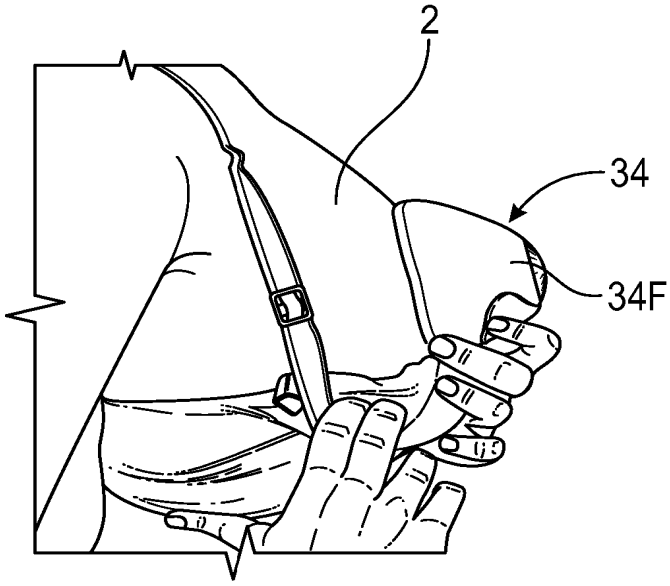


FIG. 16B

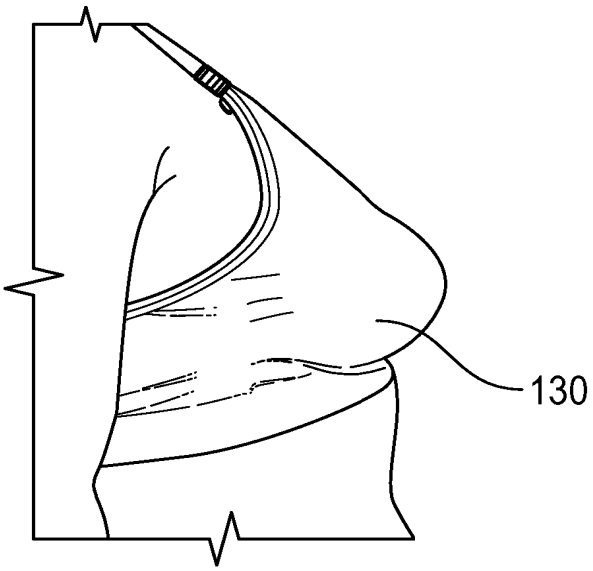


FIG. 16C

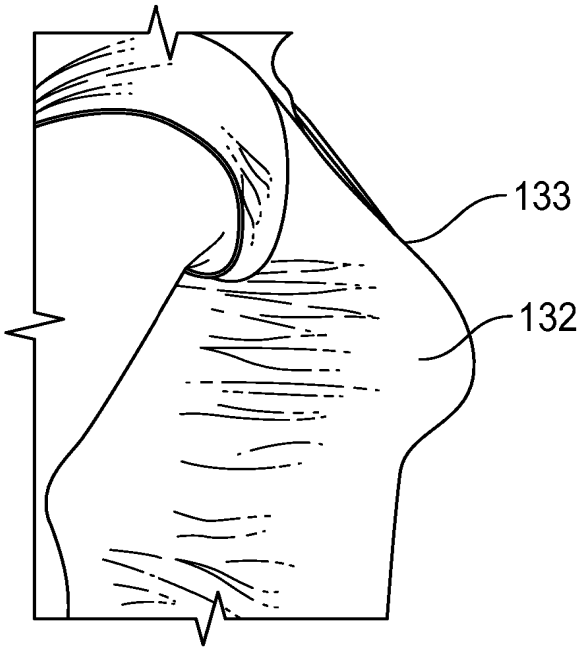


FIG. 16D

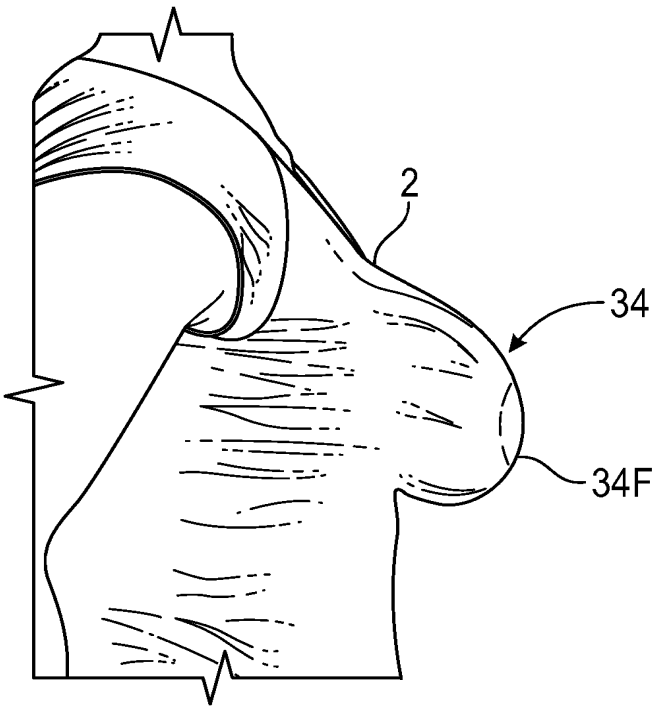


FIG. 17A

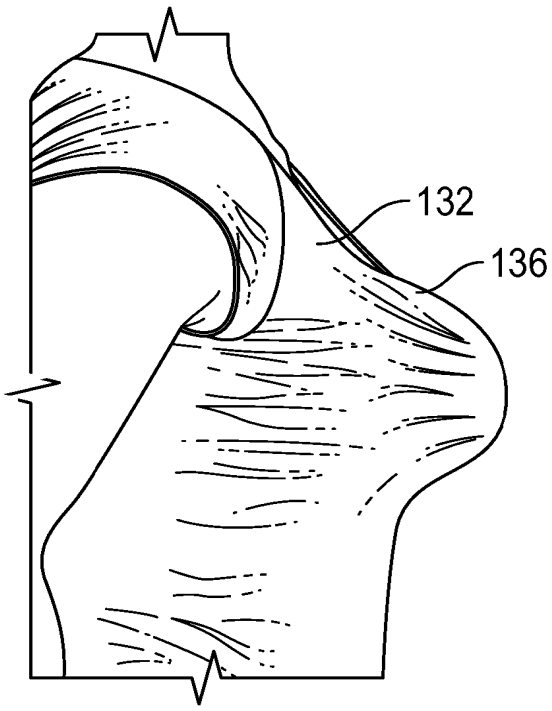


FIG. 17B

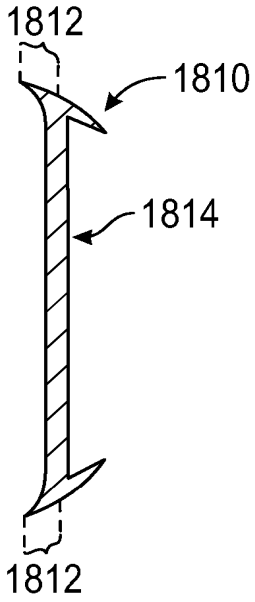


FIG. 18A

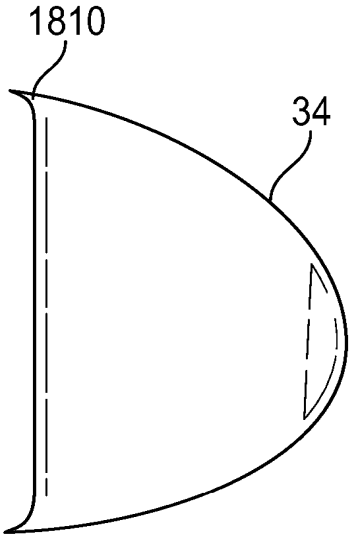


FIG. 18B

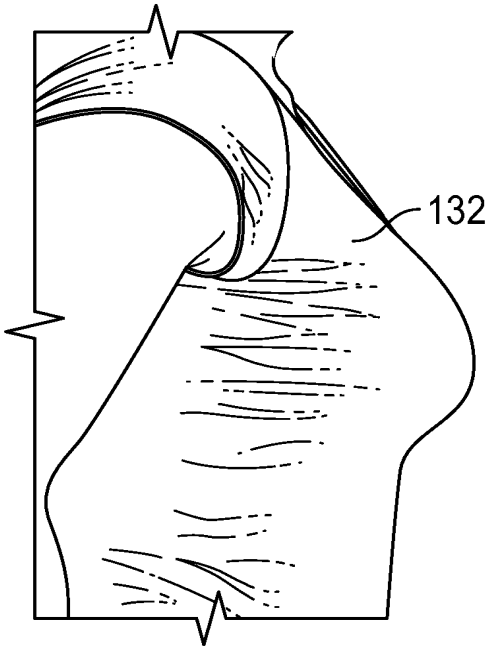


FIG. 18C

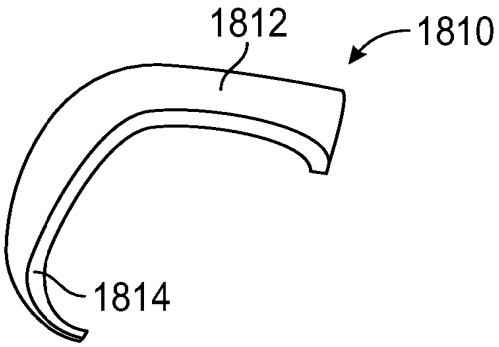


FIG. 18D

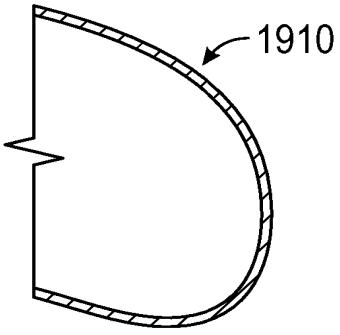


FIG. 19A

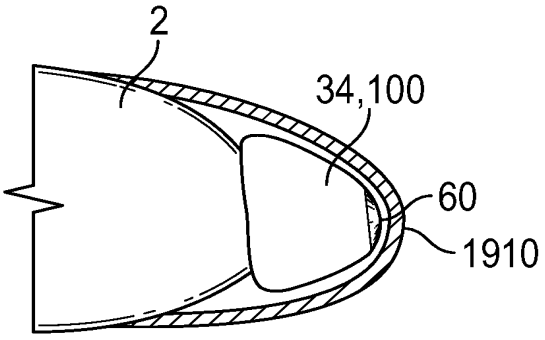


FIG. 19B

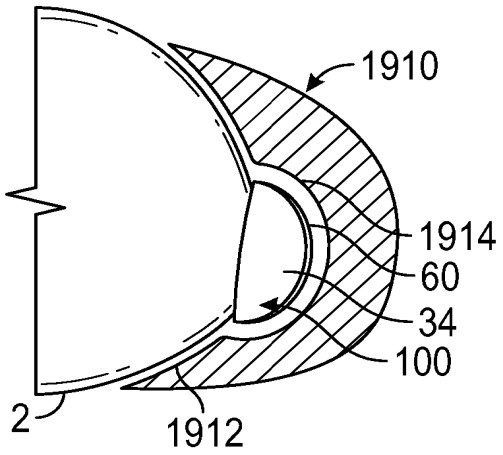


FIG. 19C

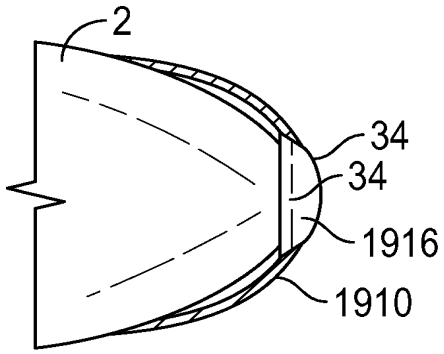


FIG. 19D

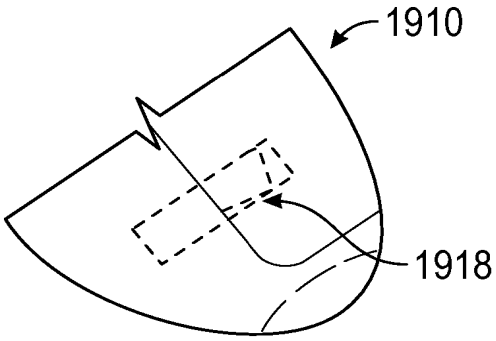


FIG. 19E

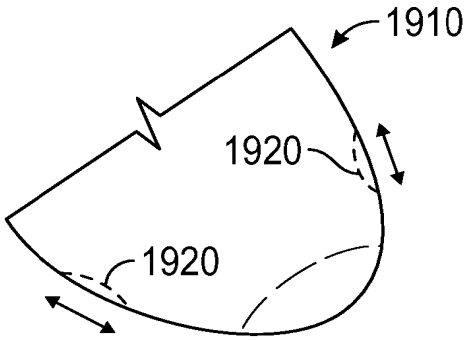


FIG. 19F

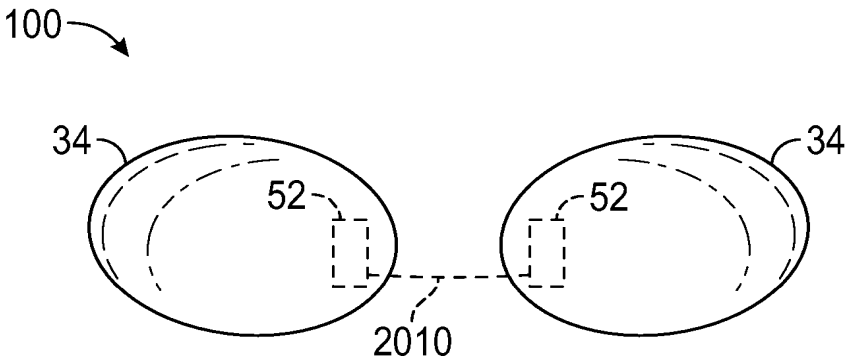


FIG. 20

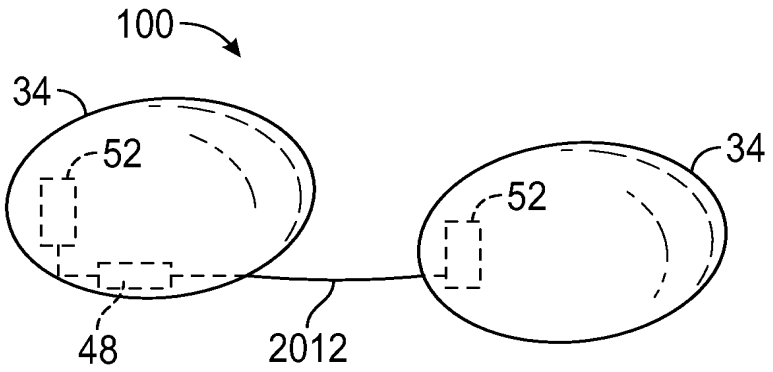


FIG. 21

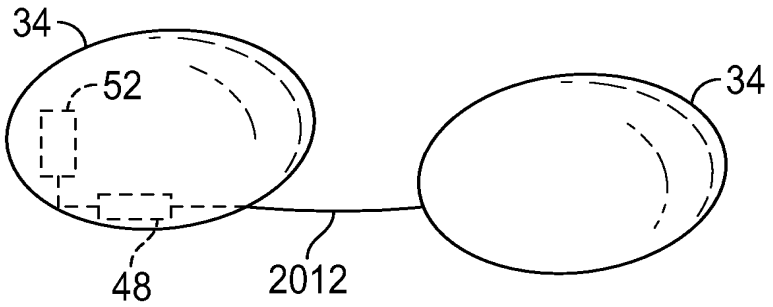


FIG. 22

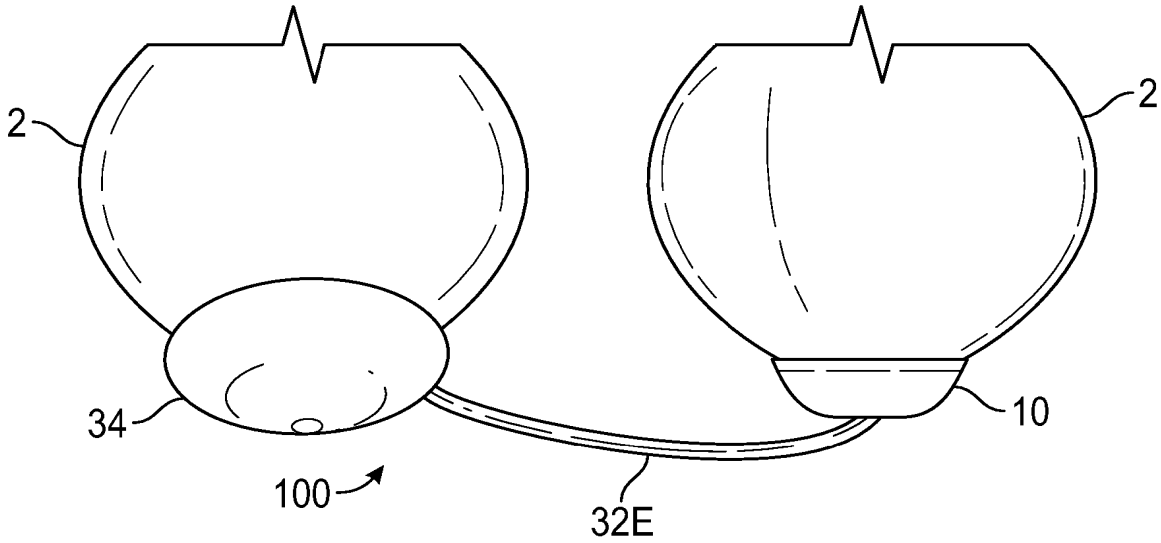


FIG. 23

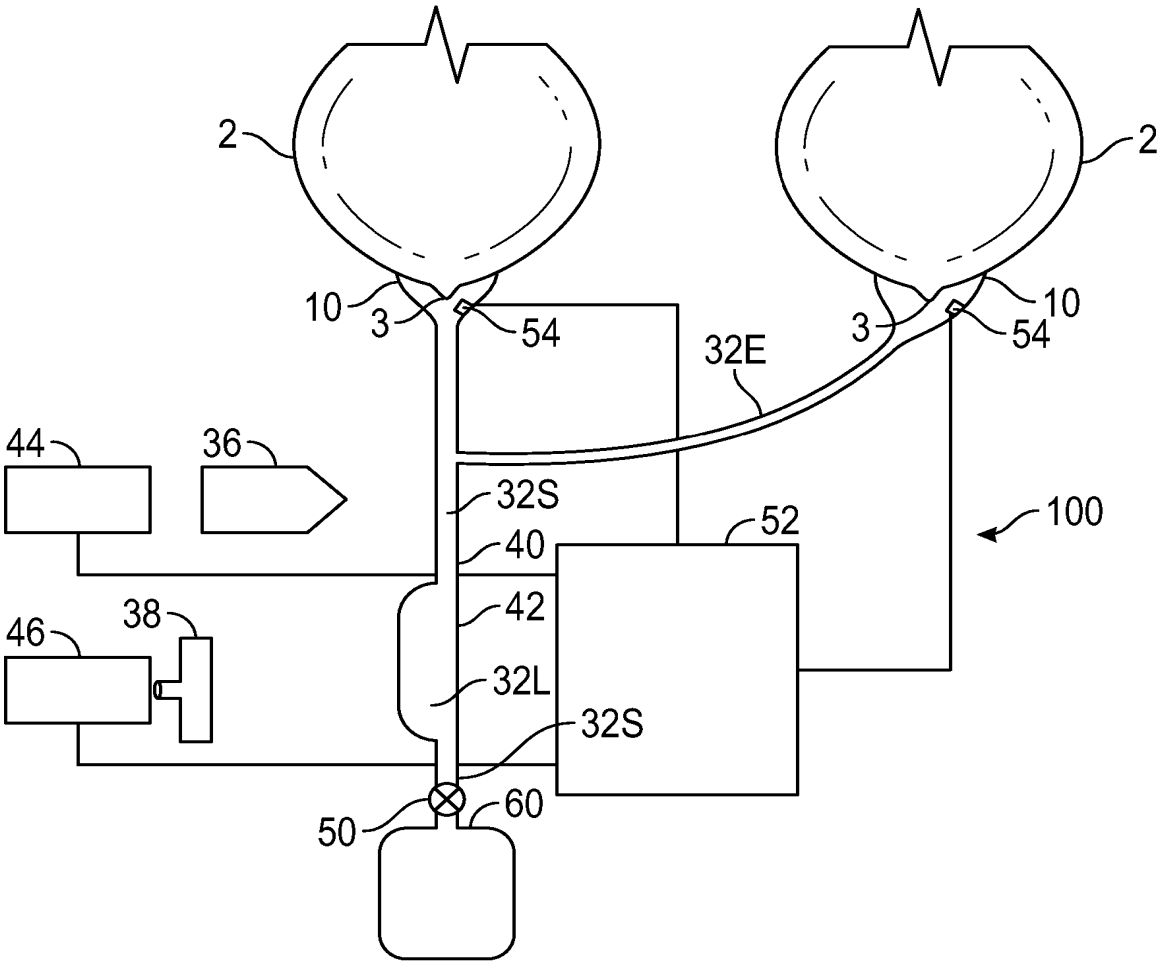


FIG. 24

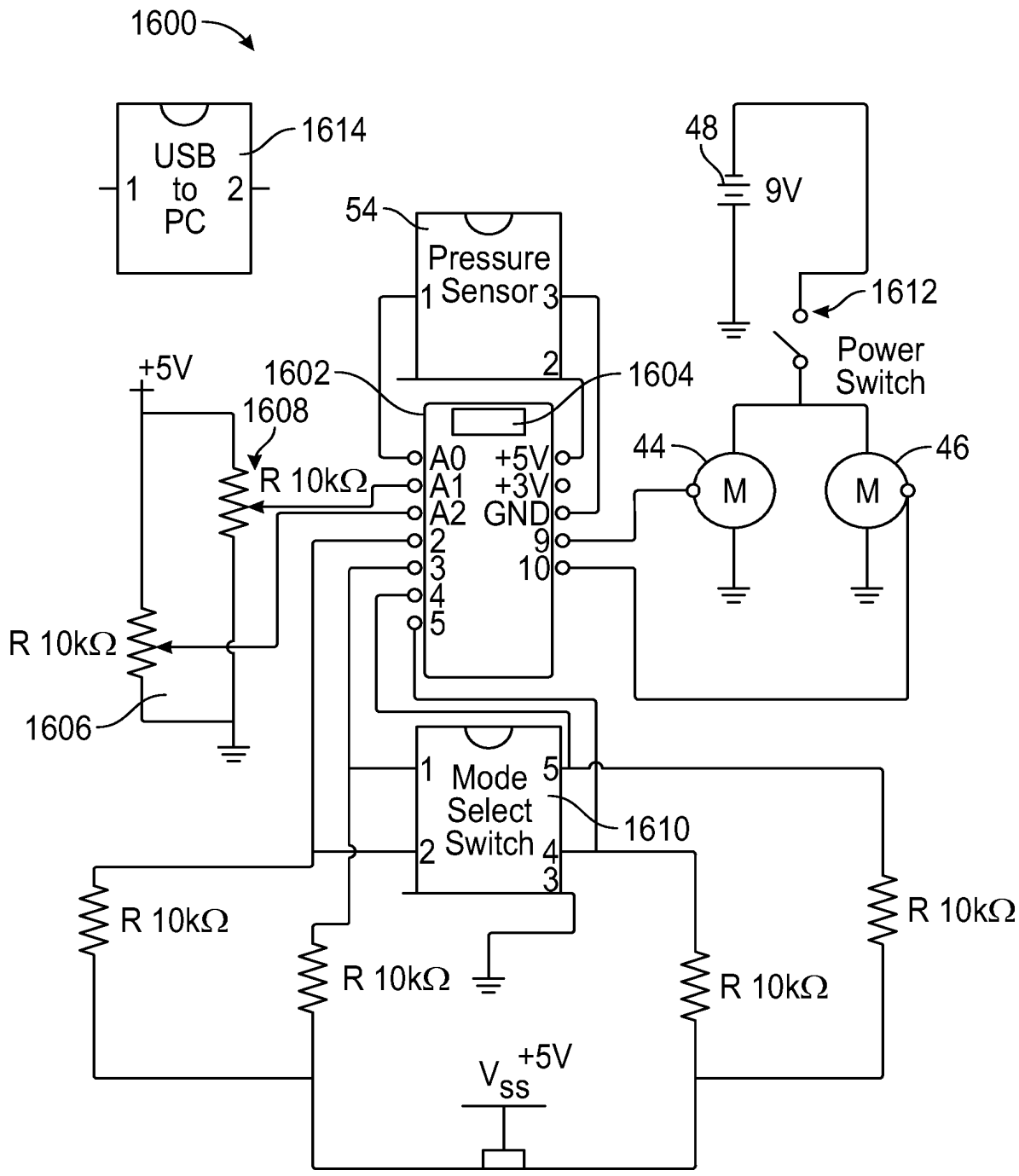

1600
USB
1 to 2
PC
1614
54
Pressure
1 Sensor 3
2
48
9V
1612
Power
Switch
+5V
1602
1604
1608
A0 +5V
A1 +3V
A2 GND
2
3
4
5
9
10
R 10kΩ
44
46
M
M
R 10kΩ
1606
1 Mode 5
Select
2 Switch 4
3
1610
R 10kΩ
R 10kΩ
R 10kΩ
R 10kΩ
+5V
Vss

FIG. 25

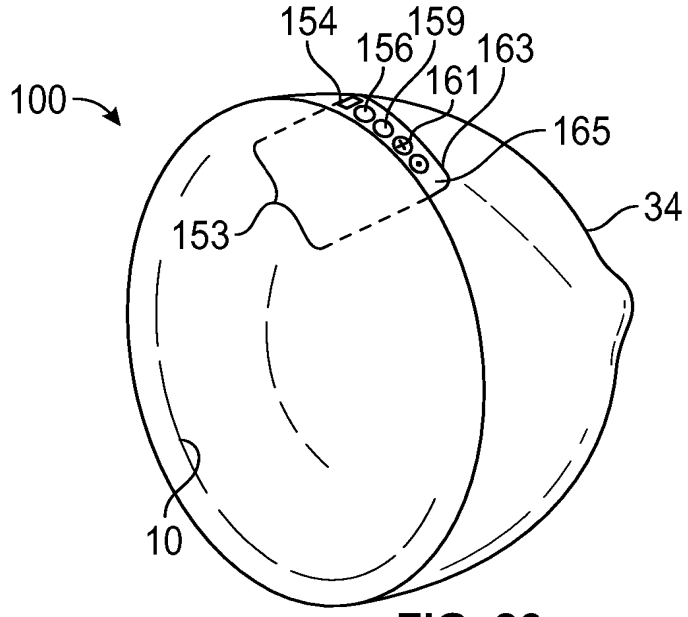

154
156
159
161
163
165
100
153
34
10

FIG. 26

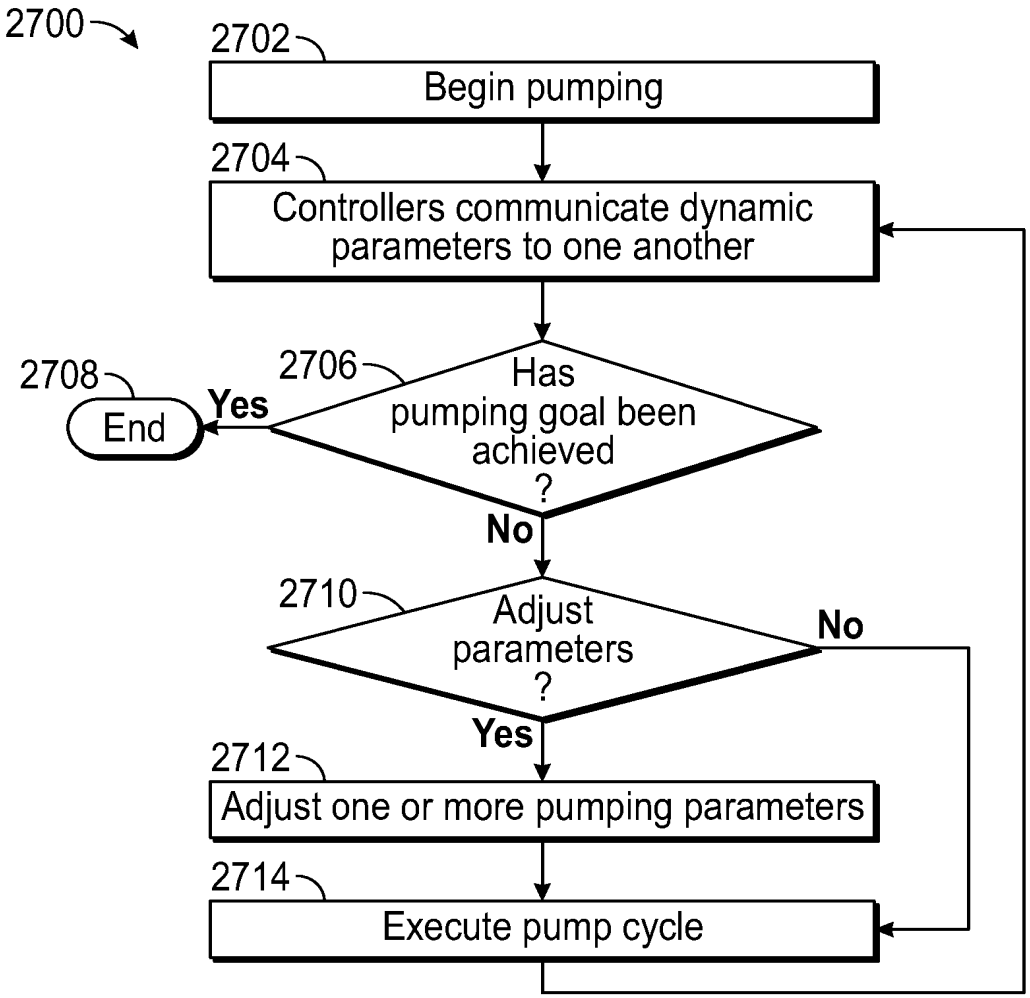

2700
2702
Begin pumping
2704
Controllers communicate dynamic parameters to one another
2706
Has pumping goal been achieved ?
Yes
2708
End
No
2710
Adjust parameters ?
No
Yes
2712
Adjust one or more pumping parameters
2714
Execute pump cycle

FIG. 27

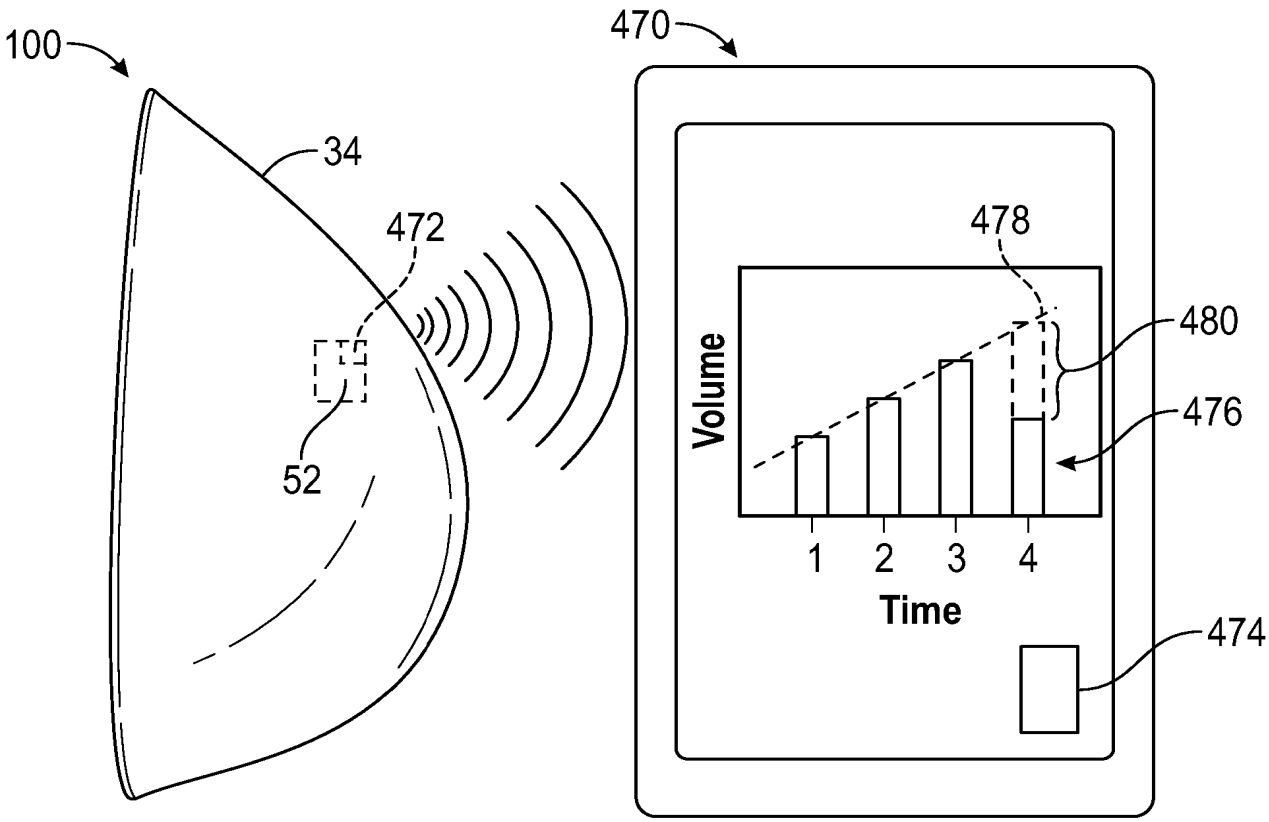


FIG. 28

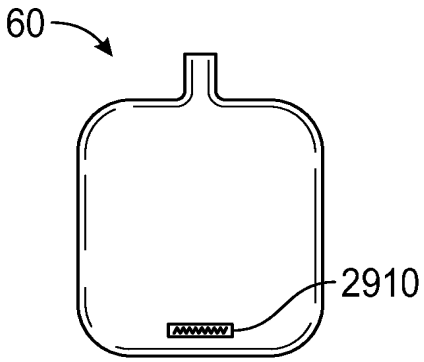


FIG. 29

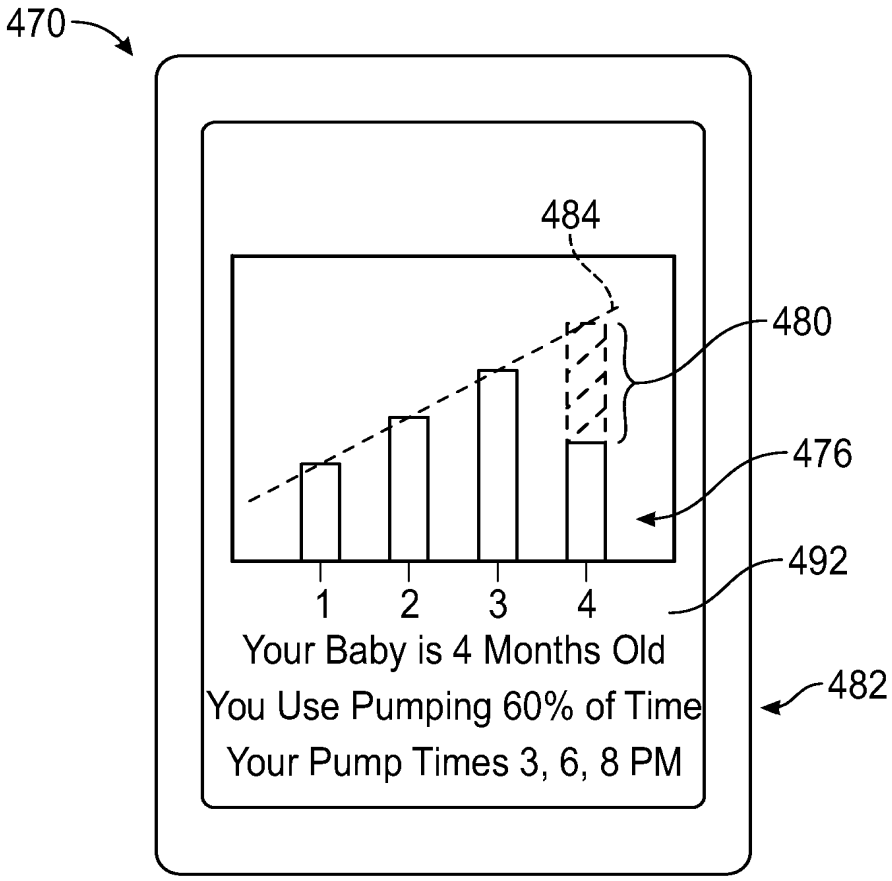

470
484
480
476
492
1
2
3
4
Your Baby is 4 Months Old
You Use Pumping 60% of Time
Your Pump Times 3, 6, 8 PM
482

FIG. 30

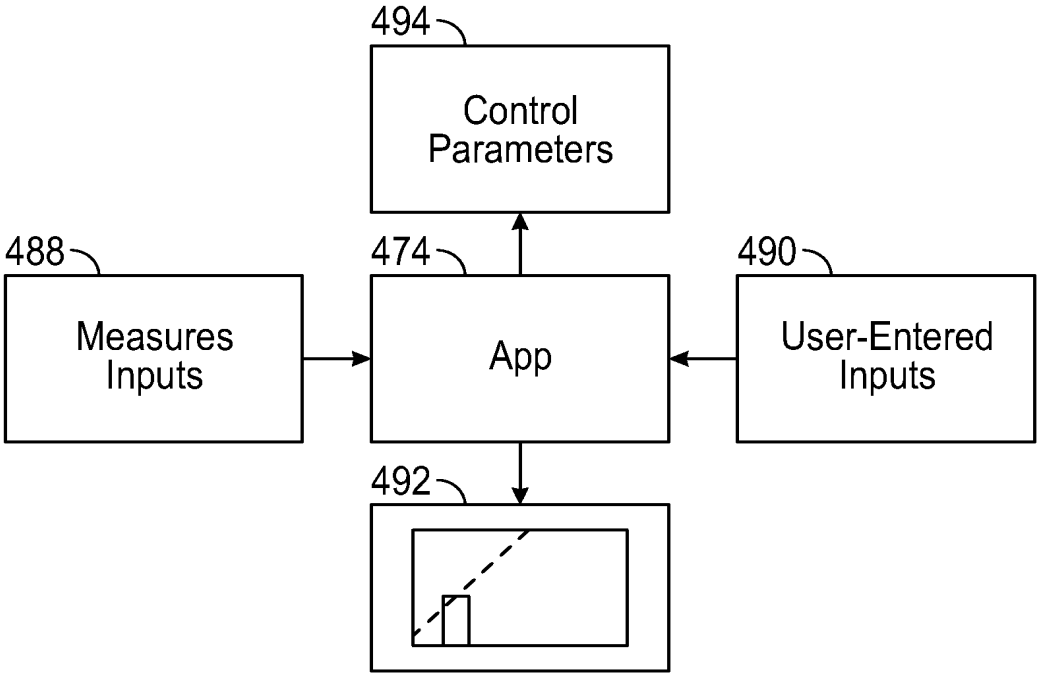

494
Control Parameters
488
Measures Inputs
474
App
490
User-Entered Inputs
492

FIG. 31

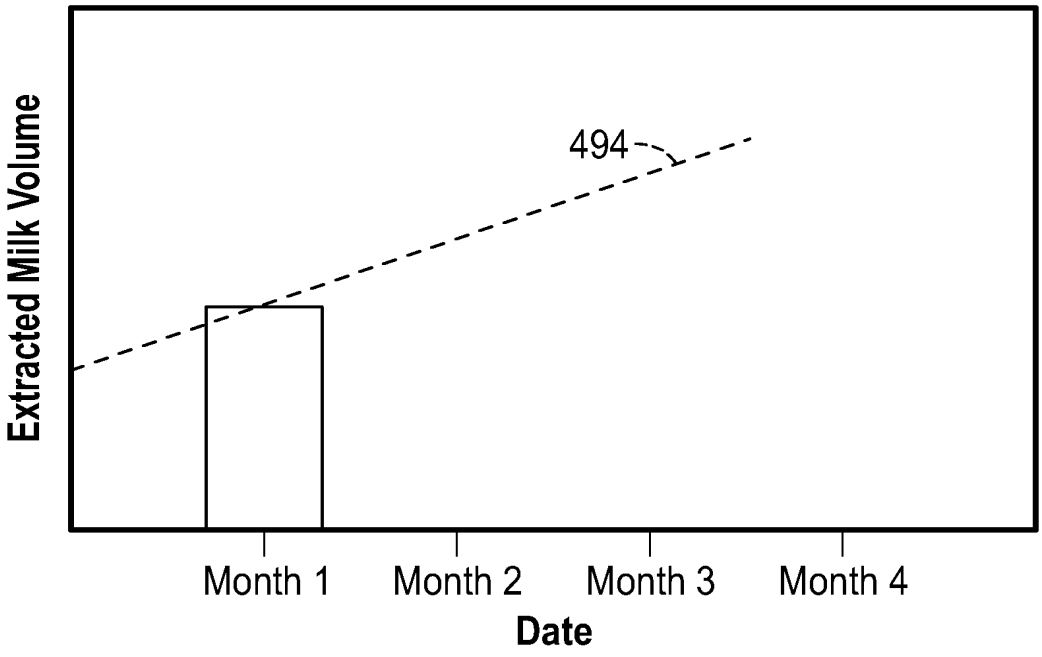

Extracted Milk Volume
494
Month 1
Month 2
Month 3
Month 4
Date

FIG. 32

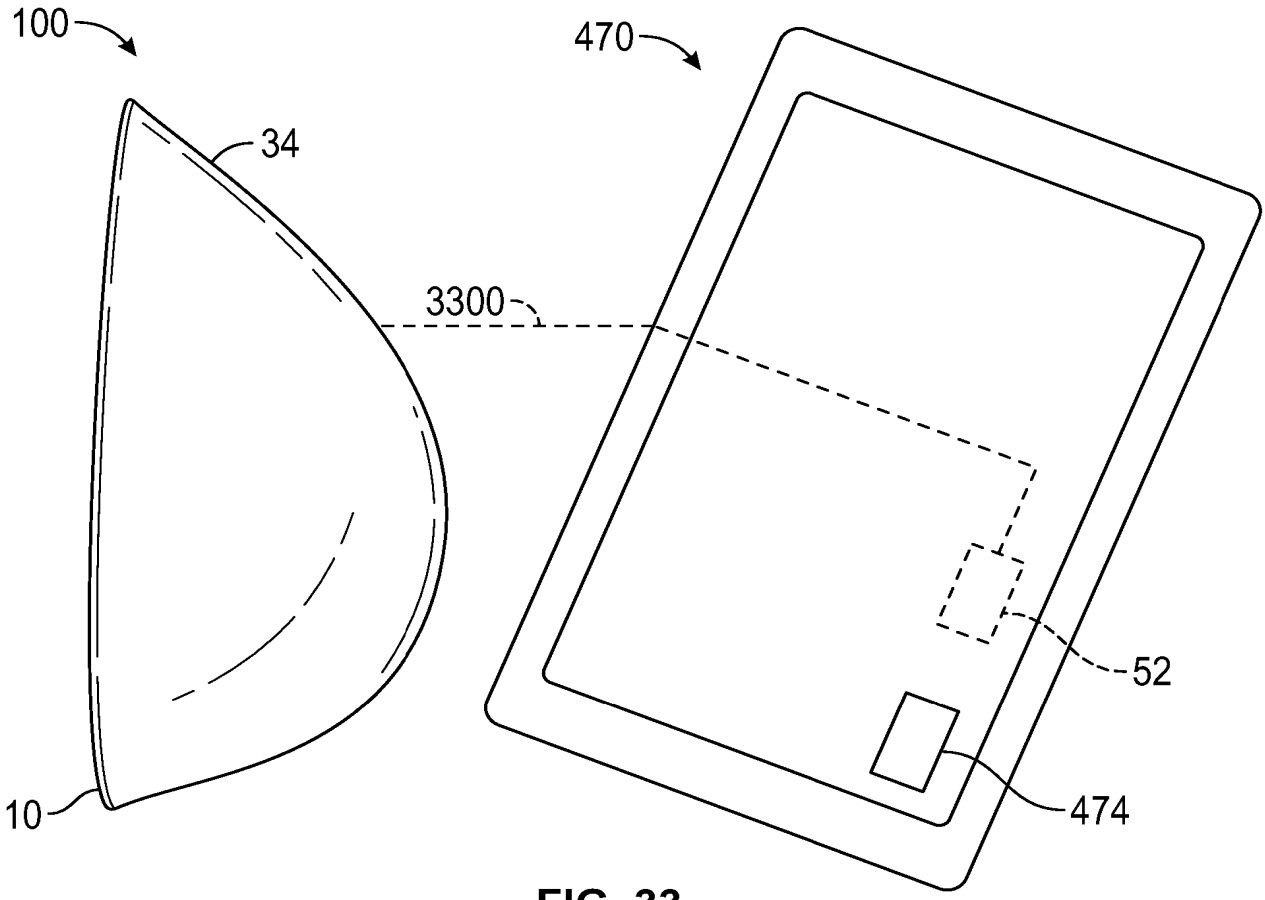

100
470
34
3300
52
474
10

FIG. 33

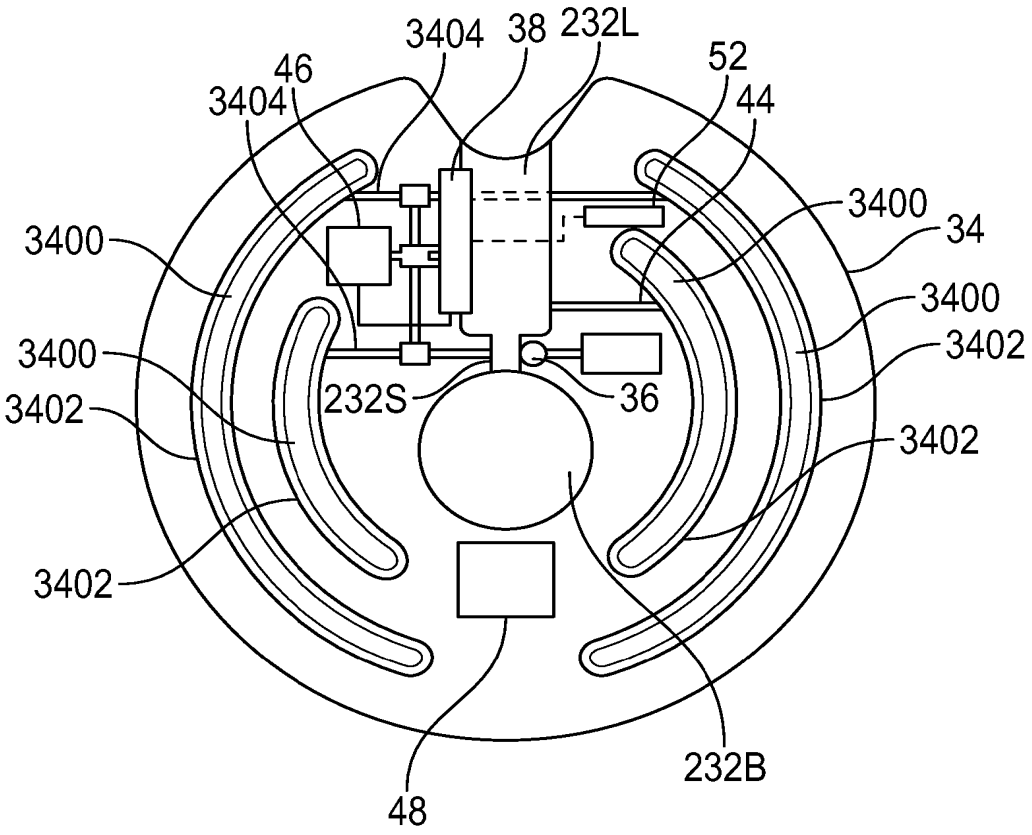

3404
38
232L
46
3404
52
44
3400
34
3400
3400
3400
3402
3402
232S
36
3402
3402
232B
48

FIG. 34

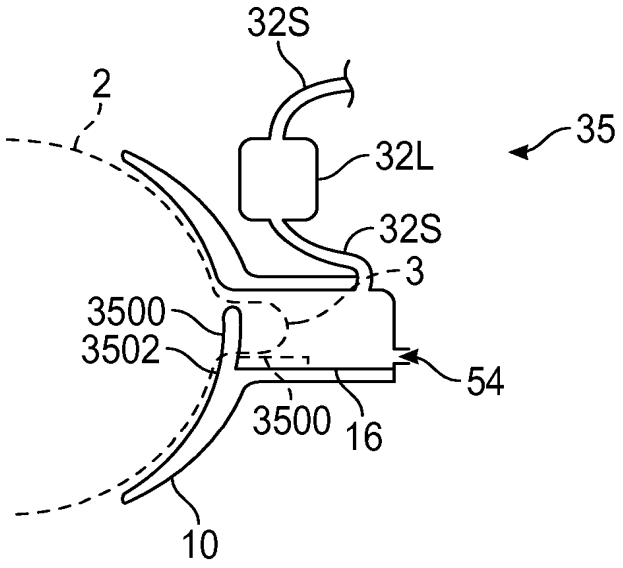

32S
2
35
32L
32S
3
3500
3502
54
3500
16
10

FIG. 35

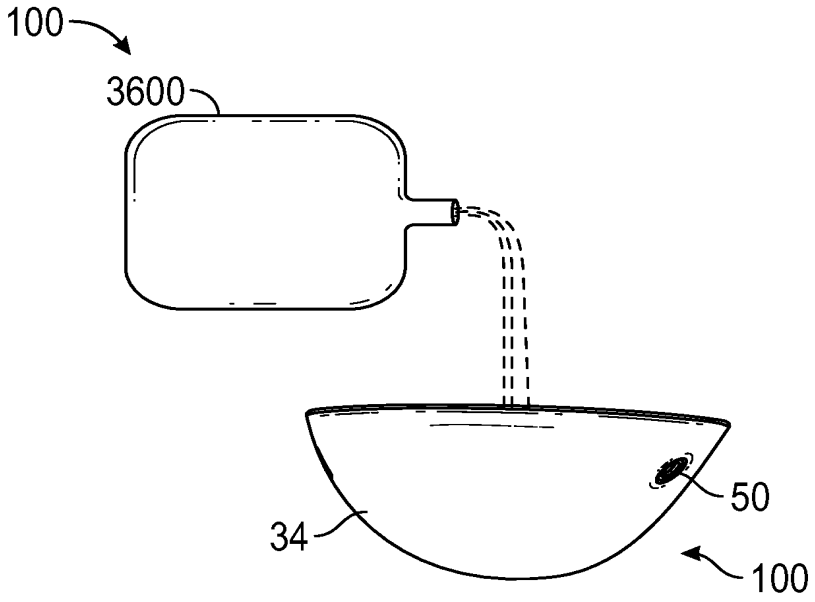


FIG. 36

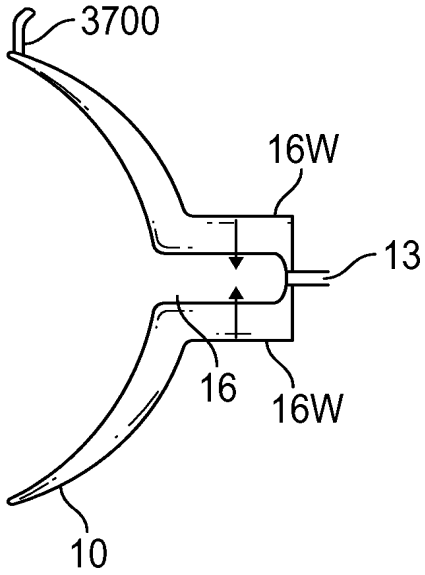


FIG. 37

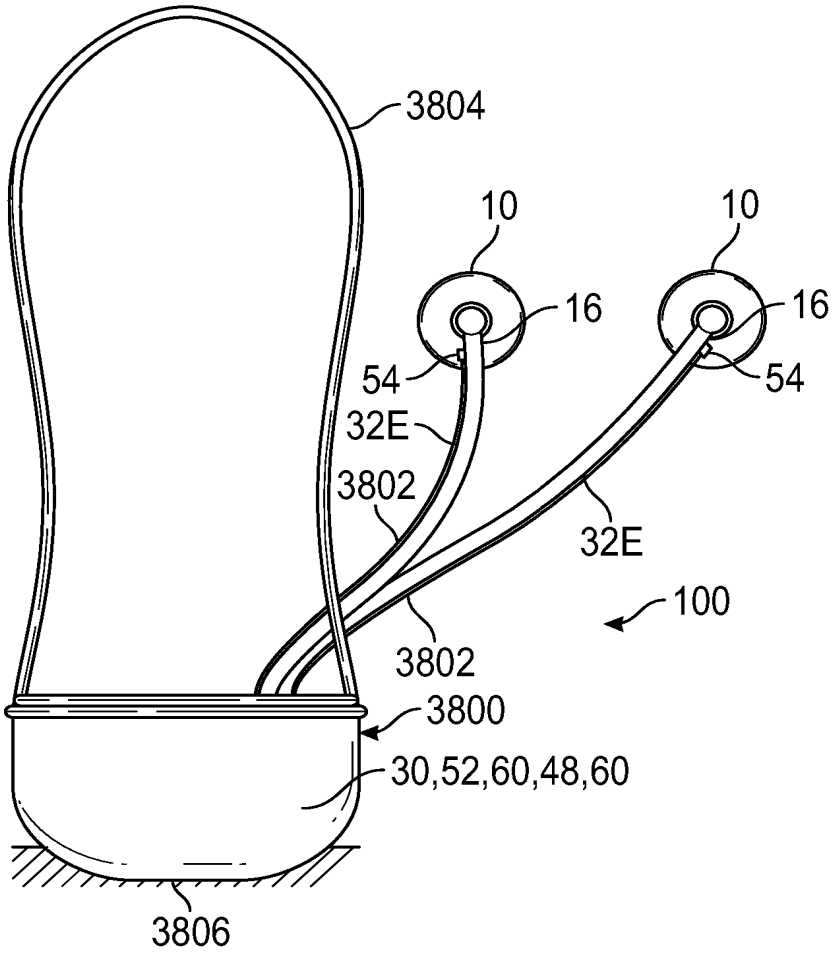

3804
10
10
16
16
54
54
32E
3802
32E
100
3802
3800
30,52,60,48,60
3806

FIG. 38

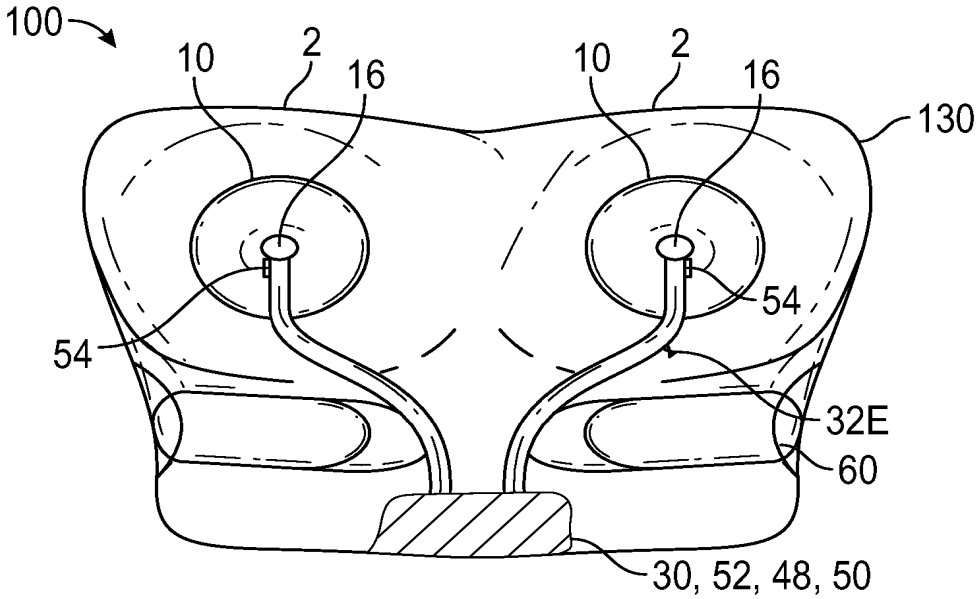

100
10
2
16
10
2
16
130
54
54
32E
60
30, 52, 48, 50

FIG. 39

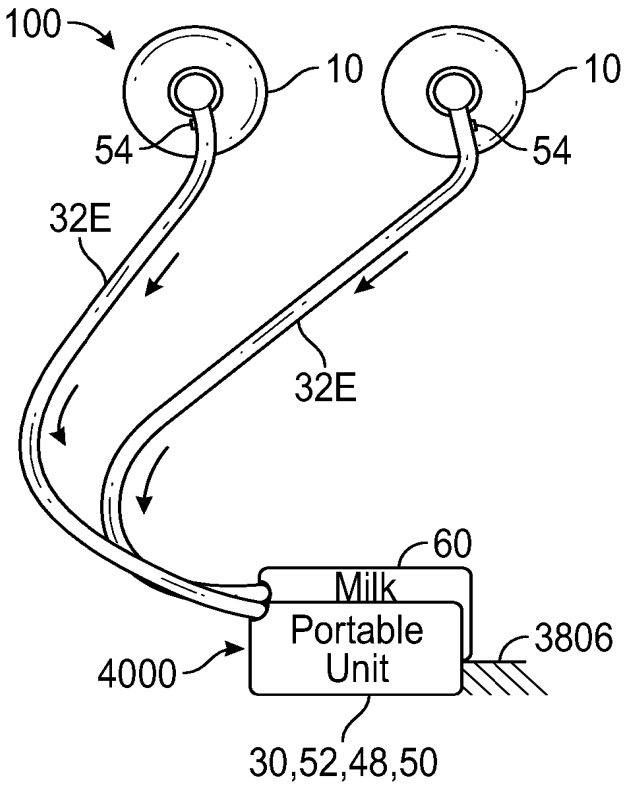

100
10
10
54
54
32E
32E
60
Milk
Portable
Unit
3806
4000
30,52,48,50

FIG. 40

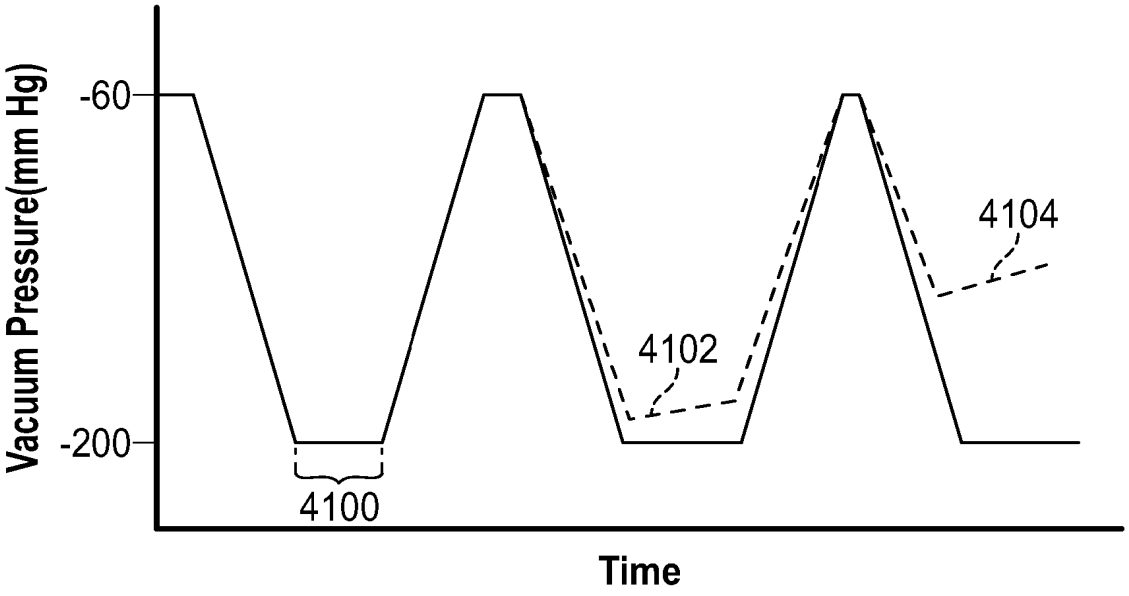

Vacuum Pressure(mm Hg)
-60
-200
4100
4102
4104
Time

FIG. 41

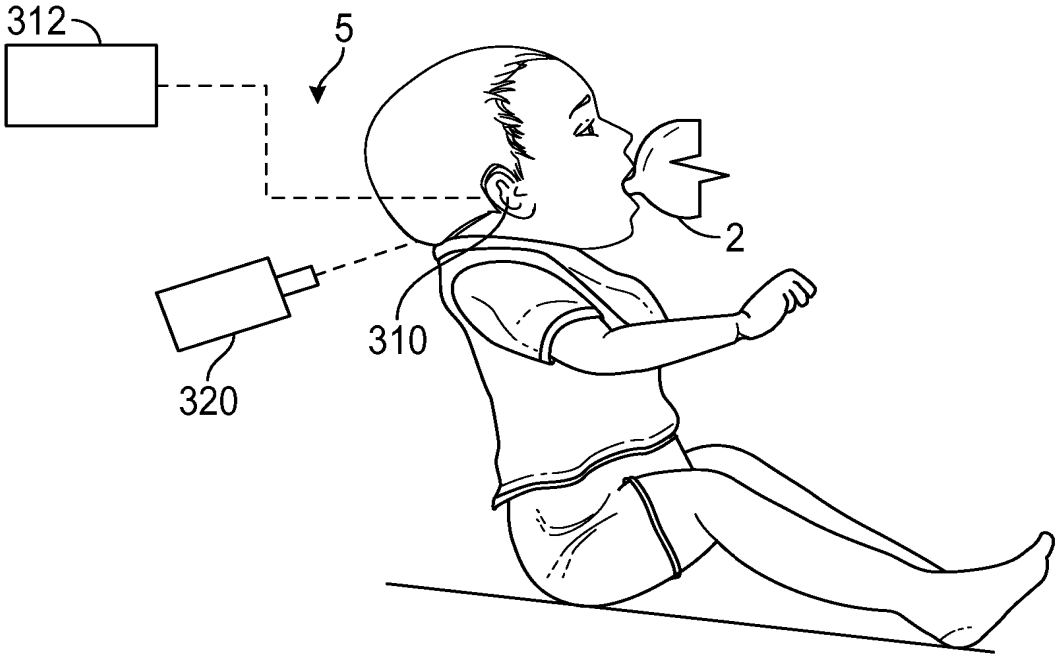

312
5
2
310
320

FIG. 42

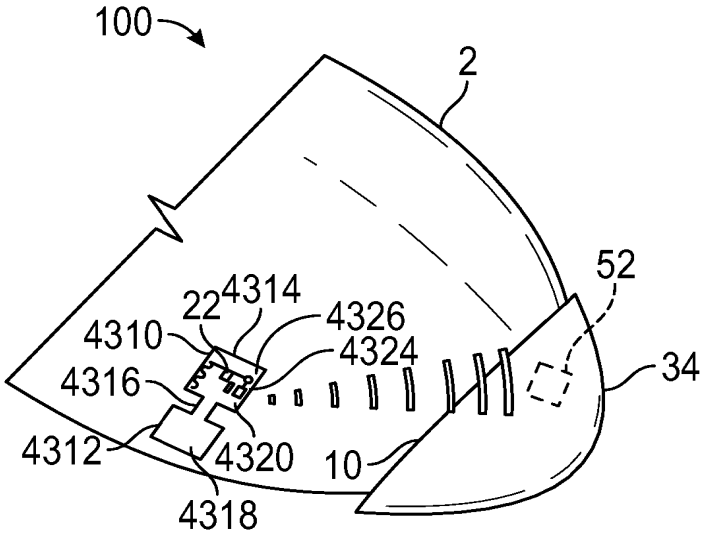

100
2
52
22
4314
4326
4310
4324
34
4316
4312
4320
10
4318

FIG. 43

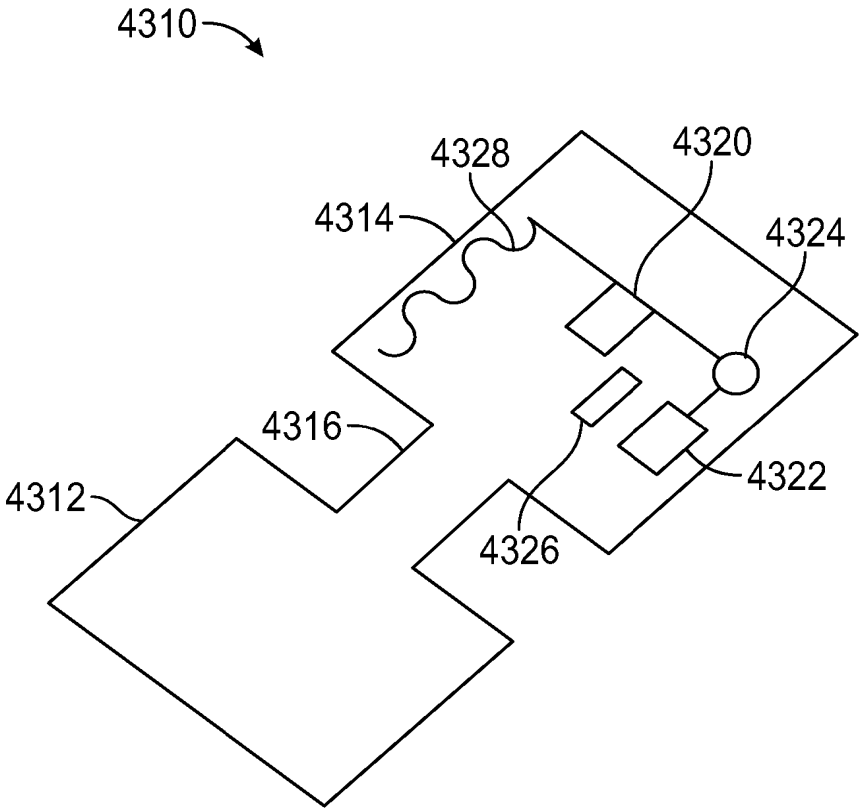


FIG. 44

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2015/041277

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Espacenet, USPTO, PatSearch, CIPO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5954690 A (MEDELA HOLDING AG) 21.09.1999, abstract, claims 1, 7-8, 10-12, col. 1 lines 57-60, col. 2-3, fig. 1	1-2 3, 11-13
Y	US 2009/0254028 A1 (LYNDON BRITTNER) 08.10.2009, claims 1, 5, paragraphs [0022], [0030], fig. 1-2	11-13
Y	US 4263912 A (FRANK H. ADAMS) 28.04.1981, abstract, col. 3 lines 5-14, 20-68, col. 10 lines 3-13, fig. 6-8	3, 13

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 October 2015 (21.10.2015)	22 October 2015 (22.10.2015)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer E. Nosova Telephone No. (495) 531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041277

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 14-30
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Patentschrift**

(11) **DE 3311982 C2**

(51) Int. Cl. 4: G01F 23/22

(21) Aktenzeichen: P 33 11 982.1-52
(22) Anmeldetag: 30. 3. 83
(43) Offenlegungstag: 13. 10. 83
(45) Veröffentlichungstag der Patenterteilung: 18. 12. 86

Innerhalb von 3 Monaten nach Veröffentlichung der Erteilung kann Einspruch erhoben werden

(30) Unionspriorität: (32) (33) (31)
01.04.82 CH 2014-82

(73) Patentinhaber:
Battelle Memorial Institute, Carouge, Genf/Genève, CH

(74) Vertreter:
Müller-Börner, R., Dipl.-Ing., 1000 Berlin; Wey, H., Dipl.-Ing., Pat.-Anw., 8000 München

(72) Erfinder:
Prost, Jean-Louis, Geneva, CH; Gross, Daniel, Carouge, CH

(56) Im Prüfungsverfahren entgegengehaltene Druckschriften nach § 44 PatG:
DE-OS 30 26 899
DE-OS 30 23 534

(54) Verfahren und Vorrichtung zur Volumenbestimmung

DE 3311982 C2

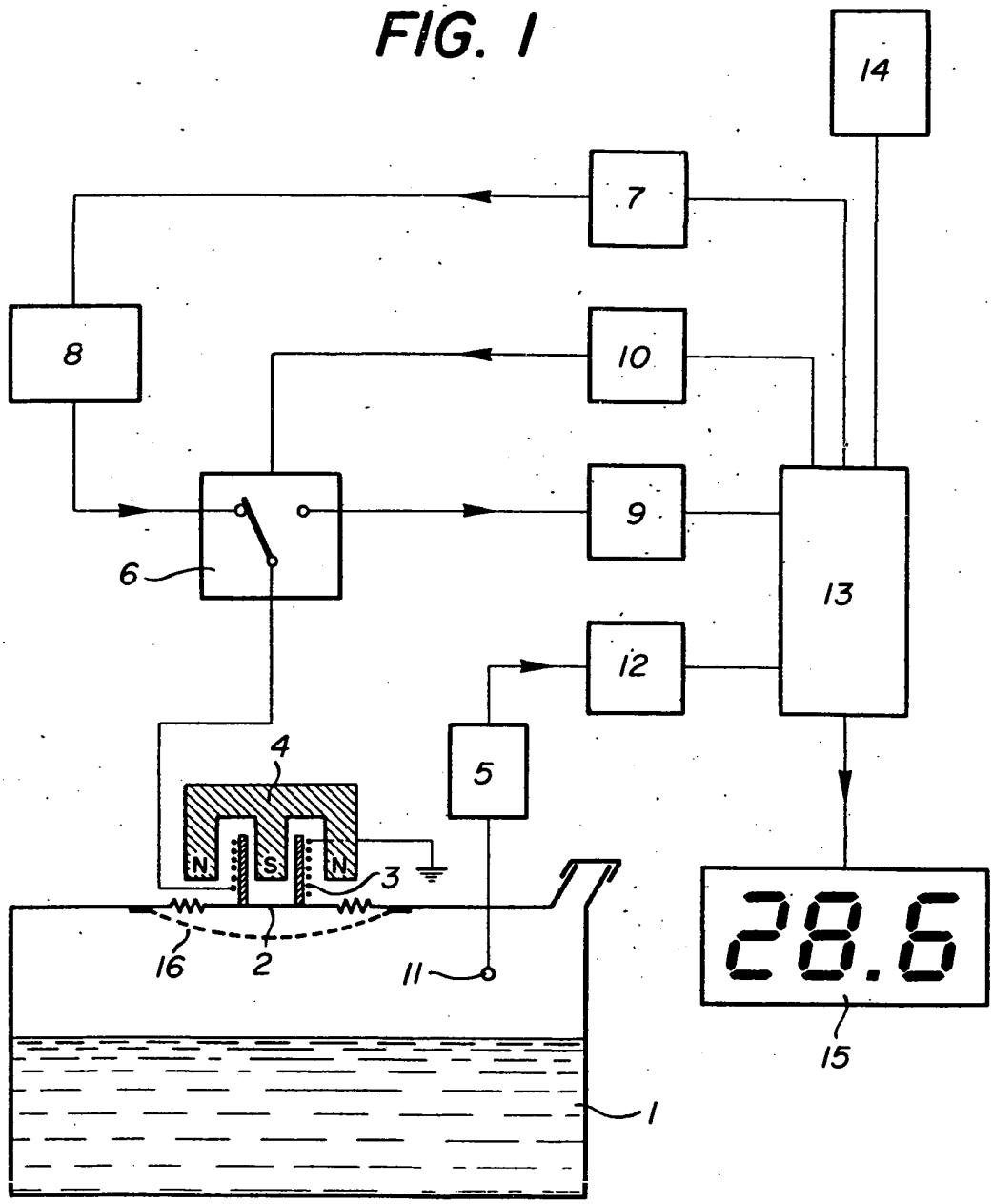
DE 3311982 C2

BUNDESDRUCKEREI 10. 86 608 151/288 70

ZEICHNUNGEN BLATT 1

Nummer: 33 11 982
Int. Cl.⁴: G 01 F 23/22
Veröffentlichungstag: 18. Dezember 1986

FIG. 1



Patentansprüche:

1. Verfahren zur Bestimmung des Volumens einer in einem geschlossenen Behälter von bekanntem Fassungsvermögen enthaltenen Flüssigkeit durch Erzeugung einer kurzzeitigen Veränderung des Gasvolumens über der Flüssigkeit in diesem Behälter, dadurch gekennzeichnet, daß

a) nach Erzeugung einer periodischen Veränderung des oberhalb der Flüssigkeit vorhandenen Gasvolumens die Druckschwingung mit einer Eigenfrequenz als Funktion des Gasvolumens erfaßt wird;
b) die Schwingung dieses Druckes in ein Signal umgewandelt wird, dessen Amplitude sich in Abhängigkeit von der Frequenz dieser Schwingung verändert;
c) die Periode dieses Signals festgestellt wird, um das Gasvolumen in Abhängigkeit von dieser Periode zu bestimmen;
d) der Unterschied zwischen dem Gasvolumen und dem bekannten Volumen des Behälters als Maß für das in dem Behälter vorhandene Flüssigkeitsvolumen dient.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Periode des festgestellten Signals mittels eines charakteristischen Temperaturfaktors korrigiert wird.

3. Vorrichtung zur Durchführung des Verfahrens nach Anspruch 1, mit einer Membran (2) nahe dem Gasvolumen und einer elektromotorischen Einrichtung (3, 4) zum periodischen Anlegen eines Impulses an diese Membran, um sie aus ihrer Ruhestellung zu entfernen, dadurch gekennzeichnet, daß ein Detektor (9) und eine Steuereinheit (13) zum Messen der Periode des Antwortsignals der Eigenschwingungen der Membran und zur Bestimmung der in dem Behälter (1) in Abhängigkeit von dieser Periode enthaltenen entsprechenden Gas- und Flüssigkeitsvolumina vorgesehen sind.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, daß

a) die Vorrichtung einen Generator mit permanentem Magnetfeld (4) und einen Anker (3) aufweist, der die Flußlinien dieses Magnetfeldes schneidet;
b) das eine (4) dieser beiden Teile stationär und das andere (3) mit der Membran (2) formschlüssig verbunden ist und
c) der Anker (3) wahlweise und alternativ mit einer Quelle Erregerstrom (7) und mit einem Detektor (9) für das alternative Spannungssignal verbunden ist, das infolge der freien Schwingungen der Membran erzeugt wird.

5. Vorrichtung nach Anspruch 3, gekennzeichnet durch ein in dem Behälter (1) angeordnetes Gitter (16), das mit dem Teil der Wand dieses Behälters verbunden ist, der sich zum Umfang der Membran (2) hin erstreckt, wobei die Maschengröße des Gitters kleiner an die Größe der Tröpfchen der in dem Behälter enthaltenen Flüssigkeit ist, die sich infolge der Bewegung der freien Oberfläche der Flüssigkeit bilden können.

Die vorliegende Erfindung bezieht sich auf ein Verfahren zur Bestimmung des Volumens entsprechend der im Gattungsbegriff des Hauptanspruchs angegebenen Art sowie auf eine zur Durchführung dieses Verfahrens bestimmte Vorrichtung.

Im allgemeinen wird das Volumen in einem Behälter durch seinen Flüssigkeitsspiegel bestimmt. In den Treibstoffbehältern eines Fahrzeugs beispielsweise hängt die Messung des Flüssigkeitsspiegels weitgehend von der Schrägstellung des Fahrzeugs, den Beschleunigungen und Erschütterungen ab. Der in diesem Fall verwendete Meßfühler ist ein Potentiometer, dessen Widerstand sich entsprechend der Stellung eines in den Behälter eingetauchten Tauchkolbens verändert. Aus diesem Grunde geben die auf dem Armaturenbrettern der Automobile montierten Kraftstoffanzeiger nur eine grobe Analoganzeige des Flüssigkeitsvolumens, und diese Anzeige verändert sich ständig entsprechend der Schrägstellung des Fahrzeugs und den Beschleunigungen, denen es unterliegen kann.

Aus dem von der Society of Automotive Engineers, Inc. im Jahre 1980 herausgegebenen Bericht »Capacitance Fuel Measurement for Automotive Applications« von John D. Freeman sind bereits verschiedene Lösungen bekanntgeworden, um diesem Nachteil abzuhelfen und die Genauigkeit der Messung zu erhöhen: Dabei können piezoelektrische, thermisch oder kapazitive Meßverfahren genannt werden. Dieses letztere Verfahren besteht darin, die Kapazität zwischen zwei parallelen Plattenelektroden zu messen, die senkrecht in dem Behälter angeordnet sind. Da der Treibstoff eine dielektrische Flüssigkeit ist, verändert sich die gemessene Kapazität entsprechend dem Flüssigkeitsspiegel. Die beiden nahe beieinander angeordneten Plattenelektroden haben weiterhin die Wirkung, die Bewegungen der Flüssigkeit abzuschwächen. Die dielektrische Konstante des Treibstoffs hängt aber von der Temperatur und der Qualität dieses Treibstoffs ab, die die Verwendung einer Bezugskapazität erfordern, die stets in den Treibstoff eingetaucht ist. Dies erhöht offensichtlich den Preis der Sonde und des elektronischen Schaltkreises. Diese Lösung wird seit vielen Jahren in der Flugzeugindustrie verwendet, ist aber für Autos zu kostenaufwendig. Auf jeden Fall ermöglichen diese verschiedenen Verfahren nur die Messung des Flüssigkeitsspiegels an einem Punkt ihrer Oberfläche.

Ein in Marine Week (Band 6, Nr. 11, 1979, Seiten 8 und 9) veröffentlichter Artikel, der sich auf die Messung des Flüssigkeitsspiegels in den chemischen Behältern bezieht, geht von Vorrichtungen aus, die gegenüber dem durch die Flüssigkeitssäule ausgeübten Druck und insbesondere gegenüber einem Magnetverstärker empfindlich sind, der mit einer schwingenden Leitung versehen und dessen Eigenfrequenz eine Funktion der Spannung ist, die ihrerseits von dem Druck der Flüssigkeit abhängt, die von der Höhe der Flüssigkeitssäule, der Dichte der Flüssigkeit und ihrer Temperatur abhängig ist. Eine solche den in einem gegebenen Punkt ausgeübten Druck durch einen Meßstab messende Vorrichtung ist aber ebenfalls von der Schrägstellung des Behälters abhängig, was genau den Nachteil darstellt, dem die vorliegende Erfindung abhelfen will.

In der japanischen Anmeldung 1 46 676/79 ist schon vorgeschlagen worden, das Gasvolumen eines Behälters durch akustische Mittel zu messen, indem der offene Behälter in dem Feld eines Schalldrucks von bestimmter Frequenz angeordnet und der Druck und die Frequenz nahe der Öffnung des Behälters festgestellt wurden, die

eine Funktion des Gasvolumens sind. Eine solche Lösung ist jedoch auf den Fall offener Behälter beschränkt.

Ein Meßsystem für Brennstoff, das im Prinzip mit dem gattungsgemäßen Verfahren übereinstimmt, ist aus Figur 2 der bereits erwähnten Literaturstelle »Capacitance Fuel Measurement for Automotive Applications« zu entnehmen.

Diese Lösung bietet verschiedene Quellen für Ungenauigkeiten, insbesondere die Druckveränderungen in dem Rohrleitungssystem, der Dampfdruck in dem Behälter, die Instabilität der kalibrierten Öffnung, und impliziert im übrigen eine Einrichtung, die aus zahlreichen Elementen, Rohren, Ventilen, kalibrierter Öffnung, besteht, die den Preis erhöhen und die Betriebssicherheit verringern.

Aufgabe der vorliegenden Erfindung ist es, ein Verfahren und eine Vorrichtung zu schaffen, die es ermöglichen, auch das Flüssigkeitsvolumen geschlossener Behälter zu messen.

Zur Lösung dieser Aufgabe dienen bei dem gattungsgemäßen Verfahren erfindungsgemäß die im Kennzeichen des Hauptanspruchs vorgesehenen Verfahrensschritte.

Aus den DE-OS 30 23 534 und 30 26 899 sind Flüssigkeitsstandanzeiger bekannt mit einem Ultraschallsystem, das es ermöglicht, durch Wellenreflektionen gegen die Oberfläche einer Flüssigkeit eine Entfernung zu bestimmen. Solange die Oberfläche der Flüssigkeit unbeweglich ist, kann diese Entfernung charakteristisch für das Flüssigkeitsvolumen in einem Behälter von bekannter Form und Größe sein. Dies ist aber schon nicht mehr der Fall in einem Kraftwagentank, wo die Entfernung zwischen einem Ultraschallsender und der Flüssigkeitsoberfläche um eine gleiches Volumen variieren kann. Dagegen ist bei der Erfindung, bei der die periodische Veränderung des Druckvolumens auf eine periodische Veränderung des Behältervolumens folgt, die Periode des Antwortsignals charakteristisch für das Gasvolumen sein, unabhängig von der Lage des Flüssigkeitsniveaus. Es wird also mit der Erfindung eine für das Gasvolumen charakteristische Größe gemessen und nicht der Abstand zwischen einem gegebenen Punkt und der Oberfläche der Flüssigkeit.

Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

Die Erfindung wird nachstehend anhand eines in der Zeichnung dargestellten Ausführungsbeispiels der Vorrichtung zur Durchführung des erfindungsgemäßen Verfahrens näher erläutert. Es zeigt

Fig. 1 ein Blockschaltbild dieser Vorrichtung,

Fig. 2 bis 4 erläuternde Kurvenbilder.

Das Blockschaltbild der Fig. 1 stellt einen geschlossenen Behälter dar, beispielsweise einen Treibstofftank 1 eines Kraftfahrzeugs, bei dem die obere Wand mit einer Membran 2 verbunden ist, die einer Lautsprechermembran vergleichbar und formschlüssig mit einem schwingenden Anker verbunden ist, der aus einer Spule 3 besteht, die sich außerhalb des Tanks erstreckt und axial in einen vertieften Permanentmagneten 4 eingreift und die mit einem bistabilen Umschalter 6 verbunden ist. Vorteilhaft besteht die Membran 2 aus einem nichtporösen Material, so daß ihre Masse sich unter Einwirkung der Absorption der Flüssigkeitsdämpfe nicht verändert. Es wird außerdem betont, daß der Ausdruck »Behälter« die Gesamtheit des geschlossenen Volumens umfaßt, wodurch auch die Auffüllleitung oder jede andere Leitung mit umfaßt wird, die unmittelbar an den Behälter selbst angeschlossen ist. Der bistabile Umschalter

6 verbindet wahlweise die Spule 3 einerseits mit einem Impulserregungsgenerator 7 mittels eines Verstärkers 8 und andererseits mit einem Detektor 9 für den Durchlauf der Spannung an den Anschlußklemmen der Erregungsspule 3 auf Null. Dieser bistabile Umschalter ist außerdem mit einem Umschaltmodul 10 verbunden, das den Übergang des Umschalters 6 von einer Stellung in die andere und umgekehrt steuert.

Eine Temperaturmeßsonde 11 taucht in das Reservoir 1 ein und ist mit einem Verstärker 5 und weiter mit einem Modul 12 verbunden, das als Grenzfläche zwischen dieser Sonde und einer Rechen- und Steuereinheit 13 dient, auf die auch die Informationen des Detektors 9 übertragen werden. Diese Rechen- und Steuereinheit 13 ist außerdem mit einem Speicher 14 verbunden, und ihre Ausgänge sind an den Impulserregungsgenerator 7, an das Umschaltmodul 10 und an ein Anzeigeelement 15 angeschlossen.

Vorteilhaft kann die Membran 2 vor den Flüssigkeitsspritzern mittels eines Gitters 16 geschützt werden, bei dem die Maschengröße feiner ist als die Form der Tröpfchen, die die Flüssigkeit infolge der Bewegung ihrer Oberfläche erzeugen kann, wobei die Größe dieser Tröpfchen von der Oberflächenspannung der in Frage stehenden Flüssigkeit abhängt.

Das Verfahren besteht darin, in die Spule 3 einen Impuls zu schicken, um schlagartig die Membran 2 aus ihrer Ruhestellung zu entfernen und so eine schnelle Veränderung des Gasvolumens in dem Behälter und damit eine Störung des Drucks in diesem Gasvolumen zu erzeugen. Dann verbindet der Umschalter die Spule 3 mit dem Detektor 9. Die in dem Gasvolumen des Behälters 1 erzeugte Druckstörung schwächt sich durch Schwingen mit einer Eigenfrequenz ab, die eine Funktion des Gasvolumens in dem Behälter ist. Das Verfahren wird dann in regelmäßigen Abständen, beispielsweise alle Sekunden, wiederholt.

Das Kurvenbild der Fig. 2 zeigt das auf die in dem Behälter 1 eingeleitete Veränderung des Volumens registrierte Signal. Die Amplitude dieses Signals liegt bei 1,5 V ohne jegliche Verstärkung. Sie wurde mit einem Lautsprecher von 11 cm Durchmesser erhalten, der der Höhe eines Metallbehälters von 31 cm Durchmesser bei 36 cm Höhe angepaßt war. Die in die Spule gesandten Erregungsstromimpulse liegen bei 0,5 A, was erhöht erscheinen mag, aber der Widerstand der Spule beträgt nur 2,9 Ohm, so daß die Kurzzeitleistung unter 0,75 W liegt und die mittlere Leistung annähernd 0,1 W beträgt. Die obere Spur entspricht einem Flüssigkeitsvolumen in dem Behälter von 18 Litern, die untere Spur einem Volumen von 4 Litern, der Abstand ΔT entspricht dem Unterschied der Perioden zwischen zwei Signalen.

Das Kurvenbild der Fig. 3 zeigt die Periode des Antwortsignals der Druck-Eigenschwingungen, die entsprechend dem Grad der Füllung des oben erwähnten Metallbehälters in dem Gasvolumen erzeugt werden. Auf diesem Kurvenbild, dessen Abszissenmaßstab dem Volumen in Litern entspricht und dessen Ordinatenmaßstab der Periode des Signals in ms entspricht, stellt man fest, daß dieses Signal tatsächlich eine nicht lineare Funktion des Gasvolumens ist. Man sieht, daß die Dauer der Periode sich langsam bis auf etwa zwei Drittel des Flüssigkeitsvolumens verringert und ruckartig absinkt, wenn der Abstand zwischen der Membran 2 und der Flüssigkeitsoberfläche gering wird.

Da die Schallgeschwindigkeit eine Funktion der Temperatur und des mittleren Molekulargewichts der gasförmigen Mischung bei einer gesättigten Atmosphäre

und einer gegebenen Flüssigkeit ist, ist das Molekulargewicht allein eine Funktion der Temperatur. Eine Messung der Temperatur erlaubt also eine Bestimmung der vollständigen Korrektur der Schallgeschwindigkeit. Ausgehend von diesem Ergebnis und der Messung der Schwingungsfrequenz kann man das Gasvolumen also berechnen und davon das Flüssigkeitsvolumen abziehen.

Es ist festzustellen, daß je leichter die Membran ist, einen großen Durchmesser hat und einer schwachen Rückholkraft unterliegt, umso größer ist die Empfindlichkeit gegenüber dem Füllungsgrad des Behälters, und umso unabhängiger ist die Messung von Störungen an der Flüssigkeitsoberfläche.

Das Kurvenbild der Fig. 4 zeigt den Einfluß der Schrägstellung des Behälters gemessen über vier Perioden des Antwortsignals. Man stellt fest, daß dieser Einfluß im Inneren einer Gabel von ± 1% bei einer Schräge zwischen 0° und 20° liegt, was im ganzen annehmbar ist.

Es ist für einen Fachmann offensichtlich, daß die Membran **2** durch andere Mittel als die nur beispielhaft beschriebenen betätigt werden kann. So ist es möglich, alle auf Lautsprecher anwendbaren Techniken zu verwenden wie piezoelektrische Wirkung oder elektrostatische Kräfte in einem Kondensatorsystem, dessen Membran **2** einen beweglichen Anker darstellen würde, wobei die Feststellung der Schwingungen dieser Membran **2** dank der konstanten Polarisation der Anker dieses Kondensatorsystems verwirklicht wird.

Einer der Vorteile der beschriebenen Vorrichtung liegt in der Tatsache, daß der Druckveränderungsgenerator und der Detektor von den gleichen Organen gebildet werden, was die Anzahl von Organen und damit den Herstellungspreis dieser Vorrichtung verringert. Diese Verringerung der Anzahl der Organe bezieht sich vor allem auf mechanische Organe, die im allgemeinen teuer und am anfälligsten gegen Zerstörung und Abnutzung sind. Außerdem ist die Montage mechanischer Organe in bezug auf Arbeitskräfte teuer. Die beschriebene Lösung ist in ihrer Konzeption daher eine gute Antwort auf die Zwänge, die durch die Automobilindustrie auferlegt werden, wenn es sich um einen Treibstofftank für ein Kraftfahrzeug handelt.

Natürlich ist die Erfindung auch anwendbar, um die Flüssigkeitsvolumen zu messen, die sich in irgendeinem beliebigen geschlossenen Behälter für irgendeinen Fahrzeugtyp befinden. Sie ist auch anwendbar zum Messen des Flüssigkeitsvolumens, das in festen Behältern enthalten ist; ihr wesentlicher Vorteil liegt aber in ihrer geringen Empfindlichkeit gegenüber Bewegungen der Flüssigkeit in dem Behälter. Außerdem ist dieses Verfahren unempfindlich gegenüber der Art der Flüssigkeit und bietet sich nach Eichung für alle Formen von Behältern an.

Hierzu 2 Blatt Zeichnungen

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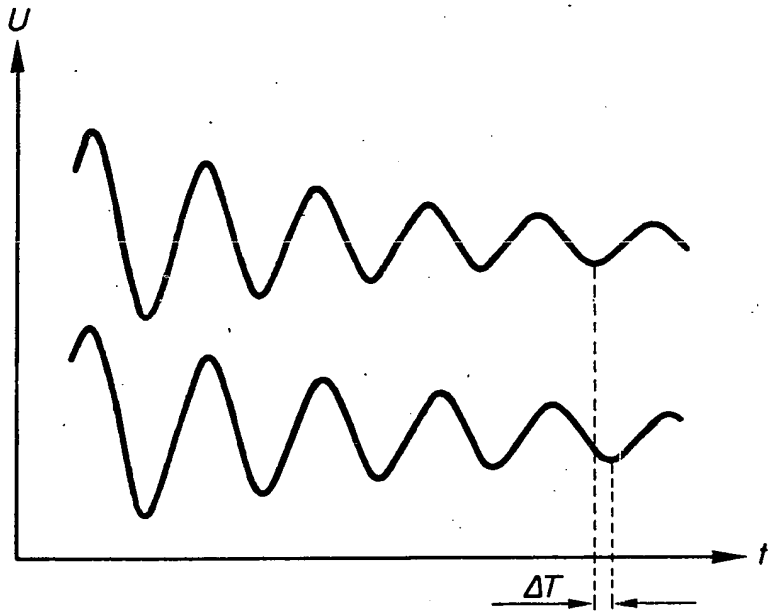


FIG. 2

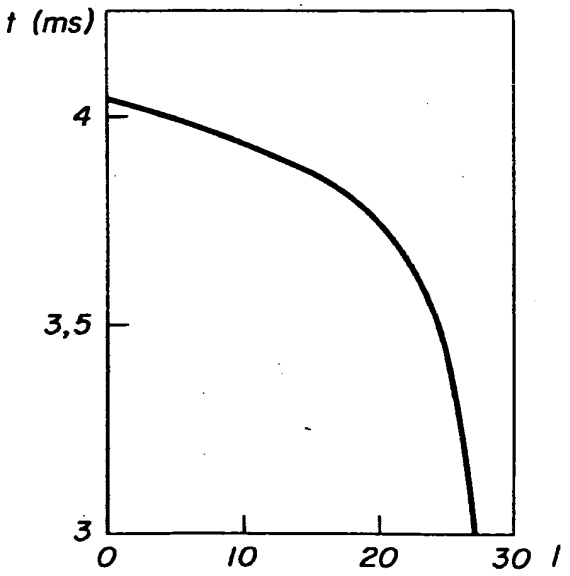


FIG. 3

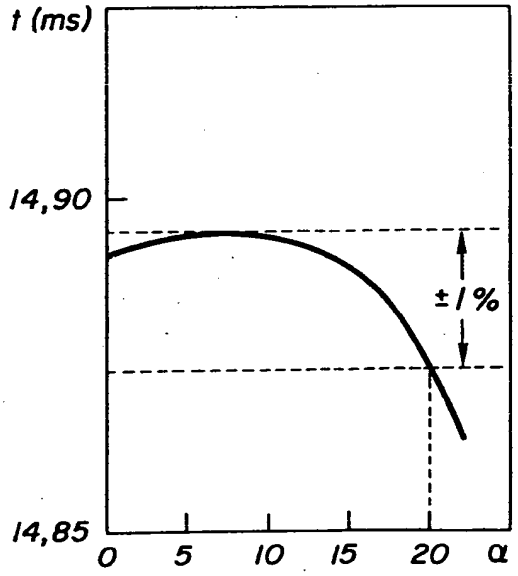


FIG. 4

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(56) Entgegenhaltungen:

DE	26 45 743 C2
DE	42 03 099 A1
DE	39 29 506 A1
DE	28 35 744 A1
DE	26 27 865 A1
DE-OS	21 52 675

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Verfahren zum Bestimmen des Füllstandes einer Flüssigkeitsmenge in einem abgeschlossenen Behälter

(57) Erzeugung einer Druckänderung im Behälter durch Unterdruck- oder Überdruckaufbau bis zu einem vorgegebenen Druckwert bei zur Umgebung abgeschlossenem Behälter und anschließendem Auswerten der Zeitkonstante, innerhalb derer ein Druckausgleich zur Atmosphäre hin erfolgt. Die Zeitkonstante ist proportional dem Füllstand im Behälter.

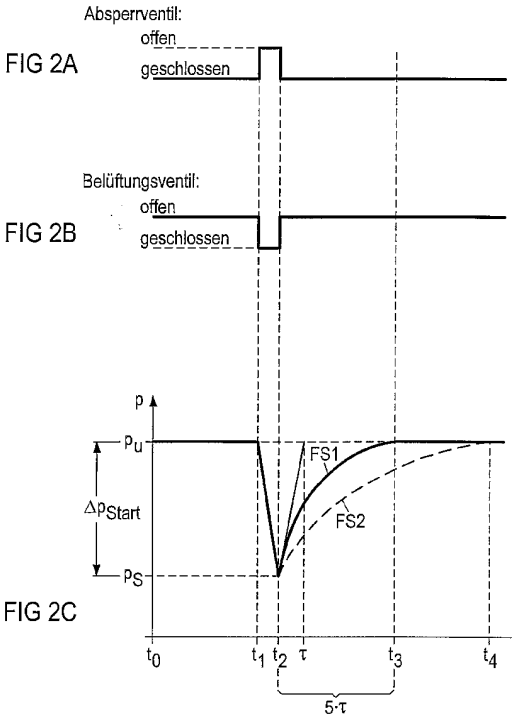


FIG 2A

FIG 2B

FIG 2C

DE 197 50 620 A 1

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Beschreibung

Die Erfindung betrifft ein Verfahren zum Bestimmen des Füllstandes einer Flüssigkeitsmenge in einem abgeschlossenen Behälter gemäß dem Oberbegriff des Patentanspruches 1.

Es sind bereits eine Vielzahl von Einrichtungen bekannt, mit deren Hilfe der Füllstand einer Flüssigkeit in einem abgeschlossenem Behälter, beispielsweise der Kraftstoffvorrat in einem Kraftfahrzeugtank bestimmt werden kann.

Neben dem Einsatz von mechanisch/elektrischen Einrichtungen, bei denen z. B. die Bewegung eines Schwimmers auf das Stellglied eines veränderlichen Widerstandes übertragen wird (DE 26 27 865 A) oder rein elektrischen Systemen, bei denen der Füllstand entweder mit einzelnen, in Reihe geschalteten und in die Flüssigkeit eintauchenden Widerstandselementen (DE 26 45 743 C2) mittels kapazitiven Mitteln (DE 28 35 744) oder mit Ultraschall (DE 21 52 675) gemessen wird, ist es auch möglich, Druckänderungen im Tank zur Bestimmung des Füllstandes heranziehen.

Aus der DE 41 07 786 A1 ist hierzu eine Vorrichtung zum Messen des Anteils an flüssigem Brennstoff in einem Tank bekannt, die einen Zylinder mit zwei durch eine Membran aufgeteilte Membranräume aufweist. Ein Membranraum ist mit dem Tank und der andere mit der Atmosphäre verbunden. Die Membran wird beim Messen unter der Kraftwirkung einer Feder aus einer definierten Stellung in den mit dem Tank verbundenen Membranraum geschoben und die bei gegenüber der Atmosphäre verschlossenem Tank auftretende Druckänderung oder eine aus dem Membranverschiebeweg abgeleitete Größe als Maß für den Anteil flüssigen Brennstoffes im Tank gewertet. Nach erfolgter Messung und bei zur Atmosphäre geöffnetem Tank wird der Membranraum zum Tank verschlossen und zu einer Brennstoff-Förderpumpe geöffnet, so daß die Membran gegen die Kraftwirkung der Feder bis in die definierte Stellung verschoben wird durch den unter Druck in den Membranraum strömenden Brennstoff, der bei erneuter Messung und zur Pumpe verschlossenen und zum Tank geöffneten Membranraum bei zur Atmosphäre verschlossenem Tank in den Tank gefördert wird.

Der Erfindung liegt die Aufgabe zugrunde, ein Verfahren anzugeben, mit dessen Hilfe auf einfache Weise mit großer Genauigkeit die Flüssigkeitsmenge in einem abgeschlossenen Behälter bestimmt werden kann.

Diese Aufgabe wird erfindungsgemäß durch die Merkmale des unabhängigen Patentanspruches 1 gelöst. Vorteilhafte Ausgestaltungen der Erfindungen sind in den Unteransprüchen angegeben.

Durch Erzeugen einer Druckänderung im Behälter durch Unterdruck- oder Überdruckaufbau bis zu einem vorgegebenen Druckwert bei zur Umgebung abgeschlossenem Behälter und anschließendem Auswerten der Zeitkonstante, innerhalb derer ein Druckausgleich zur Atmosphäre hin erfolgt, wobei die Zeitkonstante proportional dem Füllstand im Behälter ist, ergibt sich ein sehr einfaches Verfahren zum Bestimmen des Füllstandes im Behälter.

Ein Ausführungsbeispiel der Erfindung ist im folgenden unter Bezugnahme auf die Zeichnungen näher erläutert. Es zeigen:

Fig. 1 ein Blockschaltbild der Vorrichtung zur Durchführung des erfindungsgemäßen Verfahrens und

Fig. 2 ein Ablaufdiagramm der Füllstandsbestimmung.

Die in **Fig.** 1 in vereinfachter Weise dargestellte Vorrichtung weist einen teilweise mit Flüssigkeit gefüllten Behälter **1** auf, dessen nicht näher bezeichneter Einfüllstutzen mit einem Verschluß **2** hermetisch verschließbar ist. Der Behälter **1** ist über eine Verbindungsleitung **4** mit einer Pumpvorrichtung **7** verbunden. Damit auch bei vollständig gefülltem Behälter **1** keine Flüssigkeit in die Verbindungsleitung **4** und damit zur Pumpvorrichtung **7** gelangen kann, zweigt diese Versorgungsleitung an der Oberseite des Behälters ab. Damit ist gewährleistet, daß die Pumpvorrichtung **7** mit dem oberhalb der Flüssigkeit befindlichen Gasraum des Behälters in Verbindung steht. Mit dem Bezugszeichen FS1 ist in der **Fig.** 1 ein erster Füllstand der Flüssigkeit, mit dem Bezugszeichen FS2 ein zweiter, gegenüber dem ersten Füllstand geringerer Füllstand FS2 bezeichnet.

In die Verbindungsleitung **4** ist zwischen dem Behälter **1** und der Pumpvorrichtung **7** ein elektrisch ansteuerbares Absperrventil **5** eingeschaltet. Durch entsprechende Ansteuersignale für das Absperrventil **5**, die von einer Steuer- und Meßeinrichtung **8** ausgegeben werden, kann der Durchlaßquerschnitt der Verbindungsleitung **4** verändert werden, insbesondere kann die Verbindungsleitung **4** vollständig verschlossen oder geöffnet werden.

In dem Teilstück der Verbindungsleitung **4**, das den Behälter **1** mit dem Absperrventil **5** verbindet, ist ein Belüftungsventil **6** eingeschaltet. Durch entsprechende Ansteuersignale der Steuer- und Meßeinrichtung **8** kann somit der Gasraum des Behälters **1** mit der Atmosphäre verbunden werden.

An der Oberseite des Behälters **1** ist ein Drucksensor **3** angeordnet, dessen Druckanschluß mit dem Gasraum des Behälters **1** in Verbindung steht. Als Drucksensor **3** kann auch ein Differenzdrucksensor eingesetzt werden, dessen erster Anschluß mit dem Gasraum des Behälters **1** und dessen zweiter Anschluß mit der Atmosphäre in Verbindung steht. Das Signal des Drucksensors **3** wird zur Aufbereitung und Auswertung der Steuer- und Meßeinrichtung **8** zugeführt.

Anhand des Ablaufdiagrammes nach **Fig.** 2 wird das erfindungsgemäße Verfahren zur Bestimmung des Füllstandes im Behälter erläutert. Als Pumpvorrichtung **7** dient dabei eine elektrische Unterdruckpumpe, die mittels Ansteuersignale der Steuer- und Meßeinrichtung **8** aktiviert wird. Dadurch kann im Behälter **1** und der Verbindungsleitung **4** ein Unterdruck erzeugt werden. Beim Einsatz des erfindungsgemäßen Verfahrens zur Bestimmung des Kraftstoffvorrates in einem Tank eines Kraftfahrzeugs kann der bei bestimmten Betriebsbereichen der das Fahrzeug antreibenden Brennkraftmaschine herrschende Unterdruck im Saugrohr zur Erzeugung des Unterdrucks und damit zur Bestimmung des Füllstandes herangezogen werden.

Alternativ hierzu kann auch eine Pumpvorrichtung **7** verwendet werden, die einen Überdruck im Behälter **1** erzeugt. Im nachfolgenden wird eine Variante mit einem Unterdrucksystem erläutert. Für ein Überdrucksystem besteht in der Vorgehensweise kein wesentlicher Unterschied.

Als Ausgangsbedingung (Zeitpunkt t_0) ist das Belüftungsventil **6** zur Umgebung offen (**Fig.** 2b)) und das Absperrventil **5** zur Pumpvorrichtung geschlossen (**Fig.** 2a)). Damit ist der Gasraum oberhalb der Flüssigkeit im Behälter mit der Atmosphäre verbunden. Der Drucksensor **3** zeigt dann den Umgebungsdruck p_u an. Zum Zeitpunkt t_1 wird die Pumpvorrichtung **7** eingeschaltet, das Absperrventil **5** geöffnet und das Belüftungsventil **6** geschlossen, wodurch ein Unterdruck im Behälter **1** und in der Verbindungsleitung **4** aufgebaut wird. Erreicht der Unterdruck p einen vorgegebenen Schwellenwert p_s (Zeitpunkt t2), so ist die Unterdruckaufbauphase abgeschlossen und die Pumpvorrichtung **7** wird ausgeschal-

tet. Gleichzeitig wird das Absperrventil **5** geschlossen und das Belüftungsventil **6** geöffnet. Dadurch wird ein Druckausgleich zwischen Behälter und Umgebung eingeleitet. Die Luft zum Druckausgleich strömt über das offene Belüftungsventil **6** über die Verbindungsleitung **4** in den Behälter **1**.

Da sich die Verbindungsleitung wie ein Widerstand und der Behälter wie eine Kapazität verhalten, erfolgt der Druckanstieg äquivalent dem Spannungsanstieg eines RC-Gliedes (Widerstands-Kondensator-Gliedes) eines elektrischen Kreises. Der Druckanstieg hat demnach einen exponentiellen Verlauf mit der Zeitkonstante τ. Die Zeitkonstante τ hängt proportional vom Gasvolumen V im Behälter ab. Ändert sich der Flüssigkeitsinhalt im Behälter, so ändert sich linear dazu das Gasvolumen oberhalb der Flüssigkeit und damit die Zeitkonstante τ. Aus der Bestimmung dieser Zeitkonstanten τ kann somit direkt auf den Füllstand im Behälter geschlossen werden.

In **Fig.** 2c) ist die Zeitkonstante τ für den Füllstand FS1 eingetragen. Nach einer Zeitspanne 5τ ist der Druckausgleich praktisch abgeschlossen (Zeitpunkt t3). Mit gestrichelter Linie ist der Verlauf des Druckes für den Füllstand FS2 eingezeichnet. Da bei diesem Füllstand FS2 das Gasvolumen größer als dasjenige bei dem Füllstand FS1 ist, ist auch die Zeitkonstante T größer und der Druckausgleich ist erst zum Zeitpunkt t_4 abgeschlossen.

Im folgenden wird erläutert, wie aus der Zeitkonstante T der Füllstand bestimmt werden kann.

Eine erste Möglichkeit besteht darin, bei Erreichen des Schwellenwertes p_s (Zeitpunkt t2) einen Zeitzähler zu starten. Mittels des Drucksensors **3** wird der Druck p überwacht und der Zeitzähler angehalten, wenn der Druck p wieder dem Umgebungsdruck p_u entspricht (Zeitpunkt t3 für den Füllstand FS1). Diese Zeitspanne t3–t2 entspricht dann einem Wert von 5τ. Dieser Wert oder der auf die Zeitkonstante τ normierte Wert ist Eingangsgröße eines in einem Speicher **9** der Steuer- und Meßeinrichtung **8** enthaltenen Kennfeldes KF1, in dem zugehörige Werte für den Füllstand FS abgelegt sind. Die Kennfeldwerte für den Füllstand werden auf dem Prüfstand durch Versuche ermittelt und beinhalten somit u. a. die Geometrie des Behälters und der Verbindungsleitung.

Wird das erfindungsgemäße Verfahren in einem Kraftfahrzeug zur Bestimmung des Tankinhaltes verwendet, so kann der ermittelte Füllstand FS dem Führer des Fahrzeuges direkt angezeigt und auch als Parameter zur weiteren Verarbeitung, z. B. als Eingangsgröße zur Leckagediagnose einer Tankentlüftungsanlage herangezogen werden.

Der Füllstand des Behälters kann auch bestimmt werden, indem der Druckverlauf während des Druckausgleiches mit Hilfe eines Modells 1. Ordnung beschrieben wird. Wie bereits eingangs erwähnt, kann hierzu die folgende Analogie zwischen elektrischem und pneumatischen Kreis benutzt werden:

	elektrisch	**pneumatisch**
	Spannung U [V]	Druck [p]
	Stromstärke [I]	Massenstrom $\dot{m}$[kg/s]
Widerstand	R	$R = \frac{8 \cdot \eta \cdot l}{\pi \cdot \rho_u \cdot r^4}$
Kapazität	C	$C = \frac{V}{R \cdot T} = \frac{\rho_{mix} \cdot V}{p_u}$

Für den Massenstrom in den Behälter **1** bei Unterdruck gilt:

$\dot{m} = -C \cdot \Delta\dot{p}$ (1).

Für den Massenstrom in der Verbindungsleitung **4** gilt:

$$\dot{m} = \frac{1}{R} \cdot \Delta p \qquad (2)$$

(1) und (2) gleichgesetzt liefert die Differentialgleichung für den Druckverlauf während des Druckausgleiches

$$\Delta\dot{p} = -\frac{1}{R \cdot C} \cdot \Delta p \qquad (3)$$

Dies ist eine Differentialgleichung 1. Ordnung mit der Zeitkonstanten

$$\tau = R \cdot C = \frac{8 \cdot \eta \cdot l \cdot V \cdot \rho_{0,mix}}{\pi \cdot r^4 \cdot p_u \cdot \rho_{0,air}} \qquad (4)$$

und der Anfangsbedingung zum Zeitpunkt t=0: $\Delta p(0) = -\Delta p_{start}$, wobei $-\Delta p_{start}$ dem Differenzdruck $p_s - p_u$ zum Zeitpunkt t2 in der **Fig.** 2c entspricht.

Mit der Anfangsbedingung und der Dirac-Verteilung $\delta(t)$ ergibt sich die Gleichung

$$\dot{\Delta p} = -\frac{1}{\tau} \cdot \Delta p - \Delta p_{start} \cdot \delta(t) \; . \qquad (5)$$

Nach Erreichen des Druckwertes p_s zum Zeitpunkt t2 (**Fig.** 2c) wird der Druck p im Behälter während einer Mindestzeit (Zeitpunkt t3) erfaßt. Mit den in Abtastschritten der Zeit T_A (z. B. 50 msec) vorliegenden N Druckmeßwerten $\Delta p(N \cdot T_A)$ kann man Gleichung (5) für alle Zeitpunkte angeben:

$$\dot{\Delta p}(0) = -\frac{1}{\tau}\Delta p(0) + \Delta p_{start} \cdot \delta(0) \qquad \text{(Druck zum Zeitpunkt t=0)}$$

$$\dot{\Delta p}(1 \cdot T_A) = -\frac{1}{\tau}\Delta p(1 \cdot T_A) + \Delta p_{start} \cdot \delta(1 \cdot T_A) \qquad \text{(Druck 1 Abtastschritt } T_A \text{ später)}$$

$$\vdots$$

$$\dot{\Delta p}((N-1) \cdot T_A) = -\frac{1}{\tau}\Delta p((N-1) \cdot T_A) + \Delta p_{start} \cdot \delta((N-1) \cdot T_A)$$

oder als Matrixgleichung ausgedrückt

$$y = X \cdot b \quad \text{mit}$$

$$y = \begin{bmatrix} \dot{\Delta p}(0) \\ \dot{\Delta p}(1 \cdot T_A) \\ \vdots \\ \dot{\Delta p}((N-1) \cdot T_A \end{bmatrix}; \quad X = \begin{bmatrix} -\Delta p(0) & \delta(0) \\ -\Delta p(1 \cdot T_A) & \delta(1 \cdot T_A) \\ \vdots & \vdots \\ -\Delta p((N-1) \cdot T_A & \delta(N-1)T_A \end{bmatrix}; \quad b = \begin{bmatrix} \frac{1}{\tau} \\ \Delta p_{start} \end{bmatrix} \qquad (6)$$

Daraus erhält man die Schätzformel

$$\hat{b} = \left(X^T X\right)^{-1} X^T y \qquad (7)$$

$$\text{für die Parameter } \hat{b} = \begin{bmatrix} \hat{\frac{1}{\tau}} \\ \hat{\Delta p}_{start} \end{bmatrix}. \qquad (8)$$

Die Gleichung (5) wird also dazu benutzt, einen Schätzwert für diese Parameter zu erhalten. Dies kann z. B. durch Anwendung des aus der Mathematik bekannten LEAST-SQUARES-Algorithmus erfolgen. Als Ergebnis erhält man einen Wert für die Zeitkonstante τ. Aus der Gleichung (4) ist ersichtlich, daß das Volumen V des Gasraumes oberhalb der Flüssigkeit im Behälter proportional der Zeitkonstante τ ist. Andererseits ergibt sich dieses Gasvolumen aus der Differenz zwischen dem bekannten, durch die Geometrie des Behälters vorgegebenen Gesamtvolumen des Behälters und dem Flüssigkeitsvolumen, das den Füllstand bestimmt. Damit spiegelt der ermittelte Wert für die Zeitkonstante τ den Füllstand wieder.

Gleichung (5) kann auch umgestellt als Modellgleichung benutzt werden

$\Delta P = \tau \cdot \dot{\Delta p} - \tau \Delta P_{start} \cdot \delta(t)$ (9).

Die äquivalente Vorgehensweise zu Gleichung (5) liefert dann die Schätzparameter

$$\hat{b} = \begin{bmatrix} \hat{\tau} \\ \hat{\tau}\,\hat{\Delta}\,p_{start} \end{bmatrix} \qquad (10)$$

In den Schätzgleichungen zur Bestimmung der Parameter $\hat{b}$ wird die Ableitung $\Delta\dot{p}(n \cdot T_A)$ an den Abtastzeitpunkten T_A benötigt. Dies muß in der Steuer- und Meßeinrichtung numerisch, z. B. durch Differenzbildung aufeinanderfolgender Werte berechnet werden.

Um das starke Rauschen der numerischen Differentiation und die damit verbundene erhöhte Standardabweichung des Schätzfehlers zu vermindern, können statt der originalen Werte Δp, $\Delta\dot{p}$, $\delta(n \cdot T_A)$ auch gefilterte Werte Δp_f, $\Delta\dot{p}_f$, $\delta_f(n \cdot T_A)$ verwendet werden. Bedingung dabei ist, daß alle Signale dieselbe Filterfunktion durchlaufen. Als Filterfunktion kann beispielsweise ein Tiefpaßfilter 1. Ordnung verwendet werden.

Der Schätzwert für die Zeitkonstante $\hat{\tau}$ bzw.

$$\frac{\hat{1}}{\tau}$$

ist Eingangsgröße eines in einem Speicher **9** der Steuer- und Meßeinrichtung **8** enthaltenen Kennfeldes KF2, in dem zugehörige Werte für den Füllstand FS abgelegt sind. Die Kennfeldwerte für den Füllstand werden auf dem Prüfstand durch Versuche ermittelt und beinhalten somit u. a. die Geometrie des Behälters und der Verbindungsleitung.

Die in den Gleichungen angegebenen Bezeichnungen haben folgende Bedeutung:

Δp = Differenzdruck $p\text{-}p_u$
$\delta(n \cdot T_A)$ = Dirac-Verteilung
Δp_f = gefilterter Differenzdruck
$\Delta\dot{p}_f$ = gefilterte Ableitung des Differenzdruckes
$\delta_f(n \cdot T_A)$ = gefilterte Dirac-Verteilung
$\rho_{0,air}$ = Dichte der Luft bei Normalbedingungen ($\rho_{0,air} = 1{,}29\ kg/m^3$)
$\rho_{0,mix}$ = Dichte des Kraftstoffdampfes bei Normalbedingungen (Normaltemperatur $T_0 = 273{,}15$ K, Normaldruck $p_0 = 1013$ hPa)
ρ_{mix} = Dichte des Kraftstoffdampfes
ρ_u = Dichte der Umgebungsluft
T = Umgebungstemperatur (=Temperatur des Gasvolumens)
p_u = Umgebungsdruck
p = Tankdruck, absolut
V = Volumen oberhalb der Flüssigkeit im Behälter
l = Länge der Verbindungsleitung
r = Radius der Verbindungsleitung
η = Viskosität der Luft bei Normalbedingungen ($\eta = 1{,}74 \cdot 10^{-5}\ Ns/m^2$.

Da der Drucksensor einen gewissen Offset aufweist, kann zur Erhöhung der Genauigkeit vor Durchführung des Verfahrens die Nullpunktverschiebung des Sensorsignals bestimmt werden. Dies kann kann mit einer beliebigen, an sich bekannten Methode erfolgen. Für die weiteren Berechnungen wird dann das Signal vom Tankdrucksensor um diesen ermittelten Offsetwert korrigiert. Durch Ausgasen des Kraftstoffes ergibt sich schon ein Druckanstieg, der ein ähnliches Verhalten aufweist, wie der zur Füllstandsbestimmung genutzte Druckanstieg durch die einströmende Luft.

Eine bevorzugte Anwendung dieses erfindungsgemäßen Verfahrens ist die Füllstandsbestimmung bei einem Kraftstofftank eines Kraftfahrzeuges. Tanksysteme von Kraftfahrzeugen sind heutzutage vielfach mit Tankentlüftungsanlagen ausgerüstet. Darin ist u. a. ein Tankentlüftungsventil enthalten, das in einer Verbindungsleitung zwischen einem, ein Aktivkohlefilter beinhaltender Kanister zum Zwischenspeichern von Kraftstoffdämpfen und dem Saugrohr der das Fahrzeug antreibenden Brennkraftmaschine enthalten ist. Da in bestimmten Betriebsbereichen der Brennkraftmaschine im Saugrohr ein Unterdruck herrscht, kann das Saugrohr als Unterdruckerzeugungseinrichtung verwendet werden. Ein Absperrventil am Kanister, das zum Spülen des Aktivkohlefilters geöffnet wird, verbindet das Tanksystem zur Entlüftung mit der Umgebung. Für die Leckagediagnose des Tanksystems ist ein Drucksensor vorgesehen. Ein solches Tanksystem mit Diagnoseverfahren ist beispielsweise in der DE 44 27 688 A1 beschrieben.

Durch die Berücksichtigung des Füllstandes des Kraftstofftankes bei solchen Verfahren läßt sich die Genauigkeit der Leckagediagnose erhöhen, ohne zusätzlichen Aufwand an Bauteilen, da der benötigte Drucksensor für die Füllstandsbestimmung ohnehin in der Tankentlüftungsanlage bereits vorhanden ist. Die Kenntnis des Füllstandes ist insbesondere dann nötig, wenn mit Hilfe solcher Verfahren Leckagen in der Tankanlage in der Größenordnung von 0,5 mm erkannt werden sollen.

Patentansprüche

1. Verfahren zum Bestimmen des Füllstandes einer Flüssigkeit in einem abgeschlossenem Behälter, wobei
   - der Behälter wahlweise nacheinander mit einer Vorrichtung zum Erzeugen einer Druckänderung im Innern des Behälters oder der Atmosphäre verbindbar ist und
   - die Druckänderung im Behälter mittels eines Drucksensors erfaßt und zur Bestimmung des Füllstandes ausgewertet wird,

gekennzeichnet durch folgende Schritte:

- Erzeugen einer Druckänderung in dem nicht mit Flüssigkeit gefülltem Gasvolumen (V) des Behälters (**1**) bei zur Atmosphäre hin abgeschlossenem Volumen (V),
- Beenden der Druckerzeugung bei Erreichen eines vorgegebenen Druckwertes (p_s) und Verbinden des Gasvolumens (V) mit der Atmosphäre, so daß ein Druckausgleich bis zum Umgebungsdruck (p_u) stattfindet,
- Ermitteln der zum Gasvolumen (V) proportionalen Zeitkonstante (τ) des Druckverlaufes (p) zwischen Beginn und Ende des Druckausgleiches und anschließendem Bestimmen des Füllstandes (FS1; FS2) der Flüssigkeit durch Auswerten der Zeitkonstante (τ).

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Druckänderung mittels einer Pumpvorrichtung (**7**) erzeugt wird, die einen Unterdruck im Behälter (**1**) aufbaut.

3. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Druckänderung mittels einer Pumpvorrichtung (**7**) erzeugt wird, die einen Überdruck im Behälter (**1**) aufbaut.

4. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Werte für die Zeitkonstante (τ) als Eingangsgröße eines in einem Speicher (**9**) einer Steuer-und Meßeinrichtung (**8**) abgelegten Kennfeldes (KF1; KF2) dienen, in dem zugehörige Werte für den Füllstand (FS1, FS2) abgelegt sind.

5. Verfahren nach Anspruch 4, dadurch gekennzeichnet, daß die Kennfeldwerte für den Füllstand (FS1, FS2) experimentell auf dem Prüfstand durch Versuche ermittelt werden.

6. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Zeitkonstante (τ) ermittelt wird, indem die Zeitspanne (t3–t2) gemessen wird, innerhalb derer sich der Druck (p) ausgehend von dem vorgegebenen Druckwert (p_s) zu dem Atmosphärendruck (p_u) angeglichen hat und ein Fünftel dieser Zeitspanne (t3–t2) als angenäherter Wert für die Zeitkonstante (τ) betrachtet wird.

7. Verfahren nach Anspruch 1 dadurch gekennzeichnet, daß die Zeitkonstante (τ) ermittelt wird, indem der Druckverlauf (Δp) während des Druckausgleichs mit Hilfe eines mathematischen Modells in Form einer Differentialgleichung 1. Ordnung mit der Zeitkonstante (τ) beschrieben wird, die folgende Form aufweist:

$$\dot{\Delta p} = -\frac{1}{\tau}\cdot\Delta p - \Delta p_{Start}\cdot\delta(t)$$

mit

$$\dot{\Delta p} = -\frac{1}{R\cdot C}\cdot\Delta p$$

und

$$\tau = R\cdot C = \frac{8\cdot\eta\cdot l\cdot V\cdot\rho_{0,mix}}{\pi\cdot r^4\cdot p_u\cdot\rho_{0,air}}$$

$\rho_{0,air}$ = Dichte der Luft bei Normalbedingungen ($\rho_{0,air}$ = 1,29 kg/m^3)
$\rho_{0,mix}$ = Dichte des Kraftstoffdampfes bei Normalbedingungen (Normaltemperatur T_0 = 273,15 K, Normaldruck p_0 = 1013 hPa)
Δp= Druckdifferenz $p-p_u$
$\delta(t)$ = Dirac-Verteilung
Δp_{start} = Differenzdruck p_s-p_u
p_u = Umgebungsdruck
p = Tankdruck
p_s = Schwellenwert
V = Volumen oberhalb der Flüssigkeit im Behälter
l = Länge der Verbindungsleitung
r = Radius der Verbindungsleitung
η = Viskosität der Luft bei Normalbedingungen (η=1,74 · 10^{-5} Ns/m^2)
τ = Zeitkonstante.

8. Verfahren nach Anspruch 7, dadurch gekennzeichnet, daß anstelle der originalen Werte (Δp,$\dot{\Delta p}$,$\delta(t)$) gefilterte Werte Δp_f,$\dot{\Delta p}_f$,$\delta_f(t)$ verwendet werden.

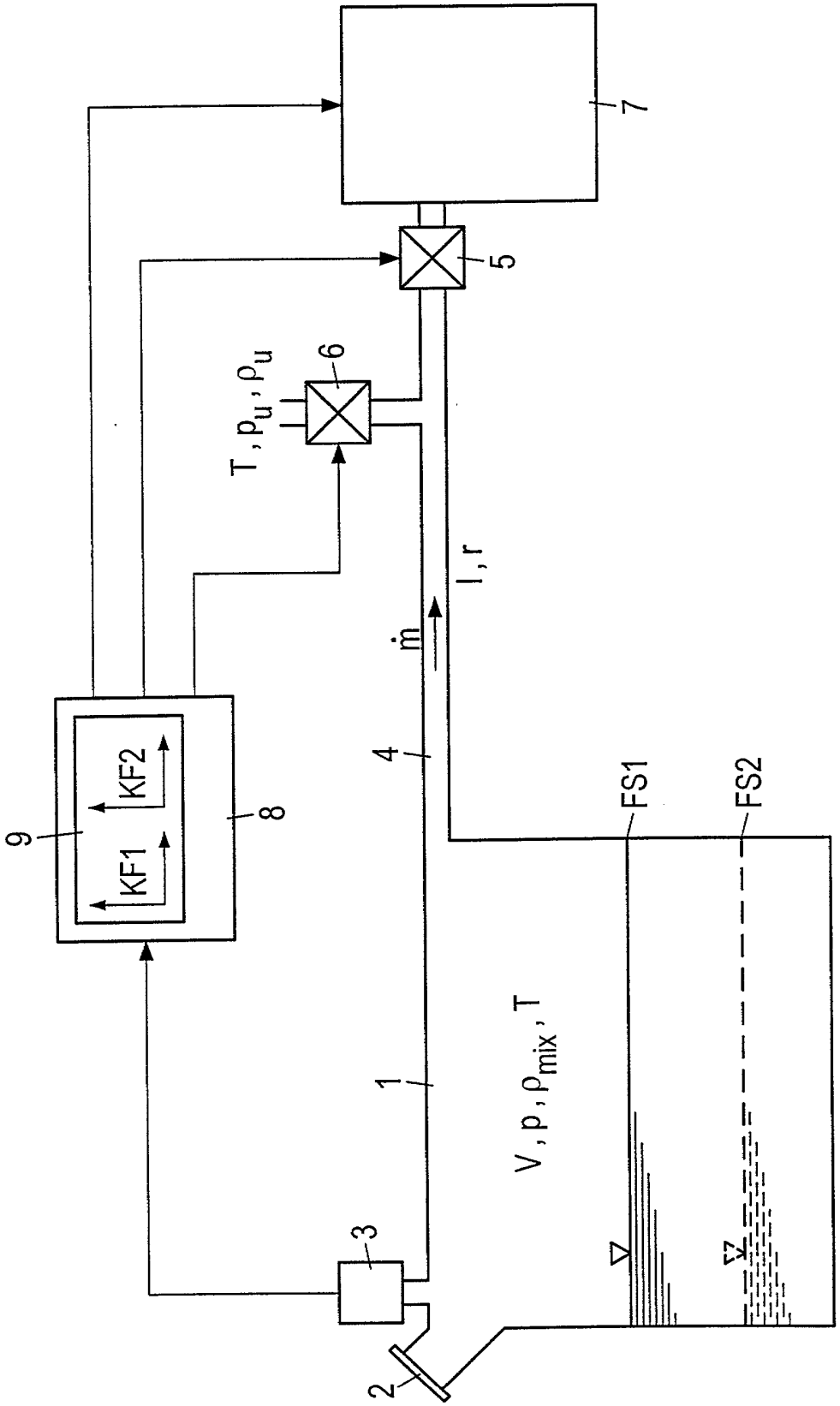
9. Verfahren nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß Schätzwerte für die Zeitkonstante (τ) mit Hilfe der Least-Squares Methode bestimmt werden.

10. Verwendung des Verfahrens nach einem der vorhergehenden Ansprüche zur Füllstandsbestimmung bei einem Kraftstofftank in einem Kraftfahrzeug.

Hierzu 2 Seite(n) Zeichnungen

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FIG 1



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FIG 2A



FIG 2B

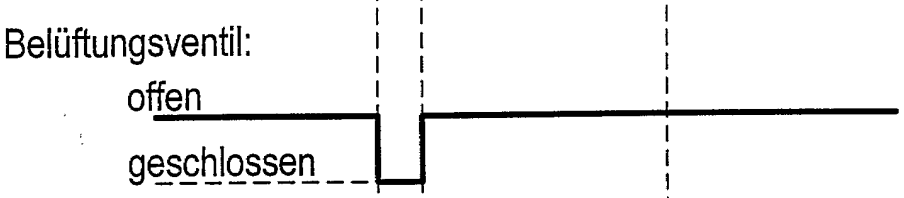
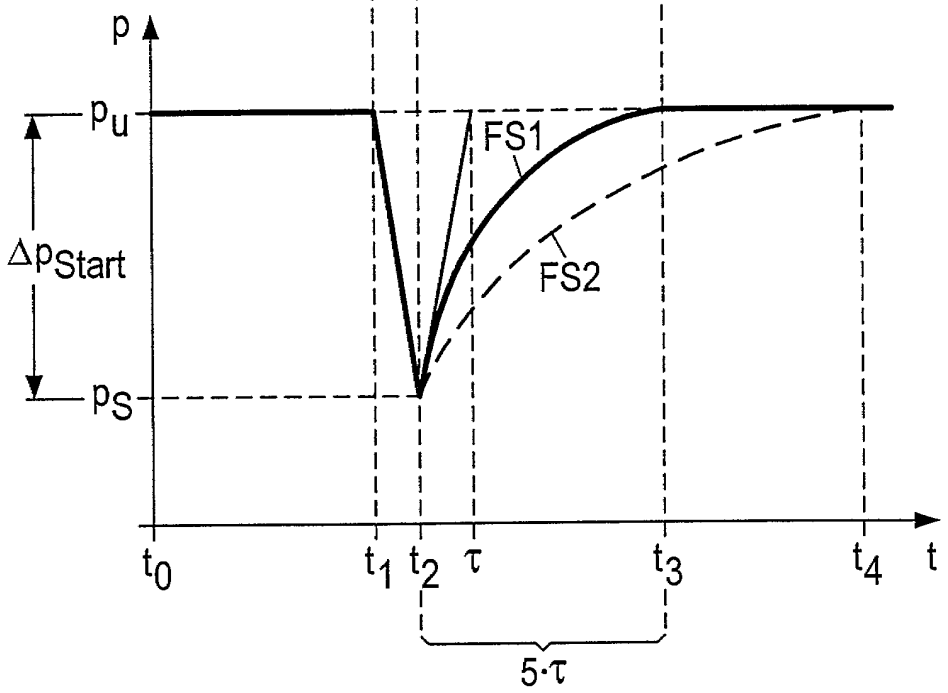


FIG 2C



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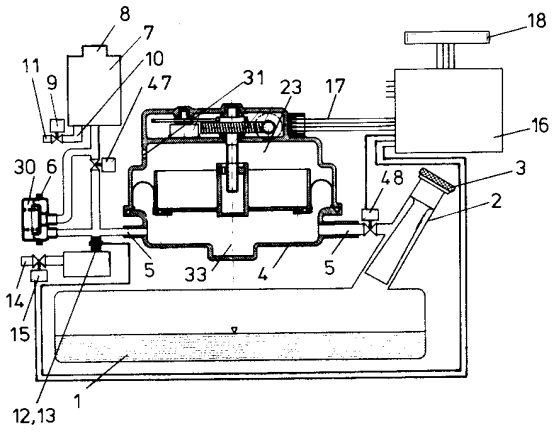
(54) Vorrichtung zum Messen des Anteils flüssigen Brennstoffs in einem Tank.

(57) 2.1
Bekannte Vorrichtungen, bei denen aus einem in den Tank gedrückten Volumen und der dabei auftretenden Druckänderung auf den Anteil flüssigen Brennstoffs geschlossen wird, sind nicht mehr zeitgemäß, bauraumaufwendig und nicht beliebig an den Tank anschließbar.

2.2
Die erfindungsgemäße Vorrichtung weist daher die Merkmale auf, daß die Membran (26) von einem Elektromotor (46) verstellt wird nach Maßgabe von Signalen eines elektronischen Steuergerätes (22), wobei zwischen Motor (46) und Membran (26) ein Untersetzungsgetriebe (47) und ein Spindeltrieb (48) angeordnet sind.

2.3
Diese Vorrichtung ermöglicht bei geringem Bauraum eine beliebige Anordnung am Tank und zusätzliche Diagnosen der Dichtheit des Tanks und/oder des Aktivkohlebehältersystems bzw. der Luftflowrate des Regenerierungssystems.

FIG.1



EP 0 503 280 A2

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Die Erfindung betrifft eine Vorrichtung zum Messen des Anteils flüssigen Brennstoffs in einem Tank nach dem Oberbegriff des Patentanspruchs 1.

Eine derartige Vorrichtung ist Gegenstand der DE-PS 697 341 und weist bereits das Prinzip auf, aus einer Kolbenverstellung und der dadurch verursachten Druckänderung im gasgefüllten Tankraum auf den Anteil flüssigen Brennstoffs zu schließen. Bei dieser Vorrichtung wird der Kolben durch Handbetätigung gegen die Kraftwirkung einer Feder in eine definierte Stellung gebracht, aus der er beim Messen durch die Federkraft verstellt wird.

Aus der DE-C2 29 53 903 ist eine ähnliche Vorrichtung bekannt, bei der der Kolben aus einer definierten Stellung beim Messen durch einen Luftmotor verstellt wird, der mit unter- oder überatmospährischem Druck arbeitet. Diese Vorrichtung weist Drucksensoren und Wegsensoren auf, deren Signale ggf. auch einem elektronischen Steuergerät zur Weiterverarbeitung zugeführt werden können.

Die Vorrichtung mit Handverstellung des Kolbens ist nicht mehr zeitgemäß, die Kolbenverstellung mittels Luftmotor ist bauraumaufwendig und die Vorrichtung nur am gasgefüllten Tankraum anschließbar, weswegen eine Anwendung bisher nicht erfolgte.

Hiervon ausgehend liegt der Erfindung daher die Aufgabe zugrunde, eine Vorrichtung der angegebenen Art zu gestalten, die ohne bisher übliche Antriebsmittel wie Hand- oder Luftantrieb, die insgesamt einen hohen Aufwand für Schaltventile, Anschlußleitungen usw. erfordern, arbeitet, einen geringen Bauraumbedarf hat und beliebig am Brennstofftank anschließbar ist.

Diese Aufgabe ist durch die im Patentanspruch 1 gekennzeichneten Merkmale gelöst worden. Vorteilhafte Weiterbildungen sind in den Unteransprüchen angegeben.

Ausführungsbeispiele der Erfindung sind in der Zeichnung dargestellt und werden nachfolgend mit Angabe erreichbarer Vorteile beschrieben.

Die Zeichnung zeigt:

Fig. 1
eine erfindungsgemäße Vorrichtung an einem Brennstofftank eines Kraftfahrzeuges;

Fig. 2 eine Einzelheit aus Fig. 1;.

Fig. 3 und 4 alternative Ausbildungen der Einzelheit nach Fig. 2,

Fig. 5 eine Einzelheit aus Fig. 1 in einer ausgestaltenden Ausbildung.

Fig. 1 zeigt einen Brennstofftank 1 mit einem Tankeinfüllstutzen 2 und einem Tankverschlußdeckel 3 sowie einem über dem oberen Tankboden angeordneten Zylinder 4. Der Zylinder 4 ist in Fig. 2, 3 und 4 in geringfügig abgewandelten Ausführungen vergrößert dargestellt. Der Brennstofftank 1 ist mit einer Tankentlüftungsleitung 5 ausgestattet, die vom Tankeinfüllstutzen 2 über ein Druckbegrenzungsventil 6 in einen Aktivkohlebehälter 7 mit einer Verbindung zur Atmosphäre über einen Anschluß 8 führt. Zur Regenerierung des Aktivkohlebehälters 7 dient ein Taktventil 9, welches in Abhängigkeit von den Betriebsbedingungen einer Brennkraftmaschine über einen Anschluß 10 und eine Leitung 11 eine Verbindung zu einem Saugrohr (nicht dargestellt) herstellt. Über einen Anschluß 12 wird ein Drucksensor 13 einerseits an den Innendruck des Brennstofftanks 1 bzw. der Tankentlüftungsleitung 5 und andererseits über eine Leitung 14 an den Atmosphärendruck angeschlossen. Abweichend von der dargestellten Anordnung kann dieser Drucksensor 13 mit dem Anschluß 12 auch an einer anderen Stelle angeordnet sein, beispielsweise am Tankeinfüllstutzen 2. Der Atmosphärendruck kann durch ein Absperrventil 15 in dieser Leitung 14 zwischen dem Absperrventil 15 und dem Drucksensor 13 eingeschlossen und gespeichert werden und damit der Bezugsdruck des Drucksensors (Atmosphärendruck zu Beginn der Messung) gespeichert. Meßwertfehler durch Atmosphärendruckänderungen, z. B. aufgrund von Höhenänderungen während der Messung, werden dadurch vermieden, wobei das gespeicherte Volumen ausreichend groß dimensioniert ist, um Störeinflüsse auszuschalten, die durch den Absperrvorgang etc. bewirkt werden können. Von einem elektronischen Steuergerät 16 werden über Signalleitungen 17 Eingangssignale eingelesen und verarbeitet sowie Ausgangssignale ausgegeben. Das Ergebnis einer nachfolgende beschriebenen Tankinhaltsberechnung und Dichtheitsdiagnose kann auf einem Display 18 ausgegeben und/oder anderweitig verarbeitet werden, wie später noch angegeben wird.

Der Zylinder 4 befindet sich außerhalb des Brennstofftanks 1 in der Tankentlüftungsleitung 5 zwischen dem Brennstofftank 1 und dem Druckbegrenzungsventil 6 bzw. dem Aktivkohlebehälter 7. Prinzipiell kann jedoch dieser Zylinder 4 in den Tank integriert werden.

Fig. 2 zeigt den Zylinder 4 vergrößert mit einer Membran 19, die mittels eines elektromotorischen Antriebs, bestehend aus einem Elektromotor 20, einem Untersetzungsgetriebe (z. B. Schneckengetriebe) 21 und einem Spindeltrieb 22, bewegt wird.

Zur Erlangung der Stellung Meßbereitschaft wird die Membran 19 bis in Nähe der Anschlagstellung in Richtung Verkleinerung eines Membranraumes 23 bewegt. Die Endstellung wird vor dem Erreichen der mechanischen Anschlagstellung durch ein Potentiometer 24 erkannt, welches über ein Untersetzungsgetriebe 25 angetrieben wird und indirekt die Hubstellung der Membran 19 erfaßt. Die Untersetzung zum Antrieb des Potentiometers

24 wird vorzugsweise so gewählt, daß die für einen vollen Hub der Membran 19 erforderlichen Umdrehungen des Spindeltriebes 22 knapp 1 Umdrehung des Potentiometers 24 ergeben. In der Endstellung 'Meßbereitschaft' wird bei dieser Ausführung nach Fig. 2 durch einen Zapfen 27 ein Ventilschließkörper 28 gegen die Kraft einer Druckfeder 29 geöffnet und damit die Tankentlüftungsleitung 5 auf Durchgang geschaltet. Ein Membranraum 30 des Druckbegrenzungsventils 6 (Fig. 1) ist ständig mit der Atmosphäre verbunden. Zur Vermeidung einer zusätzlichen Beaufschlagung des Aktivkohlebehälters 7 mit dem in der Tankentlüftungsleitung 5 befindlichen Brennstoffdampf ist es notwendig, die Volumenverdrängung im Membranraum 23 beim Verfahren der Membran 19 über eine Belüftungsbohrung 31 vorzunehmen und zur Vermeidung von Leckagen zwischen der feststehenden Wand des Membranraumes 23 und der Membran 19 eine formelastische Manschette 32 oder sonstige geeignete Abdichtung vorzusehen (Fig. 2 und 3).

Vor Beginn der Tankinhaltsmessung entsteht bei den Ausführungen nach Fig. 2 und 3 zunächst ein kleiner Leerhub der Membran 19, bis der Kontakt des Zapfens 27 mit dem Ventilschließkörper 28 gelöst und der freie Durchgang am Ventilschließkörper unterbrochen wird. Danach werden gleichzeitig der Tankinnendruck und die Stellung der Membran 19 zu Meßbeginn erfaßt und die Membran 19 in Richtung eines Membranraumes 33 verfahren.

Fig. 3 zeigt den Zylinder 4 mit einer Anordnung des Potentiometers 24 direkt auf dem drehenden Teil des Spindeltriebes 22. Da über den vollen Hub der Membran 19 das Potentiometer mit mehreren Umdrehungen überfahren wird, ist zur Erkennung der Meßbereitschaftsstellung ein Endlagenschalter 34 erforderlich. Ansonsten unterscheidet sich dieser Zylinder 4 nicht von dem Zylinder der Fig. 2.

Der in Fig. 4 dargestellte Zylinder 4 ist für den Einbau in den Brennstofftank konzipiert. Der Brennstofftank 1 weist eine Öffnung auf, die durch den Zylinder 4 im Bereich eines Flansches 35 abgedeckt wird. Im Gegensatz zu den Einrichtungen von Fig. 1, 2 bzw. 3 wird der Membranraum 33 nicht mit der Tankentlüftungsleitung 5, sondern mit dem Innenraum des Brennstofftanks 1 über mindestens eine Bohrung 36 verbunden. Die Lage der Bohrung 36 wird vorzugsweise so gewählt, daß ein guter Austausch von flüssigem Brennstoff und der Tankatmosphäre gewährleistet ist. Je nach Anordnung des Zylinders 4 am Brennstofftank 1 und je nach Tankinhalt kann der Membranraum 33 mit flüssigem Brennstoff und/oder mit Luft und Brennstoffdampf gefüllt sein. Die Tankentlüftungsleitung 5 ist bei dieser Ausführung an eine Motor-Getriebekammer 37 angeschlossen. Ein den Ausgang der Kammer absperrendes Absperrventil 38 hat die gleiche Funktion wie der Ventilschließkörper 28 der Fig. 2 und 3, wobei dessen Öffnungsstellung durch einen mechanischen Eingriff der Kontur eines Nockens 39 über einen Abtaststift 40 vorgegeben wird und bei Freigang zwischen dem Nocken 39 und dem Abtaststift 40 durch die Kraft der Druckfeder 29 in Schließstellung gehalten wird. Der Nocken 39 ist mechanisch mit der Welle des Potentiometers 24 verbunden. Die Kontur des Nockens 39 wird so gewählt, daß der Ventilschließkörper 28 beim Erreichen der Membranposition 'Meßbereitschaft' geöffnet ist und vor Beginn des Meßhubes geschlossen wird. Der Membranraum 23 ist über die Belüftungsbohrung 31 mit der Atmosphäre verbunden. Zur Abdichtung der Motor-Getriebekammer 37 gegenüber dem Membranraum 23 dient ein Dichtring 41.

Gegenüber der Vorrichtung mit Zylinder 4 nach Fig. 2 oder 3 hat die Einrichtung nach Fig. 4 insbesondere den Vorteil, daß der Zylinder 4 weitgehend in den Brennstofftank integriert werden kann und kein nennenswerter zusätzlicher Bauraum benötigt wird. Umgekehrt wird beim Volltanken durch die Füllung des Membranraumes 33 mit flüssigem Brennstoff erreicht, daß das Fassungsvermögen des Brennstofftanks praktisch nicht eingeschränkt wird.

Die Membrane 19 befindet sich in der Meßbereitschaftsstellung zur Tankinhaltsmessung. Die Membranstellung für die Meßbereitschaft wird vom elektronischen Steuergerät 16 durch das Potentiometer 24 bzw. den Endlagenschalter 34 (Fig. 1, 2, 3 bzw. Fig. 3) erkannt.

Das Absperrventil 15 ist geöffnet, so daß der Tankinnendruck als Differenzdruck zur Atmosphäre vom Drucksensor 13 gemessen werden kann. Der Atmosphärendruck, die Umgebungstemperatur und ggf. die Brennstofftemperatur werden von Sensoren für das Motormanagementsystem erfaßt (nicht dargestellt) und von diesem an das Steuergerät 16 gemeldet.

Zu Beginn der Messung des Tankinhaltes wird das Absperrventil 15 geschlossen und damit der Bezugsdruck (Atmosphärendruck zu Beginn der Messung) gespeichert. Meßwertfehler durch Atmosphärendruckänderungen, z. B. aufgrund von Höhenänderungen während der Messung, werden dadurch vermieden. Der Elektromotor 20 wird durch ein Ausgangssignal des Steuergerätes 16 in Betrieb gesetzt und treibt die Membran 19 über das Untersetzungsgetriebe 25 in Richtung auf den Membranraum 33 an. Der Membranraum 23 ist über die Belüftungsbohrung 31 mit der Atmosphäre verbunden. Der im Membranraum 33 gespeicherte Brennstoff bzw. Luft und Brennstoffdampf wird über die Bohrung 36 solange in den Tank ausgeschoben, bis ein vorgewählter Anstieg des Tankinnendruckes vom Drucksensor 13 gemeldet wird. Um

dynamische Effekte zu vermeiden, kann durch eine Ausbildung der Belüftungsbohrung 31 als Drosselstelle oder eine Drehzahlbegrenzung des Elektromotors 20 der zeitliche Ablauf des Ausschiebens im notwendigen Ausmaß gestreckt werden. Nach dem Erreichen der vorgewählten Druckänderung wird der Elektromotor 20 abgeschaltet und der Hub der Membran 19 über das Potentiometer 24 sowie gleichzeitig der Endwert der Druckänderung am Drucksensor 13 gemessen. Je nach Größe des eingeschlossenen Gasvolumens im Tank und des im Tank herrschenden Absolutdruckes sowie der Tanktemperatur oder einer für diese repräsentativen Größe, die u. U. aus der vom Motormanagement ermittelten Brennstofftemperatur abgeleitet ist, gibt es nach der allgemeinen Zustandsgleichung für ideales Gas einen bestimmten Gradienten für die Änderung von Volumen und Druck. Aus der Berechnung des im Tank eingeschlossenen Gasvolumens kann durch einfache Rechnung der Tankinhalt des Brennstofftanks bestimmt werden, wenn das Gesamtvolumen des Brennstofftanks bekannt ist. Die Messung und Berechnung des Tankinhaltes ist damit abgeschlossen. Das Ergebnis wird über das Display 18 angezeigt und/oder für weitere Berechnungen, z. B. der möglichen Restfahrstrecke für den ermittelten Tankinhalt, herangezogen werden.

Wird die Meßendestellung der Tankinhaltsmessung für einen vorzuwählenden Zeitraum beibehalten, so kann aus der Änderung des Tankinnendruckes, der Temperatur im Brennstofftank und des im Brennstofftank eingeschlossenen Gasvolumens darauf geschlossen werden, ob und in welchem Ausmaß eine Undichtheit des Brennstofftanks besteht. Falls die Undichtheit einen zulässigen Grenzwert übersteigt, kann dies ebenfalls über das Display 18 angezeigt und/oder anderweitig verarbeitet werden, z. B. kann nach einem Tankstopp bei Zündung an diagnostiziert werden, ob der Tankverschlußdeckel 3 wieder ordnungsgemäß aufgeschraubt wurde und damit HC-Emissionen aus dem Tankeinfüllstutzen 2 vermieden werden.

Nach Ablauf der Tankdichtheitsprüfung wird die Membran 19 durch den Elektromotor 20 wieder in die eingangs beschriebene Stellung gebracht, wodurch der Membranraum 33 wieder mit Brennstoff bzw. Luft und Brennstoffdampf gefüllt und Meßbereitschaft erreicht wird.

In Verbindung mit dem Steuergerät 16 kann vorteilhafterweise folgendes Betriebsprogramm für die Tankinhaltsfeststellung abgelegt sein:

1. Meßbereitschaft durch Potentiometerwert oder Endlagenschalter feststellen,
2. Tankinnendruck gegen Atmosphäre feststellen,
3. Schaltventil am Drucksensor schalten,
4. Elektromotor durch Ausgangssignal in Betrieb setzen,
5. Membran- bzw. Potentiometerverstellung ca. 5 % von maximal möglicher Verstellung laufen lassen,
6. Meßzeit 0 und Potentiometer- und Drucksensorwert für Start feststellen,
7. Potentiometer- und Drucksensorwertänderung feststellen,
8. Erreichen des Potentiometer- oder Drucksensorwert-Änderungsendes bzw. eines vorgewählten über Startbetrag liegenden Änderungsbetrages des Potentiometer- oder Drucksensorwerts feststellen,
9. Elektromotor durch Ausgangssignal abschalten,
10. Meßzeit, Potentiometer- und Drucksensorwert feststellen,
11. aktuellen Tankinhalt berechnen, wobei der aktuelle Atmosphärendruck und die Tanktemperatur berücksichtigt werden,
12. Ausgabe eines Ausgangssignals für Tankinhalt an Display oder Weiterverarbeitungsstufen,
13. Schaltventil am Drucksensor zurückschalten und den Elektromotor für Membranrückstellung in Betrieb setzen,
14. Meßbereitschaft durch Potentiometerwert oder Endlagenschalter feststellen (wie zu 1.).

Wie bereits angegeben, kann danach vorgesehen werden, daß der Meßvorgang über eine weitere Zeitspanne aufrecht erhalten wird und die sich ggf. einstellende Tankinnendruckänderung pro Zeiteinheit als Maß für eine Entleerung des Brennstofftanks gewertet wird, die durch flüssige/gasförmige Brennstoffleckage aus Tank und Anschlußleitungen hervorgerufen wird.

Sollte die erfindungsgemäße Vorrichtung jedoch nur für die Tankdichtheitsdiagnose eingesetzt werden, ist vorgesehen, daß die Membranverstellung durch den Elektromotor 20 bis zu einem vorgewählten über Startbetrag liegenden Änderungsbetrag des Potentiometer- oder Drucksensorsignals erfolgt und dann der Elektromotor 20 abgeschaltet wird und die Membranstellung über eine weitere Zeitspanne aufrecht erhalten wird und die sich ggf. einstellende Tankinnendruckänderung pro Zeiteinheit als Maß für eine Entleerung des Brennstofftanks gewertet wird.

Darüber hinaus ist vorteilhafterweise vorgesehen, daß das Maß für die Tankentleerung um den Anteil reduziert wird, der dem im Steuergerät 16 berechneten Brennstoffverbrauch der Brennkraftmaschine entspricht, oder auch, daß der Meßvorgang insgesamt oder nur nach vorliegendem Ausgangssignal für die Anzeige des flüssigen Brennstoffanteils im Tank bei abgestellter Brennkraftmaschine erfolgt. Selbstverständlich kann ein Betriebsprogramm für die Tankdichtheitsdiagnose auch in dem Steuergerät 16 abgelegt sein, wobei

im Steuergerät 16 ein zulässiger Wert für den Druckgradienten abgelegt sein kann, ab dem bei Überschreitung ein Fehlersignal ausgegeben wird.

Mit der erfindungsgemäßen Vorrichtung zum Messen des Anteils flüssigen Brennstoffs in einem Brennstofftank liegt eine mit geringem Bauraumbedarf realisierbare Lösung vor, mit der eine beliebige Anordnung des Zylinders 4 bzw. des Membranraumes 33 direkt am Tank 1 über oder unter Brennstoffspiegel möglich geworden ist.
Es versteht sich von selbst, daß der Aktivkohlebehälter 7 und ebenso die für die Maßnahme zur Speicherung des Atmosphärendrucks am Drucksensor 13 notwendigen Bauteile Absperrventil 15 und Speichervolumen entfallen können.

Es besteht jedoch u.U. auch Bedarf nach einer Überprüfung aller brennstoffdampfführenden Leitungen und Behälter auf Dichtheit und der Wirkweise der Aktivkohle-Regenerierung im Rahmen der Borddiagnose.

Hierfür ist nun in Weiterbildung der Erfindung vorgesehen, daß der in die Atmosphäre führende Anschluß 8 des Aktivkohlebehälters 7 ein doppeltwirkendes Belüftungsventil 42 aufweist, das in Fig. 5 dargestellt ist und mit einem ersten von einer Feder 43 belasteten Schließglied 44 sowie einem innerhalb des ersten Schließgliedes 44 angeordneten, von einer Feder 45 belasteten zweiten Schließglied 46 ausgestattet ist, wobei das erste Schließglied 44 den Anschluß 8 zur Atmosphäre öffnet, wenn im Aktivkohlebehälter 7 Überdruck herrscht, und das zweite Schließglied 46 den Anschluß 8 zur Atmosphäre öffnet, wenn Unterdruck im Aktivkohlebehälter 7 herrscht. Die Tankentlüftungsleitung 5 weist in diesem Falle ein Absperrventil 48 auf.

Der Druck im Tank 1 ist unabhängig vom Druck im Aktivkohlebehälter 7 durch das Druckbegrenzungsventil 6 begrenzt, wobei es erforderlich ist, daß dann ein in der Leitung 5 angeordnetes Bypaßventil 47 geschlossen bleibt.

Mit der erfindungsgemäßen Vorrichtung sind die Funktionen Tankinhalts- und Tankdichtheitsmessungen durchführbar.
Erfindungsgemäß wird nun auch eine Dichtheitsprüfung des Aktivkohlebehältersystems möglich. Für die Dauer dieser Prüfung wird dann das Absperrventil 48 geschlossen. Selbstverständlich ist dann die Anordnung des Drucksensors in der gezeigten Anordnung notwendig, um ein Drucksignal von diesem zu erhalten.
Ohne die Verwendung des Absperrventils 48 ist nur eine Dichtheitsprüfung des Gesamtsystems, bestehend aus dem Brennstofftank und dem Aktivkohlebehältersystem, möglich.

Bei Verwendung des Absperrventils 48 in der Verbindungsleitung zum Tank kann die Dichtheitsprüfung wahlweise auch nur selektiv für das Regenerierungssystem durchgeführt werden, wie noch beschrieben wird.

Im Rahmen einer weiteren Ausgestaltung der Erfindung können in Reihe und/oder parallel zum doppeltwirkenden Belüftungsventil 42 elektromagnetische Absperrventile (nicht dargestellt) eingesetzt werden, um die Abdicht- und Belüftungsfunktion auch über die von den Druckfedern bestimmten Arbeitsdrücke hinaus zu gewährleisten.

Zusätzlich zur Dichtheitsprüfung kann erfindungsgemäß auch eine qualitative und quantitative Prüfung der Flowrate des Regenerier-Taktventils 9 durchgeführt werden. Dazu ist das Meßverfahren in der Weise zu ändern, daß nach der Dichtheitsprüfung (Messung der Druckänderung während einer vorgegebenen Zeit) das Regenerier-Taktventil 9 wieder angesteuert wird und die sich aus den Ansteuerimpulsen und den jeweiligen Betriebsbedingungen einstellenden Durchsätze auf ihre Richtigkeit überprüft werden, in dem aus der Größe des eingeschlossenen Volumens und der Druckabsenkung die Flowrate berechnet und mit der Sollmenge verglichen wird.

Nur im Falle der Dichtheitsprüfung des Aktivkohlebehältersystems und zur Messung der Flowrate des Regenerier-Taktventils 9 ist es erforderlich, das Bypaßventil 47 zu öffnen und das Absperrventil 48 zu schließen.

Die erfindungsgemäße Messung der Dichtheit des gesamten brennstoffdampfführenden Systems und die Überprüfung der Flowrate des Regenerier-Taktventils sind insbesondere für die Erfüllung der Anforderungen einer 'On-Board-Diagnose' geeignet, wie sie künftig in den USA vom Gesetzgeber verlangt wird.

Mit der erfindungsgemäßen Vorrichtung kann eine Dichtheitsprüfung des Tanks und eingeschlossen des Aktivkohlebehältersystems bei verschlossenem Regenerier-Taktventil 9 erfolgen.

Soll das Aktivkohlebehältersystem separat geprüft werden, erfolgt die Messung bei geschlossenem Taktventil 9 und Absperrventil 48, wobei dann auch die erwähnte Funktion des Regenerier-Taktventils 9 überprüft werden kann unter Ansteuerung des Regenerier-Taktventils 9, in dem aus der Größe des eingeschlossenen Volumens und der Druckabsenkung die Flowrate berechnet wird.

Es versteht sich von selbst, daß bei einfacher Ausführung der Vorrichtung das Druckbegrenzungsventil 6 und das Bypassventil 47 entfallen können, und ebenso das Absperrventil 48, sofern auf eine separate Prüfung des Einzelsystems verzichtet wird.

Mit der Einrichtung ohne Druckbegrenzungsventil 6 muß während der Messung das Taktventil 9 geschlossen sein. Zum Beispiel bei einer 2-Minuten-Meßfolge kann dies jedoch einen Zeitanteil von 3 bis 5 % der Betriebszeit ausmachen. Während dieser Zeit findet keine Regeneration des

Aktivkohlebehälters 7 statt, was u. U. zu einer unzulässigen Beeinträchtigung der Regenerierung der Aktivkohle führt. Um die Meßfolge (Anzahl der Messungen pro Zeiteinheit) zu vermindern und die Füllstandsmessung trotzdem fortlaufend aktualisieren zu können, wird vorgeschlagen, daß eine Fortschreibung des aktuellen Tankinhaltwertes mittels der im Steuergerät berechneten Einspritzmenge erfolgt. Damit ist es möglich, die Meßfolge für die Füllstandsmessung stark zu reduzieren und/oder nur bei Ausschluß aller kritischen Betriebszustände auszuführen, was zu einer Verringerung des Zeitanteils ohne Regenerierung der Aktivkohle führt.

Bei kritischen Betriebszuständen, z. B. nach Betanken mit frischem Brennstoff bei aufgeheiztem Fahrzeug oder hohem Temperaturanstieg im Tank und/oder voller Beladung der Aktivkohle, ist mit einer erheblichen Ausgasungsmenge leichtflüchtiger Anteile (Benzin, Alkohol) zu rechnen und die Beimengung von dampfförmigem Brennstoff über das Taktventil 9 in die Ansaugluft der Brennkraftmaschine bis zu 30 % der von der Brennkraftmaschine benötigten Brennstoffmenge ausmachen. Um die Lamdaregelung bei sprunghafter Außer- und Infunktionssetzung des Taktventils 9 nicht in unzulässigerweise zu beeinträchtigen, ist durch Verknüpfung der Algorithmen der Füllstands-/Dichtheitsdiagnose und des Motormanagements bzw. der Borddiagnose eine Anpassung der Einspritzmenge vorteilhafterweise durchzuführen. Bei Ab- und Einschalten der Ansteuerung des Taktventils 9 kann die Größe der Einspritzmengenänderung vorteilhaft aus der vor dem Abschalten bestehenden Abweichung der Einspritzmenge zum Normalwert abgeleitet werden.

Patentansprüche

1. Vorrichtung zum Messen des Anteils von flüssigem Brennstoff in einem Brennstofftank, bestehend aus einem Zylinder, der durch eine Membran in zwei Membranräume aufgeteilt ist, von denen einer mit dem Tank und der andere mit der Atmosphäre verbunden ist, wobei die Membran beim Messen aus einer definierten Stellung in den mit dem Tank verbundenen Membranraum geschoben wird und die bei gegenüber der Atmosphäre verschlossenem Tank auftretende Druckänderung oder eine aus dem Membranverschiebeweg und der Druckänderung abgeleitete Größe als Maß für den Anteil flüssigen Brennstoffs im Tank gewertet wird, dadurch gekennzeichnet, daß die Membran (19) von einem Elektromotor (20) verstellt wird nach Maßgabe von Signalen eines elektronischen Steuergerätes (16), wobei zwischen Motor (20) und Membran (19) ein Untersetzungsgetriebe (21) und ein Spindeltrieb (22) angeordnet sind.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß in Meßbereitschaftsstellung der Membran (19) ein Ventilschließkörper (28) von einem Ventilsitz gehoben wird und so eine Verbindung zwischen zwei Abschnitten einer Tankentlüftungsleitung (5) hergestellt wird.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß der Ventilschließkörper (28) von einem Zapfen (27) des Spindeltriebes (22) betätigt wird und im Membrankörper (19) angeordnet ist, wobei die Verbindung zwischen den Abschnitten der Tankentlüftungsleitung (5) mittels einer Manschette (32) gegenüber dem nicht mit dem Tank (1) verbundenen Membranraum (23) abgedichtet ist.

4. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß der Ventilschließkörper (28) von einem Nocken (39) betätigt wird, der vom Spindeltrieb (22) angetrieben wird und in einer Motor-Getriebekammer (37) angeordnet ist.

5. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Meßbereitschaftsstellung und der Verstellweg der Membran (19) von einem Potentiometer (24) festgestellt werden, das vom Spindeltrieb (22) derart angetrieben wird, daß der maximale Verstellweg der Membran (19) maximal eine Potentiometerumdrehung ergibt.

6. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Meßbereitschaftsstellung von einem Endlagenschalter (34) und der Verstellweg der Membran (19) von einem Potentiometer (24) festgestellt werden, das vom Spindeltrieb (22) derart angetrieben wird, daß der maximale Verstellweg der Membran (19) mehrere Potentiometerdrehungen ergibt.

7. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Tankentlüftungsleitung (5) über ein Druckbegrenzungsventil (6) über einen nachgeschalteten Aktivkohlebehälter (7) in die Atmosphäre führt.

8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, daß der Aktivkohlebehälter (7) einen Anschluß (8) zur Atmosphäre aufweist mit einem doppelt-wirkenden Belüftungsventil (42), das ab einem vorgegebenen über oder unter dem atmosphärischen liegenden Aktivkohlebehälterdruck den Anschluß (8) zur Atmosphäre

öffnet.

9. Vorrichtung nach Anspruch 8, dadurch gekennzeichnet, daß in der Tankentlüftungsleitung (5) zum Tank (1) ein Absperrventil (48) angeordnet ist, wobei die Druckänderung durch den bekannten, in der zum Aktivkohlebehälter (7) führenden Tankentlüftungsleitung (5) angeordneten Drucksensor (13) ermittelt wird.

10. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß der bekannte Drucksensor (13) über eine Leitung (12) und die Tankentlüftungsleitung (5) an den Tank (1) bzw. direkt am Tankeinfüllstutzen (2) angeschlossen ist und über eine Leitung (14) an die Atmosphäre, wobei in dieser Leitung (14) ein Absperrventil (15) angeordnet ist, mit dem das zwischen dem Absperrventil (15) und dem Drucksensor (13) bestehende, größenmäßig abgestimmte Volumen eingeschlossen und gespeichert werden kann.

11. Vorrichtung nach einem der Ansprüche 7 - 10, dadurch gekennzeichnet, daß parallel zum Druckbegrenzungsventil (6) ein Bypaßventil (47) angeordnet ist und einen Bypaßkanal zum Druckbegrenzungsventil (6) steuert.

12. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß in Reihe und/oder parallel zum Belüftungsventil (42) elektromagnetische Absperrventile eingesetzt werden, um Abdicht- und Belüftungsfunktionen auch außerhalb des durch das Belüftungsventil (42) vorgegebenen Druckbereichs zu erreichen.

13. Vorrichtung nach einem der vorstehenden Ansprüche mit einem bekannten elektronischen Steuergerät, dem Sensorsignale über den Tankraumdruck und den Membranverschiebeweg zugeführt und im Steuergerät zu einem Ausgangssignal für den Anteil flüssigen Brennstoffs im Tank verarbeitet wird, dadurch gekennzeichnet, daß im Steuergerät folgendes Betriebsprogramm für die Tankinhaltsfeststellung abgelegt ist:

1. Meßbereitschaft durch Potentiometerwert oder Endlagenschalter feststellen,
2. Tankinnendruck gegen Atmosphäre feststellen,
3. Schaltventil am Drucksensor schalten,
4. Elektromotor durch Ausgangssignal in Betrieb setzen,
5. Membran- bzw. Potentiometerverstellung ca. 5 % von maximal möglicher Verstellung laufen lassen,
6. Meßzeit 0 und Potentiometer- und Drucksensorwert für Start feststellen,
7. Potentiometer- und Drucksensorwertänderung feststellen,
8. Erreichen des Potentiometer- oder Drucksensorwert-Änderungsendes bzw. eines vorgewählten über Startbetrag liegenden Änderungsbetrages des Potentiometer- oder Drucksensorwerts feststellen,
9. Elektromotor durch Ausgangssignal abschalten,
10. Meßzeit, Potentiometer- und Drucksensorwert feststellen,
11. aktuellen Tankinhalt berechnen,
12. Ausgabe eines Ausgangssignals für Tankinhalt an Display oder Weiterverarbeitungsstufen,
13. Schaltventil am Drucksensor zurückschalten und den Elektromotor für Membranrückstellung in Betrieb setzen,
14. Meßbereitschaft durch Potentiometerwert oder Endlagenschalter feststellen (wie zu 1.).

14. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, daß bei der Tankinhaltsberechnung der aktuelle Atmosphärendruck und die Tanktemperatur oder eine für die Tanktemperatur repräsentative Größe berücksichtigt werden.

15. Vorrichtung nach Anspruch 14, dadurch gekennzeichnet, daß die für die Tanktemperatur repräsentative Größe aus der Brennstofftemperatur ermittelt wird, die vom Motormanagementsystem festgestellt wird.

16. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß nach vorliegendem Ausgangssignal, das die Anzeige des Anteils flüssigen Brennstoffs im Tank (1) ermöglicht, der Meßvorgang über eine weitere Zeitspanne aufrecht erhalten wird und die sich ggf. einstellende Tankinnendruckänderung pro Zeiteinheit (Druckgradient) als Maß für eine Entleerung des Brennstofftanks gewertet wird, die durch Brennstoffentnahme für die Brennkraftmaschine und flüssige/gasförmige Brennstoffleckage aus Tank und Anschlußleitungen hervorgerufen wird.

17. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Membranverstellung durch den Elektromotor (20) bis zu einem vorgewählten über Startbetrag liegenden Änderungsbetrag des Potentiometer- oder Drucksensorsignals erfolgt und dann der Elektromotor (20) abgeschaltet

wird und die Membranstellung über eine weitere Zeitspanne aufrecht erhalten wird und die sich ggf. einstellende Tankinnendruckänderung pro Zeiteinheit als Maß für eine Entleerung des Brennstofftanks gewertet wird, die durch Brennstoffentnahme für die Brennkraftmaschine und flüssige/gasförmige Brennstoffleckage aus Tank und Anschlußleitungen hervorgerufen wird.

18. Vorrichtung nach Anspruch 16 oder 17, dadurch gekennzeichnet, daß das Maß für die Tankentleerung um den Anteil reduziert wird, der dem im Steuergerät (16) berechneten Brennstoffverbrauch der Brennkraftmaschine entspricht.

19. Vorrichtung nach Anspruch 16, 17 oder 18, dadurch gekennzeichnet, daß das Maß für die Tankentleerung unter Berücksichtigung des Absolutdruckes im Tank, der Tanktemperatur und des Anteils flüssigen Brennstoffs ermittelt wird.

20. Vorrichtung nach Anspruch 16 oder 17, dadurch gekennzeichnet, daß der Meßvorgang insgesamt oder nur nach vorliegendem Ausgangssignal für die Anzeige des flüssigen Brennstoffanteils im Tank bei abgestellter Brennkraftmaschine erfolgt.

21. Vorrichtung nach einem der vorstehenden Ansprüche, 16 - 20, dadurch gekennzeichnet, daß im Steuergerät (16) ein zulässiger Wert für das Maß der Entleerung abgelegt ist, ab dem bei Überschreitung ein Fehlersignal ausgegeben wird.

22. Vorrichtung nach einem der vorstehenden Ansprüche, 16 - 21, dadurch gekennzeichnet, daß im Steuergerät (16) ein Betriebsprogramm für die Diagnose der Dichtheit des Tanks und/oder des Aktivkohlebehältersystems bzw. der Luftflowrate des Regenerierungssystems abgelegt ist.

23. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß bei kritischen Betriebszuständen eine Fortschreibung des aktuellen Tankinhaltwertes mittels der im Steuergerät berechneten Einspritzmenge erfolgt und die Meßfolge (Anzahl der Messungen pro Zeiteinheit) verringert wird.

24. Vorrichtung nach Anspruch 22, dadurch gekennzeichnet, daß durch Verknüpfung der Algorithmen der Füllstands-/Dichtheitsdiagnose und des Motormanagements bzw. der Borddiagnose eine Anpassung der Einspritzmenge erfolgt.

25. Vorrichtung nach Anspruch 24, dadurch gekennzeichnet, daß bei Ab- und Einschaltung der Ansteuerung des Taktventils (9) die Größe der Einspritzmengenänderung aus der vor dem Abschalten bestandenen Abweichung der Einspritzmenge zum Normalwert abgeleitet wird.

FIG.1

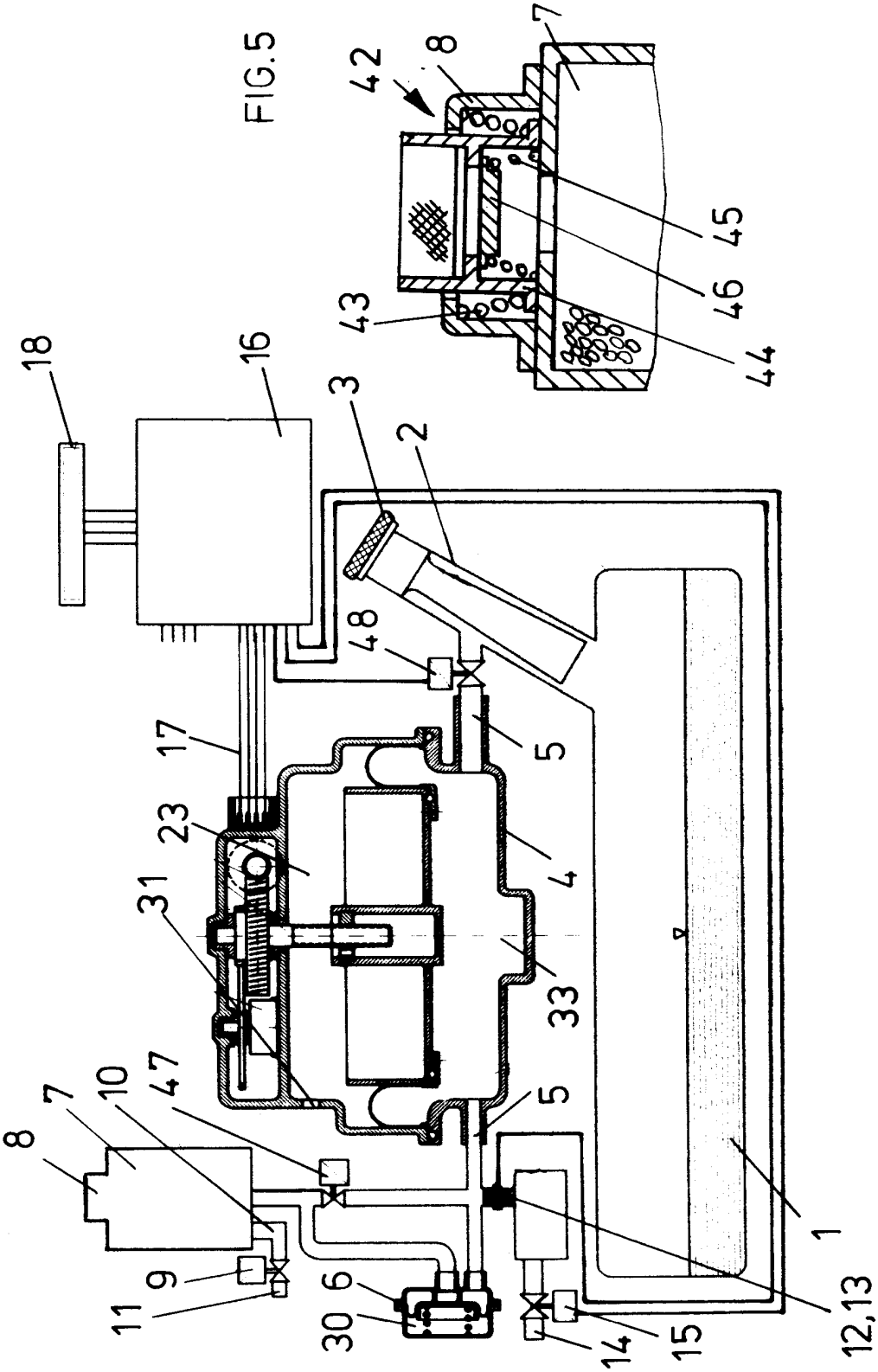

18
16
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33
47
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FIG.5

42
8
7
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43
44

FIG.2

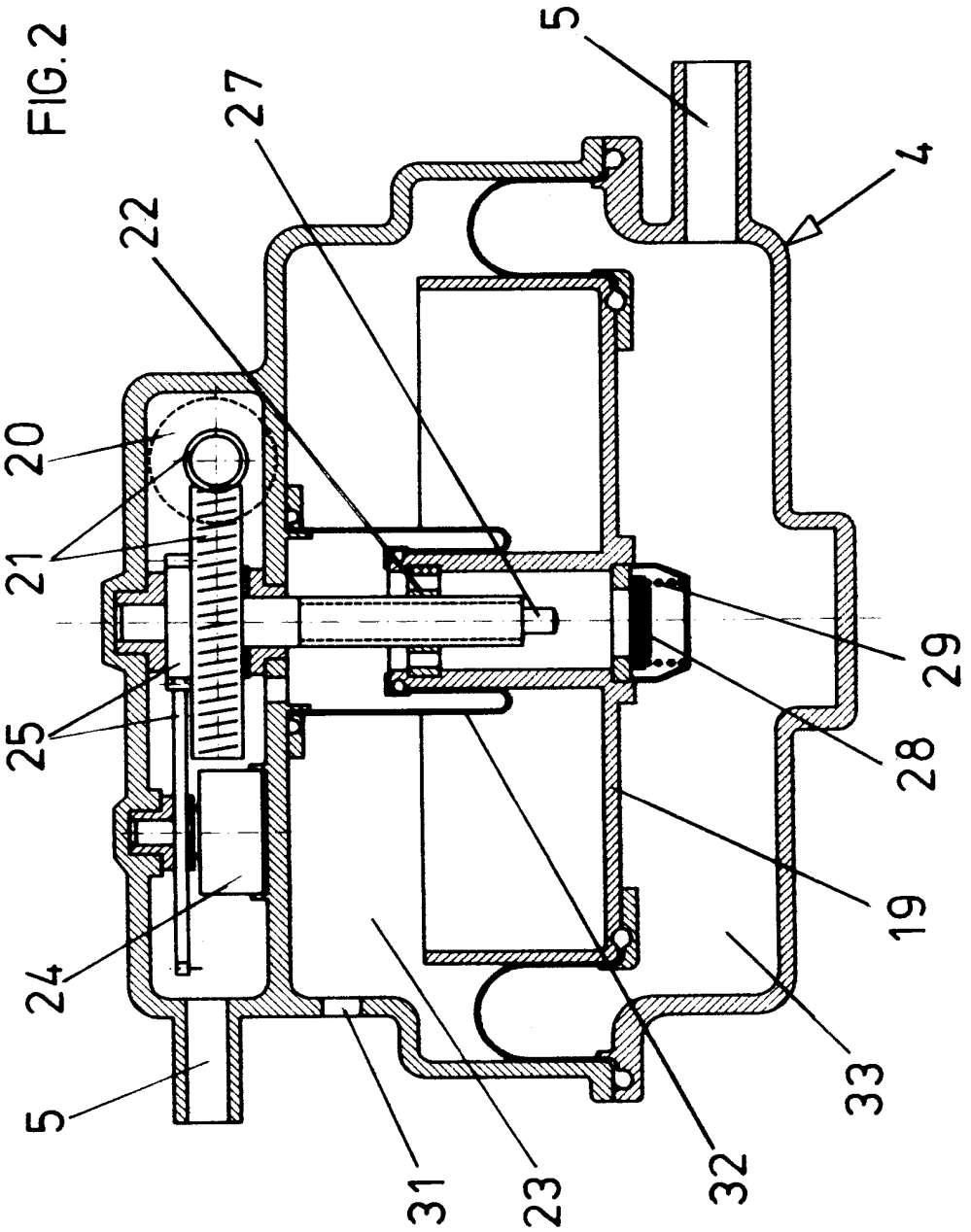


FIG.3

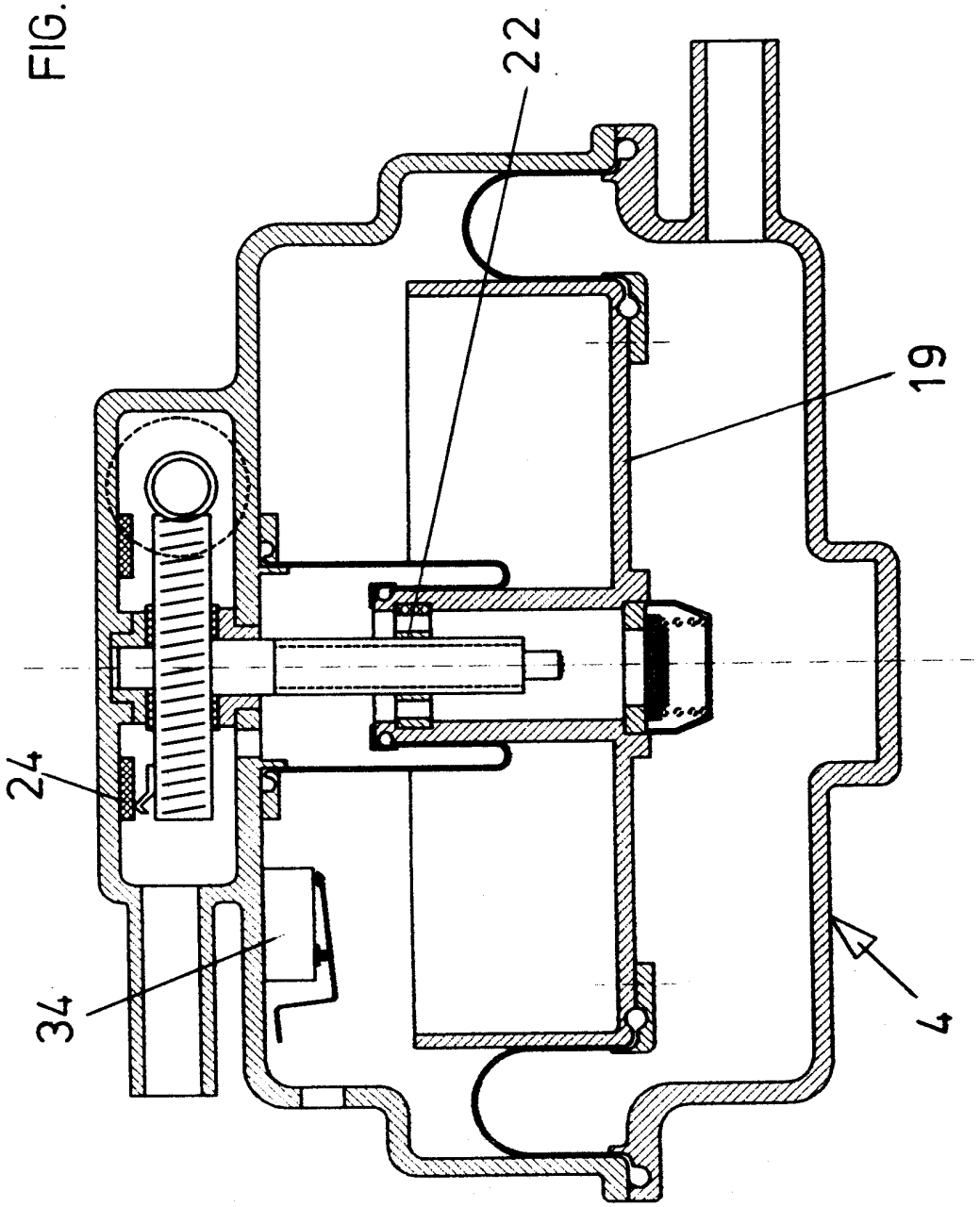
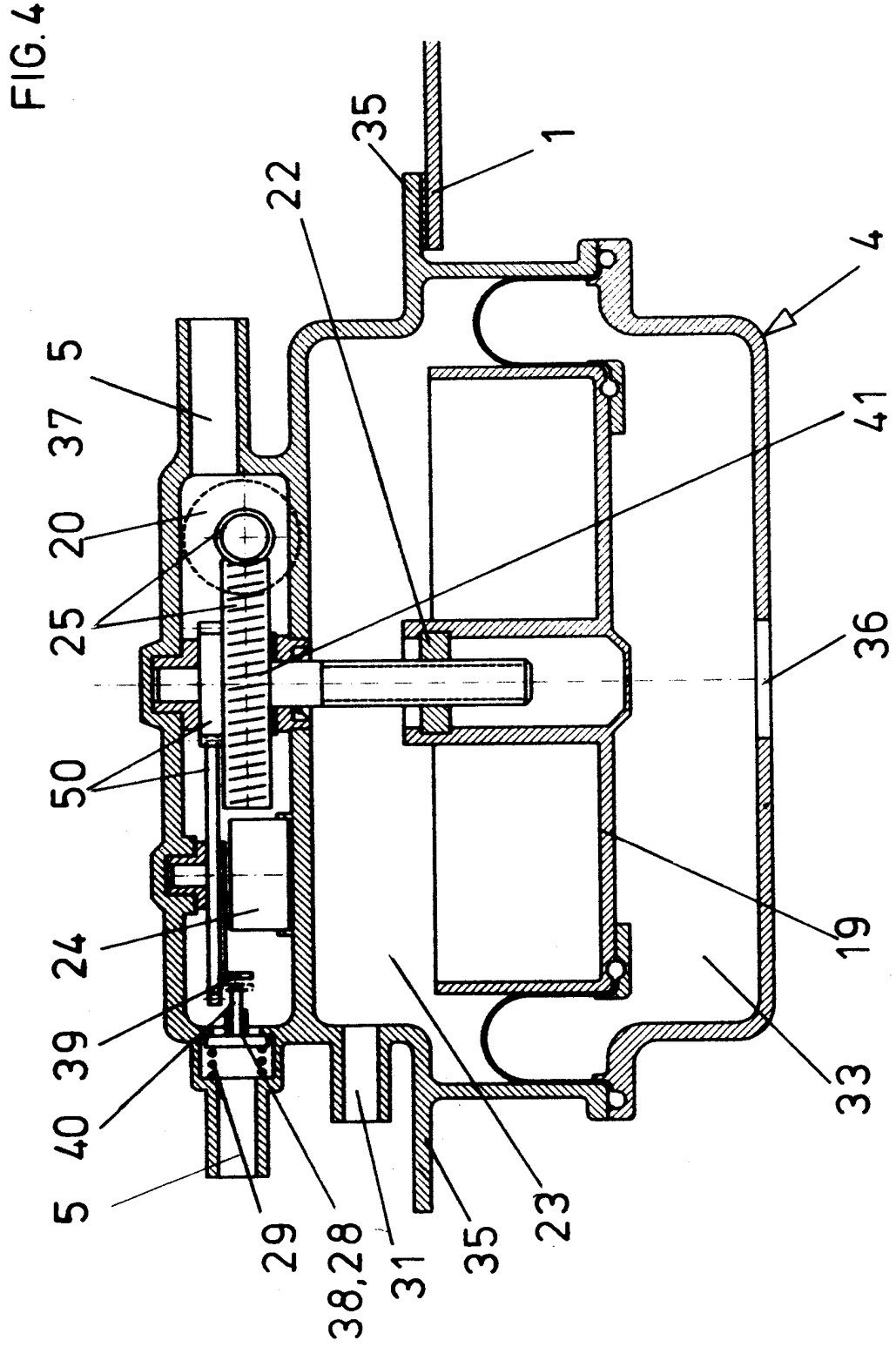


FIG.4



(19) Europäisches Patentamt
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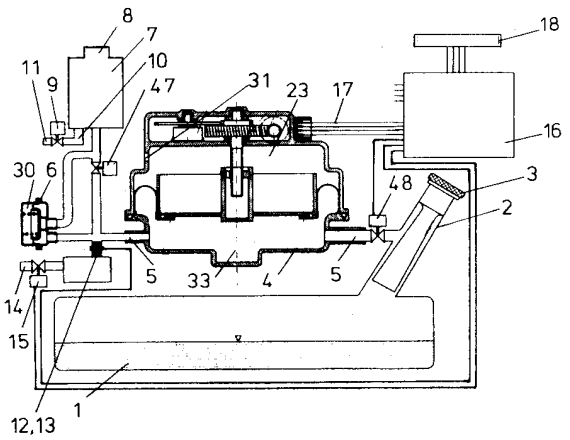
(54) **Vorrichtung zum Messen des Anteils flüssigen Brennstoffs in einem Tank.**

(57) 2.1
Bekannte Vorrichtungen, bei denen aus einem in den Tank gedrückten Volumen und der dabei auftretenden Druckänderung auf den Anteil flüssigen Brennstoffs geschlossen wird, sind nicht mehr zeitgemäß, bauraumaufwendig und nicht beliebig an den Tank anschließbar.

2.2
Die erfindungsgemäße Vorrichtung weist daher die Merkmale auf, daß die Membran (26) von einem Elektromotor (46) verstellt wird nach Maßgabe von Signalen eines elektronischen Steuergerätes (22), wobei zwischen Motor (46) und Membran (26) ein Untersetzungsgetriebe (47) und ein Spindeltrieb (48) angeordnet sind.

2.3
Diese Vorrichtung ermöglicht bei geringem Bauraum eine beliebige Anordnung am Tank und zusätzliche Diagnosen der Dichtheit des Tanks und/oder des Aktivkohlebehältersystems bzw. der Luftflowrate des Regenerierungssystems.

FIG.1



EP 0 503 280 A3

Rank Xerox (UK) Business Services

Europäisches Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung

EP 92 10 2126

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int. Cl.5)
A	GB-A-2 060 911 (BOSCH & PIERBURG SYSTEM OHG) * Zusammenfassung; Abbildungen 1-4 *	1	G01F17/00 G01F23/14
A	DE-A-3 913 096 (MOTO METER AG) * Zusammenfassung; Abbildung 1 *	1	

RECHERCHIERTE SACHGEBIETE (Int. Cl.5)

G01F

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
BERLIN	21 OKTOBER 1992	VORROPOULOS G.

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
O : nichtschriftliche Offenbarung
P : Zwischenliteratur

T : der Erfindung zugrunde liegende Theorien oder Grundsätze
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EPO FORM 1503 03.82 (P0403)

РОССИЙСКАЯ ФЕДЕРАЦИЯ

(19) **RU** (11) **2 344 380** (13) **C1**

(51) МПК
G01F 23/00 (2006.01)

ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ,
ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ

(12) ОПИСАНИЕ ИЗОБРЕТЕНИЯ К ПАТЕНТУ

(21), (22) Заявка: **2007117891/28, 14.05.2007**

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(56) Список документов, цитированных в отчете о поиске: **RU 2010174 C1, 30.03.1994. SU 1493877 A1, 15.07.1989. SU 1539447 A1, 30.01.1990. DE 19750620 A, 02.06.1999.**

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(54) СПОСОБ ИЗМЕРЕНИЯ ОБЪЕМА ЖИДКОСТИ В ЗАКРЫТОМ РЕЗЕРВУАРЕ

(57) Реферат:

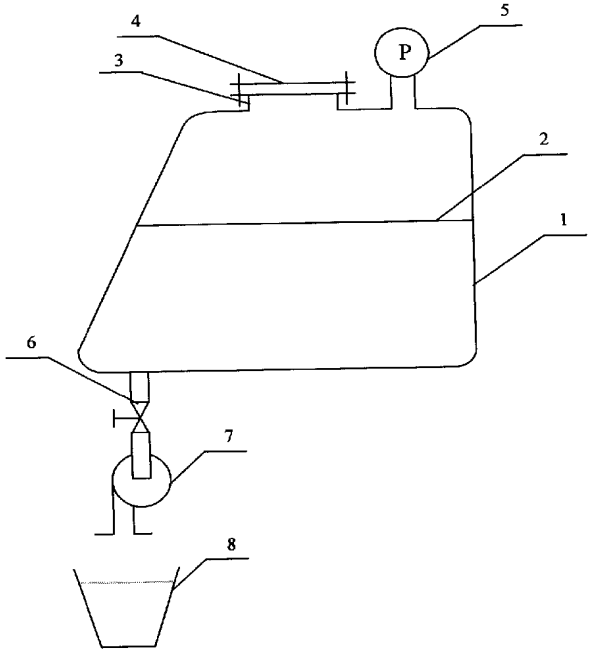
Изобретение относится к измерению уровня жидкости в колодцах, скважинах и герметичных емкостях и может найти применение в буровой технике, химической и нефтехимической промышленности и коммунальных службах. Техническим результатом является упрощение способа измерения объема жидкости в закрытом сосуде за счет уменьшения необходимых технологических операций, упрощение аппаратурного оформления и, как следствие, уменьшение затрат времени на проведение измерений. Способ измерения объема жидкости в закрытом резервуаре включает увеличение объема газа, находящегося над поверхностью жидкости, на известную величину ДУ и определение давления газа до и после увеличения объема газа. При этом увеличение объема газа проводят путем откачивания из закрытого резервуара объема жидкости, равного величине AV, измерения давлений газа над поверхностью жидкости до и после откачивания и объем жидкости в резервуаре определяют по формуле

$$V_0 = V - \frac{p_1}{p_0 - p_1} \cdot \Delta V,$$

где V_0, V - соответственно объем жидкости в закрытом резервуаре и общий объем резервуара, м^3;

ΔV - объем жидкости, откаченной из резервуара, м^3;

p_0 и p_1 - соответственно давление газа над поверхностью жидкости до и после откачивания жидкости объемом ΔV, Па (ат). 1 ил.



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RUSSIAN FEDERATION

(19) **RU** (11) **2 344 380** (13) **C1**

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G01F 23/00 (2006.01)

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PATENTS AND TRADEMARKS

(12) ABSTRACT OF INVENTION

(21), (22) Application: **2007117891/28, 14.05.2007**

(24) Effective date for property rights: **14.05.2007**

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(54) METHOD OF MEASURING VOLUME OF LIQUID IN CLOSED RESERVOIR

(57) Abstract:

FIELD: physics; measurement.

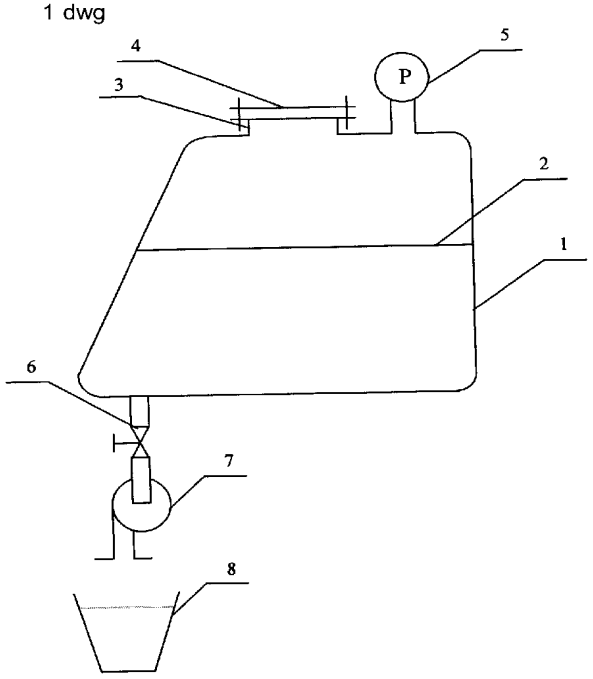
SUBSTANCE: present invention pertains to measurement of level of liquid in wells, bore holes and sealed containers and can be used in drilling technology, chemical and petrochemical industry and sanitary engineering. The method involves increasing volume of gas over the surface of the liquid, by a known value ΔV and determination of the pressure of gas before and after increasing the volume. The volume of gas is increased by pumping out a volume of liquid from the closed container equal to ΔV. Pressure of gas on the surface of the liquid is measured before and after pumping out the liquid and the volume of liquid in the container is calculated using formula

$$V_0 = V - \frac{p_1}{p_0 - p_1} \cdot \Delta V,$$

where V_0, V is the volume of liquid in the closed container and the total volume of the container respectively, in m^3, ΔV is the volume of liquid, pumped out of the container, in m^3, p_0 and p_1 is the pressure of gas on the surface of the liquid before and after pumping volume ΔV of liquid, respectively, in Pa (atm).

EFFECT: simplification of the method of measuring volume of liquid in a closed container due to less number of required operations, simplification of implementation, and consequently, shorter time spent on measuring.

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Предлагаемое техническое решение относится к измерению уровня жидкости в колодцах, скважинах и герметичных емкостях и может найти применение в буровой технике, химической и нефтехимической промышленности и коммунальных службах.

Известно устройство для измерения уровня жидкости, содержащее соединенный с преобразователем чувствительный элемент в корпусе, к которому герметично подсоединена полость противодавления с входным отверстием, при этом чувствительный элемент выполнен в виде диафрагмы, а полость противодавления представляет собой канал с разделителем в виде Г-образного колена, заполненный жидкостью или газом, вход в полость которого выполнен в нижнем конце колена (патент РФ №1493877, G01F 23/18, бюл. №26, 1989 г.).

К причинам, препятствующим достижению заданного технического результата, относится сложность конструкции, ее наладки и эксплуатации.

Известен способ определения уровня жидкости в закрытой емкости, который заключается в откачивании части воздуха над жидкостью вакуум-насосом с созданием определенного вакуума. Затем вакуум сбрасывается, и по времени восстановления атмосферного давления в емкости судят об уровне жидкости в ней (DE 19750620, B60K 15/06; G01F 17/00; G01F 20/14; B60K 15/03, 1999 г.).

К причинам, препятствующим достижению заданного технического результата, относится сложность оборудования для реализации известного способа, связанная с необходимостью установки вакуум-насоса и регистрационного прибора для определения времени выравнивания давления над жидкостью.

Наиболее близким техническим решением к заявляемому объекту и выбранным за прототип являются метод и способы для определения объемов жидкости в закрытом резервуаре или камере, общим объемом V, создание вакуума в газе над поверхностью жидкости путем увеличения объема этого газа за счет перемещения его части ΔV в другой мерный объем, определение объема газа над уровнем жидкости по формуле

$$V_1 = \frac{(p_1 / p_0) \cdot \Delta V}{1 - (p_1 / p_0)}, \qquad (1)$$

где V_1 - объем газа над уровнем жидкости;

p_0 и p_1 - соответственно абсолютные давления газа до и после создания вакуума над уровнем жидкости;

ΔV - мерный объем, в который перемещают часть газа при создании вакуума над уровнем жидкости;

При этом отношение давление p_1/p_0 определяется по формуле

$$\frac{p_1}{p_0} = \frac{m}{m + n}, \qquad (2)$$

где m и n - соответственно объемы цилиндров поршневого газового вакуум-насоса до создания вакуума и после его создания.

Окончательно объем жидкости в резервуаре рассчитывается по формуле

$$V_ж = V - V_1 \qquad (3)$$

(Патент Великобритании GB 341306, G01F 23/16, G01F 23/14, 1931 г.)

К причинам, препятствующим достижению заданного технического результата, относятся сложности измерений и промежуточных расчетов, а также аппаратурного оформления, включающего мерный сосуд для фиксации объема V, газовый поршневой вакуум-насос для фиксации объемов тип (формула 2), U-образный дифманометр и шкалу для измерения объема ΔV.

Техническим результатом предлагаемого технического решения является упрощение способа измерения объема жидкости в закрытом сосуде за счет уменьшения необходимых технологических операций, упрощения аппаратурного оформления и, как следствие, уменьшение затрат времени на проведение измерений.

Поставленный технический результат достигается тем, что в способе измерения объема жидкости в закрытом резервуаре, включающем увеличение объема газа, находящегося над

поверхностью жидкости, на известную величину ΔV и определение давления газа до и после увеличения объема газа, согласно изобретению увеличение объема газа проводят путем откачивания из закрытого резервуара объема жидкости, равного величине ΔV, измерения давление газа над поверхностью жидкости до и после откачивания и объем жидкости в резервуаре определяют по формуле

$$V_0 = V - \frac{p_1}{p_0 - p_1} \cdot \Delta V, \qquad (4)$$

где V_0, V - соответственно объем жидкости в закрытом резервуаре и общий объем резервуара, $м^3$;

ΔV - объем жидкости, откаченной из резервуара, $м^3$;

p_0 и p_1 - соответственно давление газа над поверхностью жидкости до и после откачивания жидкости объемом ΔV, Па (ат).

Откачивание из резервуара объема жидкости ΔV жидкостным насосом проще, чем откачивание такого же объема газа, находящегося над поверхностью жидкости, так как не требует использования специального герметического сосуда и поршневого вакуум-насоса для газа с фиксированными объемами m и n.

Кроме того, нет необходимости как в способе, выбранном за прототип, устанавливать герметично вспомогательный сосуд и всасывающий вакуум-насос. Обеспечить герметичность при отборе газа сложнее, чем при отборе жидкости, а значит утечки газа могут привести к потере точности измерения.

Если жидкость находится под давлением или давление равно атмосферному, то для слива из резервуара объема этой жидкости ΔV не нужен даже жидкостной насос. Измерение давления газа над поверхностью жидкости до и после откачивания ее объема ΔV несложно определить с помощью манометра.

Упрощается и процедура расчета объема жидкости в резервуаре, так как вместо использования трех формул (1-3) достаточно одной формулы (4). Все вышесказанное приводит к уменьшению затрат времени на измерение объема жидкости в резервуаре.

Схема установки для реализации предлагаемого способа измерения объема жидкости в закрытом резервуаре представлена на схеме.

Она состоит из закрытого резервуара 1 общим объемом V, в котором находится какое-то количество жидкости V_0, образующей уровень жидкости 2. Резервуар имеет сверху патрубок 3 для периодического налива жидкости. Патрубок 3 герметично закрыт крышкой 4. Сверху резервуара также установлен манометр 5 для измерения давления в газе (воздухе) над уровнем жидкости 3. В нижней части резервуара установлен патрубок с вентилем 6, к которому присоединен жидкостной насос 7. Для слива жидкости, откачиваемой жидкостным насосом 7 из резервуара 1, служит мерная емкость 8.

Реализацию предлагаемого способа измерения жидкости в закрытом резервуаре проводят следующим образом.

Измеряют давление газа в резервуаре 1 над уровнем жидкости 2 p_0, открывают вентиль 6, включают насос 7 и сливают из резервуара 1 в емкость 8 фиксированный объем жидкости ΔV.

Уровень жидкости 2 в резервуаре 1 уменьшается, а объем газа (воздуха) над жидкостью увеличивается на фиксированный объем жидкости ΔV.

Таким образом, если объем газа в резервуаре 1 увеличивается, то по закону Бойля-Мариотта давление уменьшится. Регистрируют манометром 5 давление p_1 в резервуаре 1 после слива фиксированного объема ΔV.

Тогда из закона Бойля-Мариотта следует

$p_0 \cdot (V - V_0) = p_1 \cdot [V - (V_0 - \Delta V)]$,

откуда объем жидкости в резервуаре 1 определяют по формуле (4).

Пример 1. Необходимо измерить объем жидкости V_0 в закрытом резервуаре, имеющим общий объем V=1 $м^3$. Давление газа в резервуаре, измеренное манометром 5, p_0=2 ат. Открывают вентиль 6 и сливают ΔV=10 л жидкости в мерную емкость 8. Измеряют

давление газа p_1=1,9 ат с помощью манометра в резервуаре после слива жидкости ΔV=10 л. Рассчитывают по формуле (4) объем жидкости в закрытом резервуаре 1

$$V_0 = 1000 - \left(\frac{1,9}{2-1,9}\right)\cdot 10 = 810 \text{ л.}$$

Пример 2. Необходимо измерить объем жидкости V_0 в закрытом резервуаре, имеющим общий объем V=2 м^3. Давление газа в резервуаре, измеренное манометром 5, p_0=1,033 ат (атмосферное давление). Открывают вентиль 6 и сливают часть жидкости ΔV=15 л в мерную емкость 8. Измеряют давление p_1=0,8 ат манометром 5 после слива части жидкости ΔV=15 л. Рассчитывают по формуле (4) объем жидкости в закрытом резервуаре 1

$$V_0 = 2000 - \left(\frac{0,8}{1,033-0,8}\right)\cdot 15 = 1948,6 \text{ л.}$$

Пример 3. Необходимо измерить объем жидкости V_0 в закрытом резервуаре 1, находящемся под землей и имеющим объем V=10 м^3. Давление газа в резервуаре, измеренное манометром 5, p_0=1,1 ат (небольшое избыточное давление). Открывают вентиль 6 и сливают часть жидкости ΔV=50 л в мерную емкость 8. Измеряют давление p_1=1,05 ат манометром 5 после слива части жидкости ΔV=50 л. Рассчитывают по формуле (4) объем жидкости в закрытом резервуаре 1

$$V_0 = 1000 - \left(\frac{1,05}{1,1-1,05}\right)\cdot 50 = 8950 \text{ л}$$

Таким образом, предлагаемый способ измерения объема жидкости в закрытом резервуаре позволяет определять объем жидкости в нем без применения специальных электрических или пневматических датчиков и уровнемеров в емкостях любой формы, находящихся под землей или на эстакадах, этажерках и других местах, труднодоступных для измерения. Он прост по приборному, аппаратурному и технологическому исполнению, так как требует для реализации только манометра, мерной емкости и жидкостного насоса для откачивания небольшой части жидкости из резервуара. Если в закрытом резервуаре жидкость находится под избыточным давлением, то для слива ее части ΔV не нужен даже жидкостной насос. Как видно из приведенных примеров 1-3, предлагаемый способ измерения объема жидкости в закрытом резервуаре не только прост по технологическим операциям и расчетам, но и по сравнению со способом, принятым за прототип, уменьшает затраты времени на технологических операциях и расчетах, то есть увеличивает скорость измерения. Кроме того, способ безопасен в технологическом исполнении и не требует высокой квалификации работающего персонала.

Формула изобретения

Способ измерения объема жидкости в закрытом резервуаре, включающий увеличение объема газа, находящегося над поверхностью жидкости, на известную величину ΔV и определение давления газа до и после увеличения объема газа, отличающийся тем, что увеличение объема газа проводят путем откачивания из закрытого резервуара объема жидкости, равного величине ΔV, измерение давления газа над поверхностью жидкости до и после откачивания и объем жидкости в резервуаре определяют по формуле:

$$V_0 = V - \frac{p_1}{p_0 - p_1}\cdot \Delta V,$$

где V_0 и V - соответственно объем жидкости в закрытом резервуаре и общий объем резервуара, м^3;

ΔV - объем жидкости, откаченной из резервуара, м^3;

p_0 и p_1 - соответственно давление газа над поверхностью жидкости до и после откачивания жидкости объемом ΔV, Па (ат).

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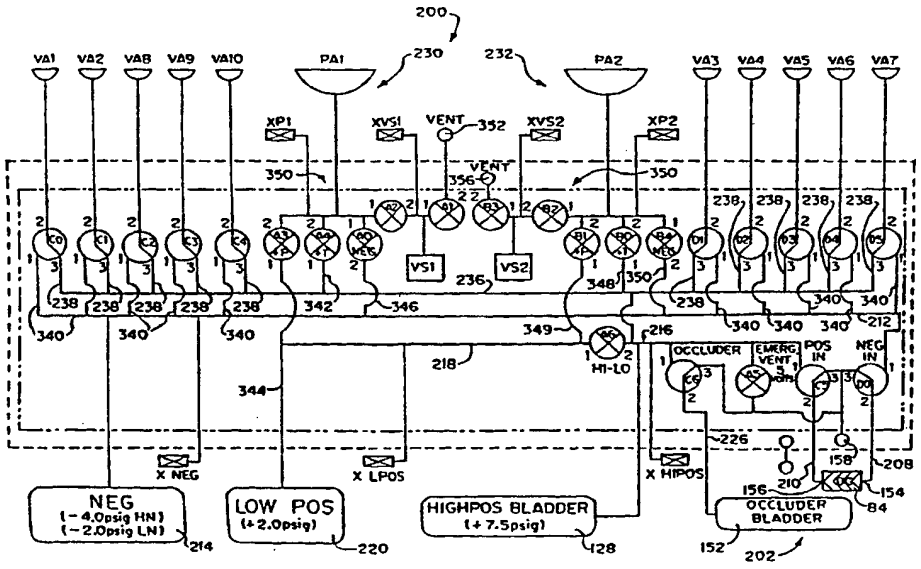
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(57) **Abstract**

Peritoneal dialysis systems and methods move liquid using a pump chamber (P1, P2) that is operated in response to pneumatic pressure variations applied by a pump actuator (PA1, PA2). The systems and methods periodically measure air pressures in the actuator (PA1, PA2) and an associated reference air chamber (VS1, VS2) and derive from these a measurement of liquid volume moved through the pump chamber (P1, P2). The systems and methods minimize derivation errors by compensating for temperature differences among the pump chamber (P1, P2); the pump actuator (PA1, PA2); and the reference chamber (VS1, VS2).

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Peritoneal dialysis system.

Field of the Invention

This invention relates to systems and methods for performing peritoneal dialysis.

Background of the Invention

Peritoneal Dialysis (PD) periodically infuses sterile aqueous solution into the peritoneal cavity. This solution is called peritoneal dialysis solution, or dialysate. Diffusion and osmosis exchanges take place between the solution and the bloodstream across the natural body membranes. These exchanges remove the waste products that the kidneys normally excrete. The waste products typically consist of solutes like sodium and chloride ions, and the other compounds normally excreted through the kidneys like urea, creatinine, and water. The diffusion of water across the peritoneal membrane during dialysis is called ultrafiltration.

Conventional peritoneal dialysis solutions include dextrose in concentrations sufficient to generate the necessary osmotic pressure to remove water from the patient through ultrafiltration.

Continuous Ambulatory Peritoneal Dialysis (CAPD) is a popular form of PD. A patient performs CAPD manually about four times a day. During CAPD, the patient drains spent peritoneal dialysis

solution from his/her peritoneal cavity. The patient then infuses fresh peritoneal dialysis solution into his/her peritoneal cavity. This drain and fill procedure usually takes about 1 hour.

Automated Peritoneal Dialysis (APD) is another popular form of PD. APD uses a machine, called a cycler, to automatically infuse, dwell, and drain peritoneal dialysis solution to and from the patient's peritoneal cavity. APD is particularly attractive to a PD patient, because it can be performed at night while the patient is asleep. This frees the patient from the day-to-day demands of CAPD during his/her waking and working hours.

The APD sequence typically last for several hours. It often begins with an initial drain cycle to empty the peritoneal cavity of spent dialysate. The APD sequence then proceeds through a succession of fill, dwell, and drain phases that follow one after the other. Each fill/dwell/drain sequence is called a cycle.

During the fill phase, the cycler transfers a predetermined volume of fresh, warmed dialysate into the peritoneal cavity of the patient. The dialysate remains (or "dwells") within the peritoneal cavity for a time. This is called the dwell phase. During the drain phase, the cycler removes the spent dialysate from the peritoneal cavity.

The number of fill/dwell/drain cycles that are required during a given APD session depends upon the total volume of dialysate prescribed for the patient's APD regime.

APD can be and is practiced in different ways.

Continuous Cycling Peritoneal Dialysis

(CCPD) is one commonly used APD modality. During each fill/dwell/drain phase of CCPD, the cycler infuses a prescribed volume of dialysate. After a prescribed dwell period, the cycler completely drains this liquid volume from the patient, leaving the peritoneal cavity empty, or "dry." Typically, CCPD employs 6 fill/dwell/drain cycles to achieve a prescribed therapy volume.

After the last prescribed fill/dwell/drain cycle in CCPD, the cycler infuses a final fill volume. The final fill volume dwells in the patient through the day. It is drained at the outset of the next CCPD session in the evening. The final fill volume can contain a different concentration of dextrose than the fill volume of the successive CCPD fill/dwell/drain fill cycles the cycler provides.

Intermittent Peritoneal Dialysis (IPD) is another APD modality. IPD is typically used in acute situations, when a patient suddenly enters dialysis therapy. IPD can also be used when a patient requires PD, but cannot undertake the responsibilities of CAPD or otherwise do it at home.

Like CCPD, IPD involves a series of fill/dwell/drain cycles. The cycles in IPD are typically closer in time than in CCPD. In addition, unlike CCPD, IPD does not include a final fill phase. In IPD, the patient's peritoneal cavity is left free of dialysate (or "dry") in between APD therapy sessions.

Tidal Peritoneal Dialysis (TPD) is another APD modality. Like CCPD, TPD includes a series of fill/dwell/drain cycles. Unlike CCPD, TPD does not completely drain dialysate from the peritoneal cavity during each drain phase. Instead, TPD establishes a base volume during the first fill phase and

drains only a portion of this volume during the first drain phase. Subsequent fill/dwell/drain cycles infuse then drain a replacement volume on top of the base volume, except for the last drain phase. The last drain phase removes all dialysate from the peritoneal cavity.

There is a variation of TPD that includes cycles during which the patient is completely drained and infused with a new full base volume of dialysis.

TPD can include a final fill cycle, like CCPD. Alternatively, TPD can avoid the final fill cycle, like IPD.

APD offers flexibility and quality of life enhancements to a person requiring dialysis. APD can free the patient from the fatigue and inconvenience that the day to day practice of CAPD represents to some individuals. APD can give back to the patient his or her waking and working hours free of the need to conduct dialysis exchanges.

Still, the complexity and size of past machines and associated disposables for various APD modalities have dampened widespread patient acceptance of APD as an alternative to manual peritoneal dialysis methods.

Summary of the Invention

The invention provides improved systems and methods for performing peritoneal dialysis and the like.

The systems and methods move liquid through a pump chamber that is operated in response to pneumatic pressure variations applied by a pump actuator. The systems and methods periodically measure air pressures in the actuator and an associated reference air chamber and derive from

these a measurement of liquid volume moved through the pump chamber. The systems and methods minimize derivation errors by compensating for temperature differences among the pump chamber; the pump actuator; and the reference chamber.

According to one aspect of the invention, the systems and methods compensate for temperature differences by mounting the pump actuator and reference chamber as close to the pump chamber as possible.

In a preferred embodiment, a peritoneal dialysis system comprises a liquid distribution cassette. The cassette has a pumping mechanism comprising a diaphragm associated with a pump chamber that communicates with the patient's peritoneal cavity.

The system that embodies this aspect of the invention also includes an operating station for the cassette. The operating station contains a holder that retains the cassette. The operating chamber also includes a pressure transfer element that applies pneumatic pressure to the diaphragm within the holder to draw liquid into the pump chamber and to expel liquid from the pump chamber.

The system includes a first mechanism that derives an initial air volume measurement V_i after conveying pneumatic pressure to draw liquid into the pump chamber. The first mechanism also derives a final air volume measurement V_f after conveying pneumatic pressure to expel liquid from the pump chamber.

The first mechanism includes a reference chamber having a known volume V_s that is carried within the holder. Like the pressure transfer element, the reference chamber is exposed to

generally the same temperature conditions as the pumping mechanism itself.

The first mechanism controls communication between the reference chamber and the pressure transfer element when liquid is drawn into the pump chamber and liquid is expelled from the pump chamber, as follows:

(i) closing communication between reference chamber and the pressure transfer means to initialize the reference chamber to a measured initial air pressure (IP_{s1}), while conveying a measured pressure to the pressure transfer element (IP_{d1});

(ii) then opening communication between the reference chamber and the pressure transfer element to allow pressure equilibration at a measured new air pressure in the pressure transfer element (IP_{d2}) and a measured new air pressure in the reference chamber (IP_{s2}); and

(iii) then deriving the air volume measurement V^i or V^f as follows:

$$V^{i \text{ or } f} = \frac{(IP_{s1} - IP_{s2}) * V_s}{(IP_{d2} - IP_{d1})}$$

The system also includes a second mechanism that derives a measurement of liquid volume delivered (V_d) by the pumping chamber as follows:

$$V_d = V_f - V_i.$$

In a preferred embodiment, the reference chamber carries within it an insert for dampening pneumatic pressure. The insert is preferably made of an open cell porous material. The insert preferably includes a heat conducting material.

According to another aspect of the invention, the systems and methods account for temperature differences among the pumping chamber;

actuator; and reference chamber by applying a temperature correction factor (F_t) to the air volume of the reference chamber V_s to derive a temperature-corrected reference air volume V_{st}, as follows:

$$V_{st} = F_t * V_s$$

where:

$$F_t = \frac{C_t}{R_t}$$

and where:

C_t is the absolute temperature of the cassette (expressed in degrees Rankine or Kelvin), and

R_t is the temperature of the reference chamber (expressed in the same units as C_t).

In a preferred embodiment, the systems and methods draw a volume of liquid to be pumped into the pumping chamber by applying negative pressure to the pump actuator. An initial air volume V_i is derived by:

(i) retaining the initial liquid volume in the pumping chamber;

(ii) initializing a reference chamber having a known air volume V_s to a measured initial air pressure (IP_{si}), the reference chamber being first isolated from the pump actuator;

(iii) applying the temperature correction factor (F_t) to the known air volume of the reference chamber V_s to derive a temperature-corrected reference air volume V_{st};

(iv) applying positive pressure to the pump actuator and measuring this air pressure (IP_{di});

(v) opening communication with the reference chamber to allow pressure equilibration and measuring the new air pressure in the pump

actuator (IP_{d2}) and the new air pressure in the reference chamber (IP_{s2}); and

(vi) calculating V_i as follows:

$$V_i = \frac{(IP_{s1} - IP_{s2}) * V_{st}}{(IP_{d2} - IP_{d1})}.$$

In this preferred embodiment, the systems and methods then expel the volume of liquid from the pumping chamber by applying positive pressure to the pump actuator. A final air volume V_f is derived by:

(i) retaining the final liquid volume in the pumping chamber;

(ii) again initializing the reference chamber a measured initial air pressure (FP_{s1}), having first isolated the reference chamber from the pump actuator chamber;

(iii) again applying positive pressure to the pump actuator and measuring this air pressure (FP_{d1});

(iv) again opening communication with the reference chamber to allow equilibration and measuring the new air pressure in the pump actuator (FP_{d2}) and the new air pressure in the reference chamber (FP_{s2}); and

(v) calculating V_i as follows:

$$V_i = \frac{(FP_{s1} - FP_{s2}) * V_{st}}{(FP_{d2} - FP_{d1})}.$$

Based upon the foregoing air volume derivations, the systems and methods that embody this aspect of the invention derive the liquid volume delivered (V_d) as follows:

$$V_d = V_f - V_i.$$

In one embodiment, the temperature correction factor F_t is calculated as follows:

$$F_t = \frac{C_t}{R_t}$$

where:

C_t is the sensed absolute temperature of the pumping chamber (expressed in degrees Rankine or Kelvin), and

R_t is the sensed temperature of the reference chamber (expressed in the same units as C_t).

Other features and advantages of the inventions are set forth in the following specification and attached drawings.

Brief Description of the Drawings

Fig. 1 is a perspective view an automated peritoneal dialysis system that embodies the features of the invention, with the associated disposable liquid delivery set ready for use with the associated cycler;

Fig. 2 is a perspective view of the cycler associated with the system shown in Fig. 1, out of association with the disposable liquid delivery set;

Fig. 3 is a perspective view of the disposable liquid delivery set and attached cassette that are associated with the system shown in Fig. 1;

Figs. 4 and 5 are perspective views of the organizer that is associated with the set shown in Fig. 3 in the process of being mounted on the cycler;

Figs. 6 and 7 are perspective views of loading the disposable cassette attached to the set shown in Fig. 3 into the cycler for use;

Fig. 8 is an exploded perspective view of one side of the cassette attached to the disposable set shown in Fig. 3;

Fig. 8A is a plan view of the one side of the cassette shown in Fig. 8, showing the liquid paths within the cassette;

Fig. 8B is a plan view of the other side of

the cassette shown in Fig. 8, showing the pump chambers and valve stations within the cassette;

Fig. 8C is an enlarged side section view of a typical cassette valve station shown in Fig. 8B;

Fig. 9 is perspective view of the cycle shown in Fig. 2 with its housing removed to show its interior;

Fig. 10 is an exploded perspective view showing the main operating modules housed within the interior of the cycler;

Fig. 11 is an enlarged perspective view of the cassette holder module housed within the cycler;

Figs. 12A and 12B are exploded views of the cassette holder module shown in Fig. 11;

Fig. 13 is a perspective view of the operative front side of the fluid pressure piston housed within the cassette module shown in Fig. 11;

Fig. 14A is a perspective view of the back side of the fluid pressure piston shown in Fig. 13;

Fig. 14B is a perspective view of an alternative, preferred embodiment of a fluid pressure piston that can be used with the system shown in Fig. 1;

Figs. 15A and 15B are top sectional views taken generally along line 15A-15A in Fig. 11, showing the interaction between the pressure plate assembly and the fluid pressure piston within the module shown in Fig. 11, with Fig. 15A showing the pressure plate holding the piston in an at rest position and Fig. 15B showing the pressure plate holding the piston in an operative position against the cassette;

Figs. 16A and 16B are side sectional view of the operation of the occluder assembly housed within the module shown in Fig. 11, with Fig. 16A

showing the occluder assembly in a position allowing liquid flow and Fig. 16B showing the occluder assembly in a position blocking liquid flow;

Fig. 17 is a perspective view of the fluid pressure manifold module housed within the cycler;

Fig. 18 is an exploded perspective view of interior of the fluid pressure manifold module shown in Fig. 17;

Fig. 19 is an exploded perspective view of the manifold assembly housed within the module shown in Fig. 18;

Fig. 20 is a plan view of the interior of the base plate of the manifold assembly shown in Fig. 19, showing the paired air ports and air conduction pathways formed therein;

Fig. 21 is a plan view of the outside of the base plate of the manifold assembly shown in Fig. 19, also showing the paired air ports;

Fig. 22 is an exploded perspective view of the attachment of a pneumatic valve on the outside of the base plate of the manifold assembly shown in Fig. 19, in registry over a pair of air ports;

Fig. 23 is a schematic view of the pressure supply system associated with the air regulation system that the manifold assembly shown in Fig. 19 defines;

Fig. 24 is a schematic view of the entire air regulation system that the manifold assembly shown in Fig. 19 defines;

Fig. 25 is a flow chart showing the operation of the main menu and ultrafiltration review interfaces that the controller for the cycler shown in Fig. 1 employs;

Fig. 26 is a flow chart showing the operation of the therapy selection interfaces that

the controller for the cycler shown in Fig. 1 employs;

Fig. 27 is a flow chart showing the operation of the set up interfaces that the controller for the cycler shown in Fig. 1 employs;

Fig. 28 is a flow chart showing the operation of the run time interfaces that the controller for the cycler shown in Fig. 1 employs;

Fig. 29 is a flow chart showing the operation of the background monitoring that the controller for the cycler shown in Fig. 1 employs;

Fig. 30 is a flow chart showing the operation of the alarm routines that the controller for the cycler shown in Fig. 1 employs;

Fig. 31 is a flow chart showing the operation of the post therapy interfaces that the controller for the cycler shown in Fig. 1 employs;

Fig. 32 is a diagrammatic representation of sequence of liquid flow through the cassette governed by the cycler controller during a typical fill phase of an APD procedure;

Fig. 33 is a diagrammatic representation of sequence of liquid flow through the cassette governed by the cycler controller during a dwell phase (replenish heater bag) of an APD procedure;

Fig. 34 is a diagrammatic representation of sequence of liquid flow through the cassette governed by the cycler controller during a drain phase of an APD procedure; and

Fig. 35 is a diagrammatic representation of sequence of liquid flow through the cassette governed by the cycler controller during a last dwell of an APD procedure.

The invention may be embodied in several forms without departing from its spirit or essential

characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

Description of the Preferred Embodiments

Fig. 1 shows an automated peritoneal dialysis system 10 that embodies the features of the invention. The system 10 includes three principal components. These are a liquid supply and delivery set 12; a cycler 14 that interacts with the delivery set 12 to pump liquid through it; and a controller 16 that governs the interaction to perform a selected APD procedure. In the illustrated and preferred embodiment, the cycler and controller are located within a common housing 82.

The cycler 14 is intended to be a durable item capable of long term, maintenance free use. As Fig. 2 shows, the cycler 14 also presents a compact footprint, suited for operation upon a table top or other relatively small surface normally found in the home. The cycler 14 is also lightweight and portable.

The set 12 is intended to be a single use, disposable item. The user loads the set 12 on the cycler 14 before beginning each APD therapy session. The user removes the set 12 from the cycler 14 upon the completing the therapy session and discards it.

In use (as Fig. 1 shows), the user connects the set 12 to his/her indwelling peritoneal catheter 18. The user also connects the set 12 to individual bags 20 containing sterile peritoneal dialysis solution for infusion. The set 12 also connects to a bag 22 in which the dialysis solution is heated to

a desired temperature (typically to about 37 degrees C) before infusion.

The controller 16 paces the cycler 14 through a prescribed series of fill, dwell, and drain cycles typical of an APD procedure.

During the fill phase, the cycler 14 infuses the heated dialysate through the set 12 and into the patient's peritoneal cavity. Following the dwell phase, the cycler 14 institutes a drain phase, during which the cycler 14 discharges spent dialysis solution from the patient's peritoneal cavity through the set into a nearby drain (not shown).

As Fig. 1 shows, the cycler 14 does not require hangers for suspending the source solution bags 20 at a prescribed head height above it. This is because the cycler 14 is not a gravity flow system. Instead, using quiet, reliable pneumatic pumping action, the cycler 14 emulates gravity flow, even when the source solution bags 20 lie right alongside it, or in any other mutual orientation.

The cycler 14 can emulate a fixed head height during a given procedure. Alternatively, the cycler 14 can change the head height to either increase or decrease the rate of flow during a procedure. The cycler 14 can emulate one or more selected head height differentials regardless of the actual head height differential existing between the patient's peritoneal cavity and the external liquid sources or destinations.

Because the cycler 14 establishes essentially an artificial head height, it has the flexibility to interact with and adapt quickly to the particular physiology and relative elevation of the patient.

The compact nature and silent, reliable op-

erating characteristics of the cycler 14 make it ideally suited for bedside use at home while the patient is asleep.

The principal system components will now be individually discussed in greater detail.

I. THE DISPOSABLE SET

As Fig. 3 best shows, the set 12 includes a cassette 24 to which lengths of flexible plastic tubes 26/28/30/32/34 are attached.

Fig. 3 shows the disposable liquid supply and delivery set 12 before it is readied for use in association with the cycler 14. Fig. 1 shows the disposable set 12 when readied for use in association with the cycler 14.

In use (as Fig. 1 shows), the distal ends of the tubes 26 to 34 connect outside the cycler 14 to the bags 20 of fresh peritoneal dialysis solution, to the liquid heater bag 22, to the patient's indwelling catheter 18, and to a drain (not shown).

For this reason, the tube 34 carries a conventional connector 36 for attachment to the patient's indwelling catheter 18. Other tubes 26/30/32 carry conventional connectors 38 for attachment to bag ports. Tube 32 contains a Y-connector 31, creating tubing branches 32A and 32B, each of which may connect to a bag 20.

The set 12 may contain multiple branches to accommodate attachment to multiple bags 20 of dialysis solution.

The tube 28 has a drain connector 39. It serves to discharge liquid into the external drain (not shown).

The tubing attached to the set carries an inline, manual clamp 40, except the drain tube 28.

As Figs. 1 and 3 show, the set 12 also preferably includes a branch connector 54 on the drain tube 28. The branch connector 54 creates a tubing branch 28A that carries a connector 55. The connector 55 attaches to a mating connector on an effluent inspection bag (not shown).

Once attached, the patient can divert a volume (about 25 ml) of spent dialysate through branch 28A into the inspection bag during the first drain cycle. The bag allows the patient to inspect for cloudy effluent, which is an indication of peritonitis.

As Figs. 6 and 7 show, in use, the cassette 24 mounts inside a holder 100 in the cycler 14 (see Fig. 1, too). The details of the holder 100 will be discussed in greater detail later. The holder 100 orients the cassette 24 for use vertically, as Fig. 7 shows.

As Figs. 3 to 5 show, the set 12 preferably includes an organizer 42 that holds the distal tube ends in a neat, compact array. This simplifies handling and shortens the set up time.

The organizer 42 includes a body with a series of slotted holders 44. The slotted holders 44 receive the distal tube ends with a friction fit.

The organizer 42 includes slot 46 that mates with a tab 48 carried on outside of the cassette holder 100. A pin 50 on the outside of the cassette holder 100 also mates with an opening 52 on the organizer 42. These attach the organizer 42 and attached tube ends to the outside of the cassette holder 100 (as Figs 1 and 5 show).

Once attached, the organizer 42 frees the user's hands for making the required connections with the other elements of the cycler 14. Having

made the required connections, the user can remove and discard the organizer 42.

The cassette 24 serves in association with the cycler 14 and the controller 16 to direct liquid flow among the multiple liquid sources and destinations that a typical APD procedure requires. As will be described in greater detail later, the cassette 24 provides centralized valving and pumping functions in carrying out the selected APD therapy.

Figs. 8/8A/8B show the details of the cassette 24. As Fig. 8 shows, the cassette 24 includes an injection molded body having front and back sides 58 and 60. For the purposes of description, the front side 58 is the side of the cassette 24 that, when the cassette 24 is mounted in the holder 100, faces away from the user.

A flexible diaphragm 59 and 61 overlies the front side and back sides 58 and 60 of the cassette 24, respectively.

The cassette 24 is preferably made of a rigid medical grade plastic material. The diaphragms 59/61 are preferably made of flexible sheets of medical grade plastic. The diaphragms 59/61 are sealed about their peripheries to the peripheral edges of the front and back sides 58/60 of the cassette 24.

The cassette 24 forms an array of interior cavities in the shapes of wells and channels. The interior cavities create multiple pump chambers P1 and P2 (visible from the front side 58 of the cassette 24, as Fig. 8B shows). The interior cavities also create multiple paths F1 to F9 to convey liquid (visible from the back side 60 of the cassette 24, as Figs. 8 and 8A shows). The interior cavities also create multiple valve stations V1 to

V10 (visible from the front side 58 of the cassette 24, as Fig. 8B shows). The valve stations V1 to V10 interconnect the multiple liquid paths F1 to F9 with the pump chambers P1 and P2 and with each other.

The number and arrangement of the pump chambers, liquid paths, and valve stations can vary.

A typical APD therapy session usually requires five liquid sources/destinations. The cassette 24 that embodies the features of the invention provides these connections with five exterior liquid lines (i.e., the flexible tubes 26 to 32), two pump chambers P1 and P2, nine interior liquid paths F1 to F9, and ten valve stations V1 to V10.

The two pump chambers P1 and P2 are formed as wells that open on the front side 58 of the cassette 24. Upstanding edges 62 peripherally surround the open wells of the pump chambers P1 and P2 on the front side 58 of the cassette 24 (see Fig. 8B).

The wells forming the pump chambers P1 and P2 are closed on the back side 60 of the cassette 24 (see Fig. 8), except that each pump chamber P1 and P2 includes a vertically spaced pair of through holes or ports 64/66 that extend through to the back side 60 of the cassette 24.

As Figs. 8/8A/8B show, vertically spaced ports 64(1) and 66(1) are associated with pump chamber P1. Port 64(1) communicates with liquid path F6, while port 66(1) communicates with liquid path F8.

As Figs. 8/8A/8B also show, vertically spaced ports 64(2) and 66(2) are associated with pump chamber P2. Port 64(2) communicates with liquid path F7, while port 66(2) communicates with liquid path F9.

As will become apparent, either port 64(1)/(2) or 66(1)/(2) can serve its associated chamber P1/P2

as an inlet or an outlet. Alternatively, liquid can be brought into and discharged out of the chamber P1/P2 through the same port associated 64(1)/(2) or 66(1)/(2).

In the illustrated and preferred embodiment, the ports 64/66 are spaced so that, when the cassette 24 is oriented vertically for use, one port 64(1)/(2) is located higher than the other port 66(1)/(2) associated with that pump chamber P1/P2. As will be described in greater detail later, this orientation provides an important air removal function.

The ten valve stations V1 to V10 are likewise formed as wells open on the front side 58 of the cassette 24. Fig. 8C shows a typical valve station V_N. As Fig. 8C best shows, upstanding edges 62 peripherally surround the open wells of the valve stations V1 to V10 on the front side 58 of the cassette 24.

As Fig. 8C best shows, the valve stations V1 to V10 are closed on the back side 60 of the cassette 24, except that each valve station V_N includes a pair of through holes or ports 68 and 68'. One port 68 communicates with a selected liquid path F_N on the back side 60 of the cassette 24. The other port 68' communicates with another selected liquid path $F_{N'}$ on the back side 60 of the cassette 24.

In each valve station V_N, a raised valve seat 72 surrounds one of the ports 68. As Fig. 8C best shows, the valve seat 72 terminates lower than the surrounding peripheral edges 62. The other port 68' is flush with the front side 58 of the cassette.

As Fig. 8C continues to show best, the flexible diaphragm 59 overlying the front side 58 of the cassette 24 rests against the upstanding peripheral

edges 62 surrounding the pump chambers and valve stations. With the application of positive force uniformly against this side 58 of the cassette 24 (as shown by the f-arrows in Fig. 8C), the flexible diaphragm 59 seats against the upstanding edges 62. The positive force forms peripheral seals about the pump chambers P1 and P2 and valve stations V1 to V10. This, in turn, isolates the pump chambers P1 and P2 and valve stations V1 to V10 from each other and the rest of the system. The cycler 14 applies positive force to the front cassette side 58 for this very purpose.

Further localized application of positive and negative fluid pressures upon the regions of the diaphragm 59 overlying these peripherally sealed areas serve to flex the diaphragm regions within these peripherally sealed areas.

These localized applications of positive and negative fluid pressures on the diaphragm regions overlying the pump chambers P1 and P2 serve to move liquid out of and into the chambers P1 and P2.

Likewise, these localized applications of positive and negative fluid pressure on the diaphragm regions overlying the valve stations V1 to V10 will serve to seat and unseat these diaphragm regions against the valve seats 72, thereby closing and opening the associated valve port 68. Fig. 8C shows in solid and phantom lines the flexing of the diaphragm 59 relative to a valve seat 72.

In operation, the cycler 14 applies localized positive and negative fluid pressures to the diaphragm 59 for opening and closing the valve ports.

The liquid paths F1 to F9 are formed as elongated channels that are open on the back side 60 of

the cassette 24. Upstanding edges 62 peripherally surround the open channels on the back side 60 of the cassette 24.

The liquid paths F1 to F9 are closed on the front side 58 of the cassette 24, except where the channels cross over valve station ports 68/68'or pump chamber ports 64(1)/(2) and 66(1)/(2).

The flexible diaphragm 61 overlying the back side 60 of the cassette 24 rests against the upstanding peripheral edges 62 surrounding the liquid paths F1 to F9. With the application of positive force uniformly against this side 60 of the cassette 24, the flexible diaphragm 61 seats against the upstanding edges 62. This forms peripheral seals along the liquid paths F1 to F9. In operation, the cycler 14 also applies positive force to the diaphragm 61 for this very purpose.

As Figs. 8/8A/8B show, five premolded tube connectors 27/29/31/33/35 extend out along one side edge of the cassette 24. When the cassette 24 is vertically oriented for use, the tube connectors 27 to 35 are vertically stacked one above the other. The first tube connector 27 is the uppermost connector, and the fifth tube connector 35 is the lowermost connector.

This ordered orientation of the tube connectors 27 to 35 provides a centralized, compact unit. It also makes it possible to cluster the valve stations within the cassette 24 near the tube connectors 27 to 35.

The first through fifth tube connectors 27 to 35 communicate with interior liquid paths F1 to F5, respectively. These liquid paths F1 to F5 constitute the primary liquid paths of the cassette 24, through which liquid enters or exits the

cassette 24.

The remaining interior liquid paths F6 to F9 of the cassette 24 constitute branch paths that link the primary liquid paths F1 to F5 to the pump chambers P1 and P2 through the valve stations V1 to V10.

Because the pump chambers P1 and P2 are vertically oriented during use, air entering the pump chambers P1/P2 during liquid pumping operations will accumulate near the upper port 64 in each pump chamber P1/P2.

The liquid paths F1 to F9 and the valve stations V1 to V10 are purposefully arranged to isolate the patient's peritoneal cavity from the air that the pump chambers P1/P2 collect. They are also purposefully arranged so that this collected air can be transferred out of the pump chambers P1/P2 during use.

More particularly, the cassette 24 isolates selected interior liquid paths from the upper ports 64 of the pump chambers P1 and P2. The cassette 24 thereby isolates these selected liquid paths from the air that accumulates in the pump chambers P1/P2. These air-isolated liquid paths can be used to convey liquid directly into and from the patient's peritoneal cavity.

The cassette 24 also connects other selected liquid paths only to the upper ports 64(1)/(2) of the pump chambers P1 and P2. These liquid paths can be used to transfer air out of the respective pump chamber P1/P2. These liquid paths can also be used to convey liquid away from the patient to other connected elements in the system 10, like the heater bag 22 or the drain.

In this way, the cassette 24 serves to

discharge entrapped air through established noncritical liquid paths, while isolating the critical liquid paths from the air. The cassette 24 thereby keeps air from entering the patient's peritoneal cavity.

More particularly, valve stations V1 to V4 serve only the upper ports 64(1)/(2) of both pump chambers P1 and P2. These valve stations V1 to V4, in turn, serve only the primary liquid paths F1 and F2. Branch liquid path F6 links primary paths F1 and F2 with the upper port 64(1) of pump chamber P1 through valve stations V1 and V2. Branch liquid path F7 links primary paths F1 and F2 with the upper port 64(2) of pump chamber P2 through valve stations V3 and V4.

These primary paths F1 and F2 can thereby serve as noncritical liquid paths, but not as critical liquid paths, since they are not isolated from air entrapped within the pumping chambers P1/P2. By the same token, the primary paths F1 and F2 can serve to convey entrapped air from the pump chambers P1 and P2.

Tubes that, in use, do not directly convey liquid to the patient can be connected to the noncritical liquid paths F1 and F2 through the upper two connectors 27 and 29. One tube 26 conveys liquid to and from the heater bag 22. The other tube 28 conveys spent peritoneal solution to the drain.

When conveying liquid to the heater bag 22 or to the drain, these tubes 26/28 can also carry air that accumulates in the upper region of the pump chambers P1/P2. In this arrangement, the heater bag 22, like the drain, serves as an air sink for the system 10.

Valve stations V5 to V10 serve only the lower ports 66(1)/(2) of both pump chambers P1 and P2. These valve stations V5 to V10, in turn, serve only the primary liquid paths F3; F4; and F5. Branch liquid path F8 links primary paths F3 to F5 with the lower port 66(1) of pump chamber P1 through valve stations V8; V9; and V10. Branch liquid path F9 links primary paths F3 to F5 with the lower port 66(2) of pump chamber P2 through valve stations V5; V6; and V7.

Because the primary paths F3 to F5 are isolated from communication with the upper ports 64 of both pump chambers P1 and P2, they can serve as critical liquid paths.

Thus, the tube 34 that conveys liquid directly to the patient's indwelling catheter can be connected to one of the lower three connectors 31/33/35 (i.e., to the primary liquid paths F3 to F5).

The same tube 34 also carries spent dialysate from the patient's peritoneal cavity. Likewise, the tubes 30/32 that carry sterile source liquid into the pump chambers enter through the lower pump chamber ports 66(1)/(2).

This arrangement makes it unnecessary to incorporate bubble traps and air vents in the tubing serving the cassette. The cassette is its own self contained air trap.

II. THE CYCLER

As Figs. 9 and 10 best show, the cycler 14 carries the operating elements essential for an APD procedure within a portable housing 82 that occupies a relatively small footprint area (as Figs. 1 and 2 also show).

As already stated, the housing 82 encloses the

cycle controller 16.

The housing 82 also encloses a bag heater module 74 (see Fig. 9). It further encloses a pneumatic actuator module 76. The pneumatic actuator module 76 also incorporates the cassette holder 100 already described, as well as a failsafe liquid shutoff assembly 80, which will be described later.

The housing 82 also encloses a source 84 of pneumatic pressure and an associated pneumatic pressure distribution module 88, which links the pressure source 84 with the actuator module 76.

The housing 82 also encloses an AC power supply module 90 and a back-up DC battery power supply module 92 for the cycler 14.

Further structural and functional details of these operating modules of the cycler 14 will be described next.

(A) <u>The Bag Heating Module</u>

The bag heating module 74 includes an exterior support plate 94 on the top of the cycler housing 82 for carrying the heater bag 22 (as Fig. 1 shows). The support plate 94 is made of a heat conducting material, like aluminum.

As Fig. 9 shows, the module 74 includes a conventional electrical resistance heating strip 96 that underlies and heats the support plate 94.

Four thermocouples T1/T2/T3/T4 monitor the temperatures at spaced locations on the left, right, rear, and center of the heating strip 96. Fifth and sixth thermocouples T5/T6 (see Figs. 2 and 10) independently monitor the temperature of the heater bag 22 itself.

A circuit board 98 (see Fig. 9) receives the

output of the thermocouples T1 to T6. The board 98 conditions the output before transmitting it to the controller 16 for processing.

In the preferred embodiment, the controller 16 includes a heater control algorithm that elevates the temperature of liquid in the heater bag 22 to about 33 degrees C before the first fill cycle. A range of other safe temperature settings could be used, which could be selected by the user. The heating continues as the first fill cycle proceeds until the heater bag temperature reaches 36 degrees C.

The heater control algorithm then maintains the bag temperature at about 36 degrees C. The algorithm functions to toggle the heating strip 96 on and off at a sensed plate temperature of 44 degrees C to assure that plate temperature never exceeds 60 degrees C.

(B) <u>The Pneumatic Actuator Module</u>

The cassette holder 100, which forms a part of the pneumatic actuator module 76, includes a front plate 105 joined to a back plate 108 (see Fig. 12A). The plates 105/108 collectively form an interior recess 110.

A door 106 is hinged to the front plate 105 (see Figs. 6 and 7). The door 106 moves between an opened position (shown in Figs. 6 and 7) and a closed position (shown in Figs. 1; 2; and 11).

A door latch 115 operated by a latch handle 111 contacts a latch pin 114 when the door 106 is closed. Moving the latch handle 111 downward when the door 106 is closed engages the latch 115 to the pin 114 to lock the door 106 (as Figs. 4 and 5 show). Moving the latch handle 111 upward when the

door 106 is closed releases the latch 115 from the pin 114. This allows the door 106 to be opened (as Fig. 6 shows) to gain access to the holder interior.

With the door 106 opened, the user can insert the cassette 24 into the recess 110 with its front side 58 facing the interior of the cycler 14 (as Figs. 6 and 7 show).

The inside of the door 106 carries an upraised elastomeric gasket 112 positioned in opposition to the recess 110. Closing the door 106 brings the gasket 112 into facing contact with the diaphragm 61 on the back side 60 of the cassette 24.

The pneumatic actuator module 76 contains a pneumatic piston head assembly 78 located behind the back plate 108 (see Fig. 12A).

The piston head assembly 78 includes a piston element 102. As Figs. 12A; 13 and 14 show, the piston element 102 comprises a molded or machined plastic or metal body. The body contains two pump actuators PA1 and PA2 and ten valve actuators VA1 to VA10. The pump actuators PA1/PA2 and the valve actuators VA1 to VA10 are mutually oriented to form a mirror image of the pump stations P1/P2 and valve stations V1 to V10 on the front side 58 of the cassette 24.

Each actuator PA1/PA2/VA1 to VA10 includes a port 120. The ports 120 convey positive or negative pneumatic pressures from the pneumatic pressure distribution module 88 (as will be described in greater detail later).

As Fig. 13 best shows, interior grooves 122 formed in the piston element 102 surround the pump and valve actuators PA1/PA2/VA1 to VA10. A preformed gasket 118 (see Fig. 12A) fits into these grooves 122. The gasket 118 seals the peripheries

of the actuators PA1/PA2/VA1 to VA10 against pneumatic pressure leaks.

The configuration of the preformed gasket 118 follows the pattern of upstanding edges that peripherally surround and separate the pump chambers P1 and P2 and valve stations V1 to V10 on the front side 58 of the cassette 24.

The piston element 102 is attached to a pressure plate 104 within the module 76 (see Fig. 12B). The pressure plate 104 is, in turn, supported on a frame 126 for movement within the module 76.

The side of the plate 104 that carries the piston element 102 abuts against a resilient spring element 132 in the module 76. In the illustrated and preferred embodiment, the spring element 132 is made of an open pore foam material.

The frame 126 also supports an inflatable main bladder 128. The inflatable bladder 128 contacts the other side of the plate 104.

The piston element 102 extends through a window 134 in the spring element 132 (see Fig. 12A). The window 134 registers with the cassette receiving recess 110.

With a cassette 24 fitted into the recess 110 and the holder door 106 closed, the piston element 102 in the window 134 is mutually aligned with the diaphragm 59 of the cassette 24 in the holder recess 110.

As Fig. 15A shows, when the main bladder 128 is relaxed (i.e., not inflated), the spring element 132 contacts the plate 104 to hold the piston element 102 away from pressure contact with a cassette 24 within the holder recess 110.

As will be described in greater detail later, the pneumatic pressure distribution module 88 can

supply positive pneumatic pressure to the main bladder 128. This inflates the bladder 128.

As Fig. 15B shows, when the main bladder 128 inflates, it presses the plate 104 against the spring element 132. The open cell structure of the spring element 132 resiliently deforms under the pressure. The piston element 102 moves within the window 134 into pressure contact against the cassette diaphragm 59.

The bladder pressure presses the piston element gasket 118 tightly against the cassette diaphragm 59. The bladder pressure also presses the back side diaphragm 61 tightly against the interior of the door gasket 112.

As a result, the diaphragms 59 and 61 seat against the upstanding peripheral edges 62 that surround the cassette pump chambers P1/P2 and valve stations V1 to V10. The pressure applied to the plate 104 by the bladder 128 seals the peripheries of these regions of the cassette 24.

The piston element 102 remains in this operating position as long as the main bladder 128 retains positive pressure and the door 106 remains closed.

In this position, the two pump actuators PA1 and PA2 in the piston element 102 register with the two pump chambers P1 and P2 in the cassette 24. The ten valve actuators VA1 to VA10 in the piston element 102 likewise register with the ten valve stations V1 to V10 in the cassette 24.

As will be described in greater detail later, the pneumatic pressure distribution module 88 conveys positive and negative pneumatic fluid pressure to the actuators PA1/PA2/VA1 to VA10 in a sequence governed by the controller 16. These

positive and negative pressure pulses flex the diaphragm 59 to operate the pump chambers P1/P2 and valve stations V1 to V10 in the cassette 24. This, in turn, moves liquid through the cassette 24.

Venting the positive pressure in the bladder 128 relieves the pressure the plate 104 applies to the cassette 24. The resilient spring element 132 urges the plate 104 and attached piston element 102 away from pressure contact with the cassette diaphragm 59. In this position, the door 106 can be opened to unload the cassette 24 after use.

As Fig. 12A shows, the gasket 118 preferably includes an integral elastomeric membrane 124 stretched across it. This membrane 124 is exposed in the window 134. It serves as the interface between the piston element 102 and the diaphragm 59 of the cassette 24, when fitted into the holder recess 110.

The membrane 124 includes one or more small through holes 125 in each region overlying the pump and valve actuators PA1/PA2/VA1 to VA10. The holes 125 are sized to convey pneumatic fluid pressure from the piston element actuators to the cassette diaphragm 59. Nevertheless, the holes 125 are small enough to retard the passage of liquid. This forms a flexible splash guard across the exposed face of the gasket 118.

The splash guard membrane 124 keeps liquid out of the pump and valve actuators PA1/PA2/VA1 to VA10, should the cassette diaphragm 59 leak. The splash guard membrane 124 also serves as a filter to keep particulate matter out of the pump and valve actuators of the piston element 102. The splash guard membrane 124 can be periodically wiped clean when cassettes are exchanged.

As Fig. 12A shows, inserts 117 preferably occupy the pump actuators PA1 and PA2 behind the membrane 124.

In the illustrated and preferred embodiment, the inserts 117 are made of an open cell foam material. The inserts 117 help dampen and direct the pneumatic pressure upon the membrane 124. The presence of inserts 117 stabilizes air pressure more quickly within the pump actuators PA1 and PA2, helping to negate transient thermal effects that arise during the conveyance of pneumatic pressure.

(C) The Liquid Shutoff Assembly

The liquid shutoff assembly 80, which forms a part of the pneumatic actuator module 76, serves to block all liquid flow through the cassette 24 in the event of a power failure or another designated error condition.

As Fig. 12B shows, the liquid shutoff assembly 80 includes a movable occluder body 138 located behind the pressure plate frame 126. The occluder body 138 has a side hook element 140 that fits into a slot 142 in the pressure plate frame 126 (see Figs. 16A/B). This hook-in-slot fit establishes a contact point about which the occluder body 138 pivots on the pressure plate frame 126.

The occluder body 138 includes an elongated occluder blade 144 (see Figs. 12A; 15; and 16). The occluder blade 144 extends through a slot 146 in the front and back plates 105/108 of the holder 100. When the holder door 106 is closed, the blade 144 faces an elongated occluder bar 148 carried on the holder door 106 (see Figs. 15 and 16).

When the cassette 24 occupies the holder recess 110 (see Fig. 7) and the holder door 106 is closed,

all tubing 26 to 34 attached to the cassette 24 passes between the occluder blade 144 and the occluder bar 148 (as Figs. 15 and 16 show).

In the illustrated and preferred embodiment, a region 145 of the flexible tubing 26 to 34 is held in a mutually close relationship near the cassette 24 (see Fig. 3). This bundled tubing region 145 further simplifies the handling of the cassette 24. This bundled region 145 also arranges the cassette tubing 26 to 34 in a close, side by side relationship in the region between the occluder blade 144 and bar 148 (see Fig. 7).

In the illustrated and preferred embodiment, the sidewalls of the flexible tubing 26 to 34 are RF surface welded together to form the bundled region 145.

Pivotal movement of the occluder body 138 moves the occluder blade 144 toward or away from the occluder bar 148. When spaced apart (as Fig. 16A shows), the occluder blade and bar 144/148 allow clear passage of the cassette tubing 26 to 34. When brought together (as Fig. 16B shows), the occluder blade and bar 144/148 crimp the cassette tubing 26 to 34 closed. Occluder springs 150 carried within sleeves 151 normally bias the occluder blade and bar 144/148 together.

An occluder bladder 152 occupies the space between the occluder body 138 and the frame 126 (see Fig. 12B).

As Fig. 16B shows, when the occluder bladder 152 is relaxed (i.e., not inflated), it makes no contact against the occluder body 138. The occluder springs 150 urge the occluder blade and bar 144/148 together, simultaneously crimping all cassette tubing 26 to 34 closed. This prevents all liquid

flow to and from the cassette 24.

As will be described in greater detail later, the pneumatic pressure distribution module 88 can supply positive pneumatic pressure to the occluder bladder 152. This inflates the bladder 128.

As Fig. 16A shows, when the occluder bladder 152 inflates, it presses against the occluder body 138 to pivot it upward. This moves the occluder blade 144 away from the occluder bar 158. This permits liquid to flow through all tubing to and from the cassette 24.

The occluder blade and bar 144/148 remain spaced apart as long as the occluder bladder 152 retains positive pressure.

Venting of positive pressure relaxes the occluder bladder 152. The occluder springs 150 immediately urge the occluder blade and bar 144/148 back together to crimp the tubing closed.

As will be described in greater detail later, an electrically actuated valve C6 communicates with the occluder bladder 152. When receiving electrical power, the valve C6 is normally closed. In the event of a power loss, the valve C6 opens to vent the occluder bladder 152, crimping the cassette tubing 26 to 34 closed.

The assembly 80 provides a pneumatically actuated fail-safe liquid shut off for the pneumatic pumping system.

(D) <u>The Pneumatic Pressure Source</u>

The pneumatic pressure source 84 comprises a linear vacuum pump and air compressor capable of generating both negative and positive air pressure. In the illustrated and preferred embodiment, the pump 84 is a conventional air compressor/vacuum pump

commercially available from Medo Corporation.

As Fig. 23 shows, the pump 84 includes an inlet 154 for drawing air into the pump 84. The pump inlet 154 supplies the negative pressure required to operate the cycler 14.

As Fig. 23 also shows, the pump 84 also includes an outlet 156 for discharging air from the pump 84. The pump outlet 156 supplies positive pressure required to operate the cycler 14.

Figs. 9 and 10 also show the inlet 154 and outlet 156.

The pump inlet 154 and the pump outlet 156 communicate with ambient air via a common vent 158 (shown schematically in Fig. 23). The vent 158 includes a filter 160 that removes particulates from the air drawn into the pump 84.

(E) <u>The Pressure Distribution System</u>

Figs. 17 to 22 show the details of the pneumatic pressure distribution module 88. The module 88 encloses a manifold assembly 162. The manifold assembly 162 controls the distribution of positive and negative pressures from the pump 84 to the piston element 102, the main bladder 128, and the occluder bladder 152. The controller 16 provides the command signals that govern the operation of the manifold assembly 162.

As Figs. 18 shows, a foam material 164 preferably lines the interior of the module 88 enclosing the manifold assembly 162. The foam material 164 provides a barrier to dampen sound to assures quiet operation.

As Figs. 18 and 19 show, the manifold assembly 162 includes a top plate 166 and a bottom plate 168. A sealing gasket 170 is sandwiched between the

plates 166/168.

The bottom plate 168 (see Figs. 20 and 21) includes an array of paired air ports 172. Fig. 20 shows the inside surface of the bottom plate 168 that faces the gasket 170 (which is designated IN in Figs. 19 and 20). Fig. 21 shows the outside surface of the bottom plate 168 (which is designated OUT in Figs. 19 and 21).

The inside surface (IN) of the bottom plate 168 also contains an array of interior grooves that form air conduction channels 174 (see Fig. 20). The array of paired air ports 172 communicates with the channels 174 at spaced intervals. A block 176 fastened to the outside surface (OUT) of the bottom plate 168 contains an additional air conduction channels 174 that communicate with the channels 174 on the inside plate surface (IN) (see Figs. 19 and 22).

Transducers 178 mounted on the exterior of the module 88 sense through associated sensing tubes 180 (see Fig. 18) pneumatic pressure conditions present at various points along the air conduction channels 174. The transducers 178 are conventional semi-conductor piezo-resistance pressure sensors. The top of the module 88 includes stand-off pins 182 that carry a board 184 to which the pressure transducers 178 are attached.

The outside surface (OUT) of the bottom plate 168 (see Figs. 19 and 22) carries a solenoid actuated pneumatic valves 190 connected in communication with each pair of air ports 172. In the illustrated embodiment, there are two rows of valves 190 arranged along opposite sides of the outside surface (OUT) of the plate 168. Twelve valves 190 form one row, and thirteen valves 190

form the other row.

As Fig. 22 shows, each pneumatic valve 190 is attached in communication with a pair of air ports 172 by screws fastened to the outside surface (OUT) of the bottom plate 168. As Figs. 19 and 22 also show, each valve 190 is electrically connected by ribbon cables 192 to the cycler controller 16 by contacts on a junction board 194. There are two junction boards 194, one for each row of valves 190.

Each pneumatic valve 190 operates to control air flow through its associated pair of ports 172 to link the ports 172 to the various air channels 174 the bottom plate 168 carries. As will be described in greater detail later, some of the valves 190 are conventional three way valves. Others are conventional normally closed two way valves.

The air channels 174 within the manifold assembly 162 are coupled by flexible tubing 196 (see Fig. 17) to the system components that operate using pneumatic pressure. Slots 198 in the side of the module 88 accommodate the passage of the tubing 196 connected to the manifold assembly 162.

Figs. 9 and 10 also show the flexible tubing 196 that links the manifold assembly 162 to the pneumatically actuated and controlled system components.

Fig. 11 further shows the tubing 196 from the manifold assembly 162 entering the pneumatic actuator module 76, where they connect to the main bladder 128, the occluder bladder 152, and the piston element 102. Fig. 14A further shows the T-fittings that connect the tubing 196 to the ports of the valve actuators VA1 to VA10 and the ports of the pump actuators PA1/PA2 of the piston element 102. These connections are made on the back side of the

piston element 102.

1. The Pressure Regulation System

The air conduction passages 174 and the flexible tubing 196 associated with the manifold assembly 162 define a fluid pressure regulation system 200 that operates in response to command signals from the cycler controller 16. Figs. 23 and 24 show the details of the air regulation system 200 in schematic form.

In response to the command signals of the controller 16, the pressure regulation system 200 directs the flow of positive and negative pneumatic pressures to operate the cycler 14. When power is applied, the system 200 maintains the occluder assembly 80 in an open, flow-permitting condition; it seals the cassette 24 within the holder 100 for operation; and it conveys pneumatic pressure to the piston element 102 to move liquid through the cassette 24 to conduct an APD procedure. The pressure regulation system 200 also provides information that the controller 16 processes to measure the volume of liquid conveyed by the cassette 24.

a. Pressure Supply Network

As Fig. 23 shows, the regulation system 200 includes a pressure supply network 202 having a positive pressure side 204 and a negative pressure side 206. The positive and negative pressure sides 204 and 206 can each be selectively operated in either a low-relative pressure mode or high-relative pressure mode.

The controller 16 calls for a low-relative pressure mode when the cycler 14 circulates liquid

directly through the patient's indwelling catheter 18 (i.e., during patient infusion and drain phases). The controller 16 calls for a high-relative pressure mode when the cycler 14 circulates liquid outside the patient's indwelling catheter 18 (i.e., during transfers of liquid from supply bags 20 to the heater bag 22).

In other words, the controller 16 activates the low-relative pressure mode when considerations of patient comfort and safety predominate. The controller 16 activates the high-relative pressure mode when considerations of processing speed predominate.

In either mode, the pump 84 draws air under negative pressure from the vent 158 through an inlet line 208. The pump 84 expels air under positive pressure through an outlet line 210 to the vent 158.

The negative pressure supply side 206 communicates with the pump inlet line 208 through a negative pressure branch line 212. The three way pneumatic valve D0 carried on the manifold assembly 162 controls this communication.

The branch line 212 supplies negative pressure to a reservoir 214 carried within the cycler housing 82 (this can be seen in Figs. 9 and 10). The reservoir 214 preferably has a capacity greater than about 325 cc and a collapse pressure of greater than about -10 psig. The transducer XNEG carried on the manifold assembly 162 senses the amount of negative pressure stored within the negative pressure reservoir 214.

When in the high-relative negative pressure mode, the transducer XNEG transmits a control signal when the predefined high-relative negative pressure of -5.0 psig is sensed. When in the low-relative

negative pressure mode, the transducer XNEG transmits a control signal when the predefined low-relative negative pressure of -1.2 psig is sensed. The pressure reservoir 214 serves as both a low-relative and a high-relative pressure reservoir, depending upon the operating mode of the cycler 14.

The positive pressure supply side 204 communicates with the pump outlet line 210 through a main positive pressure branch line 216. The three way pneumatic valve C5 controls this communication.

The main branch line 216 supplies positive pressure to the main bladder 128, which seats the piston head 116 against the cassette 24 within the holder 100. The main bladder 128 also serves the system 202 as a positive high pressure reservoir.

The main bladder 128 preferably has a capacity of greater than about 600 cc and a fixtured burst pressure over about 15 psig.

Transducer XHPOS carried on the manifold assembly 162 senses the amount of positive pressure within the main bladder 128. Transducer XHPOS transmits a control signal when the predetermined high-relative pressure of 7.5 psig is sensed.

A first auxiliary branch line 218 leads from the main branch line 216 to a second positive pressure reservoir 220 carried within the housing 82 (which can also be seen in Figs. 9 and 10). The two way, normally closed pneumatic valve A6 carried by the manifold assembly 168 controls the passage of positive pressure to the second reservoir 220. The second reservoir 220 serves the system 202 as a reservoir for low-relative positive pressure.

The second reservoir 220 preferably has a capacity of greater than about 325 cc and a fixtured burst pressure greater than about 10 psig.

Transducer XLPOS carried on the manifold assembly 162 senses the amount of positive pressure within the second pressure reservoir 220. Transducer XLPOS is set to transmit a control signal when the predetermined low-relative pressure of 2.0 psig is sensed.

The valve A6 divides the positive pressure supply side 204 into a high-relative positive pressure region 222 (between valve station C5 and valve station A6) and a low-relative positive pressure region 224 (between valve station A6 and the second reservoir 220).

A second auxiliary positive pressure branch line 226 leads from the main branch line 216 to the occluder bladder 152 through three way pneumatic valve C6. The occluder bladder 152 also serves the system 202 as a positive high pressure reservoir.

A bypass branch line 228 leads from the main branch 216 to the vent 158 through the two way, normally closed valve A5. The valve C6 also communicates with the bypass branch line 228.

The pressure supply network 202 has three modes of operation. In the first mode, the network 202 supplies the negative pressure side 206. In the second mode, the network 202 supplies the positive pressure side 204. In the third mode, the network 202 supplies neither negative or positive pressure side 204/206, but serves to circulate air in a continuous manner through the vent 158.

With the three modes of operation, the pump 84 can be continuously operated, if desired. This avoids any time delays and noise occasioned by cycling the pump 84 on and off.

In the first mode, valve station D0 opens communication between the negative branch line 212

and the pump inlet line 208. Valve C5 opens communication between the pump outline line 210 and the vent 158, while blocking communication with the main positive branch line 216.

The pump 84 operates to circulate air from the vent 158 through its inlet and outlet lines 208/210 to the vent 158. This circulation also draws air to generating negative pressure in the negative branch line 212. The reservoir 214 stores this negative pressure.

When the transducer XNEG senses its predetermined high-relative or low-relative negative pressure, it supplies a command signal to operate valve D0, closing communication between the pump inlet line 208 and the negative branch line 212.

In the second mode, valve D0 closes communication between the negative branch line 212 and the pump inlet line 208. Valve C5 closes communication with the vent 158, while opening communication with the main positive branch line 216.

The pump 84 operates to convey air under positive pressure into the main positive branch line 216. This positive pressure accumulates in the main bladder 128 for conveyance to the pump and valve actuators on the piston element 102.

By operating three way valve C6, the positive pressure can also be directed to fill the occluder bladder 152. When the valve C6 is in this position, the positive pressure in the occluder bladder 152 also can be conveyed to the pump and valve actuators on the piston element 102

Otherwise, valve C6 directs the positive pressure through the bypass line 228 to the vent 158. In the absence of an electrical signal (for example, if there is a power failure), valve C6

opens the occluder bladder 152 to the bypass line 228 to the vent 158.

Valve A6 is either opened to convey air in the main branch line 216 to the low pressure reservoir 214 or closed to block this conveyance. The transducer XLPOS opens the valve A6 upon sensing a pressure below the low-relative cut-off. The transducer XLPOS closes the valve station A6 upon sensing pressure above the low-relative cut-off.

The transducer XHIPOS operates valve C5 to close communication between the pump outlet line 210 and the main positive branch line 216 upon sensing a pressure above the high-relative cut-off of 7.5 psig.

In the third mode, valve D0 closes communication between the negative branch line 212 and the pump inlet line 208. Valve C5 opens communication between the pump outlet line 210 and the vent 158, while blocking communication with the main positive branch line 216.

The pump 84 operates to circulate air in a loop from the vent 158 through its inlet and outlet lines 208/210 back to the vent 158.

b. <u>The Pressure Actuating Network</u>

As Fig. 24 shows, the regulation system also includes first and second pressure actuating networks 230 and 232.

The first pressure actuating network 230 distributes negative and positive pressures to the first pump actuator PA1 and the valve actuators that serve it (namely, VA1; VA2; VA8; VA9; and VA10). These actuators, in turn, operate cassette pump station P1 and valve stations V1; V2; V8; V9; and V10, respectively, which serve pump station P1.

The second pressure actuating network 232 distributes negative and positive pressures to the second pump actuator PA2 and the valve actuators that serve it (namely, VA3; VA4; VA5; VA6; and VA7). These actuators, in turn, operate cassette pump station P2 and cassette valve stations V3; V4; V5; V6; and V7, which serve pump station P2.

The controller 16 can operate the first and second actuating networks 230 and 232 in tandem to alternately fill and empty the pump chambers P1 and P2. This provides virtually continuous pumping action through the cassette 24 from the same source to the same destination.

Alternatively, the controller 16 can operate the first and second actuating networks 230 and 232 independently. In this way, the controller 16 can provide virtually simultaneous pumping action through the cassette 24 between different sources and different destinations.

This simultaneous pumping action can be conducted with either synchronous or non-synchronous pressure delivery by the two networks 230 and 232. The networks 230 and 232 can also be operated to provide pressure delivery that drifts into an out of synchronousness.

The first actuating network 230 provides high-relative positive pressure and negative pressures to the valve actuators VA1; VA2; VA8; VA9; and VA10.

The first actuating network 230 also selectively provides either high-relative positive and negative pressure or low-relative positive and negative pressure to the first pumping actuator PA1.

Referring first to the valve actuators, three way valves C0; C1; C2; C3; and C4 in the manifold assembly 162 control the flow of high-relative

positive pressure and negative pressures to the valve actuators VA1; VA2; VA8; VA9; and VA10.

The high-relative positive pressure region of the main branch line 216 communicates with the valves C0; C1: C2; C3; and C4 through a bridge line 234, a feeder line 236, and individual connecting lines 238.

The negative pressure branch 212 communicates with the valves C0; C1; C2; C3; and C4 through individual connecting lines 340. The controller 16 sets this branch 212 to a high-relative negative pressure condition by setting the transducer XNEG to sense a high-relative pressure cut-off.

By applying negative pressure to one or more given valve actuators, the associated cassette valve station is opened to accommodate liquid flow. By applying positive pressure to one or more given valve actuators, the associated cassette value station is closed to block liquid flow. In this way, the desired liquid path leading to and from the pump chamber P1 can be selected.

Referring now to the pump actuator PA1, two way valve A4 in the manifold assembly 162 communicates with the high-relative pressure feeder line 236 through connecting line 342. Two way valve A3 in the manifold assembly 162 communicates with the low-relative positive pressure reservoir through connecting line 344. By selectively operating either valve A4 or A3, either high-relative or low-relative positive pressure can be supplied to the pump actuator PA1.

Two way valve A0 communicates with the negative pressure branch 212 through connecting line 346. By setting the transducer XNEG to sense either a low-relative pressure cut-off or a high-relative

pressure cut-off, either low-relative or high-relative pressure can be supplied to the pump actuator VA1 by operation of valve A0.

By applying negative pressure (through valve A0) to the pump actuator PA1, the cassette diaphragm 59 flexes out to draw liquid into the pump chamber P1. By applying positive pressure (through either valve A3 or A4) to the pump actuator PA1, the cassette diaphragm 59 flexes in to pump liquid from the pump chamber P1 (provided, of course, that the associated inlet and outlet valves are opened). By modulating the time period during which pressure is applied, the pumping force can be modulated between full strokes and partial strokes with respect to the pump chamber P1.

The second actuating network 232 operates like the first actuating network 230, except it serves the second pump actuator PA2 and its associated valve actuators VA3; VA4; VA5; VA6; and VA7.

Like the first actuating network 230, the second actuating network 232 provides high-relative positive pressure and high-relative negative pressures to the valve actuators VA3; VA4; VA5; VA6; and VA7. Three way valves D1; D2: D3; D4; and D5 in the manifold assembly 162 control the flow of high-relative positive pressure and high-relative negative pressures to the valve actuators VA3; VA4; VA5; VA6; and VA7.

The high-relative positive pressure region 222 of the main branch line communicates with the valves D1; D2; D3; D4; and D5 through the bridge line 234, the feeder line 236, and connecting lines 238.

The negative pressure branch 212 communicates with the valves D1: D2; D3; D4; and D5 through connecting lines 340. This branch 212 can be set to

a high-relative negative pressure condition by setting the transducer XNEG to sense a high-relative pressure cut-off.

Like the first actuating network 230, the second actuating network 232 selectively provides either high-relative positive and negative pressure or low-relative positive and negative pressure to the second pumping actuator PA2. Two way valve B0 in the manifold assembly 162 communicates with the high-relative pressure feeder line through connecting line 348. Two way valve station B1 in the manifold assembly 162 communicates with the low-relative positive pressure reservoir through connecting line 349. By selectively operating either valve B0 or B1, either high-relative or low-relative positive pressure can be supplied to the pump actuator PA2.

Two way valve B4 communicates with the negative pressure branch through connecting line 350. By setting the transducer XNEG to sense either a low-relative pressure cut-off or a high-relative pressure cut-off, either low-relative or high-relative pressure can be supplied to the pump actuator PA2 by operation of valve B4.

Like the first actuating network 230, by applying negative pressure to one or more given valve actuators, the associated cassette value station is opened to accommodate liquid flow. By applying positive pressure to one or more given valve actuators, the associated cassette value station is closed to block liquid flow. In this way, the desired liquid path leading to and from the pump chamber P2 can be selected.

By applying a negative pressure (through valve B4) to the pump actuator PA2, the cassette diaphragm

flexes out to draw liquid into the pump chamber P2. By applying a positive pressure (through either valve BB0 or B1) to the pump actuator PA2, the cassette diaphragm flexes in to move liquid from the pump chamber P2 (provided, of course, that the associated inlet and outlet valves are opened). By modulating the time period during which pressure is applied, the pumping force can be modulated between full strokes and partial strokes with respect to the pump chamber P2.

The first and second actuating networks 230/232 can operate in succession, one drawing liquid into pump chamber P1 while the other pump chamber P2 pushes liquid out of pump chamber P2, or vice versa, to move liquid virtually continuously from the same source to the same destination.

The first and second actuating networks 230/232 can also operate to simultaneously move one liquid through pump chamber P1 while moving another liquid through pump chamber P2. The pump chambers P1 and P2 and serve the same or different destinations.

Furthermore, with additional reservoirs, the first and second actuation networks 232/232 can operate on the same or different relative pressure conditions. The pump chamber P1 can be operated with low-relative positive and negative pressure, while the other pump chamber P2 is operated with high-relative positive and negative pressure.

c. Liquid Volume Measurement

As Fig. 24 shows, the pressure regulating system 200 also includes a network 350 that works in conjunction with the controller 16 for measuring the liquid volumes pumped through the cassette.

The liquid volume measurement network 350

includes a reference chamber of known air volume (V_s) associated with each actuating network. Reference chamber VS1 is associated with the first actuating network. Reference chamber VS2 is associated with the second actuating network.

The reference chambers VS1 and VS2 may be incorporated at part of the manifold assembly 162, as Fig. 20 shows.

In a preferred arrangement (as Fig. 14B shows), the reference chambers VS1 and VS2 are carried by the piston element 102' itself, or at another located close to the pump actuators PA1 and PA2 within the cassette holder 100.

In this way, the reference chambers VS1 and VS2, like the pump actuators PA1 and PA2, exposed to generally the same temperature conditions as the cassette itself.

Also in the illustrated and preferred embodiment, inserts 117 occupy the reference chambers VS1 and VS2. Like the inserts 117 carried within the pump actuators PA1 and PA2, the reference chamber inserts 117 are made of an open cell foam material. By dampening and directing the application of pneumatic pressure, the reference chamber inserts 117 make measurement of air volumes faster and less complicated.

Preferably, the insert 117 also includes a heat conducting coating or material to help conduct heat into the reference chamber VS1 and VS2. In the illustrated embodiment, a thermal paste is applied to the foam insert.

This preferred arrangement minimizes the effects of temperature differentials upon liquid volume measurements.

Reference chamber VS1 communicates with the

outlets of valves A0; A3: and A4 through a normally closed two way valve A2 in the manifold assembly 162. Reference chamber VS1 also communicates with a vent 352 through a normally closed two way valve A1 in the manifold assembly 162.

Transducer XVS1 in the manifold assembly 162 senses the amount of air pressure present within the reference chamber VS1. Transducer XP1 senses the amount of air pressure present in the first pump actuator PA1.

Likewise, reference chamber VS2 communicates with the outlets of valve B0; B1; and B4 through a normally closed two way valve B2 in the manifold assembly 162. Reference chamber VS2 also communicates with a filtered vent 356 through a normally closed two way valve B3 in the manifold assembly 162.

Transducer XVS2 in the manifold assembly 162 senses the amount of air pressure present within the reference chamber VS2. Transducer XP2 senses the amount of air pressure present in the second pump actuator PA2.

The controller 16 operates the network 350 to perform an air volume calculation twice, once during each draw (negative pressure) cycle and once again during each pump (positive pressure) cycle of each pump actuator PA1 and PA2.

The controller 16 operates the network 350 to perform the first air volume calculation after the operating pump chamber is filled with the liquid to be pumped (i.e., after its draw cycle). This provides an initial air volume (V_i).

The controller 16 operates the network 350 to perform the second air volume calculation after moving fluid out of the pump chamber (i.e., after

the pump cycle). This provides a final air volume (V_f).

The controller 16 calculates the difference between the initial air volume V_i and the final air volume V_f to derive a delivered liquid volume (V_d), where:

$$V_d = V_f - V_i$$

The controller 16 accumulates V_d for each pump chamber to derive total liquid volume pumped during a given procedure. The controller 16 also applies the incremental liquid volume pumped over time to derive flow rates.

The controller 16 derives V_i in this way (pump chamber P1 is used as an example):

(1) The controller 16 actuates the valves C0 to C4 to close the inlet and outlet passages leading to the pump chamber P1 (which is filled with liquid). Valves A2 and A1 are normally closed, and they are kept that way.

(2) The controller 16 opens valve A1 to vent reference chamber VS1 to atmosphere. The controller 16 then conveys positive pressure to the pump actuator PA1, by opening either valve A3 (low-reference) or A4 (high-reference), depending upon the pressure mode selected for the pump stroke.

(3) The controller 16 closes the vent valve A1 and the positive pressure valve A3 or A4, to isolate the pump chamber PA1 and the reference chamber VS1.

(4) The controller 16 measures the air pressure in the pump actuator PA1 (using transducer XP1) (IP_{d1}) and the air pressure in the reference chamber VS1 (using transducer XVS1) (IP_{s1}).

(5) The controller 16 opens valve A2 to allow the reference chamber VS1 to equilibrate with

the pump chamber PA1.

(6) The controller 16 measures the new air pressure in the pump actuator PA1 (using transducer XP1) (IP_{d2}) and the new air pressure in the reference chamber (using transducer XVS1) (IP_{s2}).

(7) The controller 16 closes the positive pressure valve A3 or A4.

(8) The controller 16 calculates initial air volume V_i as follows:

$$V_i = \frac{(IP_{s1} - IP_{s2}) * V_s}{(IP_{d2} - IP_{d1})}$$

After the pump chamber P1 is emptied of liquid, the same sequence of measurements and calculations are made to derive V_f, as follows:

(9) Keeping valve stations A2 and A1 closed, the controller 16 actuates the valves C0 to C4 to close the inlet and outlet passages leading to the pump chamber P1 (which is now emptied of liquid).

(10) The controller 16 opens valve A1 to vent reference chamber VS1 to atmosphere, and then conveys positive pressure to the pump actuator PA1, by opening either valve A3 (low-reference) or A4 (high-reference), depending upon the pressure mode selected for the pump stroke.

(11) The controller 16 closes the vent valve A1 and the positive pressure valve A3 or A4, to isolate the pump actuator PA1 and the reference chamber VS1.

(12) The controller 16 measures the air pressure in the pump actuator PA1 (using transducer XP1) (FP_{d1}) and the air pressure in the reference chamber VS1 (using transducer XVS1) (FP_{s1}).

(13) The controller 16 opens valve A2, allowing the reference chamber VS1 to equilibrate

with the pump actuator.

(14) The controller 16 measures the new air pressure in the pump actuator PA1 (using transducer XP1) (FP_{d2}) and the new air pressure in the reference chamber (using transducer XVS1) (FP_{s2}).

(15) The controller 16 closes the positive pressure valve A3 or A4.

(16) The controller 16 calculates final air volume V_f as follows:

$$V_f = \frac{(FP_{s1} - FP_{s2}) * V_s}{(FP_{d2} - FP_{d1})}$$

The liquid volume delivered (V_d) during the preceding pump stroke is:

$$V_d = V_f - V_i$$

Preferably, before beginning another pump stroke, the operative pump actuator is vented to atmosphere (by actuating valves A2 and A1 for pump actuator PA1, and by actuating valves B2 and B3 for pump actuator PA2).

The controller 16 also monitors the variation of V_d over time to detect the presence of air in the cassette pump chamber P1/P2. Air occupying the pump chamber P1/P2 reduces the capacity of the chamber to move liquid. If V_d decrease over time, or if V_d falls below a set expected value, the controller 16 attributes this condition to the buildup of air in the cassette chamber.

When this condition occurs, the controller 16 conducts an air removal cycle, in which liquid flow through the affected chamber is channeled through the top portion of the chamber to the drain or to the heater bag for a period of time. The air removal cycle rids the chamber of excess air and restores V_d to expected values.

In another embodiment, the controller 16 periodically conducts an air detection cycle. In this cycle, the controller 16 delivers fluid into a given one of the pump chambers P1 and P2. The controller 16 then closes all valve stations leading into and out of the given pump chamber, to thereby trap the liquid within the pump chamber.

The controller 16 then applies air pressure to the actuator associated with the pump chamber and derives a series of air volume V_i measurements over a period of time in the manner previously disclosed. Since the liquid trapped within the pump chamber is relatively incompressible, there should be virtually no variation in the measured V_i during the time period, unless there is air present in the pump chamber. If V_i does vary over a prescribed amount during the time period, the controller 16 contributes this to the presence of air in the pump chamber.

When this condition occurs, the controller 16 conducts an air removal cycle in the manner previously described.

The controller 16 performs the liquid volume calculations assuming that the temperature of the reference chamber VS1/VS2 does not differ significantly from the temperature of the pump chamber P1/P2.

One way to minimize any temperature difference is to mount the reference chamber as close to the pump chamber as possible. Fig. 14B shows this preferred alternative, where the reference chamber is physically mounted on the piston head 116.

Temperature differences can also be accounted for by applying a temperature correction factor (F_t) to the known air volume of the reference chamber V_s

to derive a temperature-corrected reference air volume V_{st}, as follows:

$$V_{st} = F_t * V_s$$

where:

$$F_t = \frac{C_t}{R_t}$$

and where:

C_t is the absolute temperature of the cassette (expressed in degrees Rankine or Kelvin), and

R_t is the temperature of the reference chamber (expressed in the same units as C_t).

In this embodiment, the network substitutes V_{st} for V_s in the above volume derivation calculations.

The value of F_t can be computed based upon actual, real time temperature calculations using temperature sensors associated with the cassette and the reference chamber.

Because liquid volume measurements are derived after each pumping stroke, the same accuracy is obtained for each cassette loaded into the cycler, regardless of variations in tolerances that may exist among the cassettes used.

III. THE CYCLER CONTROLLER 16

Figs. 9; 10; 17; and 18 show the cycler controller 16.

The controller 16 carries out process control and monitoring functions for the cycler 14. The controller 16 includes a user interface 367 with a display screen 370 and keypad 368. The user interface 367 receives characters from the keypad 368, displays text to a display screen 370, and sounds the speaker 372 (shown in Figs. 9 and 10). The interface 367 presents status information to the

user during a therapy session. The interface 367 also allows the user to enter and edit therapy parameters, and to issue therapy commands.

In the illustrated embodiment, the controller 16 comprises a central microprocessing unit (CPU) 358. The CPU is etched on the board 184 carried on stand off pins 182 atop the second module 88. Power harnesses 360 link the CPU 358 to the power supply 90 and to the operative elements of the manifold assembly 162.

The CPU 358 employs conventional real-time multi-tasking to allocate CPU cycles to application tasks. A periodic timer interrupt (for example, every 10 milliseconds) preempts the executing task and schedules another that is in a ready state for execution. If a reschedule is requested, the highest priority task in the ready state is scheduled. Otherwise, the next task on the list in the ready state is scheduled.

The following provides an overview of the operation of the cycler 14 under the direction of the controller CPU 358.

(A) <u>The User Interface</u>

1. <u>System Power Up/MAIN MENU (Fig. 25)</u>

When power is turned on, the controller 16 runs through an INITIALIZATION ROUTINE.

During the initialization routine, the controller 16 verifies that its CPU 358 and associated hardware are working. If these power-up tests fail, the controller 16 enters a shutdown mode.

If the power-up tests succeed, the controller 16 loads the therapy and cycle settings saved in non-volatile RAM during the last power-down. The

controller 16 runs a comparison to determine whether these settings, as loaded, are corrupt.

If the therapy and cycle settings loaded from RAM are not corrupt, the controller 16 prompts the user to press the GO key to begin a therapy session.

When the user presses the GO key, the controller 16 displays the MAIN MENU. The MAIN MENU allows the user to choose to (a) select the therapy and adjust the associated cycle settings; (b) review the ultrafiltrate figures from the last therapy session, and (c) start the therapy session based upon the current settings.

2. THERAPY SELECTION MENU (Fig. 26)

With choice (a) of the MAIN MENU selected, the controller 16 displays the THERAPY SELECTION MENU. This menu allows the user to specify the APD modality desired, selecting from CCPD, IPD, and TPD (with an without full drain phases).

The user can also select an ADJUST CYCLE SUBMENU. This submenu allows the user to select and change the therapy parameters.

For CCPD and IPD modalities, the therapy parameters include the THERAPY VOLUME, which is the total dialysate volume to be infused during the therapy session (in ml); the THERAPY TIME, which is the total time allotted for the therapy (in hours and minutes); the FILL VOLUME, which is the volume to be infused during each fill phase (in ml), based upon the size of the patient's peritoneal cavity; the LAST FILL VOLUME, which is the final volume to be left in the patient at the end of the session (in ml); and SAME DEXTROSE (Y OR N), which allows the user to specify a different dextrose concentration for the last fill volume.

For the TPD modality, the therapy parameters include THERAPY VOLUME, THERAPY TIME, LAST FILL VOLUME, AND SAME DEXTROSE (Y OR N), as above described. In TPD, the FILL VOLUME parameter is the initial tidal fill volume (in ml). TPD includes also includes as additional parameters TIDAL VOLUME PERCENTAGE, which is the fill volume to be infused and drained periodically, expressed as a percentage of the total therapy volume; TIDAL FULL DRAINS, which is the number of full drains in the therapy session; and TOTAL UF, which is the total ultrafiltrate expected from the patient during the session (in ml), based upon prior patient monitoring.

The controller 16 includes a THERAPY LIMIT TABLE. This Table sets predetermined maximum and minimum limits and permitted increments for the therapy parameters in the ADJUST CYCLE SUBMENU.

The controller 16 also includes a THERAPY VALUE VERIFICATION ROUTINE. This routine checks the parameters selected to verify that a reasonable therapy session has been programmed. The THERAPY VALUE VERIFICATION ROUTINE checks to assure that the selected therapy parameters include a dwell time of at least one minute; at least one cycle; and for TPD the expected filtrate is not unreasonably large (i.e., it is less than 25% of the selected THERAPY VOLUME). If any of these parameters is unreasonable, the THERAPY VALUE VERIFICATION ROUTINE places the user back in the ADJUST CYCLE SUBMENU and identifies the therapy parameter that is most likely to be wrong. The user is required to program a reasonable therapy before leaving the ADJUST CYCLE SUBMENU and begin a therapy session.

Once the modality is selected and verified, the

controller 16 returns to user to the MAIN MENU.

3. REVIEW ULTRAFILTRATION MENU

With choice (b) of the MAIN MENU selected, the controller 16 displays the REVIEW ULTRAFILTRATION MENU (see Fig. 25).

This Menu displays LAST UF, which is the total volume of ultrafiltrate generated by the pervious therapy session. For CCPD and IPD modalities, the user can also select to ULTRAFILTRATION REPORT. This Report provides a cycle by cycle breakdown of the ultrafiltrate obtained from the previous therapy session.

4. SET-UP PROMPTS/LEAK TESTING

With choice (c) of the MAIN MENU selected, the controller 16 first displays SET-UP PROMPTS to the user (as shown in Fig. 27).

The SET-UP PROMPTS first instruct the user to LOAD SET. The user is required to open the door; load a cassette; close the door; and press GO to continue with the set-up dialogue.

When the user presses GO, the controller 16 pressurizes the main bladder and occluder bladder and tests the door seal.

If the door seal fails, the controller 16 prompts the user to try again. If the door continues to fail a predetermined period of times, the controller 16 raises a SYSTEM ERROR and shuts down.

If the door seal is made, the SET-UP PROMPTS next instruct the user to CONNECT BAGS. The user is required to connect the bags required for the therapy session; to unclamp the liquid tubing lines being use and assure that the liquid lines that are

not remained clamped (for example, the selected therapy may not require final fill bags, so liquid lines to these bags should remain clamped). Once the user accomplishes these tasks, he/she presses GO to continue with the set-up dialogue.

When GO is pressed, the controller 16 checks which lines are clamped and uses the programmed therapy parameters to determine which lines should be primed. The controller 16 primes the appropriate lines. Priming removes air from the set lines by delivering air and liquid from each bag used to the drain.

Next, the controller 16 performs a predetermined series of integrity tests to assure that no valves in the cassette leak; that there are no leaks between pump chambers; and that the occluder assembly stops all liquid flow.

The integrity tests first convey the predetermined high-relative negative air pressure (-5.0 psig) to the valve actuators VA1 to VA10. The transducer XNEG monitors the change in high-relative negative air pressure for a predetermined period. If the pressure change over the period exceeds a predetermined maximum, the controller 16 raises a SYSTEM ERROR and shuts down.

Otherwise, the integrity tests convey the predetermined high-relative positive pressure (7.0 psig) to the valve actuators VA1 to VA10. The transducer XHPOS monitors the change in high-relative positive air pressure for a predetermined period. If the pressure change over the period exceeds a predetermined maximum, the controller 16 raises a SYSTEM ERROR and shuts down.

Otherwise, the integrity tests proceed. The valve actuators VA1 to VA10 convey positive pressure

to close the cassette valve stations V1 to V10. The tests first convey the predetermined maximum high-relative negative pressure to pump actuator PA1, while conveying the predetermined maximum high-relative positive pressure to pump actuator PA2. The transducers XP1 and XP2 monitor the pressures in the respective pump actuators PA1 and PA2 for a predetermined period. If pressure changes over the period exceed a predetermined maximum, the controller 16 raises a SYSTEM ERROR and shuts down.

Otherwise, the tests next convey the predetermined maximum high-relative positive pressure to pump actuator PA1, while conveying the predetermined maximum high-relative negative pressure to pump actuator PA2. The transducers XP1 and XP2 monitor the pressures in the respective pump actuators PA1 and PA2 for a predetermined period. If pressure changes over the period exceed a predetermined maximum, the controller 16 raises a SYSTEM ERROR and shuts down.

Otherwise, power to valve C6 is interrupted. This vents the occluder bladder 152 and urges the occluder blade and plate 144/148 together, crimping cassette tubing 26 to 34 closed. The pump chambers P1 and P2 are operated at the predetermined maximum pressure conditions and liquid volume measurements taken in the manner previously described. If either pump chamber P1/P2 moves liquid pass the closed occluder blade and plate 144/148, the controller 16 raises a SYSTEM ERROR and shuts down.

If all integrity tests succeed, the SET-UP PROMPTS next instruct the user to CONNECT PATIENT. The user is required to connect the patient according to the operator manual and press GO to begin the dialysis therapy session selected.

The controller 16 begins the session and displays the RUN TIME MENU.

5. RUN TIME MENU

Attention is now directed to Fig. 28.

The RUN TIME MENU is the active therapy interface. The RUN TIME MENU provides an updated real-time status report of the current progress of the therapy session.

The RUN TIME MENU includes the CYCLE STATUS, which identifies the total number of fill/dwell/drain phases to be conducted and the present number of the phase underway (e.g., Fill 3 of 10); the PHASE STATUS, which displays the present fill volume, counting up from 0 ml; the ULTRAFILTRATION STATUS, which displays total ultrafiltrate accumulated since the start of the therapy session; the TIME, which is the present time; and FINISH TIME, which is the time that the therapy session is expected to end.

Preferably, the user can also select in the RUN TIME MENU an ULTRAFILTRATION STATUS REVIEW SUBMENU, which displays a cycle by cycle breakdown of ultrafiltration accumulated.

From the RUN TIME MENU, the user can also select to STOP. The controller 16 interrupts the therapy session and displays the STOP SUBMENU. The STOP SUBMENU allows the user to REVIEW the programmed therapy parameters and make change to the parameters; to END the therapy session; to CONTINUE the therapy session; to BYPASS the present phase; to conduct a MANUAL DRAIN; or ADJUST the intensity of the display and loudness of alarms.

REVIEW restricts the type of changes that the user can make to the programmed parameters. For

example, in REVIEW, the user cannot adjust parameters above or below a maximum specified amounts.

CONTINUE returns the user to the RUN TIME MENU and continue the therapy session where it left off.

The controller 16 preferably also includes specified time-outs for the STOP SUBMENU. For example, if the user does not take any action in the STOP SUBMENU for 30 minutes, the controller 16 automatically executes CONTINUE to return to the RUN TIME MENU and continue the therapy session. If the user does not take any action for 2 minutes after selecting REVIEW, the controller 16 also automatically executes CONTINUE.

6. Background Monitoring Routine/System Errors

The controller 16 includes a BACKGROUND MONITORING ROUTINE that verifies system integrity at a predetermined intervals during the therapy session (e.g., every 10 seconds) (as Fig. 29 shows).

The BACKGROUND MONITORING ROUTINE includes

BAG OVER TEMP, which verifies that the heater bag is not too hot (e.g., not over 44 degrees C);

DELIVERY UNDER TEMP, which verifies that the liquid delivered to the patient is not too cold (e.g, less than 33 degrees C);

DELIVERY OVER TEMP, which verifies that the liquid delivered to the patient is not too hot (e.g, over 38 degrees C);

MONITOR TANKS, which verifies that the air tanks are at their operating pressures (e.g., positive tank pressure at 7.5 psi +/- 0.7 psi; patient tank at 5.0 psi +/- 0.7 psi, except for

heater to patient line, which is 1.5 psi +/- 0.2 psi; negative tank pressure at -5.0 psi +/- 0.7psi, except for patient to drain line, which is at -0.8 psi +/- 0.2 psi);

CHECK VOLTAGES, which verify that power supplies are within their noise and tolerance specs;

VOLUME CALC, which verifies the volume calculation math; and

CHECK CPU, checks the processor and RAM.

When the BACKGROUND MONITORING ROUTINE senses an error, the controller 16 raises a SYSTEM ERROR. Loss of power also raises a SYSTEM ERROR. When SYSTEM ERROR occurs, the controller 16 sounds an audible alarm and displays a message informing the user about the problem sensed.

When SYSTEM ERROR occurs, the controller 16 also shuts down the cycler 14. During shut down, the controller 16 ensures that all liquid delivery is stopped, activates the occluder assembly, closes all liquid and air valves, turns the heater plate elements off. If SYSTEM ERROR occurs due to power failure, the controller 16 also vents the emergency bladder, releasing the door.

7. SELF-DIAGNOSTICS AND TROUBLE SHOOTING

According to the invention, the controller 16 monitors and controls pneumatic pressure within the internal pressure distribution system 86. Based upon pneumatic pressure measurements, the controller 16 calculates the amount and flow rate of liquid moved. The controller does not require an additional external sensing devices to perform any of its control or measurement functions.

As a result, the system 10 requires no external pressure, weight, or flow sensors for the tubing 26

to 34 or the bags 20/22 to monitor and diagnose liquid flow conditions. The same air pressure that moves liquid through the system 10 also serves to sense and diagnose all relevant external conditions affecting liquid flow, like an empty bag condition, a full bag condition, and an occluded line condition.

Moreover, strictly by monitoring the pneumatic pressure, the controller 16 is able to distinguish a flow problem emanating from a liquid source from a flow problem emanating from a liquid destination.

Based upon the liquid volume measurements derived by the measurement network 350, the controller 16 also derives liquid flow rate. Based upon values and changes in derived liquid flow rate, the controller 16 can detect an occluded liquid flow condition. Furthermore, based upon derived liquid flow rates, the controller can diagnose and determine the cause of the occluded liquid flow condition.

The definition of an "occluded flow" condition can vary depending upon the APD phase being performed. For example, in a fill phase, an occluded flow condition can represent a flow rate of less than 20 ml/min. In a drain phase, the occluded flow condition can represent a flow rate of less than 10 ml/min. In a bag to bag liquid transfer operation, an occluded flow condition can represent a flow rate of less than 25 ml/min. Occluded flow conditions for pediatric APD sessions can be placed at lower set points.

When the controller 16 detects an occluded flow condition, it implements the following heuristic to determine whether the occlusion is attributable to a given liquid source or a given liquid destination.

When the controller 16 determines that the cassette cannot draw liquid from a given liquid source above the occluded flow rate, the controller 16 determines whether the cassette can move liquid toward the source above the occluded flow rate (i.e., it determines whether the liquid source can serve as a liquid destination). If it can, the controller 16 diagnoses the condition as an empty liquid source condition.

When the controller 16 determines that the cassette cannot push liquid toward a given destination above the occluded flow rate, it determines whether the cassette can draw liquid from the destination above the occluded flow rate (i.e., it determines whether the liquid destination can serve as a liquid source). If it can, the controller diagnoses the condition as being a full liquid destination condition.

When the controller 16 determines that the cassette can neither draw or push liquid to or from a given source or destination above the occluded flow rate, the controller 16 interprets the condition as an occluded line between the cassette and the particular source or destination.

In this way, the system 10 operates by controlling pneumatic fluid pressure, but not by reacting to external fluid or liquid pressure or flow sensing.

8. ALARMS

With no SYSTEM ERRORS, the therapy session automatically continues unless the controller 16 raises an ALARM1 or ALARM2. Fig. 30 shows the ALARM1 and ALARM2 routines.

The controller 16 raises ALARM1 in situations

that require user intervention to correct. The controller 16 raises ALARM1 when the controller 16 senses no supply liquid; or when the cycler 14 is not level. When ALARM1 occurs, the controller 16 suspends the therapy session and sounds an audible alarm. The controller 16 also displays an ALARM MENU that informs the user about the condition that should be corrected.

The ALARM MENU gives the user the choice to correct the condition and CONTINUE; to END the therapy; or to BYPASS (i.e., ignore) the condition and resume the therapy session.

The controller 16 raises ALARM2 in situations that are anomalies but will typically correct themselves with minimum or no user intervention. For example, the controller 16 raises ALARM2 when the controller 16 initially senses a low flow or an occluded lines. In this situation, the patient might have rolled over onto the catheter and may need only to move to rectify the matter.

When ALARM2 occurs, the controller 16 generates a first audible signal (e.g., 3 beeps). The controller 16 then mutes the audible signal for 30 seconds. If the condition still exists after 30 second, the controller 16 generates a second audible signal (e.g., 8 beeps) The controller 16 again mutes the audible signal. If the condition still exists 30 seconds later, the controller 16 raises an ALARM1, as described above. The user is then required to intervene using the ALARM MENU.

9. POST THERAPY PROMPTS

The controller 16 terminates the session when (a) the prescribed therapy session is successfully completed; (b) the user selects END in the STOP

SUBMENU or the ALARM MENU; or (c) a SYSTEM ERROR condition occurs (see Fig. 31).

When any of these events occur, the controller 16 displays POST THERAPY PROMPTS to the user. The POST THERAPY PROMPTS inform the user THERAPY FINISHED, to CLOSE CLAMPS, and to DISCONNECT PATIENT. The user presses GO to advance the prompts.

Once the user disconnects the patient and presses GO, the controller 16 displays PLEASE WAIT and depressurizes the door. Then the controller 16 then directs the user to REMOVE SET.

Once the user removes the set and presses GO, the controller 16 returns to user to the MAIN MENU.

(B) Controlling an APD Therapy Cycle

1. Fill Phase

In the fill phase of a typical three phase APD cycle, the cycler 14 transfers warmed dialysate from the heater bag 22 to the patient.

The heater bag 22 is attached to the first (uppermost) cassette port 27. The patient line 34 is attached to the fifth (bottommost) cassette port 35.

As Fig. 32 shows, the fill phase involves drawing warmed dialysate into cassette pump chamber P1 through primary liquid path F1 via branch liquid path F6. Then, pump chamber P1 expels the heated dialysate through primary liquid path F5 via branch liquid path F8.

To expedite pumping operations, the controller 16 preferably works pump chamber P2 in tandem with pump chamber P1. The controller 16 draws heated dialysate into pump chamber P2 through primary liquid path F1 via branch liquid path F7. Then,

pump chamber P2 expels the heated dialysate through primary liquid path F5 through branch liquid path F9.

The controller 16 works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa.

In this sequence, heated dialysate is always introduced into the top portions of pump chambers P1 and P2. The heated dialysate is always discharged through the bottom portions of pump chambers P1 and P2 to the patient free of air.

Furthermore, during liquid transfer directly with the patient, the controller 16 can supply only low-relative positive and negative pressures to the pump actuators PA1 and PA2.

In carrying out this task, the controller 16 alternates the following sequences 1 and 2:

1. Perform pump chamber P1 draw stroke (drawing a volume of heated dialysate into pump chamber P1 from the heater bag), while performing pump chamber P2 pump stroke (expelling a volume of heated dialysate from pump chamber P2 to the patient).

(i) Open inlet path F1 to pump chamber P1, while closing inlet path F1 to pump chamber P2. Actuate valve C0 to supply high-relative negative pressure to valve actuator VA1, opening cassette valve station V1. Actuate valves C1; D1; and D2 to supply high-relative positive pressure to valve actuators VA2; VA3: and VA4, closing cassette valve station V2; V3; and V4.

(ii) Close outlet path F5 to pump chamber P1, while opening outlet path F5 to pump chamber P2. Actuate valves C2 to C4 and D3 to D5 to supply high-relative positive pressure to valve

actuators VA8 to V10 and VA5 to VA7, closing cassette valve stations V8 to V10 and V5 to V7. Actuate valve D5 to supply high-relative negative pressure to valve actuator VA7, opening cassette valve station V7.

(iii) Flex the diaphragm underlying actuator PA1 out. Actuate valve A0 to supply low-relative negative pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 in. Actuate valve B1 to supply low-relative positive pressure to pump actuator PA2.

2. Perform pump chamber P2 draw stroke (drawing a volume of heated dialysate into pump chamber P2 from the heater bag), while performing pump chamber P1 pump stroke (expelling a volume of heated dialysate from pump chamber P1 to the patient).

(i) Open inlet path F1 to pump chamber P2, while closing inlet path F1 to pump chamber P1. Actuate valves C0; C1; and D2 to supply high-relative positive pressure to valve actuators VA1; VA2; and VA4, closing cassette valve stations V1; V2; and V4. Actuate valve D1 to supply high-relative negative pressure to valve actuator VA3, opening cassette valve station V3.

(ii) Close outlet path F5 to pump chamber P2, while opening outlet path F5 to pump chamber P1. Actuate valve C2 to supply high-relative negative pressure to valve actuator VA8, opening cassette valve station V8. Actuate valves D3 to D5; C2; and C4 to supply high-relative positive pressure to valve actuators VA5 to VA7; V9; and V10, closing cassette valve stations V5 to V7; V9; and V10.

(iii) Flex the diaphragm underlying actuator PA1 in. Actuate valve A3 to supply low-

relative positive pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 out. Actuate valve B4 to supply low-relative negative pressure to pump actuator PA2.

2. Dwell Phase

Once the programmed fill volume has been transferred to the patient, the cycler 14 enters the second or dwell phase. In this phase, the cycler 14 replenishes the heater bag by supplying fresh dialysate from a source bag.

The heater bag is attached to the first (uppermost) cassette port. The source bag line is attached to the fourth cassette port, immediately above the patient line.

As Fig. 33 shows, the replenish heater bag phase involves drawing fresh dialysate into cassette pump chamber P1 through primary liquid path F4 via branch liquid path F8. Then, pump chamber P1 expels the dialysate through primary liquid path F1 via branch liquid path F6.

To expedite pumping operations, the controller 16 preferably works pump chamber P2 in tandem with pump chamber P1. The controller 16 draws fresh dialysate into cassette pump chamber P2 through primary liquid path F4 via branch liquid path F9. Then, pump chamber P2 expels the dialysate through primary liquid path F1 via branch liquid path F7.

The controller 16 works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa.

In this sequence, fresh dialysate is always introduced into the bottom portions of pump chambers P1 and P2. The fresh dialysate is always discharged through the top portions of pump chambers P1 and P2

to the heater bag. This allows entrapped air to be removed from the pump chambers P1 and P2.

Furthermore, since liquid transfer does not occur directly with the patient, the controller 16 supplies high-relative positive and negative pressures to the pump actuators PA1 and PA2.

In carrying out this task, the controller 16 alternates the following sequences:

1. Perform pump chamber P1 draw stroke (drawing a volume of fresh dialysate into pump chamber P1 from a source bag), while performing pump chamber P2 pump stroke (expelling a volume of fresh dialysate from pump chamber P2 to the heater bag).

(i) Open inlet path F4 to pump chamber P1, while closing inlet path F4 to pump chamber P2. Actuate valve C3 to supply high-relative negative pressure to valve actuator VA9, opening cassette valve station V9. Actuate valves D3 to D5; C2; and C4 to supply high-relative positive pressure to valve actuators VA5 to VA8; and VA10, closing cassette valve stations V5 to V8 and V10.

(ii) Close outlet path F1 to pump chamber P1, while opening outlet path F1 to pump chamber P2. Actuate valves C0; C1; and D2 to supply high-relative positive pressure to valve actuators VA1; VA2 and VA4, closing cassette valve stations V1; V2; and V4. Actuate valve D1 to supply high-relative negative pressure to valve actuator VA3, opening cassette valve station V3.

(iii) Flex the diaphragm underlying actuator PA1 out. Actuate valve A0 to supply high-relative negative pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 in. Actuate valve B0 to supply high-relative positive pressure to pump actuator PA2.

2. Perform pump chamber P2 draw stroke (drawing a volume of fresh dialysate into pump chamber P2 from a source bag), while performing pump chamber P1 pump stroke (expelling a volume of fresh dialysate from pump chamber P1 to heater bag).

(i) Close inlet path F4 to pump chamber P1, while opening inlet path F4 to pump chamber P2. Actuate valve D5 to supply high-relative negative pressure to valve actuator VA6, opening cassette valve station V6. Actuate valves C3 to C4; D3; and D5 to supply high-relative positive pressure to valve actuators VA5 and VA7 to VA10, closing cassette valve stations V5 and V7 to V10.

(ii) Open outlet path F1 to pump chamber P1, while closing outlet path F1 to pump chamber P2. Actuate valve C0 to supply high-relative negative pressure to valve actuator VA1, opening cassette valve station V1. Actuate valves C1; D1; and D2 to supply high-relative positive pressure to valve actuators VA2 to VA4, closing cassette valve station V2 to V4.

(iii) Flex the diaphragm underlying actuator PA1 in. Actuate valve A4 to supply high-relative positive pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 out. Actuate valve B4 to supply high-relative negative pressure to pump actuator PA2.

3. <u>Drain Phase</u>

When the programmed drain phase ends, the cycler 14 enters the third or drain phase. In this phase, the cycler 14 transfers spent dialysate from the patient to a drain.

The drain line is attached to the second cassette port. The patient line is attached to the

fifth, bottommost cassette port.

As Fig. 34 shows, the drain phase involves drawing spent dialysate into cassette pump chamber P1 through primary liquid path F5 via branch liquid path F8. Then, pump chamber P1 expels the dialysate through primary liquid path F2 via branch liquid path F6.

To expedite pumping operations, the controller 16 works pump chamber P2 in tandem with pump chamber P1. The controller 16 draws spend dialysate into cassette pump chamber P2 through primary liquid path F5 via branch liquid path F9. Then, pump chamber P2 expels the dialysate through primary liquid path F2 via branch liquid path F7.

The controller 16 works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa.

In this sequence, spent dialysate is always introduced into the bottom portions of pump chambers P1 and P2. The spent dialysate is always discharged through the top portions of pump chambers P1 and P2 to the heater bag. This allows air to be removed from the pump chambers P1 and P2.

Furthermore, since liquid transfer does occur directly with the patient, the controller 16 supplies low-relative positive and negative pressures to the pump actuators PA1 and PA2.

In carrying out this task, the controller 16 alternates the following sequences:

1. Perform pump chamber P1 draw stroke (drawing a volume of spent dialysate into pump chamber P1 from the patient), while performing pump chamber P2 pump stroke (expelling a volume of spent dialysate from pump chamber P2 to the drain).

(i) Open inlet path F5 to pump chamber

P1, while closing inlet path F5 to pump chamber P2. Actuate valve C2 to supply high-relative negative pressure to valve actuator VA8, opening cassette valve station V8. Actuate valves D3 to D5, C3, and C4 to supply high-relative positive pressure to valve actuators VA5 to VA7, VA9 and VA10, closing cassette valve stations V5 to V7, V9, and V10.

(ii) Close outlet path F2 to pump chamber P1, while opening outlet path F2 to pump chamber P2. Actuate valves C0; C1; and D1 to supply high-relative positive pressure to valve actuators VA1; VA2 and VA3, closing cassette valve stations V1; V2; and V3. Actuate valve D2 to supply high-relative negative pressure to valve actuator VA4, opening cassette valve station V4.

(iii) Flex the diaphragm underlying actuator PA1 out. Actuate valve A0 to supply low-relative negative pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 in. Actuate valve B1 to supply low-relative positive pressure to pump actuator PA2.

2. Perform pump chamber P2 draw stroke (drawing a volume of spent dialysate into pump chamber P2 from the patient), while performing pump chamber P1 pump stroke (expelling a volume of spent dialysate from pump chamber P1 to the drain).

(i) Close inlet path F5 to pump chamber P1, while opening inlet path F5 to pump chamber P2. Actuate valve D5 to supply high-relative negative pressure to valve actuator VA7, opening cassette valve station V7. Actuate valves D3; D4 and C2 to C4 to supply high-relative positive pressure to valve actuators VA5; VA6; and VA8 to VA10, closing cassette valve stations V5, V6, and V8 to V10.

(ii) Open outlet path F2 to pump chamber

P1, while closing outlet path F2 to pump chamber P2. Actuate valve C1 to supply high-relative negative pressure to valve actuator VA2, opening cassette valve station V2. Actuate valves C0; D1; and D2 to supply high-relative positive pressure to valve actuators VA1; VA3; and VA4, closing cassette valve station V1; V3; and V4.

(iii) Flex the diaphragm underlying actuator PA1 in. Actuate valve A3 to supply low-relative positive pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 out. Actuate valve B4 to supply low-relative negative pressure to pump actuator PA2.

The controller 16 senses pressure using transducers XP1 and XP2 to determine when the patient's peritoneal cavity is empty.

The drain phase is followed by another fill phase and dwell phase, as previously described.

4. Last Dwell Phase

In some APD procedures, like CCPD, after the last prescribed fill/dwell/drain cycle, the cycler 14 infuses a final fill volume. The final fill volume dwells in the patient through the day. It is drained at the outset of the next CCPD session in the evening. The final fill volume can contain a different concentration of dextrose than the fill volume of the successive CCPD fill/dwell/drain fill cycles the cycler 14 provides. The chosen dextrose concentration sustains ultrafiltration during the day-long dwell cycle.

In this phase, the cycler 14 infuses fresh dialysate to the patient from a "last fill" bag. The "last fill" bag is attached to the third cassette port. During the last swell phase, the

heater bag is emptied, and solution from last bag volume is transferred to the heater bag. From there, the last fill solution is transferred to the patient to complete the last fill phase.

The last dwell phase involves drawing liquid from the heater bag into pump chamber P1 through primary liquid path F1 via branch path F6. The, the pump chamber P1 expels the liquid to the drain through primary liquid path F2 via branch liquid path F6.

To expedite drainage of the heater bag, the controller 16 works pump chamber P2 in tandem with pump chamber P1. The controller 16 draws liquid from the heater bag into pump chamber P2 through primary liquid path F1 via branch liquid path F7. Then, pump chamber P2 expels liquid to the drain through primary liquid path F2 via branch liquid path F7.

The controller 16 works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa.

Once the heater bag is drained, the controller 16 draws fresh dialysate from the "last fill" bag into cassette pump chamber P1 through primary liquid path F3 via branch liquid path F8. Then, pump chamber P1 expels the dialysate to the heater bag through primary liquid path F1 via the branch liquid path F6.

As before, to expedite pumping operations, the controller 16 preferably works pump chamber P2 in tandem with pump chamber P1. The controller 16 draws fresh dialysate from the "last fill" bag into cassette pump chamber P2 through primary liquid path F3 via branch liquid path F9. Then, pump chamber P2 expels the dialysate through primary liquid path F1

via the branch liquid path F7.

The controller 16 works pump chamber P1 in a draw stroke, while working pump chamber P2 in a pump stroke, and vice versa.

In this sequence, fresh dialysate from the "last fill" bag is always introduced into the bottom portions of pump chambers P1 and P2. The fresh dialysate is always discharged through the top portions of pump chambers P1 and P2 to the heater bag. This allows air to be removed from the pump chambers P1 and P2.

Furthermore, since liquid transfer does not occur directly with the patient, the controller 16 can supply high-relative positive and negative pressures to the pump actuators PA1 and PA2.

In carrying out this task, the controller 16 alternates the following sequences (see Fig. 35):

1. Perform pump chamber P1 draw stroke (drawing a volume of fresh dialysate into pump chamber P1 from the "last fill" bag), while performing pump chamber P2 pump stroke (expelling a volume of fresh dialysate from pump chamber P2 to the heater bag).

(i) Open inlet path F3 to pump chamber P1, while closing inlet path F3 to pump chamber P2. Actuate valve C4 to supply high-relative negative pressure to valve actuator VA10, opening cassette valve station V10. Actuate valves D3 to D5; C2; and C3 to supply high-relative positive pressure to valve actuators VA5 to VA9, closing cassette valve stations V5 to V9.

(ii) Close outlet path F1 to pump chamber P1, while opening outlet path F1 to pump chamber P2. Actuate valves C0; C1; and D2 to supply high-relative positive pressure to valve actuators VA1;

VA2 and VA4, closing cassette valve stations V1; V2; and V4. Actuate valve D1 to supply high-relative negative pressure to valve actuator VA3, opening cassette valve station V3.

(iii) Flex the diaphragm underlying actuator PA1 out. Actuate valve A0 to supply high-relative negative pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 in. Actuate valve B0 to supply high-relative positive pressure to pump actuator PA2.

2. Perform pump chamber P2 draw stroke (drawing a volume of fresh dialysate into pump chamber P2 from the "last fill" bag), while performing pump chamber P1 pump stroke (expelling a volume of fresh dialysate from pump chamber P1 to heater bag).

(i) Close inlet path F3 to pump chamber P1, while opening inlet path F3 to pump chamber P2. Actuate valve D3 to supply high-relative negative pressure to valve actuator VA5, opening cassette valve station V5. Actuate valves C2 to C4; D4; and D5 to supply high-relative positive pressure to valve actuators VA6 to VA10, closing cassette valve stations V6 to V10.

(ii) Open outlet path F1 to pump chamber P1, while closing outlet path F1 to pump chamber P2. Actuate valve C0 to supply high-relative negative pressure to valve actuator VA1, opening cassette valve station V1. Actuate valves C1; D1; and D2 to supply high-relative positive pressure to valve actuators VA2 to VA4, closing cassette valve station V2 to V4.

(iii) Flex the diaphragm underlying actuator PA1 in. Actuate valve A4 to supply high-relative positive pressure to pump actuator PA1.

(iv) Flex the diaphragm underlying actuator PA2 out. Actuate valve B4 to supply high-relative negative pressure to pump actuator PA2.

Once the last fill solution has been heated, it is transferred to the patient in a fill cycle as described above (and as Fig. 32 shows).

According to one aspect of the invention, every important aspect of the APD procedure is controlled by fluid pressure. Fluid pressure moves liquid through the delivery set, emulating gravity flow conditions based upon either fixed or variable headheight conditions. Fluid pressure controls the operation of the valves that direct liquid among the multiple destinations and sources. Fluid pressure serves to seal the cassette within the actuator and provide a failsafe occlusion of the associated tubing when conditions warrant. Fluid pressure is the basis from which delivered liquid volume measurements are made, from which air entrapped in the liquid is detected and elimination, and from which occluded liquid flow conditions are detected and diagnosed.

According to another aspect of the invention, the cassette serves to organize and mainfold the multiple lengths of tubing and bags that peritoneal dialysis requires. The cassette also serves to centralize all pumping and valving activities required in an automated peritoneal dialysis procedure, while at the same time serving as an effective sterility barrier.

Various features of the invention are set forth in the following claims.

I Claim:

1. A peritoneal dialysis system comprising

a liquid distribution cassette including

a pumping mechanism comprising a diaphragm associated with the pump chamber, and

means for establishing flow communication between the pumping mechanism and the patient's peritoneal cavity,

an operating station for the cassette including

a holder for receiving the cassette body, and

pressure transfer means within the holder operative, when the cassette is received within the holder, for applying pneumatic pressure to the diaphragm to draw liquid into the pump chamber and to expel liquid from the pump chamber, and

first means for deriving an initial air volume measurement V_i after conveying pneumatic pressure to draw liquid into the pump chamber and for deriving a final air volume measurement V_f after conveying pneumatic pressure to expel liquid from the pump chamber, the first means including

a reference chamber having a known volume V_s carried within the holder and, like the pressure transfer means, exposed to generally the same temperature conditions as the pumping mechanism,

means for controlling communication between the reference chamber and the pressure transfer means by, when liquid is drawn into the pump chamber and liquid is expelled from the pump chamber, closing communication between reference chamber and the pressure transfer means to initialize the reference chamber to a measured initial air pressure (IP_{s1}) while conveying a measured pressure to the pressure transfer means

(IP_{d1}); (ii) then opening communication between the reference chamber and the pressure transfer means to allow pressure equilibration at a measured new air pressure in the pressure transfer means (IP_{d2}) and a measured new air pressure in the reference chamber (IP_{s2}), and (iii) then deriving the air volume measurement V^i or V^f as follows:

$$V^{i \text{ or } f} = \frac{(IP_{s1} - IP_{s2}) * V_s}{(IP_{d2} - IP_{d1})}$$

and

second means for deriving a measurement of liquid volume delivered (V_d) by the pumping chamber as follows:

$$V_d = V_f - V_i.$$

2. A system according to claim 1

wherein the first means further includes means for applying a temperature correction factor (F_t) to the known volume of the reference chamber V_s to derive a temperature-corrected reference volume V_{st}, as follows:

$$V_{st} = F_t * V_s$$

and wherein the second means derives the liquid volume measurement V:

$$V = \frac{(IP_{s2} - IP_{s1}) * V_{st}}{(IP_{d2} - IP_{d1})}$$

3. A system according to claim 2

wherein the means for applying a temperature correction factor (F_t) includes means for sensing the temperature of the reference chamber and means for sensing the temperature of the pump chamber so that

$$F_t = \frac{C_t}{R_t}$$

where:

C_t is the sensed absolute temperature of the pumping chamber (expressed in degrees Rankine

or Kelvin), and

R_t is the sensed absolute temperature of the reference chamber (expressed in the same units as C_t).

4. A system according to claim 1

wherein the reference chamber carries within it an insert for dampening pneumatic pressure.

5. A system according to claim 4

wherein the insert is made of an open cell porous material.

6. A system according to claim 4

wherein the insert includes a heat conducting material.

7. A method for performing peritoneal dialysis comprising the steps of

establishing flow communication with the patient's peritoneal cavity through a pumping mechanism that comprises a pump chamber and a diaphragm, and

emulating a selected gravity flow condition by applying pneumatic pressure to the diaphragm through an actuator to operate the pump chamber to draw dialysis liquid into the pump chamber and to expel dialysis liquid from the pump chamber to either move dialysis liquid from the peritoneal cavity or move dialysis liquid into the peritoneal cavity, and

deriving a measurement of liquid volume pumped through the pump chamber by deriving an initial air volume measurement V_i after operating the actuator to draw liquid into the pumping chamber; deriving a final air volume measurement V_f after operating the actuator to expel liquid from the pumping chamber; and deriving the liquid volume delivered (V_d) by the pumping chamber as follows:

$$V_d = V_f - V_i, \text{ and}$$

wherein V_i and V_f are derived by controlling communication between a reference chamber having a known air volume V_s and the actuator by: (i) applying a temperature correction factor (F_t) to the known volume of the reference chamber V_s to derive a temperature-corrected reference air volume V_{st}, as follows:

$$V_{st} = F_t * V_s$$

(ii) when liquid is either drawn into or expelled from the pump chamber, closing communication between reference chamber and the actuator to initialize the reference chamber to a measured initial air pressure (IP_{s1}) while applying a measured pressure to the actuator (IP_{d1}); (iii) opening communication between the reference chamber and the actuator to allow pressure equilibration at a measured new air pressure in the actuator (IP_{d2}) and a measured new air pressure in the reference chamber (IP_{s2}), and (iv) deriving the air volume measurement V_i or V_f as follows:

$$V_{i \text{ or } f} = \frac{(IP_{s1} - IP_{s2}) * V_{st}}{(IP_{d2} - IP_{d1})}$$

8. A method according to claim 7 wherein the step of applying a temperature correction factor (F_t) includes the steps of

sensing the temperature of the reference chamber, and

sensing the temperature of the pump chamber so that

$$F_t = \frac{C_t}{R_t}$$

where:

C_t is the sensed absolute temperature of the pumping chamber (expressed in degrees Rankine or Kelvin), and

R_t is the sensed absolute temperature of the reference chamber (expressed in the same units as C_t).

9. A method for deriving the volume of liquid pumped through a pumping chamber that is operated in response to pneumatic pressure variations applied by a pump actuator comprising the steps of

drawing a volume of liquid to be pumped into the pumping chamber by applying negative pressure to the pump actuator,

deriving an initial air volume V_i by

retaining the initial liquid volume in the pumping chamber,

initializing a reference chamber having a known air volume V_s to a measured initial air pressure (IP_{s1}), the reference chamber being first isolated from the pump actuator,

applying a temperature correction factor (F_t) to the known air volume of the reference chamber V_s to derive a temperature-corrected reference air volume V_{st}, as follows:

$$V_{st} = F_t * V_s$$

applying positive pressure to the pump actuator and measuring this air pressure (IP_{d1}),

opening communication with the reference chamber to allow pressure equilibration and measuring the new air pressure in the pump actuator (IP_{d2}) and the new air pressure in the reference chamber (IP_{s2}),

calculating V_i as follows:

$$V_i = \frac{(IP_{s1} - IP_{s2}) * V_{st}}{(IP_{d2} - IP_{d1})}$$

expelling the volume of liquid from the pumping chamber by applying positive pressure to the pump actuator,

deriving a final air volume V_f by:

retaining the final liquid volume in the pumping chamber,

again initializing the reference chamber a measured initial air pressure (FP_{s1}), having first isolated the reference chamber from the pump actuator chamber,

again applying positive pressure to the pump actuator and measuring this air pressure (FP_{d1}),

again opening communication with the reference chamber to allow equilibration and measuring the new air pressure in the pump actuator (FP_{d2}) and the new air pressure in the reference chamber (FP_{s2}),

calculating V_i as follows:

$$V_i = \frac{(FP_{s1} - FP_{s2}) * V_{st}}{(FP_{d2} - FP_{d1})}$$

deriving the liquid volume delivered (V_d) as follows:

$$V_d = V_f - V_i$$

10. A method according to claim 9 wherein

$$F_t = \frac{C_t}{R_t}$$

and where:

C_t is the sensed absolute temperature of the pumping chamber (expressed in degrees Rankine or Kelvin), and

R_t is the sensed temperature of the reference chamber (expressed in the same units as

C_t).

11. A peritoneal dialysis system comprising

a pumping mechanism comprising a diaphragm,

means for establishing flow communication with the patient's peritoneal cavity through the pumping mechanism, and

actuating means for emulating a selected gravity flow condition by applying pneumatic pressure to the diaphragm to operate the pumping mechanism to either move dialysis liquid from the peritoneal cavity or move dialysis liquid into the peritoneal cavity, and

control means selectively operating the actuating means for applying pneumatic pressure to emulate either a fixed head height condition or different head height conditions, and

means for deriving a measurement of liquid volume moving through the pumping mechanism including

a reference chamber having a known air volume V_s,

an insert occupying the reference chamber for dampening pneumatic pressure,

means controlling communication between the reference chamber and the actuating means being operable for (i) closing communication between reference chamber and the actuating means to initialize the reference chamber to a measured initial air pressure (IP_{s1}) while applying a measured air pressure to the actuating means (IP_{d1}) and (ii) opening communication between the reference chamber and the actuating means to allow pressure equilibration at a measured new air pressure in the actuating means (IP_{d2}) and a measured new air pressure in the reference chamber (IP_{s2}), and

means for deriving an air volume measurement V as follows:

$$V = \frac{(IP_{s1} - IP_{s2}) * V_s}{(IP_{d2} - IP_{d1})}$$

wherein the means for deriving a measurement of liquid volume moving through the pumping mechanism further includes

means for deriving an initial air volume measurement V_i upon operating the actuating means to draw liquid into the pumping mechanism,

means for deriving a final air volume measurement V_f upon operating the actuating means to expel liquid from the pumping mechanism, and

means for deriving liquid volume delivered (V_d) by the pumping mechanism as follows:

$$V_d = V_f - V_i$$

12. A system according to claim 11

wherein the actuating means includes an actuating chamber for receiving pneumatic pressure and an insert occupying the actuating chamber for dampening pneumatic pressure.

13. A system according to claim 12

wherein the insert in the actuating chamber is made of an open cell porous material.

14. A system according to claim 11

wherein the insert in the reference chamber is made of an open cell porous material.

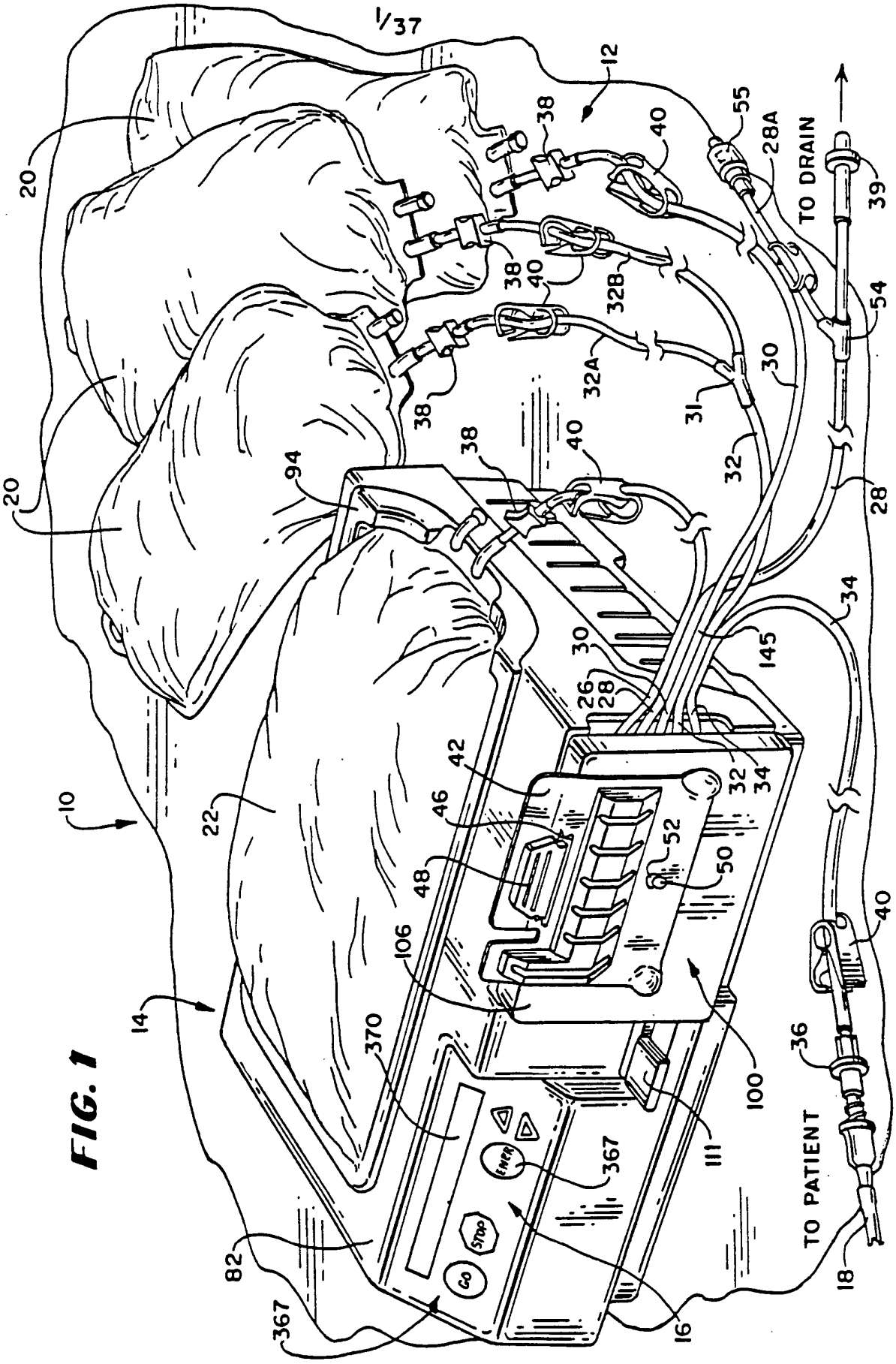

1/37
12
20
38
40
55
28A
TO DRAIN
39
54
30
32A
32B
31
32
28
34
145
26
42
46
48
52
50
106
14
370
100
36
TO PATIENT
18
16
111
367
82
STOP
GO
ENTER
10
22
94

FIG. 1

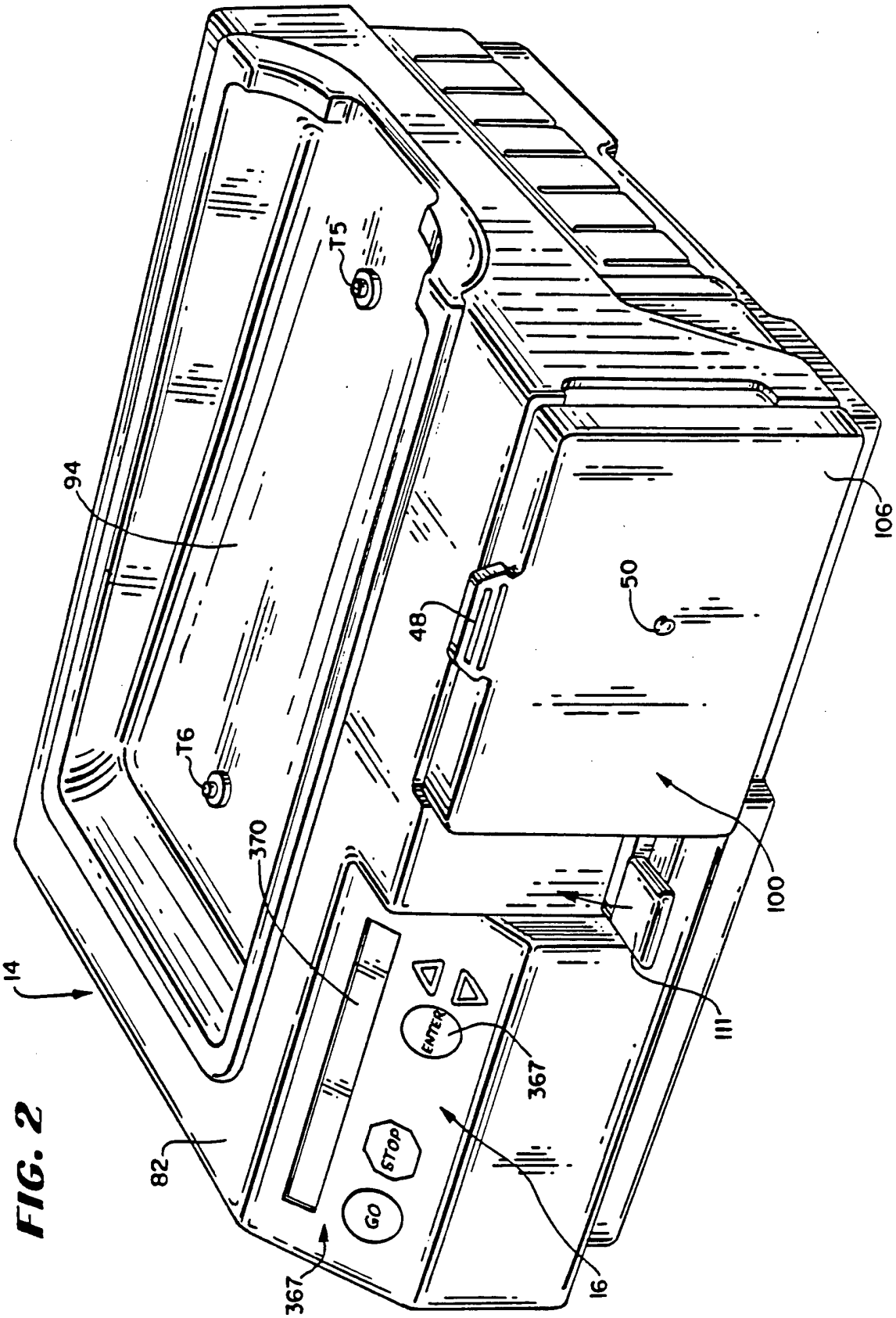


FIG. 2

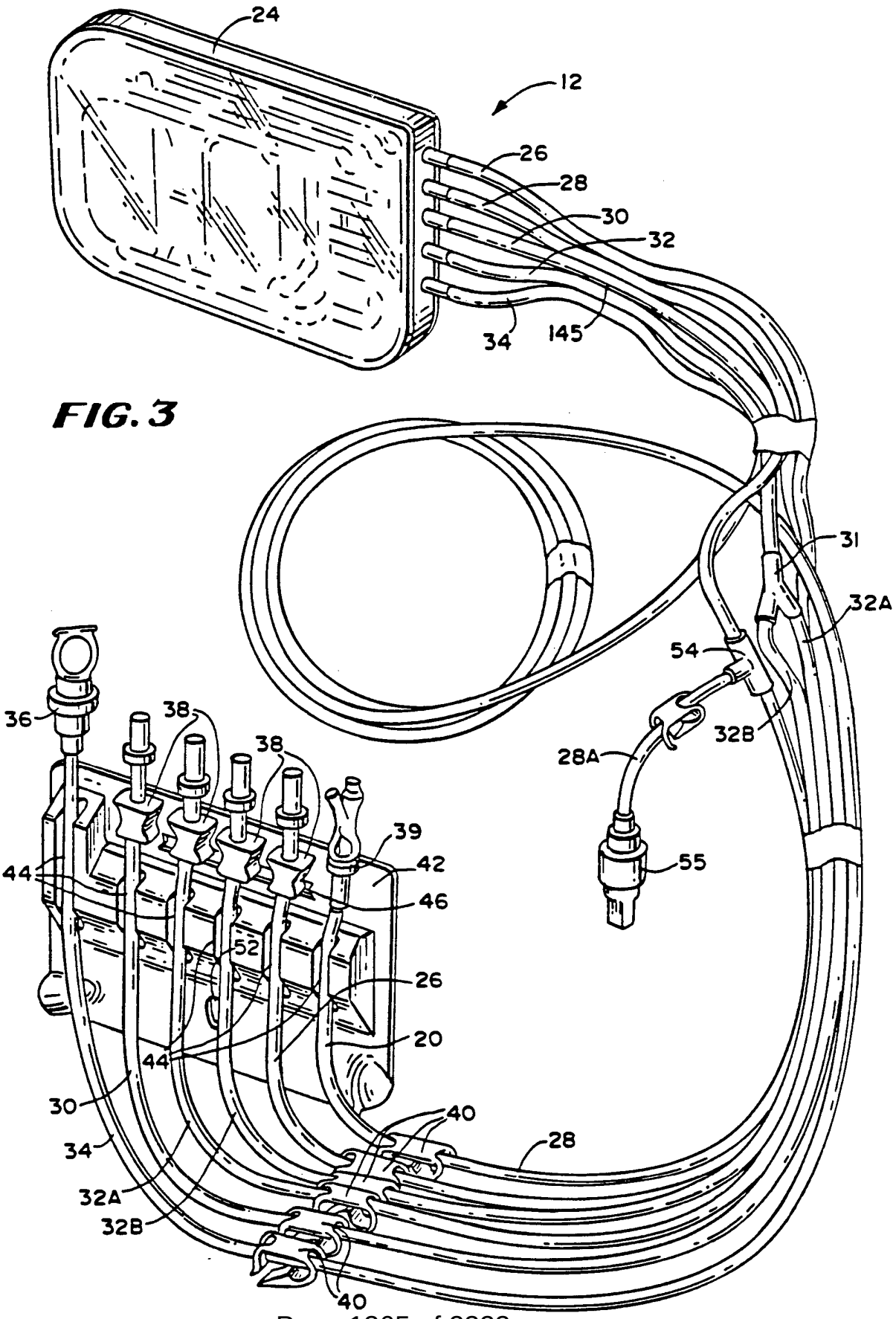

24
12
26
28
30
32
34
145
31
32A
54
32B
28A
55
36
38
38
39
42
44
46
52
26
20
44
30
34
32A
32B
40
28
40

FIG. 3

FIG. 4

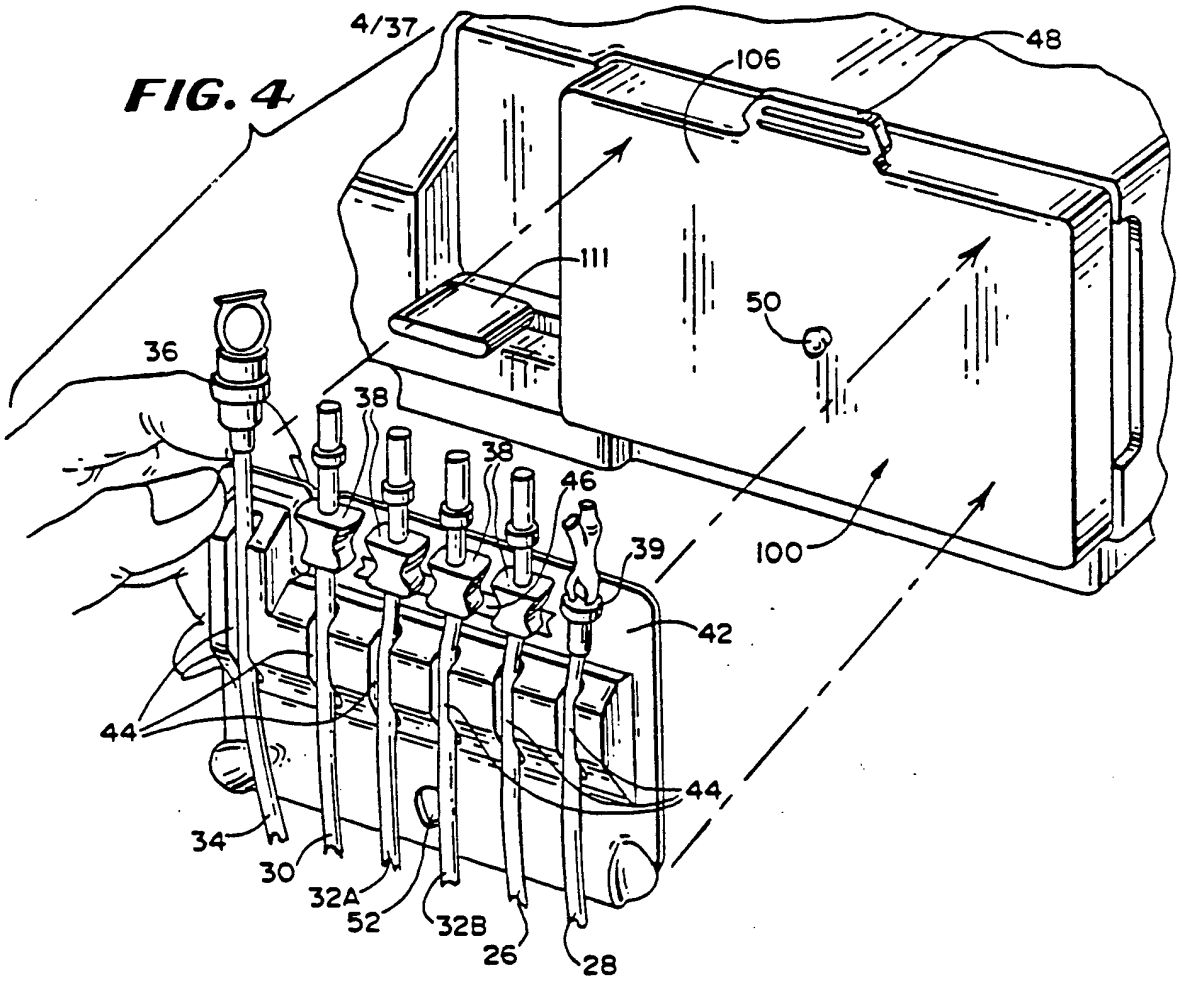
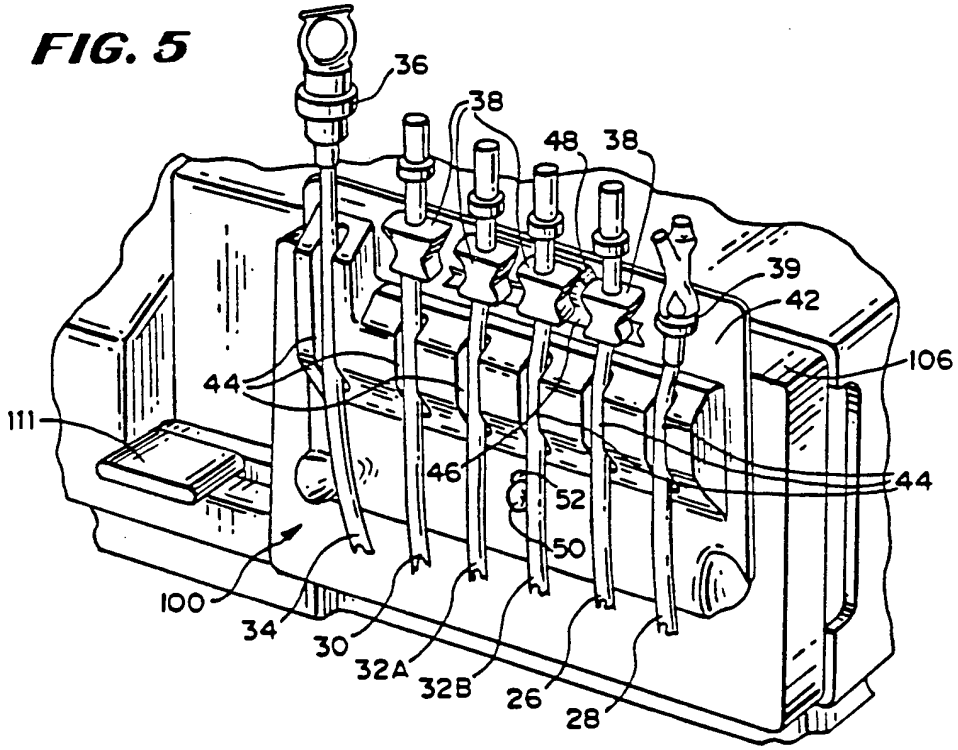

4/37
48
106
111
50
36
38
38
46
39
100
42
44
44
34
30
32A
52
32B
26
28

FIG. 5


36
38
48
38
39
42
106
44
111
46
44
52
50
100
34
30
32A
32B
26
28

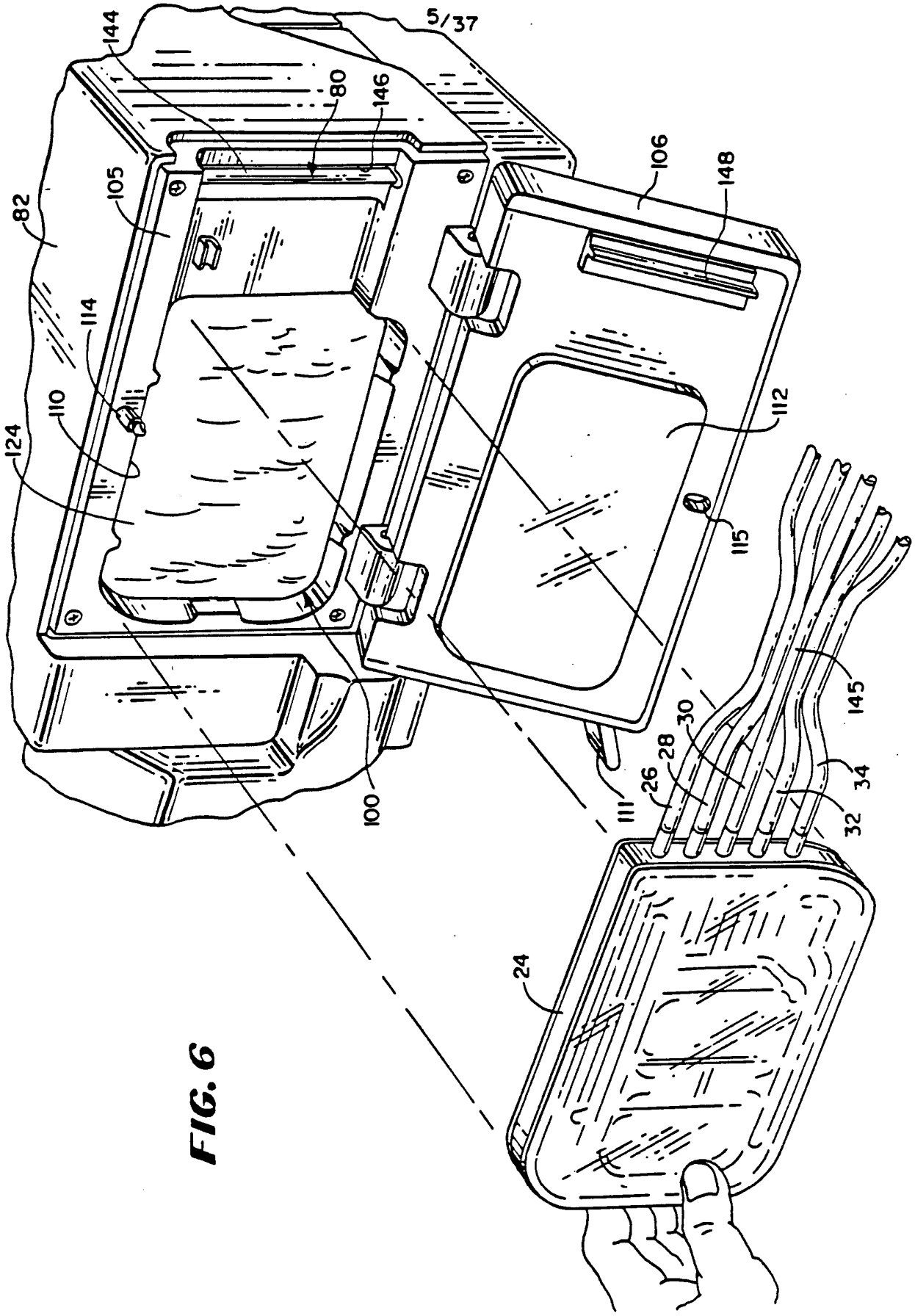
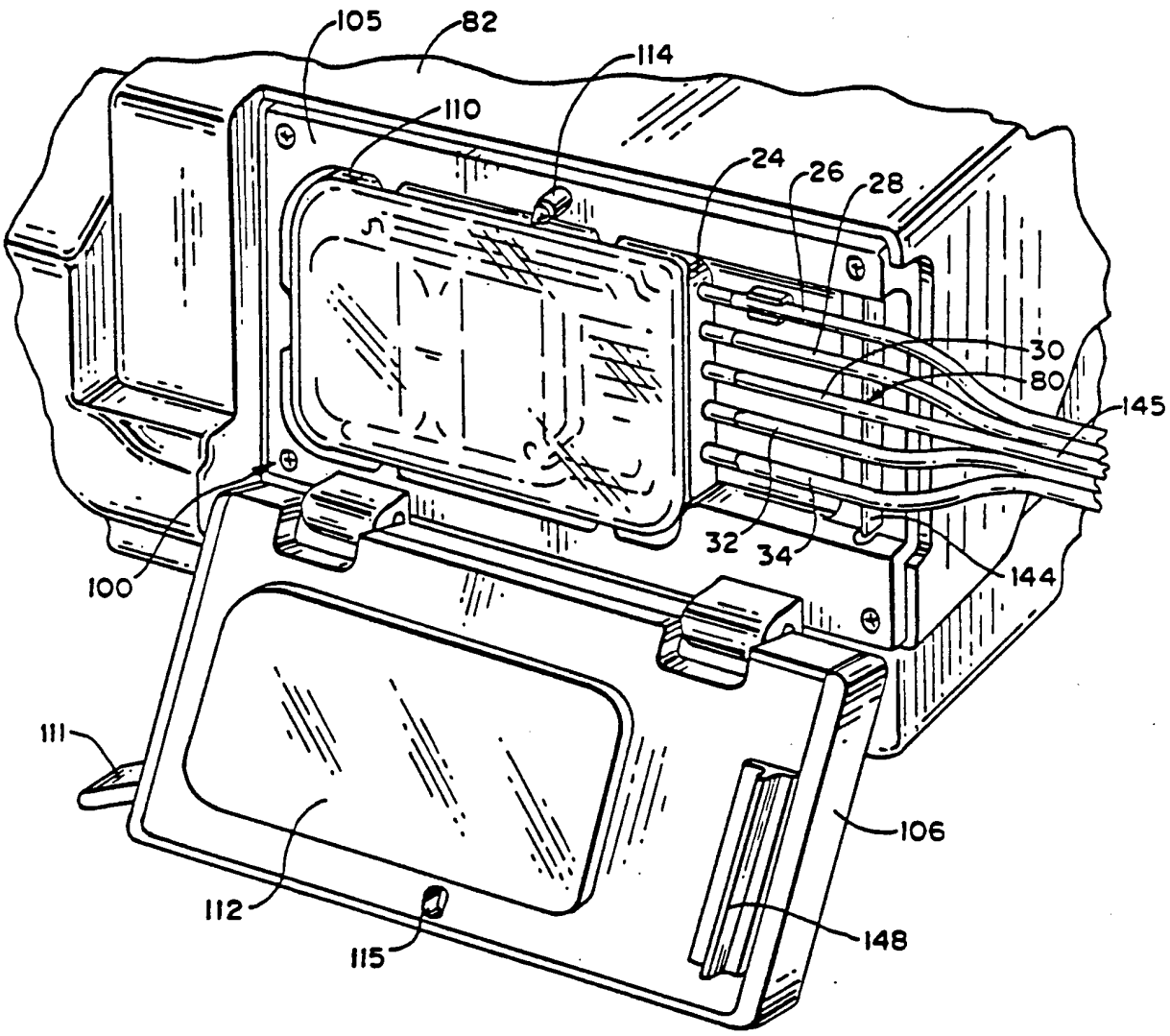

144
80
146
106
148
105
82
114
110
124
112
115
145
30
28
26
34
32
111
100
24

FIG. 6

FIG. 7



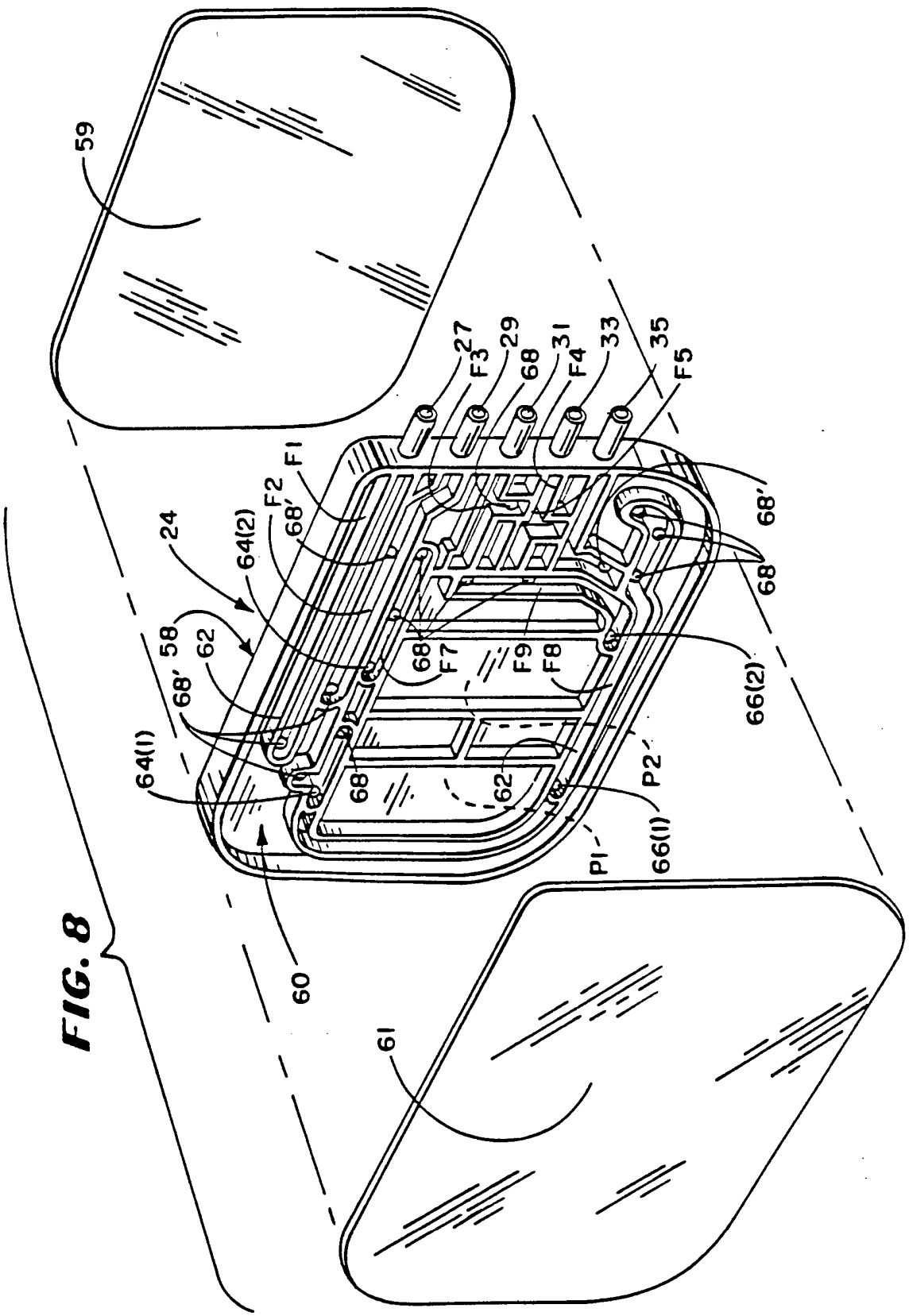

59
27
F3
29
68
31
F4
33
35
F5
F1
F2
68'
24
64(2)
58
62
68'
64(1)
68
F7
F9
F8
68'
68
66(2)
68
62
P2
66(1)
P1
60
61

FIG. 8

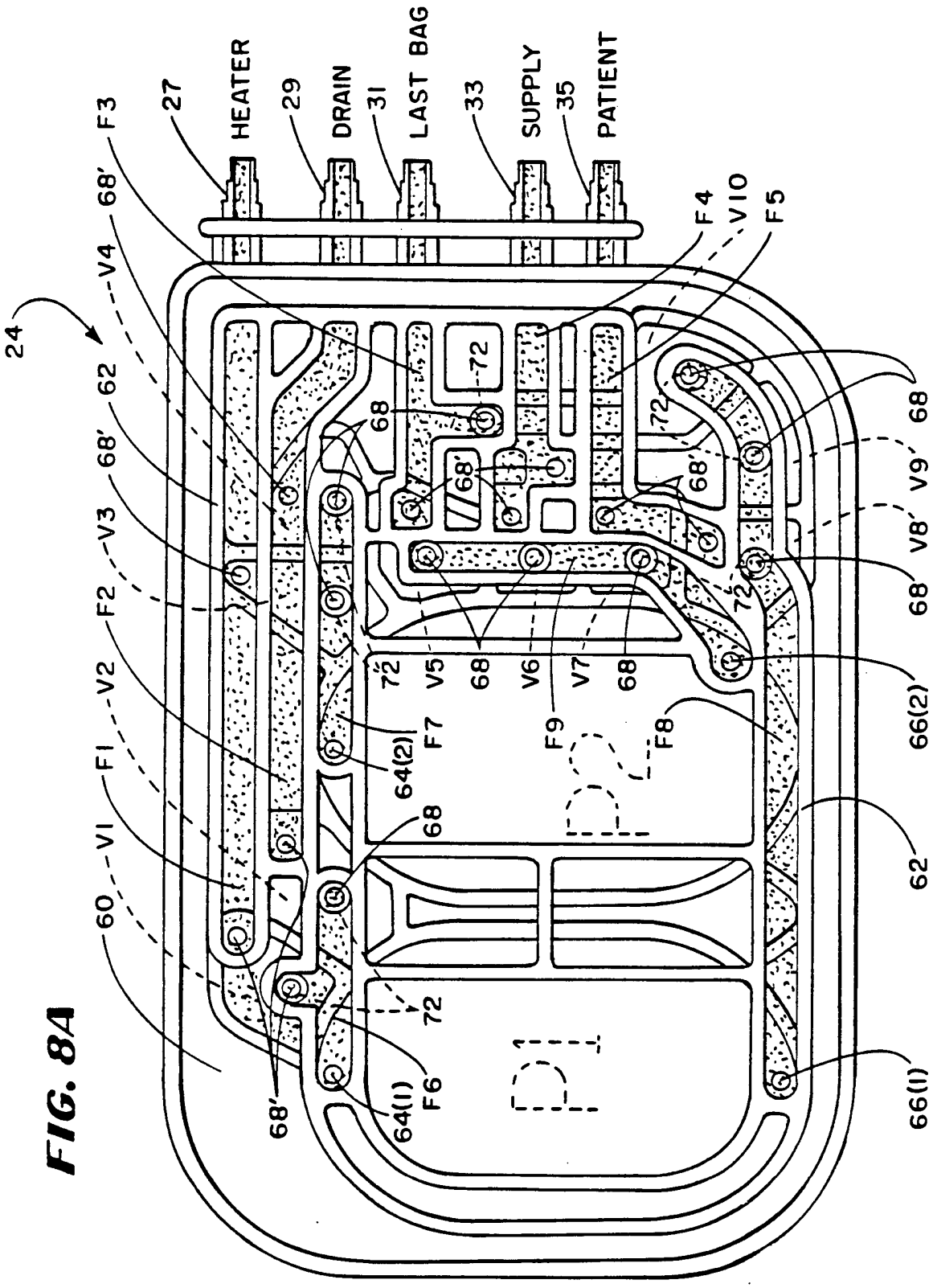

HEATER
DRAIN
LAST BAG
SUPPLY
PATIENT
27
29
31
33
35
24
60
62
64(1)
64(2)
66(1)
66(2)
68
68'
72
V1
V2
V3
V4
V5
V6
V7
V8
V9
V10
F1
F2
F3
F4
F5
F6
F7
F8
F9

FIG. 8A

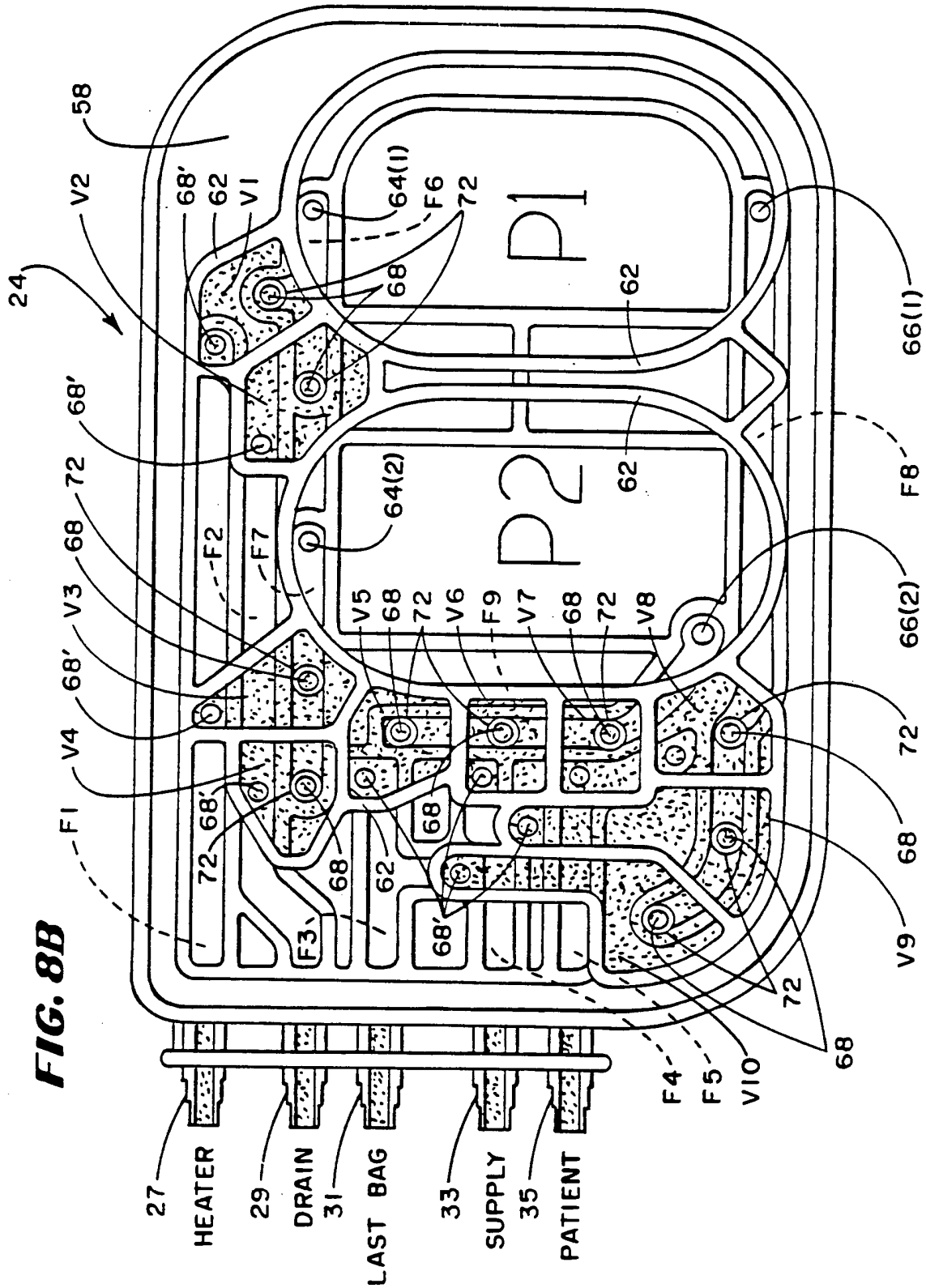

24
58
V2
68'
62
V1
64(1)
F6
72
68
62
66(1)
F8
68'
72
68
V3
68'
V4
F1
72
68'
68
F2
F7
64(2)
62
P2
P1
V5
68
72
V6
F9
V7
68
72
V8
66(2)
72
68
V9
72
68
F3
62
68'
F4
F5
V10
27
HEATER
29
DRAIN
31
LAST BAG
33
SUPPLY
35
PATIENT

FIG. 8B

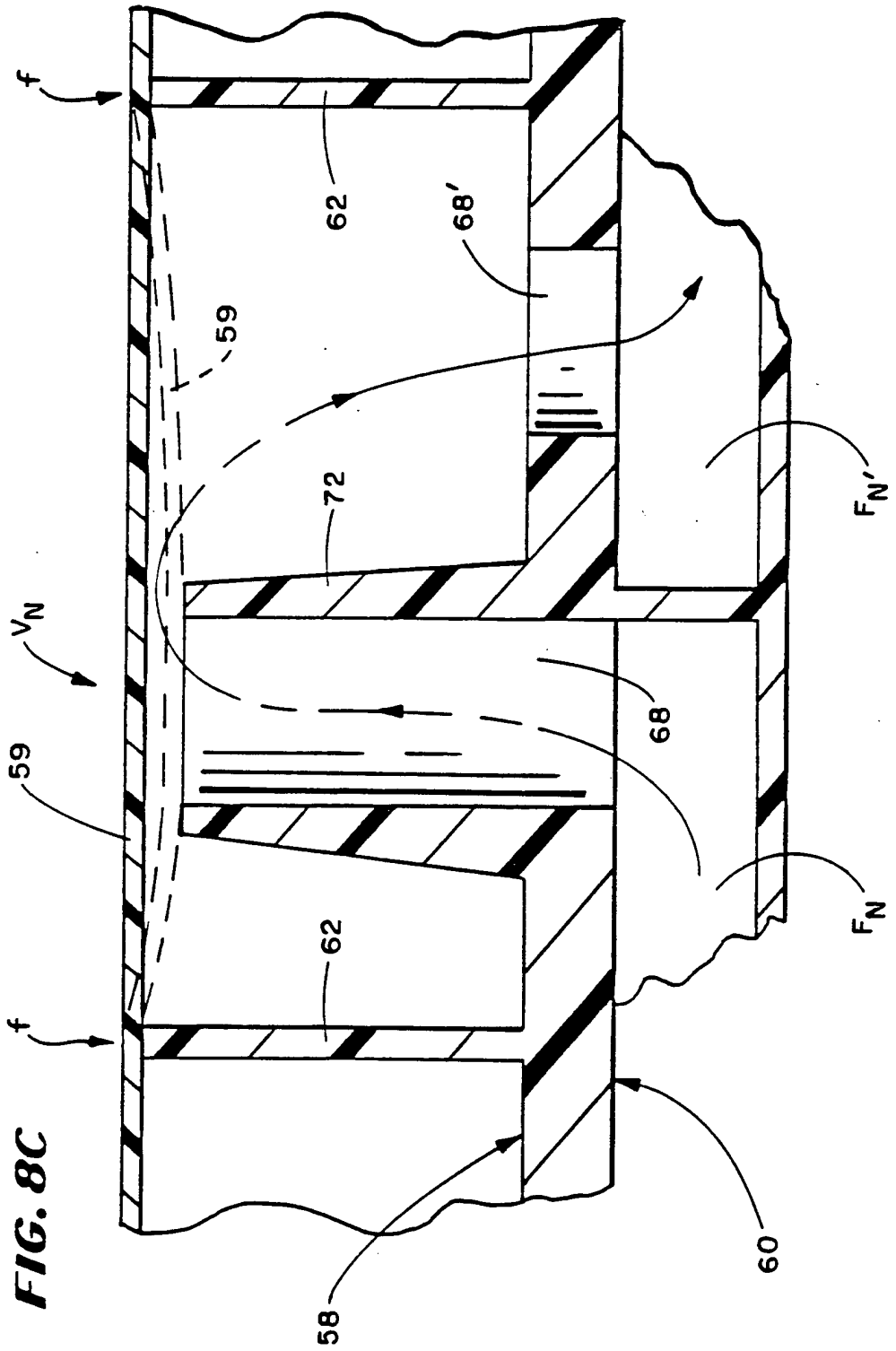


FIG. 8C

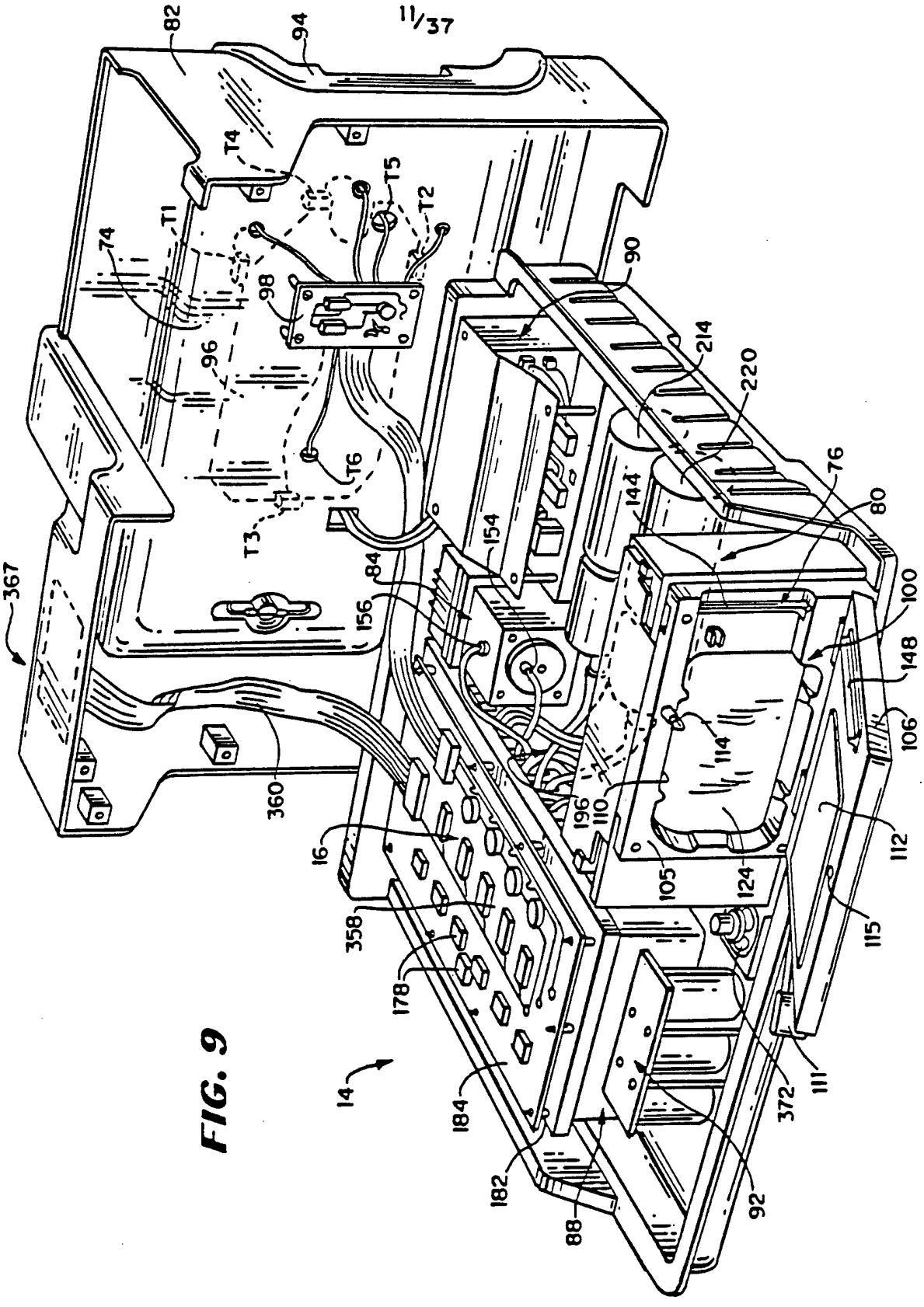
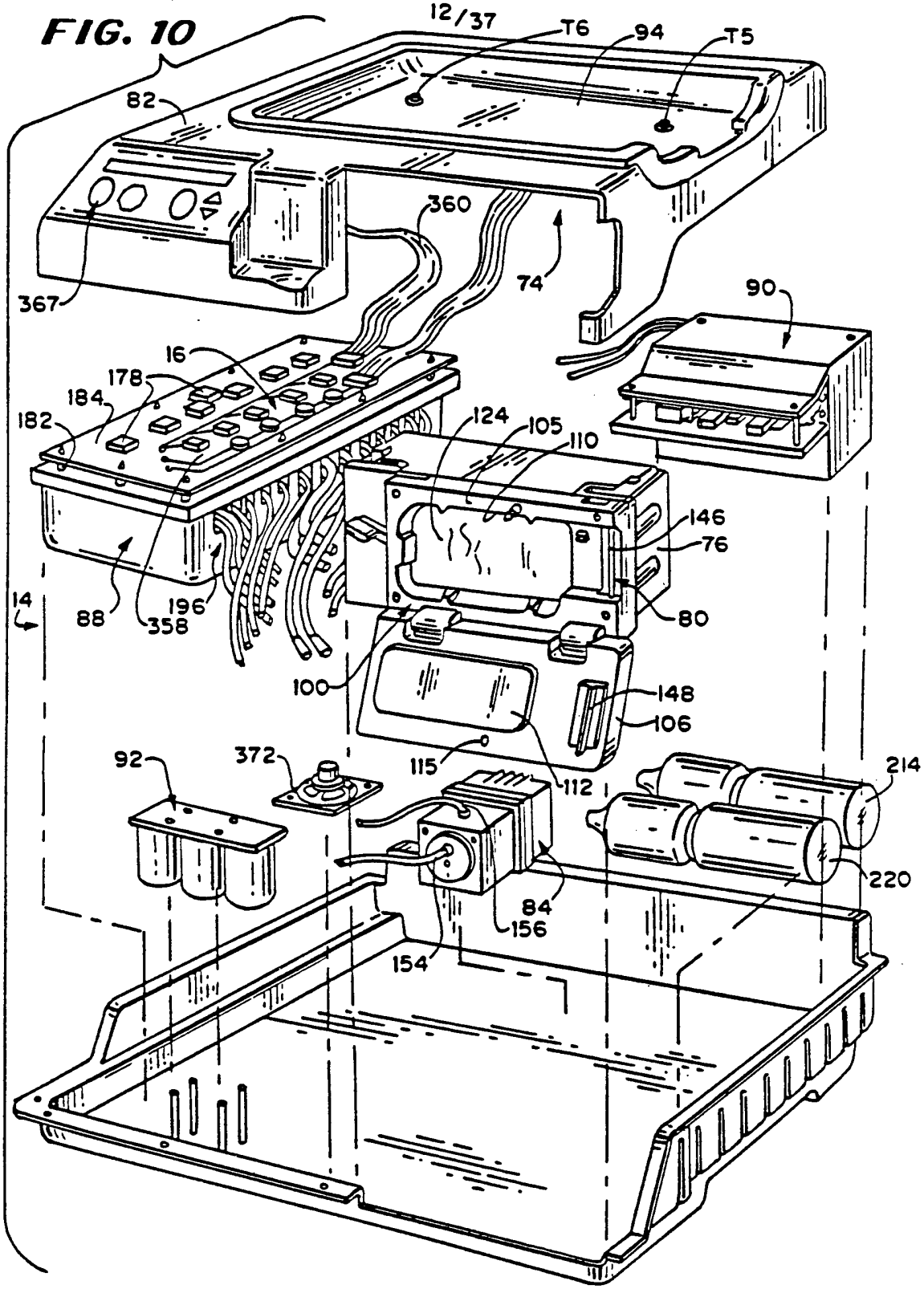

82
94
T4
T5
T2
T1
74
98
96
T6
T3
90
214
220
76
80
144
154
84
156
367
100
148
106
114
360
196
110
112
16
105
124
115
358
178
14
184
372
111
182
92
88

FIG. 9

FIG. 10


12/37
T6
94
T5
82
360
74
367
90
16
178
184
182
124
105
110
146
76
14
88
196
358
80
100
148
106
115
112
92
372
214
220
84
156
154

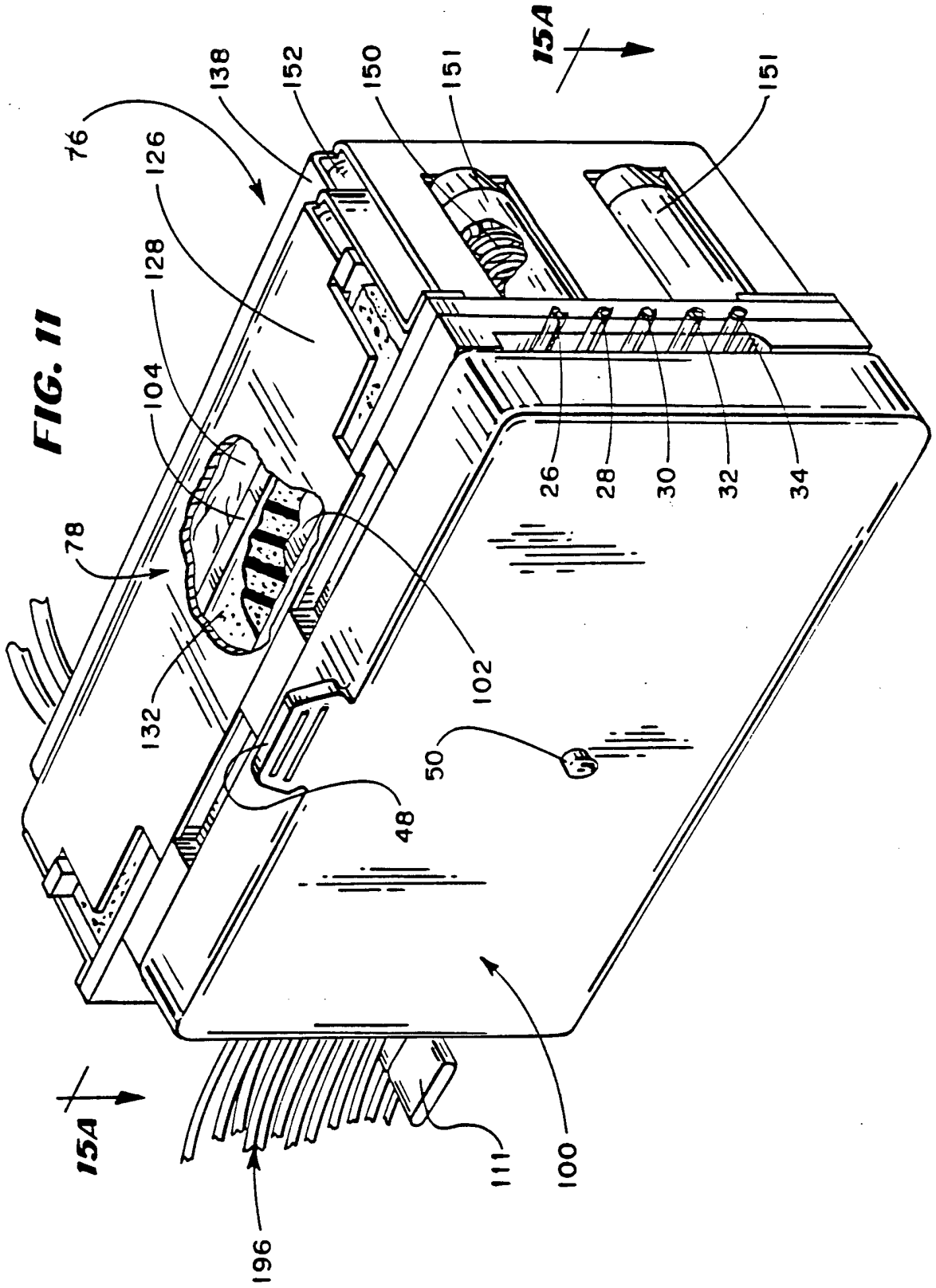

15A
138
152
150
151
151
76
126
128
104
78
132
102
50
48
26
28
30
32
34
15A
111
100
196

FIG. 11

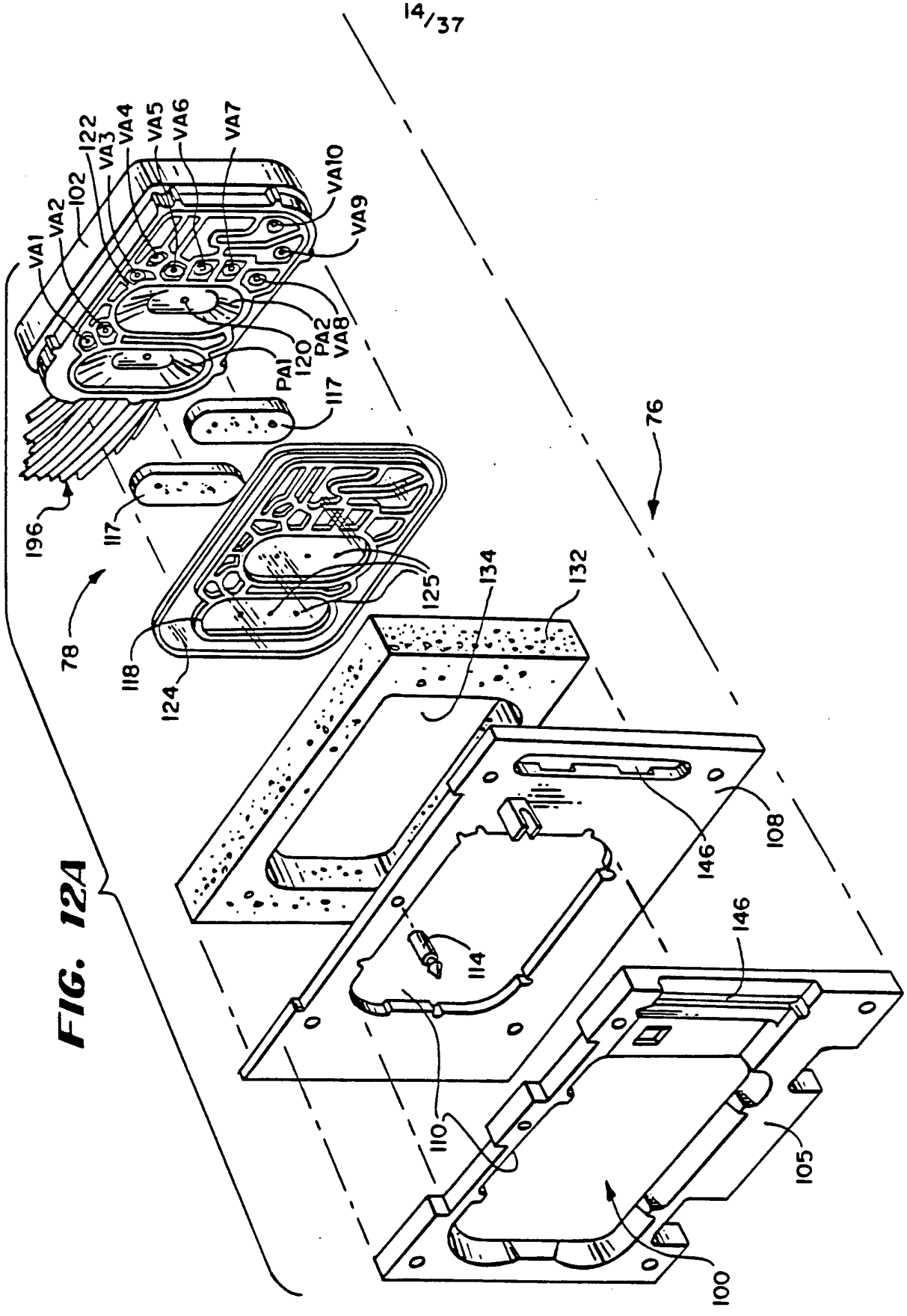

VA1
VA2
102
122
VA3
VA4
VA5
VA6
VA7
VA10
VA9
PA2
VA8
PA1
120
117
196
117
76
78
118
124
125
134
132
108
146
114
146
110
105
100

FIG. 12A

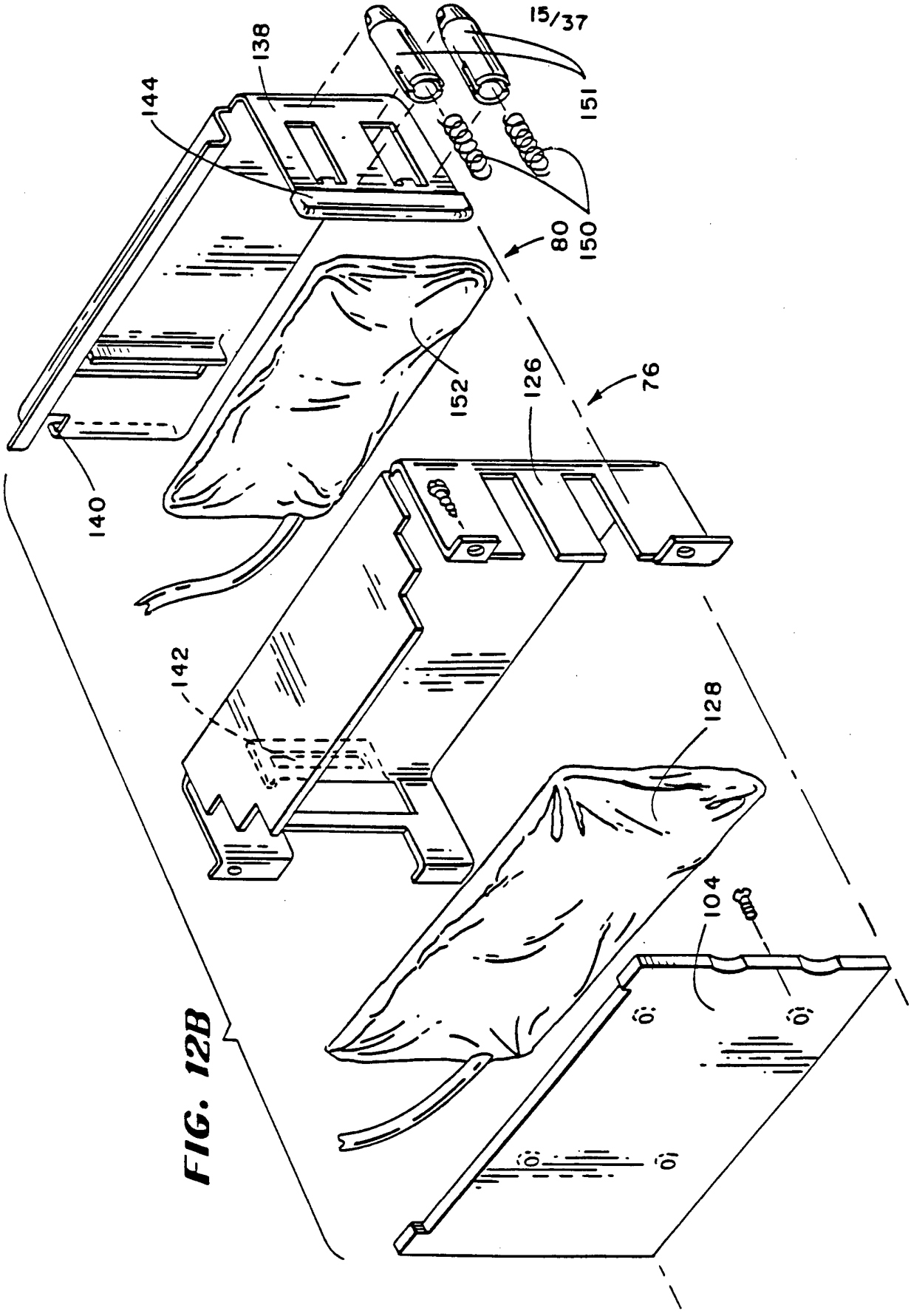


FIG. 12B

FIG. 13

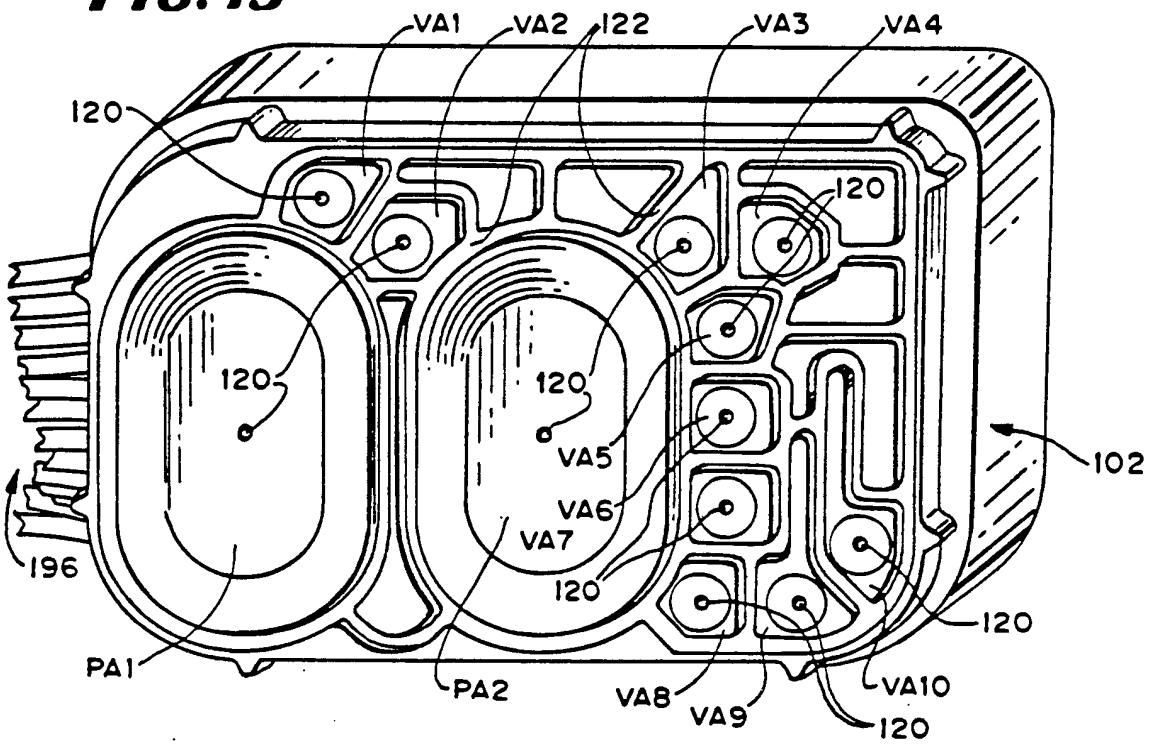
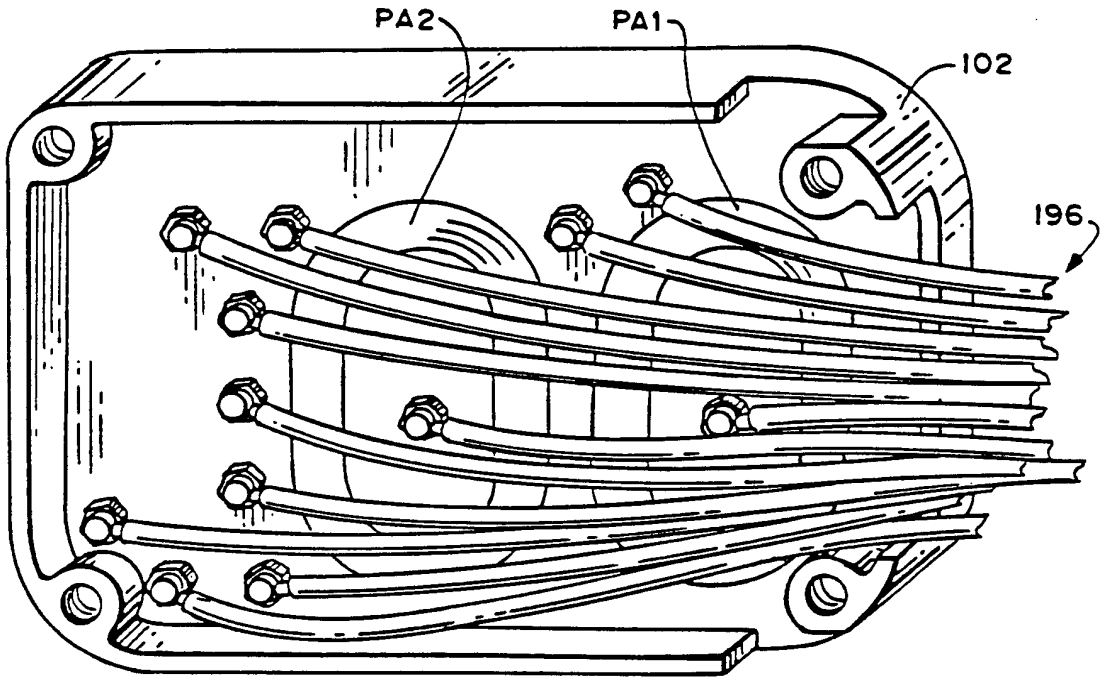


FIG. 14A



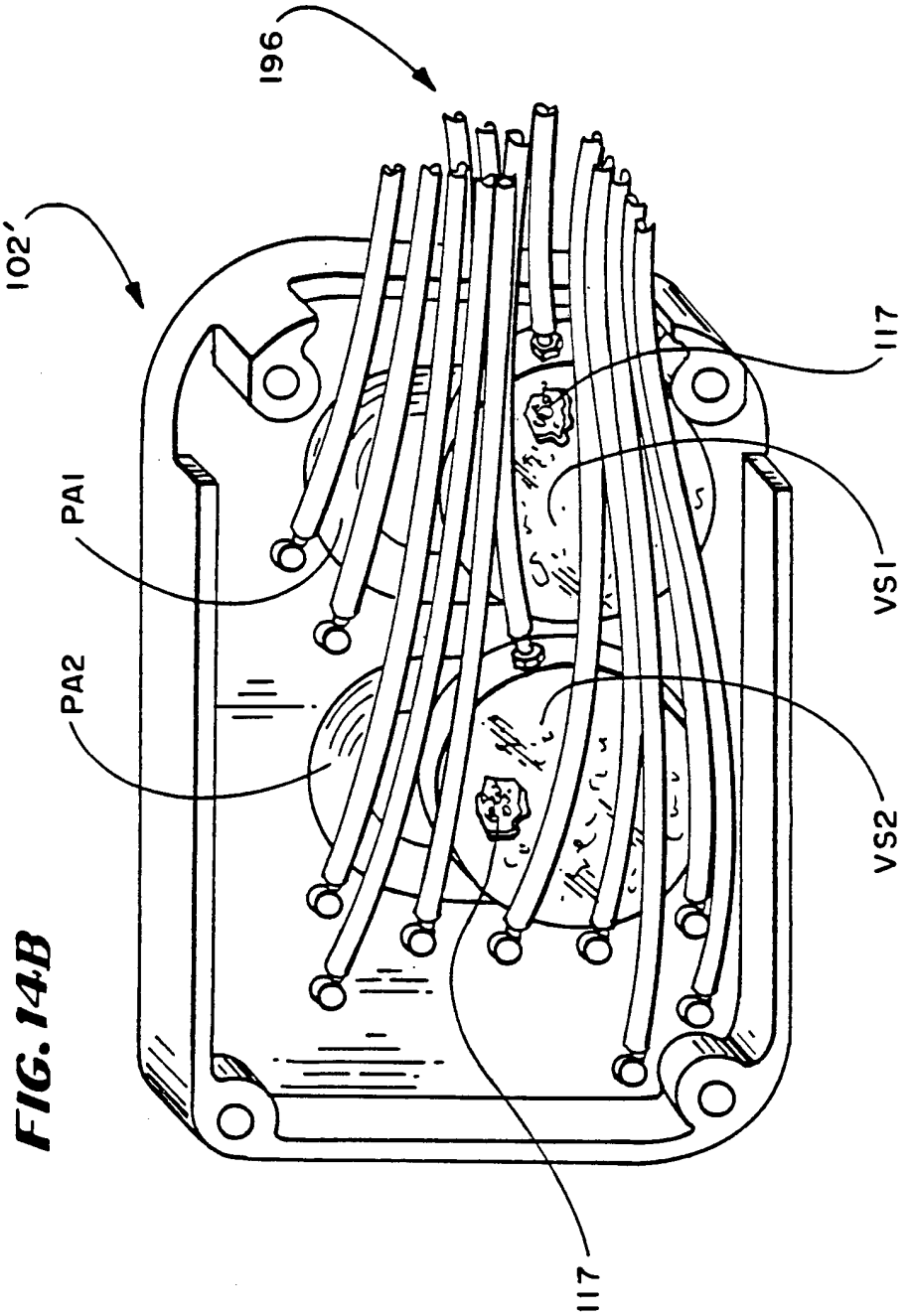


FIG. 14B

FIG. 15A

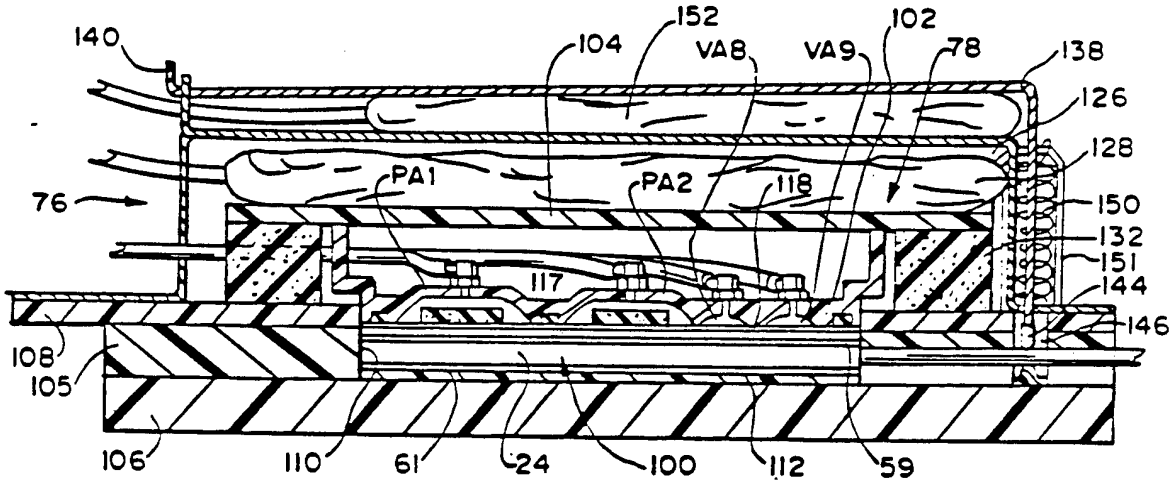


FIG. 15B

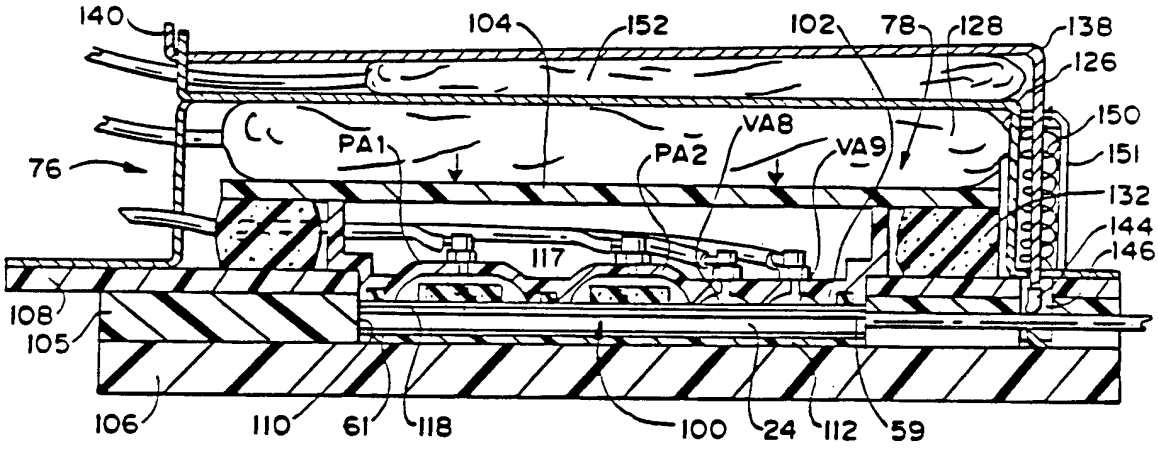


FIG. 16A

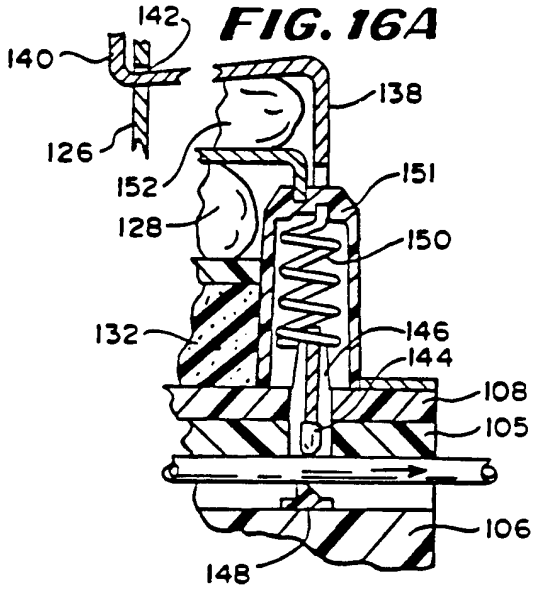
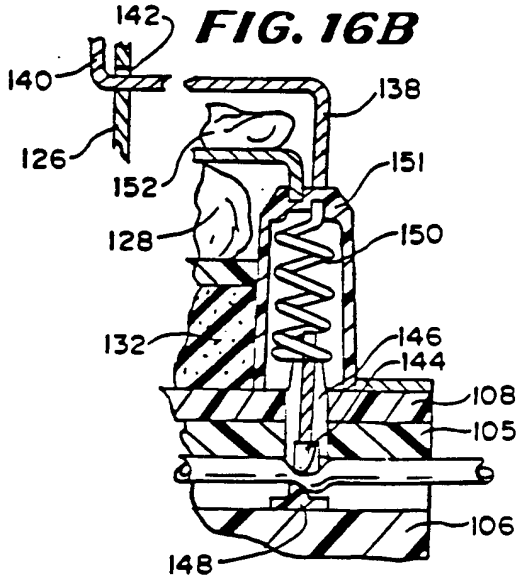


FIG. 16B



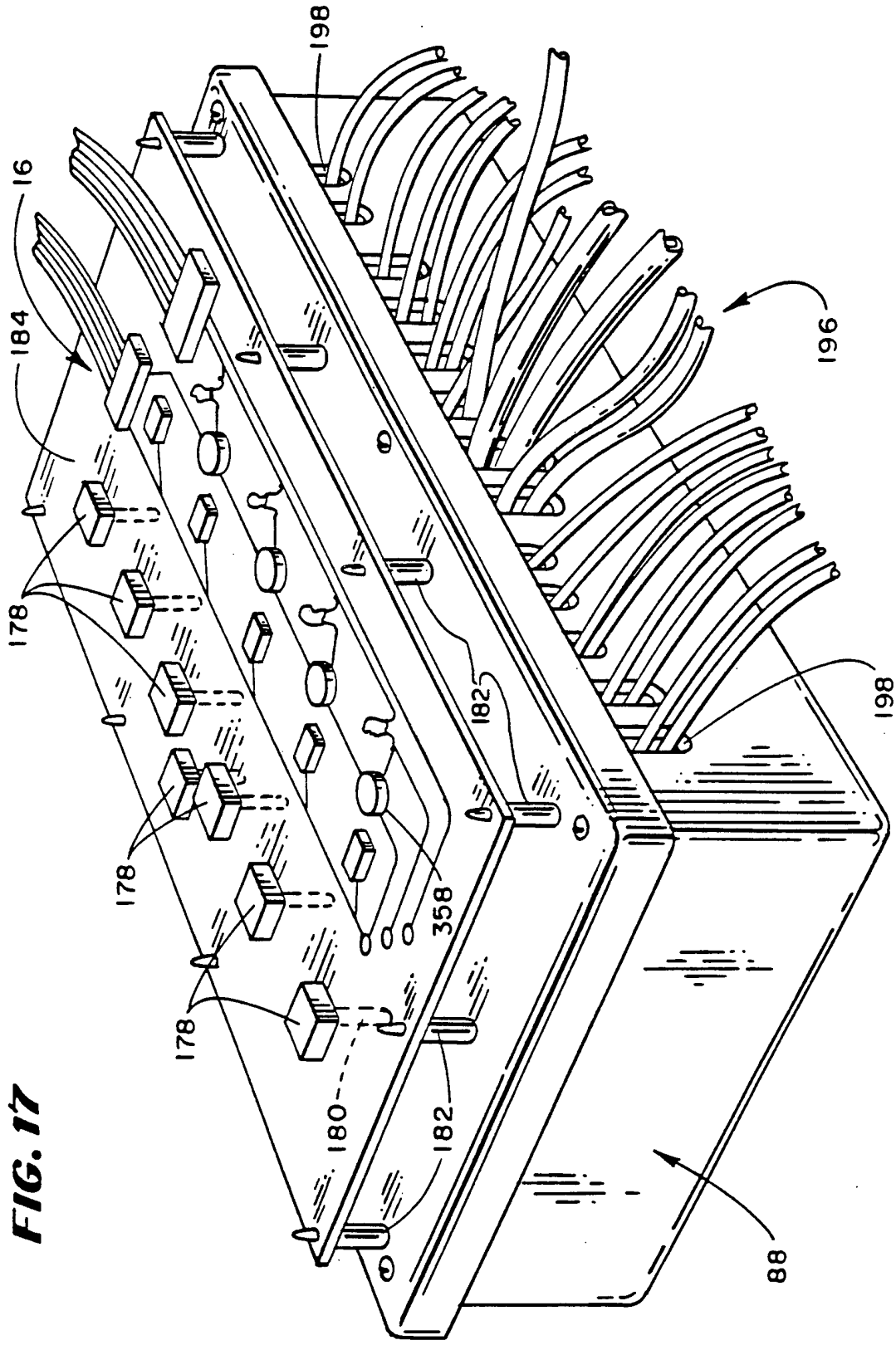


FIG. 17

FIG. 18

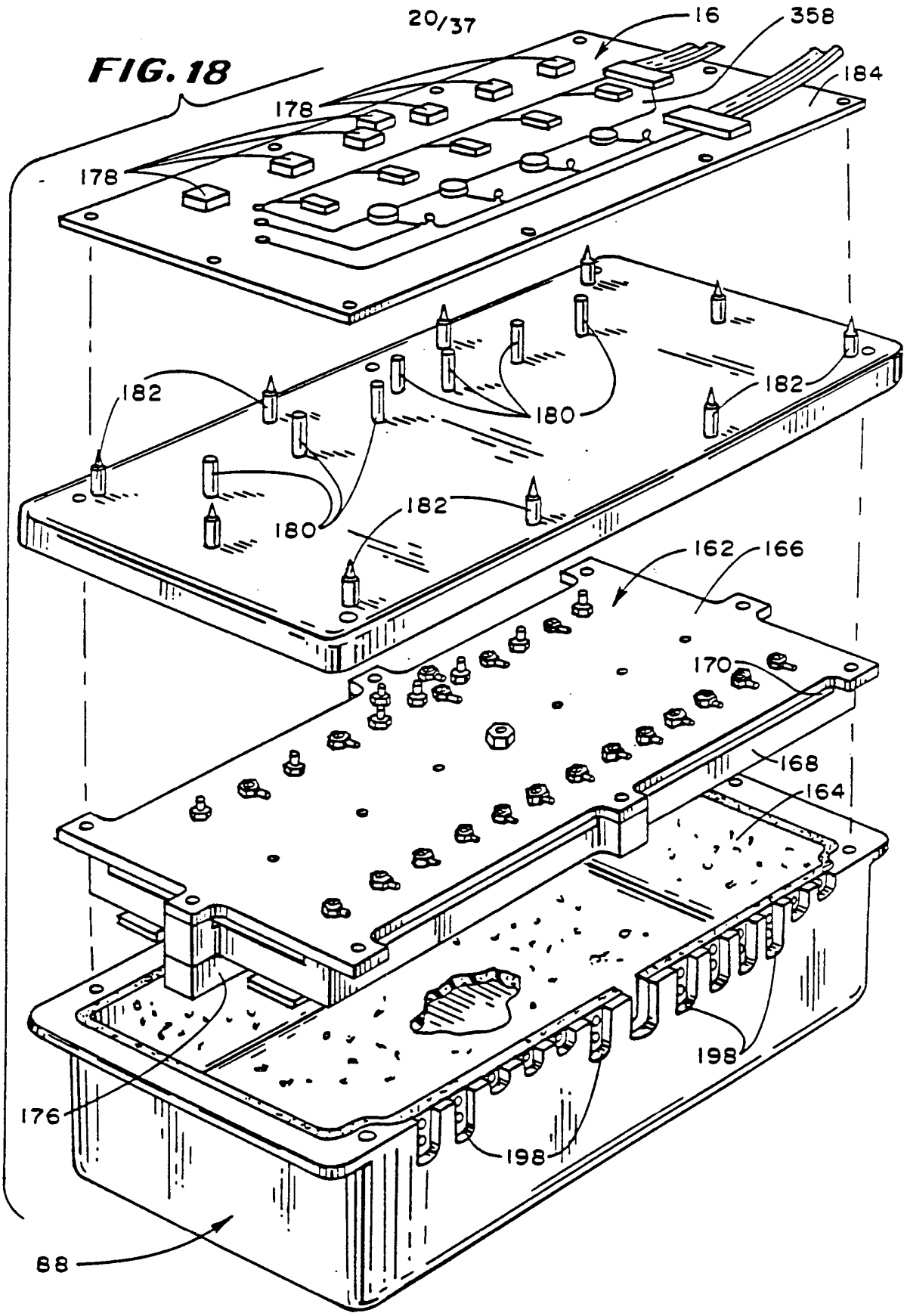
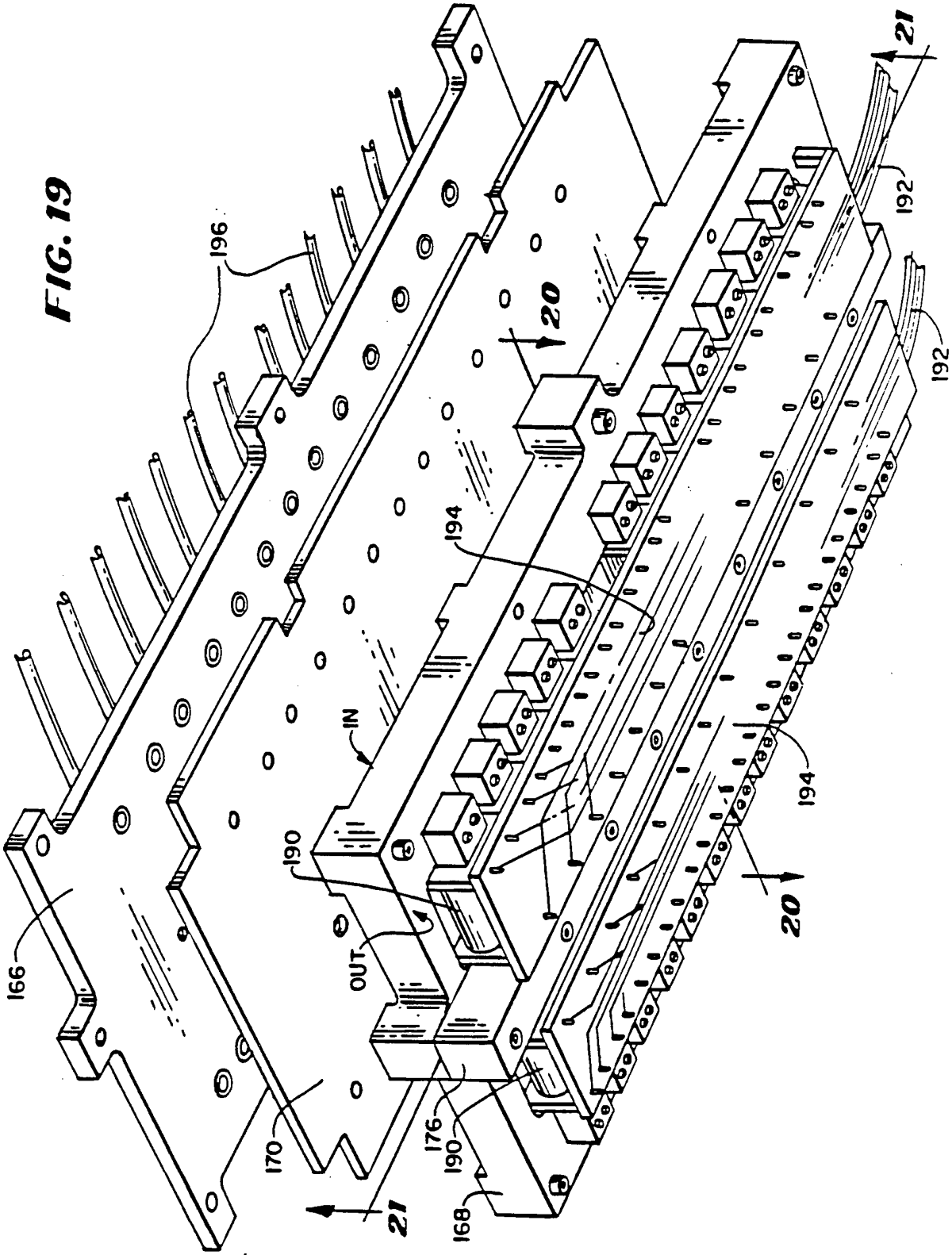

16
358
184
178
178
182
182
180
180
182
162
166
170
168
164
198
176
198
88

FIG. 19



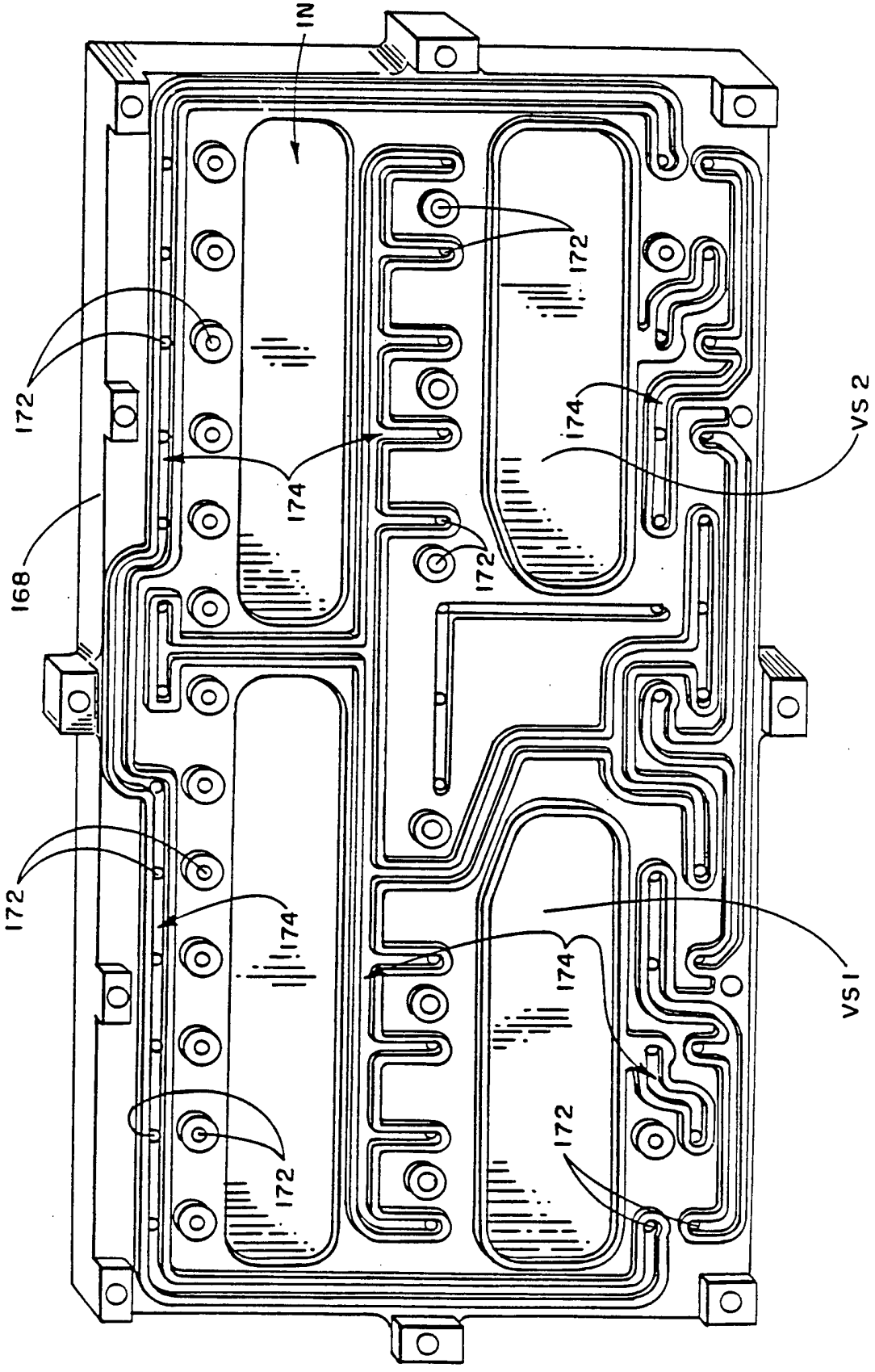


FIG. 20

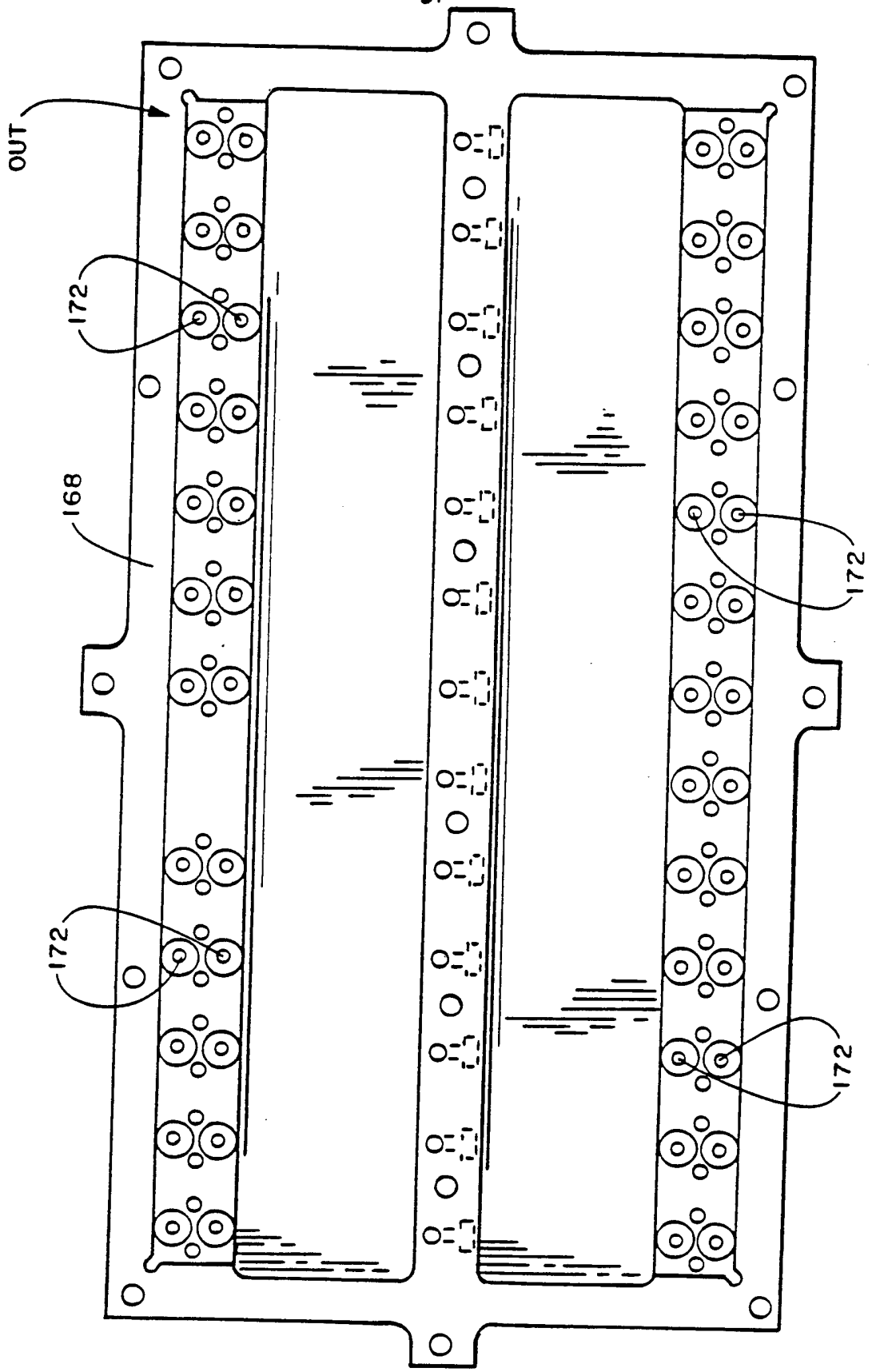
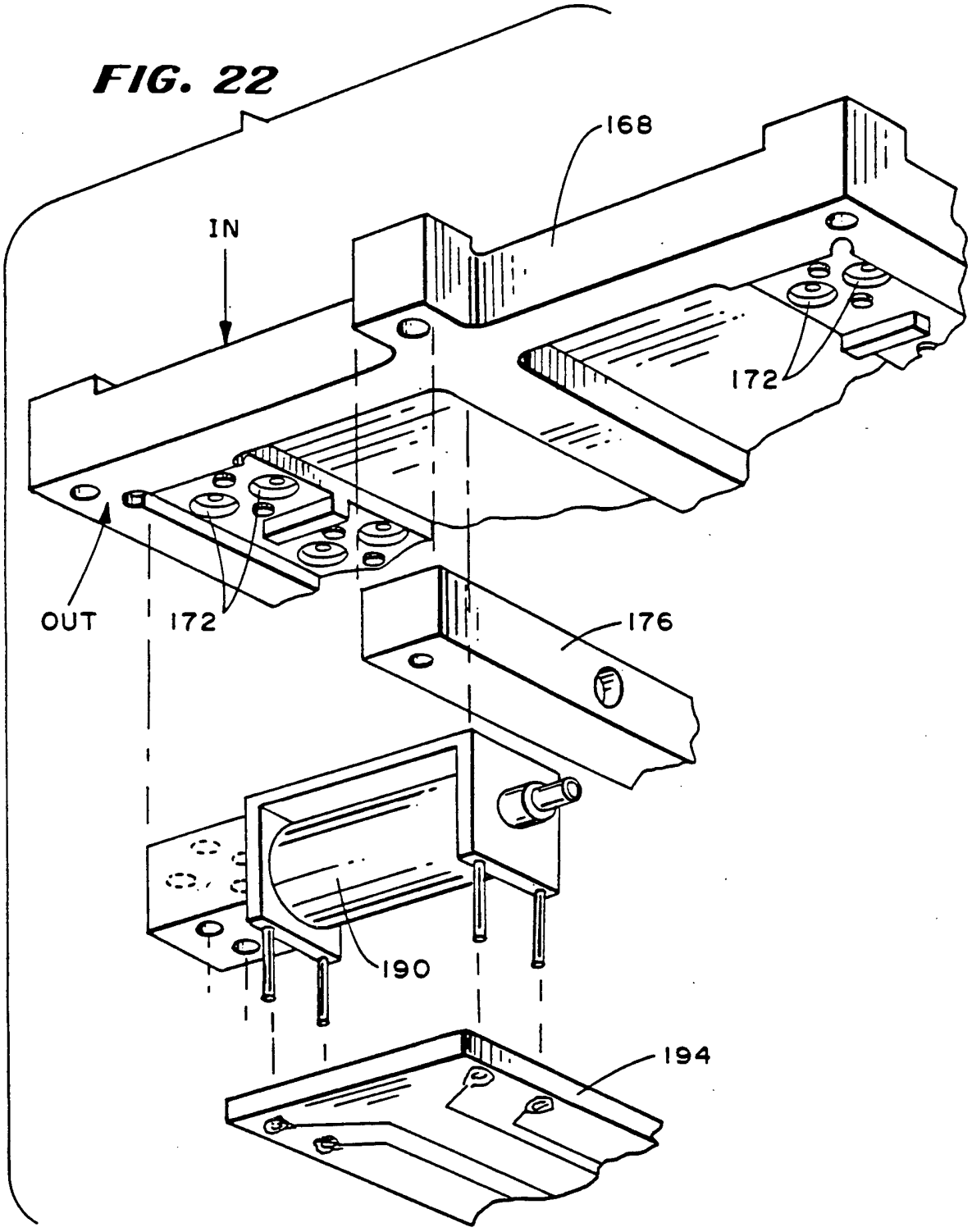


FIG. 21

FIG. 22



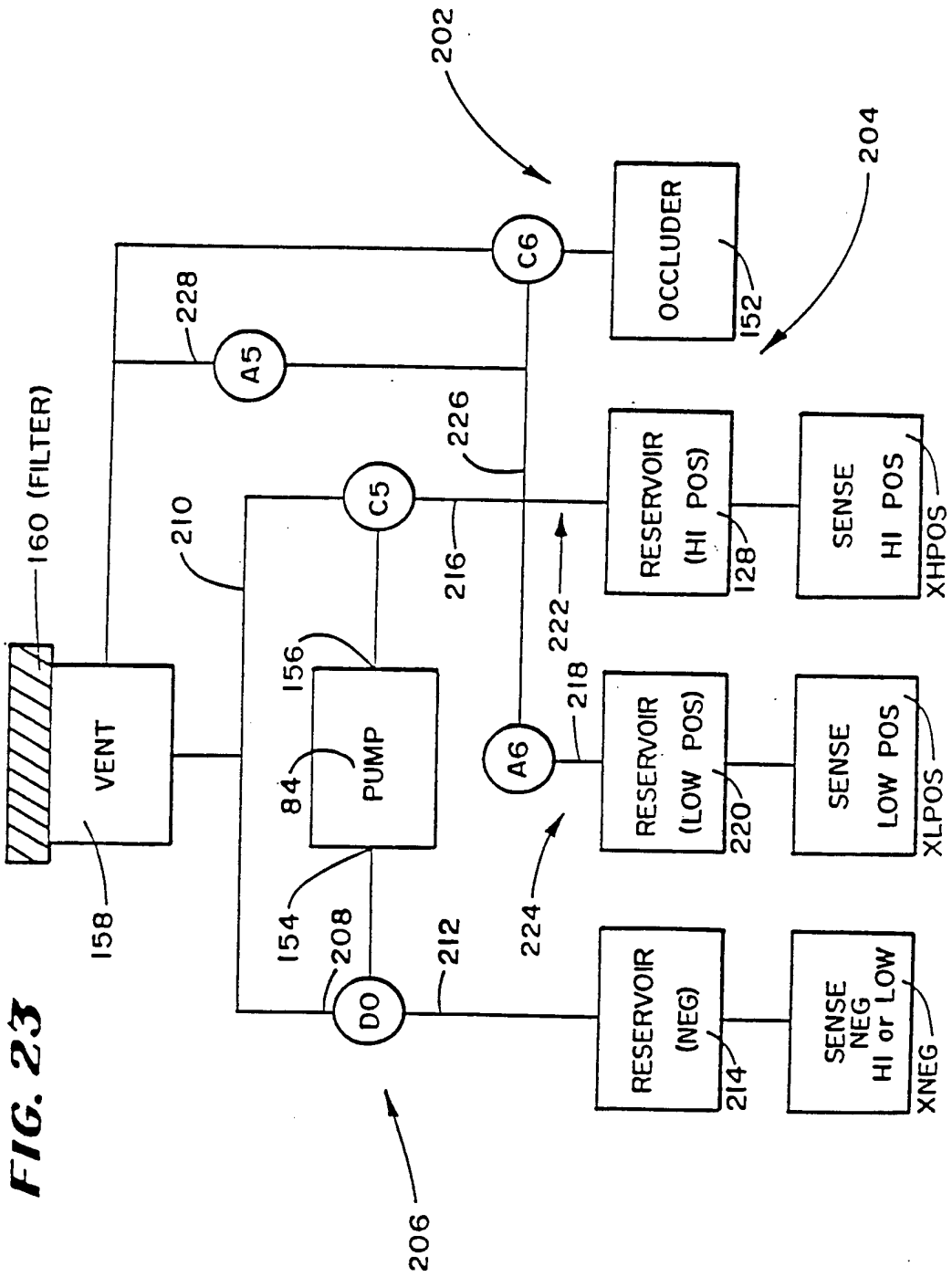

202
204
C6
OCCLUDER
152
228
A5
226
C5
RESERVOIR (HI POS)
128
SENSE HI POS
XHPOS
160 (FILTER)
210
216
222
156
VENT
PUMP
84
A6
218
RESERVOIR (LOW POS)
220
SENSE LOW POS
XLPOS
158
154
208
212
224
DO
RESERVOIR (NEG)
214
SENSE NEG HI or LOW
XNEG
206

FIG. 23

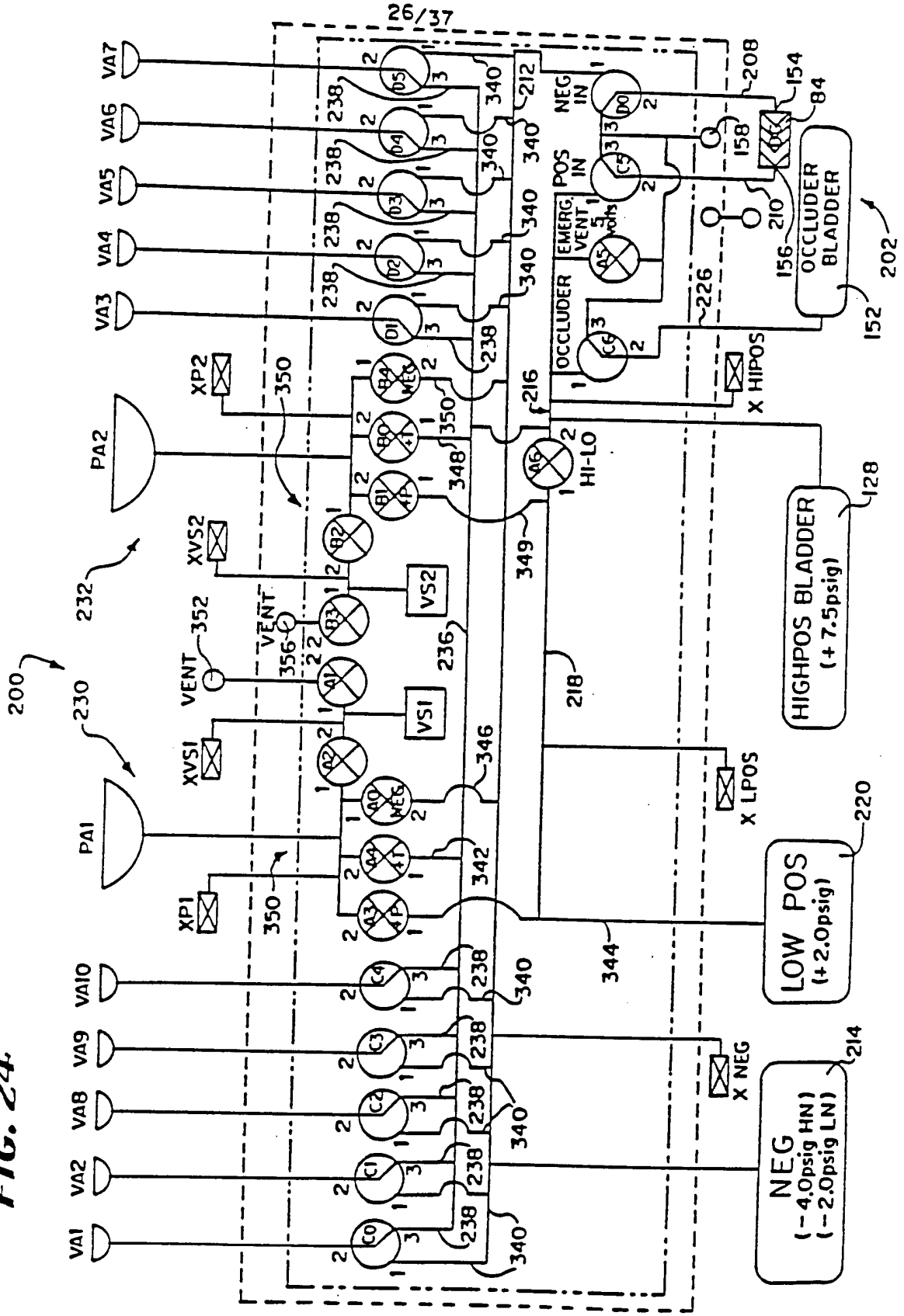

200
230
232
PA1
PA2
XP1
XP2
XVS1
XVS2
VS1
VS2
VENT
VENT
352
356
VA1
VA2
VA3
VA4
VA5
VA6
VA7
VA8
VA9
VA10
C0
C1
C2
C3
C4
C5
C6
C7
C8
C9
A0 MES
A1 4P
A2
A3 4P
A4 4T
B0 4T
B1 4P
B2
B3
B4 MES
A6
HI-LO
NEG IN
POS IN
EMERG. VENT
OCCLUDER
X HIPOS
X LPOS
X NEG
OCCLUDER BLADDER
HIGHPOS BLADDER (+7.5psig)
LOW POS (+2.0psig)
NEG (-4.0psig HN) (-2.0psig LN)
340
342
344
346
348
349
350
212
216
218
220
226
128
152
154
156
158
202
208
210
214
236
238

FIG. 24.

FIG. 25

MAIN MENU
AND
REVIEW UF MENU

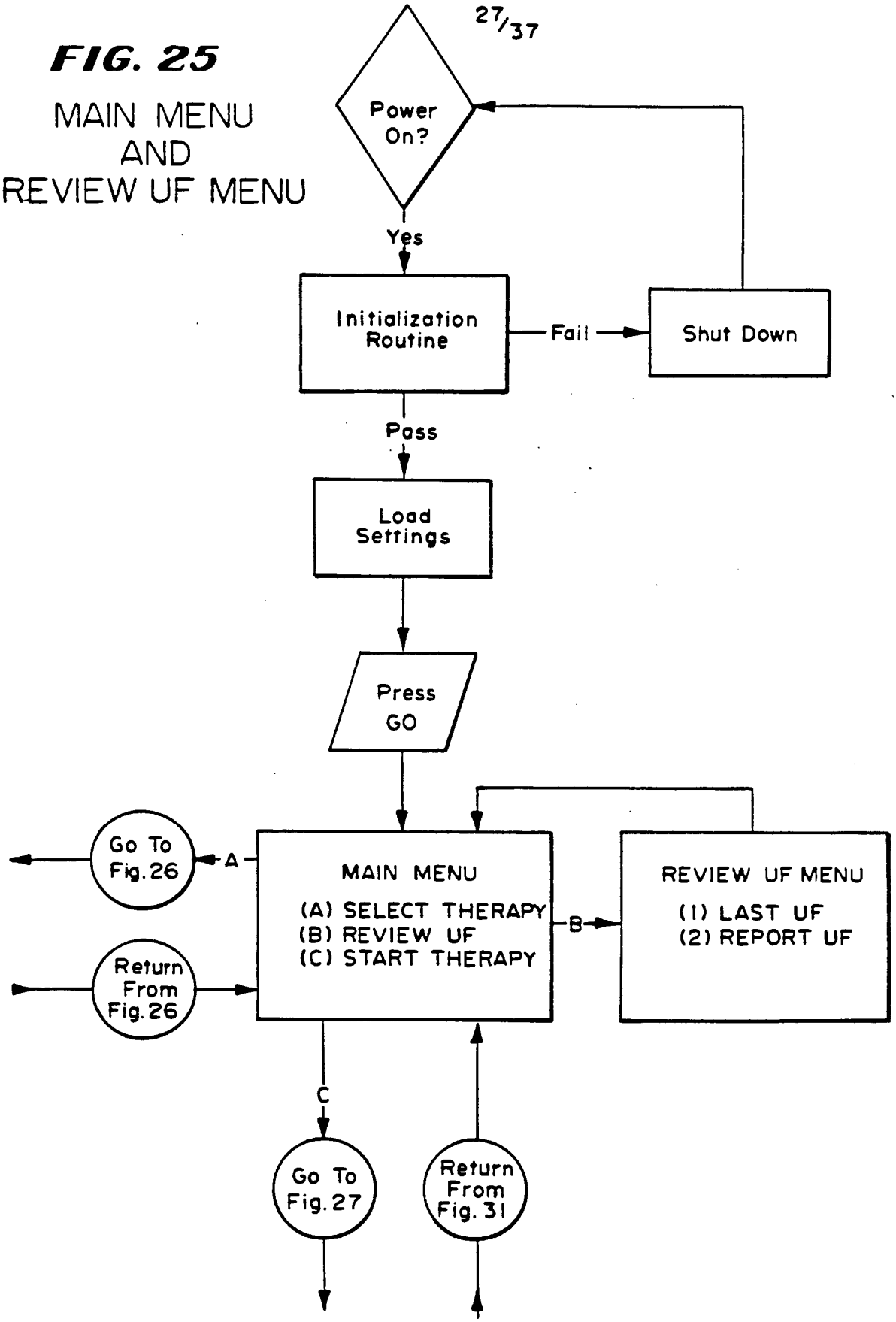


FIG. 26

SELECT THERAPY MENU

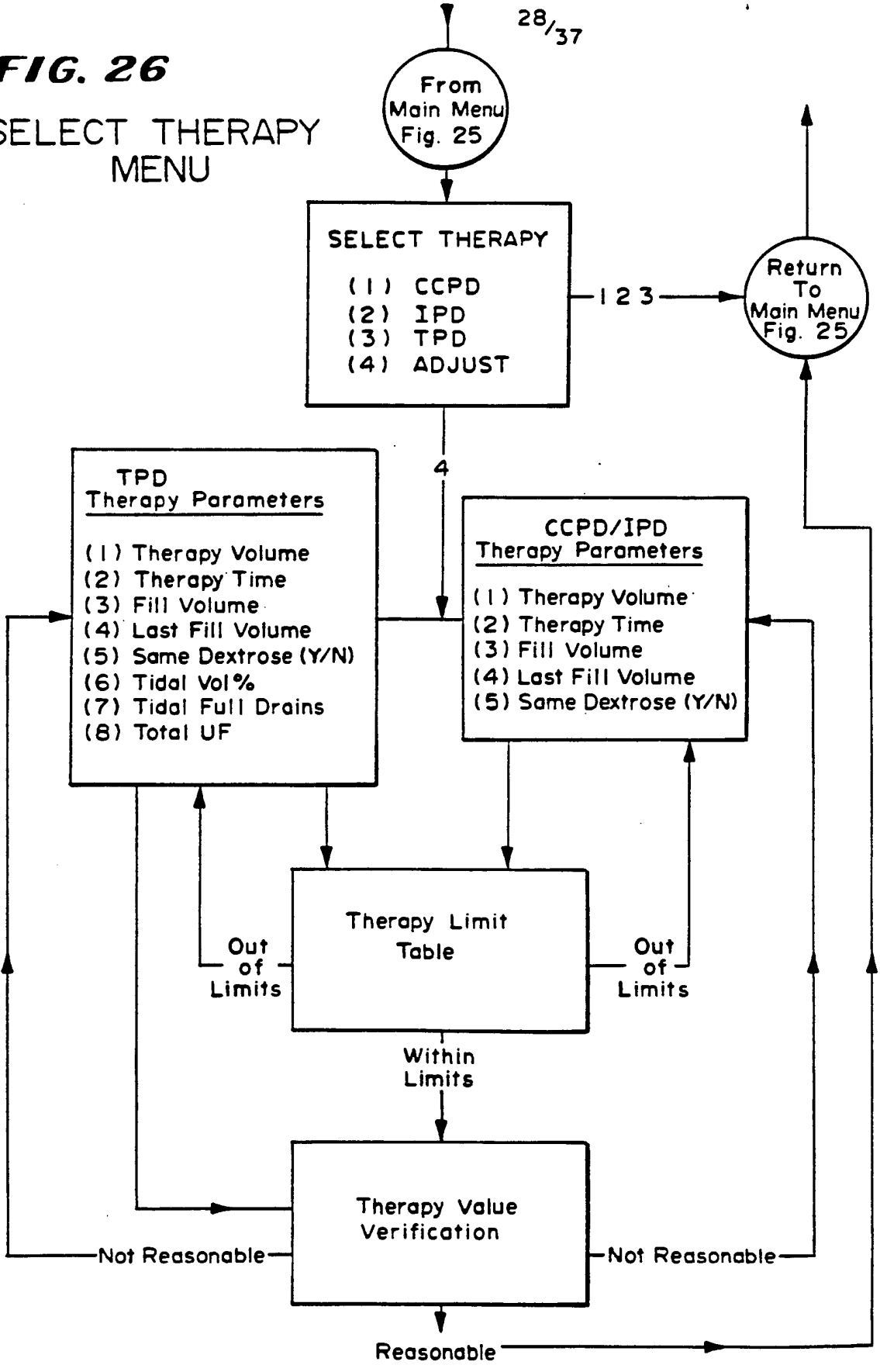
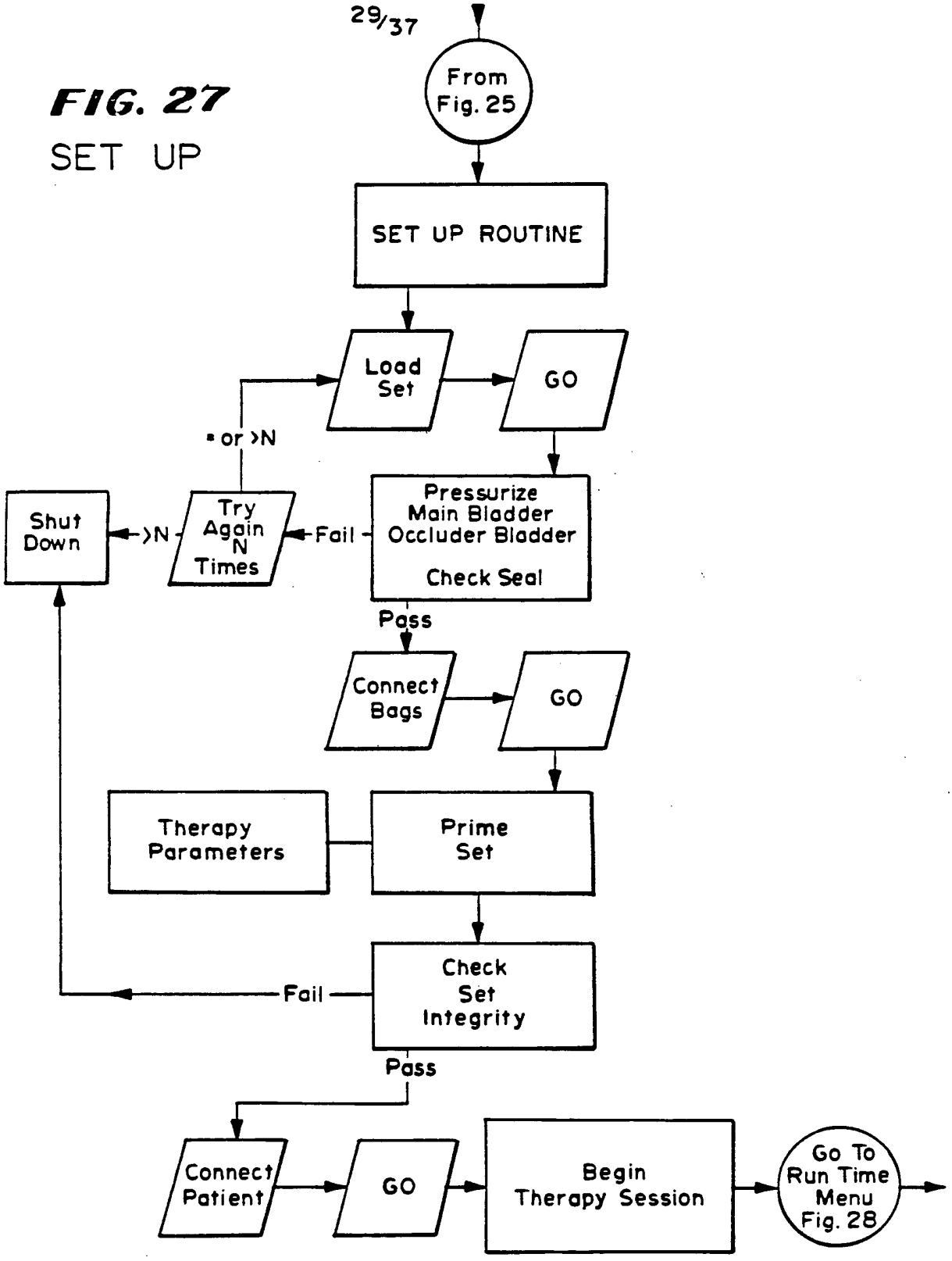


FIG. 27

SET UP


From Fig. 25
SET UP ROUTINE
Load Set
GO
= or >N
Shut Down
>N
Try Again N Times
Fail
Pressurize Main Bladder Occluder Bladder
Check Seal
Pass
Connect Bags
GO
Therapy Parameters
Prime Set
Check Set Integrity
Fail
Pass
Connect Patient
GO
Begin Therapy Session
Go To Run Time Menu Fig. 28

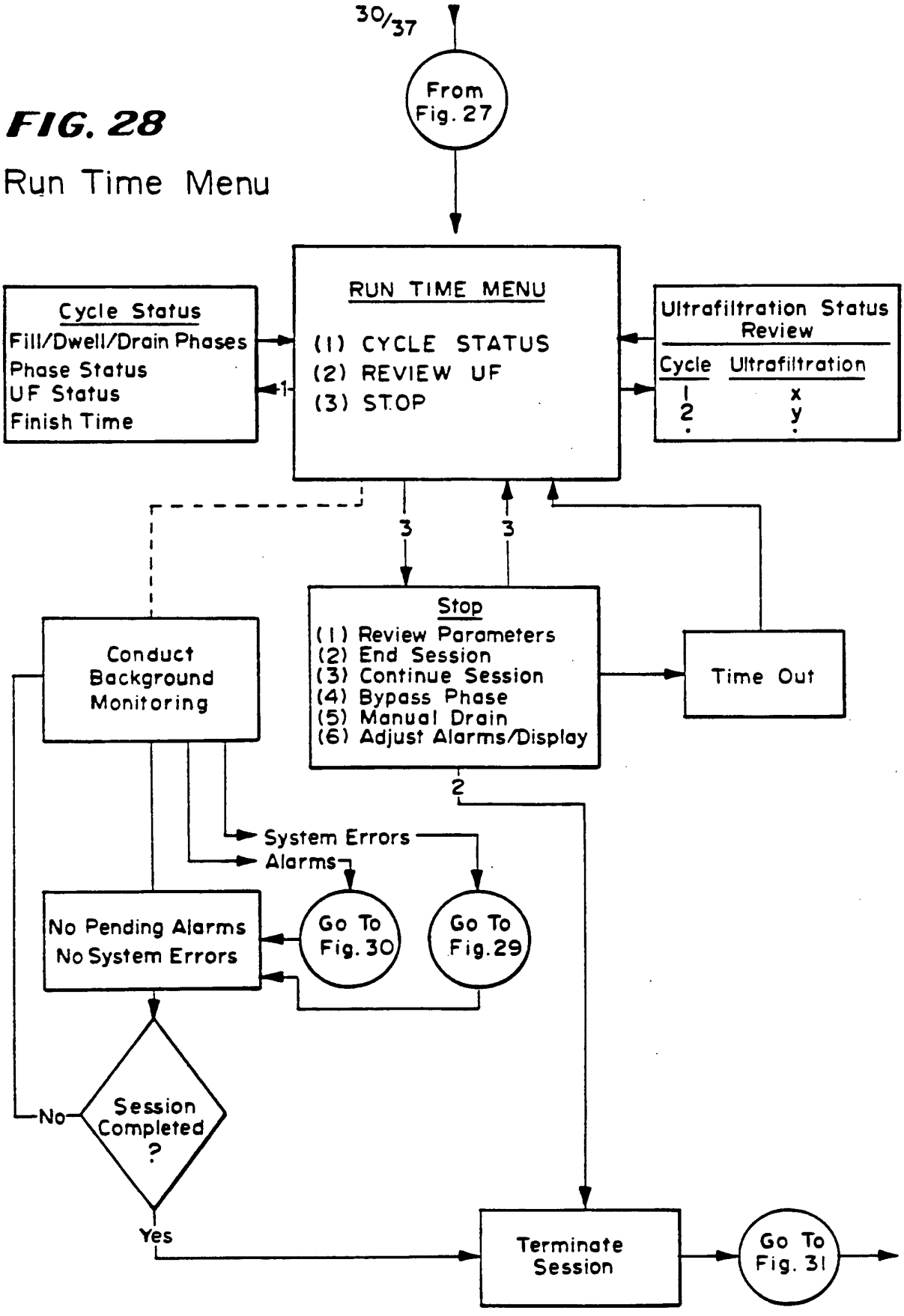


FIG. 28

Run Time Menu

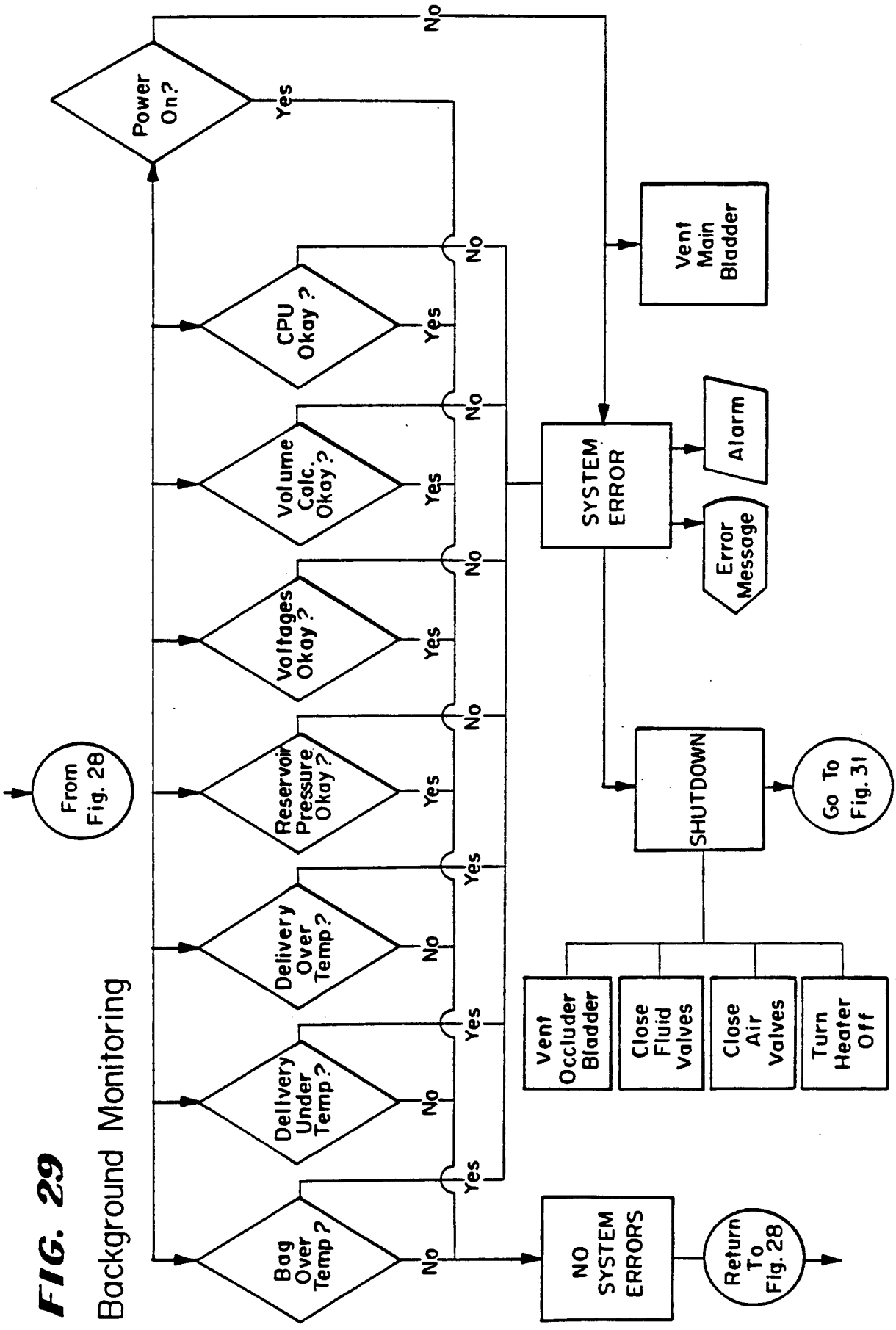


FIG. 29
Background Monitoring

FIG. 30

Alarm Routines

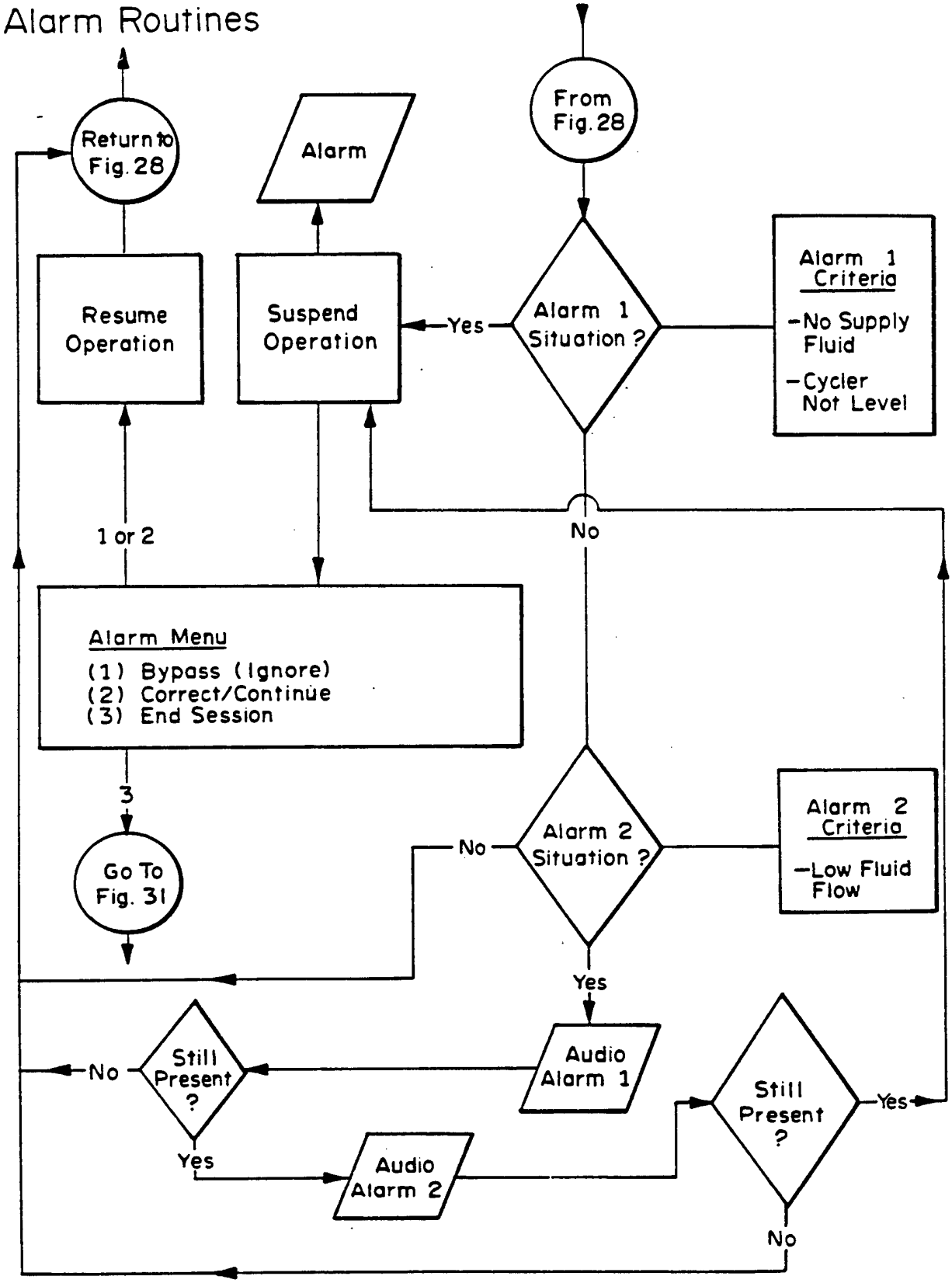
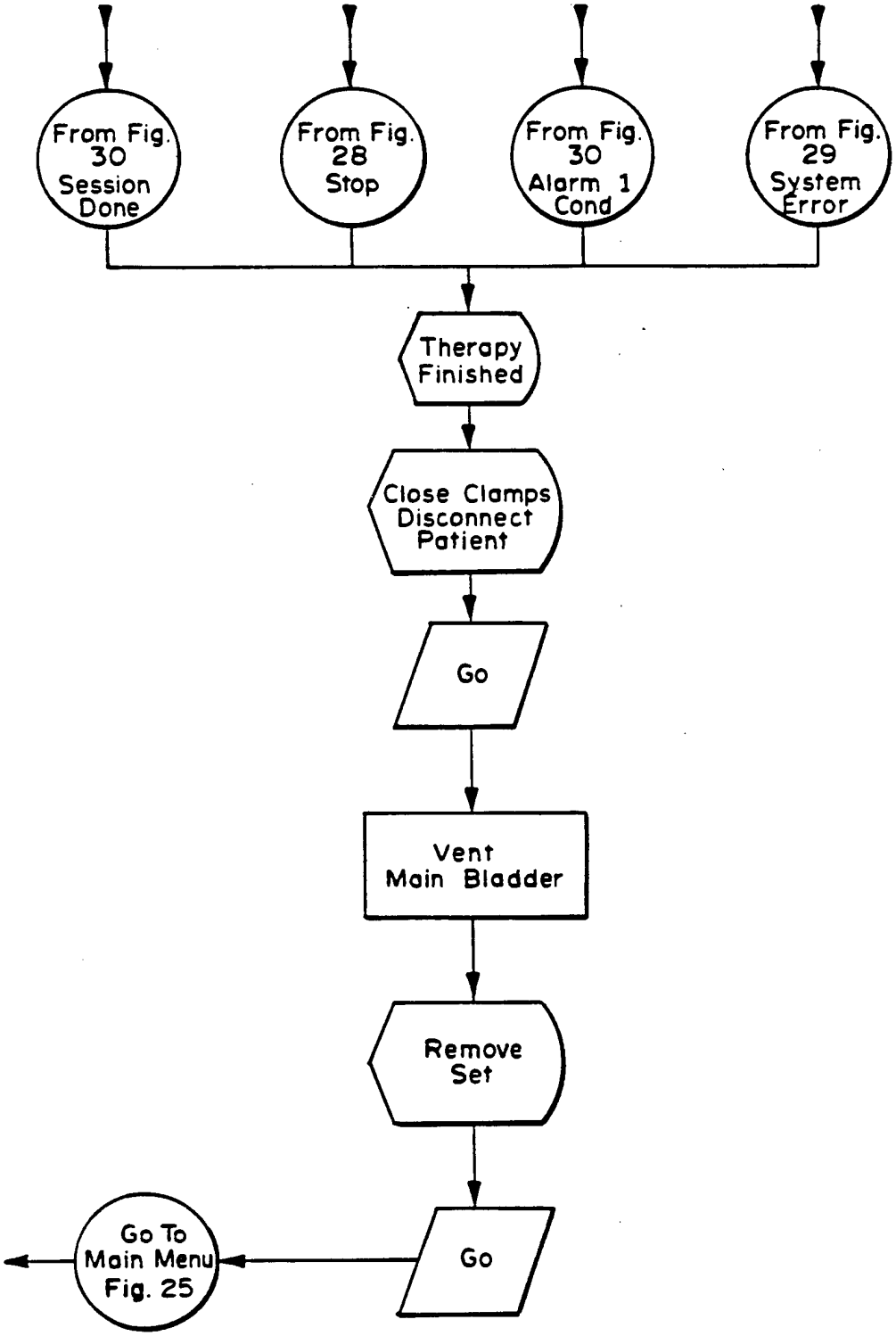


FIG. 31

Post-Therapy



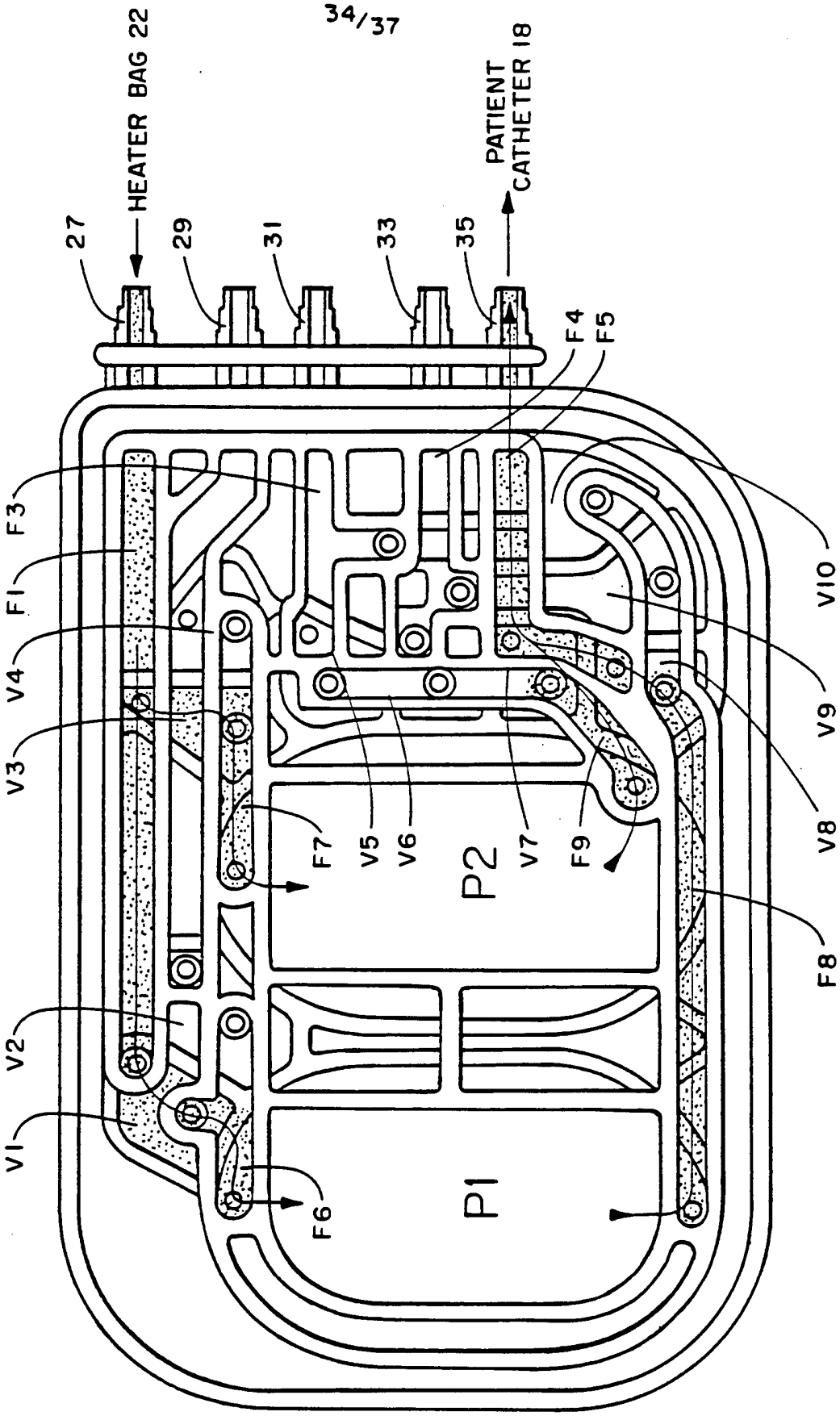

HEATER BAG 22
PATIENT CATHETER 18
27
29
31
33
35
F1
F2
F3
F4
F5
F6
F7
F8
F9
V1
V2
V3
V4
V5
V6
V7
V8
V9
V10
P1
P2

FIG. 32
(FILL)

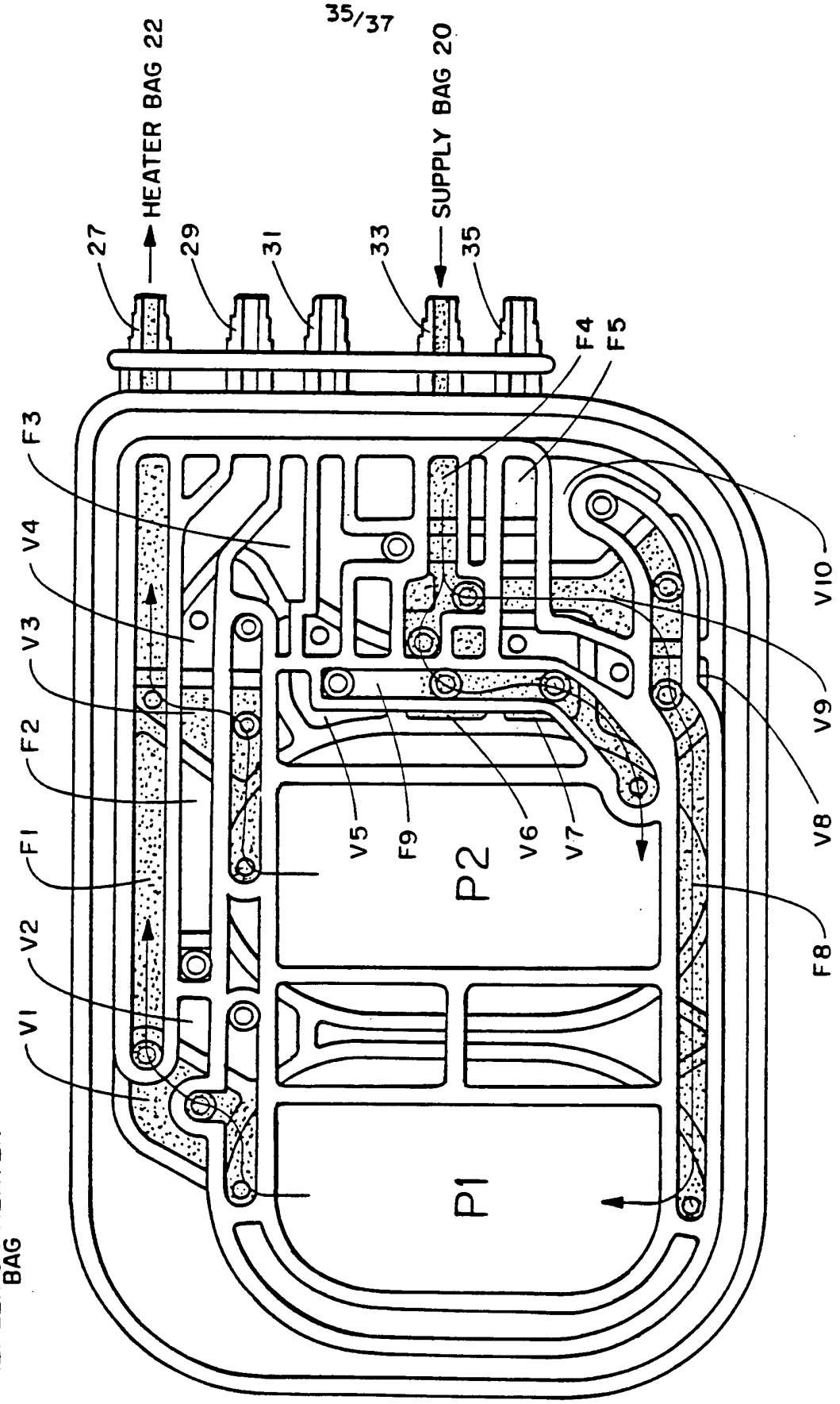


FIG. 33
(DWELL)
REPLENISH HEATER BAG

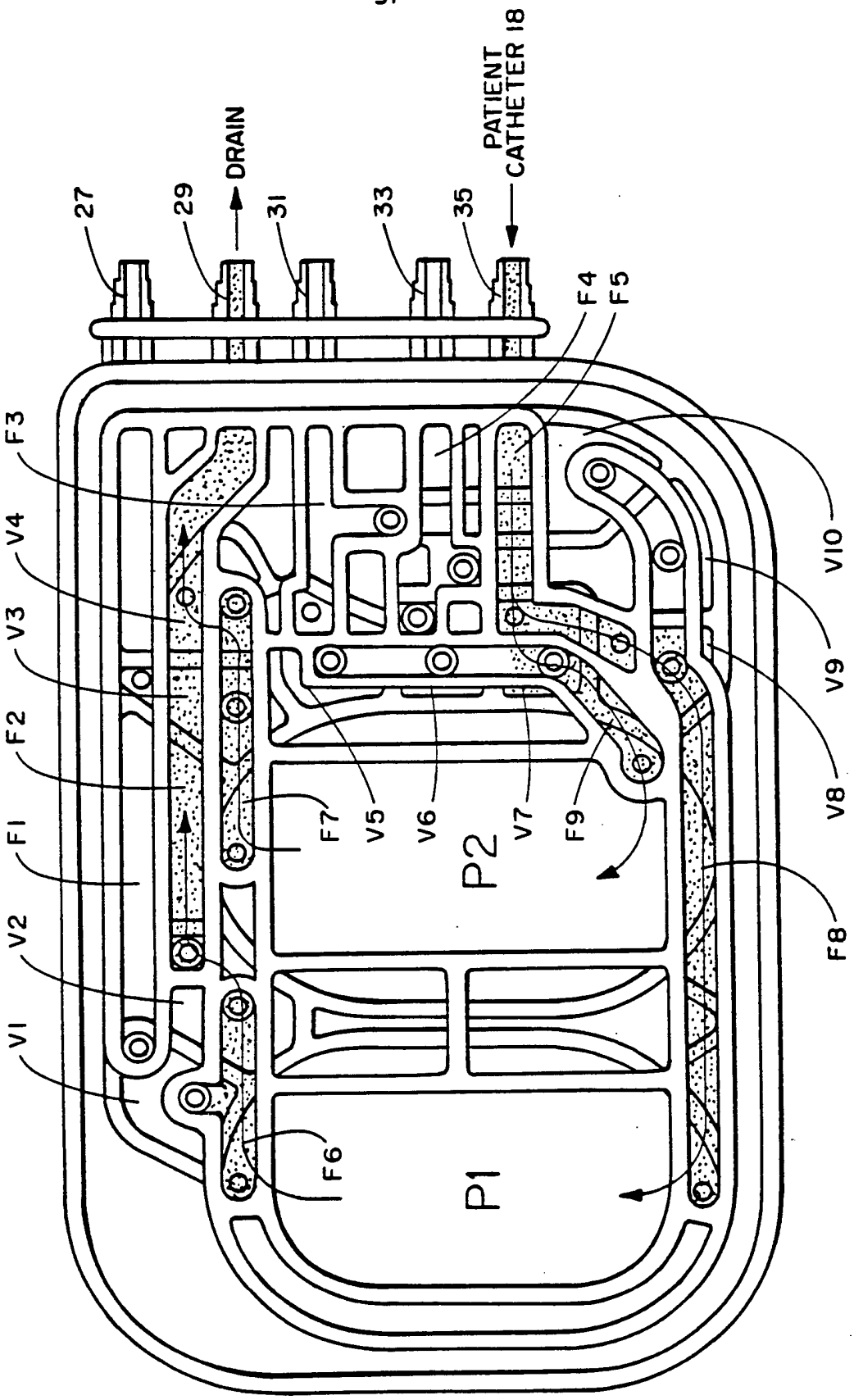

PATIENT CATHETER 18
DRAIN
27
29
31
33
35
F4
F5
F3
V4
V3
F2
F1
V2
V1
V10
V9
V8
F8
F7
V5
V6
V7
F9
F6
P2
P1

FIG. 34
(DRAIN)

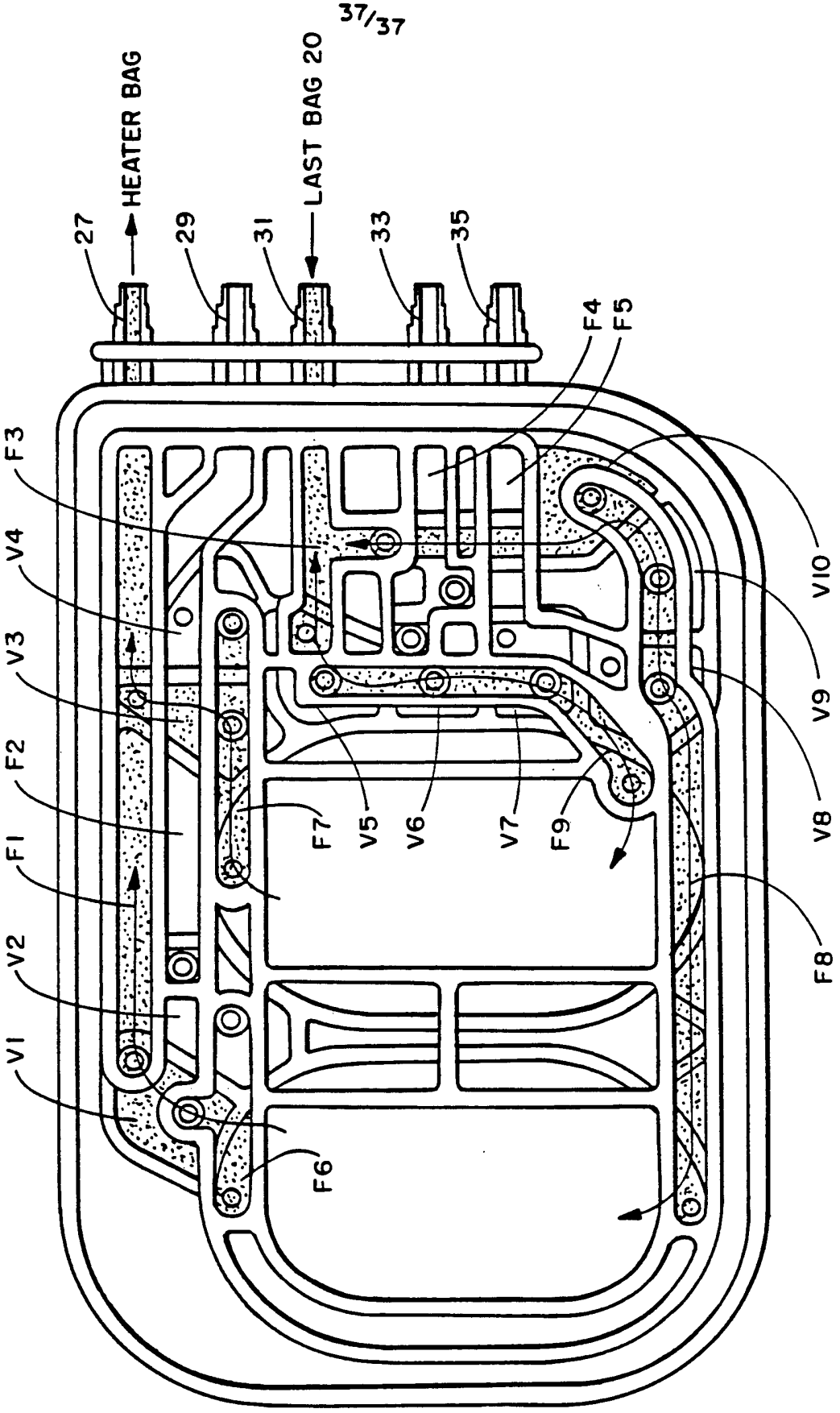


FIG. 35
(LAST DWELL)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 94/02129

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M1/28 A61M5/168 G01F15/04 G01F1/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO,A,90 13795 (DEKA LIMITED PARTNERSHIP) 15 November 1990 see abstract; figures 1-3,8,10,11 see page 8, line 22 - page 11, line 10 see page 21, line 20 - page 22, line 17 ---	1 2-6,9-14
Y	US,A,4 956 996 (MORRIS) 18 September 1990 see abstract; figures see column 5, line 17 - column 6, line 28 ---	2,3,9,10
Y	EP,A,0 491 159 (ROBERT BOSCH GMBH) 24 June 1992 see abstract; claim 1; figures see column 3, line 3 - column 4, line 2 --- -/--	4-6, 11-14

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 June 1994	28.07.94
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Zeinstra, H

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR,A,2 593 911 (SOCIÉTÉ CERM SARL ET SOCIÉTÉ ANONYME DITE: CENTRE TECHNIQUE DE L'APAVE) 7 August 1987 see abstract see page 4, line 2 - line 6	2
A	WO,A,89 01795 (KAMEN) 9 March 1989 see page 5, line 4 - page 9, line 13	1
A	WO,A,87 05223 (KAMEN) 11 September 1987	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/02129

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7 and 8
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1 (iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US 94/02129

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9013795	15-11-90	US-A-	4976162	11-12-90
		CA-A-	2049337	02-11-90
		EP-A-	0471000	19-02-92
		JP-T-	5502096	15-04-93
		US-A-	5088515	18-02-92
		US-A-	5193990	16-03-93
		US-A-	5178182	12-01-93
		US-A-	5211201	18-05-93
		US-A-	5222946	29-06-93
		US-A-	5195986	23-03-93
US-A-4956996	18-09-90	US-A-	4984457	15-01-91
EP-A-0491159	24-06-92	DE-A-	4040277	25-06-92
		JP-A-	4274953	30-09-92
FR-A-2593911	07-08-87	NONE		
WO-A-8901795	09-03-89	US-A-	4826482	02-05-89
		DE-A-	3882966	09-09-93
		DE-T-	3882966	25-11-93
		EP-A,B	0332690	20-09-89
		JP-T-	2501198	26-04-90
		US-A-	4976162	11-12-90
		US-A-	5193990	16-03-93
		US-A-	5178182	12-01-93
		US-A-	5211201	18-05-93
		US-A-	5222946	29-06-93
		US-A-	5195986	23-03-93
WO-A-8705223	11-09-87	US-A-	4778451	18-10-88
		AU-A-	7161887	28-09-87
		AU-A-	7162187	28-09-87
		AU-A-	7164687	28-09-87
		CA-A-	1278843	08-01-91
		CA-A-	1282737	09-04-91
		DE-A-	3773091	24-10-91
		DE-A-	3775318	30-01-92
		EP-A,B	0258424	09-03-88
		EP-A,B	0259464	16-03-88

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US 94/02129

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-8705223		EP-A,B 0262182	06-04-88
		JP-T- 63503116	17-11-88
		JP-T- 63503117	17-11-88
		JP-T- 1501446	25-05-89
		US-A- 4816019	28-03-89
		US-A- 4804360	14-02-89
		US-A- 4808161	28-02-89
		WO-A- 8705224	11-09-87
		WO-A- 8705225	11-09-87
		US-A- 4826482	02-05-89
		US-A- 5193990	16-03-93
		US-A- 5116021	26-05-92
		US-A- 5178182	12-01-93
		US-A- 5211201	18-05-93
		US-A- 5222946	29-06-93
		US-A- 5195986	23-03-93
		US-A- 5241985	07-09-93

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 December 2005 (01.12.2005)

PCT

(10) International Publication Number
WO 2005/114113 A3

(51) International Patent Classification:
G01F 23/14 (2006.01) *G01F 17/00* (2006.01)

(21) International Application Number:
PCT/GB2005/002062

(22) International Filing Date: 23 May 2005 (23.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0411490.6 22 May 2004 (22.05.2004) GB

(71) Applicant *(for all designated States except US)*: **ACCU-GAUGE LIMITED** [GB/GB]; 3 St. Davids Business Park, Dalgety Bay, Fife KY11 9PF (GB).

(71) Applicants and
(72) Inventors: **ESPARZA, Joseph, L.** [US/GB]; 41 Donibristle Gardens, Dalgety Bay, Fife KY11 9NQ (GB). **NICHOLSON, David, J.** [GB/GB]; 39 Lakeside Road, Kirkcaldy, Fife KY2 5QJ (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **IDDON, Robin, A.** [GB/GB]; 5 Belgrave Place, Edinburgh EH4 3AN (GB). **MCBRIDE, Richard** [GB/GB]; Priory House, The Shore, Aberdour KY3 0TY (GB). **FITZWATER, Ian** [GB/GB]; Ionic Manufacturing Limited, 5 Gosforth Close, Middlefield Industrial Estate, Sandy, Beds SG19 1RB (GB).

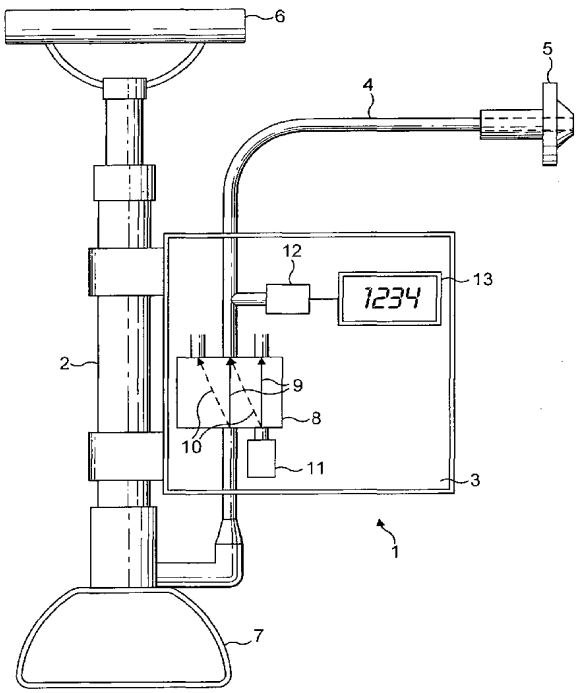
(74) Agent: **HINDLE, Alistair, Andrew**; Hindle Lowther, 28 Rutland Square, Edinburgh EH1 2BW (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

(54) Title: METHOD AND DEVICE FOR MEASURING THE VOLUME OF AIR SPACE IN A CONTAINER



(57) Abstract: There is provided a device and methods for determining the volume of air space within a container, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means. A particular application is determining a change in the amount of fuel in a fuel tank between the beginning and end of a vehicle rental.

WO 2005/114113 A3

GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) **Date of publication of the international search report:**
2 March 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

PCT/GB2005/002062

A. CLASSIFICATION OF SUBJECT MATTER
G01F23/14 G01F17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 50 620 A1 (SIEMENS AG, 80333 MUENCHEN, DE) 2 June 1999 (1999-06-02) page 1, line 60 - page 2, line 9; figures 1-2c	1-29, 31-35
X	DE 39 29 506 A1 (MOTO METER AG, 7250 LEONBERG, DE) 14 March 1991 (1991-03-14) column 2, line 15 - column 3, line 1; figure 1	1-29, 31-35
A	US 6 065 335 A (DENZ ET AL) 23 May 2000 (2000-05-23) column 4, line 14 - column 5, line 1; figures 1-2b	1-29, 31-35

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 2005	28.12.05

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Boerrigter, H

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2005/002062

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-29,31-35

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-29,31-35

Method and device for determining a volume of air or liquid in a container of known volume.

---

2. claim: 30

Method of calculating a charge to be issued in relation to the rental of a vehicle.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB2005/002062

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19750620 A1	02-06-1999	FR 2771170 A1	21-05-1999
DE 3929506 A1	14-03-1991	NONE	
US 6065335 A	23-05-2000	DE 19648688 A1	28-05-1998
		JP 10170384 A	26-06-1998
		SE 518041 C2	20-08-2002
		SE 9704301 A	26-05-1998

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 December 2005 (01.12.2005)

PCT

(10) International Publication Number
WO 2005/114116 A1

(51) International Patent Classification[7]: G01F 23/14, 17/00

(21) International Application Number: PCT/GB2005/002023

(22) International Filing Date: 23 May 2005 (23.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0411490.6 22 May 2004 (22.05.2004) GB

(71) Applicants and
(72) Inventors: **LANE, John, Dennis** [GB/GB]; 30 Snaith Crescent, Loughton, Milton Keynes MK5 8HG (GB). **ESPARZA, Joseph, Luis** [GB/GB]; 41 Donibristle Gardens, Dalgety Bay, Fife KY11 9NQ (GB). **NICHOLSON, David, James** [GB/GB]; 39 Lakeside Road, Kircaldy, Fife KY2 5QJ (GB).

(74) Agent: **GREGORY, Timothy, Mark**; 26 Cyril Street, Northampton NN1 5EL (GB).

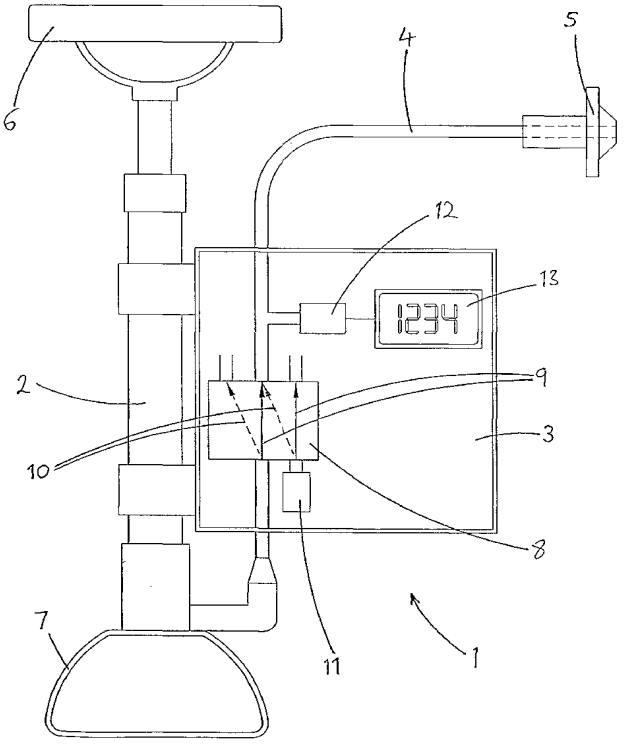
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) **Title:** METHOD AND DEVICE FOR MEASURING THE VOLUME OF AIR SPACE IN A CONTAINER



(57) **Abstract:** A meter (1), for determining a volume of a liquid, such as fuel, present in a tank of known volume, comprises a pressurising pump (2) connectable via a measurement unit (3) and a flexible pressure hose (4) to a fitting (5) capable of forming a gas-tight seal with an opening of a fuel tank filler pipe, or the like. The measurement unit (3) contains a valve (8) which in a first position (9) connects the pump (2) to the hose (4), fitting (5) and fuel tank, and in a second position (10) connects the hose (4), fitting (5) and fuel tank to a calibrated restrictor (11) leading to open air. The measurement unit (3) also contains a pressure transducer (12) to measure the pressure within the hose (4), and an electronic control unit, linked to the transducer (12), that controls the valve (8). The fuel tank is pumped up to a preselected pressure, above ambient, at which point the valve (8) is operated to connect it to the restrictor (11), so that pressurised air in the tank is released at a substantially constant rate therethrough. A timer measures how long the pressure in the hose (4) and tank takes to fall between two preselected values, from which an air volume in the tank is calculated, and hence a fuel volume.

WO 2005/114116 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND DEVICE FOR MEASURING THE VOLUME OF AIR SPACE IN A CONTAINER

The present invention relates to a device to determine a volume of fluid present in a tank or other container. More particularly, but not exclusively, it relates to a device to determine a volume of fuel present in a vehicle fuel tank, for example so as to compare volumes present before and after use, and to a method of use of such a device.

When a car, van or other vehicle is hired out, it is common for a hire agreement to specify that the vehicle should be returned with the same volume of fuel in its fuel tank as was present when it was driven away. Should there be a deficit, the hirer is liable to pay for the vehicle to be refuelled to the initial level.

However, in practice, it is difficult to assess exactly how much fuel is present in a vehicle fuel tank, using only the vehicle's dashboard fuel gauge, which is usually connected to a float sensor within the tank. The gauge can normally be read to no better than the nearest eighth of a tank-full, which will typically represent five to ten litres of fuel. It is thus possible to return a vehicle with significantly less fuel in its tank, without this being clearly indicated by its fuel gauge. Furthermore, in borderline situations, considerations such as good customer

relations will often militate against arguing with a customer over whether a fuel gauge needle is nearer to three-eighths of a tank or a quarter of a tank, for example.

It is estimated that such shortfall causes loss to vehicle hirers of around £250,000 per year in the United Kingdom alone. This could be extrapolated to an annual loss for the entire vehicle hire market of approximately £80 million. There is hence a need for a precise and unequivocal means of measuring how much fuel is present in a vehicle's tank, before and after use.

Such means should, however, preferably not involve modification to the vehicles themselves, on grounds of cost and inconvenience. It should be quick and easy to use, and must be safe for use in the presence of highly inflammable fuel vapours.

Conventional liquid level sensors would not be appropriate, since they would be significantly affected by the exact attitude of the vehicle to the horizontal when the measurements are taken. In any case, it is difficult to access the fuel itself from outside the tank. However, an approach that appears to have received little attention is to measure the volume of the air above the fuel in the tank. In practice, the volume of air above the fuel will include the volume of a filler pipe leading from a filler cap or the like to the fuel tank, so the term "tank" hereinafter should be understood also to comprise such piping.

Vehicle fuel tanks will be produced to a standard size for any given model. Thus, the volume of fuel in the tank plus the volume of air above it will be a constant (strictly speaking, only true at a constant temperature, but such considerations can be allowed for mathematically, or by calibrating at a range of temperatures). In principle, a change of air volume in the tank

will indicate a change in fuel volume, and measuring air volume has the advantage that a direct connection with this volume can be established through an existing, unmodified filler cap.

While a particular problem to be addressed is the measurement of fuel volumes within vehicle fuel tanks, as discussed above, there will be many other applications in which quick and accurate measurements of liquid volumes within substantially rigid containers will be required. A device suitable for measuring fuel volumes may well also be applicable to other such measurement needs.

It is hence an object of the present invention to produce a device to determine the volume of liquid present in a container by measuring the volume of gas in the container, and provide a method for determining such volumes and changes in such volumes, using said apparatus.

According to a first aspect of the present invention, there is provided a device to measure a volume of liquid held within a container comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to time a period taken for the pressure within the container to change from a first predetermined value to a second predetermined value while the container is connected to the restrictor means.

Preferably, the device is provided with display means to indicate said period.

Alternatively or additionally, the device may be provided with memory means adapted to record said period for future reference, or for subsequent transmission to a separate computing device.

Advantageously, said display means may comprise numeric or alphanumeric display means.

Optionally, said display means comprises a liquid crystal display.

Preferably, the device is provided with electronic control means.

Advantageously, said electronic control means is adapted to operate the valve means.

The electronic control means may be adapted to operate the valve means so as to connect the container to the restrictor means when the pressure in the container has been altered to a third preselected value, further than said first and second values from ambient pressure.

The gas flow restrictor means preferably comprises calibrated orifice means through which gas may flow at a substantially constant rate.

The device may be provided with means to convert said period to a liquid volume within a particular container.

Said conversion means may comprise a set of graphs or tables of said periods against gas volume and/or liquid volume for particular preselected containers.

Alternatively or additionally, the device may be provided with memory means containing data to enable conversion of said periods to gas volumes and/or liquid volumes for particular preselected containers, and the electronic control means is adapted to perform said conversion.

The device may then be provided with display means adapted to indicate a calculated volume.

The pressure-altering means preferably comprises pump means.

Advantageously, the pump means is manually- or pedally-operable.

The pump means may be adapted to raise the pressure within the container above ambient pressure.

Alternatively, the pump means may be adapted to reduce the pressure within the container below ambient pressure.

The pressure-altering means may alternatively comprise a source of gas under pressure, such as a compressed-air line or a reservoir vessel containing gas under pressure.

The device may be provided with pressure release means adapted to operate at a pressure differential within the container below that which might damage the container.

The connecting means may be adapted to form a gas-tight connection with a range of different container apertures, for example fuel tank filler pipe openings of different models of vehicle.

According to a second aspect of the present invention, there is provided a method for measuring a volume of liquid held within a container comprising the steps of providing a device as described in the first aspect above, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, timing the period taken for the pressure within the container to fall from said first predetermined value to a second predetermined value, and calculating from said period a gas volume and hence a liquid volume within the container.

Preferably, the method further comprises the steps of subsequently measuring an altered liquid volume within the container as described above and calculating a change in liquid volume between said measurements.

An embodiment of the present invention will now be more particularly described by way of example and with reference to the accompanying drawing, in which:

Figure 1 is a frontal elevation of a fuel volume meter embodying the present invention.

Referring now to the figure, a fuel volume meter 1 comprises a pressuring pump 2 connected to a measurement unit 3, which is in turn linked by means of a flexible pressure hose 4 to a tank connector fitting 5. The tank connector fitting 5 is shaped to form a gas-tight seal with an external opening of a fuel filler pipe leading to a fuel tank of a vehicle. (Where a wide range of different sizes of and/or shapes of openings may be encountered, it may be necessary to provide alternative, exchangeable fittings 5).

The pressurising pump 2 is here a manually-operable stirrup pump, with a reciprocally vertically-moveable pump handle 6 and a stirrup base 7 into which a user may insert a foot in order to stabilize the meter 1 during pumping. Other embodiments may use foot-operated pumps, or even (at the expense of portability) an existing or dedicated compressed-air supply, via a suitable regulator. It would even be possible to use a regulated compressed gas cylinder, for example to provide a source of inert gas for use in connection with extremely flammable fuels or other liquids.

The measuring unit 3 contains a two-position valve 8. In a first position, represented by solid arrows 9, the valve 8 connects the pressurising pump 2 to the pressure hose 4, and hence to the fuel tank. In a second position, represented by broken arrows 10, the pressurising pump 2 is connected to open air, while the pressure hose 4 and fuel tank are connected to a restrictor 11 comprising a calibrated orifice through which air may exit the meter 1. A pressure transducer 12 measures the air pressure within the pressure hose 4 (and hence within the fuel tank). The measuring unit 3 also contains electronic control apparatus (including a timing circuit), which is adapted to control the valve 8 and to receive data from the pressure transducer 12. The measuring unit 3 is also provided with a display 13, most conveniently a liquid crystal numeric or alphanumeric display, although light emitting diode or analogue

displays may also be used. The electronic components are all encapsulated for safety in the presence of highly flammable fuel vapours. The portable meter 1 shown uses a low-voltage dry cell battery as power supply, which is also located within a gas-tight chamber.

To use the meter 1, a filler cap is removed from a fuel filler pipe of a vehicle, and the fitting 5 is securely and sealingly connected to its external opening. The meter 1 is turned on, the valve 8 being in its first position 9. The user pumps the handle 6 of the pressurising pump 2, transferring air through the hose 4 to an interior of the fuel tank.

When the pressure within the fuel tank, the filler pipe and the hose 4 reaches 250 millibars above atmospheric pressure, as indicated by the pressure transducer 12, the electronic control apparatus switches the valve 8 from its first position 9 to its second position 10. The pressurising pump 2 is now connected to the atmosphere, so no more air can be pumped into the fuel tank, which is now linked, via the hose 4, to the restrictor 11. The slightly pressurised air within the fuel tank is now free to bleed out via the calibrated orifice of the restrictor 11, so that the pressure in the fuel tank, etc, begins to fall.

When the pressure transducer 12 registers a first pre-set pressure, for example 200 millibars, the timing circuit begins to run. Air continues to bleed out through the restrictor 11 until a second pre-set pressure is reached, for example 100 millibars, at which point the timing circuit stops. The display 13 indicates an elapsed time between reaching the first and second pre-set pressures, which the user may record. The pressure within the tank is then allowed to return to atmospheric pressure, and the fitting 5 is removed.

In principle, the behaviour of a gas under pressure is governed by the ideal gas equation:

$$PV = nRT$$

where P is pressure, V is volume, T is temperature, R is the ideal gas constant, and n is the number of moles of gas present. In the course of the above pressurisation and de-pressurisation sequence, V is the free volume of the fuel tank above the fuel (which includes, as defined, the volume of the filler pipe and the hose 4, which will be substantially constant). Over the range of pressure changes envisaged, it may be assumed that the temperature T will not vary appreciably, the volume V will not change and R is an universal constant. Thus, the pressure is in effect directly related to n, the amount of gas present, and a change in pressure, ΔP, is directly related to a change in the amount of gas present, Δn:

$$\Delta P = \Delta n.RT/V$$

Hence, the larger the value of V, the greater the value of Δn to give a particular value of ΔP.

The calibrated orifice in the restrictor 11 allows gas to escape at a relatively constant rate (for the overpressure ranges in question), i.e. it allows n to change at a substantially constant rate over time.

Thus, the time t, measured for a specific pressure drop to occur through the restrictor 11 is a measure of the amount of gas that has escaped to produce that pressure drop:

$$\Delta n = k.t, \text{ where k is a constant}$$

$$\therefore \Delta P = k.t.RT/V$$

or $V = k.t.RT/\Delta P$

Since k and R are constant, and T is effectively constant and ΔP is predetermined, the free volume V above the fuel in the tank is directly proportional to the time t.

In reality, gas behaviour tends to diverge from idea gas behaviour, but in a repeatable fashion. Thus, a graph of V versus t may not be a straight line, but it is possible to produce a reliable calibration curve for any given standard fuel tank by part-filling it with a range of known volumes of liquid, and measuring t in each case.

Thus, one may use the meter 1 on a tank of known type containing an unknown volume of fuel, to obtain an accurate assessment of the free volume within the tank, and hence the volume of fuel.

This procedure may be carried out when a vehicle is hired out, repeated when the vehicle is returned, and any difference calculated. If there is a deficit, the hire company may charge the person who has hired the vehicle for the exact shortfall.

In its basic form, the meter 1 indicates only the time taken for the pressure to drop from a first to a second preset value, leaving the user to read off a fuel volume from a calibration curve for the particular vehicle model being used. However, it is envisaged that the meter could be provided with a memory chip or the like containing the calibration curves for a range of vehicles, and a touch-pad or the like allowing the user to select a particular model. The meter display 13 would then show a calculated fuel volume.

Alternatively, the meter could record the time in its memory, and then be connected to a computer, over a standard RS232 connection, USB port or the like, in order to transfer this time data. In this case, the computer could hold the calibration curves in its memory and use them to calculate the fuel volume present. It would store the "as hired" fuel volume of each vehicle, compare it with the "as returned" fuel volume of that vehicle, and calculate any refuelling charges automatically.

The computer could be a conventional personal computer or mainframe, or it might usefully be a portable device, such as a PDA (portable digital assistant) or a dedicated handheld computing device.

Many such devices have wireless connectivity, using radio frequency or infra-red beam communications, such as Bluetooth technology (Bluetooth is a registered trade mark). The meter could then be provided with an appropriate data transmission system in place of, or as well as, an RS232 connection or the like.

The meter may also be provided with a printer system, so that a ticket bearing the time and optionally volume data may be printed out, either as a confirmatory hard copy/receipt or as its main data output.

The meter described will be safe in use, as its electrical components are isolated from any fuel vapour mixed with the air above the fuel in the vehicle's tank. Also, the overpressures used, approximately one-quarter of atmospheric pressure at most, will be well within the range of what a vehicle fuel tank is designed to withstand. If safety regulations require, a

pressure relief valve, bursting disc, or the like can be provided to release excess pressure if the valve fails to operate at 250mbar as described above.

It should also be noted that while operation of the meter 1 is described above with the fuel tank, etc, being pressurised to a slight overpressure, it is equally possible to evacuate the tank partially, creating an underpressure that sucks air into the tank through the restrictor 11.

A further application for a meter similar to that described above is to check accurately the volume of fuel present in a fuel tank of a racing car, such as a Formula One racing car. At present, the volume of fuel added to the tank is estimated using a flow meter in the fuel delivery hose system and a timer; no direct accurate measurement of the volume present in the tank is available. The mass of fuel carried is of vital importance to the performance of a racing car, but if no safety margin is left, the car could run out of fuel before finishing. An accurate measurement of the volume actually present in the tank would thus be of great assistance.

Another potential application is believed to be in the field of fuel delivery tanker vehicles. It is still common practice for a tanker driver to check the volume present in a tanker trailer or the like by using a dipstick. This cannot be particularly accurate, may expose the driver and his surroundings to noxious, inflammable fuel vapours, and often requires the driver to climb on top of the tanker, risking a potentially fatal fall.

The empty volume of a tanker will be known or measurable, and so a meter similar to that described above would be able to determine the volume of fuel present therein.

CLAIMS

1. A device to measure a volume of liquid held within a container comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to time a period taken for the pressure within the container to change from a first predetermined value to a second predetermined value while the container is connected to the restrictor means.

2. A device as claimed in claim 1, provided with display means, optionally numeric or alphanumeric display means, to indicate said period, and optionally provided with memory means adapted to record said period for future reference, or for subsequent transmission to a separate computing device.

3. A device as claimed in any one of the preceding claims, provided with electronic control means, optionally adapted to operate the valve means.

4. A device as claimed in claim 3, wherein the electronic control means is adapted to operate the valve means so as to connect the container to the restrictor means when the pressure in the container has been altered to a third preselected value, further from ambient pressure than said first and second values.

5. A device as claimed in any one of the preceding claims, wherein the gas flow restrictor means comprises calibrated orifice means through which gas may flow at a substantially constant rate.

6. A device as claimed in any one of the preceding claims, provided with means to convert said period to a liquid volume within a particular container.

7. A device as claimed in any one of the preceding claims, wherein the pressure-altering means comprises pump means, optionally manually- or pedally-operated pump means, or a source of gas under pressure, such as a compressed-air line or a reservoir vessel containing gas under pressure.

8. A device as claimed in any one of the preceding claims, provided with pressure release means adapted to operate at a pressure differential within the container below that which might damage the container.

9. A method for measuring a volume of liquid held within a container comprising the steps of providing a device as claimed in any one of the preceding claims, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, timing the period taken for the pressure within the container to fall from said first predetermined value to a second predetermined value, and calculating from said period a gas volume and hence a liquid volume within the container.

10. A method as claimed in claim 9, further comprising the steps of subsequently measuring an altered liquid volume within the container as described above and calculating a change in liquid volume between said measurements.

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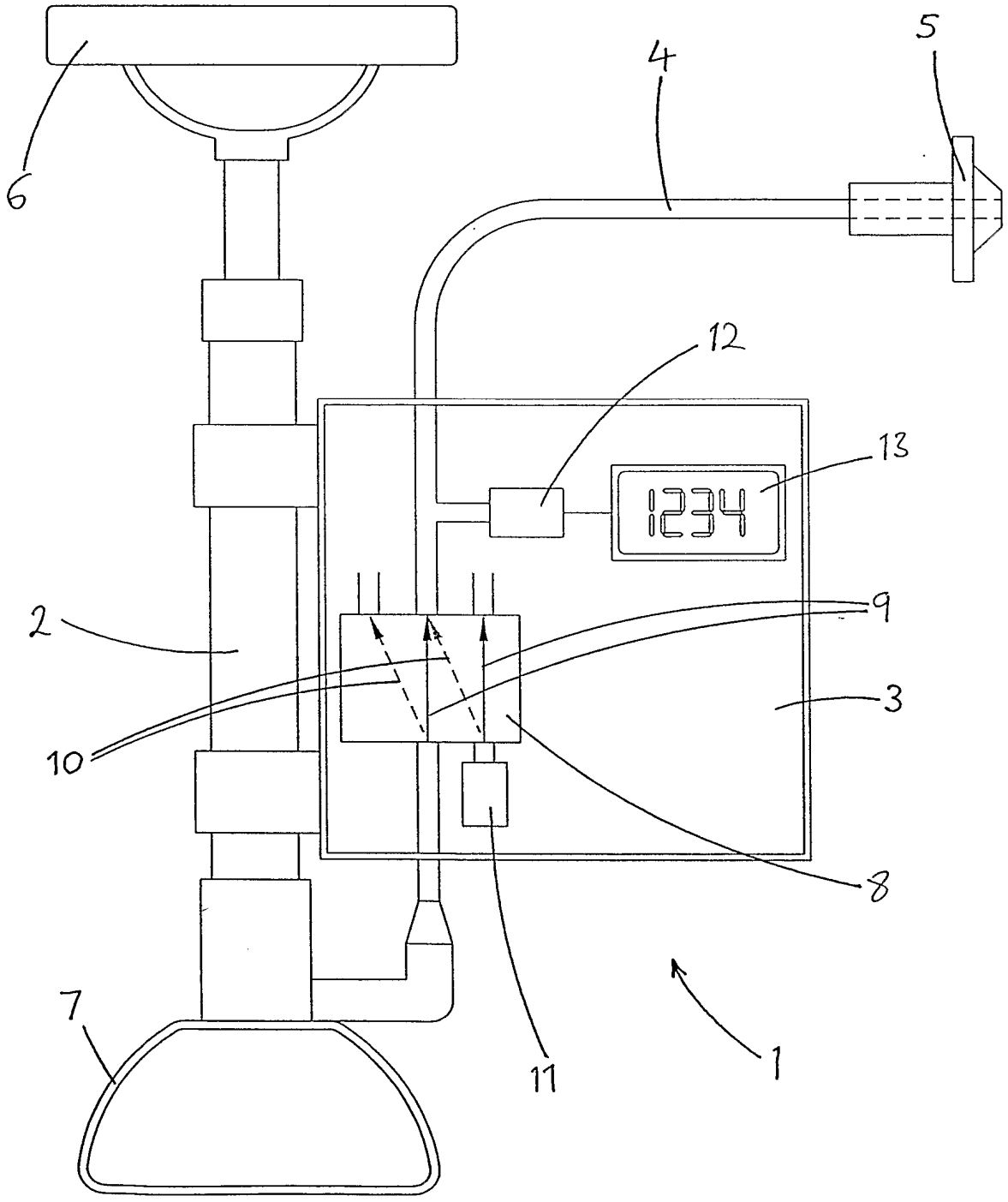


Fig 1

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/GB2005/002023

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01F23/14 G01F17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 50 620 A1 (SIEMENS AG, 80333 MUENCHEN, DE) 2 June 1999 (1999-06-02) page 1, line 60 - page 2, line 9; figures 1-2c	1-10
X	DE 39 29 506 A1 (MOTO METER AG, 7250 LEONBERG, DE) 14 March 1991 (1991-03-14) column 2, line 15 - column 3, line 1; figure 1	1-10
A	US 6 065 335 A (DENZ ET AL) 23 May 2000 (2000-05-23) column 4, line 14 - column 5, line 1; figures 1-2b	1-10
A	DE 800 435 C (LEPPER WILLY DR.-ING) 6 November 1950 (1950-11-06) the whole document	7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 September 2005	06/10/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Boerrigter, H

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/GB2005/002023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19750620 A1	02-06-1999	FR 2771170 A1	21-05-1999
DE 3929506 A1	14-03-1991	NONE	
US 6065335 A	23-05-2000	DE 19648688 A1	28-05-1998
		JP 10170384 A	26-06-1998
		SE 518041 C2	20-08-2002
		SE 9704301 A	26-05-1998
DE 800435 C	06-11-1950	NONE	

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(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG, KZ, RU, TJ, TM), ヨーロッパ (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

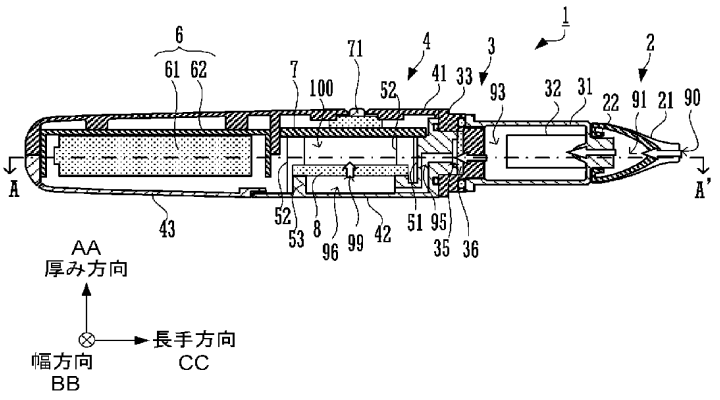
添付公開書類:

— 国際調査報告（条約第 21 条(3)）

(54) **Title**: ASPIRATION DEVICE

(54) 発明の名称 : 吸入装置

【図2】



AA Thickness direction
BB Width direction
CC Longitudinal direction

(57) **Abstract**: An aspiration device (1) provided with an aspiration port (90) exposed to the outside, flow channels (91-98) leading to the aspiration port (90), and a discharge port (99) for discharging fluid from the flow channels (91-98), wherein are provided a diaphragm (83) having one principal surface facing a pump chamber (98) and another principal surface facing the one principal surface, and a piezoelectric element (81) for displacing the one principal surface of the diaphragm with respect to the pump chamber (98), the piezoelectric element (81) being attached to the diaphragm (83), and the one principal surface and other principal surface of the diaphragm (83) are oriented in a different direction from the direction in which the aspiration port (90) is oriented.

(57) 要約: 外部に露出する吸入口（９０）、前記吸入口（９０）に通じる流路（９１～９８）、および、前記流路（９１～９８）から流体を吐出する吐出口（９９）を設けた吸入装置（１）であって、ポンプ室（９８）に面する一方主面、および、前記一方主面に対向する他方主面を有するダイヤフラム（８３）と、前記ダイヤフラム（８３）に付設した、前記ダイヤフラム（８３）の一方主面をポンプ室（９８）に対して変位させる圧電素子（８１）と、を備え、前記ダイヤフラム（８３）の一方主面および他方主面は、前記吸入口（９０）が向く方向とは異なる方向を向いている。

WO 2015/166749 A1

明　細　書

発明の名称 ： 吸入装置

技術分野

[0001] 本発明は、鼻水などの液体等を除去する際に利用される吸入装置に関する。

背景技術

[0002] 風邪や鼻炎、蓄膿症などにかかると、鼻水の分泌が過剰になることで鼻づまり等の症状が生じる。一般的には鼻をかむことで鼻づまりを解消することが可能であるが、自ら鼻をかむことができない乳幼児等の場合には、介助者が鼻水を除去する必要がある。この際、ちり紙や綿棒を用いて少量の鼻水を除去することは可能であるが、多量の鼻水を除去することは難しかった。そこで、近年では、電動モータとポンプを用いて、鼻水を多量に除去できるようにした吸入装置が普及してきている（例えば特許文献１および２参照。）。

先行技術文献

特許文献

[0003] 特許文献1：特表２０１０－５２７６３６号公報

発明の概要

発明が解決しようとする課題

[0004] しかしながら、従来の吸入装置は、使用時に発生するモータ音や振動が大きく、乳幼児等がモータ音や振動に反応して体を動かして鼻水の吸引作業を行い難くなる場合があった。そこで、出願人は、電動モータに替えて、使用時に発生するモータ音や振動が小さい圧電素子を用いた吸入装置を開発している。

[0005] 図６は、駆動源に圧電素子を用いた吸入装置を模式的に示す図である。吸入装置１０１は、ノズル１０２とセパレータ１０３と圧電駆動部１０４とを備えている。ノズル１０２は、鼻腔等に挿入され、外部の流体を吸引する。

セパレータ１０３は、ノズル１０２の後端に接続して設けられ、ノズル１０２で吸引した鼻水を空気から分離する。圧電駆動部１０４は、セパレータ１０３の後端に接続して設けられ、セパレータ１０３が分離した空気を吸引して外部に吐出する。また、圧電駆動部１０４は、ダイヤフラム１０５と圧電素子１０６とを備えている。ダイヤフラム１０５は、吐出口に対向するように設けられている。圧電素子１０６は、駆動によりダイヤフラム１０５を振動させる。このような構成の吸入装置１０１では、圧電素子１０６の駆動に摺動や摩擦が伴うことがなく、駆動音や振動を大幅に抑制することができる。

[0006] しかしながら、圧電素子では、振動によって電動モータでは生じない高音域可聴音、所謂モスキート音が生じることがあり、この高音域可聴音が乳幼児等に拒否反応を引き起こすことがあった。

[0007] そこで、本発明の目的は、高音域可聴音の影響を抑制できる吸入装置を提供することにある。

課題を解決するための手段

[0008] この発明は、外部に露出する吸入口、前記吸入口に通じる流路、および、前記流路から流体を吐出する吐出口を設けた吸入装置であって、前記流路に面する一方主面、および、前記一方主面に対向する他方主面を有する振動板と、前記振動板に付設した、前記振動板の一方主面を前記流路に対して変位させる圧電素子と、を備え、前記振動板の一方主面および他方主面は、前記吸入口が向く方向（吸入口において液体等が吸入される方向）とは異なる方向を向いている。

[0009] この吸入装置では、圧電素子の駆動に摺動や摩擦が伴うことがなく、駆動音や振動を大幅に抑制することができる。その上、圧電素子の振動によって高音域可聴音が発生することがあっても、振動板の主面が向く方向を吸入口が向く方向とは異なる方向にすることにより、高音域可聴音の指向方向を吸入口が向く方向から外すことができる。このことにより、吸入口に面することになる乳幼児等に対して、高音域可聴音を聞こえ難くすることができる。

[0010] 前記吐出口は、前記吸入口が位置する方向とは異なる方向を向いていることが好ましい。この構成では、吐出口から漏れる高音域可聴音を乳幼児等に対して聞こえ難くすることができる。

[0011] 前記振動板の一方主面または他方主面は、前記吐出口が位置する方向を向いていることが好ましい。この構成では、高音域可聴音を吸入口側から漏れ難くすることができる。

[0012] 前記振動板の一方主面および他方主面は、前記吸入口が位置する方向に対して略直交する方向を向いていることが好ましい。これにより、高音域可聴音の指向方向が吸入口から最も外れる方向になるので、より確実に高音域可聴音を乳幼児等に聞こえ難くすることができる。

[0013] 前記吸入装置は、前記圧電素子に駆動電圧を印加する回路基板を備え、前記振動板の一方主面または他方主面は、前記回路基板が位置する方向を向いていることが好ましい。これにより、高音域可聴音が外部に漏れることを回路基板によって抑制でき、また、吐出口から吐出される流体を回路基板にあてて回路基板を効果的に冷却できる。

[0014] 前記吸入装置は、遮蔽板を備え、前記振動板の一方主面または他方主面は、前記遮蔽板が位置する方向を向いていることが好ましい。このようにしても、高音域可聴音が外部に漏れることを遮蔽板によって抑制できる。

[0015] 前記吸入装置は、前記振動板の一方主面および他方主面に対向する位置を把持部とする筐体を備えることが好ましい。これにより、高音域可聴音が外部に漏れることを、筐体を把持する手によって抑制できる。

[0016] 前記振動板の主面面内方向のサイズが、前記振動板の一方主面および他方主面が向く方向での前記筐体の内部空間のサイズよりも大きいことが好ましい。これにより、吸入装置を薄型に構成しても、高効率に流体の流れを生じさせることができる。

発明の効果

[0017] 本発明によれば、吸入装置で生じる高音域可聴音を乳幼児等に聞こえ難くすることができるので、鼻水等の吸引作業に対する乳幼児等の拒否反応を抑

えることができる。

図面の簡単な説明

[0018] [図1]第１の実施形態に係る吸入装置の側面断面図である。

[図2]第１の実施形態に係る吸入装置の平面断面図である。

[図3]第１の実施形態に係る吸入装置における圧電駆動部の拡大断面図である。

[図4]第１の実施形態に係る吸入装置における圧電駆動部の振動態様を示す模式図である。

[図5]第２の実施形態に係る吸入装置の側面断面図である。

[図6]従来構成に係る吸入装置を説明する図である。

発明を実施するための形態

[0019] 以下、幾つかの具体的な例を挙げて、本発明を実施するための複数の形態を示す。各実施形態は例示であり、異なる実施形態で示した構成の部分的な置換または組み合わせが可能であることは言うまでもない。

[0020] 図１は、第１の実施形態に係る吸入装置を側面側から視た側面断面図であり、図２中に一点鎖線Ａ－Ａ’で示す位置の断面を示している。図２は、第１の実施形態に係る吸入装置を天面側から視た平面断面図であり、図１中に一点鎖線Ｂ－Ｂ’で示す位置の断面を示している。

[0021] 図１および図２に示す吸入装置１は、ここでは鼻水等の液体吸入装置である。該吸入装置１は、全体として長手方向を有する長尺な形状であり、長手方向の一方（以下、前方と称する。）を患者等に向けて使用される。また、該吸入装置１は、長手方向に直交する幅方向と厚み方向とを有しており、厚み方向の寸法が幅方向の寸法よりも薄い薄型に構成されている。

[0022] 吸入装置１の概略の構成は次のようなものである。吸入装置１は、ノズル２とセパレータ３と筐体４とを備えている。ノズル２、セパレータ３、および筐体４は、この記載順に長手方向の前方から後方にかけて並んでいる。ノズル２は、吸入装置１の使用時に患者等の鼻腔に挿入され、鼻水等の流体を吸入する。セパレータ３は、吸入装置１の使用時にノズル２が吸引する流体

に含まれる鼻水等の混合物を分離して貯留する。筐体４は、使用時に操作者等に把持され、セパレータ３から混合物が除去された流体を吸引する。

[0023] また、吸入装置１は、筐体４の内蔵部品として電池部６と回路基板７と圧電駆動部８とを備えている。電池部６は、電池６１と電池ケース６２とを備えている。電池ケース６２は、電池６１を取り換え可能に保持している。回路基板７は、給電回路等を構成しており、電源スイッチ７１を備えている。電源スイッチ７１は、筐体４に設けられた開口から外部に露出している。回路基板７は、電源スイッチ７１の押下状態に応じて電池部６から圧電駆動部８への給電をオンまたはオフする。圧電駆動部８は、筐体４内の流路に負圧を生じさせ、セパレータ３から筐体４に流体を吸引する。

[0024] 以下に、各部の詳細な構成について説明する。

[0025] ノズル２は、一体の弾性材料からなり、前端部２１と後端部２２とを備えている。前端部２１は、ノズル２の前方側に設けられた環状の部位であり、前方ほど細くなるように外形に傾斜がついている。後端部２２は、ノズル２の後方側に設けられた環状の部位であり、ノズル２の内側に折り返されている。そして、ノズル２には、吸入口９０と流路９１とが設けられている。吸入口９０は、ノズル２の前方端に設けられた、鼻水等を含む外部の流体を吸入する開口である。流路９１は、ノズル２の内側を長手方向に貫通して設けられており、吸入口９０に通じている。このノズル２は、セパレータ３の前方側に気密した状態で連結されており、セパレータ３から取り外し可能になっている。

[0026] セパレータ３は、ケース部３１と筒状部３２とキャップ部３３と筒状部３４とを備えている。ケース部３１は、後方に開口する箱状の部材である。筒状部３２は、ケース部３１に付設された筒状の部位であり、ケース部３１の前方面から前方に突出し、ケース部３１の開口内底面から後方に伸びている。筒状部３２の前方端には、ノズル２の後端部２２が嵌め合わされている。キャップ部３３は、ケース部３１の後方に嵌め合わされる蓋状の部材である。筒状部３４は、キャップ部３３に付設された筒状の部位であり、キャップ

部３３から前方に伸びている。

[0027] また、セパレータ３には流路９２，９３，９４が設けられている。流路９２は、筒状部３２の内側を長手方向に貫通して設けられており、ノズル２の流路９１に通じている。流路９３は、ケース部３１の内側に設けられており、筒状部３２の流路９２と通じている。流路９４は、筒状部３４の内側を長手方向に貫通して設けられており、ケース部３１の流路９３と通じている。

[0028] 筒状部３２と筒状部３４とは、ケース部３１の内部で長手方向に互い違いになるように配置され、流路９３を介して流路９２と流路９３とは通じている。このことによってノズル２からセパレータ３に導かれた流体に含まれる鼻水等の液体は、ケース部３１の内部（流路９３）から漏出し難くなっており、流体に含まれる気体のみがセパレータ３から筐体４側に吸引される。

[0029] このセパレータ３は、キャップ部３３の後方面に凹部３５が設けられており、この凹部３５に筐体４を嵌め込むことで、筐体４の前方側に気密した状態で連結されている。凹部３５の内底面にはフィルタ３６が設けられている。フィルタ３６は、不織紙状やスポンジ状の膜体であり、セパレータ３側から筐体４側に鼻水等の液体が漏出することを防ぐ機能を有している。なお、フィルタ３６は必ずしも設けなくても良い。

[0030] また、セパレータ３は、ねじ３７によって筐体４と連結されており、ねじ３７を外すことによって筐体４から分離可能となっている。また、ケース部３１とキャップ部３３との間も、ねじ３７を外すことによって分割可能となっている。このため、セパレータ３からの鼻水の除去と洗浄が可能である。各部の連結部分には気密のために適宜オーリングを設けている。なお、各部は、ねじ３７の他の連結手段を用いて分離可能に連結されていてもよく、各々が一体に構成されていてもよい。

[0031] 筐体４は、天面側外装体４１と底面側外装体４２と電池カバー４３を備えている。天面側外装体４１は、厚み方向の底面側に開口が開いた薄手の箱状である。底面側外装体４２は、厚み方向の天面側に開口が開いた薄手の箱状であり、容器状となるように天面側外装体４１の底面側に連結されている。

このため、筐体４の内部には、内部空間１００が設けられている。内部空間１００には、電池部６と回路基板７と圧電駆動部８とが収容されている。底面側外装体４２には、電池部６の電池６１を取り換え可能にするための開口が底面側に設けられており、電池カバー４３は、当該開口を覆うように底面側外装体４２の底面側に取り付けられている。内部空間１００は、底面側外装体４２と電池カバー４３との継ぎ目部分を介して筐体４の外部空間と通じ外気圧と略等しくなっている。

[0032] 底面側外装体４２は、前端部５１と、柱状部５２と、円環状部５３と、を備えている。前端部５１は、底面側外装体４２の前端側に設けられており、セパレータ３側に突出し、セパレータ３の凹部３５に嵌め合わされている。円環状部５３は、底面側外装体４２の内底面から厚み方向の天面側に突出する円管状の部位であり、内部空間１００で圧電駆動部８を支持している。柱状部５２は、底面側外装体４２の内底面から厚み方向の天面側に突出する柱状の部位であり、内部空間１００にて圧電駆動部８と間隔を開けて対向するように回路基板７を支持している。

[0033] また、底面側外装体４２には、流路９５，９６が設けられている。流路９５は、セパレータ３の流路９４に通じており、そこから前端部５１の内側を長手方向の後方に延び、途中で厚み方向の底面側に屈曲するように設けられている。流路９６は、円環状部５３の内側に有底孔状に設けられており、円環状部５３の流路９５に通じている。

[0034] 圧電駆動部８は、厚み方向を薄手とする円板状であり、円環状部５３の内側の流路９５を気密するように、円環状部５３の天面側に接合されている。そして、圧電駆動部８には天面の中央付近に開口する吐出口９９が設けられている。

[0035] この吸入装置１では、電源スイッチ７１がオンされて圧電駆動部８が駆動すると、圧電駆動部８が底面側の流路９６から流体を吸引し、吐出口９９から内部空間１００に流体を吐出する。これにより、吐出口９９から吐出された流体は、内部空間１００で拡散し、流体圧が大気圧まで低下することにな

る。また、圧電駆動部８が流体を吸引する底面側の流路９６には負圧が発生することになる。

[0036] したがって、吸入装置１の全体としては、筐体４で流路９６に発生する負圧によって、筐体４の流路９５、セパレータ３の流路９４，９３，９２、およびノズル２の流路９１に流体の流れが生じ、ノズル２の吸入口９０から外部の流体が吸引されることになる。

[0037] ここで、圧電駆動部８の詳細な構成と振動態様について説明する。

[0038] 図３は、圧電駆動部８の周辺を拡大して示す側面断面図である。圧電駆動部８は、圧電素子８１と、構造体８２と、を備えている。構造体８２は、概略の外形が厚み方向に薄い円板状である。この構造体８２の内部には、流路９７とポンプ室９８とが設けられている。また、構造体８２の天面の中央付近には、吐出口９９が開口している。流路９７は、構造体８２の天面で吐出口９９に通じており、構造体８２の内部で中央付近から外周側に延び、構造体８２の底面に開口している。この流路９７は、構造体８２の底面で円環状部５３の内側に設けた流路９６に通じている。ポンプ室９８は、吐出口９９と流路９７との連通部分の底面側に設けられた薄い円筒状の空間であり、吐出口９９と流路９７との連通部分に開口している。このポンプ室９８は、流路９７とともに吸入装置１における流路の一部を構成している。

[0039] 構造体８２におけるポンプ室９８の内底面は、屈曲振動が可能なダイヤフラム（振動板）８３として構成されている。ダイヤフラム８３は円板状であり、天面がポンプ室９８に面していて、底面に圧電素子８１が貼り付けられている。ダイヤフラム８３の天面は、ポンプ室９８を間に介して吐出口９９と対向している。圧電素子８１は、厚み方向に薄い円板状であり、交流の駆動電圧が印加されることで主面の面内方向に伸縮しようとする圧電性を有している。

[0040] 図４は、圧電駆動部８の振動態様を示す模式図である。

[0041] 圧電素子８１とダイヤフラム８３とは、互いに貼り付いてユニモルフ構造を構成しており、圧電素子８１の駆動によって厚み方向に変位する。具体的

には、図４（Ａ）に示すような静止状態から圧電素子８１が伸びようとする場合には、図４（Ｂ）に示すように、ダイヤフラム８３が圧電素子８１側（底面側）に凸に屈曲してポンプ室９８の体積が増大する。これにより、ポンプ室９８に負圧が生じ、ポンプ室９８に連通する流路９７に負圧が伝わり、流路９７の流体がポンプ室９８に吸引される。

[0042] 次に、圧電素子８１が縮もうとすると、図４（Ｃ）に示すように、ダイヤフラム８３がポンプ室９８側（天面側）に凸に屈曲してポンプ室９８の体積が減少する。すると、流路９７を間に介してポンプ室９８と吐出口９９とが対向しているために、ポンプ室９８の流体が吐出口９９から外部（内部空間１００）に吐出されるとともに、その流体の流れに引き込まれて流路９７内の流体が吐出口９９から吐出される。

[0043] このように、圧電駆動部８では、圧電素子８１とダイヤフラム８３との屈曲振動に伴い、ポンプ室９８では周期的な体積変動と圧力変動とが繰り返し生じ、気体の流れに慣性力が働くようになる。これにより、流路９７の流体が吐出口９９から吐出される気体の流れが定常的に生じるようになる。

[0044] この圧電駆動部８では、部材同士が摩擦（摺動）することが無いため、従来の電動モータ式の駆動部よりも、発生する駆動音や振動が小さい。したがって、吸入装置１から外部空間に漏れる圧電駆動部８の駆動音や振動は極めて小さなものになる。また、ダイヤフラム８３が吐出口９９に対して流路９７およびポンプ室９８を介して対面するため、圧電駆動部８の流体効率が高く、粘性の高い鼻水のような流体であっても吸入装置１で容易に吸引することができる。

[0045] ただし、この圧電駆動部８には、１０００Ｈｚ程度の比較的高い周波数の駆動電圧を印加する必要がある。このため、ダイヤフラム８３の振動周波数も１０００Ｈｚ程度の比較的高い周波数となる。これにより、ダイヤフラム８３や吐出口９９から振動周波数と略一致する周波数帯域の可聴音（高音域可聴音）が発生することになる。このような高音域可聴音は、ダイヤフラム８３の振動方向（主面が向く方向）や、吐出口９９が開口する方向に指向性

を持つため、高音域可聴音の指向方向では高音域可聴音が大きく聞こえ、高音域可聴音の指向方向から外れる方向では高音域可聴音が小さく聞こえる傾向が現れることになる。

[0046] そこで、この吸入装置１では、ダイヤフラム８３の振動方向や吐出口９９の向く方向が、吸入口９０の位置する方向に対して略直交する吸入装置１の厚み方向となるように、圧電駆動部８を配置している。これにより、圧電駆動部８で発生する高音域可聴音の指向方向が吸入装置１の厚み方向となり、吸入装置１の長手方向の前方端に位置するノズル２が、高音域可聴音の指向方向から外れる位置となるようにしている。また、ノズル２が向く方向が高音域可聴音の指向方向とは異なる方向になるようにしている。さらには、圧電駆動部８を、ダイヤフラム８３と吐出口９９とが対面するように構成して、ダイヤフラム８３や吐出口９９をノズル２や吸入口９０から物理的に離して配置し、圧電駆動部８で発生する高音域可聴音をノズル２側に伝わり難くしている。これらのことによって、ノズル２を鼻腔に挿入する吸引作業を受ける乳幼児等に対して、高音域可聴音を聞こえ難くすることができる。

[0047] 更には、筐体４の外部を操作者の手が把持するように構成するので、圧電駆動部８に対向する位置を覆う操作者の手によって、筐体４から漏れようとする高音域可聴音を遮ることができる。また、筐体４の内部で圧電駆動部８の吐出口９９側に回路基板７を対向するように配置するので、圧電駆動部８の吐出口９９側に漏れようとする高音域可聴音を回路基板７で遮ることができる。これらのことによっても、高音域可聴音を筐体４外部に漏れ難くすることができる。その上、吐出口９９から吐出される流体が回路基板７にあたることによって、回路基板７の冷却効果を高めることもできる。

[0048] 以上のように、本実施形態の吸入装置１によれば、鼻水の吸引作業を受ける乳幼児等に対して、圧電駆動部８で生じる高音域可聴音を極めて聞こえ難くすることができ、吸引作業に対する乳幼児等の拒否反応を抑えることができる。また、この吸入装置１では、圧電駆動部８の両主面が吸入装置１の厚み方向を向くように、圧電駆動部８を筐体４内に寝かせた状態で配置するの

で、筐体４の内部空間１００における厚み方向のサイズよりも、圧電駆動部８の主面方向のサイズを大きくすることができる。したがって、吸入装置１を薄型の構成にしても、サイズが大きな圧電駆動部８を用いて、流体の流れを高効率に生じさせることができる。

[0049] 次に、本発明の第２の実施形態に係る吸入装置について説明する。

[0050] 図５は、第２の実施形態に係る吸入装置の側面断面図である。

[0051] 図５に示す吸入装置１Ａは、前述の第１の実施形態に係る構成とほとんど同じであるが、筐体４に遮蔽板８Ａを備えている。遮蔽板８Ａは、筐体４の内部空間１００にて圧電駆動部８の天面側に、圧電駆動部８との間に間隔を開けて配置されている。遮蔽板８Ａと圧電駆動部８との間は、圧電駆動部８からの流体の吐出が阻害されることがないように、一定以上の間隔を開けている。このような遮蔽板８Ａを設けることにより、圧電駆動部８の吐出口９９側に漏れる高音域可聴音を遮ることができ、より一層、筐体４の外部に高音域可聴音を聞こえ難くすることができる。

[0052] 以上の各実施形態に示したように本発明は実施することができる。なお、ノズル２の形状は、上述の例に限らず、他の形状であってもよい。例えば、母乳吸入装置や痰吸入装置として吸入装置１を用いる場合には、漏斗状やストロー状にノズル２を構成してもよい。

[0053] また、セパレータ３において、流体に含まれる気体と混合物（液体）とを分離する構造は、上記以外の構造であってもよい。例えば、セパレータ３に弁構造を採用したりすることでも、流体に含まれる気体と液体とを容易に分離することができる。

[0054] また、圧電駆動部８の構造も、上記以外の構造であってもよい。例えば、圧電駆動部８に設ける吐出側流路の数や、吸入側流路の数、それぞれの経路等を適宜に変更することができる。

[0055] また、吸引する対象となる流体は、液体に限られず、固体やゲル状の物質であってもよい。本発明は、微小な埃や粉塵を回収する集塵装置や、工作物に塗布しすぎた糊や接着剤を回収する装置などへの応用も可能である。

符号の説明

[0056] １…吸入装置

２…ノズル

３…セパレータ

４…筐体

６…電池部

７…回路基板

８…圧電駆動部

２１…前端部

２２…後端部

３１…ケース部

３２…筒状部

３３…キャップ部

３４…筒状部

３５…凹部

３６…フィルタ

４１…天面側外装体

４２…底面側外装体

４３…電池カバー

５１…前端部

５２…柱状部

５３…円環状部

６１…電池

６２…電池ケース

７１…電源スイッチ

８１…圧電素子

８２…構造体

８３…ダイヤフラム（振動板）

９０…吸入口

９１，９２，９３，９４，９５，９６，９７…流路

９８…ポンプ室（流路）

９９…吐出口

１００…内部空間

請求の範囲

[請求項1] 外部に露出する吸入口、前記吸入口に通じる流路、および、前記流路から流体を吐出する吐出口を設けた吸入装置であって、

前記流路に面する一方主面、および、前記一方主面に対向する他方主面を有する振動板と、

前記振動板に付設した、前記振動板の一方主面を前記流路に対して変位させる圧電素子と、

を備え、

前記振動板の一方主面および他方主面は、前記吸入口が向く方向とは異なる方向を向いている、

吸入装置。

[請求項2] 前記吐出口は、前記吸入口が位置する方向とは異なる方向を向いている、

請求項１に記載の吸入装置。

[請求項3] 前記振動板の一方主面または他方主面は、前記吐出口が位置する方向を向いている、

請求項１または請求項２に記載の吸入装置。

[請求項4] 前記振動板の一方主面および他方主面は、前記吸入口が位置する方向に対して略直交する方向を向いている、

請求項１乃至請求項３のいずれかに記載の吸入装置。

[請求項5] 前記圧電素子に駆動電圧を印加する回路基板を備え、

前記振動板の一方主面または他方主面は、前記回路基板が位置する方向を向いている、

請求項１乃至請求項４のいずれかに記載の吸入装置。

[請求項6] 遮蔽板を備え、前記振動板の一方主面または他方主面は、前記遮蔽板が位置する方向を向いている、

請求項１乃至請求項５のいずれかに記載の吸入装置。

[請求項7] 前記振動板の一方主面および他方主面に対向する位置を把持部とす

る筐体を備える、

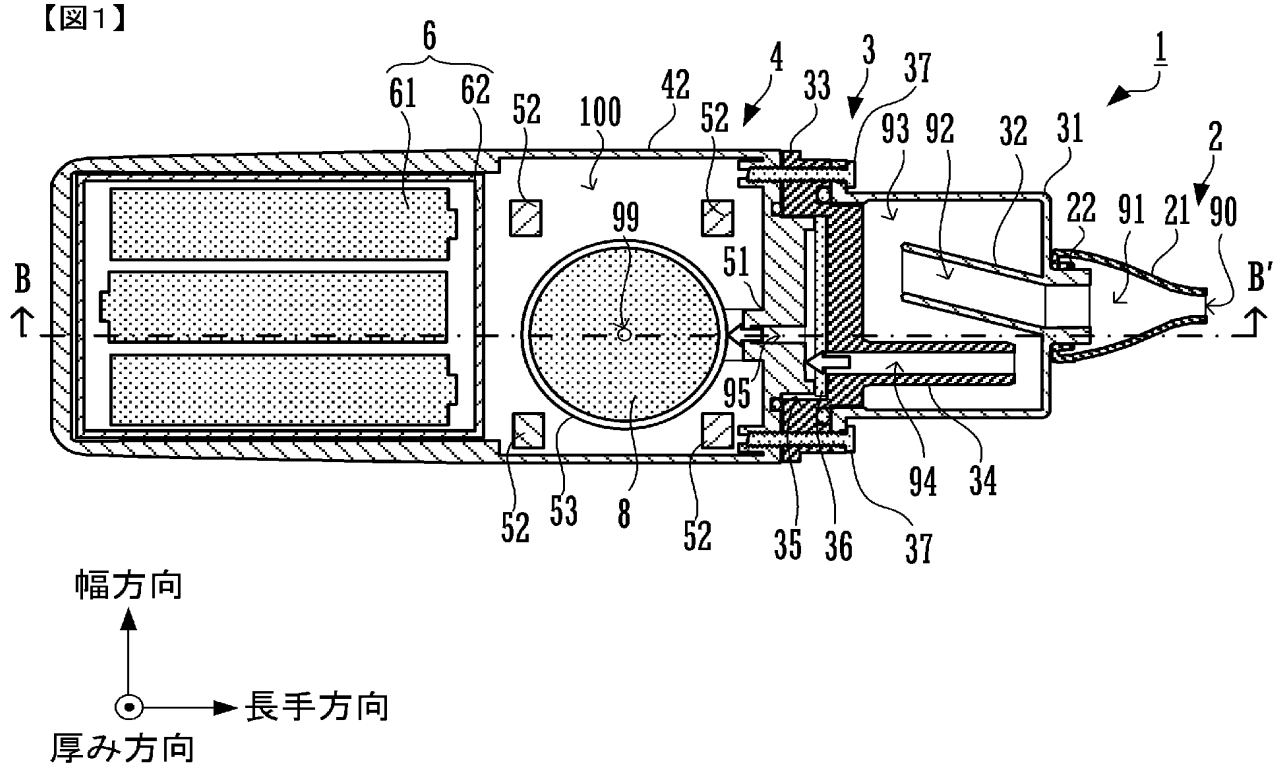
請求項１乃至請求項６のいずれかに記載の吸入装置。

[請求項8] 前記振動板の主面面内方向のサイズが、前記振動板の一方主面および他方主面が向く方向での前記筐体の内部空間のサイズよりも大きい、

請求項７に記載の吸入装置。

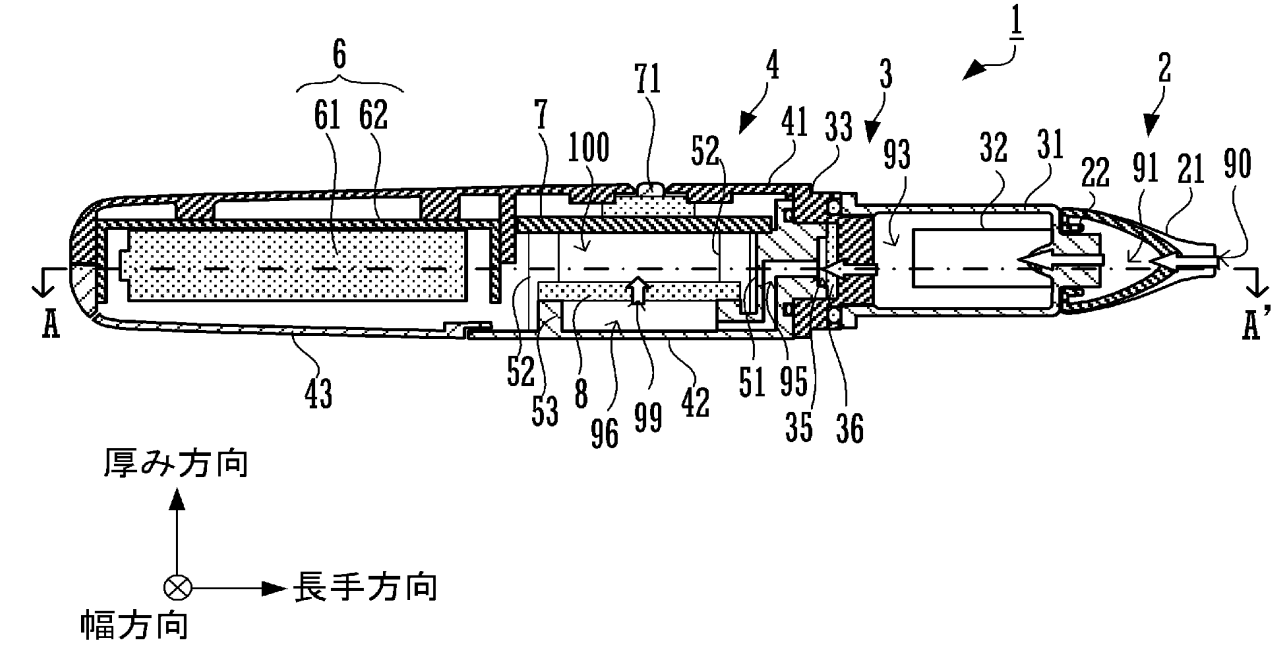
[図1]

【図1】


6
61
62
52
100
42
52
4
33
3
37
1
93
92
32
31
2
22
91
21
90
99
51
B
B'
95
94
34
52
53
8
52
35
36
37
幅方向
長手方向
厚み方向

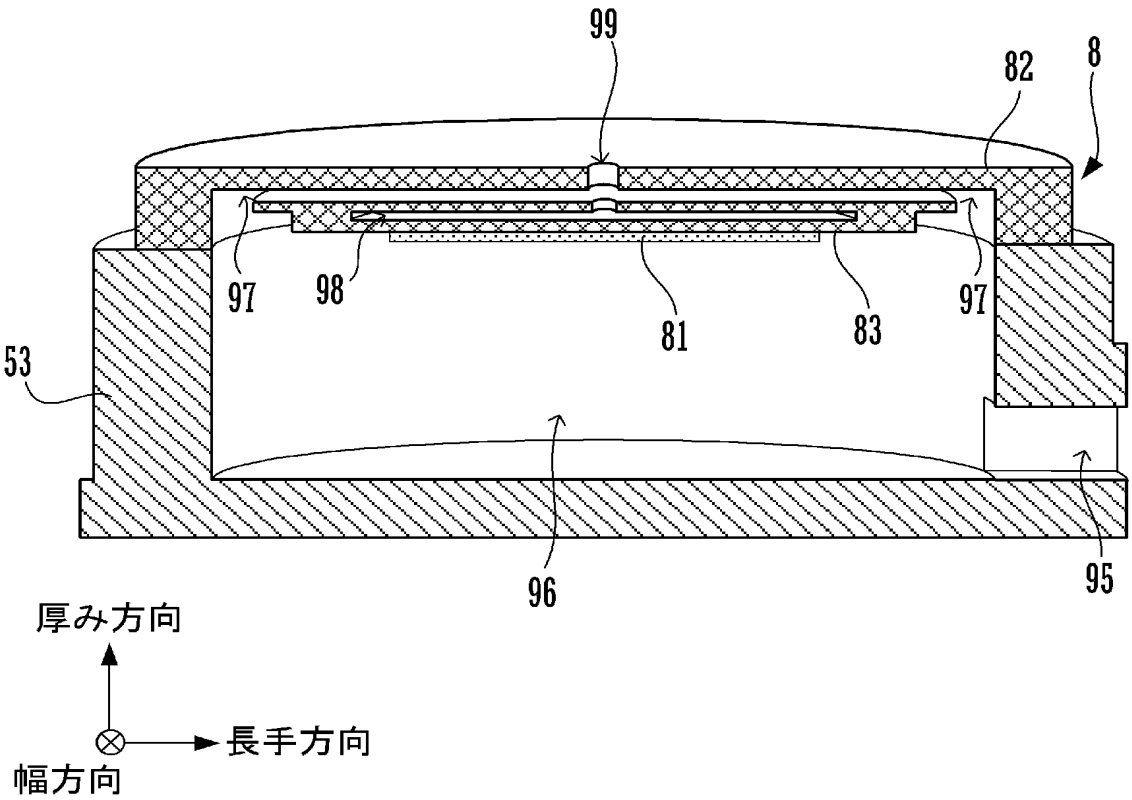
[図2]

【図2】


1
6
61
62
7
71
4
3
2
100
52
41
33
93
32
31
22
91
21
90
A
A'
43
52
53
8
96
99
42
51
95
35
36
厚み方向
長手方向
幅方向

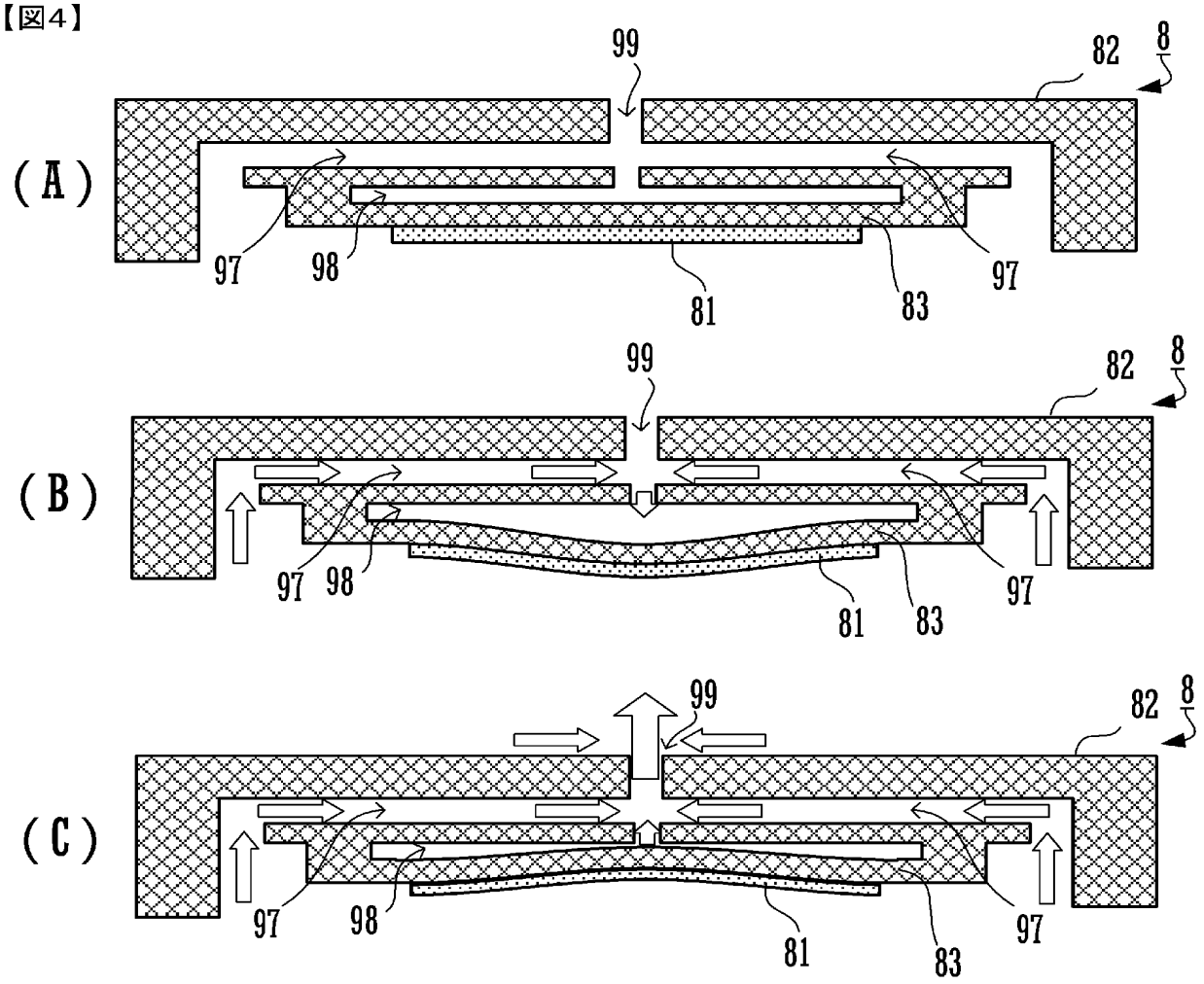
[図3]

【図３】



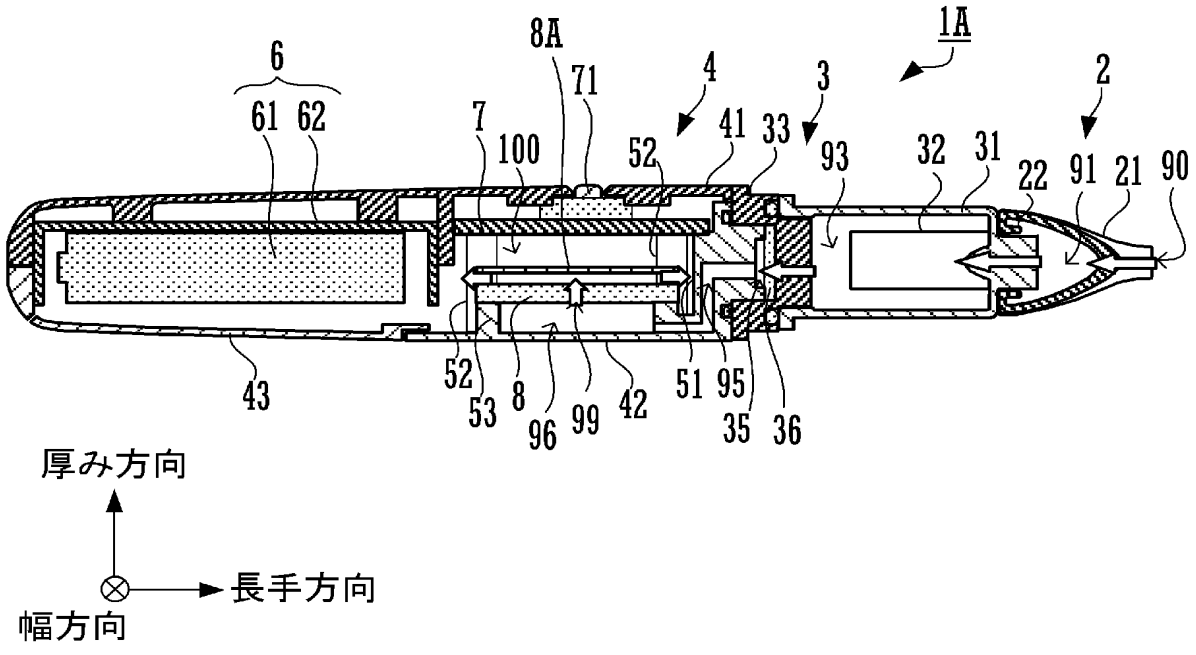
[図4]

【図４】


(A)
99
82
8
97
98
81
83
97
(B)
99
82
8
97
98
81
83
97
(C)
99
82
8
97
98
81
83
97

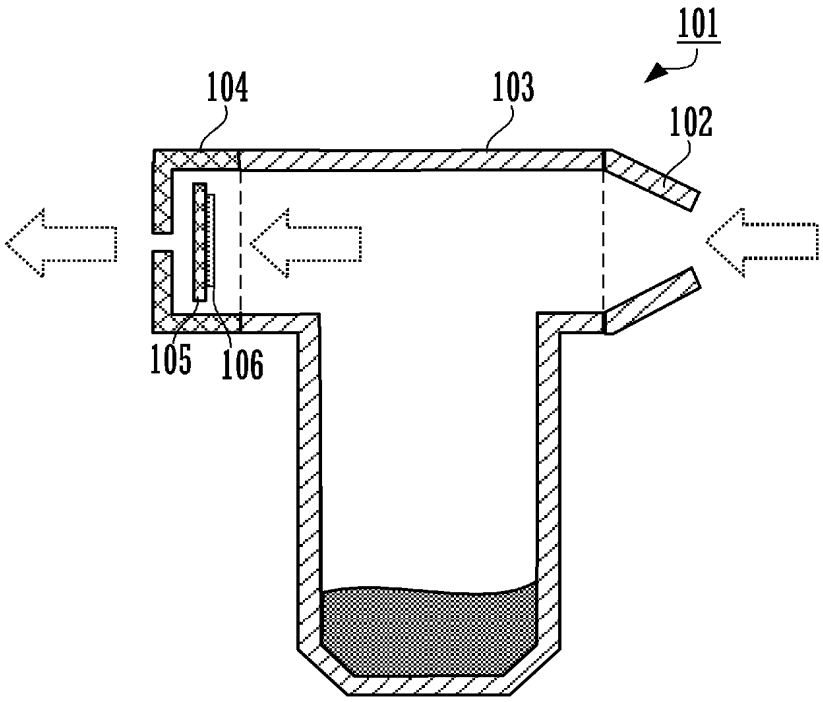
[図5]

【図５】


1A
6
61
62
8A
71
7
100
4
52
41
33
3
93
32
31
22
2
91
21
90
43
52
53
8
96
99
42
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95
35
36
厚み方向
長手方向
幅方向

[図6]

【図6】



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/059307

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1922-1996	Jitsuyo Shinan Toroku Koho	1996-2015
Kokai Jitsuyo Shinan Koho	1971-2015	Toroku Jitsuyo Shinan Koho	1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 93908/1990(Laid-open No. 51956/1992) (Kabushiki Kaisha Sugie Shoji et al.), 01 May 1992 (01.05.1992), page 4, line 13 to page 10, line 14; fig. 5 (Family: none)	1-8
Y	JP 2009-264135 A (Sony Corp.), 12 November 2009 (12.11.2009), paragraphs [0005] to [0006], [0072] to [0082]; fig. 8 to 10 (Family: none)	1-8

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 2015 (11.06.15)	23 June 2015 (23.06.15)

Name and mailing address of the ISA/	Authorized officer
Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Telephone No.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2011/078218 A1 (Murata Mfg. Co., Ltd.), 30 June 2011 (30.06.2011), paragraph [0021]; fig. 3(B) & JP 5447535 B2 & CN 102665940 A & KR 10-2012-0086362 A	6-8
Y	WO 2011/090201 A1 (Murata Mfg. Co., Ltd.), 28 July 2011 (28.07.2011), paragraphs [0005], [0021]; fig. 1 to 2 & JP 5387697 B2 & US 2012/0286626 A1 & EP 2530953 A1 & KR 10-2012-0093446 A & CN 102726064 A	6-8
A	JP 2000-325466 A (G Intek Co., Ltd.), 28 November 2000 (28.11.2000), entire text; all drawings & EP 1051984 A2 & KR 10-0300441 B1 & CN 1273863 A	1
A	JP 2014-504190 A (Convertech Technologies Inc.), 20 February 2014 (20.02.2014), paragraphs [0050] to [0052]; fig. 12 to 13 & US 2013/0304007 A1 & WO 2012/078723 A1 & CN 103338811 A	1
A	JP 2004-517240 A (Par Technologies, L.L.C.), 10 June 2004 (10.06.2004), entire text; all drawings & US 2004/0021398 A1 & WO 2002/022358 A1 & DE 10196634 T5 & CN 1474749 A & KR 10-2003-0034192 A	1

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０５９３０７

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	日本国実用新案登録出願 2-93908 号（日本国実用新案登録出願公開 4-51956 号）の願書に添付した明細書及び図面の内容を撮影したマイクロフィルム（株式会社杉江商事，外１名）1992.05.01，４頁 13 行-10 頁 14 行，図５（ファミリーなし）	1-8
Y	JP 2009-264135 A（ソニー株式会社）2009.11.12，段落 [0005]-[0006]，[0072]-[0082]，図 8-10（ファミリーなし）	1-8

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

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「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日 １１．０６．２０１５	国際調査報告の発送日 ２３．０６．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｉ　３９４４ 胡谷　佳津志 電話番号　０３－３５８１－１１０１　内線　３３８６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	WO 2011/078218 A1 (株式会社村田製作所) 2011.06.30, 段落[0021], 図 3(B) & JP 5447535 B2 & CN 102665940 A & KR 10-2012-0086362 A	6-8
Y	WO 2011/090201 A1 (株式会社村田製作所) 2011.07.28, 段落[0005], [0021], 図 1-2 & JP 5387697 B2 & US 2012/0286626 A1 & EP 2530953 A1 & KR 10-2012-0093446 A & CN 102726064 A	6-8
A	JP 2000-325466 A (株式会社ジーインテック) 2000.11.28, 全文, 全図 & EP 1051984 A2 & KR 10-0300441 B1 & CN 1273863 A	1
A	JP 2014-504190 A (コンバテック・テクノロジーズ・インコーポレイテッド) 2014.02.20, 段落[0050]-[0052], 図 12-13 & US 2013/0304007 A1 & WO 2012/078723 A1 & CN 103338811 A	1
A	JP 2004-517240 A (パー　テクノロジーズ　エルエルシー．) 2004.06.10, 全文, 全図 & US 2004/0021398 A1 & WO 2002/022358 A1 & DE 10196634 T5 & CN 1474749 A & KR 10-2003-0034192 A	1

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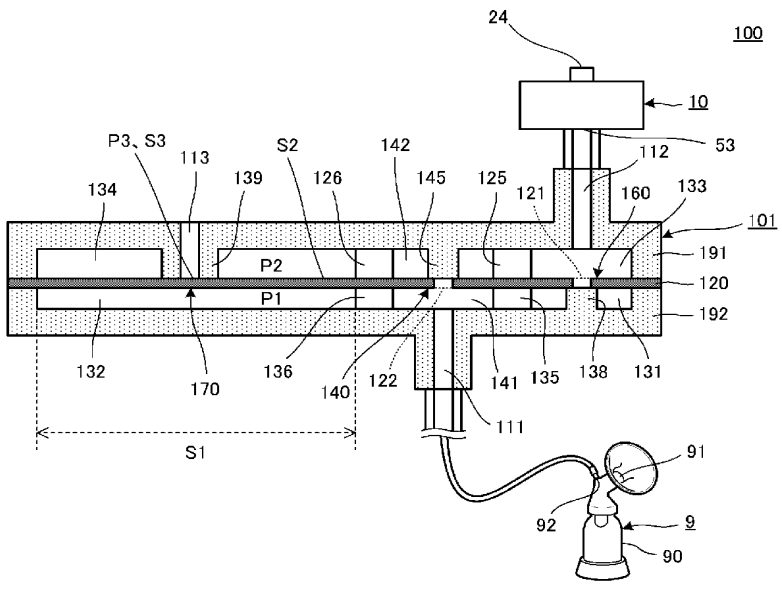
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(54) **Title**: VALVE AND FLUID CONTROL DEVICE

(54) 発明の名称 : バルブ、流体制御装置

図1



(57) **Abstract**: A fluid control device (100) is provided with a piezoelectric pump (10), a suction device (9), and a valve (101). The piezoelectric pump (10) has a gas suction hole (53) and a gas discharge hole (24). The suction device (9) has a container (90), a suction opening (91), and a connection opening (92). The valve (101) has a first gas passage hole (111), a second gas passage hole (112), a third gas passage hole (113), a first valve housing (191), a second valve housing (192), and a diaphragm (120). The first gas passage hole (111) of the valve (101) connects to the connection hole (92) of the suction device (9). The second gas passage hole (112) of the valve (101) connects to the suction hole (53) of the piezoelectric pump (10). The third gas passage hole (113) of the valve (101) is open to the atmosphere. The diaphragm (120) is gripped between the first valve housing (191) and the second valve housing (192) and constitute a first region and a second region.

(57) 要約: 流体制御装置（１００）は、圧電ポンプ（１０）と吸入器（９）とバルブ（１０１）とを備える。圧電ポンプ（１０）は、気体の吸引孔（５３）と気体の吐出孔（２４）とを有する。吸入器（９）は、容器（９０）と吸入口（９１）と接続孔（９２）とを有する。バルブ（１０１）は、第１通気孔（１１１）と第２通気孔（１１２）と第３通気孔（１１３）と第１弁筐体（１９１）と第２弁筐体（１９２）とダイヤフラム（１２０）とを有する。バルブ（１０１）の第１通気孔（１１１）は吸入器（９）の接続孔（９２）に接続する。バルブ（１０１）の第２通気孔（１１２）は圧電ポンプ（１０）の吸引孔（５３）に接続する。バルブ（１０１）の第３通気孔（１１３）は大気開放されている。ダイヤフラム（１２０）は、第１弁筐体（１９１）及び第２弁筐体（１９２）に挟持され、第１領域と第２領域を構成する。

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明　細　書

発明の名称 ： バルブ、流体制御装置

技術分野

[0001] この発明は、気体の流れを切り替えるバルブ、及び当該バルブを備える流体制御装置に関する。

背景技術

[0002] 従来、気体の流れをバルブによって制御する流体制御装置が各種考案されている。例えば特許文献１には、ポンプとバルブとを備える流体制御装置が開示されている。

[0003] ポンプは、空気の吸引孔と空気の吐出孔とを有している。

[0004] バルブは、ダイヤフラムと第１弁筐体と第２弁筐体とを備え、それらが順に積層された構造を有している。さらに、バルブには、通気孔と排気口とカフ接続口とが設けられている。通気孔には、ポンプの吐出孔が接続されている。排気口は大気開放されている。カフの腕帯ゴム管がバルブのカフ接続口に接続されることにより、流体制御装置がカフに接続されている。

[0005] 以上の構成において、特許文献１の流体制御装置は、ポンプを駆動し、空気をポンプの吐出孔からバルブ内へ吐出する。バルブ内へ吐出された空気は、カフ接続口からカフ内へ流入する。

[0006] これにより、特許文献１の流体制御装置は、カフ（容器）内に圧縮空気を充填している。そして、特許文献１の流体制御装置は、ポンプの駆動を停止し、カフ（容器）内の圧縮空気を排気口から排気している。

先行技術文献

特許文献

[0007] 特許文献1：国際公開第２０１２／１４１１１３号パンフレット

発明の概要

発明が解決しようとする課題

[0008] しかしながら、特許文献１の流体制御装置は、容器内から気体を吸入して

、容器内の圧力を負圧にする装置ではない。そのため、特許文献１の流体制御装置は、容器内から気体を吸入して、容器内の圧力を負圧にする用途には適さなかった。

[0009] 本発明の目的は、容器内から気体を吸入して容器内の圧力を負圧にした後、容器内に気体を流入させて容器内の圧力を戻すことができるバルブ、及び当該バルブを備える流体制御装置を提供することにある。

課題を解決するための手段

[0010] 本発明のバルブは、前記課題を解決するために以下の構成を備えている。

[0011] （１）第１通気孔、第２通気孔、及び第３通気孔が形成された弁筐体と、

弁筐体内を分割して弁筐体内に第１領域及び第２領域を構成するダイヤフラムと、を有し、

ダイヤフラムは、

弁筐体内において第１通気孔に連通する第１領域の圧力が、弁筐体内において第２通気孔に連通する第２領域の圧力よりも高い場合、第１通気孔と第２通気孔とを連通させるとともに、第１通気孔および第２通気孔と第３通気孔との連通を遮断し、

第１領域の圧力が第２領域の圧力よりも低い場合、第１通気孔と第３通気孔とを連通させるよう、弁筐体に固定されている。

[0012] この構成では、例えば、吸入口を有する吸入器を第１通気孔に接続し、ポンプの吸引孔を第２通気孔に接続し、第３通気孔を大気開放する。この場合においてポンプが駆動すると、第２領域の空気が第２通気孔及び吸引孔を介してポンプ内に吸引される。そして、ポンプ内の空気が吐出孔から吐出される。これにより、バルブでは、第１領域の圧力が第２領域の圧力より高くなる。

[0013] この構成のバルブでは、第１領域の圧力が第２領域の圧力より高い場合、第１通気孔と第２通気孔とを連通させるとともに、第１通気孔および第２通気孔と第３通気孔との連通を遮断する。

[0014] この結果、吸入器の容器内の気体が第１通気孔を介してバルブの第１領域

へ排出され、第２通気孔及び吸引孔を介してポンプ内に吸引される。これにより、容器内の圧力（気体の圧力）が大気圧から低下し、負圧になる。そのため、吸入器は、容器外部の液体（例えば母乳、血液、胸水、痰など）を吸入口から容器内へ吸入することができる。

[0015] 次に、ポンプが駆動を停止したとき、第２領域が大気圧より低くなっているため、ポンプの吐出孔から微量の気体がポンプ内へ流入し、吸引孔及び第２通気孔を介して第２領域に流入する。これにより、バルブでは、第１領域の圧力が第２領域の圧力より低下する。

[0016] この構成のバルブでは、第１領域の圧力が第２領域の圧力より低い場合、第１通気孔と第３通気孔とが連通する。そして、気体が第３通気孔から流入して第１通気孔から流出し、容器内へ流入する。これにより、容器内の圧力（気体の圧力）が上昇し、大気圧になる。そのため、吸入器は、吸入口を、ヒトや動物の乳房から容易に取り外すことができる。

[0017] したがって、この構成によれば、容器内から気体を吸入して容器内の圧力を負圧にした後、容器内に気体を流入させて容器内の圧力を戻すことができる。

[0018] （２）ダイヤフラムは、第１領域と第２領域との圧力差により、弁筐体の一部に対して接触または離間し、第１通気孔と第３通気孔との連通状態を切り替えることが好ましい。

[0019] この構成において、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも高い場合、弁筐体の一部に対して接触し、第１通気孔および第２通気孔と第３通気孔との連通を遮断する。

[0020] 一方、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも低い場合、弁筐体の一部に対して離間し、第１通気孔と第３通気孔とを連通させる。

[0021] （３）弁筐体の一部には、第２領域においてダイヤフラム側へ突出した第１弁座が設けられ、

ダイヤフラムには、第１孔部が設けられ、

ダイヤフラムは、ダイヤフラムにおける第１孔部の周囲が第１弁座に接触

するよう、弁筐体に固定されていることが好ましい。

[0022] この構成において、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも高い場合、第１弁座に対して接触し、第１通気孔および第２通気孔と第３通気孔との連通を遮断する。

[0023] 一方、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも低い場合、第１弁座に対して離間し、第１通気孔と第２領域とを連通させる。

[0024] （４）弁筐体の一部には、第２領域においてダイヤフラム側へ突出した第２弁座が設けられ、

第２弁座には、第３通気孔が設けられ、

ダイヤフラムは、第２弁座に接触するよう、弁筐体に固定されていることが好ましい。

[0025] この構成において、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも高い場合、第２弁座に対して接触し、第１通気孔および第２通気孔と第３通気孔との連通を遮断する。

[0026] 一方、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも低い場合、第２弁座に対して離間し、第３通気孔と第２領域とを連通させる。

[0027] （５）弁筐体には、第１領域においてダイヤフラム側へ突出した第３弁座が設けられ、

ダイヤフラムには、第２孔部が設けられ、

ダイヤフラムは、ダイヤフラムにおける第２孔部の周囲が第３弁座に接触するよう、弁筐体に固定されていることが好ましい。

[0028] この構成において、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも高い場合、第３弁座に対して離間し、第１通気孔と第２通気孔とを連通させる。

[0029] 一方、ダイヤフラムは、第１領域の圧力が第２領域の圧力よりも低い場合、第３弁座に対して接触する。

[0030] （６）弁筐体には、第１領域に連通する第４通気孔が形成されている。

[0031] また、本発明の流体制御装置は、前記課題を解決するために以下の構成を

備えている。

[0032] （７）気体の吸引孔と気体の吐出孔とを有するポンプと、

流体を吸入する吸入口および接続部を有する吸入器と、

上記（１）～（６）のいずれかに記載のバルブと、を備え、

第１通気孔は、吸入器の接続部に接続され、

第２通気孔は、ポンプの吸引孔に接続されている。

[0033] この構成により、上記（１）～（６）のいずれかのバルブを用いることで、当該バルブを備える流体制御装置にも同様の効果を奏する。

[0034] （８）吸入器は、

吸入口に接続し、吸入口から吸入された液体を貯蔵する第１容器と、

第１容器に接続し、気体を通過させて液体の通過を阻止する第２容器と、

第２容器およびポンプの吸引孔に接続し、ポンプが吸引する気体の吸引圧力を調整する第３容器と、を有することが好ましい。

[0035] この構成では、流体制御装置はドレナージとして用いられる。吸入口から吸入された血液や胸水等は、第１容器に貯蔵される。

発明の効果

[0036] 本発明によれば、容器内から気体を吸入して容器内の圧力を負圧にした後、容器内に気体を流入させて容器内の圧力を戻すことができる。

図面の簡単な説明

[0037] [図1]本発明の第１実施形態に係る流体制御装置１００の要部の断面図である。

[図2]図１に示す圧電ポンプ１０の外観斜視図である。

[図3]図２に示す圧電ポンプ１０の分解斜視図である。

[図4]図２に示す圧電ポンプ１０のＳ－Ｓ線の断面図である。

[図5]図１に示すバルブ１０１の分解斜視図である。

[図6]図１に示すバルブ１０１の分解斜視図である。

[図7]図７は、図２に示す圧電ポンプ１０を１次モードで動作させた時における圧電ポンプ１０のＳ－Ｓ線の断面図である。図７（Ａ）はポンプ室の容積

が増大したときの図、図７（Ｂ）はポンプ室の容積が減少したときの図である。

[図8]圧電ポンプ１０が駆動している間における流体制御装置１００の空気の流れを示す説明図である。

[図9]圧電ポンプ１０が駆動を停止した直後における、流体制御装置１００の空気の流れを示す説明図である。

[図10]本発明の第２実施形態に係る流体制御装置２００の外観図である。

[図11]図１０に示すバルブ２０１の断面図である。

[図12]本発明の第３実施形態に係る流体制御装置３００の断面図である。

[図13]本発明の第４実施形態に係る流体制御装置４００の断面図である。

[図14]圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置４００の空気の流れを示す説明図である。

[図15]容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置４００の空気の流れを示す説明図である。

[図16]圧電ポンプ１０が駆動を停止した直後における、流体制御装置４００の空気の流れを示す説明図である。

発明を実施するための形態

[0038] 以下、本発明の第１実施形態に係る流体制御装置１００について説明する。

[0039] 図１は、本発明の第１実施形態に係る流体制御装置１００の要部の断面図である。流体制御装置１００は、圧電ポンプ１０と吸入器９とバルブ１０１とを備える。

[0040] 圧電ポンプ１０は、詳細を後述するが、気体の吸引孔５３と気体の吐出孔２４とを有する。

[0041] 吸入器９は、容器９０と吸入口９１と接続孔９２とを有する。吸入器９は、例えば搾乳器である。吸入口９１は、例えばヒトや動物の乳房に装着する。容器９０は、液体（例えば母乳など）を貯蔵する。

[0042] バルブ１０１は、詳細を後述するが、第１通気孔１１１と第２通気孔１１２と第３通気孔１１３とを有する。バルブ１０１の第１通気孔１１１は、吸入器９の接続孔９２に接続する。バルブ１０１の第２通気孔１１２は、圧電ポンプ１０の吸引孔５３に接続する。バルブ１０１の第３通気孔１１３は、大気開放されている。

[0043] なお、図１において、バルブ１０１の第１通気孔１１１と吸入器９の接続孔９２との接続は、簡便に描いている。同様に、図１において、バルブ１０１の第２通気孔１１２と圧電ポンプ１０の吸引孔５３との接続も、簡便に描いている。実施の際、これらの接続は、任意の接続方法を採用すればよい。

[0044] 次に、圧電ポンプ１０とバルブ１０１との構造について詳述する。まず、図２、図３、図４を用いて圧電ポンプ１０の構造について詳述する。

[0045] 図２は、図１に示す圧電ポンプ１０の外観斜視図である。図３は、図２に示す圧電ポンプ１０の分解斜視図である。図４は、図２に示す圧電ポンプ１０のＳ－Ｓ線の断面図である。

[0046] 圧電ポンプ１０は、上から順に、外筐体１７、天板３７、側板３８、振動板３９、圧電素子４０、及びキャップ４２を備え、それらを順に積層した構造を有している。天板３７、側板３８、及び振動板３９は、ポンプ室３６を構成している。圧電ポンプ１０は、幅２０ｍｍ×長さ２０ｍｍ×ノズル１８以外の領域の高さ１．８５ｍｍの寸法となっている。

[0047] 外筐体１７は、空気が吐出される吐出孔２４が中心に形成されたノズル１８を有する。このノズル１８は、外形の直径２．０ｍｍ×内形（即ち吐出孔２４）の直径０．８ｍｍ×高さ１．６ｍｍの寸法となっている。外筐体１７の四角には、ネジ穴５６Ａ～５６Ｄが形成されている。

[0048] 外筐体１７は、下方が開口した断面コ字状に形成されており、外筐体１７は、ポンプ室３６の天板３７、ポンプ室３６の側板３８、振動板３９及び圧電素子４０を収納する。外筐体１７は、例えば樹脂から構成される。

[0049] ポンプ室３６の天板３７は、円板状であり、例えば金属から構成されている。天板３７には、中央部６１と、中央部６１から水平方向に突出し、外筐

体１７の内壁に当接する鍵状の突出部６２と、外部回路に接続するための外部端子６３とが形成されている。

[0050] また、天板３７の中央部６１には、ポンプ室３６の内部と外部とを連通させる通気孔４５が設けられている。この通気孔４５は、外筐体１７の吐出孔２４と対向する位置に形成されている。天板３７は、側板３８の上面に接合する。

[0051] ポンプ室３６の側板３８は、円環状であり、例えば金属から構成されている。側板３８は、振動板３９の上面に接合する。そのため、側板３８の厚みは、ポンプ室３６の高さとなる。

[0052] 振動板３９は、円板状であり、例えば金属から構成されている。振動板３９は、ポンプ室３６の底面を構成する。

[0053] 圧電素子４０は、円板形状であり、例えばチタン酸ジルコン酸鉛系セラミックスから構成されている。圧電素子４０は、振動板３９のポンプ室３６とは逆側の主面に接合されており、印加された交流電圧に応じて屈曲する。圧電素子４０及び振動板３９は、アクチュエータを構成する。

[0054] そして、天板３７、側板３８、振動板３９、及び圧電素子４０の接合体は、天板３７に設けられている４個の突出部６２によって外筐体１７に対して弾性的に支持されている。

[0055] 電極導通用板７０は、圧電素子４０に接続するための内部端子７３と、外部回路に接続するための外部端子７２とで構成されている。内部端子７３の先端は圧電素子４０の平板面にはんだ付けされている。はんだ付け位置を圧電素子４０の屈曲振動の節に相当する位置とすることにより、内部端子７３の振動がより抑制できる。

[0056] キャップ４２には、円板形状の吸引孔５３が形成されている。吸引孔５３の直径は、圧電素子４０の直径より長い。また、キャップ４２には、外筐体１７のネジ穴５６Ａ～５６Ｄに対応する位置に切欠き５５Ａ～５５Ｄが形成されている。

[0057] また、キャップ４２は、外周縁に、天板３７側へ突出する突出部５２を有

する。キャップ４２は、突出部５２で外筐体１７を挟持し、ポンプ室３６の天板３７、ポンプ室３６の側板３８、振動板３９及び圧電素子４０を、外筐体１７とともに収納する。キャップ４２は、例えば樹脂から構成されている。

[0058] そして、図４に示すように、天板３７、側板３８、振動板３９及び圧電素子４０の接合体と外筐体１７及びキャップ４２との間には通気路３１が形成されている。

[0059] 次に、図１、図５、図６を用いてバルブ１０１の構造について詳述する。

[0060] 図５、図６は、図１に示すバルブ１０１の分解斜視図である。図５は、当該バルブ１０１を上面側から見た分解斜視図であり、図６は、当該バルブ１０１を底面側から見た分解斜視図である。

[0061] バルブ１０１は、図１、図５、図６に示すように、第２弁筐体１９２と、第２シール材１５２と、ダイヤフラム１２０と、第１シール材１５１と、第１弁筐体１９１とを備え、それらが順に積層された構造を有している。

[0062] 第１弁筐体１９１は、図１、図５、図６に示すように、圧電ポンプ１０の吸引孔５３に連通する第２通気孔１１２と、流体制御装置１００外部に連通する第３通気孔１１３と、第３通気孔１１３の周囲からダイヤフラム１２０側へ突出した弁座１３９と、ダイヤフラム１２０側へ突出した円柱状の弁座１４５と、第１上バルブ室１４２及び第２上バルブ室１３３を連通させる連通路１２５と、第１上バルブ室１４２及び第３上バルブ室１３４を連通させる連通路１２６と、を有する。第１弁筐体１９１は、例えば樹脂からなる。弁座１３９は中央部に第３通気孔１１３を有する円筒形状である。

[0063] 第２弁筐体１９２は、図１、図５、図６に示すように、吸入器９の接続孔９２に連通する第１通気孔１１１と、ダイヤフラム１２０側へ突出した円柱状の弁座１３８と、第１下バルブ室１４１及び第２下バルブ室１３１を連通させる連通路１３５と、第１下バルブ室１４１及び第３下バルブ室１３２を連通させる連通路１３６と、を有する。第２弁筐体１９２は、例えば樹脂からなる。

[0064] ダイヤフラム１２０には、図１、図５、図６に示すように、弁座１３８に対向する領域の中心部に円形の孔部１２１が設けられている。孔部１２１の直径は、ダイヤフラム１２０に当接する弁座１３８の面の直径よりも小さく設けられている。

[0065] また、ダイヤフラム１２０には、図１、図５、図６に示すように、弁座１４５に対向する領域の中心部に円形の孔部１２２が設けられている。孔部１２２の直径は、ダイヤフラム１２０に当接する弁座１４５の面の直径よりも小さく設けられている。

[0066] ダイヤフラム１２０は、長方形状の薄膜からなる。ダイヤフラム１２０の材料は、例えばＥＰＤＭ（エチレンプロピレンジエンゴム）やシリコーンなどのゴムである。

[0067] ダイヤフラム１２０は、第１シール材１５１及び第２シール材１５２を介して第１弁筐体１９１及び第２弁筐体１９２に挟持されている。

[0068] 第１シール材１５１及び第２シール材１５２のそれぞれは、長方形状の薄膜からなる。第１シール材１５１及び第２シール材１５２の材料は、例えば両面テープや接着剤である。第１シール材１５１には、第１上バルブ室１４２、連通路１２５、第２上バルブ室１３３、連通路１２６及び第３上バルブ室１３４に面する領域に開口部が設けられている。第２シール材１５２には、第１下バルブ室１４１、連通路１３５、第２下バルブ室１３１、連通路１３６及び第３下バルブ室１３２に面する領域に開口部が設けられている。

[0069] ダイヤフラム１２０は、図１に示すように、ダイヤフラム１２０における孔部１２１の周囲が弁座１３８に接触し、ダイヤフラム１２０における孔部１２２の周囲が弁座１４５に接触するよう、第１弁筐体１９１および第２弁筐体１９２に固定されている。このとき、弁座１３８は、ダイヤフラム１２０における孔部１２１の周囲を与圧する。弁座１４５は、ダイヤフラム１２０における孔部１２２の周囲を与圧する。

[0070] ダイヤフラム１２０は、第１弁筐体１９１及び第２弁筐体１９２に固定されることにより、第１弁筐体１９１及び第２弁筐体１９２内を分割する。

[0071] これにより、ダイヤフラム１２０は、第１弁筐体１９１及び第２弁筐体１９２内に、円柱状の第１下バルブ室１４１と、円環状の第２下バルブ室１３１と、円柱状の第３下バルブ室１３２と、円環状の第１上バルブ室１４２と、円柱状の第２上バルブ室１３３と、円環状の第３上バルブ室１３４と、を構成する。

[0072] ここで、第１下バルブ室１４１は、第１通気孔１１１に連通する。第２下バルブ室１３１は、連通路１３５を介して第１下バルブ室１４１に連通する。第３下バルブ室１３２は、連通路１３６を介して第１下バルブ室１４１に連通する。第２上バルブ室１３３は、連通路１２５を介して第１上バルブ室１４２に連通し、第２通気孔１１２に連通する。第３上バルブ室１３４は、連通路１２６を介して第１上バルブ室１４２に連通する。

[0073] なお、第１下バルブ室１４１、連通路１３５、第２下バルブ室１３１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」に相当する。第１上バルブ室１４２、連通路１２５、第２上バルブ室１３３、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」に相当する。弁座１４５が本発明の「第１弁座」に相当する。弁座１３９が本発明の「第２弁座」に相当する。弁座１３８が本発明の「第３弁座」に相当する。孔部１２２が本発明の「第１孔部」に相当する。孔部１２１が本発明の「第２孔部」に相当する。

[0074] さらに、ダイヤフラム１２０は、逆止弁１４０を、第１弁筐体１９１及び第２弁筐体１９２とともに構成する。逆止弁１４０は、第１下バルブ室１４１と第１上バルブ室１４２と弁座１４５と第１下バルブ室１４１及び第１上バルブ室１４２に面するダイヤフラム１２０の領域とで構成される。

[0075] また、ダイヤフラム１２０は、逆止弁１６０を、第１弁筐体１９１及び第２弁筐体１９２とともに構成する。逆止弁１６０は、第２下バルブ室１３１と第２上バルブ室１３３と弁座１３８と第２下バルブ室１３１及び第２上バルブ室１３３に面するダイヤフラム１２０の領域とで構成される。

[0076] また、ダイヤフラム１２０は、排気弁１７０を、第１弁筐体１９１及び第

２弁筐体１９２とともに構成する。排気弁１７０は、第３下バルブ室１３２と第３上バルブ室１３４と弁座１３９と第３下バルブ室１３２及び第３上バルブ室１３４に面するダイヤフラム１２０の領域とで構成される。

[0077] 逆止弁１４０では、第１下バルブ室１４１と第１上バルブ室１４２との圧力差によってダイヤフラム１２０が弁座１４５に対して当接または離間する。これにより、逆止弁１４０は、第１上バルブ室１４２から第１下バルブ室１４１への空気の流れを許可し、第１下バルブ室１４１から第１上バルブ室１４２への空気の流れを遮断する。

[0078] 逆止弁１６０では、第２下バルブ室１３１と第２上バルブ室１３３との圧力差によってダイヤフラム１２０が弁座１３８に対して当接または離間する。これにより、逆止弁１６０は、第２下バルブ室１３１から第２上バルブ室１３３への空気の流れを許可し、第２上バルブ室１３３から第２下バルブ室１３１への空気の流れを遮断する。

[0079] 排気弁１７０では、図１に示すように、第３下バルブ室１３２に面するダイヤフラム１２０の部分の面積をＳ１、第３下バルブ室１３２の圧力をＰ１、第３上バルブ室１３４に面するダイヤフラム１２０の部分の面積をＳ２、第３上バルブ室１３４の圧力をＰ２、第３通気孔１１３に面するダイヤフラム１２０の部分の面積をＳ３、第３通気孔１１３の圧力（本実施形態では大気圧）をＰ３、としたとき、Ｓ１×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）の関係を満たす場合、ダイヤフラム１２０が弁座１３９に対して接触する。反対に、Ｓ１×（Ｐ１－Ｐ２）≦Ｓ３×（Ｐ３－Ｐ１）の関係を満たす場合、ダイヤフラム１２０は弁座１３９から離間する。すなわち、圧電ポンプ１０のオンオフに同調してダイヤフラム１２０が弁座１３９に対して接触又は離間する。これにより、吸入器９の容器９０内の気圧が、圧電ポンプ１０のオンオフに同調して自動的に変化する。

[0080] なお、このバルブ１０１では、図５、図６に示すように、各バルブ室１３１、１３２、１３３、１３４、１４１、１４２のそれぞれの外形が円形状であるため、ダイヤフラム１２０（特に孔部１２１、１２２付近の周囲）に張

力が均等にかかる。

[0081] このため、ダイヤフラム１２０の孔部１２１が弁座１３８に対して傾いた状態で当接されたり、ダイヤフラム１２０の孔部１２１が弁座１３８に対して水平方向にずれたりすることが抑制される。

[0082] 同様に、ダイヤフラム１２０の孔部１２２が弁座１４５に対して傾いた状態で当接されたり、ダイヤフラム１２０の孔部１２２が弁座１４５に対して水平方向にずれたりすることが抑制される。したがって、このバルブ１０１によれば、それぞれの弁の開閉をより確実に行うことができる。

[0083] 次に、駆動している時の圧電ポンプ１０の動作について説明する。

[0084] 図７（Ａ）（Ｂ）は、図１に示す圧電ポンプ１０を１次モードの周波数（基本波）で動作させた時における圧電ポンプ１０のＳ－Ｓ線の断面図である。ここで、図中の矢印は、空気の流れを示している。

[0085] 図４に示す状態において、１次モードの周波数（基本波）の交流駆動電圧が外部端子６３，７２から圧電素子４０に印加されると、振動板３９は同心円状に屈曲振動する。同時に、天板３７は、振動板３９の屈曲振動に伴うポンプ室３６の圧力変動により、振動板３９の屈曲振動に伴って（この実施形態では振動位相が１８０°遅れて）同心円状に屈曲振動する。

[0086] これにより、図７（Ａ）（Ｂ）に示すように、振動板３９及び天板３７が屈曲変形してポンプ室３６の体積が周期的に変化する。

[0087] 図７（Ａ）に示すように、圧電素子４０に交流電圧を印加して振動板３９を圧電素子４０側へ屈曲させると、ポンプ室３６の容積が増大する。これに伴い、圧電ポンプ１０の外部の空気が吸引孔５３、通気路３１、及び通気孔４５を介してポンプ室３６内に吸引される。ポンプ室３６からの空気の流出は無いものの、吐出孔２４から圧電ポンプ１０の外部への空気の流れの慣性力が働いている。

[0088] 図７（Ｂ）に示すように、圧電素子４０に交流電圧を印加して振動板３９をポンプ室３６側へ屈曲させると、ポンプ室３６の容積が減少する。これに伴い、ポンプ室３６内の空気が通気孔４５、通気路３１を介して吐出孔２４

から吐出する。

[0089] このとき、ポンプ室３６から吐出される空気が，圧電ポンプ１０の外部の空気を吸引孔５３及び通気路３１を介して引き込みながら吐出孔２４から吐出する。そのため、圧電ポンプ１０では、吐出孔２４から吐出される空気の流量が、引き込まれる空気の流量分増大する。

[0090] 次に、流体制御装置１００の空気の流れについて説明する。

[0091] 図８は、圧電ポンプ１０が駆動している間における流体制御装置１００の空気の流れを示す説明図である。図中の矢印は、空気の流れを示している。また、図８では、圧電ポンプ１０及び吸入器９の図示を省略している。

[0092] なお、前述したように、第１下バルブ室１４１、連通路１３５、第２下バルブ室１３１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」に相当する。第１上バルブ室１４２、連通路１２５、第２上バルブ室１３３、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」に相当する。弁座１４５が本発明の「第１弁座」に相当する。弁座１３９が本発明の「第２弁座」に相当する。弁座１３８が本発明の「第３弁座」に相当する。孔部１２２が本発明の「第１孔部」に相当する。孔部１２１が本発明の「第２孔部」に相当する。

[0093] まず、ユーザが、吸入器９の吸入口９１を例えばヒトや動物の乳房に装着する。圧電ポンプ１０が駆動する前における容器９０内の圧力は大気圧となっている。流体制御装置１００は、吸入器９による液体の吸入を開始するとき、圧電ポンプ１０をオンする。

[0094] 圧電ポンプ１０が駆動すると、第２上バルブ室１３３の空気が第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引される。そして、圧電ポンプ１０内の空気が吐出孔２４から吐出される。

[0095] これにより、逆止弁１６０では、第２下バルブ室１３１の圧力が第２上バルブ室１３３の圧力より高くなる。このため、逆止弁１６０では、ダイヤフラム１２０における孔部１２１の周囲が弁座１３８から離間し、第１通気孔１１１と第２通気孔１１２とが孔部１２１を介して連通する。

[0096] また、逆止弁１４０では、第１下バルブ室１４１の圧力が第１上バルブ室１４２の圧力より高くなる。このため、ダイヤフラム１２０における孔部１２２の周囲が弁座１４５に接触したままの状態を維持し、第１下バルブ室１４１と第１上バルブ室１４２との連通を遮断する。

[0097] 一方、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より高くなる。このため、ダイヤフラム１２０が第３通気孔１１３をシールして第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0098] 即ち、バルブ１０１では、第１領域の圧力が第２領域の圧力より高い場合、第１通気孔１１１と第２通気孔１１２とを連通させ、第１通気孔１１１及び第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0099] この結果、吸入器９の容器９０内の空気が接続孔９２から第１通気孔１１１を介してバルブ１０１の第１下バルブ室１４１へ排出される。これにより、容器９０内の圧力（空気圧）が大気圧より低下し、負圧になる。

[0100] そのため、吸入器９は、容器９０外部の液体（例えば母乳など）を吸入口９１から容器９０内へ吸入することができる。吸入器９は、液体を容器９０内に貯蔵し、容器９０内の空気を接続孔９２から排出する。

[0101] なお、第１下バルブ室１４１に排出された空気は、連通路１３５、第２下バルブ室１３１、及び孔部１２１を介して第２上バルブ室１３３に流入する。そして、第２上バルブ室１３３の空気は、第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引され、吐出孔２４から吐出される。

[0102] 図９は、圧電ポンプ１０が駆動を停止した直後における、流体制御装置１００の空気の流れを示す説明図である。図中の矢印は、空気の流れを示している。また、図９では、圧電ポンプ１０及び吸入器９の図示を省略している。

[0103] 吸入器９による液体の吸入を終了するとき、流体制御装置１００は、圧電ポンプ１０をオフし、圧電ポンプ１０の駆動を停止する。このとき、第２領域が大気圧より低くなっているため、圧電ポンプ１０の吐出孔２４から微量

の空気が圧電ポンプ１０内へ流入し、吸引孔５３及び第２通気孔１１２を介して第２領域に流入する。

[0104] この結果、逆止弁１６０では、第２下バルブ室１３１の圧力が第２上バルブ室１３３の圧力より低下する。このため、ダイヤフラム１２０は、弁座１３８に当接して孔部１２１を閉じる。

[0105] また、逆止弁１４０では、第１下バルブ室１４１の圧力が第１上バルブ室１４２の圧力より低下する。このため、ダイヤフラム１２０における孔部１２２の周囲が弁座１４５から離間し、第１通気孔１１１と第２領域とを連通させる。

[0106] 一方、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より低下する。このため、ダイヤフラム１２０は、弁座１３９から離間して第３通気孔１１３を開放する。

[0107] 即ち、バルブ１０１では、第１領域の圧力が第２領域の圧力より低い場合、第１通気孔１１１と第３通気孔１１３とが連通する。これにより、空気が第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第１上バルブ室１４２、孔部１２２、第１下バルブ室１４１を経由して第１通気孔１１１から容器９０内へ急速に流入する（図９参照）。

[0108] これにより、容器９０内の圧力（空気圧）が上昇し、大気圧に戻る。そのため、吸入器９は、吸入口９１を、ヒトや動物の乳房から容易に取り外すことができる。

[0109] 従って、この実施形態のバルブ１０１によれば、容器９０内から空気を吸入して容器９０内の圧力を負圧にした後、容器９０内に空気を流入させて容器９０内の圧力を大気圧に急速に戻すことができることができる。また、この実施形態のバルブ１０１を備える流体制御装置１００にも同様の効果を奏する。

[0110] 以下、本発明の第２実施形態に係る流体制御装置２００について説明する。

[0111] 図１０は、本発明の第２実施形態に係る流体制御装置２００の外観図であ

る。図１１は、図１０に示すバルブ２０１の断面図である。流体制御装置２００は、液体（例えば痰など）を吸引する装置である。流体制御装置２００は、ポンプ２１０と吸入器２０９とバルブ２０１とを備える。

[0112] ポンプ２１０は、空気を吸引するための吸引孔２５３と、空気を吐出するための吐出孔（不図示）と、空気の吸引圧力を示す圧力計２１５と、を有する。

[0113] 吸入器２０９は、容器２９０と接続孔２９２とチューブ２９４とを有する。チューブ２９４の先端である吸入口２９１は、例えばヒトや動物の口腔内に挿入される。容器２９０は、液体（例えば痰など）を貯蔵する。

[0114] なお、接続孔２９２は、本発明の接続部の一例に相当する。

[0115] バルブ２０１がバルブ１０１と相違する点は、フィルタ２５０を第２筐体２９３内に有する点である。バルブ２０１の第２筐体２９３がバルブ１０１の第２筐体１９２と相違する点は、フィルタ２５０を配置するスペースが設けられている点である。その他の点に関しては同じである。

[0116] フィルタ２５０は、気体を通過させ、液体の通過を阻止する。フィルタ２５０は、感染や汚染防止のため、例えばバクテリアを吸着する。フィルタ２５０は、第２筐体２９３の内壁に接着剤等で接合されている。

[0117] 以上の構成において、吸入口２９１は、チューブ２９４を介して容器２９０に接続する。バルブ２０１の第１通気孔１１１は、チューブ２９５を介して吸入器２０９の接続孔２９２に接続する。バルブ２０１の第２通気孔１１２は、チューブ２９６を介してポンプ２１０の吸引孔２５３に接続する。バルブ２０１の第３通気孔１１３は、大気開放されている。

[0118] なお、前述したように、第１下バルブ室１４１、連通路１３５、第２下バルブ室１３１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」に相当する。第１上バルブ室１４２、連通路１２５、第２上バルブ室１３３、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」に相当する。弁座１４５が本発明の「第１弁座」に相当する。弁座１３９が本発明の「第２弁座」に相当する。弁座１３８が本発明の「第３弁座」に相

当する。孔部１２２が本発明の「第１孔部」に相当する。孔部１２１が本発明の「第２孔部」に相当する。

[0119] 次に、ポンプ２１０が駆動している間における流体制御装置２００の空気の流れは、図８に示す流体制御装置１００の空気の流れとほぼ同じである。流体制御装置２００において空気は、フィルタ２５０を通過しながら流れる。

[0120] ポンプ２１０が駆動を停止した時、容器２９０内の圧力がポンプ２１０の最大吸引圧力に達した時、又は流路が閉塞した時における流体制御装置２００の空気の流れも、図９に示す流体制御装置１００の空気の流れとほぼ同じである。流体制御装置２００において空気は、フィルタ２５０を通過しながら流れる。

[0121] 例えば、吸入口２９１は、吸着対象物がない状態で人体の組織を吸引すると、閉塞する。吸入口２９１の閉塞により、第１領域の圧力が第２領域の圧力以下となる。第１領域の圧力が第２領域の圧力以下となった場合、図９に示すようにダイヤフラム１２０が自動的に第３通気孔１１３及び孔部１２２を開放し、吸入口２９１が大気解放される。

[0122] したがって、バルブ２０１は、バルブ１０１と同様の効果を奏する。すなわち、バルブ２０１は、容器２９０内から空気を吸入して容器２９０内の圧力を負圧にした後、容器２９０内に空気を流入させて容器２９０内の圧力を大気圧に急速に戻すことができることができる。また、バルブ２０１を備える流体制御装置２００も同様の効果を奏する。

[0123] ここで、ポンプ２１０が駆動している間、フィルタ２５０に液体が付着した場合、フィルタ２５０が詰り、フィルタ２５０の流路抵抗（通気抵抗）が増加する。すなわち、流体制御装置２００は、空気を適切に吸引できなくなる。

[0124] 一般的な従来の吸引装置もフィルタを備えるが、フィルタが詰まったことを検出することができない。従来の吸引装置では看護師等が、フィルタの外観を確認したりフィルタの使用時間を管理したりして、フィルタを交換して

いる。すなわち、従来の吸引装置では、フィルタの定量的な管理が難しかった。

[0125] 一方、流体制御装置２００のバルブ２０１では、フィルタ２５０の流路抵抗が増加すると、第１領域と第２領域の圧力差が無くなり、ダイヤフラム１２０が第３通気孔１１３及び孔部１２２を開放する。この大気開放によって空気が通過する際に音が発生する。

[0126] したがって、バルブ２０１及び流体制御装置２００では、看護師等が大気開放時の音によりフィルタ２５０が詰まったことを容易に検出できる。

[0127] 以下、本発明の第３実施形態に係る流体制御装置３００について説明する。

[0128] 図１２は、本発明の第３実施形態に係る流体制御装置３００の断面図である。図１２中に示す矢印は、流体の流れを示している。流体制御装置３００は、液体（例えば胸水や血液など）を吸引するドレナージである。流体制御装置３００は、ポンプ３１０と吸入器３０９とバルブ１０１とを備える。

[0129] ポンプ３１０は、任意のポンプであり、空気を吸引するための吸引孔（不図示）と、空気を吐出するための吐出孔（不図示）と、を有する。

[0130] 吸入器３０９は、所謂胸腔ドレーンバックである。吸入器３０９は、第１容器３９０Ａと第２容器３９０Ｂと第３容器３９０Ｃとチューブ３３０と接続孔３９２とチューブ３３０とを有する。チューブ３３０の先端である吸入口３９１は、患者３０８の胸腔内に挿入される。患者３０８は、例えばヒトや動物である。

[0131] なお、接続孔３９２が本発明の接続部の一例に相当する。

[0132] 第１容器３９０Ａは、所謂排液ボトルである。第１容器３９０Ａは、吸入口３９１に接続する。第１容器３９０Ａは、吸入口３９１から吸入された患者３０８の液体Ｂ（例えば胸水や血液など）を貯蔵する。

[0133] 第２容器３９０Ｂは、所謂水封ボトルである。第２容器３９０Ｂは、第１容器３９０Ａに接続する。第２容器３９０Ｂ内には、水Ｗ１が入れられている。第２容器３９０Ｂは、水Ｗ１によって、空気を通過させて液体Ｂの通過

を阻止する。

[0134] 第３容器３９０Ｃは、所謂吸引圧制御ボトルである。第３容器３９０Ｃは、第２容器３９０Ｂおよびポンプ３１０の吸引孔に接続する。第３容器３９０Ｃ内には、水Ｗ２が入れられている。第３容器３９０Ｃ内には、管３３６が挿入され、管３３６の先端は水Ｗ２に浸かっている。第３容器３９０Ｃは、水Ｗ２の水位と管３３６の先端から流入する空気とによって、ポンプ３１０が吸引する空気の吸引圧力を調整する。

[0135] バルブ１０１は、第３容器３９０Ｃの出口である接続孔３９２を塞ぐよう、第３容器３９０Ｃの上面に装着されている。

[0136] 以上の構成において、吸入口３９１は、チューブ３３０を介して容器３９０Ａに接続する。バルブ１０１の第１通気孔１１１は、吸入器３０９の接続孔３９２に接続する。バルブ１０１の第２通気孔１１２は、チューブ３３７を介してポンプ３１０の吸引孔に接続する。バルブ１０１の第３通気孔１１３は、大気開放されている。

[0137] 次に、ポンプ３１０が駆動している間における流体制御装置３００の空気の流れは、図８に示す流体制御装置１００の空気の流れと同じである。

[0138] ポンプ３１０が駆動を停止した時、容器３９０Ａ内の圧力がポンプ３１０の最大吸引圧力に達した時、又は流路が閉塞した時における流体制御装置３００の空気の流れも、図９に示す流体制御装置１００の空気の流れと同じである。

[0139] 例えば、吸入口３９１は、吸着対象物がない状態で人体の組織を吸引すると、閉塞する。吸入口３９１の閉塞により、第１領域の圧力が第２領域の圧力以下となる。第１領域の圧力が第２領域の圧力以下となった場合、ダイヤフラム１２０が自動的に第３通気孔１１３及び孔部１２２を開放し、吸入口３９１が大気解放される。

[0140] したがって、バルブ１０１は、バルブ１０１と同様の効果を奏する。すなわち、バルブ１０１は、第３容器３９０Ｃ内から空気を吸入して第３容器３９０Ｃ内の圧力を負圧にした後、第３容器３９０Ｃ内に空気を流入させて第

３容器３９０Ｃ内の圧力を大気圧に急速に戻すことができることができる。

[0141] また、肺気胸では傷口が小さくなり、流量が低下してきた場合、吸引を止めた方が治癒期間を短縮できるといわれている。そのため、自動的に吸入口３９１を開放するバルブ１０１は、肺気胸の治療に用いることが好適である。

[0142] また、バルブ１０１の構造が簡単で安価である事から、吸入器３０９及びバルブ１０１の使い捨て使用が可能となる。そのため、バルブ１０１は、病院のメンテナンス費用を削減できる。

[0143] また、バルブ１０１を備える流体制御装置３００も同様の効果を奏する。

[0144] 以下、本発明の第４実施形態に係る流体制御装置４００について説明する。

[0145] 図１３は、本発明の第４実施形態に係る流体制御装置４００の断面図である。流体制御装置４００が流体制御装置１００と相違する点は、バルブ４０１である。バルブ４０１がバルブ１０１と相違する点は、第４通気孔１１４を有する点である。第４通気孔１１４の直径は、第１通気孔１１１の直径に比べて小さい。また、第４通気孔１１４の直径は、第２通気孔１１２の直径に比べて小さい。なお、その他の流体制御装置４００の構成に関しては、流体制御装置１００と同じであるため、説明を省略する。

[0146] 次に、流体制御装置４００の空気の流れについて説明する。流体制御装置４００の空気の流れは、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達するまでの第１段階と、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの第２段階と、圧電ポンプ１０が駆動を停止した直後における第３段階と、に分かれている。

[0147] まず、第１段階における空気の流れについて説明する。

図１４は、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置４００の空気の流れを示す説明図である。図中の矢印は、空気の流れを示している。また、図１４では

、圧電ポンプ１０及び吸入器９の図示を省略している。

[0148] まず、ユーザが、吸入器９の吸入口９１を例えばヒトや動物の乳房に装着する。圧電ポンプ１０が駆動する前における容器９０内の圧力は大気圧となっている。流体制御装置４００は、吸入器９による液体の吸入を開始するとき、圧電ポンプ１０をオンする。

[0149] 圧電ポンプ１０が駆動すると、第２上バルブ室１３３の空気が第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引される。そして、圧電ポンプ１０内の空気が吐出孔２４から吐出される。

[0150] これにより、逆止弁１４０では、第１下バルブ室１４１の圧力が第１上バルブ室１４２の圧力より高くなる。このため、ダイヤフラム１２０における孔部１２２の周囲が弁座１４５に接触したままの状態を維持し、第１下バルブ室１４１と第１上バルブ室１４２との連通を遮断する。

[0151] また、逆止弁１６０では、第２下バルブ室１３１の圧力が第２上バルブ室１３３の圧力より高くなる。このため、逆止弁１６０では、ダイヤフラム１２０における孔部１２１の周囲が弁座１３８から離間し、第１通気孔１１１と第２通気孔１１２とが孔部１２１を介して連通する。

[0152] また、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より高くなる。このため、ダイヤフラム１２０が第３通気孔１１３をシールして第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0153] 即ち、バルブ４０１では、第１領域の圧力が第２領域の圧力より高い場合、第１通気孔１１１と第２通気孔１１２とを連通させ、第１通気孔１１１及び第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0154] この結果、吸入器９の容器９０内の空気が接続孔９２から第１通気孔１１１を介してバルブ４０１の第１下バルブ室１４１へ排出される。これにより、容器９０内の圧力（空気圧）が大気圧より低下し、負圧になる。

[0155] そのため、吸入器９は、容器９０外部の液体（例えば母乳など）を吸入口９１から容器９０内へ吸入することができる。吸入器９は、液体を容器９０

内に貯蔵し、容器９０内の空気を接続孔９２から排出する。

[0156] なお、第１下バルブ室１４１に排出された空気は、連通路１３５、第２下バルブ室１３１、及び孔部１２１を介して第２上バルブ室１３３に流入する。そして、第２上バルブ室１３３の空気は、第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引され、吐出孔２４から吐出される。

[0157] ここで、流体制御装置４００では、第４通気孔１１４を介して、少量の空気がバルブ４０１の外部からバルブ４０１の内部へ吸引される。そのため、流体制御装置４００では流体制御装置１００に比べて、容器９０から吸引される空気の流量が減る。

[0158] しかし、第４通気孔１１４の直径は第１通気孔１１１の直径に比べて微小であるため、影響が小さい。そのため、空気は主に第１通気孔１１１からバルブ４０１の内部へ吸引され、容器９０から圧電ポンプ１０へ空気が流れる。これにより、排気弁１７０では、Ｐ２＜＜Ｐ１の関係とＳ１×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。

[0159] 次に、第２段階における空気の流れについて説明する。

図１５は、容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置４００の空気の流れを示す説明図である。図中の矢印は、空気の流れを示している。また、図１５では、圧電ポンプ１０及び吸入器９の図示を省略している。

[0160] 容器９０が十分に減圧されていくと、圧電ポンプ１０は、容器９０から空気を吸引できなくなる。しかし、第２段階では、空気が第４通気孔１１４から吸引され、逆止弁１６０の孔部１２１を通って圧電ポンプ１０に空気が流れる。そのため、排気弁１７０では、Ｐ２＜Ｐ１の関係とＳ１×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。

[0161] これにより、流体制御装置４００は、第３通気孔１１３が閉じた状態を維持する。すなわち流体制御装置４００は、圧電ポンプ１０を駆動し続ける間、容器９０の減圧状態を維持することができる。

[0162] 次に、第３段階における空気の流れについて説明する。

図１６は、圧電ポンプ１０が駆動を停止した直後における、流体制御装置４００の空気の流れを示す説明図である。図中の矢印は、空気の流れを示している。また、図１６では、圧電ポンプ１０及び吸入器９の図示を省略している。

[0163] 吸入器９による液体の吸入を終了するとき、流体制御装置４００は、圧電ポンプ１０をオフし、圧電ポンプ１０の駆動を停止する。このとき、バルブ４０１の内部が大気圧より低くなっている。そのため、第４通気孔１１４を介して、少量の空気がバルブ４０１の外部からバルブ４０１の内部へ吸引される。

[0164] しかし、第４通気孔１１４の直径は第２通気孔１１２の直径に比べて微小であるため、影響が小さい。そのため、主に、圧電ポンプ１０の吐出孔２４から微量の空気が圧電ポンプ１０内へ流入し、吸引孔５３及び第２通気孔１１２を介して第２領域に流入する。

[0165] この結果、逆止弁１６０では、第２下バルブ室１３１の圧力が第２上バルブ室１３３の圧力より低下する。このため、ダイヤフラム１２０は、弁座１３８に当接して孔部１２１を閉じる。

[0166] また、逆止弁１４０では、第１下バルブ室１４１の圧力が第１上バルブ室１４２の圧力より低下する。このため、ダイヤフラム１２０における孔部１２２の周囲が弁座１４５から離間し、第１通気孔１１１と第２領域とを連通させる。

[0167] また、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より低下する。即ち排気弁１７０では、圧力Ｐ２≧Ｐ１の関係とＳ１×（Ｐ１－Ｐ２）＜Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。このため、ダイヤフラム１２０は、弁座１３９から離間して第３通気孔１１３を開放する。

[0168] 即ち、バルブ４０１では、第１領域の圧力が第２領域の圧力より低い場合、第１通気孔１１１と第３通気孔１１３とが連通する。これにより、空気が第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第１

上バルブ室１４２、孔部１２２、第１下バルブ室１４１を経由して第１通気孔１１１から容器９０内へ急速に流入する（図９参照）。

[0169] これにより、容器９０内の圧力（空気圧）が上昇し、大気圧に戻る。そのため、吸入器９は、吸入口９１を、ヒトや動物の乳房から容易に取り外すことができる。

[0170] 従って、バルブ４０１は、容器９０内から空気を吸入して容器９０内の圧力を負圧にした後、容器９０内に空気を流入させて容器９０内の圧力を大気圧に急速に戻すことができることができる。また、この実施形態のバルブ４０１を備える流体制御装置４００にも同様の効果を奏する。

[0171] 《その他の実施形態》

なお、前述の実施形態では気体として空気を用いているが、これに限るものではなく、当該気体が、空気以外の気体であっても適用できる。

[0172] また、前述の実施形態においては、液体を吸入器で吸入する例を示したが、吸入する対象物は液体以外のもの（例えばゲル状の物質）であってもよい。

[0173] また、前述の実施形態における圧電ポンプ１０は、ユニモルフ型で屈曲振動するアクチュエータを備えるが、振動板の両面に圧電素子を貼着してバイモルフ型で屈曲振動するアクチュエータを備えてもよい。

[0174] また、前述の実施形態における圧電ポンプ１０は、圧電素子４０の伸縮によって屈曲振動するアクチュエータを備えるが、これに限るものではない。例えば、電磁駆動で屈曲振動するアクチュエータを備えてもよい。

[0175] また、前述の実施形態において、圧電素子４０はチタン酸ジルコン酸鉛系セラミックスからなるが、これに限るものではない。例えば、ニオブ酸カリウムナトリウム系及びアルカリニオブ酸系セラミックス等の非鉛系圧電体セラミックスの圧電材料などからなってもよい。

[0176] 最後に、上述の実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、上述の実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特

許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0177] ９…吸入器

１０…圧電ポンプ

１７…外筐体

１８…ノズル

２４…吐出孔

３１…通気路

３６…ポンプ室

３７…天板

３８…側板

３９…振動板

４０…圧電素子

４２…キャップ

４５…通気孔

５２…突出部

５３…吸引孔

５５Ａ～Ｄ…切欠き

５６Ａ～Ｄ…ネジ穴

６１…中央部

６２…突出部

６３，７２…外部端子

７０…電極導通用板

７３…内部端子

９０…容器

９１…吸入口

９２…接続孔

１００、２００、３００、４００…流体制御装置

１０１、２０１、４０１…バルブ

１１１…第１通気孔

１１２…第２通気孔

１１３…第３通気孔

１１４…第４通気孔１２０…ダイヤフラム

１２１、１２２…孔部

１２５、１２６…連通路

１３１…第２下バルブ室

１３２…第３下バルブ室

１３３…第２上バルブ室

１３４…第３上バルブ室

１３５、１３６…連通路

１３８、１３９…弁座

１４０…逆止弁

１４１…第１下バルブ室

１４２…第１上バルブ室

１４５…弁座

１５１…第１シール材

１５２…第２シール材

１６０…逆止弁

１７０…排気弁

１９１…第１弁筐体

１９２…第２弁筐体

２０９…吸入器

２１０…ポンプ

２１５…圧力計

２５０…フィルタ

２５３…吸引孔

２９０…容器

２９１…吸入口

２９２…接続孔

２９３…第２筐体

２９４、２９５、２９６…チューブ

３０８…患者

３０９…吸入器

３１０…ポンプ

３３０…チューブ

３３６…管

３９０Ａ…第１容器

３９０Ｂ…第２容器

３９０Ｃ…第３容器

３９１…吸入口

３９２…接続孔

請求の範囲

[請求項1] 第１通気孔、第２通気孔、及び第３通気孔が形成された弁筐体と、

前記弁筐体内を分割して前記弁筐体内に、前記第１通気孔に連通する第１領域と前記第２通気孔に連通する第２領域とを構成するダイヤフラムと、を有し、

前記ダイヤフラムは、

前記第１領域の圧力が前記第２領域の圧力よりも高い場合、前記第１通気孔と前記第２通気孔とを連通させるとともに、前記第１通気孔および前記第２通気孔と前記第３通気孔との連通を遮断し、

前記第１領域の圧力が前記第２領域の圧力よりも低い場合、前記第１通気孔と前記第３通気孔とを連通させるよう、前記弁筐体に固定された、バルブ。

[請求項2] 前記ダイヤフラムは、前記第１領域と前記第２領域との圧力差により、前記弁筐体の一部に対して接触または離間し、前記第１通気孔と前記第３通気孔との連通状態を切り替える、請求項１に記載のバルブ。

[請求項3] 前記弁筐体の前記一部には、前記第２領域において前記ダイヤフラム側へ突出した第１弁座が設けられ、

前記ダイヤフラムには、第１孔部が設けられ、

前記ダイヤフラムは、前記ダイヤフラムにおける前記第１孔部の周囲が前記第１弁座に接触するよう、前記弁筐体に固定されている、請求項２に記載のバルブ。

[請求項4] 前記弁筐体の前記一部には、前記第２領域において前記ダイヤフラム側へ突出した第２弁座が設けられ、

前記第２弁座には、前記第３通気孔が設けられ、

前記ダイヤフラムは、前記第２弁座に接触するよう、前記弁筐体に固定されている、請求項２又は請求項３に記載のバルブ。

[請求項5] 前記弁筐体には、前記第１領域において前記ダイヤフラム側へ突出

した第３弁座が設けられ、

前記ダイヤフラムには、第２孔部が設けられ、

前記ダイヤフラムは、前記ダイヤフラムにおける前記第２孔部の周囲が前記第３弁座に接触するよう、前記弁筐体に固定されている、請求項１から請求項４のいずれか１項に記載のバルブ。

[請求項6] 前記弁筐体には、前記第１領域に連通する第４通気孔が形成されている、請求項１から請求項５のいずれか１項に記載のバルブ。

[請求項7] 気体の吸引孔と前記気体の吐出孔とを有するポンプと、

流体を吸入する吸入口および接続部を有する吸入器と、

請求項１から請求項５のいずれか１項に記載のバルブと、を備え、

前記第１通気孔は、前記吸入器の前記接続部に接続され、

前記第２通気孔は、前記ポンプの前記吸引孔に接続されている、流体制御装置。

[請求項8] 前記吸入器は、

前記吸入口に接続し、前記吸入口から吸入された液体を貯蔵する第１容器と、

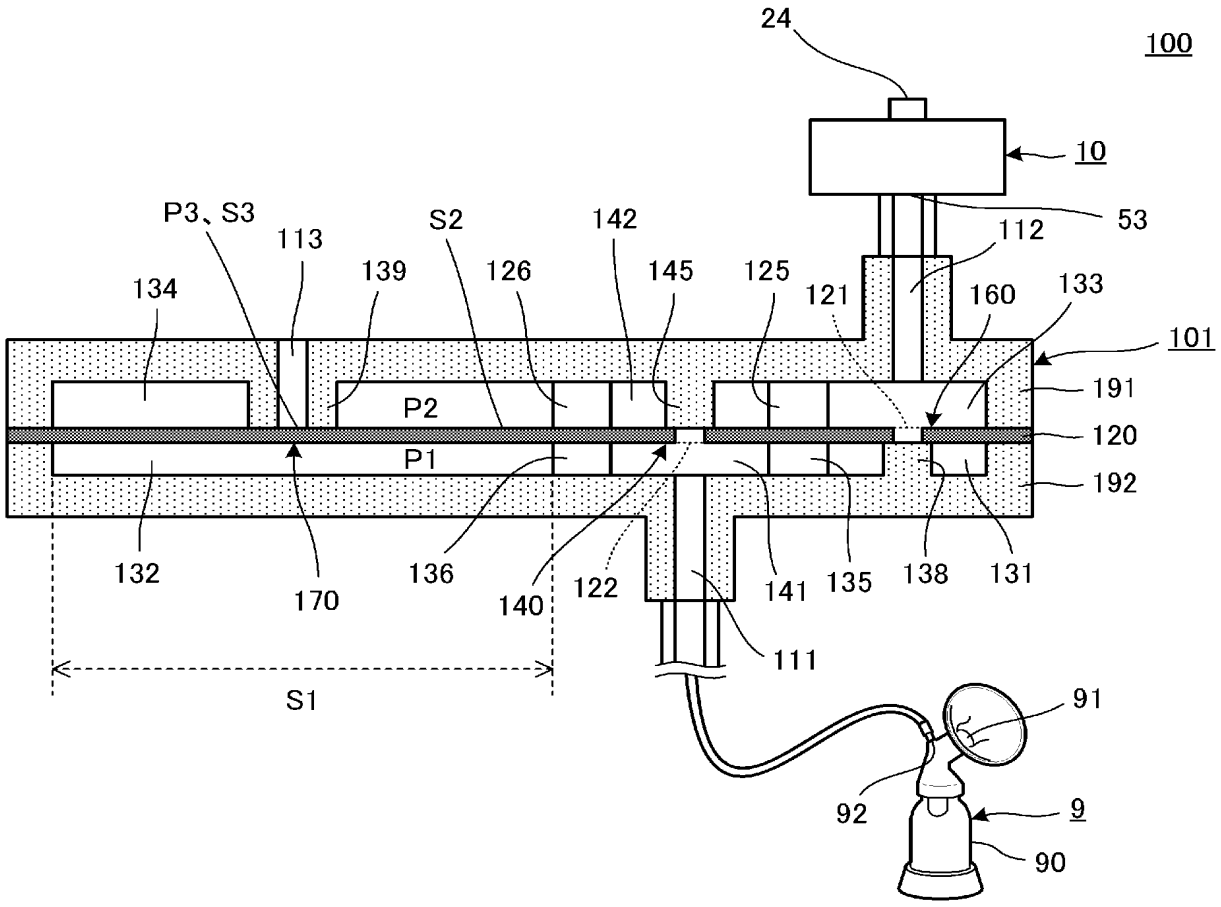
前記第１容器に接続し、前記気体を通過させて前記液体の通過を阻止する第２容器と、

前記第２容器および前記ポンプの前記吸引孔に接続し、前記ポンプが吸引する前記気体の吸引圧力を調整する第３容器と、

を有する、請求項７に記載の流体制御装置。

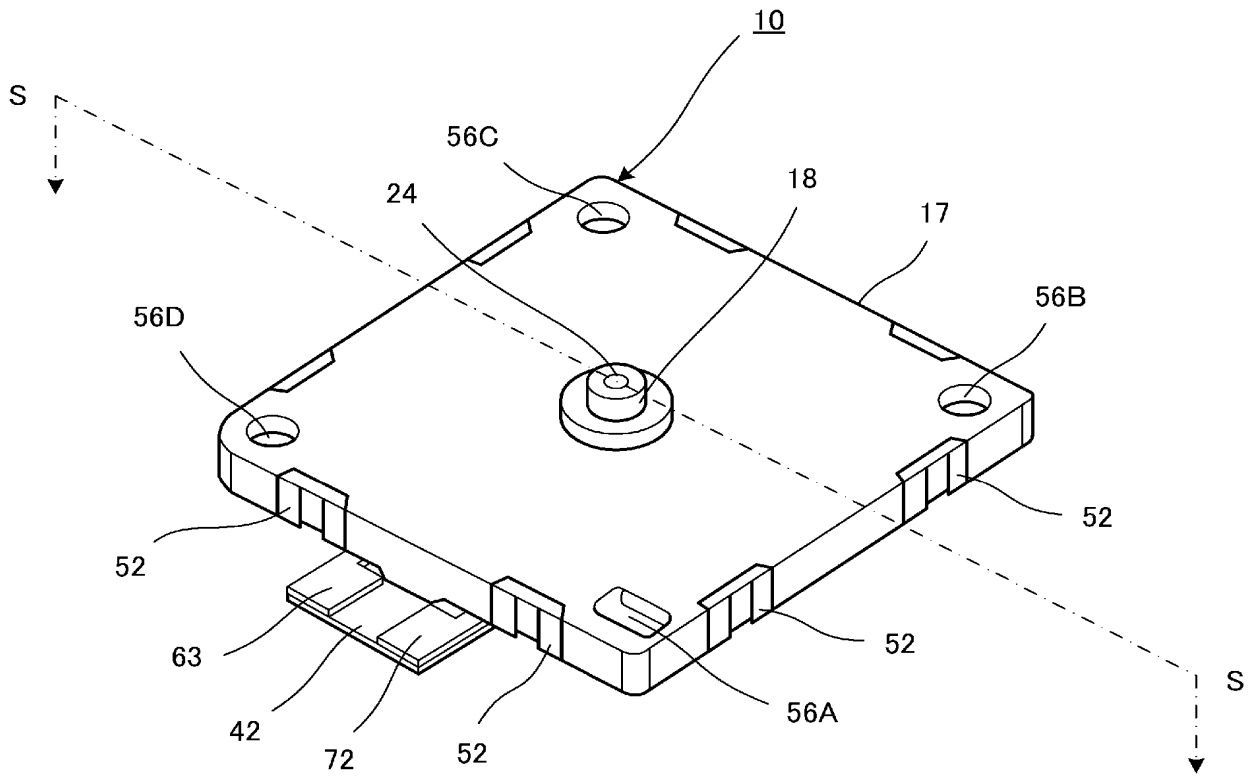
[図1]

図1


24
100
10
53
112
P3、S3
113
S2
142
139
126
145
125
121
160
133
134
101
191
P2
120
P1
192
132
170
136
140
122
141
135
138
131
111
S1
91
92
9
90

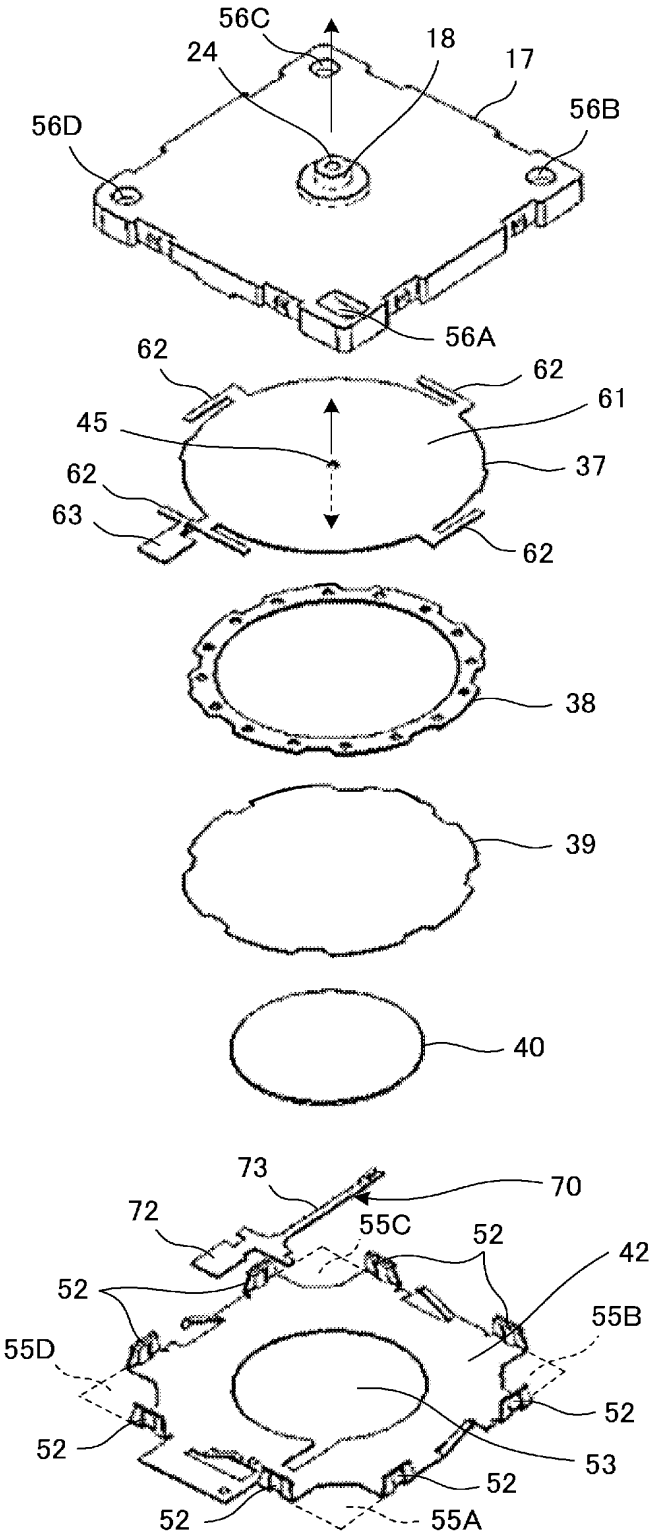
[図2]

図2

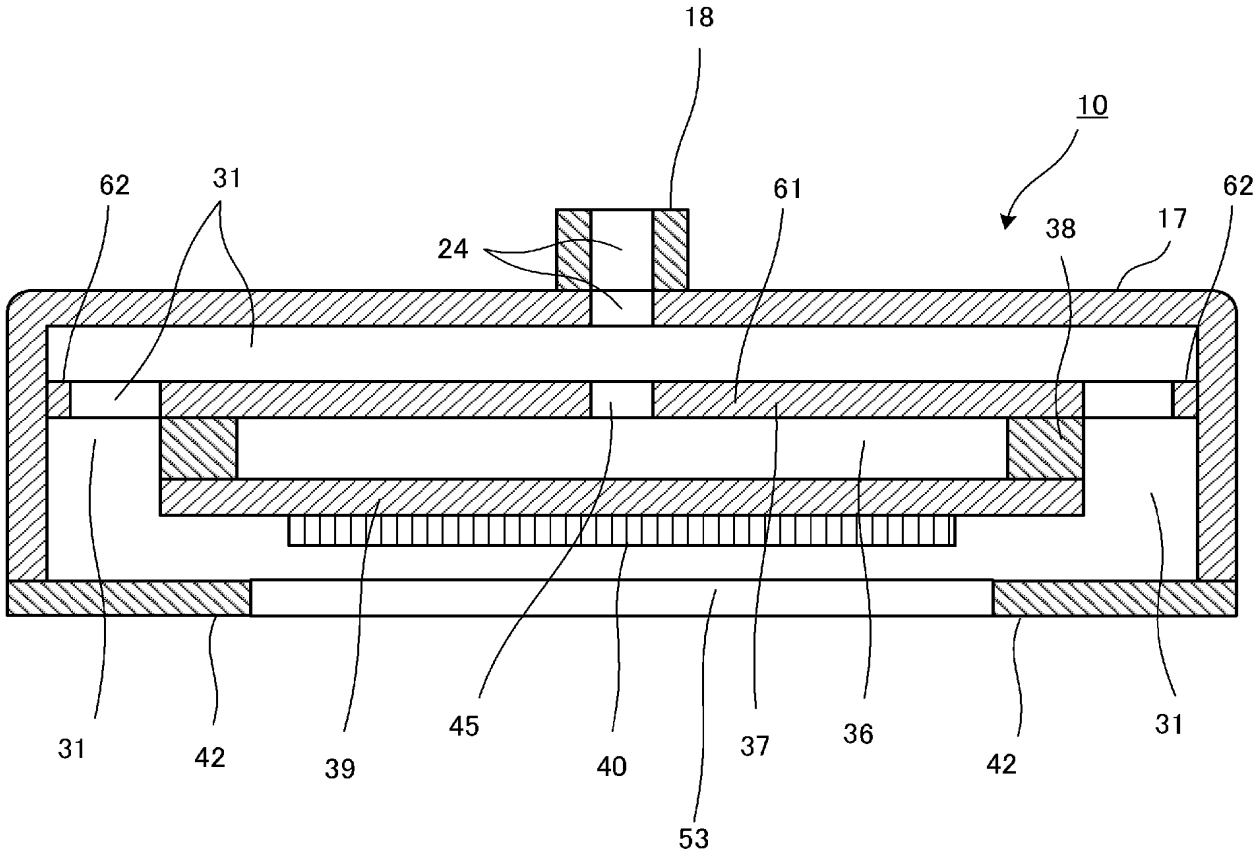


[図3]

図3

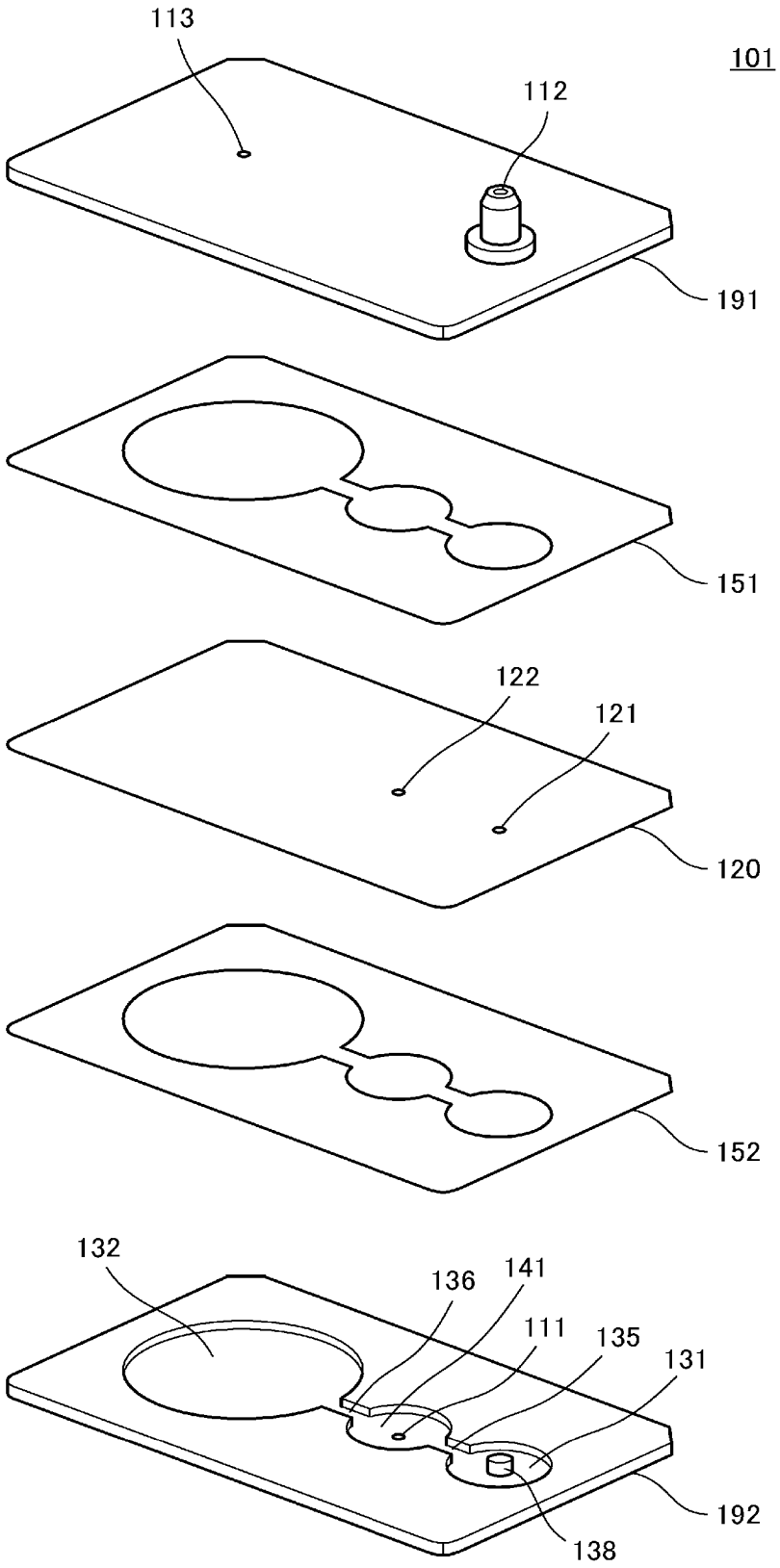

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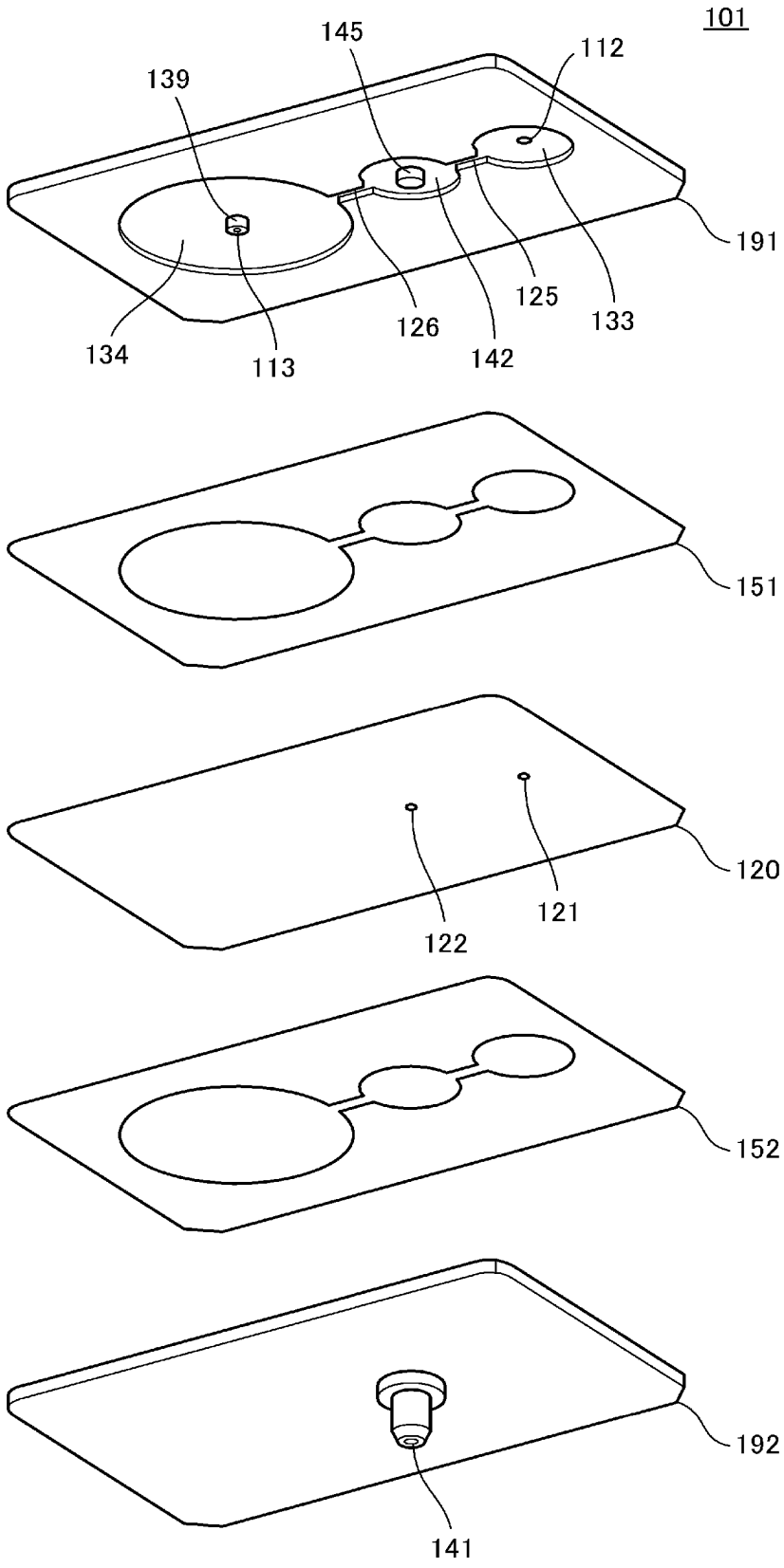
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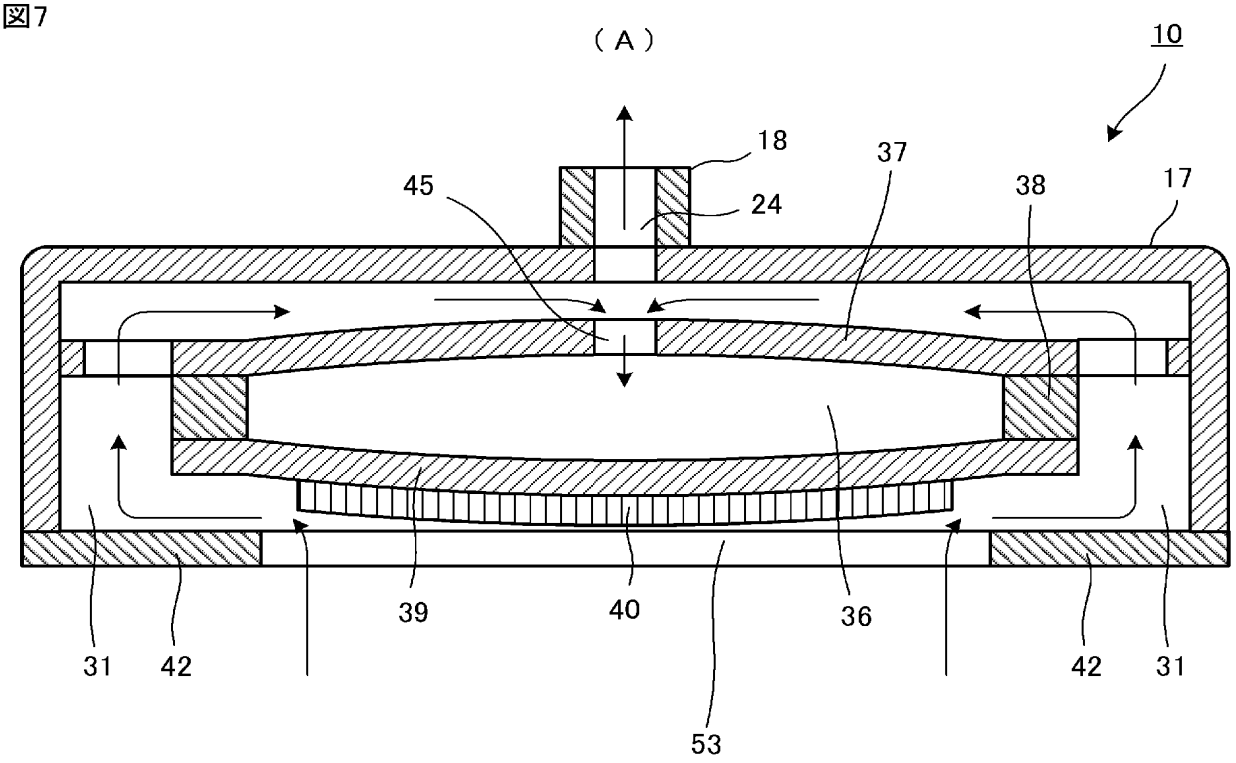

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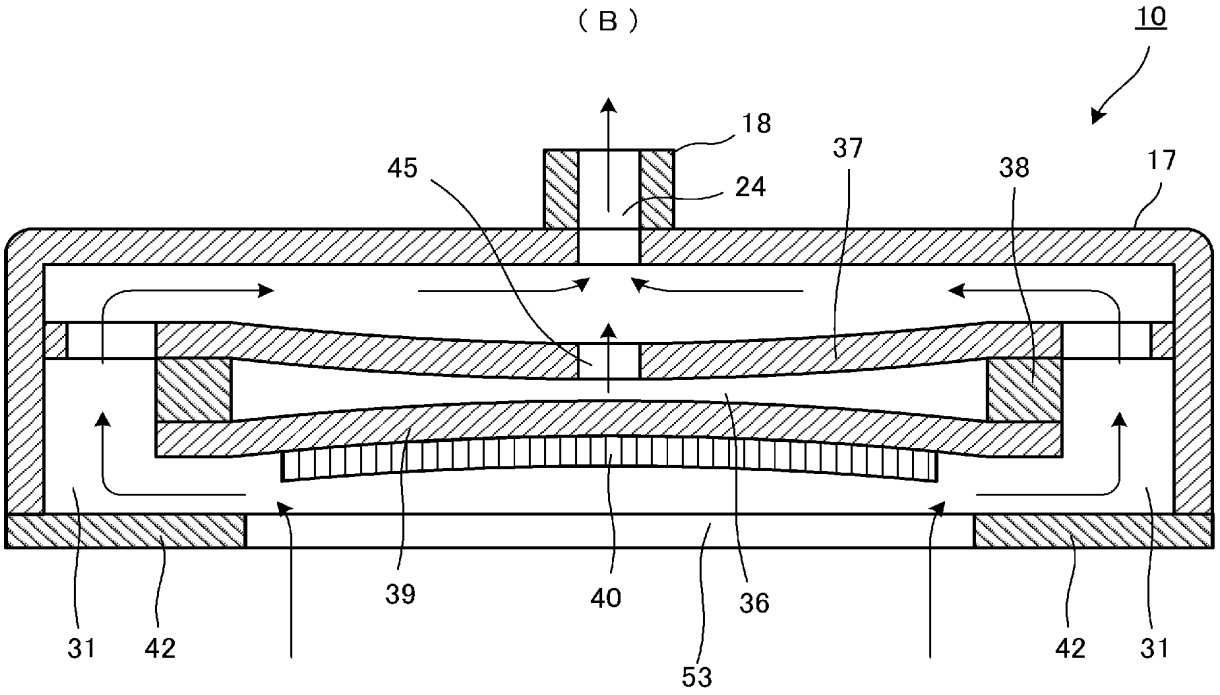
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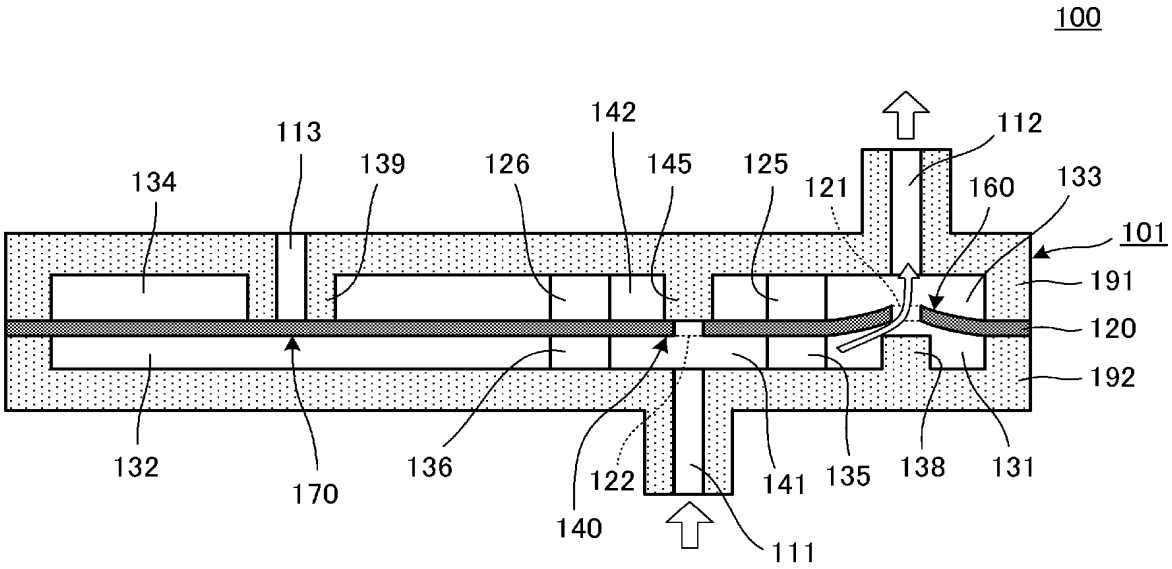

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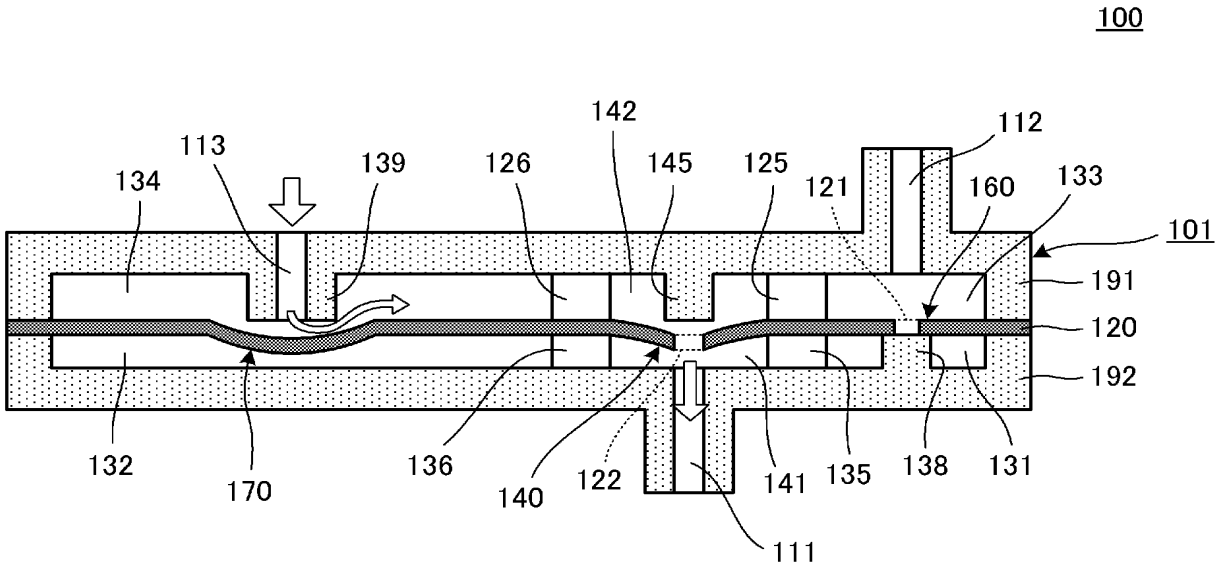

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[図8]
図8

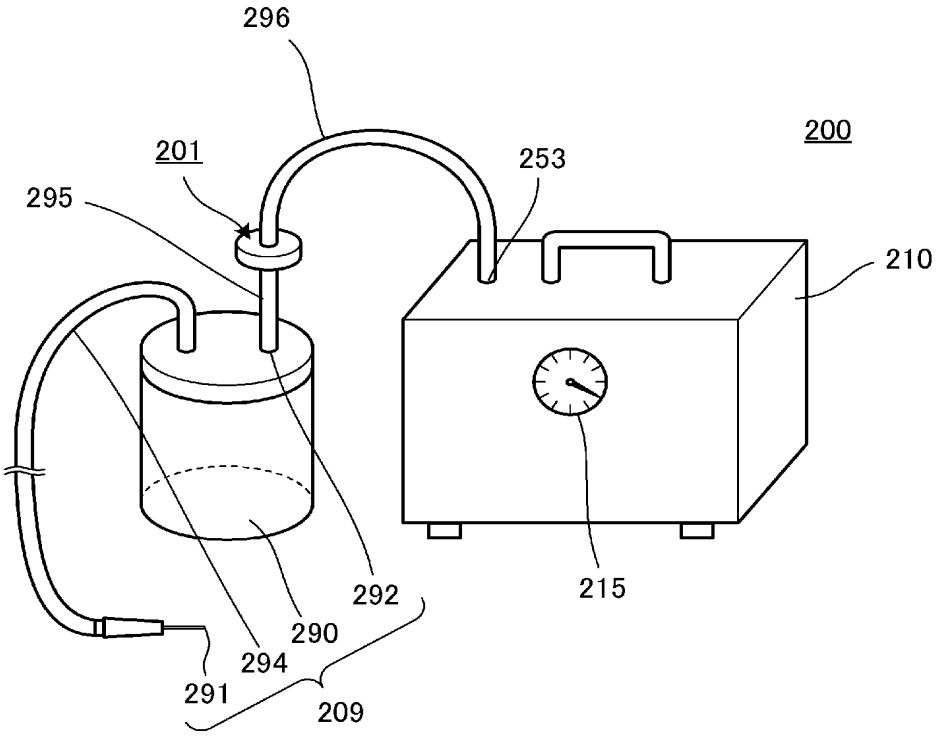

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図9

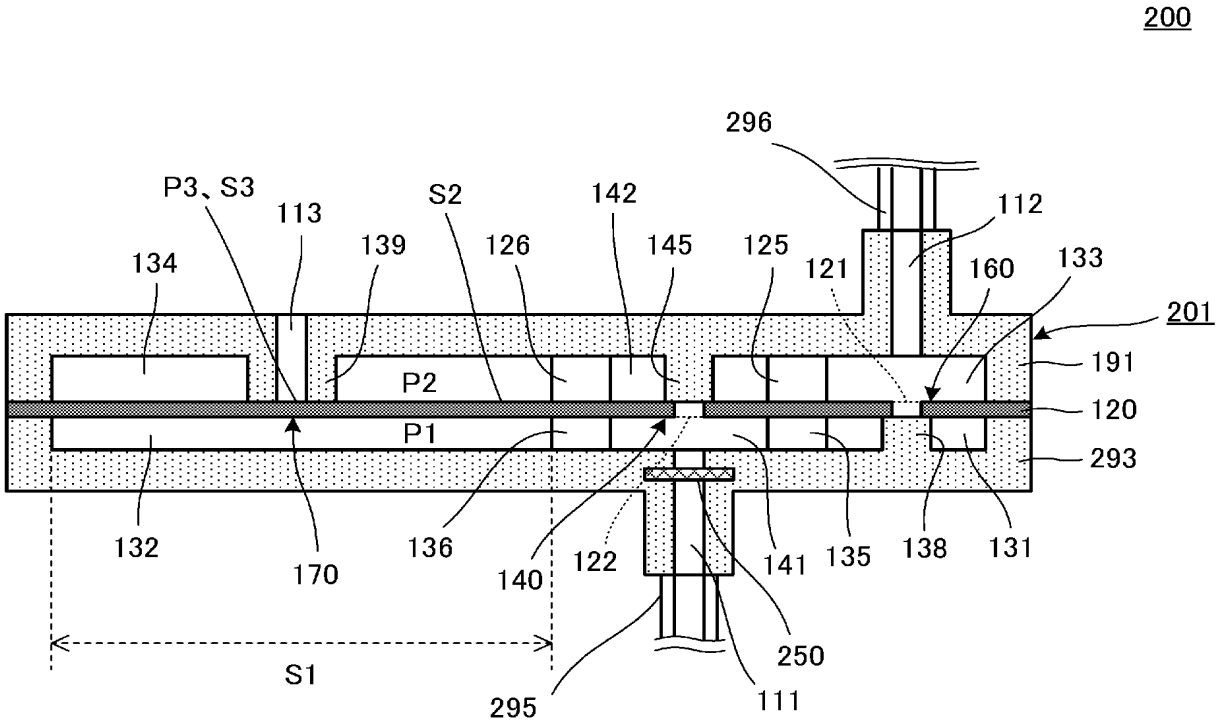

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[図10]

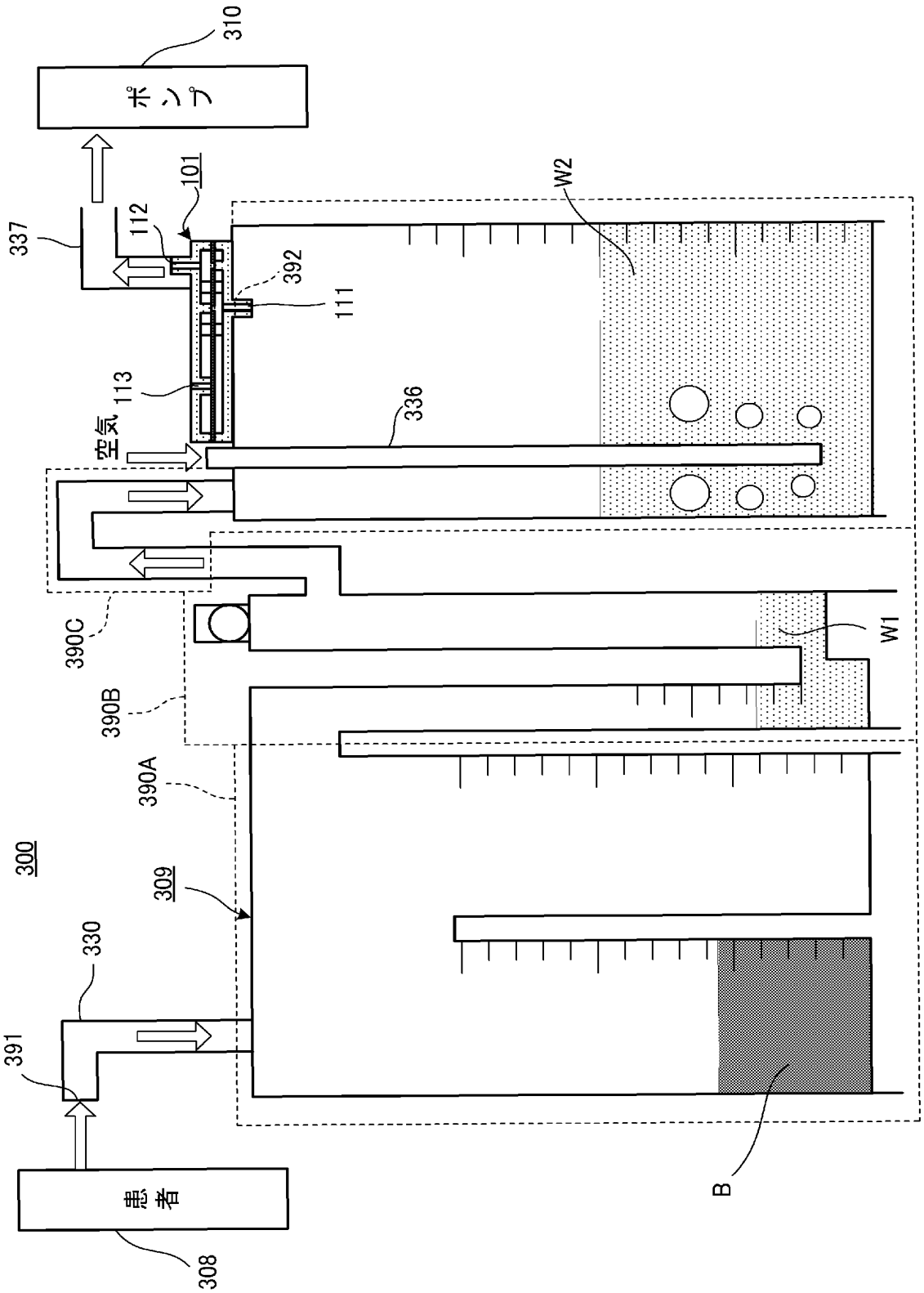
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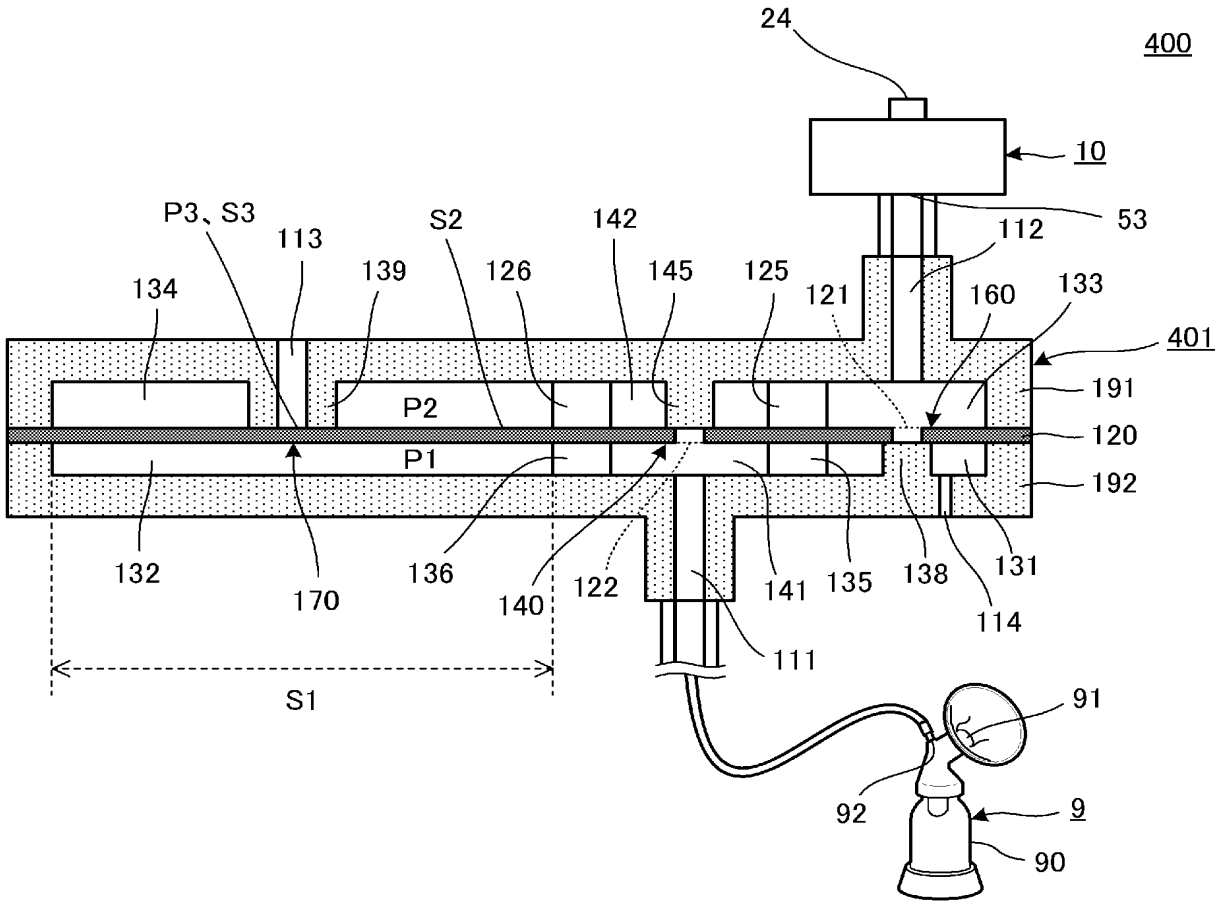
[図11]
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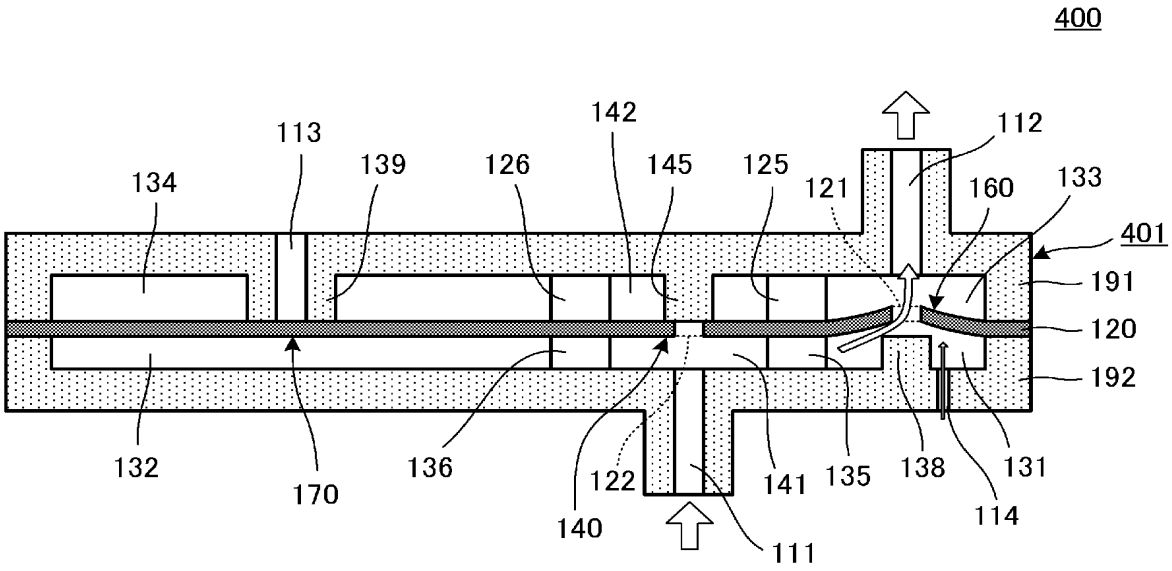
[図12]
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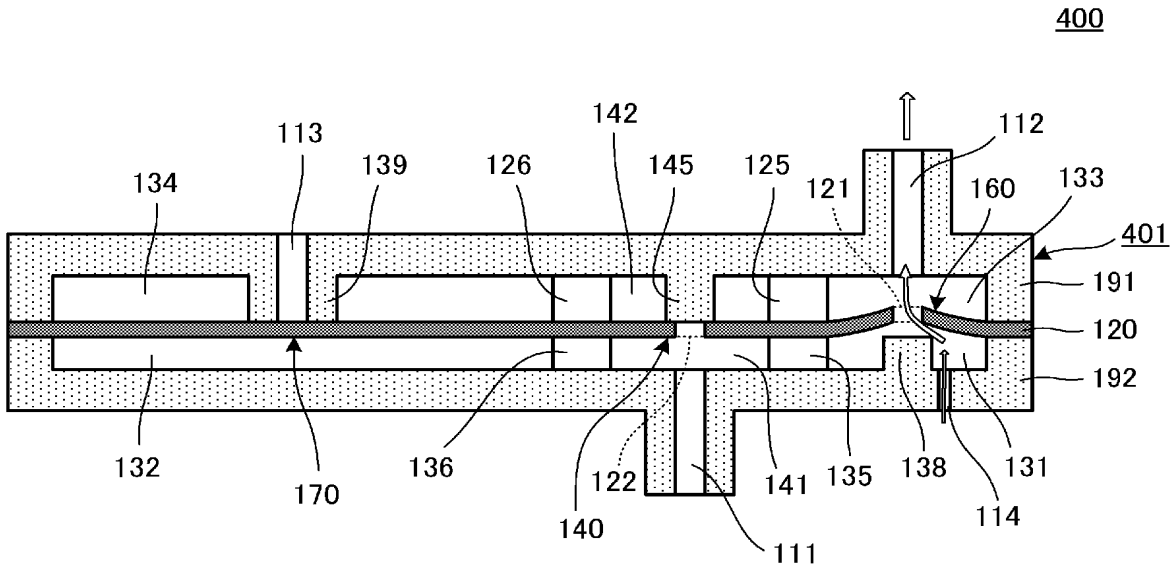
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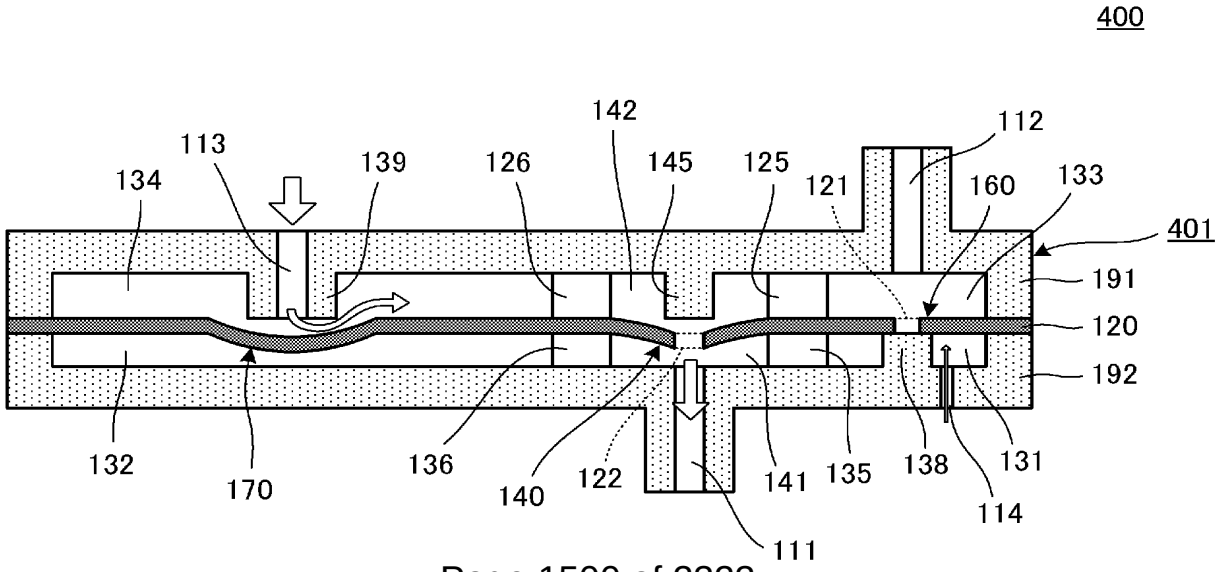
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[図15]
図15



[図16]
図16



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/063256

A. CLASSIFICATION OF SUBJECT MATTER
F16K7/17(2006.01)i, *A61G12/00*(2006.01)i, *A61M1/06*(2006.01)i, *A61M27/00*(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
F16K7/17, A61G12/00, A61M1/06, A61M27/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 5185475 B2 (Murata Mfg. Co., Ltd.), 17 April 2013 (17.04.2013), paragraphs [0003], [0008] to [0017]; fig. 1, 2 & US 2013/0178752 A1 & US 2015/0096638 A1 & WO 2012/141113 A1 & EP 2698107 A1	1-8
A	WO 2010/137578 A1 (Murata Mfg. Co., Ltd.), 02 December 2010 (02.12.2010), paragraphs [0012], [0016] to [0024]; fig. 1 to 4 & JP 5494658 B2 & US 2012/0244454 A1 & EP 2436961 A1 & CN 102449363 A	1-8

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 July 2015 (08.07.15)	21 July 2015 (21.07.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/063256

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 55410/1987(Laid-open No. 163157/1988) (Pigeon Corp.), 25 October 1988 (25.10.1988), specification, page 4, line 8 to page 7, line 14; fig. 1 (Family: none)	7
A	JP 2013-74914 A (Sumitomo Bakelite Co., Ltd.), 25 April 2013 (25.04.2013), paragraphs [0021] to [0031]; fig. 1 (Family: none)	7
A	JP 11-178915 A (Sumitomo Bakelite Co., Ltd.), 06 July 1999 (06.07.1999), paragraphs [0009] to [0010]; fig. 2 (Family: none)	7,8

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６３２５６

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　F16K7/17(2006.01)i, A61G12/00(2006.01)i, A61M1/06(2006.01)i, A61M27/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　F16K7/17, A61G12/00, A61M1/06, A61M27/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Ａ	JP 5185475 B2 (株式会社村田製作所) 2013.04.17, 段落【０００３】, 【０００８】－【００１７】, 【図１】, 【図２】 & US 2013/0178752 A1 & US 2015/0096638 A1 & WO 2012/141113 A1 & EP 2698107 A1	1-8
Ａ	WO 2010/137578 A1 (株式会社村田製作所) 2010.12.02, 段落 [0012], [0016]－[0024], [図１]－[図４] & JP 5494658 B2 & US 2012/0244454 A1 & EP 2436961 A1 & CN 102449363 A	1-8
Ａ	日本国実用新案登録出願 62-55410 号(日本国実用新案登録出願公開 63-163157 号)の願書に添付した明細書及び図面の内容を撮影したマイクロフィルム（ピジョン株式会社）1988.10.25, 明細書第４頁第	7

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日 ０８．０７．２０１５	国際調査報告の発送日 ２１．０７．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｏ　９１４５ 関　義彦 電話番号　０３－３５８１－１１０１　内線　３３５８

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
	８行－第７頁第１４行，第１図（ファミリーなし）	
Ａ	JP 2013-74914 A (住友ベークライト株式会社) 2013.04.25, 段落【００２１】－【００３１】,【図１】（ファミリーなし）	7
Ａ	JP 11-178915 A (住友ベークライト株式会社) 1999.07.06, 段落【０００９】－【００１０】,【図２】（ファミリーなし）	7,8

(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2016 年 1 月 7 日(07.01.2016)

WIPO | PCT

(10) 国際公開番号
WO 2016/002606 A1

(51) 国際特許分類:
A61M 1/00 (2006.01)

(21) 国際出願番号: PCT/JP2015/068282

(22) 国際出願日: 2015 年 6 月 25 日(25.06.2015)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願 2014-136711 2014 年 7 月 2 日(02.07.2014) JP

(71) 出願人: 株式会社村田製作所 (**MURATA MANUFACTURING CO., LTD.**) [JP/JP]; 〒6178555 京都府長岡京市東神足１丁目１０番１号 Kyoto (JP).

(72) 発明者: 近藤大輔 (**KONDO, Daisuke**); 〒6178555 京都府長岡京市東神足１丁目１０番１号 株式会社村田製作所内 Kyoto (JP). 岡口健二朗 (**OKAGUCHI, Kenjiro**); 〒6178555 京都府長岡京市東神足１丁目１０番１号 株式会社村田製作所内 Kyoto (JP). 竹村洋 (**TAKEMURA, Hiroshi**); 〒6178555 京都府長岡京市東神足１丁目１０番１号 株式会社村田製作所内 Kyoto (JP).

(74) 代理人: 特許業務法人 楓国際特許事務所 (**KAEDE PATENT ATTORNEYS' OFFICE**); 〒5400011 大阪府大阪市中央区農人橋１丁目４番３４号 Osaka (JP).

(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

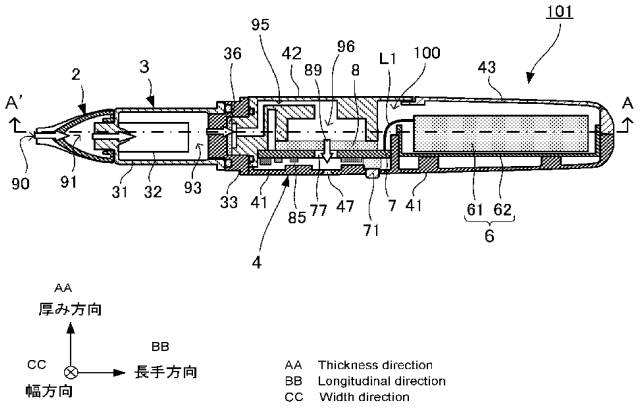
(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG, KZ, RU, TJ, TM), ヨーロッパ (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

添付公開書類:
— 国際調査報告（条約第 21 条(3)）

(54) **Title**: SUCTION DEVICE

(54) 発明の名称 : 吸入装置

【図2】



(57) **Abstract**: A suction device (101) is provided with a nozzle (2), a separator (3), a housing (4), a battery unit (6), a circuit board (7), and a piezoelectric blower (8). The piezoelectric blower (8) has: a suction hole (89) opened close to the center of the top surface of the piezoelectric blower (8); and a discharge hole (99)opened at the center of the bottom surface of the piezoelectric blower (8). The piezoelectric blower (8) is mounted on a first main surface of the circuit board (7), said first main surface being on the upper housing (42) side of the circuit board. The circuit board (7) drives the piezoelectric blower (8) by applying a drive voltage to the piezoelectric blower (8). The circuit board (7) has a through hole (77) facing the discharge hole (99). The through hole (77) overlaps the discharge hole (99) out of the suction hole (89) and the discharge hole (99) in a front view of the first main surface of the circuit board (7). The through hole (77) is wider than the discharge hole (99), and includes the discharge hole (99) in the front view of the first main surface of the circuit board (7).

(57) 要約: 吸入装置（１０１）は、ノズル（２）とセパレータ（３）と筐体（４）とバッテリ部（６）と回路基板（７）と圧電ブロア（８）とを備えている。圧電ブロア（８）は、圧電ブロア（８）の天面の中央付近に開口する吸引孔（８９）と、圧電ブロア（８）の底面の中心に開口する吐出孔（９９）と、を有している。圧電ブロア（８）は、回路基板（７）の上筐体（４２）側の第１主面上に実装されている。回路基板（７）は、圧電ブロア（８）に駆動電圧を印加して圧電ブロア（８）を駆動する。回路基板（７）は、吐出孔（９９）と対向する貫通口（７７）を有する。貫通口（７７）は、回路基板（７）の第１主面を正面視したとき、吸引孔（８９）および吐出孔（９９）のうち、吐出孔（９９）と重なる。貫通口（７７）は、回路基板（７）の第１主面を正面視したとき、吐出孔（９９）より広く、吐出孔（９９）を含んでいる。

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明　細　書

発明の名称 ： 吸入装置

技術分野

[0001] 本発明は、鼻水などの液体等を除去する際に利用される吸入装置に関する。

背景技術

[0002] 風邪や鼻炎、蓄膿症などにかかると、鼻水の分泌が過剰になることで鼻づまり等の症状が生じる。一般的には鼻をかむことで鼻づまりを解消することが可能であるが、自ら鼻をかむことができない乳幼児等の場合には、介助者が鼻水を除去する必要がある。

[0003] この際、ちり紙や綿棒を用いて少量の鼻水を除去することは可能であるが、多量の鼻水を除去することは難しかった。そこで、近年では、電動モータとポンプを用いて、鼻水を多量に除去できるようにした吸入装置が普及してきている（例えば特許文献１参照。）。

先行技術文献

特許文献

[0004] 特許文献1：特表２０１０－５２７６３６号公報

発明の概要

発明が解決しようとする課題

[0005] しかしながら、従来の吸入装置は、使用時に発生するモータ音や振動が大きく、乳幼児等がモータ音や振動に反応して体を動かして鼻水の吸引作業を行い難くなる場合があった。そこで、出願人は、電動モータに代えて、使用時に発生するモータ音や振動が小さい圧電素子を用いた吸入装置を開発している。

[0006] 図１７は、駆動源に圧電素子を用いた吸入装置９０１を模式的に示す図である。吸入装置９０１は、ノズル２とセパレータ３と筐体９０４とを備えている。さらに、吸入装置９０１は、筐体９０４内に、バッテリ６１とバッテ

リケース６２と回路基板９０７と圧電ブロア８と固定部１０とを備えている。

[0007] 固定部１０には、円柱状の開口部１１が設けられている。固定部１０上には、圧電ブロア８が載置されている。

[0008] 回路基板９０７は、電源線Ｌ１を介してバッテリ６１に接続している。また、回路基板９０７は、給電線Ｌ２を介して圧電ブロア８に接続している。回路基板９０７には、複数の電子部品８５が実装されている。回路基板９０７は、バッテリ６１の電源電圧から駆動電圧を生成する。そして、回路基板９０７は、圧電ブロア８に駆動電圧を印加して圧電ブロア８を駆動する。

[0009] ノズル２は、吸入口９０を有する。ノズル２は、鼻腔等に挿入され、外部の流体を吸入口９０から吸引する。セパレータ３は、ノズル２の後端に接続して設けられている。セパレータ３の内部は、ノズル２の内部を介して吸入口９０に通じている。セパレータ３は、ノズル２で吸引した鼻水を空気から分離する。筐体９０４は、セパレータ３の内部に通じる流路９５及び流路９６を構成している。また、筐体９０４には気体の排気口４７が設けられている。

[0010] 圧電ブロア８は、セパレータ３の後端に接続して設けられている。圧電ブロア８は、気体の吸引孔８９と気体の吐出孔９９と圧電素子と振動板とを備えている。圧電素子は、振動板に貼付されている。圧電素子は、駆動により振動板を屈曲振動させる。これにより、圧電ブロア８は、セパレータ３が分離した流路９６の空気を吸引孔８９から吸引し、吐出孔９９から吐出する。吐出孔９９から吐出された空気は、排気口４７から筐体９０４の外部に排出される。

[0011] このような構成の吸入装置９０１では、圧電素子の駆動に摺動や摩擦が伴うことがなく、駆動音や振動を大幅に抑制することができる。

[0012] しかしながら、吸入装置９０１の構造では、ノズル２、セパレータ３、圧電ブロア８、回路基板９０７、及びバッテリ６１が長手方向に並んでいる。そのため、近年の吸入装置では装置本体のサイズの一層の小型化が求められ

ているにも係らず、吸入装置９０１では、長手方向の長さが長いという問題がある。

[0013] そこで、本発明の目的は、装置本体のサイズを小型化できる吸入装置を提供することにある。

課題を解決するための手段

[0014] 本発明の吸入装置は、気体の吸引孔と気体の吐出孔と駆動源としての圧電素子とを有する圧電ブロアと、

吸引孔または吐出孔と対向する貫通口を有し、圧電素子に駆動電圧を印加して圧電ブロアを駆動する回路基板と、を備えている。

[0015] そして、貫通口は、回路基板の一方主面を正面視したとき、吸引孔および吐出孔のうち、対向する方の孔と重なる。

[0016] この構成において、駆動電圧が回路基板から圧電素子に印加されると、圧電素子が伸縮する。そして、圧電ブロアは、圧電素子の伸縮力によって駆動する。これにより、圧電ブロアは、気体を回路基板の貫通口を介して吸引孔から吸引し、吐出孔から気体を吐出する。又は、圧電ブロアは、気体を吸引孔から吸引し、吐出孔から回路基板の貫通口を介して気体を吐出する。

[0017] この構成の吸入装置は、圧電ブロアに吸引される気体、又は圧電ブロアから吐出される気体を、回路基板の貫通口から通過させている。そのため、この構成の吸入装置は、圧電ブロアを回路基板の近傍または回路基板上に配置することができる。

[0018] すなわち、この構成の吸入装置は、回路基板および圧電ブロアを重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板および圧電ブロアを並べて配置しなくとも済む。

[0019] したがって、この構成の吸入装置によれば、吸入装置本体のサイズを小型化できる。

[0020] また、吐出孔から回路基板の貫通口を介して吐出される気体を、回路基板またはバッテリ等にあてることで、回路基板またはバッテリ等を冷却することもできる。

[0021] また、圧電ブロアは、回路基板の一方主面上に実装されていることが好ましい。

[0022] この構成では、回路基板上に圧電ブロアを直接実装することで、回路基板に設けた貫通口による強度低下を補い、更なる強度向上を図ることができる。

[0023] また、回路基板の一方主面上には、駆動電圧を供給するための給電パターンが設けられ、圧電ブロアは、給電パターンに接合する電極端子を有することが好ましい。

[0024] この構成では、圧電ブロアと回路基板とを接続する給電線を省略できる。これにより、構成の簡略化、低スペース化、及び低コスト化を実現できる。

[0025] また、貫通口は、回路基板の一方主面を正面視したとき、孔より広く、孔を含んでいることが好ましい。

[0026] この構成では、圧電ブロアから吐出される気体の全ては、貫通口を通過する。すなわち、圧電ブロアから吐出される気体が回路基板にあたって阻害されない。

[0027] したがって、この構成によれば、圧電ブロアの吸引力が低下することを防止できる。

[0028] また、吸入装置は、圧電ブロア及び回路基板を収納する筐体を備えることが好ましい。そして、筐体は、第１流路を介して吸引孔に連通し、筐体の外部に露出する第１開口部と、第２流路を介して吐出孔に連通し、筐体の外部に露出する第２開口部と、を有することが好ましい。

[0029] 筐体は、第１開口部を有する第１筐体と、第２開口部を有する第２筐体と、から構成されることが好ましい。

発明の効果

[0030] 本発明によれば、吸入装置本体のサイズを小型化できる。

図面の簡単な説明

[0031] [図1]本発明の第１の実施形態に係る吸入装置１０１の平面断面図である。

[図2]本発明の第１の実施形態に係る吸入装置１０１の側面断面図である。

[図3]図２に示す圧電ブロア８及び回路基板７の外観斜視図である。

[図4]図２に示す圧電ブロア８及び回路基板７の分解斜視図である。

[図5]図２に示す圧電ブロア８の拡大断面図である。

[図6]図２に示す圧電ブロア８の振動態様を示す模式図である。

[図7]本発明の第２の実施形態に係る吸入装置２０１の側面断面図である。

[図8]図７に示す圧電ブロア８及び回路基板７の分解斜視図である。

[図9]本発明の第３の実施形態に係る吸入装置３０１の側面断面図である。

[図10]本発明の第４の実施形態に係る吸入装置４０１の主要部の側面断面図である。

[図11]本発明の第５の実施形態に係る吸入装置５０１の主要部の側面断面図である。

[図12]本発明の第６の実施形態に係る吸入装置６０１の側面断面図である。

[図13]図１２に示す圧電ブロア８及び回路基板６０７の外観斜視図である。

[図14]図１２に示す筐体６０４の主要部の外観斜視図である。

[図15]本発明の第７の実施形態に係る吸入装置７０１の側面断面図である。

[図16]本発明の第８の実施形態に係る吸入装置８０１の側面断面図である。

[図17]本発明の比較例に係る吸入装置９０１の側面断面図である。

発明を実施するための形態

[0032] 以下、本発明の第１の実施形態に係る吸入装置について図を用いて説明する。

[0033] 図１は、第１の実施形態に係る吸入装置１０１を天面側から視た平面断面図である。図２は、第１の実施形態に係る吸入装置１０１を側面側から視た側面断面図である。図３は、図２に示す圧電ブロア８及び回路基板７の外観斜視図である。図４は、図２に示す圧電ブロア８及び回路基板７の分解斜視図である。

[0034] なお、図１は、図２中に一点鎖線Ａ－Ａ’で示す位置の断面を示している。図１中の矢印は、気体の流れを示している。図２は、図１中に一点鎖線Ｂ－Ｂ’で示す位置の断面を示している。図２中の矢印は、気体の流れを示し

ている。

[0035] 図１および図２に示す吸入装置１０１は、ここでは鼻水等の液体吸入装置である。該吸入装置１０１は、全体として長手方向を有する長尺な形状であり、長手方向の一方（以下、前方と称する。）を患者等に向けて使用される。また、該吸入装置１０１は、長手方向に直交する幅方向と厚み方向とを有しており、厚み方向の寸法が幅方向の寸法よりも薄い薄型に構成されている。

[0036] 吸入装置１０１の概略の構成は次のようなものである。吸入装置１０１は、ノズル２とセパレータ３と筐体４とを備えている。ノズル２、セパレータ３、および筐体４は、この記載順に長手方向の前方から後方にかけて並んでいる。

[0037] ノズル２は、吸入装置１０１の使用時に患者等の鼻腔に挿入され、鼻水等の流体を吸入する。セパレータ３は、吸入装置１０１の使用時にノズル２が吸引する流体に含まれる鼻水等の混合物を分離して貯留する。一方、流体から混合物が分離した気体（この実施形態では空気）は、セパレータ３から筐体４内へ吸引される。筐体４は、使用時に操作者等に把持される。

[0038] また、吸入装置１０１は、筐体４の内蔵部品としてバッテリ部６と回路基板７と圧電ブロア８とを備えている。バッテリ部６は、バッテリ６１とバッテリケース６２とを備えている。バッテリケース６２は、バッテリ６１を取り換え可能に保持している。

[0039] 回路基板７は、給電回路等を構成しており、電源スイッチ７１を備えている。電源スイッチ７１は、筐体４に設けられた開口から外部に露出している。回路基板７は、電源スイッチ７１の押下状態に応じてバッテリ部６から圧電ブロア８への給電をオンまたはオフする。

[0040] 圧電ブロア８は、筐体４内の流路に負圧を生じさせ、セパレータ３から筐体４内に気体を吸引する。

[0041] 以下に、各部の詳細な構成について説明する。

[0042] ノズル２は、一体の弾性材料からなる。ノズル２は、前方ほど細くなるよ

うに外形に傾斜がついている。そして、ノズル２には、吸入口９０と流路９１とが設けられている。吸入口９０は、ノズル２の前方端に設けられた、鼻水等を含む外部の流体を吸入する開口である。

[0043] 流路９１は、ノズル２の内側を長手方向に貫通して設けられており、吸入口９０に通じている。このノズル２は、セパレータ３の前方側に気密した状態で連結されており、セパレータ３から取り外し可能になっている。

[0044] セパレータ３は、ケース部３１と筒状部３２とキャップ部３３と筒状部３４とを備えている。ケース部３１は、後方に開口する箱状の部材である。筒状部３２は、ケース部３１に付設された筒状の部位であり、ケース部３１の前方面から前方に突出し、ケース部３１の開口内底面から後方に伸びている。

[0045] 筒状部３２の前方端には、ノズル２が嵌め合わされている。キャップ部３３は、ケース部３１の後方に嵌め合わされる蓋状の部材である。筒状部３４は、キャップ部３３に付設された筒状の部位であり、キャップ部３３から前方に伸びている。

[0046] また、セパレータ３には流路９２，９３，９４が設けられている。流路９２は、筒状部３２の内側を長手方向に貫通して設けられており、ノズル２の流路９１に通じている。流路９３は、ケース部３１の内側に設けられており、筒状部３２の流路９２と通じている。流路９４は、筒状部３４の内側を長手方向に貫通して設けられており、ケース部３１の流路９３と通じている。

[0047] 筒状部３２と筒状部３４とは、ケース部３１の内部で長手方向に互い違いになるように配置され、流路９３を介して流路９２と流路９４とは通じている。このことによってノズル２からセパレータ３に導かれた流体に含まれる鼻水等の液体は、ケース部３１の内部（流路９３）から漏出し難くなっており、流体に含まれる気体のみがセパレータ３から筐体４内へ吸引される。

[0048] キャップ部３３の後方面には凹部３５が設けられている。このセパレータ３は、この凹部３５に筐体４を嵌め込むことで、筐体４の前方側に気密した状態で連結されている。凹部３５の内底面にはフィルタ３６が設けられてい

る。

[0049] フィルタ３６は、不織紙状やスポンジ状の膜体であり、セパレータ３側から筐体４側に鼻水等の液体が漏出することを防ぐ機能を有している。なお、フィルタ３６は必ずしも設けなくても良い。

[0050] また、セパレータ３は、ねじ３７によって筐体４と連結されており、ねじ３７を外すことによって筐体４から分離可能となっている。また、ケース部３１とキャップ部３３との間も、ねじ３７を外すことによって分割可能となっている。

[0051] このため、セパレータ３からの鼻水の除去と洗浄が可能である。各部の連結部分には気密のために適宜オーリングを設けている。なお、各部は、ねじ３７の他の連結手段を用いて分離可能に連結されていてもよく、各々が一体に構成されていてもよい。

[0052] 筐体４は、下筐体４１と上筐体４２とバッテリカバー４３とによって構成されている。下筐体４１は、厚み方向の天面側に開口が開いた薄手の箱状である。上筐体４２は、厚み方向の底面側に開口が開いた薄手の箱状である。

[0053] 上筐体４２は、容器状となるように下筐体４１に連結されている。このため、下筐体４１、バッテリカバー４３、及び上筐体４２の一部は、内部空間１００を構成している。内部空間１００には、バッテリ部６と回路基板７と圧電ブロア８とが収納されている。

[0054] 下筐体４１には、バッテリ部６のバッテリ６１を取り換え可能にするための開口が天面側に設けられており、バッテリカバー４３は、当該開口を覆うように下筐体４１の天面側に取り付けられている。下筐体４１には、詳細を後述する排気口４７が設けられている。内部空間１００は、上筐体４２とバッテリカバー４３との継ぎ目部分や排気口４７を介して筐体４の外部空間と通じ外気圧と等しくなっている。

[0055] 下筐体４１と上筐体４２とは、内部空間１００において回路基板７を支持している。

[0056] また、上筐体４２の内側には、流路９５及び流路９６が設けられている。

流路９５は、セパレータ３の流路９４に通じている。流路９５は、流路９４と通じている箇所から上筐体４２の内側を長手方向の後方に延び、途中で逆Ｕ字状に屈曲し、流路９６に通じている。流路９６は、円柱状であり、圧電ブロア８の吸引孔８９に通じている。

[0057] 圧電ブロア８は、板状であり、流路９５及び流路９６を気密するように、上筐体４２に接合されている。そして、圧電ブロア８は、圧電ブロア８の天面の中央付近に開口する吸引孔８９と、圧電ブロア８の底面の中心に開口する吐出孔９９と、を有している。圧電ブロア８は、回路基板７の上筐体４２側の第１主面（一方主面）上に実装されている。

[0058] なお、圧電ブロア８と回路基板７の接合方法としては、例えば、接着剤による接着、両面テープによる固定、ネジによる締結、駆動回路上に設けた突起への篏合、スポット溶接、掘り込み部への嵌め合い等により行われる。

[0059] 回路基板７は、電源線Ｌ１を介してバッテリ６１に接続している。回路基板７の第１主面上には、給電パターン７８が実装されている。回路基板７の下筐体４１側の第２主面（他方主面）上には、複数の電子部品８５が実装されている。回路基板７は、バッテリ６１の電源電圧から駆動電圧を生成する。そして、回路基板７は、圧電ブロア８に駆動電圧を印加して圧電ブロア８を駆動する。

[0060] ここで、回路基板７は、吐出孔９９と対向する貫通口７７を有する。貫通口７７は、回路基板７の第１主面を正面視したとき、吸引孔８９および吐出孔９９のうち、吐出孔９９と重なる。貫通口７７は、回路基板７の第１主面を正面視したとき、吐出孔９９より広く、吐出孔９９を含んでいる。

[0061] この吸入装置１０１では、電源スイッチ７１がオンされて圧電ブロア８が駆動すると、圧電ブロア８は、流路９６から気体を吸引孔８９から吸引し、吐出孔９９から貫通口７７を介して内部空間１００に気体を吐出する。吐出孔９９から吐出された気体は、排気口４７から排出される。これにより、流路９６には負圧が発生することになる。

[0062] したがって、吸入装置１０１の全体としては、筐体４で流路９６に発生す

る負圧によって、筐体４の流路９５、セパレータ３の流路９４，９３，９２、およびノズル２の流路９１に流体の流れが生じ、ノズル２の吸入口９０から外部の流体が吸引されることになる。

[0063] なお、吸入口９０が、本発明の第１開口部に相当する。排気口４７が、本発明の第２開口部に相当する。流路９６，流路９５，流路９４，流路９３，流路９２、および流路９１が、本発明の第１流路に相当する。内部空間１００が、本発明の第２流路に相当する。ノズル２、セパレータ３、及び流路９６，流路９５を構成する上筐体４２の部分が、本発明の第１筐体に相当する。下筐体４１、バッテリカバー４３、及び内部空間１００を構成する上筐体４２の部分が、本発明の第２筐体に相当する。

[0064] ここで、圧電ブロア８の詳細な構成について説明する。

[0065] 図５は、圧電ブロア８の周辺を拡大して示す側面断面図である。圧電ブロア８は、圧電素子８１と、構造体８２と、電極端子８８と、を備えている。構造体８２は、円板状である。構造体８２の天面の中央付近には、吸引孔８９が開口している。また、構造体８２の底面の中心には、吐出孔９９が開口している。また、この構造体８２の内側には、流路９７とポンプ室９８とが設けられている。

[0066] 流路９７は、吸引孔８９及び吐出孔９９に通じている。ポンプ室９８は、薄い円柱状の空間であり、吐出孔９９に面する流路９７の一部に通じている。このポンプ室９８は、流路９７とともに吸入装置１０１における流路の一部を構成している。

[0067] 構造体８２は、例えばステンレススチール（ＳＵＳ）から構成されている。構造体８２におけるポンプ室９８の内天面は、屈曲振動が可能な振動板８３として構成されている。振動板８３は円板状であり、底面がポンプ室９８に面していて、天面に圧電素子８１が貼付されている。振動板８３の底面は、ポンプ室９８を間に介して吐出孔９９と対向している。

[0068] 圧電素子８１は、例えばチタン酸ジルコン酸鉛系セラミックスから構成されている。圧電素子８１は、厚み方向に薄い円板状であり、交流の駆動電圧

が回路基板７から印加されることで圧電素子８１の面方向に伸縮しようとする圧電性を有している。

[0069] 圧電素子８１の両主面には、電極が設けられている。圧電素子８１の両主面の電極は、電極端子８８に接続している。電極端子８８は、回路基板７の給電パターン７８に接合している。

[0070] 次に、圧電ブロア８の振動態様について説明する。図６は、圧電ブロア８の振動態様を示す模式図である。図６中の矢印は、気体の流れを示している。

[0071] 圧電素子８１と振動板８３とは、互いに貼付されてユニモルフ構造を構成している。交流の駆動電圧が回路基板７から電極端子８８を介して圧電素子８１の両電極に印加されると、圧電素子８１が伸縮する。そして、圧電素子８１と振動板８３とは、圧電素子８１の伸縮によって図６（Ｂ）（Ｃ）に示すように周期的に同心円状に屈曲振動する。

[0072] 具体的には、図６（Ａ）に示す静止状態から圧電素子８１が伸びようとする場合には、図６（Ｂ）に示すように、振動板８３が圧電素子８１側（底面側）に凸に屈曲してポンプ室９８の体積が増大する。これにより、ポンプ室９８に負圧が生じ、ポンプ室９８に連通する流路９７に負圧が伝わり、流路９７の流体がポンプ室９８に吸引される。

[0073] 次に、圧電素子８１が縮もうとすると、図６（Ｃ）に示すように、振動板８３がポンプ室９８側（天面側）に凸に屈曲してポンプ室９８の体積が減少する。これにより、ポンプ室９８の気体が吐出孔９９から貫通口７７を介して外部（内部空間１００）に吐出されるとともに、その気体の流れに引き込まれて流路９７内の気体が吐出孔９９から貫通口７７を介して外部（内部空間１００）に吐出される。内部空間１００に吐出された気体は、排気口４７から筐体４の外部へ排出される（図２参照）。

[0074] このように、圧電ブロア８では、圧電素子８１と振動板８３との屈曲振動に伴い、ポンプ室９８では周期的な体積変動と圧力変動とが繰り返し生じ、気体の流れに慣性力が働くようになる。これにより、流路９７の流体が吐出

孔９９から吐出される気体の流れが定常的に生じるようになる。

[0075] この圧電ブロア８では、部材同士が摩擦（摺動）することが無いため、従来の電動モータ式の駆動部よりも、発生する駆動音や振動が小さい。したがって、吸入装置１０１から外部空間に漏れる圧電ブロア８の駆動音や振動は極めて小さなものになる。

[0076] また、吸入装置１０１は、圧電ブロア８から吐出される気体を、回路基板７の貫通口７７から通過させている。そのため、吸入装置１０１は、圧電ブロア８を回路基板７の近傍または回路基板７上に配置することができる。

[0077] すなわち、吸入装置１０１は、回路基板７および圧電ブロア８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板９０７および圧電ブロア８を長手方向へ並べて配置しなくとも済む。

[0078] したがって、吸入装置１０１によれば、装置本体のサイズを小型化できる。

[0079] また、吸入装置１０１は、回路基板７上に圧電ブロア８を直接実装している。そのため、吸入装置１０１は、回路基板７に設けた貫通口７７による強度低下を補い、更なる強度向上を図ることができる。

[0080] また、圧電ブロア８は、給電パターン７８に接合する電極端子８８を有している。

[0081] そのため、吸入装置１０１は、圧電ブロア８と回路基板７とを接続する給電線Ｌ２（図１７参照）を省略できる。これにより、構成の簡略化、低スペース化、及び低コスト化を実現できる。

[0082] また、貫通口７７は、回路基板７の一方主面を正面視したとき、孔より広く、孔を含んでいる。

[0083] そのため、吸入装置１０１では、圧電ブロア８から吐出される気体の全ては、貫通口７７を通過する。すなわち、圧電ブロア８から吐出される気体が回路基板７にあたって阻害されない。

[0084] したがって、吸入装置１０１によれば、圧電ブロア８の吸引力が低下することを防止できる。

[0085] 次に、本発明の第２の実施形態に係る吸入装置について説明する。

[0086] 図７は、本発明の第２の実施形態に係る吸入装置２０１の側面断面図である。図８は、図７に示す圧電ブロア８及び回路基板７の分解斜視図である。

[0087] なお、図７は、模式図であり、説明簡略化のため詳細な図示を省略している。図７中の矢印は、気体の流れを示している。

[0088] 第２の実施形態に係る吸入装置２０１が吸入装置１０１と相違する点は、回路基板７及び圧電ブロア８の配置である。その他の点は、吸入装置１０１と同じであるため、説明を省略する。

[0089] 圧電ブロア８は、回路基板７の第１主面（一方主面）上に実装されている。回路基板７の貫通口７７は、吸引孔８９と対向する。貫通口７７は、回路基板７の第１主面を正面視したとき、吸引孔８９と重なる。なお、圧電ブロア８の電極端子８８は、回路基板７の給電パターン７８に接合している。

[0090] この構成において、圧電ブロア８は駆動時、気体を回路基板７の貫通口７７を介して吸引孔８９から吸引し、吐出孔９９から気体を吐出する。

[0091] 吸入装置２０１は、圧電ブロア８に吸引される気体を、回路基板７の貫通口７７から通過させている。そのため、吸入装置２０１は、圧電ブロア８を回路基板７の近傍または回路基板７上に配置することができる。

[0092] すなわち、吸入装置２０１は、回路基板７および圧電ブロア８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板７および圧電ブロア８を長手方向へ並べて配置しなくとも済む。

[0093] したがって、吸入装置２０１によれば、吸入装置１０１と同様に、装置本体のサイズを小型化できる。

[0094] 次に、本発明の第３の実施形態に係る吸入装置について説明する。

[0095] 図９は、本発明の第３の実施形態に係る吸入装置３０１の側面断面図である。

[0096] なお、図９は、模式図であり、説明簡略化のため詳細な図示を省略している。図９中の矢印は、気体の流れを示している。

[0097] 第３の実施形態に係る吸入装置３０１が吸入装置１０１と相違する点は、

回路基板７及び圧電ブロア８の配置である。吸入装置３０１では、回路基板７及び圧電ブロア８の配置に併せて、厚みの厚いセパレータ３０３及び筐体３０４を備えている。その他の点は、吸入装置１０１と同じであるため、説明を省略する。

[0098] この実施形態においても、圧電ブロア８は、回路基板７の第１主面（一方主面）上に実装されている。回路基板７の貫通口７７は、吐出孔９９と対向する。また、貫通口７７は、回路基板７の第１主面を正面視したとき、吸引孔８９および吐出孔９９のうち、吐出孔９９と重なる。貫通口７７は、回路基板７の第１主面を正面視したとき、吐出孔９９より広く、吐出孔９９を含んでいる。

[0099] 吸入装置３０１は、圧電ブロア８から吐出される気体を、回路基板７の貫通口７７から通過させている。そのため、吸入装置３０１は、圧電ブロア８を回路基板７の近傍または回路基板７上に配置することができる。

[0100] すなわち、吸入装置３０１は、回路基板７および圧電ブロア８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板９０７および圧電ブロア８を長手方向へ並べて配置しなくとも済む。

[0101] したがって、吸入装置３０１によれば、吸入装置１０１と同様に、装置本体のサイズを小型化できる。吸入装置３０１によれば、長手方向の長さを、吸入装置１０１より短くできる。

[0102] さらに、吸入装置３０１では、吐出孔９９及び回路基板７の貫通口７７がバッテリに向くよう、回路基板７及び圧電ブロア８が配置されている。すなわち、吐出孔９９から回路基板７の貫通口７７を介して吐出される気体がバッテリにあたるよう、回路基板７及び圧電ブロア８が配置されている。これにより、吸入装置３０１は、さらに、バッテリ６１を冷却することができる。

[0103] 次に、本発明の第４の実施形態に係る吸入装置について説明する。

[0104] 図１０は、本発明の第４の実施形態に係る吸入装置４０１の主要部の側面断面図である。

[0105] なお、図１０は、模式図であり、説明簡略化のため詳細な図示を省略している。図１０中の矢印は、気体の流れを示している。

[0106] 第４の実施形態に係る吸入装置４０１が吸入装置１０１と相違する点は、排気口４７を有さない筐体４０４を備える点である。その他の点は、吸入装置１０１と同じであるため、説明を省略する。

[0107] 吸入装置４０１では、筐体４０４が排気口４７を有さないため、吐出孔９９から回路基板７の貫通口７７を介して吐出される気体が筐体４０４にあたり、回路基板７の第２主面の面方向へ流れる。これにより、吸入装置４０１は、さらに、回路基板７上の複数の電子部品８５を冷却することができる。

[0108] 次に、本発明の第５の実施形態に係る吸入装置について説明する。

[0109] 図１１は、本発明の第５の実施形態に係る吸入装置５０１の主要部の側面断面図である。

[0110] なお、図１１は、模式図であり、説明簡略化のため詳細な図示を省略している。図１１中の矢印は、気体の流れを示している。

[0111] 第５の実施形態に係る吸入装置５０１が吸入装置１０１と相違する点は、カバー５０４を備える点である。カバー５０４は、支持部５０５によって回路基板７に取り付けられている。支持部５０５は、通気孔５０６を有する。その他の点は、吸入装置１０１と同じであるため、説明を省略する。

[0112] 吸入装置５０１では、カバー５０４を備えるため、吐出孔９９から回路基板７の貫通口７７を介して吐出される気体がカバー５０４にあたり、回路基板７の第２主面の面方向へ流れる。これにより、吸入装置５０１は、さらに、回路基板７上の複数の電子部品８５を冷却することができる。

[0113] 次に、本発明の第６の実施形態に係る吸入装置について説明する。

[0114] 図１２は、本発明の第６の実施形態に係る吸入装置６０１の側面断面図である。図１３は、図１２に示す圧電ブロア８及び回路基板６０７の外観斜視図である。図１４は、図１２に示す筐体６０４の主要部の外観斜視図である。

[0115] なお、図１２は、模式図であり、説明簡略化のため詳細な図示を省略して

いる。図１２中の矢印は、気体の流れを示している。

[0116] 第６の実施形態に係る吸入装置６０１が吸入装置１０１と主に相違する点は、回路基板６０７及び筐体６０４である。回路基板６０７は、吸入装置１０１の回路基板７より長手方向に長い。複数の電子部品８５と圧電ブロア８とは、回路基板６０７の同一面上に実装されている。

[0117] また、筐体６０４は、回路基板６０７の長手方向の長さに併せて長手方向に長くなっている。筐体６０４は、排気口４７を有さず、Ｕ字状の突起６４０及び壁部６４１を有している。突起６４０の上面は、圧電ブロア８の底面に接合している。セパレータ６０３も、筐体６０４の長手方向の長さに併せて長手方向に長くなっている。

[0118] なお、その他の吸入装置６０１の構成は、吸入装置１０１の構成と同じであるため、説明を省略する。

[0119] この構成において、圧電ブロア８は駆動時、貫通口７７を介して気体を吸引孔８９から吸引し、吐出孔９９から外部に吐出する。

[0120] 吸入装置６０１は、圧電ブロア８が吸引する気体を、回路基板６０７の貫通口７７から通過させている。そのため、吸入装置６０１は、圧電ブロア８を回路基板６０７の近傍または回路基板６０７上に配置することができる。

[0121] すなわち、吸入装置６０１は、回路基板６０７および圧電ブロア８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板６０７および圧電ブロア８を長手方向へ並べて配置しなくとも済む。

[0122] したがって、吸入装置６０１によれば、吸入装置１０１と同様に、装置本体のサイズを小型化できる。

[0123] ここで、吸入装置６０１では筐体６０４が、排気口４７を有さず、Ｕ字状の突起６４０及び壁部６４１を有している。そのため、吐出孔９９から吐出される気体は、突起６４０及び壁部６４１にあたり、回路基板６０７上の複数の電子部品８５側へ流れる。

[0124] これにより、吸入装置６０１は、さらに、回路基板６０７上の複数の電子部品８５を冷却することができる。

[0125] また、複数の電子部品８５と圧電ブロア８とが回路基板６０７の同一面上に実装されているため、吸入装置６０１は、装置本体の厚みを吸入装置１０１より薄くできる。

[0126] ここで、ｎ個の圧電ブロアを直列または並列に配置した場合でも、吸入装置１００と同様の効果を奏する。

[0127] まず、ｎ個の圧電ブロアを直列に配置した場合について説明する。

[0128] 図１５は、本発明の第７の実施形態に係る吸入装置７０１の側面断面図である。

[0129] なお、図１５は、ｎ＝２のときの図である。また、図１５は、模式図であり、説明簡略化のため詳細な図示を省略している。図１５中の矢印は、気体の流れを示している。

[0130] 第７の実施形態に係る吸入装置７０１が吸入装置１０１と相違する点は、圧電ブロア２８を備える点である。その他の点は、吸入装置１０１と同じであるため、説明を省略する。

[0131] 圧電ブロア２８の構成は、圧電ブロア８の構成と同じである。圧電ブロア２８の吐出孔９９が圧電ブロア８の吸引孔８９に接続するよう、圧電ブロア８及び圧電ブロア２８は積層されている。すなわち圧電ブロア２８は、圧電ブロア８と直列に配置されている。なお、圧電ブロア２８の電極端子８８は、回路基板７の給電パターンに接続している。

[0132] そして、圧電ブロア８は、回路基板７の上筐体４２側の第１主面（一方主面）上に実装されている。回路基板７の貫通口７７は、吐出孔９９と対向する。貫通口７７は、回路基板７の第１主面を正面視したとき、吐出孔９９と重なる。

[0133] この構成において、圧電ブロア２８は駆動時、気体を吸引孔８９から吸引し、吐出孔９９から気体を吐出する。圧電ブロア８は駆動時、圧電ブロア２８の吐出孔９９から吐出された気体を、吐出孔９９から回路基板７の貫通口７７及び排気口４７を介して吸入装置７０１の外部に吐出する。

[0134] 吸入装置７０１は、圧電ブロア８が吐出する気体を、回路基板７の貫通口

７７から通過させている。そのため、吸入装置７０１は、圧電ブロア８、２８を回路基板７の近傍または回路基板７上に配置することができる。

[0135] すなわち、吸入装置７０１は、回路基板７および圧電ブロア８、２８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板７および圧電ブロア８、２８を長手方向へ並べて配置しなくとも済む。

[0136] したがって、吸入装置７０１によれば、吸入装置１０１と同様に、装置本体のサイズを小型化できる。

[0137] また、吸入装置７０１では、２個の圧電ブロア８、２８が直列に配置されている。そのため、吸入装置７０１は、圧電ブロア８を１個配置した場合と比べて最大吸引圧力を２倍に増加させることができる。

[0138] なお、吸入装置７０１では、ｎ＝２、すなわち２個の圧電ブロア８、２８が直列に配置されているが、これに限るものではない。実施の際は、ｎ≧３の場合、すなわち３個以上の圧電ブロアが直列に配置されていてもよい。この場合、最大吐出流量をｎ倍に増加させることができる。

[0139] 次に、ｎ個の圧電ブロアを並列に配置した場合について説明する。

[0140] 図１６は、本発明の第８の実施形態に係る吸入装置８０１の側面断面図である。

[0141] なお、図１６は、ｎ＝２のときの図である。また、図１６は、模式図であり、説明簡略化のため詳細な図示を省略している。図１６中の矢印は、気体の流れを示している。

[0142] 第８の実施形態に係る吸入装置８０１が吸入装置６０１と相違する点は、貫通口８７７及び圧電ブロア２８を備え、突起６４０を備えない点である。その他の点は、吸入装置６０１と同じであるため、説明を省略する。

[0143] 圧電ブロア２８の構成は、圧電ブロア８の構成と同じである。圧電ブロア２８は、回路基板６０７の圧電ブロア８と同じ第１主面（一方主面）上に実装されている。

[0144] また、回路基板６０７は、貫通口８７７を有する。回路基板６０７の貫通口８７７は、吸引孔８９と対向する。貫通口８７７は、回路基板６０７の第

１主面を正面視したとき、吸引孔８９と重なる。なお、圧電ブロア２８の電極端子８８は、回路基板６０７の給電パターンに接合している。

[0145] また、圧電ブロア８は、回路基板６０７の第１主面（一方主面）上に実装されている。回路基板６０７の貫通口７７は、吸引孔８９と対向する。貫通口７７は、回路基板６０７の第１主面を正面視したとき、吸引孔８９と重なる。

[0146] すなわち、圧電ブロア８及び圧電ブロア２８は、並列に配置されている。

[0147] この構成において、圧電ブロア２８は駆動時、貫通口８７７を介して気体を吸引孔８９から吸引し、吐出孔９９から外部に吐出する。圧電ブロア８は駆動時、貫通口７７を介して気体を吸引孔８９から吸引し、吐出孔９９から外部に吐出する。

[0148] 吸入装置８０１は、圧電ブロア８、２８が吸引する気体を、回路基板６０７の貫通口７７、８７７から通過させている。そのため、吸入装置８０１は、圧電ブロア８、２８を回路基板６０７の近傍または回路基板６０７上に配置することができる。

[0149] すなわち、吸入装置８０１は、回路基板６０７および圧電ブロア８、２８を重ねて配置できるため、図１７に示す吸入装置９０１のように回路基板６０７および圧電ブロア８、２８を並べて長手方向へ配置しなくとも済む。

[0150] したがって、吸入装置８０１によれば、吸入装置１０１と同様に、装置本体のサイズを小型化できる。

[0151] また、吸入装置８０１では、２個の圧電ブロア８、２８が並列に配置されている。そのため、吸入装置８０１は、圧電ブロア８を１個配置した場合と比べて最大吸引流量を２倍に増加させることができる。

[0152] なお、吸入装置８０１では、ｎ＝２、すなわち２個の圧電ブロア８、２８が並列に配置され、回路基板６０７が２つの貫通口７７、８７７を有しているが、これに限るものではない。実施の際は、ｎ≧３の場合、すなわち３個以上の圧電ブロアが並列に配置され、回路基板が３個以上の貫通口（すなわち圧電ブロアと同数の貫通口）を有していてもよい。この場合、最大吸引流

量をｎ倍に増加させることができる。

[0153] なお、前記各実施形態において、ノズル２の形状は、上述の例に限らず、他の形状であってもよい。例えば、母乳吸入装置や痰吸入装置として吸入装置１０１を用いる場合には、漏斗状やストロー状にノズル２を構成してもよい。

[0154] また、前記各実施形態にでは、セパレータ３において、流体に含まれる気体と混合物（液体）とを分離する構造は、上記以外の構造であってもよい。例えば、セパレータ３に弁構造を採用したりすることでも、流体に含まれる気体と液体とを容易に分離することができる。

[0155] また、前記各実施形態において、圧電ブロア８の構造も、上記以外の構造であってもよい。例えば、圧電ブロア８に設ける吐出側流路の数や、吸入側流路の数、それぞれの経路等を適宜に変更することができる。

[0156] また、前記各実施形態では気体として空気を用いているが、これに限るものではない。例えば、空気以外の気体であっても適用できる。

[0157] また、前記各実施形態において、吸入する対象となる流体は、液体に限られず、固体やゲル状の物質であってもよい。本発明は、微小な埃や粉塵を回収する集塵装置や、工作物に塗布しすぎた糊や接着剤を回収する装置などへの応用も可能である。

[0158] 最後に、前記各実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、上述の実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0159] Ｌ１…電源線

Ｌ２…給電線

２…ノズル

３…セパレータ

４…筐体

６…バッテリ部

７…回路基板

８…圧電ブロア

１０…固定部

１１…開口部

２８…圧電ブロア

３１…ケース部

３２…筒状部

３３…キャップ部

３４…筒状部

３５…凹部

３６…フィルタ

４１…下筐体

４２…上筐体

４３…バッテリカバー

４７…排気口

６１…バッテリ

６２…バッテリケース

７１…電源スイッチ

７７…貫通口

７８…給電パターン

８１…圧電素子

８２…構造体

８３…振動板

８５…電子部品

８８…電極端子

８９…吸引孔

９０…吸入口

９１，９２，９３，９４，９５，９６，９７…流路

９８…ポンプ室

９９…吐出孔

１００…内部空間

１０１…吸入装置

２０１…吸入装置

３０１…吸入装置

３０３…セパレータ

３０４…筐体

４０１…吸入装置

４０４…筐体

５０１…吸入装置

５０４…カバー

５０５…支持部

６０１…吸入装置

６０３…セパレータ

６０４…筐体

６０７…回路基板

６４０…突起

６４１…壁部

７０１…吸入装置

８０１…吸入装置

８７７…貫通口

９０１…吸入装置

９０４…筐体

９０７…回路基板

請求の範囲

[請求項1] 気体の吸引孔と前記気体の吐出孔と駆動源としての圧電素子とを有する圧電ブロアと、

前記吸引孔または前記吐出孔と対向する貫通口を有し、前記圧電素子に駆動電圧を印加して前記圧電ブロアを駆動する回路基板と、を備え、

前記貫通口は、前記回路基板の一方主面を正面視したとき、前記吸引孔および前記吐出孔のうち、対向する方の孔と重なる、

吸入装置。

[請求項2] 前記圧電ブロアは、前記回路基板の前記一方主面上に実装されている、

請求項１に記載の吸入装置。

[請求項3] 前記回路基板の前記一方主面上には、前記駆動電圧を供給するための給電パターンが設けられ、

前記圧電ブロアは、前記給電パターンに接合する電極端子を有する、

請求項２に記載の吸入装置。

[請求項4] 前記貫通口は、前記回路基板の一方主面を正面視したとき、前記孔より広く、前記孔を含んでいる、

請求項１乃至請求項３のいずれかに記載の吸入装置。

[請求項5] 前記圧電ブロア及び前記回路基板を収納する筐体を備え、

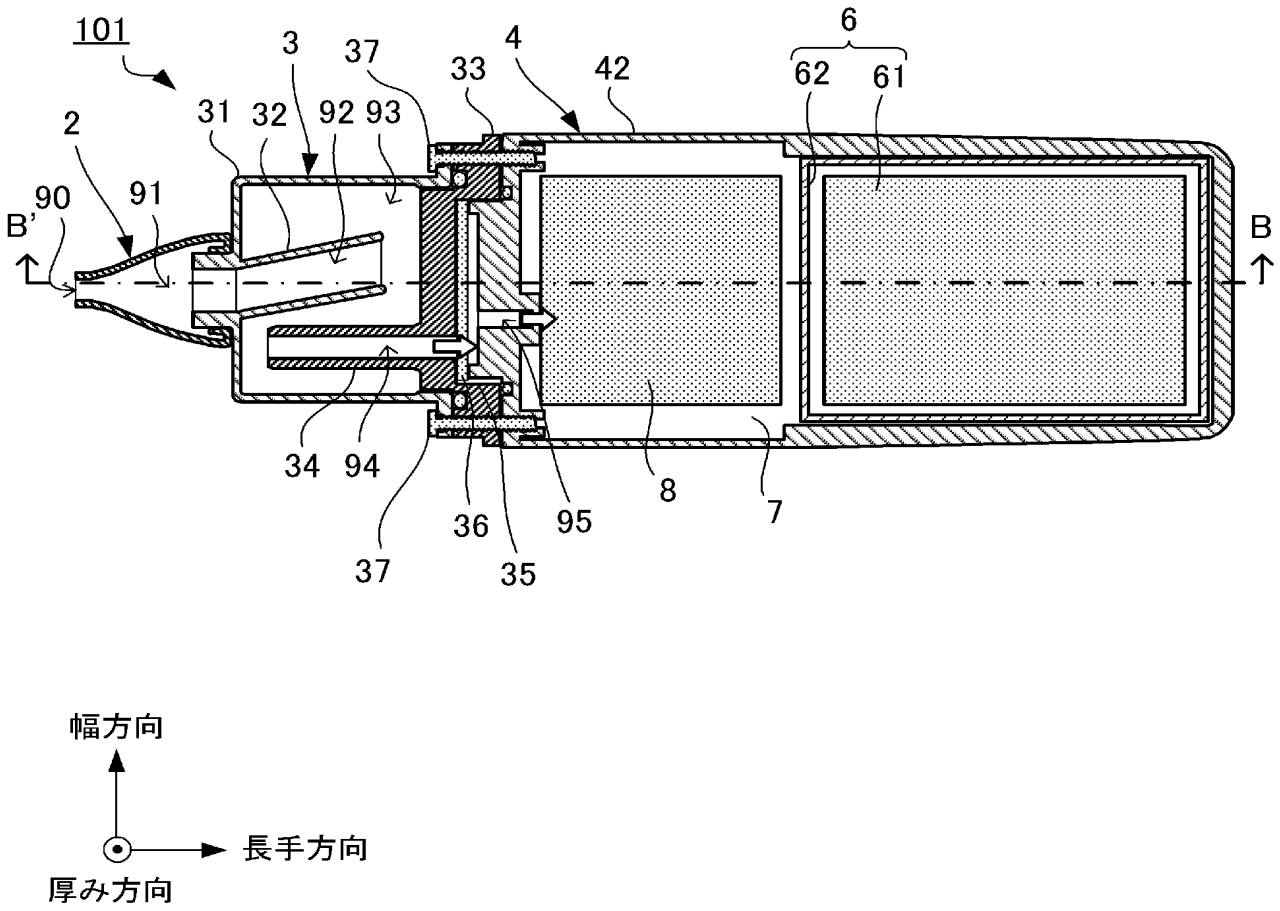
前記筐体は、第１流路を介して前記吸引孔に連通し、前記筐体の外部に露出する第１開口部と、第２流路を介して前記吐出孔に連通し、前記筐体の外部に露出する第２開口部と、を有する、

請求項１乃至請求項４のいずれかに記載の吸入装置。

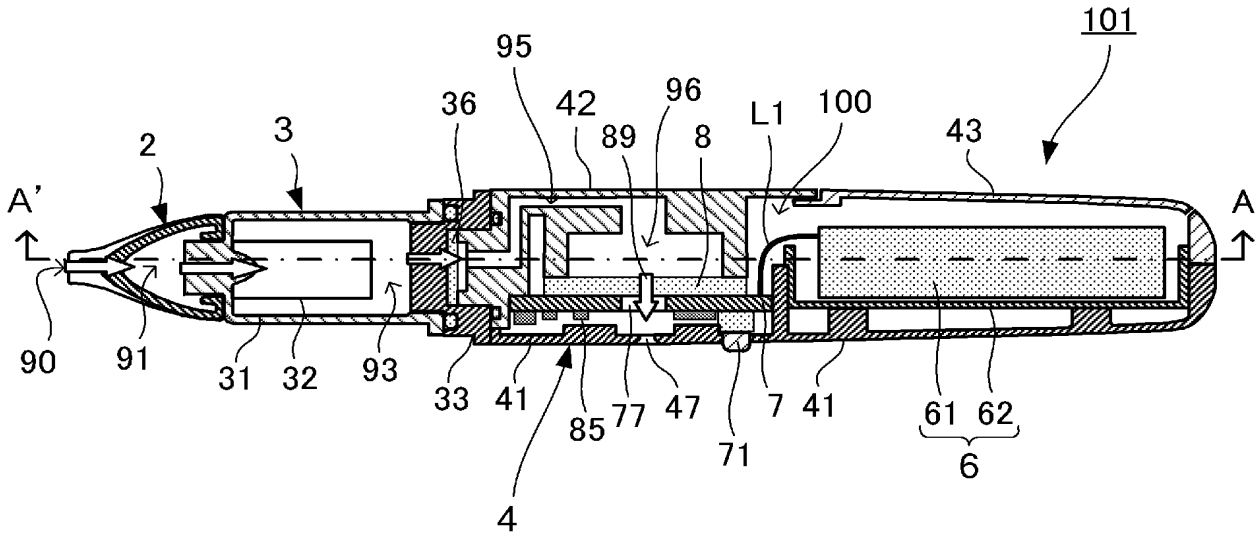
[請求項6] 前記筐体は、前記第１開口部を有する第１筐体と、前記第２開口部を有する第２筐体と、から構成される、

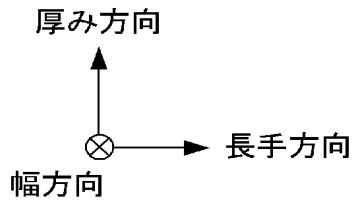
請求項５に記載の吸入装置。

[図1]
【図1】


101
3
37
4
33
42
6
62
61
31
32
92
93
2
90
91
B'
B
34
94
8
7
36
95
37
35
幅方向
長手方向
厚み方向

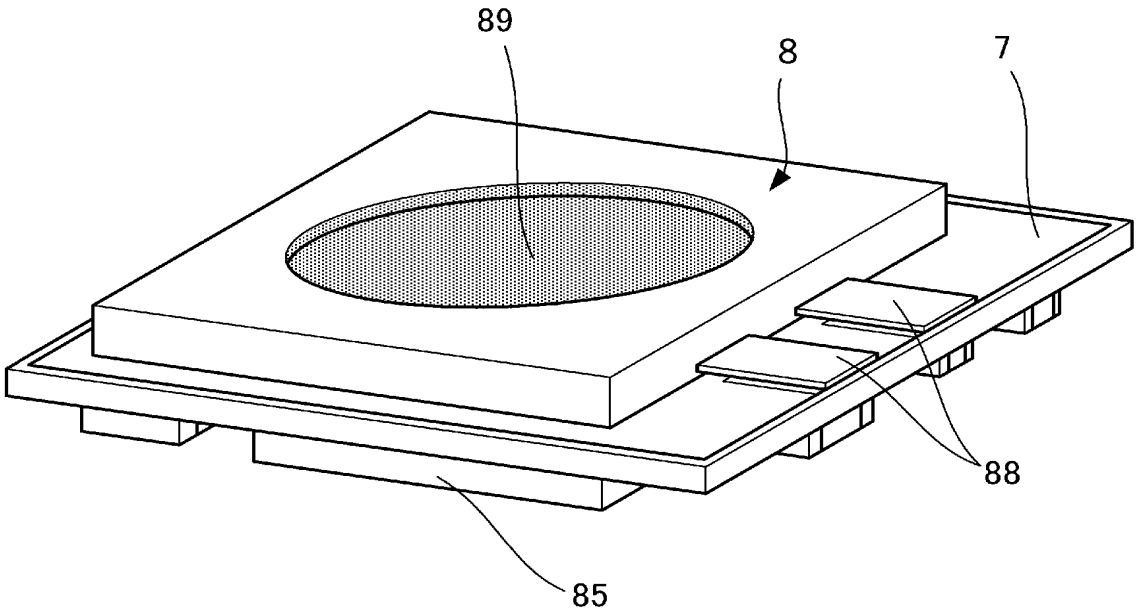
[図2]
【図２】


101
95
36
42
96
L1
100
43
2
3
89
8
A'
A
90
91
31
32
93
33
41
85
77
47
71
7
41
61
62
6
4


厚み方向
長手方向
幅方向

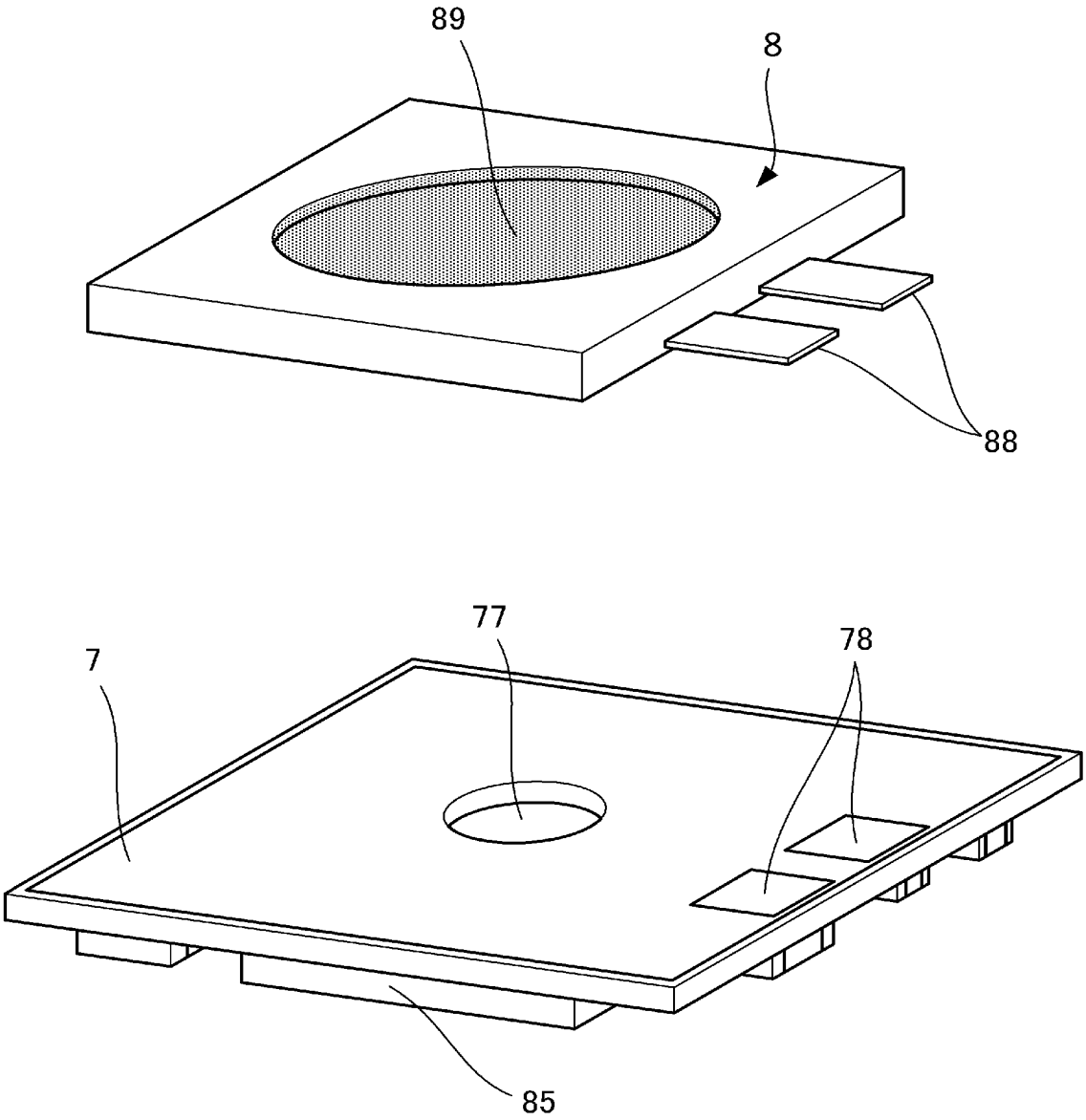
[図3]

【図3】



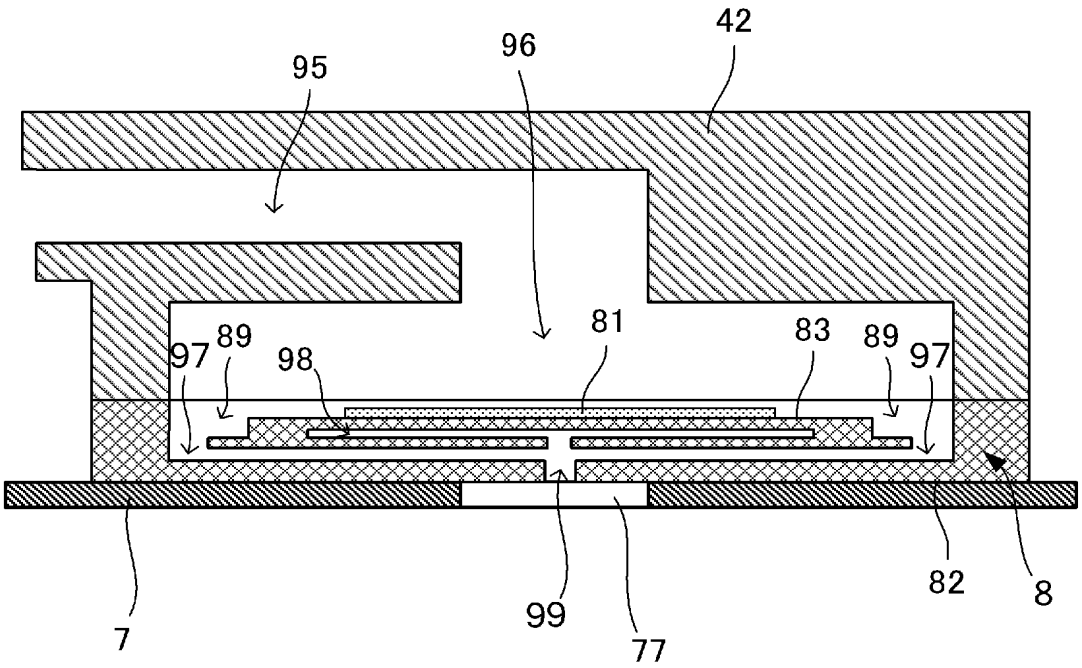
[図4]

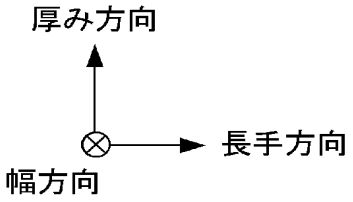
【図4】



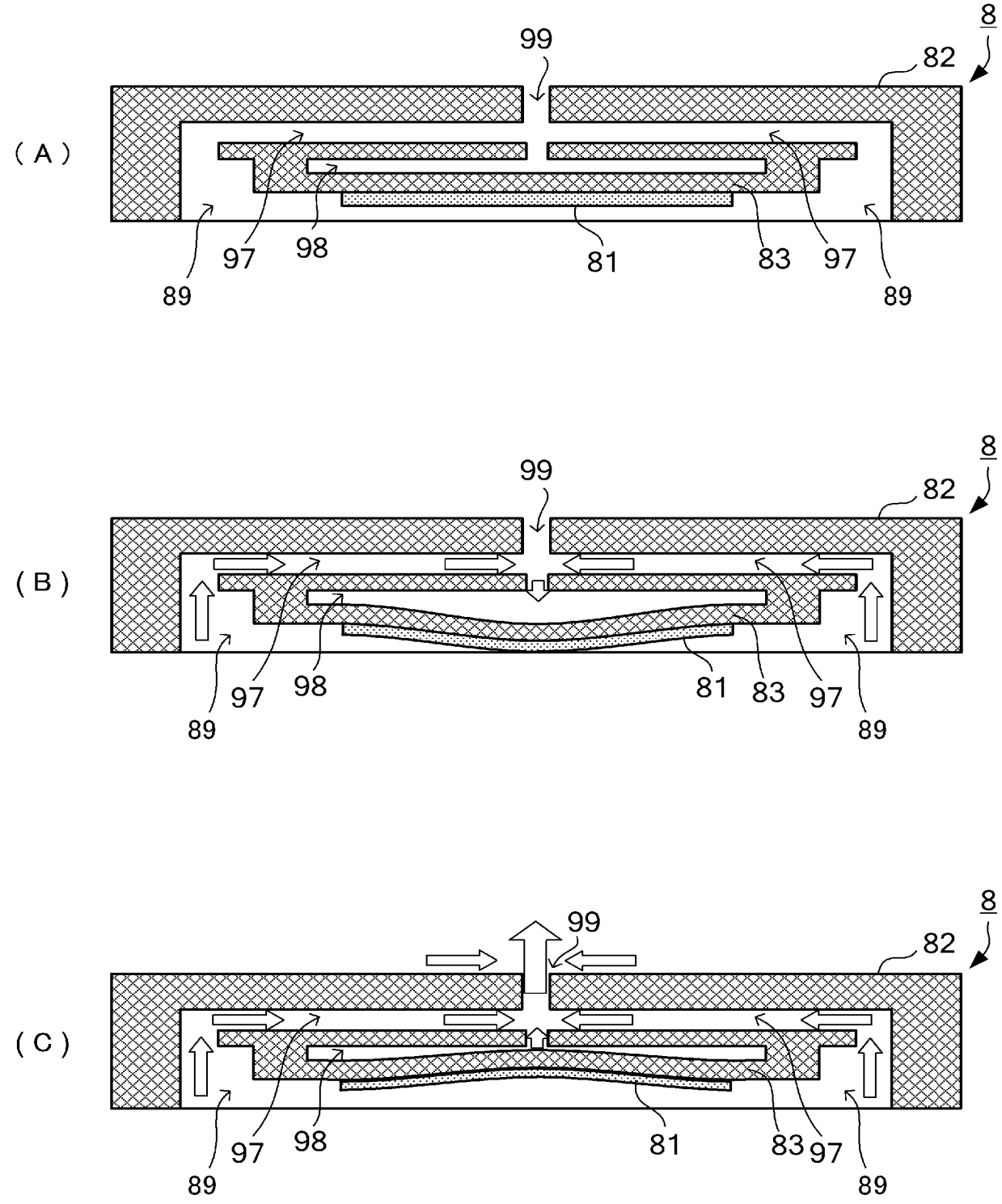
[図5]

【図5】



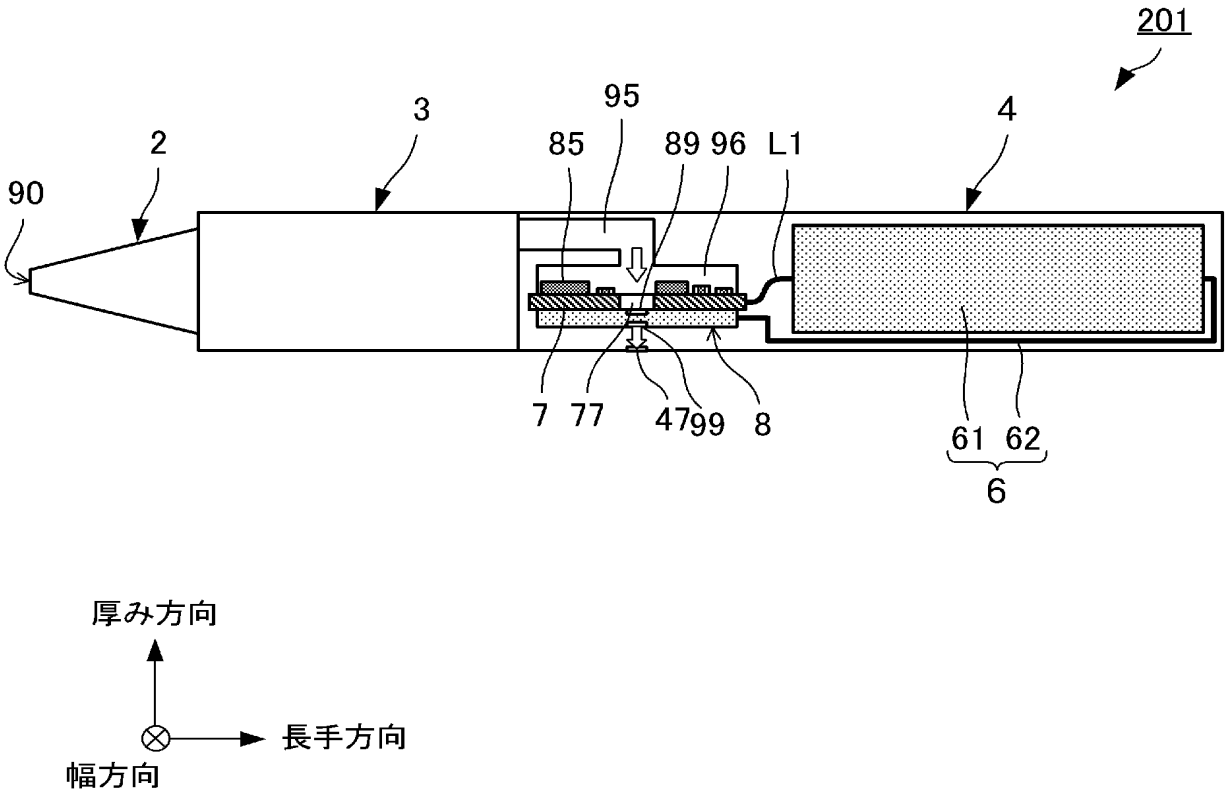


[図6]
【図6】


(A)
8
99
82
97
98
81
83
97
89
89
(B)
8
99
82
97
98
81
83
97
89
89
(C)
8
99
82
97
98
81
83
97
89
89

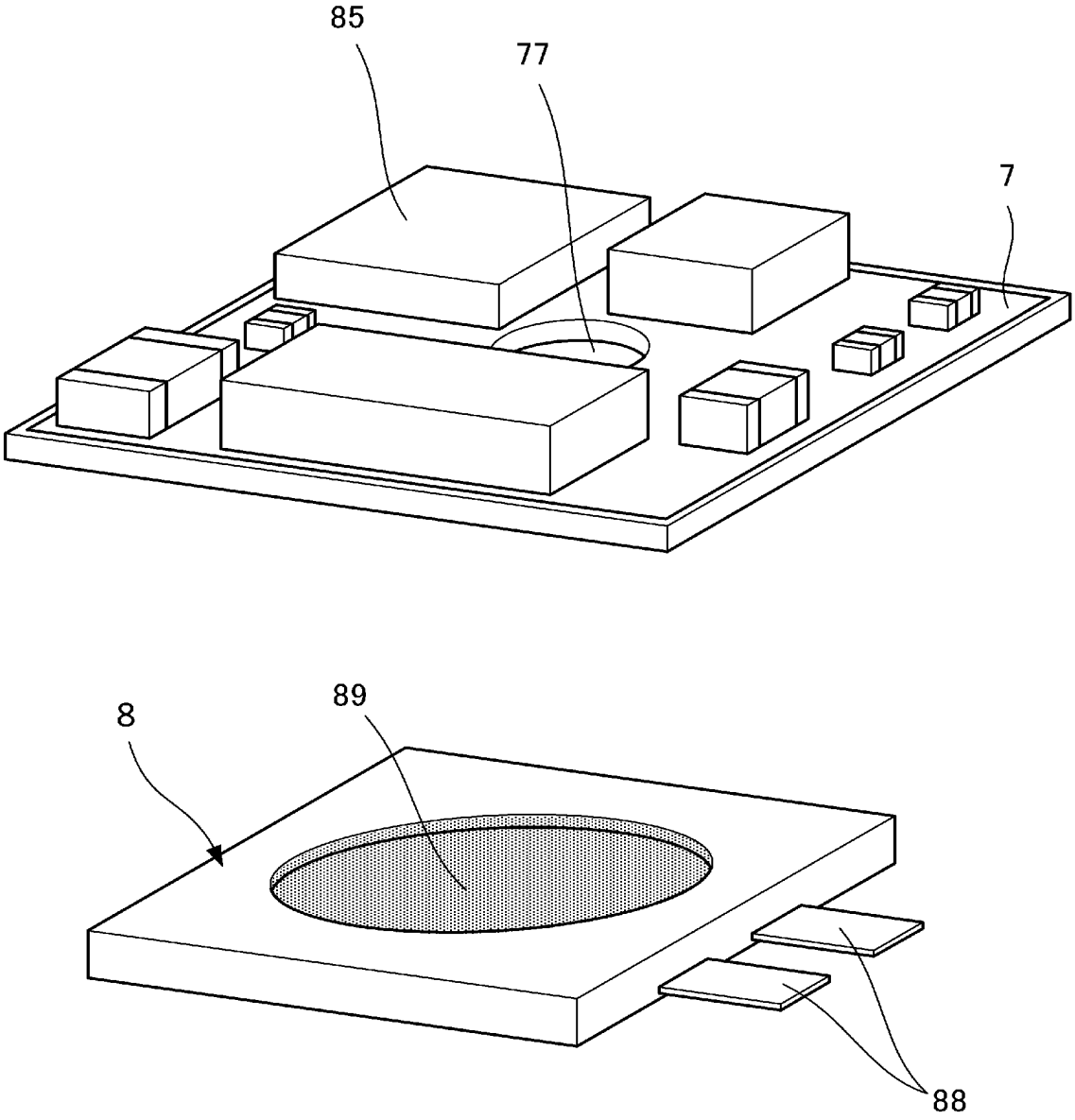
[図7]

【図7】



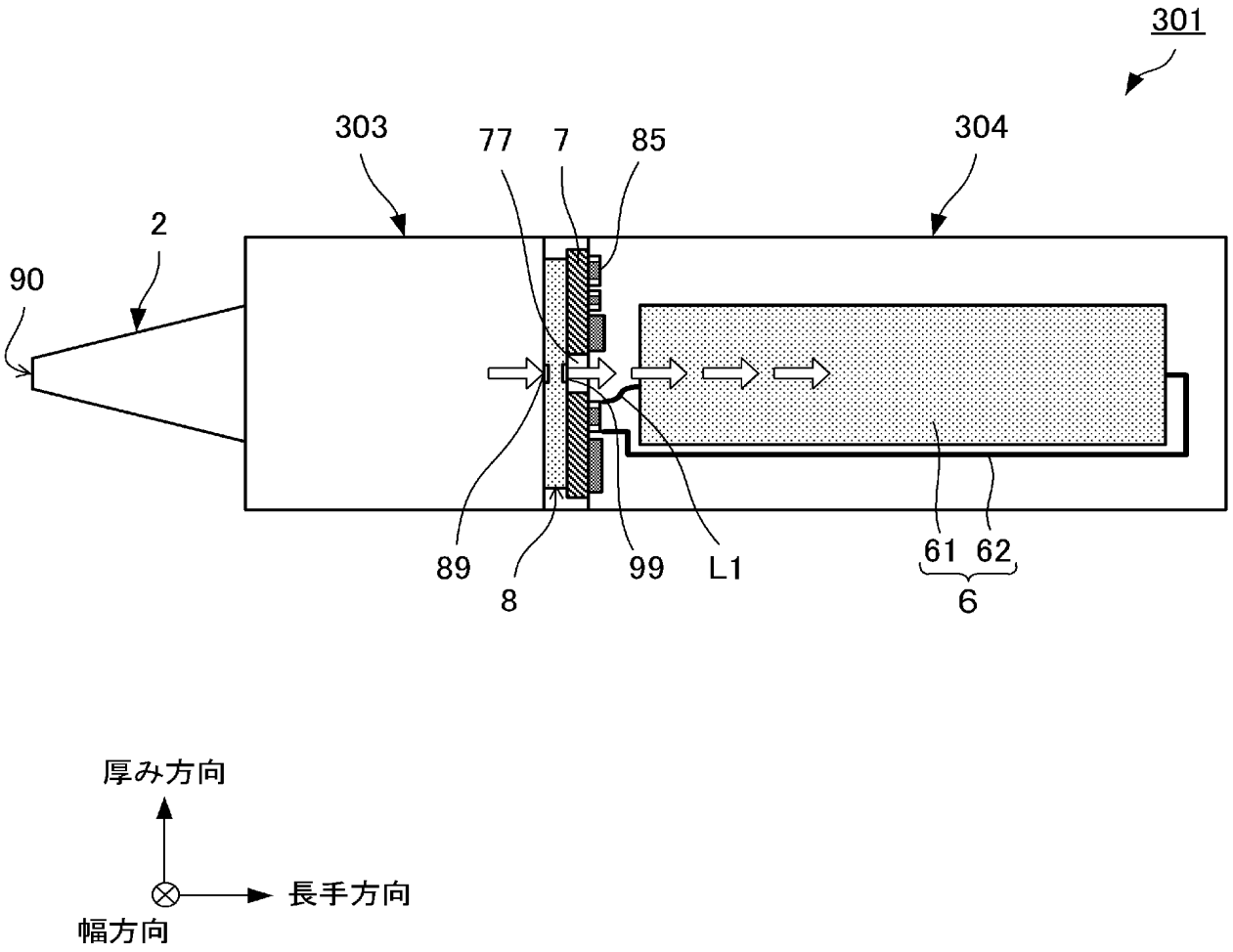
[図8]

【図8】

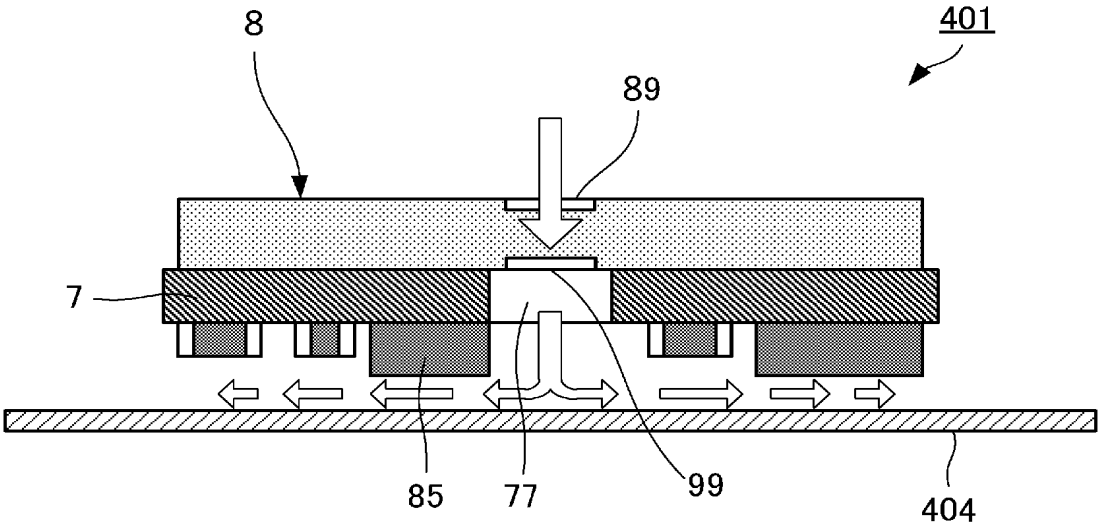


[図9]

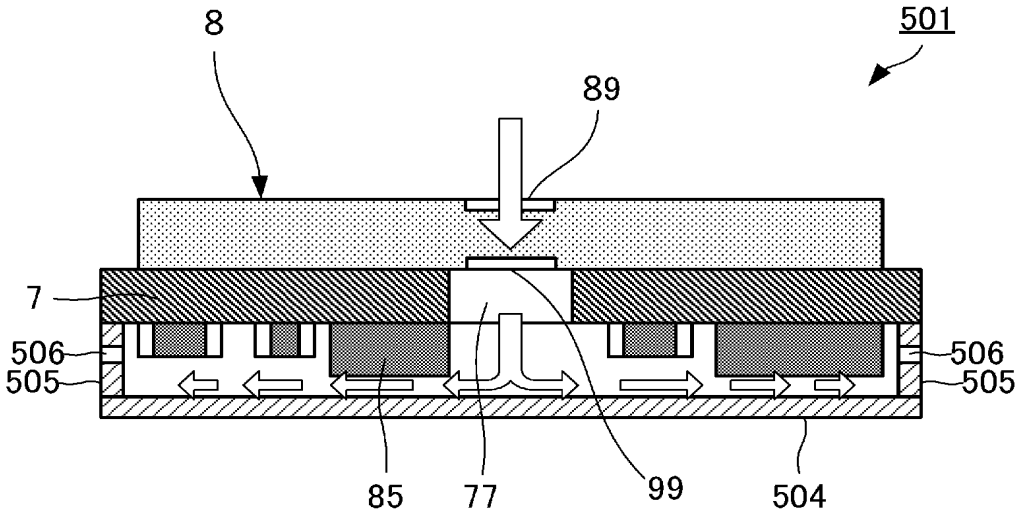
【図9】



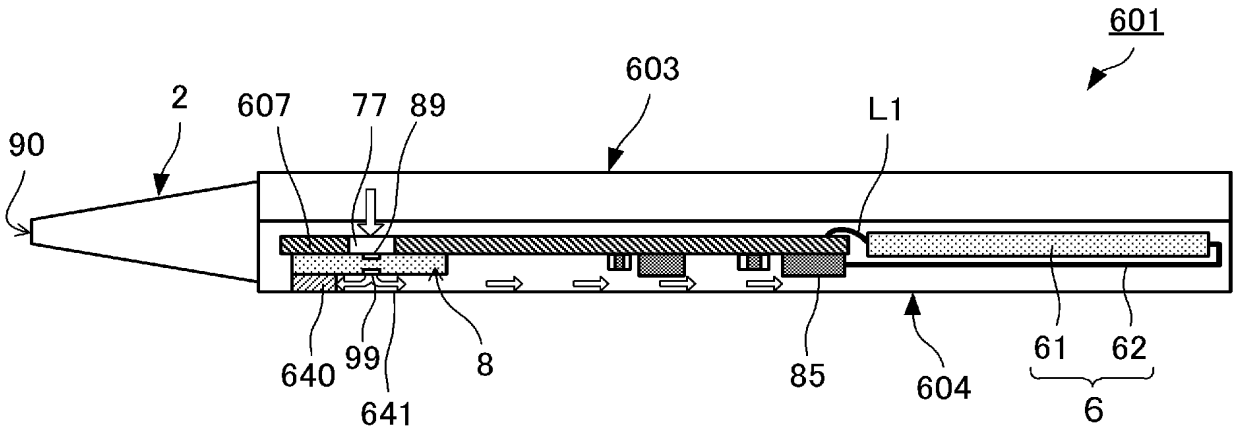
[図10]
【図10】

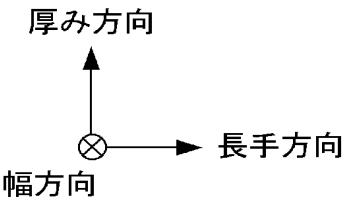


[図11]
【図11】

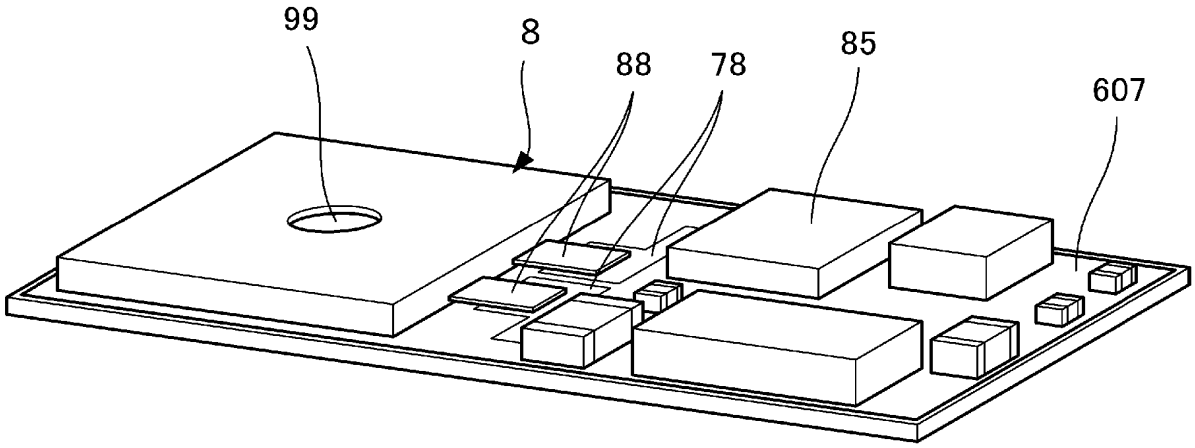


[図12]
【図１２】

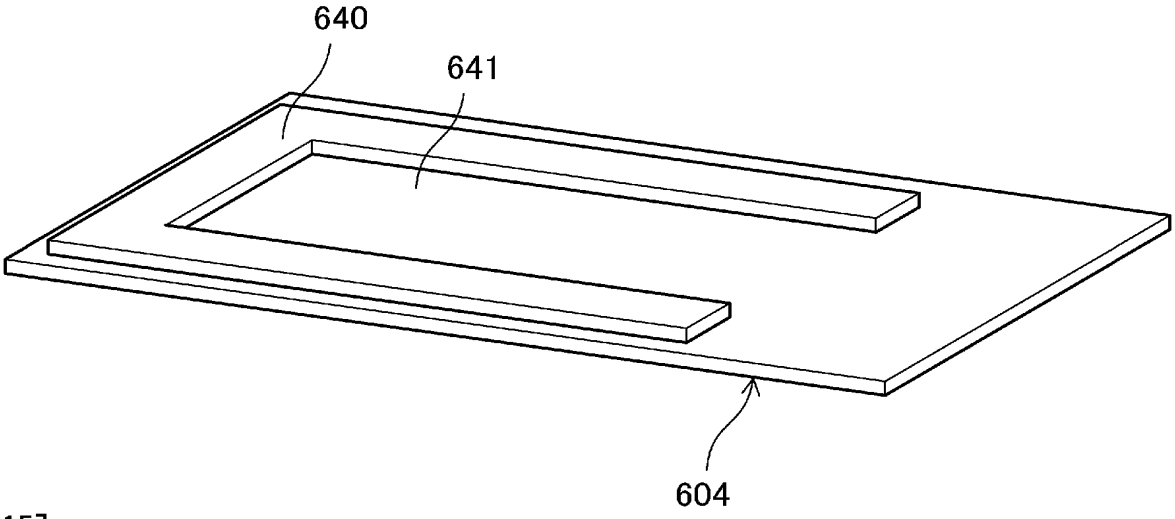




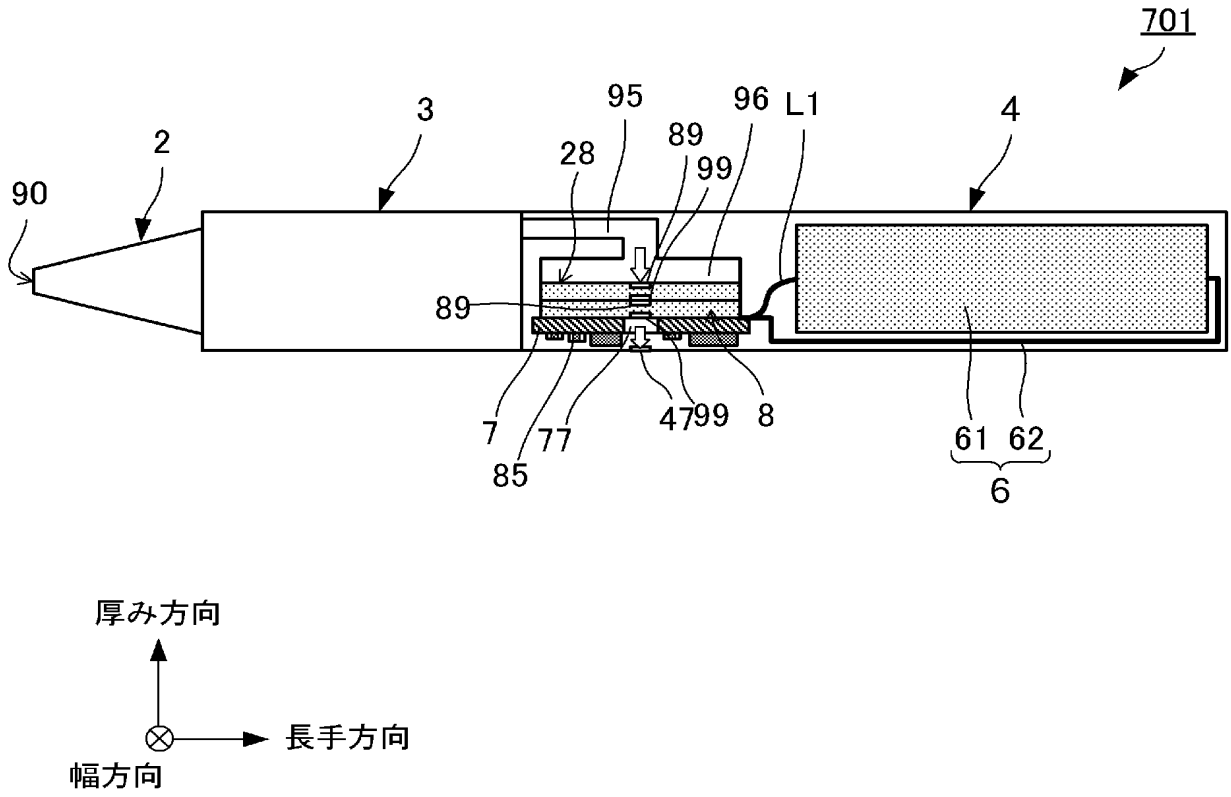
[図13]
【図１３】



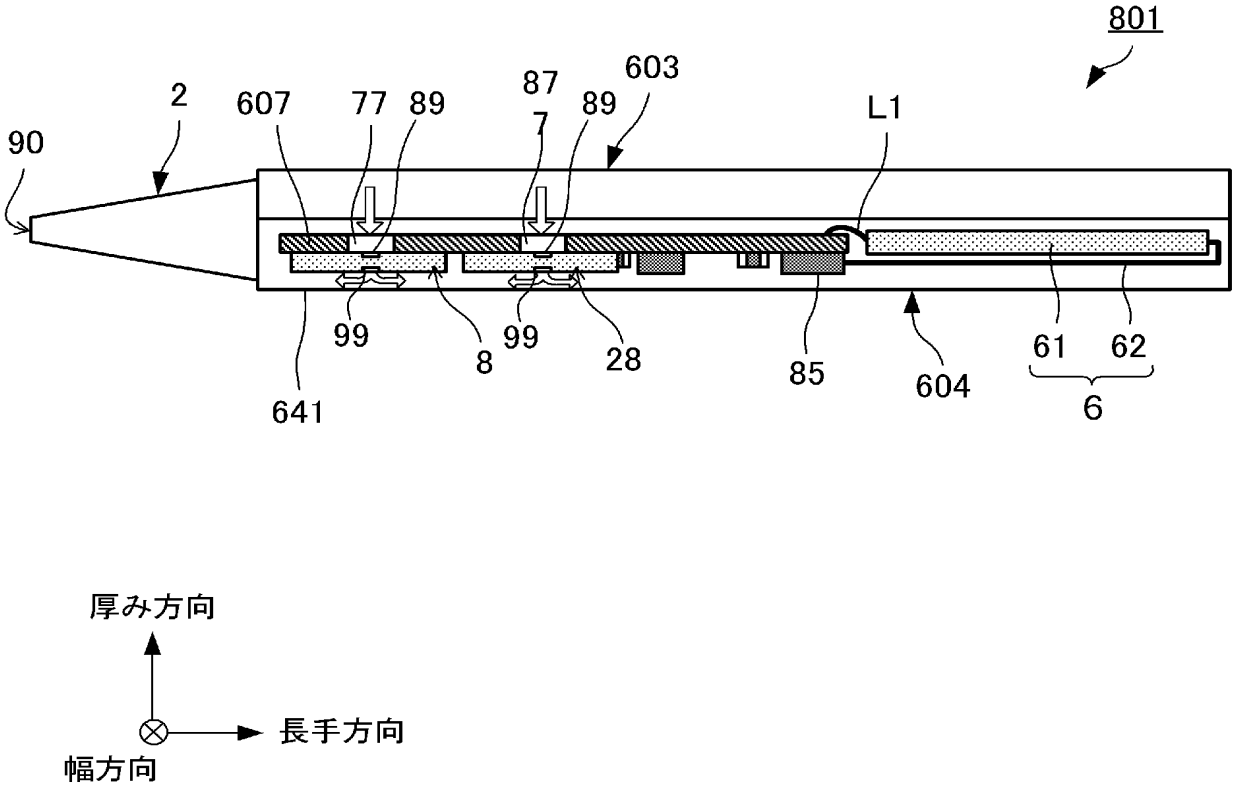
[図14]
【図14】



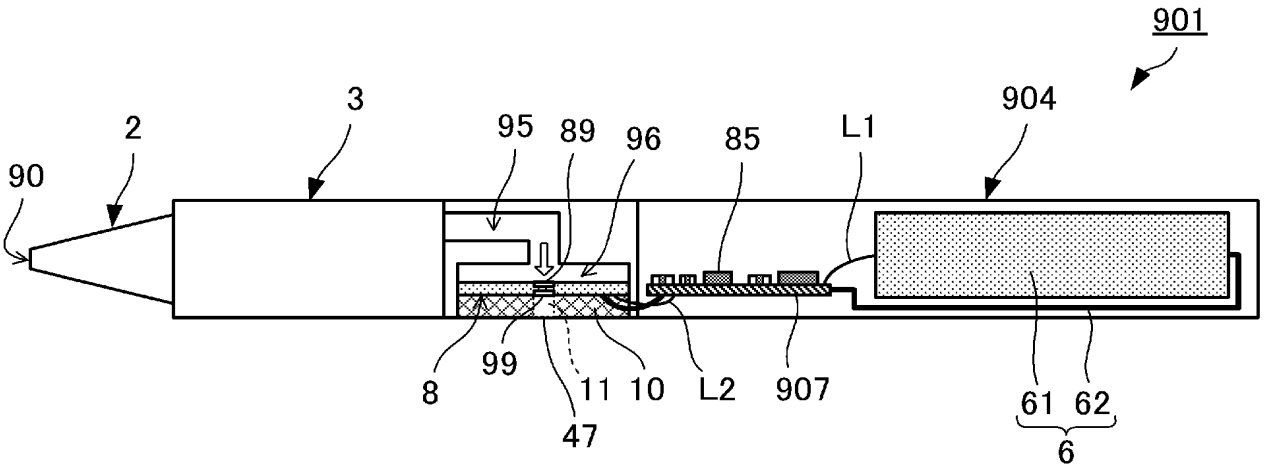
[図15]
【図15】

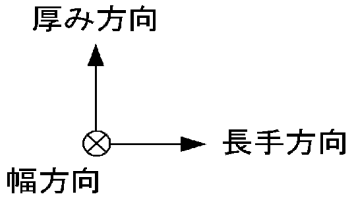


[図16]
【図16】


801
2
607
77
89
87
7
89
603
L1
90
99
99
8
28
85
604
61
62
6
641
厚み方向
長手方向
幅方向

[図17]
【図１７】


901
2
3
90
95
89
96
85
L1
904
8
99
47
11
10
L2
907
61
62
6


厚み方向
長手方向
幅方向

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068282

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/187270 A1 (Murata Mfg. Co., Ltd.), 19 December 2013 (19.12.2013), paragraphs [0003] to [0009], [0046] to [0060]; fig. 2, 10 (Family: none)	1-6
Y	JP 2002-538001 A (S.C. Johnson & Son, Inc.), 12 November 2002 (12.11.2002), paragraph [0016]; fig. 1 to 5 & US 2001/0042794 A1 & WO 2000/053337 A1 & EP 1159078 A1	1-6
Y	JP 2010-527636 A (Aardvark Medical, LLC), 19 August 2010 (19.08.2010), paragraphs [0114] to [0118]; fig. 23, 24 & US 2008/0154183 A1 & WO 2010/126586 A1 & EP 2083877 A2	1-6

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 July 2015 (09.07.15)	21 July 2015 (21.07.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2002-524134 A (Langerhans ApS), 06 August 2002 (06.08.2002), paragraph [0049]; fig. 3 & US 6821484 B1 & WO 2000/013609 A2 & EP 1157091 B1	1-6
A	JP 5166527 B2 (Molnlycke Health Care AB), 21 March 2013 (21.03.2013), paragraph [0029] & US 2010/0324510 A1 & WO 2009/002260 A1 & EP 2195069 A1	1-6
A	JP 2013-229281 A (Nitto Denko Corp.), 07 November 2013 (07.11.2013), paragraph [0013] & US 2015/0050877 A1 & WO 2013/145604 A1 & EP 2833706 A1	1-6
A	Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 2863/1973(Laid-open No. 106196/1974) (Ken KAGOTE), 11 September 1974 (11.09.1974), claims; fig. 1, 2 (Family: none)	1-6

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６８２８２

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	WO 2013/187270 A1（村田製作所）2013.12.19,［０００３］－［０００９］,［００４６］－［００６０］, 図２, 図１０ (ファミリーなし)	1-6
Y	JP 2002-538001 A（エス．シー．ジョンソン　アンド　サン、インコーポレイテッド）2002.11.12,【００１６】, 図１－５ & US 2001/0042794 A1 & WO 2000/053337 A1 & EP 1159078 A1	1-6

☑　Ｃ欄の続きにも文献が列挙されている。　　☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー
「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの
「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの
「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）
「Ｏ」口頭による開示、使用、展示等に言及する文献
「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの
「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの
「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの
「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
０９．０７．２０１５	２１．０７．２０１５

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｉ　９２５８
石田　宏之
電話番号　０３－３５８１－１１０１　内線　３３８６

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	JP 2010-527636 A（アードバーク　メディカル　エルエルシー）2010.08.19,【０１１４】－【０１１８】，図２３，図２４ & US 2008/0154183 A1 & WO 2010/126586 A1 & EP 2083877 A2	1-6
A	JP 2002-524134 A（ランゲルハンス・アンパルトセルスカブ）2002.08.06,【００４９】，図３ & US 6821484 B1 & WO 2000/013609 A2 & EP 1157091 B1	1-6
A	JP 5166527 B2（メンリッケ・ヘルス・ケア・アーベー）2013.03.21,【００２９】 & US 2010/0324510 A1 & WO 2009/002260 A1 & EP 2195069 A1	1-6
A	JP 2013-229281 A（日東電工株式会社）2013.11.07,【００１３】 & US 2015/0050877 A1 & WO 2013/145604 A1 & EP 2833706 A1	1-6
A	日本国実用新案登録出願 48-2863 号(日本国実用新案登録出願公開 49-106196 号)の願書に添付した明細書及び図面の内容を撮影したマイクロフィルム（籠手健）1974.09.11, 実用新案登録請求の範囲，第一，二図（ファミリーなし）	1-6

(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2016 年 1 月 14 日(14.01.2016)

WIPO | PCT

(10) 国際公開番号
WO 2016/006494 A1

(51) 国際特許分類:
A61M 1/06 (2006.01)

(21) 国際出願番号: PCT/JP2015/068747

(22) 国際出願日: 2015 年 6 月 30 日(30.06.2015)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願 2014-143123 2014 年 7 月 11 日(11.07.2014) JP

(71) 出願人: 株式会社村田製作所 (**MURATA MANUFACTURING CO., LTD.**) [JP/JP]; 〒6178555 京都府長岡京市東神足１丁目１０番１号 Kyoto (JP).

(72) 発明者: 田中伸拓 (**TANAKA, Nobuhira**); 〒6178555 京都府長岡京市東神足１丁目１０番１号 株式会社村田製作所内 Kyoto (JP).

(74) 代理人: 特許業務法人 楓国際特許事務所 (**KAEDE PATENT ATTORNEYS' OFFICE**); 〒5400011 大阪府大阪市中央区農人橋１丁目４番３４号 Osaka (JP).

(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), ユー

[続葉有]

WO 2016/006494 A1

(54) **Title**: MILKER

(54) 発明の名称 : 搾乳器

図5

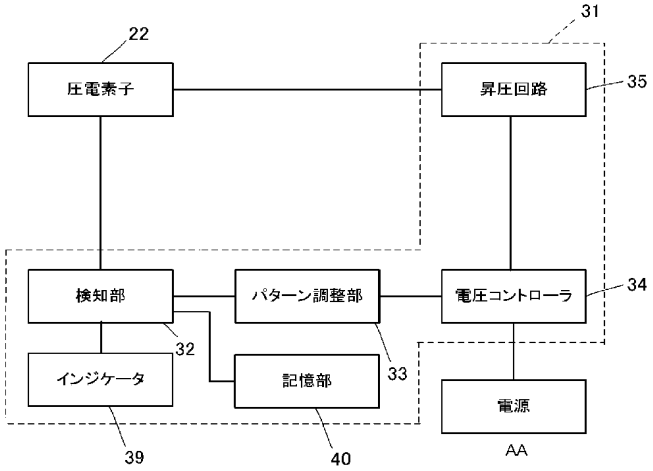


Fig. 5

22 Piezoelectric element
32 Detection unit
33 Pattern adjustment unit
34 Voltage controller
35 Voltage boosting circuit
39 Indicator
40 Memory unit
AA Power source

(57) **Abstract**: A milker (10) that comprises: a milking cup (11) that is installed on a breast; a suction pump (21) that suctions fluid from a breast side of the milking cup (11); a detection unit (32) that detects temporal variations in the suction state of the breast at the milking cup (11); and an indicator (39) and a pattern adjustment unit (33) that perform processing on the basis of the temporal variations in suction state detected by the detection unit (32).

(57) 要約: 乳房に装着される搾乳カップ（１１）と、搾乳カップ（１１）の乳房側から流体を吸引する吸引ポンプ（２１）と、搾乳カップ（１１）での乳房の吸引状態の時間変化を検知する検知部（３２）と、検知部（３２）が検出した吸引状態の時間変化に基づいて処理を行うインジケータ（３９）およびパターン調整部（３３）と、を備える搾乳器（１０）。

ラシア (AM, AZ, BY, KG, KZ, RU, TJ, TM), ヨーロッパ (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

添付公開書類:

— 国際調査報告（条約第 21 条(3)）

明　細　書

発明の名称 ： 搾乳器

技術分野

[0001] 本発明は、母乳等を吸引する際に利用される搾乳器に関する。

背景技術

[0002] 近年、母乳を容易に搾乳することができる電動式の吸入装置（搾乳器）が普及してきている。通常、搾乳器は、乳房に装着される搾乳カップと、搾乳カップの乳房側（内側）から流体を吸引する吸引ポンプと、母乳を貯蔵する容器とを備えて構成される。搾乳器では、吸引圧の時間変化のパターン（以下、吸引パターンと称する。）を適切に設定することで、例えば、乳房にマッサージ効果を与えて搾乳効率を向上させることや、搾乳に伴う痛みの低減を図ることができる。そこで、搾乳器において、吸引パターンの設定を複数用意しておき、利用者が吸引パターンの設定を選択できるようにしたものや、吸引パターンの設定を書き換え自在にしたものが存在している（例えば、特許文献１参照。）。

先行技術文献

特許文献

[0003] 特許文献1：特開２０１０－１１５５１７号公報

発明の概要

発明が解決しようとする課題

[0004] 上述の搾乳器では、最適であると想定される吸引パターンの設定が製造段階や使用前に書き込まれるが、個人の体質や乳房の張り具合は極めて多様であり、必ずしも設定した通りの吸引パターンが実際に実現されるわけではなかった。また、利用者が自らの判断で適切と思われる吸引パターンの設定を選択する場合には、利用者にとって自らに適切な吸引パターンの設定を判断すること自体が容易でなかった。

[0005] そこで、乳房表面の皮膚の硬さを検出するようなセンサを搾乳カップに付

設することができれば、乳房表面の皮膚の硬さに応じて適切な吸引パターンを搾乳器が自動的に設定するような処理が可能になる。しかしながら、通常、搾乳カップは弾性材料で構成されており、上記のようなセンサを搾乳カップに付設することは、搾乳器の構成の複雑化や、搾乳の準備作業に掛かる手間の増加などを招いてしまうため、現実的ではなかった。

[0006] そこで本発明の目的は、乳房表面の皮膚の硬さを直接検出しなくても、乳房表面の皮膚の硬さに応じた処理を行うことができる搾乳器を提供することにある。

課題を解決するための手段

[0007] 本発明の搾乳器は、吸入部と、吸引ポンプと、検知手段と、制御部とを備える。吸入部は、乳房に装着される。吸引ポンプは、前記吸入部の乳房側から流体を吸引する。検知手段は、前記吸入部での乳房の吸引状態の時間変化を検知する。制御部は、前記検知手段が検出した前記吸引状態の時間変化に基づいて処理を行う。

[0008] この構成において、吸入部での乳房の吸引状態の時間変化は、吸入部が装着される乳房表面の皮膚の硬さに応じたものになる。このため、吸入部での乳房の吸引状態の時間変化に基づくことで、乳房表面の皮膚の硬さに基づいた処理を行うことができる。

[0009] また、前記検知手段は、前記吸入部での乳房の吸引状態を、前記吸引ポンプの吸引圧に基づいて検知することが好ましい。この構成では、検知手段となる部材を吸入部に追加して設ける必要が無く、吸入部とその接続構成を簡易化することができる。

[0010] また、前記吸引ポンプは、駆動電圧が印加されて動作する圧電素子を有することが好ましい。この構成において、圧電素子では、駆動電圧の周波数を可聴音の周波数から外すことができるので、モータのような動力源に比べて動作音を低減することができる。

[0011] また、前記検知手段は、前記圧電素子のインピーダンスの状態を検出し、検出した前記圧電素子のインピーダンスの状態に基づいて前記吸引ポンプの

吸引圧を検知することが好ましい。特には、前記吸引装置は、前記圧電素子のインピーダンスの状態と前記吸引ポンプの吸引圧との対応関係を予め記憶した記憶部を更に備え、前記検知手段は、前記記憶部を参照することにより、前記吸引ポンプの吸引圧を検知することが好ましい。

[0012] 圧電素子のインピーダンスの状態は、吸引ポンプの吸引圧に応じて変化する。したがって、圧電素子のインピーダンスの状態に基づいて、吸入部での乳房の吸引状態を検知することができる。そして、この構成では、圧力センサのような部材を別途追加することなく、吸入部での乳房の吸引状態を検知することができる。

[0013] また、前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子に流れる電流の振幅を検出することが好ましい。圧電素子のインピーダンスの大きさは、吸引ポンプの吸引圧に応じて変化する。そして、圧電素子のインピーダンスの大きさは、圧電素子に流れる電流と圧電素子の駆動電圧との振幅比として求めることができる。したがって、圧電素子の駆動電圧が既知であれば、圧電素子に流れる電流の振幅に基づいて、吸入部での乳房の吸引状態を検知することができる。そして、電流の振幅は小型かつ簡易な回路で検出することができるので、検知手段を容易に実現することができる。

[0014] また、前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差を検出することが好ましい。圧電素子に流れる電流と圧電素子の駆動電圧との位相差は、吸引ポンプでの吸引圧に応じて変化する。このため、圧電素子に流れる電流と圧電素子の駆動電圧との位相差に基づいて、吸入部での乳房の吸引状態を検知することができる。位相差に基づくことで、駆動電圧の変動や温度変動があるような条件下であっても、吸入部での乳房の吸引状態を精度良く把握することができる。

[0015] また、前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子の共振周波数を検出し、前記制御部は、前記共振周波数で前記圧

電素子を駆動することが好ましい。圧電素子の共振周波数は、吸引ポンプでの吸引圧に応じて変化する。このため、圧電素子の共振周波数に基づいて、吸入部での乳房の吸引状態を検知することができる。その上、吸引ポンプの駆動周波数を圧電素子の共振周波数に合わせることにより、圧電素子の振動を最大化することができ、所望の吸引圧を得るために必要な電力を抑制できる。

[0016] 前記搾乳器は、前記検知手段で検知した状態を報知する報知部を更に備えることが好ましい。この構成では、報知部を介して乳房表面の皮膚の硬さを利用者に伝えることができ、利用者が乳房の異常などを把握できるようにすることができる。報知部としては、液晶表示部や、表示ランプ、無線通信部などを用いることができる。

発明の効果

[0017] 本発明によれば、搾乳器において、乳房表面の皮膚の硬さを直接検出しなくても、乳房表面の皮膚の硬さに応じた処理を行うことができる。

図面の簡単な説明

[0018] [図1]第１の実施形態に係る搾乳器の模式的断面図である。

[図2]第１の実施形態に係る吸引ポンプの断面図である。

[図3]第１の実施形態に係る吸引ポンプの振動態様を示す模式図である。

[図4]第１の実施形態に係る搾乳カップでの乳房の吸引状態の時間変化を例示するグラフである。

[図5]第１の実施形態に係る駆動制御部のブロック図である。

[図6]第１の実施形態に係る圧電素子に印加する駆動電圧の振幅パターンを例示するグラフである。

[図7]第１の実施形態に係る駆動制御部の動作を示すフローチャートである。

[図8]第２の実施形態に係る駆動制御部のブロック図である。

[図9]第２の実施形態に係る駆動制御部の動作を示すフローチャートである。

[図10]第３の実施形態に係る駆動制御部のブロック図である。

[図11]第３の実施形態に係る駆動制御部の動作を示すフローチャートである

。

発明を実施するための形態

[0019] 《第１の実施形態》

以下、本発明の第１の実施形態に係る搾乳器１０について説明する。

[0020] 図１は、搾乳器１０の模式的断面図である。搾乳器１０は、搾乳カップ１１、セパレータ１３、保存容器１４、および、圧電駆動部１５を備えている。搾乳カップ１１は、本発明の吸入部に相当し、乳房の表面に沿う形状の凹面を有する器状であり、凹面の中央に吸入口を有している。セパレータ１３は、下方に開口する容器状である。保存容器１４は、上方に開口する容器状であり、セパレータ１３の下方に設けられている。また、図１中では図示していないが、搾乳器１０には、搾乳カップ１１での乳房の吸引状態を表示するインジケータ３９（図５参照）と、流路１６の内圧（吸引圧）を開放するための弁が設けられている。また、圧電駆動部１５には、吸引ポンプ２１（図２参照）と、駆動制御部３１（図５参照）とが設けられている。

[0021] 搾乳カップ１１、セパレータ１３、および、圧電駆動部１５は、この順に搾乳器１０の前方から後方に向かって並べた状態で接続している。搾乳カップ１１、セパレータ１３、保存容器１４、および、圧電駆動部１５には、搾乳カップ１１の先端から圧電駆動部１５の後端まで繋がる流路１６が設けられている。

[0022] 圧電駆動部１５が駆動すると、流路１６では、搾乳カップ１１の凹面側（乳房側）から圧電駆動部１５の後端へと向かう流体の流れが生じる。搾乳カップ１１は、乳房表面の皮膚に吸着するとともに、乳房から母乳を吸引する。セパレータ１３は、搾乳カップ１１から母乳を吸引し、吸引した母乳を下方に滴下させる。保存容器１４は、セパレータ１３から滴下してくる母乳を貯蔵する。

[0023] 図２は吸引ポンプ２１の断面図である。吸引ポンプ２１は圧電素子２２および構造体２３を備えている。構造体２３は、概略の外形が厚み方向に薄い円板状である。構造体２３の天面の中央付近には、吐出口２６が開口してい

る。構造体２３の底面の縁付近には、吸入口２７が開口している。吸引ポンプ２１は、吸入口２７側がセパレータ１３側を向くように配置される。

[0024] 構造体２３の内部には、流路２４とポンプ室２５とが設けられている。流路２４は、構造体２３の天面で吐出口２６に通じており、構造体２３の内部で中央付近から外周側に延び、構造体２３の底面で吸入口２７に通じている。ポンプ室２５は、吐出口２６と流路２４との連通部分の底面側に設けられた薄い円筒状の空間であり、吐出口２６と流路２４との連通部分に開口している。

[0025] 構造体２３におけるポンプ室２５の内底面は、屈曲振動が可能なダイヤフラム（振動板）２８として構成されている。ダイヤフラム２８は円板状であり、天面がポンプ室２５に面している。ダイヤフラム２８の天面は、ポンプ室２５を間に介して吐出口２６と対向している。圧電素子２２は、厚み方向に薄い円板状であり、ダイヤフラム２８の底面に貼り付いている。圧電素子２２は、交流の駆動電圧が印加されることで主面の面内方向に伸縮しようとする圧電性を有している。

[0026] 図３は、吸引ポンプ２１の振動態様を示す模式図である。圧電素子２２とダイヤフラム２８とは、互いに貼り付いてユニモルフ構造を構成しており、圧電素子２２の駆動により厚み方向に変位する。具体的には、図３（Ａ）に示すような静止状態から圧電素子２２が伸びようとする場合には、図３（Ｂ）に示すように、ダイヤフラム２８が圧電素子２２側（底面側）に凸に屈曲してポンプ室２５の体積が増大する。これにより、ポンプ室２５に負圧が生じ、ポンプ室２５に連通する流路２４に負圧が伝わり、流路２４の流体がポンプ室２５に吸引される。

[0027] 図３（Ａ）に示すような静止状態から圧電素子２２が縮もうとすると場合には、図３（Ｃ）に示すように、ダイヤフラム２８がポンプ室２５側（天面側）に凸に屈曲してポンプ室２５の体積が減少する。すると、流路２４を間に介してポンプ室２５と吐出口２６とが対向しているために、ポンプ室２５の流体が吐出口２６から外部に吐出されるとともに、その流体の流れに引き

込まれて流路２４内の流体が吐出口２６から吐出される。

[0028] このような圧電素子２２とダイヤフラム２８との屈曲振動に伴い、吸引ポンプ２１では、ポンプ室２５で周期的な体積変動と圧力変動とが繰り返し生じ、気体の流れに慣性力が働くようになる。これにより、流路２４の流体が吐出口２６から吐出される気体の流れが定常的に生じるようになる。この吸引ポンプ２１では、ダイヤフラム２８が吐出口２６に対して流路２４およびポンプ室２５を介して対面するため、吸引ポンプ２１の流体効率が高く、高い吸引圧と低い消費電力とを同時に実現することができる。

[0029] ここで、搾乳カップ１１での乳房の吸引状態が、乳房表面の皮膚の硬さに応じてどのような時間変化を示すかを説明する。

[0030] 図４は、表面の皮膚が柔らかく張っていない状態の乳房を吸引する場合と、表面の皮膚が硬く張っている状態の乳房を吸引する場合とで、搾乳カップ１１での乳房の吸引状態の時間変化を比較して示すグラフである。

[0031] 搾乳器の最大吸引圧が同じになるように圧電素子２２を一定の駆動電圧で駆動する場合、張っていない柔らかい状態の乳房を吸引する搾乳カップ１１では、駆動開始時から吸引圧が次第に増加していくが、柔らかい状態の乳房は搾乳カップ１１に吸着され易いため、吸引圧の増加の程度、即ち、時間変化は比較的なだらかである。したがって、柔らかい状態の乳房を吸引する場合には、駆動開始時から最大吸引圧に到達するまでに比較的長い時間を要する。一方、張っていて硬い状態の乳房を吸引する搾乳カップ１１では、駆動開始時から次第に吸引圧が増加していくが、硬い状態の乳房は搾乳カップ１１に吸着され難いため、吸引圧の増加の程度、即ち、時間変化は比較的急峻である。したがって、硬い状態の乳房を吸引する場合には、駆動開始時から最大吸引圧に到達するまでに比較的短い時間を要する。このように、乳房の張り具合、即ち乳房表面の皮膚の硬さに応じて、搾乳カップ１１での乳房の吸引状態の時間変化は相違するため、搾乳カップ１１での乳房の吸引状態の時間変化に基づいて、乳房表面の皮膚の硬さは把握することができる。

[0032] 図５は駆動制御部３１の構成例を示すブロック図である。

[0033] ここで示す駆動制御部３１は、搾乳カップ１１での乳房の吸引状態を検知して圧電素子２２の駆動電圧および駆動時間のパターンを制御する機能を有している。また、駆動制御部３１は、圧電素子２２のインピーダンスに基づいて、搾乳カップ１１での乳房の吸引状態を検知する機能を有している。

[0034] 駆動制御部３１は、検知部３２、パターン調整部３３、記憶部４０、電圧コントローラ３４、昇圧回路３５、および、インジケータ３９を備えている。検知部３２は本発明の検知手段を構成するものである。

[0035] 電圧コントローラ３４は、電源電圧を制御して昇圧回路３５に供給する。昇圧回路３５は、電源電圧を昇圧して駆動電圧を生成し、その駆動電圧を圧電素子２２に印加する。これにより、圧電素子２２が駆動し、搾乳器１０に母乳を吸引させる。

[0036] 圧電素子２２の駆動電圧は、周波数が可聴音の周波数帯域から外れていて、このため圧電素子２２はモータ等に比べて駆動音が静かである。また、圧電素子２２は、図２に示す流路２４を流れる流体の圧力（吸引圧）に応じて、インピーダンスが影響を受けるという性質を有している。したがって、吸引圧と圧電素子２２のインピーダンスが受ける影響との対応関係が既知であれば、圧電素子２２のインピーダンスに基づいて、吸引圧は把握することができる。また、この吸引圧は、搾乳カップ１１での乳房の吸引状態に影響を受ける。したがって、搾乳カップ１１での乳房の吸引状態と吸引圧との対応関係が既知であれば、吸引圧に基づいて、搾乳カップ１１での乳房の吸引状態は把握することができる。

[0037] 検知部３２は、圧電素子２２のインピーダンスの状態を検出する。記憶部４０は、圧電素子２２のインピーダンスの状態と、吸引圧または搾乳カップ１１の状態との対応関係がテーブルや演算式として予め記憶されている。検知部３２は、記憶部４０を参照することにより、検出した圧電素子２２のインピーダンスの状態に基づいて、吸引圧、および、搾乳カップ１１の状態を把握する。これにより、検知部３２で、圧電素子２２のインピーダンスの状態の時間変化に基づいて、吸引圧の時間変化、搾乳カップ１１での乳房の吸

引状態の時間変化、および、乳房表面の皮膚の硬さを把握することが可能になる。パターン調整部３３は、検知部３２の検知結果に基づいて、乳房表面の皮膚の硬さに応じた最適な駆動電圧のパターンとなるように、電圧コントローラ３４を設定し、電圧コントローラ３４から昇圧回路３５に電圧を出力させる。電圧コントローラ３４は、出力電圧を変圧したり、昇圧回路３５の昇圧比を制御したりすることで、昇圧回路３５が出力する駆動電圧を制御する。インジケータ３９は、検知部３２の検知結果についての情報を、液晶表示部や表示ランプ等に表示させる機能や、通信回線を介して外部に送信する機能を有している。インジケータ３９が通信回線を介して外部に情報を送信する場合には、外部機器で、乳房の張りの状態を時系列で表示したり、乳房の張りの異常状態を判定して表示するようにすれば、利用者に自らの乳房の状態を把握させたり、病気などの発生の危険性を把握させることができる。

[0038] なお、パターン調整部３３、電圧コントローラ３４、および検知部３２の機能の一部は、例えば、単一のマイコンに構成することができる。例えば、ＰＷＭ制御を行うマイコンを用いる場合には、マイコンのＩ／Ｏ端子を検知部３２に接続し、マイコンのＰＷＭ出力端子を昇圧回路３５に直接接続する。そして、マイコンでＰＷＭ制御出力のデューティー比を変更することにより、昇圧回路３５の出力する駆動電圧を制御することができる。

[0039] 駆動制御部３１を上記の構成にすることで、乳房表面の皮膚の硬さに応じて適切な吸引パターンを搾乳器１０が自動的に設定することができる。そして、検知部３２で、乳房表面の皮膚の硬さを、圧電素子２２のインピーダンスに基づいて検知するので、乳房表面の皮膚の硬さを検出するようなセンサを搾乳カップ１１に設ける必要が無く、搾乳器１０の構成の複雑化や、搾乳の準備作業に掛かる手間の増加などを防ぐことができる。

[0040] 図６（Ａ）は、所定振幅の駆動電圧を間欠的に出力するように駆動電圧のパターンを設定する場合の、吸引圧の時間変化を示すグラフである。図６（Ａ）中に示す実線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲内である場合の吸引圧の時間変化を示している。図６（Ａ）中に示す破

線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも硬い場合の吸引圧の時間変化を示している。図６（Ａ）中に示す一点鎖線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも柔らかい場合の吸引圧の時間変化を示している。

[0041] 乳房表面の皮膚の硬さが予め設定された硬さの範囲内である場合を基準とすると、乳房表面の皮膚が硬い場合には、圧電素子２２への駆動電圧の印加に伴う吸引圧の立ち下がりと、駆動電圧の印加停止に伴う吸引圧の立ち上がりとが、いずれも基準より急峻になる。一方、乳房表面の皮膚が柔らかい場合には、圧電素子２２への駆動電圧の印加に伴う吸引圧の立ち下がりと、駆動電圧の印加停止に伴う吸引圧の立ち上がりとが、いずれも基準より緩やかになる。また、吸引圧の立ち下がりと吸引圧の立ち上がりとを比較すると、吸引圧が立ち下がる際のほうが、吸引圧の時間変化が緩やかである。

[0042] したがって、図６（Ａ）中に時刻ｔ１で示すような駆動電圧の印加開始から所定時間経過後の吸引圧が立ち下がる途中のタイミングで、検知部３２で圧電素子２２のインピーダンスの状態を検出し、予め把握しておいた時刻ｔ１での基準となる吸引圧での対応するインピーダンスの状態と比較すれば、乳房の状態を検知することができる。

[0043] 図６（Ｂ）は、パターン調整部３３で設定する駆動電圧のパターンを例示するグラフである。図６（Ｂ）中に示す実線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲内である場合に設定する駆動電圧の振幅パターンを示している。図６（Ｂ）中に示す破線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも硬い場合に設定する駆動電圧の振幅パターンを示している。図６（Ｂ）中に示す一点鎖線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも柔らかい場合の駆動電圧の振幅パターンを示している。

[0044] パターン調整部３３は、例えば、所定振幅の駆動電圧を一定の周期で間欠的に出力するように駆動電圧のパターンを設定する。そして、１周期目の駆動電圧の印加後の所定時間が経過した状況での検知部３２で圧電素子２２の

インピーダンスの状態の時間変化を検知し、その検知結果に基づいて、２周期目以降での駆動電圧の振幅を変化させる。

[0045] より具体的には、例えば、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲内であれば、パターン調整部３３は、駆動電圧を初期振幅のまま変更しないように、２周期目以降の駆動電圧のパターンを設定する。一方、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも硬い場合には、パターン調整部３３は、２周期目以降の駆動電圧を初期振幅よりも小さな振幅に変更するとともに、停止時間を短縮するように、駆動電圧のパターンを設定する。また、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも柔らかい場合には、パターン調整部３３は、２周期目以降の駆動電圧を初期振幅よりも大きな振幅に変更するとともに、停止時間を伸長するように、駆動電圧のパターンを設定する。

[0046] 図６（Ｃ）は、上記の変更を駆動電圧に設定する場合の、吸引圧の時間変化を示すグラフである。図６（Ｃ）中に示す実線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲内である場合の吸引圧の時間変化を示している。図６（Ａ）中に示す破線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも硬い場合の吸引圧の時間変化を示している。図６（Ａ）中に示す一点鎖線は、乳房表面の皮膚の硬さが予め設定された基準の硬さの範囲よりも柔らかい場合の吸引圧の時間変化を示している。

[0047] 前述したように駆動電圧のパターンを変更すると、図６（Ａ）のように駆動電圧のパターンを変更しない場合と比較して、２周期目以降での吸引圧の時間変化が異なるものになる。具体的には、乳房表面の皮膚が硬い場合には、駆動電圧の印加開始のタイミング及び印加停止のタイミングが早まる。一方、乳房表面の皮膚が柔らかい場合には、駆動電圧の印加開始のタイミング及び印加停止のタイミングが遅くなる。そして、駆動電圧の印加開始のタイミングに続く吸引圧の立ち下がりの期間の吸引圧の波形が、乳房表面の皮膚の硬さによらず均一化する。したがって、個人の体質や乳房の張り具合が異なる場合にも、最適であると想定される吸引パターンを設定した通りに実現

することができ、個人の体質や乳房の張り具合によらずに搾乳の効率を高めたり、利用者が感じる痛みを低減したりすることが可能になる。

[0048] なお、駆動電圧の印加停止のタイミングに続く吸引圧の立ち上がりの期間の吸引圧の波形は、乳房表面の皮膚の硬さによって相違しているが、搾乳の効率や利用者が感じる痛みには、この相違はほとんど影響しない。

[0049] 次に、搾乳カップ１１での乳房の吸引状態を検知する機能について、更に詳細に説明する。

[0050] 圧電素子２２のインピーダンスの大きさは、搾乳カップ１１での乳房の吸引状態に影響を受ける。また、圧電素子２２のインピーダンスの大きさは、圧電素子２２に流れる電流の振幅と圧電素子２２に印加する駆動電圧の振幅との比として表わすことができる。したがって、搾乳カップ１１での乳房の吸引状態と、圧電素子２２に流れる電流の振幅値と、圧電素子２２に印加する駆動電圧の振幅値と、の対応関係が既知であれば、検知部３２で電流の振幅値を検出するとともに昇圧回路３５の出力電圧を把握することで、搾乳カップ１１での乳房の吸引状態を把握することができる。

[0051] 図７は、上記の圧電素子２２に流れる電流の変化を検出して駆動電圧のパターンを制御する場合の駆動制御部３１の動作例を示すフローチャートである。

[0052] 駆動制御部３１は、まず、圧電素子２２に初期振幅に設定された駆動電圧を印加する（Ｓ１１）。これにより、圧電素子２２が駆動して、搾乳器１０は搾乳カップ１１を介した母乳の吸引動作を開始する。次に、駆動制御部３１は、圧電素子２２への駆動電圧の印加を停止する（Ｓ１２）。次に、駆動制御部３１は、前述の図６（Ａ）で示した吸引圧が立ち下がる途中の既定の時刻ｔ１となるのを待ち（Ｓ１３：Ｙｅｓ）、圧電素子２２に流れる電流の振幅を計測する（Ｓ１３→Ｓ１４）。

[0053] この時刻ｔ１には駆動電圧は立ち下がる途中であり、時刻ｔ１において、駆動電圧の振幅値は乳房表面の皮膚の硬さに寄らず、およそ一定である。したがって、圧電素子２２に流れる電流の振幅は、圧電素子２２のインピーダ

ンスの大きさに応じて変化する。このため、乳房表面の皮膚の硬さが基準範囲である場合の、圧電素子２２に流れる電流の振幅の範囲を予め把握して記憶部等に記憶しておくことで、圧電素子２２に流れる電流の振幅を基準範囲と比較して、乳房表面の皮膚の硬さが基準と比べて硬いものなのか柔らかいものなのかを把握することが可能になる。

[0054] そこで、駆動制御部３１は、計測した電流の振幅と、予め登録された基準範囲とを比較する（Ｓ１５，Ｓ１７）。計測した電流の振幅が基準範囲に収まる場合には（Ｓ１５：Ｙｅｓ）、駆動電圧を初期電圧のまま維持し、また、休止時間を所定の設定のまま維持する（Ｓ１６）。また、駆動制御部３１は、計測した電流の振幅が基準範囲よりも大きい場合には（Ｓ１７：Ｙｅｓ）、乳房表面の皮膚が基準よりも硬いことを意味しているため、駆動電圧を初期電圧から低減させた振幅に変更し、また、休止時間を所定の設定から短縮する（Ｓ１８）。また、駆動制御部３１は、計測した電流の振幅が基準範囲よりも小さい場合には（Ｓ１７：Ｎｏ）、乳房表面の皮膚が基準よりも柔らかいことを意味しているため、駆動電圧を初期電圧から増加させた振幅に変更し、また、休止時間を所定の設定から伸長する（Ｓ１９）。

[0055] そして、駆動制御部３１は、上記のような電圧振幅と休止時間の長さに駆動電圧のパターンを設定し、圧電素子２２に駆動電圧を印加する（Ｓ２０）。そして、駆動制御部３１は、圧電素子２２への駆動電圧の印加と（Ｓ２０）と、駆動電圧の印加停止と（Ｓ２１）を繰り返す。

[0056] 以上に説明したように、圧電素子２２に流れる電流を検出して圧電素子２２の駆動電圧のパターンを制御する場合には、検知部３２は電流を検出する機能を有していれば良く、回路構成を非常に簡易で小型のものにできる。

[0057] なお、ここで示した駆動制御部３１では、乳房表面の皮膚が基準よりも硬い場合に、圧電素子２２に流れる電流の振幅が基準範囲よりも大きくなり、乳房表面の皮膚が基準よりも柔らかい場合に、圧電素子２２に流れる電流の振幅が基準範囲よりも小さくなるような場合について示したが、吸引ポンプ２１の構成や駆動制御部３１の構成によっては、逆に、乳房表面の皮膚が基

準よりも硬い場合に、圧電素子２２に流れる電流の振幅が基準範囲よりも小さくなり、乳房表面の皮膚が基準よりも柔らかい場合に、圧電素子２２に流れる電流の振幅が基準範囲よりも大きくなるような場合もある。そのため、上記の動作フローにおいて、駆動電圧の振幅や休止時間をどのように設定するかは、乳房表面の皮膚の硬さと圧電素子２２に流れる電流との実際の対応関係に基づいて、適宜設定することが好ましい。

[0058] 《第２の実施形態》

次に、本発明の第２の実施形態に係る搾乳器について説明する。

[0059] 本発明の第２の実施形態に係る搾乳器では、搾乳カップ１１での乳房の吸引状態を検知する検知部の構成やパターン調整部の機能が第１の実施形態と相違している。

[0060] 図８は、第２の実施形態に係る搾乳器が備える駆動制御部４１のブロック図である。

[0061] ここで示す駆動制御部４１は、圧電素子２２における電流と電圧との位相差に基づいて搾乳カップ１１での乳房の吸引状態を検知する機能を有している。圧電素子２２を流れる電流と駆動電圧との位相差は、吸引圧に応じて変化する。したがって、搾乳カップ１１での乳房の吸引状態と、圧電素子２２における電流と電圧との位相差との対応関係が既知であれば、電流の位相と電圧の位相とを検出して、搾乳カップ１１での乳房の吸引状態を把握することができる。

[0062] 駆動制御部４１は、検知部４２、パターン調整部４３、記憶部４０、電圧コントローラ３４、および昇圧回路３５、を備えている。検知部４２は本発明の検知手段を構成するものであり、電流検出部４４、電圧検出部４５、位相比較器４６、および抵抗４７を備えている。電流検出部４４は、抵抗値が既知である抵抗４７の両端の電圧を計測することにより、圧電素子２２に流れる電流を計測する。抵抗４７は、圧電素子２２と昇圧回路３５とを接続する電圧線に挿入されている。電圧検出部４５は、圧電素子２２に印加される駆動電圧を計測する。位相比較器４６は、電流検出部４４が計測した電流と

電圧検出部４５が計測した電圧との位相差θを出力する。パターン調整部４３は、位相比較器４６が出力した位相差θに基づいて、搾乳カップ１１での乳房の吸引状態に応じた最適な駆動電圧のパターンとなるように、電圧コントローラ３４を設定し、電圧コントローラ３４から昇圧回路３５に電圧を出力させる。

[0063] なお、位相比較器４６としては、例えば、ＰＬＬ（Phase Locked Loop）等で用いられる位相周波数比較器（Phase FrequencyComparator）のような回路方式のデジタル型比較器を使用することができる。また、パターン調整部４３、電圧コントローラ３４および検知部４２の機能の一部は、例えば、マイコンに構成することができる。例えば、ＰＷＭ制御を行うマイコンを用いる場合には、マイコンのＩ／Ｏ端子を検知部４２に接続し、マイコンのＰＷＭ出力端子を昇圧回路３５に直接接続する。そして、マイコンでＰＷＭ制御出力のデューティー比を変更することにより、昇圧回路３５の出力する駆動電圧の振幅を制御することができる。

[0064] 図９は、上記の圧電素子２２に流れる電流と駆動電圧との位相差を検出して圧電素子２２の駆動電圧のパターンを制御する場合の駆動制御部４１の動作例を示すフローチャートである。

[0065] 駆動制御部４１は、まず、圧電素子２２に初期振幅に設定された駆動電圧を印加する（Ｓ１１）。これにより、圧電素子２２が駆動して、搾乳器１０は搾乳カップ１１を介した母乳の吸引動作を開始する。次に、駆動制御部４１は、圧電素子２２への駆動電圧の印加を停止する（Ｓ１２）。次に、駆動制御部４１は、前述の図６（Ａ）で示した吸引圧が立ち下がる途中の既定の時刻ｔ１となるのを待ち（Ｓ１３：Ｙｅｓ）、圧電素子２２に流れる電流と駆動電圧との位相差を計測する（Ｓ１３→Ｓ２４）。

[0066] 次に、駆動制御部４１は、計測した位相差と、予め登録された位相差の基準範囲とを比較する（Ｓ２５，Ｓ２７）。計測した位相差が基準範囲に収まる場合には（Ｓ２５：Ｙｅｓ）、駆動電圧を初期電圧のまま維持し、また、休止時間を所定の設定のまま維持する（Ｓ１６）。また、駆動制御部４１は

、計測した位相差が基準範囲よりも大きい場合には（Ｓ２７：Ｙｅｓ）、駆動電圧を初期電圧から増加させた振幅に変更し、また、休止時間を所定の設定から短縮する（Ｓ１８）。また、駆動制御部４１は、計測した位相差が基準範囲よりも小さい場合には（Ｓ２７：Ｎｏ）、駆動電圧を初期電圧から低減させた振幅に変更し、また、休止時間を所定の設定から伸長する（Ｓ１９）。

[0067] そして、駆動制御部４１は、上記のように設定した電圧振幅と休止時間の長さで、駆動電圧のパターンを設定し、圧電素子２２に駆動電圧を印加する（Ｓ２０）。そして、駆動制御部４１は、圧電素子２２への駆動電圧の印加と（Ｓ２０）と、駆動電圧の印加停止と（Ｓ２１）を繰り返す。

[0068] 以上に説明したように、圧電素子２２に流れる電流と駆動電圧との位相差を検出して圧電素子２２の駆動電圧のパターンを制御する場合には、駆動電圧の変動や温度変化がある条件下であっても、搾乳カップ１１での乳房の吸引状態を精度良く把握し、吸引圧を高精度に調整することができる。

[0069] なお、ここで示した駆動制御部４１では、乳房表面の皮膚が基準よりも硬い場合に、位相差が基準範囲よりも大きくなり、乳房表面の皮膚が基準よりも柔らかい場合に、位相差が基準範囲よりも小さくなるような場合について示したが、吸引ポンプ２１の構成や駆動制御部４１の構成によっては、逆に、乳房表面の皮膚が基準よりも硬い場合に、位相差が基準範囲よりも小さくなり、乳房表面の皮膚が基準よりも柔らかい場合に、位相差が基準範囲よりも大きくなるような場合もある。そのため、上記の動作フローにおいて、駆動電圧の振幅や休止時間をどのように設定するかは、乳房表面の皮膚の硬さと位相差との実際の対応関係に基づいて、適宜設定することが好ましい。

[0070] 《第３の実施形態》

次に、本発明の第３の実施形態に係る搾乳器について説明する。

[0071] 本発明の第３の実施形態に係る搾乳器では、搾乳カップ１１での乳房の吸引状態を検知する検知部の構成やパターン調整部の機能が第１の実施形態および第２の実施形態と相違している。

[0072] 図１０は、第３の実施形態に係る搾乳器が備える駆動制御部５１のブロック図である。

[0073] ここで示す駆動制御部５１は、圧電素子２２の共振周波数に基づいて搾乳カップ１１での乳房の吸引状態を検知する機能を有している。圧電素子２２の共振周波数は、圧電素子２２のインピーダンスの大きさが極小となる周波数、すなわち、圧電素子２２を流れる電流の振幅が極大となる周波数である。そこで、駆動電圧の周波数を所定範囲で変化させ、各周波数で圧電素子２２を流れる電流を計測し、計測された電流の振幅が極大になる周波数を選択することにより、圧電素子２２の共振周波数を算出することができる。また、圧電素子２２の共振周波数は、吸引圧に応じて変化する。したがって、搾乳カップ１１での乳房の吸引状態と、圧電素子２２の共振周波数との対応関係が既知であれば、共振周波数を検出して、搾乳カップ１１での乳房の吸引状態を把握することができる。

[0074] 駆動制御部５１は、検知部５２、パターン調整部５３、記憶部４０、電圧コントローラ３４、および昇圧回路３５、を備えている。検知部５２は本発明の検知手段を構成するものであり、電流検出部５４および共振周波数演算部５５を備えている。電流検出部５４は、圧電素子２２に流れる電流を計測する。共振周波数演算部５５は、電流検出部５４が計測した電流に基づいて、圧電素子２２の共振周波数を算出する。パターン調整部５３は、共振周波数演算部５５が算出した共振周波数に基づいて搾乳カップ１１での乳房の吸引状態を把握する。

[0075] なお、パターン調整部５３、電圧コントローラ３４、および共振周波数演算部５５は、例えば、マイコンに構成することができる。例えば、ＰＷＭ制御を行うマイコンを用いる場合には、マイコンのＩ／Ｏ端子を電流検出部５４に接続し、マイコンのＰＷＭ出力端子を昇圧回路３５に直接接続する。そして、マイコンでＰＷＭ制御出力のデューティー比を変更することにより、昇圧回路３５の出力する駆動電圧を制御することができる。

[0076] 図１１は、上記の圧電素子２２の共振周波数を検出する場合の駆動制御部

５１の動作例を示すフローチャートである。

[0077] 駆動制御部５１は、まず、圧電素子２２に初期振幅に設定された駆動電圧を印加する（Ｓ１１）。これにより、圧電素子２２が駆動して、搾乳器１０は搾乳カップ１１を介した母乳の吸引動作を開始する。次に、駆動制御部５１は、圧電素子２２への駆動電圧の印加を停止する（Ｓ１２）。次に、駆動制御部５１は、前述の図６（Ａ）で示した吸引圧が立ち下がる途中の既定の時刻ｔ１となるのを待ち（Ｓ１３：Ｙｅｓ）、圧電素子２２の共振周波数を計測する（Ｓ１３→Ｓ３４）。なお、ここでは詳細なフローの記載は省いているが、前述のように共振周波数演算部５５は、電圧コントローラ３４を介して昇圧回路３５が出力する駆動電圧の周波数を所定範囲で変化させ、各周波数で圧電素子２２を流れる電流を計測し、計測された電流の振幅が極大になる周波数を選択することにより、圧電素子２２の共振周波数を算出する。

[0078] 次に、駆動制御部５１は、計測した共振周波数と、予め登録された基準範囲とを比較する（Ｓ３５，Ｓ３７）。計測した共振周波数が基準範囲に収まる場合には（Ｓ３５：Ｙｅｓ）、駆動電圧を初期電圧のまま維持し、また、休止時間を所定の設定のまま維持する（Ｓ１６）。また、駆動制御部５１は、計測した共振周波数が基準範囲よりも大きい場合には（Ｓ３７：Ｙｅｓ）、駆動電圧を初期電圧から増加させた振幅に変更し、また、休止時間を所定の設定から短縮する（Ｓ１８）。また、駆動制御部５１は、計測した共振周波数が基準範囲よりも小さい場合には（Ｓ３７：Ｎｏ）、駆動電圧を初期電圧から低減させた振幅に変更し、また、休止時間を所定の設定から伸長する（Ｓ１９）。

[0079] そして、駆動制御部５１は、上記のように設定した電圧振幅と休止時間の長さで、駆動電圧のパターンを設定し、圧電素子２２に駆動電圧を印加する（Ｓ２０）。そして、駆動制御部５１は、圧電素子２２への駆動電圧の印加と（Ｓ２０）と、駆動電圧の印加停止と（Ｓ２１）を繰り返す。

[0080] 以上に説明したように、圧電素子２２の共振周波数を検出して圧電素子２２の駆動電圧のパターンを制御する場合には、駆動電圧の周波数を検知部５

２で計測する共振周波数に合わせこむことで、駆動電圧の振幅を変化させずに圧電素子２２の振動を大きくすることができ、他の実施形態と同じような消費電力であってもより高い吸引圧を得ることや、他の実施形態と同じような吸引圧を得る場合であっても消費電力をより低減することができる。

[0081] なお、ここで示した駆動制御部５１では、乳房表面の皮膚が基準よりも硬い場合に、共振周波数が基準範囲よりも大きくなり、乳房表面の皮膚が基準よりも柔らかい場合に、共振周波数が基準範囲よりも小さくなるような場合について示したが、吸引ポンプ２１の構成や駆動制御部５１の構成によっては、逆に、乳房表面の皮膚が基準よりも硬い場合に、共振周波数が基準範囲よりも小さくなり、乳房表面の皮膚が基準よりも柔らかい場合に、共振周波数が基準範囲よりも大きくなるような場合もある。そのため、上記の動作フローにおいて、駆動電圧の振幅や休止時間をどのように設定するかは、乳房表面の皮膚の硬さと共振周波数との実際の対応関係に基づいて、適宜設定することが好ましい。

符号の説明

[0082] １０…搾乳器
１１…搾乳カップ
１３…セパレータ
１４…保存容器
１５…圧電駆動部
１６…流路
２１…吸引ポンプ
２２…圧電素子
２３…構造体
２４…流路
２５…ポンプ室
２６…吐出口
２７…吸入口

２８…ダイヤフラム

３１，４１，５１…駆動制御部

３２，４２，５２…検知部

３３，４３，５３…パターン調整部

３４…電圧コントローラ

３５…昇圧回路

３９…インジケータ

４４，５４…電流検出部

４５…電圧検出部

４６…位相比較器

４７…抵抗

５５…共振周波数演算部

請求の範囲

[請求項1] 乳房に装着される吸入部と、

前記吸入部の乳房側から流体を吸引する吸引ポンプと、

前記吸入部での乳房の吸引状態の時間変化を検知する検知手段と、

前記検知手段が検出した前記吸引状態の時間変化に基づいて処理を行う制御部と、

を備える搾乳器。

[請求項2] 前記検知手段は、前記吸入部での乳房の吸引状態を、前記吸引ポンプの吸引圧に基づいて検知する、

請求項１に記載の搾乳器。

[請求項3] 前記吸引ポンプは、駆動電圧が印加されて動作する圧電素子を有する、

請求項２に記載の搾乳器。

[請求項4] 前記検知手段は、前記圧電素子のインピーダンスの状態を検出し、検出した前記圧電素子のインピーダンスの状態に基づいて前記吸引ポンプの吸引圧を検知する、

請求項３に記載の搾乳器。

[請求項5] 前記圧電素子のインピーダンスの状態と前記吸引ポンプの吸引圧との対応関係を予め記憶した記憶部を更に備え、

前記検知手段は、前記記憶部を参照することにより、前記吸引ポンプの吸引圧を検知する、

請求項４に記載の搾乳器。

[請求項6] 前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子に流れる電流の振幅を検出する、

請求項５に記載の搾乳器。

[請求項7] 前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差を検出する、

請求項５に記載の搾乳器。

[請求項8] 前記検知手段は、前記圧電素子のインピーダンスの状態として、前記圧電素子の共振周波数を検出し、

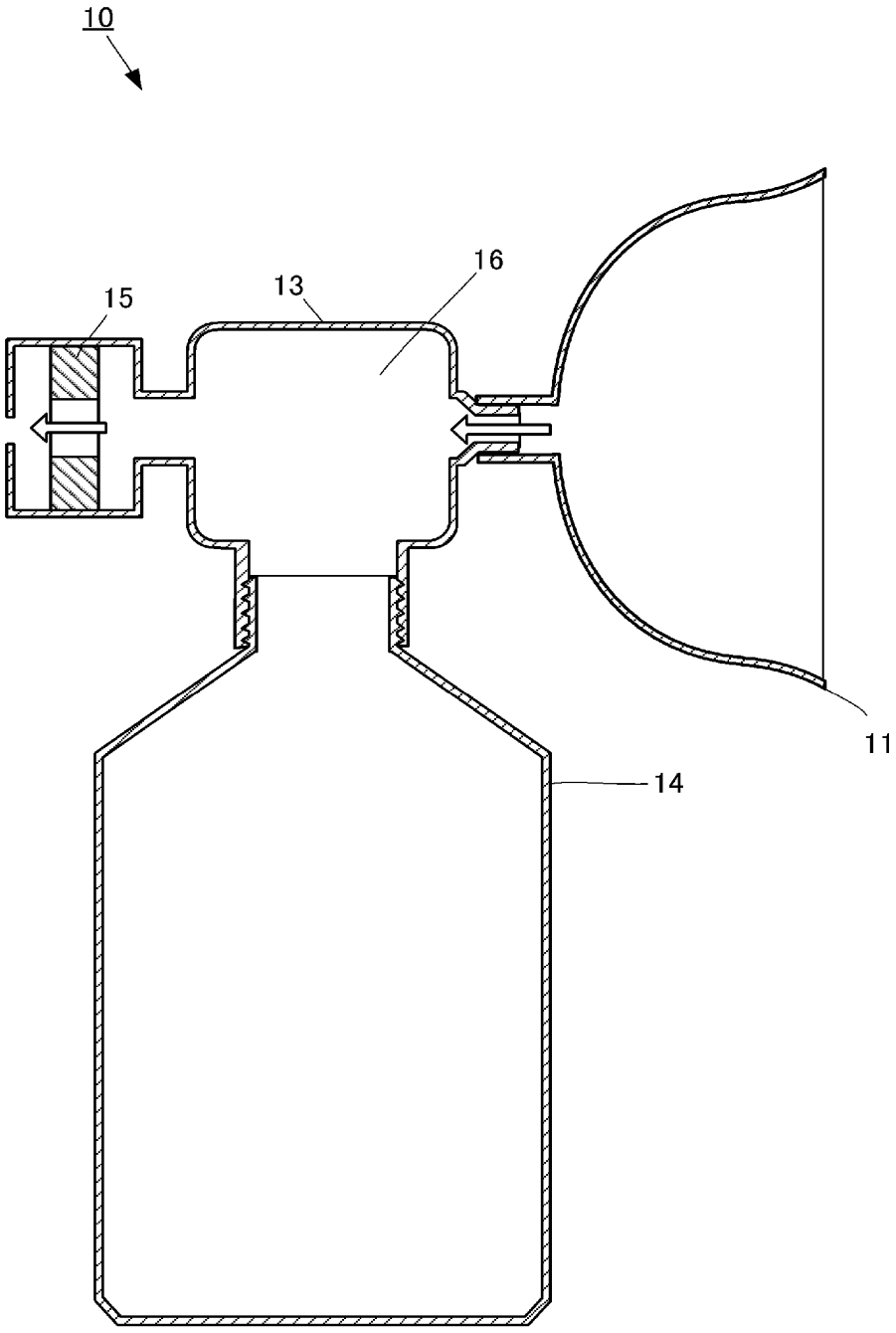
前記制御部は、前記共振周波数で前記圧電素子を駆動する、

請求項５に記載の搾乳器。

[請求項9] 前記検知手段で検知した状態を報知する報知部を更に備える、

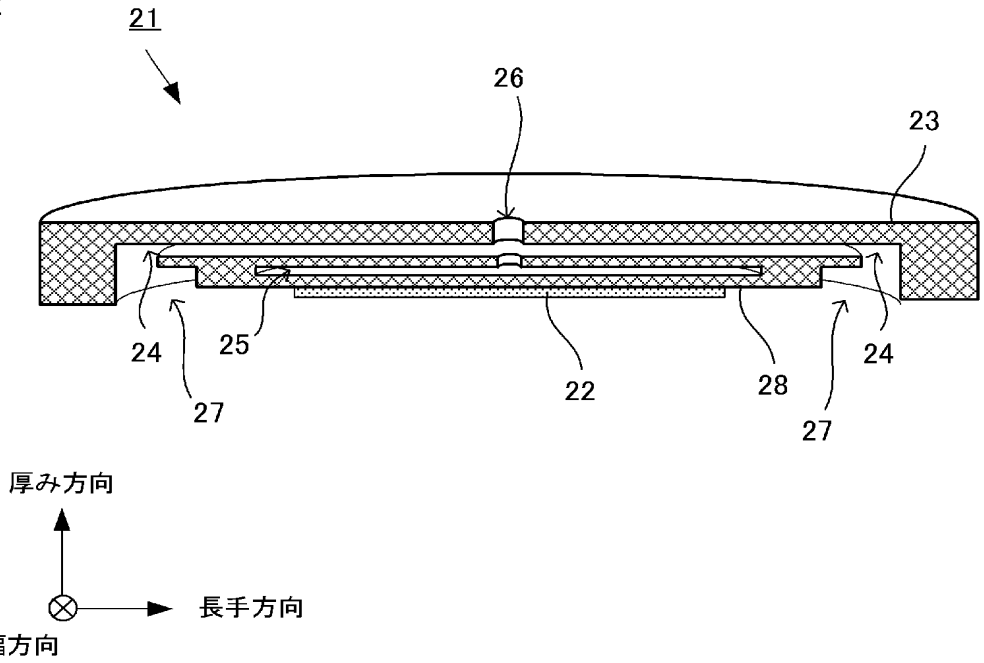
請求項１乃至請求項８のいずれかに記載の搾乳器。

[図1]
図1



[図2]

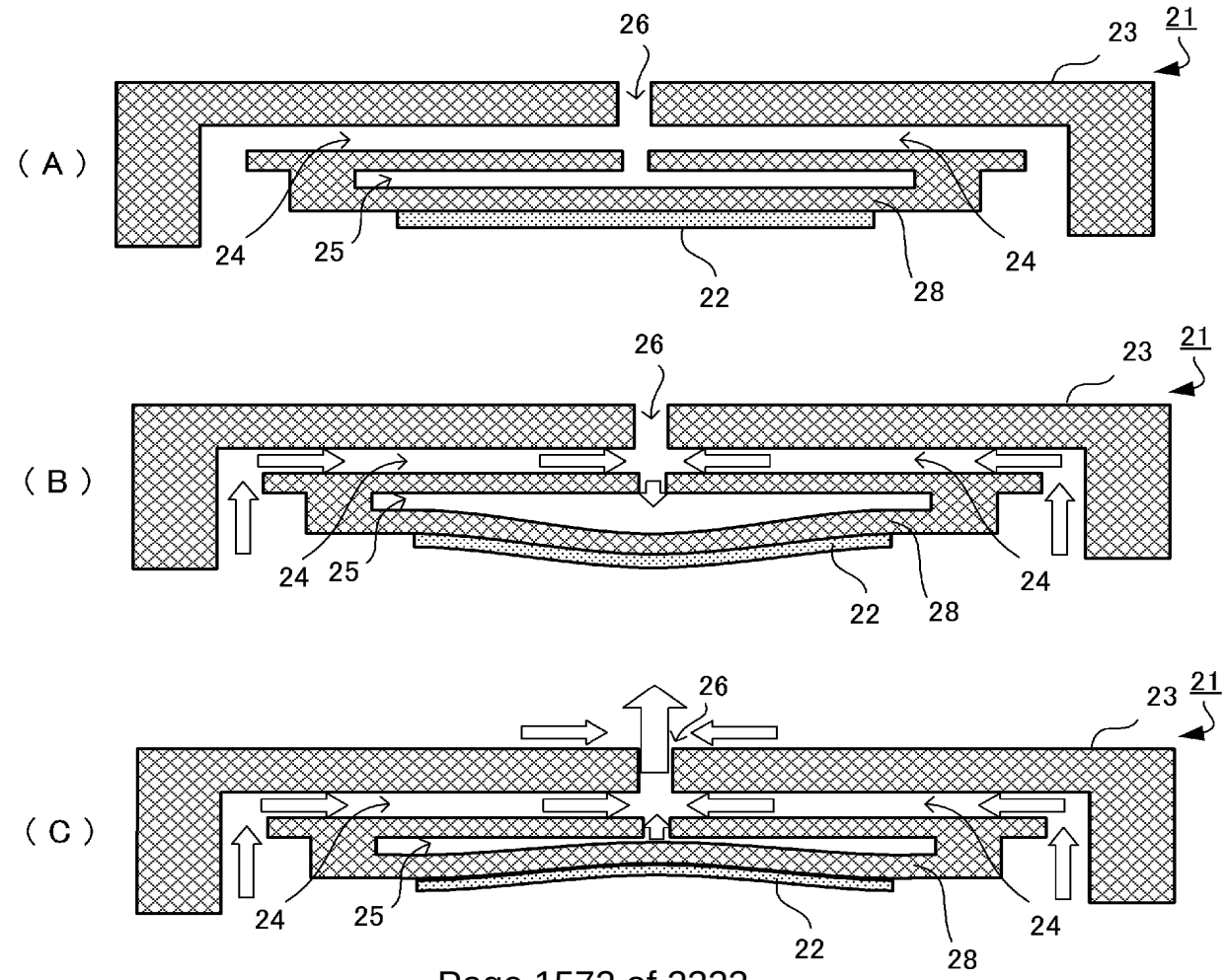
図2


21
26
23
24
25
27
22
28
27
24

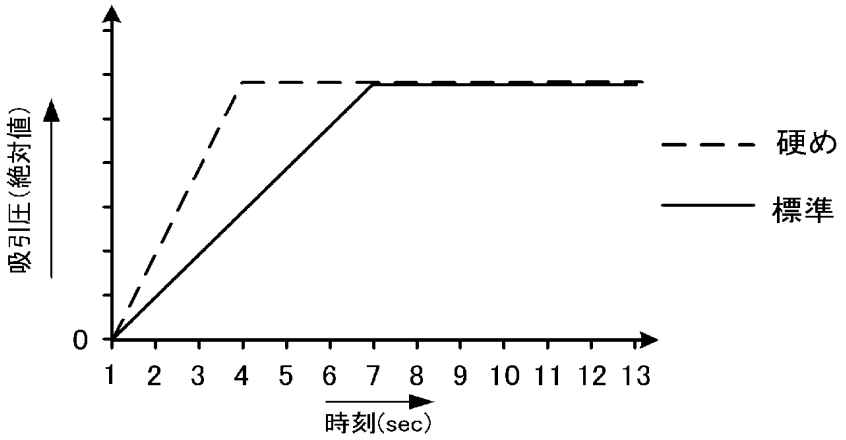
厚み方向
長手方向
幅方向

[図3]

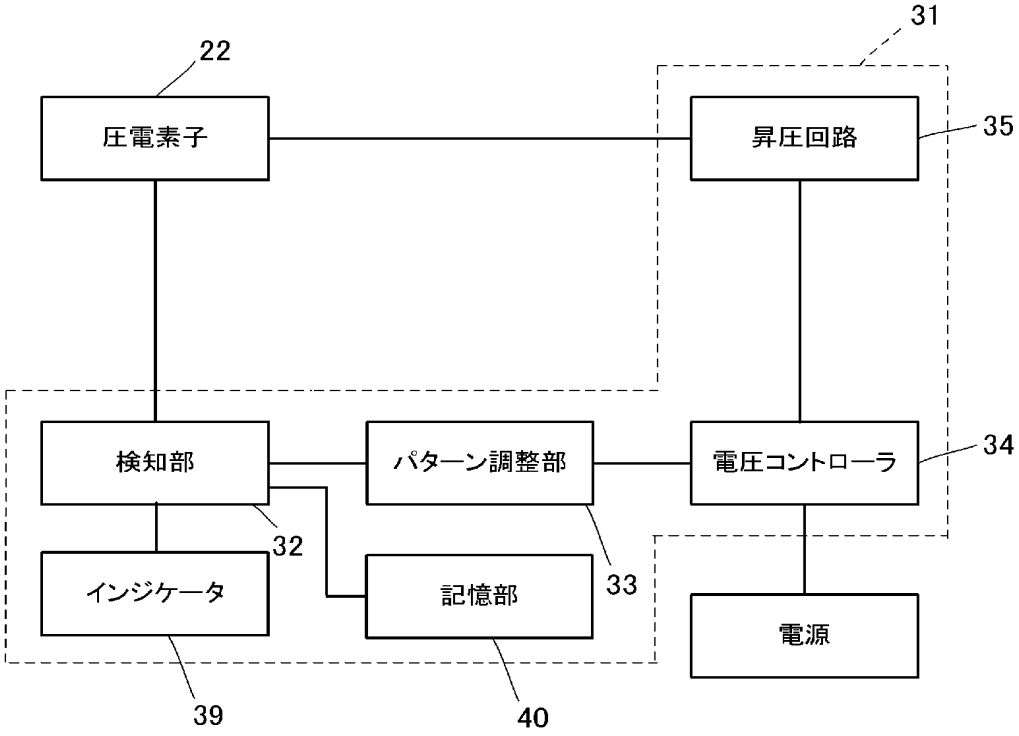
図3


（A）
26
23
21
24
25
22
28
24
（B）
26
23
21
24
25
22
28
24
（C）
26
23
21
24
25
22
28
24

[図4]
図4

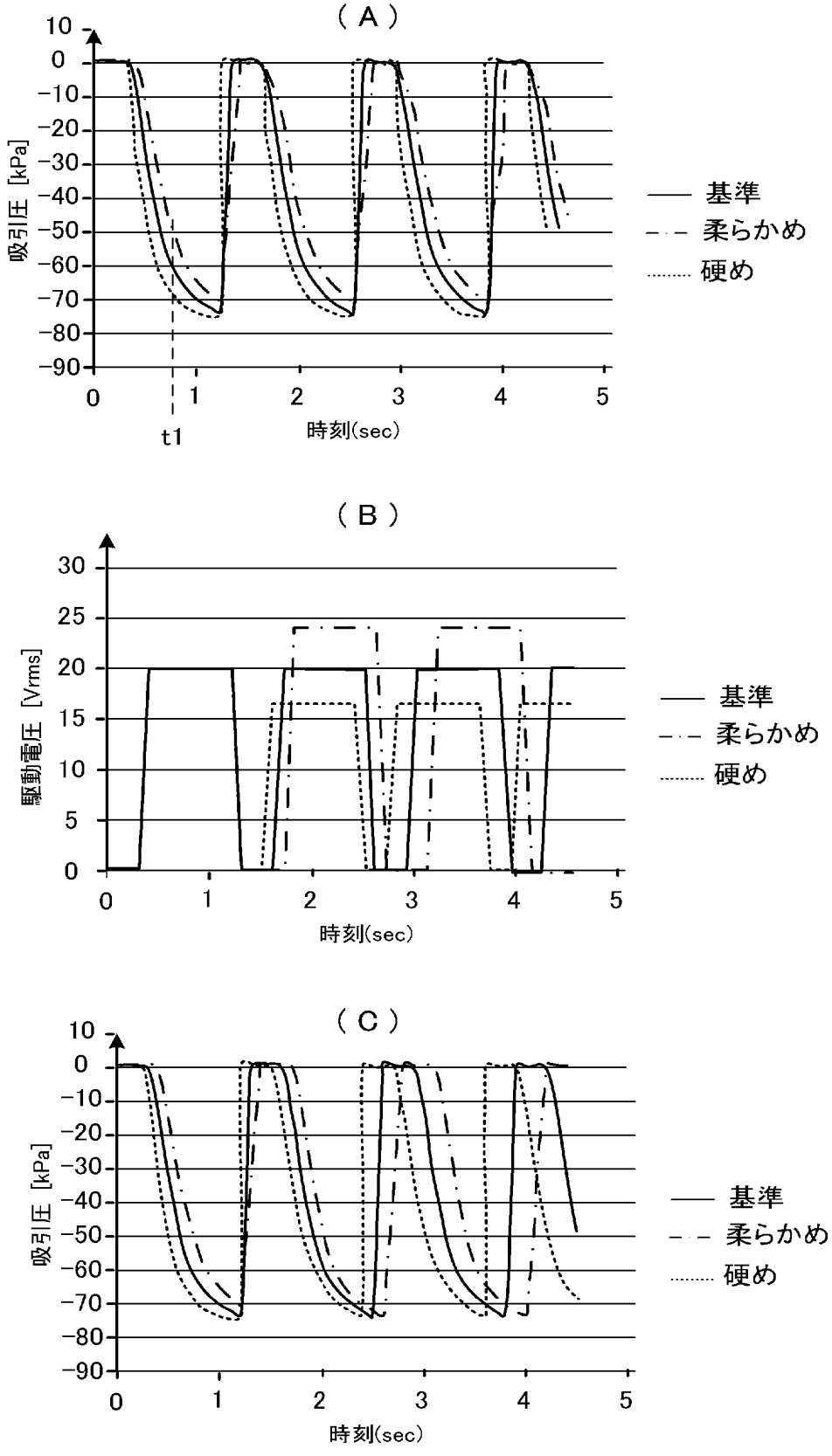

吸引圧（絶対値）
0
1 2 3 4 5 6 7 8 9 10 11 12 13
時刻(sec)
硬め
標準

[図5]
図5


31
22
圧電素子
昇圧回路
35
検知部
パターン調整部
電圧コントローラ
34
32
33
インジケータ
記憶部
電源
39
40

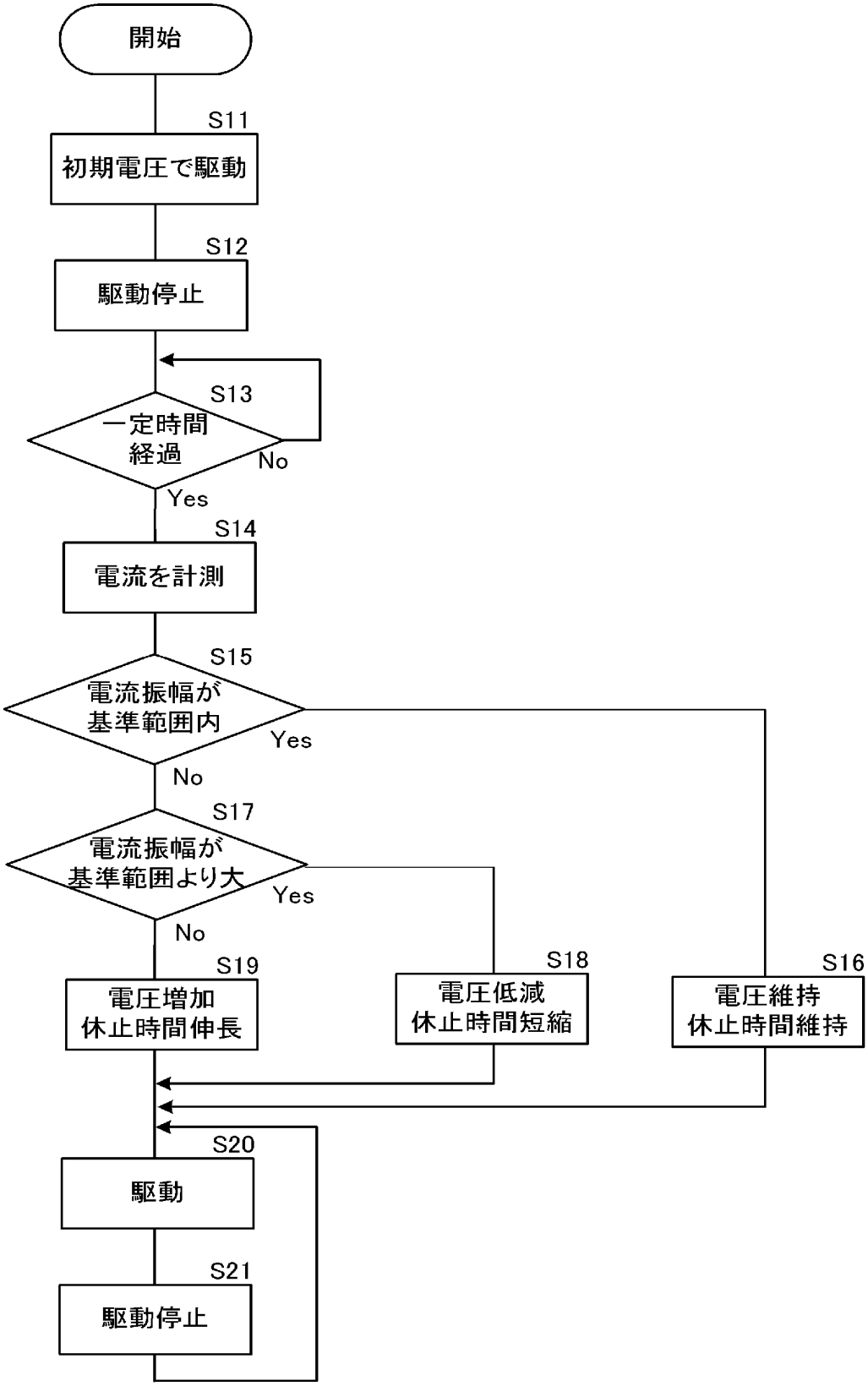
[図6]

図6

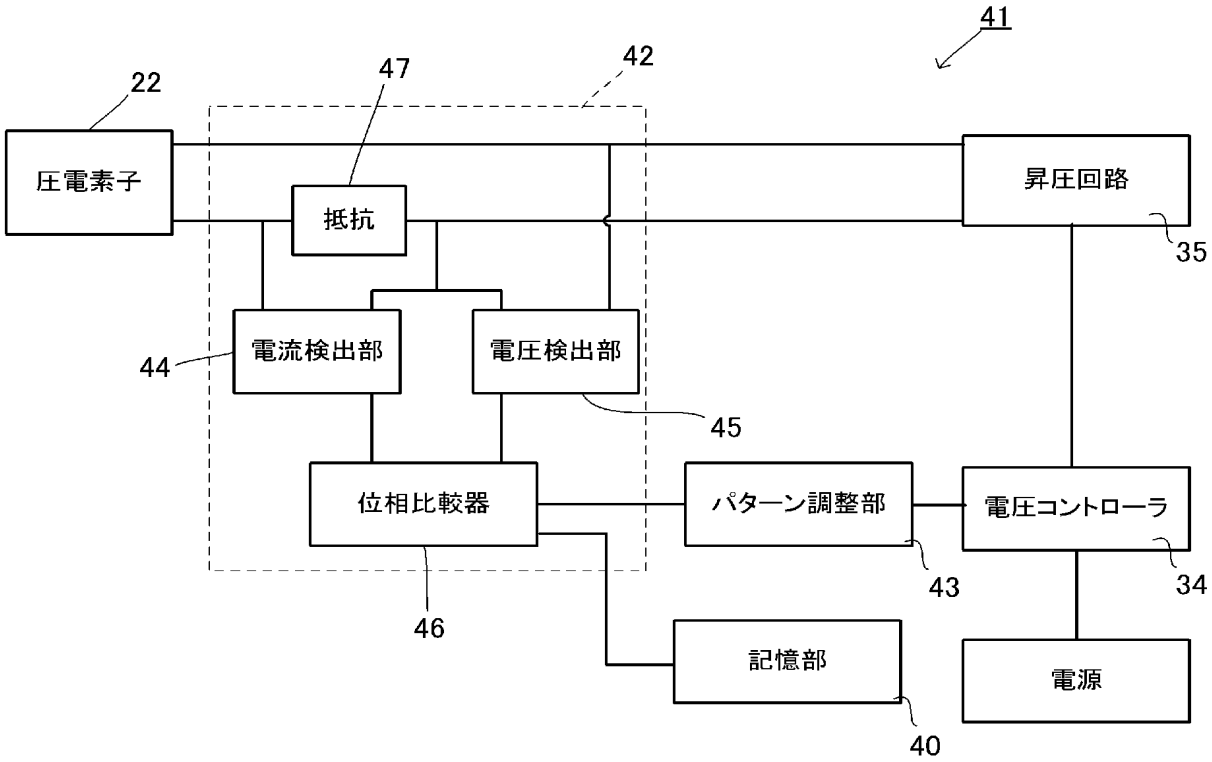

（A）
吸引圧 [kPa]
10
0
−10
−20
−30
−40
−50
−60
−70
−80
−90
0
1
2
3
4
5
t1
時刻(sec)
基準
柔らかめ
硬め
（B）
駆動電圧 [Vrms]
30
25
20
15
10
5
0
時刻(sec)
基準
柔らかめ
硬め
（C）
吸引圧 [kPa]
時刻(sec)
基準
柔らかめ
硬め

[図7]

図7

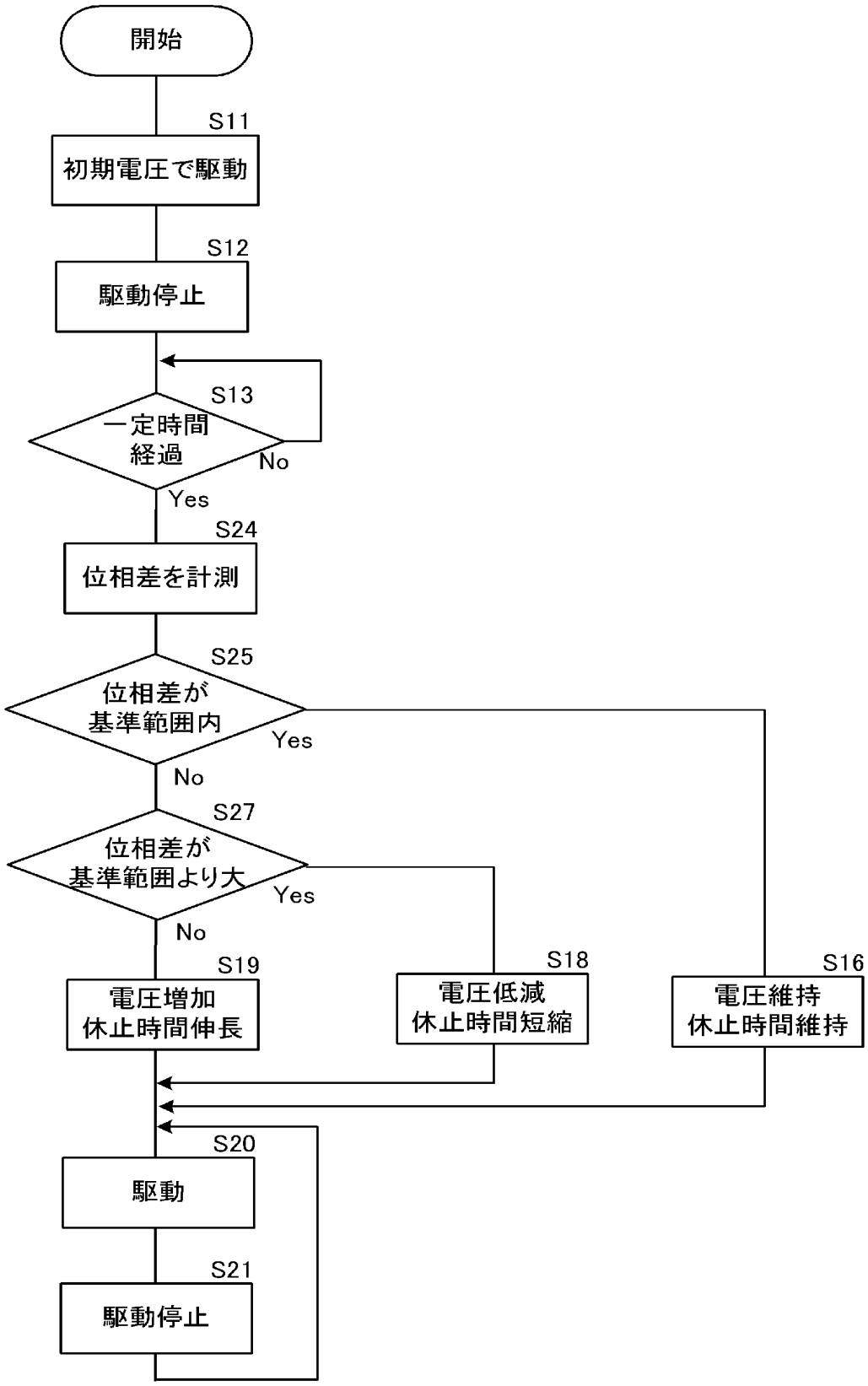

開始
S11
初期電圧で駆動
S12
駆動停止
S13
一定時間
経過
No
Yes
S14
電流を計測
S15
電流振幅が
基準範囲内
Yes
No
S17
電流振幅が
基準範囲より大
Yes
No
S19
電圧増加
休止時間伸長
S18
電圧低減
休止時間短縮
S16
電圧維持
休止時間維持
S20
駆動
S21
駆動停止

[図8]
図８

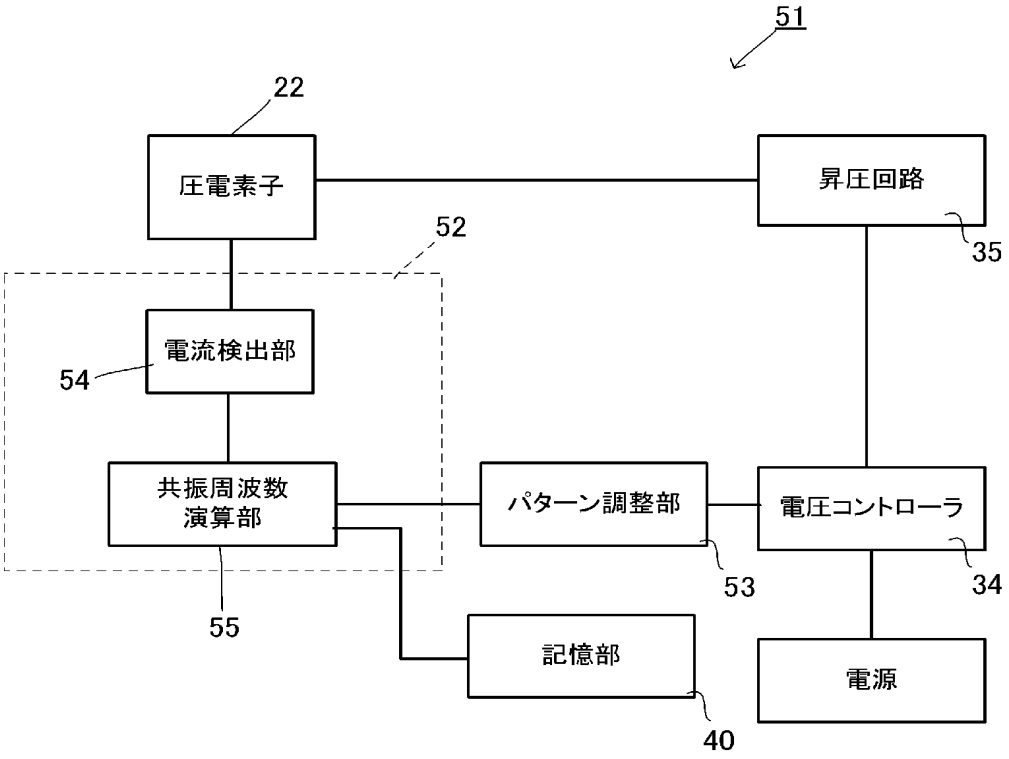

41
42
47
22
圧電素子
抵抗
昇圧回路
35
電流検出部
電圧検出部
44
45
位相比較器
パターン調整部
電圧コントローラ
43
34
46
記憶部
電源
40

[図9]

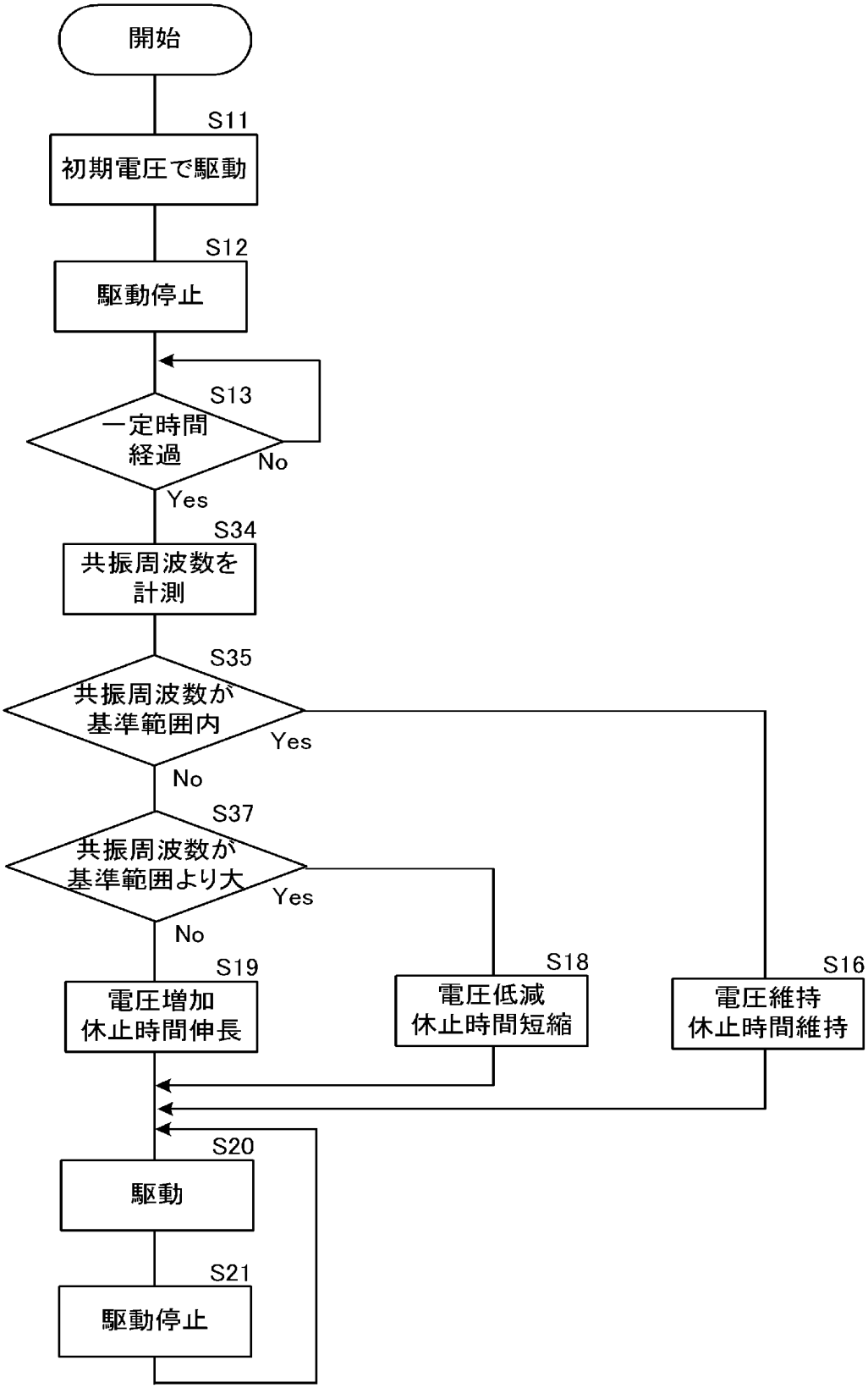
図９


開始
S11
初期電圧で駆動
S12
駆動停止
S13
一定時間
経過
No
Yes
S24
位相差を計測
S25
位相差が
基準範囲内
Yes
No
S27
位相差が
基準範囲より大
Yes
No
S19
電圧増加
休止時間伸長
S18
電圧低減
休止時間短縮
S16
電圧維持
休止時間維持
S20
駆動
S21
駆動停止

[図10]
図10


51
22
圧電素子
昇圧回路
35
52
電流検出部
54
共振周波数
演算部
パターン調整部
電圧コントローラ
53
34
55
記憶部
電源
40

[図11]
図１１


開始
S11
初期電圧で駆動
S12
駆動停止
S13
一定時間
経過
No
Yes
S34
共振周波数を
計測
S35
共振周波数が
基準範囲内
Yes
No
S37
共振周波数が
基準範囲より大
Yes
No
S19
電圧増加
休止時間伸長
S18
電圧低減
休止時間短縮
S16
電圧維持
休止時間維持
S20
駆動
S21
駆動停止

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068747

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/06(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 2008/0177224 A1 (KELLY Patricia A. et al.), 24 July 2008 (24.07.2008), paragraphs [0023] to [0037]; fig. 1, 3, 5 to 8, 11 (Family: none)	1-2,9 3 4-8
X Y A	JP 2011-507577 A (Koninklijke Philips Electronics N.V.), 10 March 2011 (10.03.2011), paragraphs [0004] to [0006], [0018] to [0030]; fig. 2 to 3 & US 2011/0004154 A1 paragraphs [0004] to [0006], [0020] to [0032]; fig. 2 to 3 & WO 2009/081313 A1 & EP 2196230 A1 & CN 101903054 A	1-2,9 3 4-8

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Telephone No.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/141113 A1 (Murata Mfg. Co., Ltd., Omron Healthcare Co., Ltd.), 18 October 2012 (18.10.2012), paragraphs [0045] to [0048]; fig. 1 to 2, 4 & US 2013/0178752 A1 paragraphs [0088] to [0091]; fig. 1 to 2, 4 & JP 5185475 B2 & US 2015/0096638 A1 & EP 2698107 A1	3
A	JP 2012-533390 A (Koninklijke Philips Electronics N.V.), 27 December 2012 (27.12.2012), entire text; all drawings & US 2012/0116298 A1 & WO 2011/010255 A1 & EP 2277571 A1 & CN 102470202 A & KR 10-2012-0069669 A	1-9
A	JP 2005-279043 A (Pigeon Corp.), 13 October 2005 (13.10.2005), entire text; all drawings & US 2005/0234400 A1	1-9
A	JP 2003-518412 A (Medela, Inc., Silver Brian H.), 10 June 2003 (10.06.2003), entire text; all drawings & US 6547756 B1 & WO 2001/047577 A2	1-9
A	US 2012/0277636 A1 (BLOMDHEIM David Simeon, et al.), 01 November 2012 (01.11.2012), entire text; all drawings & US 2015/0148709 A1 & WO 2012/172437 A2	1-9

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６８７４７

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X Y A	US 2008/0177224 A1 (KELLY Patricia A. et al.) 2008.07.24, 段落[0023]-[0037], 第1, 3, 5-8, 11図 (ファミリーなし)	1-2, 9 3 4-8
X Y A	JP 2011-507577 A (コーニンクレッカ　フィリップス　エレクトロニクス　エヌ　ヴィ) 2011.03.10, 段落[0004]-[0006], [0018]-[0030], 第2-3図 & US 2011/0004154 A1, 段落[0004]-[0006], [0020]-[0032], 第2-3図	1-2, 9 3 4-8

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日 ２７．０８．２０１５	国際調査報告の発送日 １５．０９．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｉ　４１３８ 川島　徹 電話番号　０３－３５８１－１１０１　内線　３３８６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
	& WO 2009/081313 A1 & EP 2196230 A1 & CN 101903054 A	
Y	WO 2012/141113 A1 (株式会社村田製作所, オムロンヘルスケア株式会社) 2012.10.18, 段落[0045]-[0048], 第1-2, 4図 & US 2013/0178752 A1, 段落[0088]-[0091], 第1-2, 4図 & JP 5185475 B2 & US 2015/0096638 A1 & EP 2698107 A1	3
A	JP 2012-533390 A (コーニンクレッカ　フィリップス　エレクトロニクス　エヌ　ヴィ) 2012.12.27, 全文, 全図 & US 2012/0116298 A1 & WO 2011/010255 A1 & EP 2277571 A1 & CN 102470202 A & KR 10-2012-0069669 A	1-9
A	JP 2005-279043 A (ピジョン株式会社) 2005.10.13, 全文, 全図 & US 2005/0234400 A1	1-9
A	JP 2003-518412 A (メデラ　インコーポレイテッド, シルヴァー　ブライアン　エイチ) 2003.06.10, 全文, 全図 & US 6547756 B1 & WO 2001/047577 A2	1-9
A	US 2012/0277636 A1 (BLOMDHEIM David Simeon, et al.) 2012.11.01, 全文, 全図 & US 2015/0148709 A1 & WO 2012/172437 A2	1-9

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(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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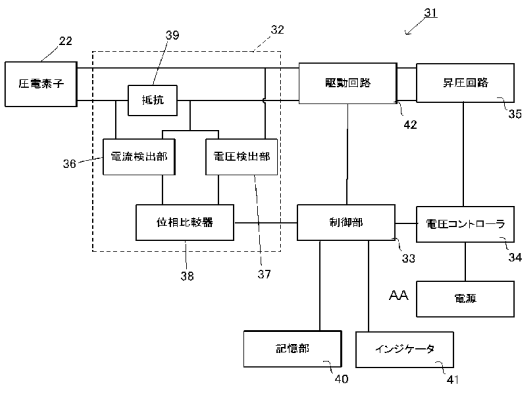
添付公開書類:

— 国際調査報告（条約第 21 条(3)）

(54) **Title**: SUCTION DEVICE

(54) 発明の名称 : 吸引装置

図5



22 Piezoelectric element
33 Control unit
34 Voltage controller
35 Voltage boosting circuit
36 Current detection unit
37 Voltage detection unit
38 Phase comparator
39 Resistance
40 Memory unit
41 Injector
42 Drive circuit
AA Power source

(57) **Abstract**: A suction device (10) that comprises: a suction unit (11) that suctions an external fluid; a piezoelectric pump (21) that has a piezoelectric element (22) that has a drive voltage applied thereto and oscillates, and that suctions the fluid via the suction unit (11) by means of the oscillation of the piezoelectric element (22); a detection circuit (32) that detects the phase difference between the current flowing in the piezoelectric element (22) and the drive voltage of the piezoelectric element; and a control unit (33) that performs processing on the basis of the phase difference detected by the detection circuit (32).

(57) 要約: 外部の流体を吸入する吸入部（１１）と、駆動電圧が印加されて振動する圧電素子（２２）を有し、前記圧電素子（２２）の振動により前記吸入部（１１）を介して流体を吸引する圧電ポンプ（２１）と、前記圧電素子（２２）に流れる電流と前記圧電素子の駆動電圧との位相差を検出する検出回路（３２）と、前記検出回路（３２）が検出した前記位相差に基づいて処理を行う制御部（３３）と、を備える吸引装置（１０）。

WO 2016/006496 A1

明　細　書

発明の名称 ： 吸引装置

技術分野

[0001] 本発明は、鼻水や痰、母乳等の流体を吸引する際に利用される吸引装置に関する。

背景技術

[0002] 近年、鼻水や痰、母乳などを吸入することができる電動式の吸入装置（吸引装置）が普及してきている。通常、吸引装置は、外部の流体を吸入する吸入部と、吸入部から流体を吸引する吸引ポンプと、吸引した流体を貯蔵する容器とを備えて構成される（例えば、特許文献１参照。）。

先行技術文献

特許文献

[0003] 特許文献1：特開２００１－２１８８３１号公報

発明の概要

発明が解決しようとする課題

[0004] 従来の吸引装置では、吸引ポンプの動力源にモータを用いることが一般的であったが、鼻水や痰、母乳等の体液を吸引する用途では、吸引装置の静音化や小型化の要望が強く、本願発明者は吸引ポンプの動力源に圧電素子を用いる吸引装置の開発を進めている。

[0005] 以下、本願発明者が検討した内容を説明する。

[0006] 圧電素子を用いる吸引装置では、圧電素子の駆動に伴う自己発熱などにより、時間の経過とともに圧電素子の出力が上昇することがあった。このため、吸引装置による吸引圧を比較的高く設定する場合には、吸引圧が口腔内や鼻腔内からの吸引に適切とされる－２０ｋＰａを超える過吸引の状態になり、吸入部を当接させる対象部位の皮膚や粘膜を損傷させてしまう恐れがあった。

[0007] また、吸引装置の吸入部と対象部位とが十分に密着していない場合には、

対象部位の流体を十分に吸引することができない未吸引状態となるため、未吸引状態であることを確認できるようにすることも好ましいと考えた。

[0008] これらのことから、吸引装置は、過吸引状態や未吸引状態を把握するために吸引圧を検出する機能を有することが好ましい。吸引装置に吸引圧を検出する機能を持たせるためには、圧力センサを設ければよいが、このことは吸引装置の構成の複雑化などを招いてしまう。また、吸引ポンプの消費電流から吸引圧の状態を推定することも考えられるが、吸引ポンプの吸引圧を消費電流から推定する場合、吸引ポンプの駆動電圧（電圧振幅）が一定であるなどの所定条件下でしか、吸引圧を精度良く推定できない。

[0009] そこで本発明の目的は、圧力センサを用いること無く、吸引圧に応じた処理を高精度に行うことができる吸引装置を提供することにある。

課題を解決するための手段

[0010] 本発明の吸引装置は、吸入部と、圧電ポンプと、検出部と、制御部と、を備える。吸入部は、外部の流体を吸入する。圧電ポンプは、駆動電圧が印加されて振動する圧電素子を有し、前記圧電素子の振動により前記吸入部を介して流体を吸引する。検出部は、前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差を検出する。制御部は、前記検出部が検出した前記位相差に基づいて処理を行う。

[0011] この構成において、圧電素子に流れる電流（消費電流）と圧電素子の駆動電圧との位相差（以下、電流電圧位相差と称する。）は、圧電ポンプの吸引圧に応じたものになる。このため、電流電圧位相差に基づくことで、駆動電圧の変動や温度変動があるような条件下であっても、圧電ポンプの吸引圧に応じた処理を高精度に行うことができる。また、電流電圧位相差は温度変化の影響を受けにくく、このことによっても吸引圧に応じた処理を高精度に行うことができる。そして、この構成では、検出部として圧力センサを追加して設ける必要が無く、吸引装置の構成を簡易化することができる。更には、圧電素子では、駆動電圧の周波数を可聴音の周波数から外すことができ、モータのような動力源に比べて動作音を低減することができる。

[0012] 前記吸引装置は、前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差と前記圧電ポンプの吸引圧との対応関係を予め記憶した記憶部を更に備え、前記制御部は、前記記憶部を参照することにより、前記検出部が検出した位相差に基づいて処理を行うことが好ましい。

[0013] 前記制御部は、前記圧電ポンプの吸引圧が第１閾値を超える場合に、前記圧電ポンプへの駆動電圧の印加を停止させることが好ましい。この構成では、圧電素子の駆動に伴う自己発熱などにより、時間の経過とともに圧電素子の出力が上昇して過吸引状態になって、吸入部を当接させる対象部位の皮膚や粘膜を損傷させてしまうことを防ぐことができる。

[0014] 前記制御部は、前記圧電ポンプの吸引圧が第１閾値を超えて前記圧電ポンプへの駆動電圧の印加を停止させてから所定時間が経過する場合に、前記圧電ポンプへの駆動電圧の印加を開始させることが好ましい。この構成では、吸引圧を圧電ポンプの電流電圧位相差で検出することで過吸引状態になることを防ぐことができる。

[0015] 前記吸引装置は、情報を報知する報知部を更に備え、前記制御部は、前記圧電ポンプの吸引圧に関する情報を前記報知部に報知させることが好ましい。この構成では、報知部を介して圧電ポンプの吸引圧に関する情報を利用者に伝えることができる。報知部としては、液晶表示部や、表示ランプ、ブザー、無線通信部などを用いることができる。

[0016] 前記制御部は、前記圧電ポンプの吸引圧が第２閾値よりも小さい場合に、未吸引状態であることを示す情報を前記報知部に報知させることが好ましい。この構成では、未吸引状態であることを利用者が確認できる。

[0017] 前記制御部は、前記圧電ポンプの吸引圧が第２閾値よりも小さい状態が閾時間よりも長く続く場合に、前記圧電ポンプへの駆動電圧の印加を停止させることが好ましい。この構成では、未吸引状態である場合に圧電ポンプの駆動を停止して、消費電力を抑制することができる。

[0018] 前記制御部は、前記圧電ポンプの吸引圧が－２０ｋＰａを超える場合に、前記圧電ポンプへの駆動電圧の印加を停止させることが好ましい。この場合

、前記吸入部は、鼻腔に挿入される形状を有することが好ましい。これにより、鼻腔内の皮膚や粘膜を損傷させることを防ぎながら、鼻水を吸引することができる。また、前記吸入部は、乳房に沿う形状を有することが好ましい。これにより、胸部の皮膚や粘膜を損傷させることを防ぎながら、母乳を吸引することができる。また、前記吸入部は、咽頭部に挿入される形状を有することが好ましい。これにより、咽頭部の皮膚や粘膜を損傷させることを防ぎながら、痰を吸引することができる。

発明の効果

[0019] 本発明によれば、吸引装置において、圧力センサを用いること無く、吸引圧に応じた処理を高精度に行うことができる。

図面の簡単な説明

[0020] [図1]第１の実施形態に係る吸引装置の模式的断面図である。

[図2]第１の実施形態に係る吸引ポンプの断面図である。

[図3]第１の実施形態に係る吸引ポンプの振動態様を示す模式図である。

[図4]電流電圧位相差と吸引圧との対応関係を例示するグラフである。

[図5]第１の実施形態に係る駆動制御部のブロック図である。

[図6]第１の実施形態に係る駆動制御部が制御する吸引圧のパターンを例示するグラフである。

[図7]第１の実施形態に係る駆動制御部の第１の動作例を示すフローチャートである。

[図8]第１の実施形態に係る駆動制御部の第２の動作例を示すフローチャートである。

[図9]第２の実施形態に係る吸引装置の模式的断面図である。

[図10]第３の実施形態に係る吸引装置の吸入部を示す斜視図である。

発明を実施するための形態

[0021] 《第１の実施形態》

以下、本発明の第１の実施形態に係る吸引装置１０について説明する。

[0022] 図１は、吸引装置１０の模式的断面図である。吸引装置１０は、吸入部１

１、セパレータ１３、容器１４、および、圧電駆動部１５を備えている。吸引装置１０は鼻水吸引装置であり、吸入部１１は、左右の鼻腔に同時に挿入することができる形状の、いわゆるノーズピースとして構成されている。セパレータ１３は、下方に開口する容器状である。容器１４は、上方に開口する容器状であり、セパレータ１３の下方に設けられている。また、図１中では図示していないが、吸引装置１０には、吸入部１１での吸引状態を表示するインジケータ４１（図４参照）が設けられている。また、圧電駆動部１５には、圧電ポンプ２１（図２参照）と、駆動制御部３１（図４参照）とが設けられている。

[0023] 吸入部１１、セパレータ１３、および、圧電駆動部１５は、この順に吸引装置１０の前方から後方に向かって並べた状態で接続している。吸入部１１、セパレータ１３、容器１４、および、圧電駆動部１５には、吸入部１１の先端から圧電駆動部１５の後端まで繋がる流路１６が設けられている。

[0024] 圧電駆動部１５が駆動すると、流路１６には、吸入部１１の先端から圧電駆動部１５の後端へと向かう流体の流れが生じる。これにより、吸入部１１は鼻腔内の鼻水を空気とともに吸引する。セパレータ１３は、吸入部１１から吸引する鼻水と空気とを分離し、分離した鼻水を下方に滴下させる。容器１４は、セパレータ１３から滴下してくる鼻水を貯蔵する。

[0025] 図２は圧電ポンプ２１の断面図である。圧電ポンプ２１は圧電素子２２および構造体２３を備えている。構造体２３は、概略の外形が厚み方向に薄い円板状である。構造体２３の天面の中央付近には、吐出口２６が開口している。構造体２３の底面の縁付近には、吸入口２７が開口している。圧電ポンプ２１は、吸入口２７側がセパレータ１３側を向くように配置される。

[0026] 構造体２３の内部には、流路２４とポンプ室２５とが設けられている。流路２４は、構造体２３の天面で吐出口２６に通じており、構造体２３の内部で中央付近から外周側に延び、構造体２３の底面で吸入口２７に通じている。ポンプ室２５は、吐出口２６と流路２４との連通部分の底面側に設けられた薄い円筒状の空間であり、吐出口２６と流路２４との連通部分に開口して

いる。

[0027] 構造体２３におけるポンプ室２５の内底面は、屈曲振動が可能なダイヤフラム（振動板）２８として構成されている。ダイヤフラム２８は円板状であり、天面がポンプ室２５に面している。ダイヤフラム２８の天面は、ポンプ室２５を間に介して吐出口２６と対向している。圧電素子２２は、厚み方向に薄い円板状であり、ダイヤフラム２８の底面に貼り付いている。圧電素子２２は、交流の駆動電圧が印加されることで主面の面内方向に伸縮しようとする圧電性を有している。

[0028] 図３は、圧電ポンプ２１の振動態様を示す模式図である。圧電素子２２とダイヤフラム２８とは、互いに貼り付いてユニモルフ構造を構成しており、圧電素子２２の駆動により厚み方向に変位する。具体的には、図３（Ａ）に示すような静止状態から圧電素子２２が伸びようとする場合には、図３（Ｂ）に示すように、ダイヤフラム２８が圧電素子２２側（底面側）に凸に屈曲してポンプ室２５の体積が増大する。これにより、ポンプ室２５に負圧が生じ、ポンプ室２５に連通する流路２４に負圧が伝わり、流路２４の流体がポンプ室２５に吸引される。

[0029] 図３（Ａ）に示すような静止状態から圧電素子２２が縮もうとすると場合には、図３（Ｃ）に示すように、ダイヤフラム２８がポンプ室２５側（天面側）に凸に屈曲してポンプ室２５の体積が減少する。すると、流路２４を間に介してポンプ室２５と吐出口２６とが対向しているために、ポンプ室２５の流体が吐出口２６から外部に吐出されるとともに、その流体の流れに引き込まれて流路２４内の流体が吐出口２６から吐出される。

[0030] このような圧電素子２２とダイヤフラム２８との屈曲振動に伴い、圧電ポンプ２１では、ポンプ室２５で周期的な体積変動と圧力変動とが繰り返し生じ、気体の流れに慣性力が働くようになる。これにより、流路２４の流体が吐出口２６から吐出される気体の流れが定常的に生じるようになる。この圧電ポンプ２１では、ダイヤフラム２８が吐出口２６に対して流路２４およびポンプ室２５を介して対面するため、圧電ポンプ２１の流体効率が高く、高

い吸引圧と低い消費電力とを同時に実現することができる。

[0031] この圧電ポンプ２１は、駆動制御部３１（図５参照）に制御されて駆動する。駆動制御部３１は、圧電素子２２における電流電圧位相差に基づいて吸引圧を検知する機能と、検知した吸引圧に基づいて圧電素子２２の駆動電圧のパターンを制御する機能とを有している。

[0032] 図４は、圧電素子２２における電流電圧位相差と吸引圧との対応関係を例示するグラフである。このグラフからは、圧電素子２２における電流電圧位相差と吸引圧とが、１対１の対応関係にあることが読み取れる。具体的には、吸引圧の変化に対して、圧電素子２２における電流電圧位相差は２次曲線状に変化し、吸引圧（絶対値）が大きいほど電流電圧位相差（絶対値）は大きく、吸引圧（絶対値）が小さいほど電流電圧位相差（絶対値）は小さくなることが読み取れる。このように、圧電素子２２における電流電圧位相差は、吸引圧に応じて変化する。したがって、この圧電素子２２における電流電圧位相差と吸引圧との対応関係が既知であれば、実際に圧電素子２２に流れる電流と駆動電圧とを検出して電流電圧位相差を計測することにより、吸引圧を把握することができる。

[0033] 図５は、駆動制御部３１の構成例を示すブロック図である。駆動制御部３１は、検出回路３２、制御部３３、記憶部４０、電圧コントローラ３４、昇圧回路３５、駆動回路４２およびインジケータ４１を備えている。

[0034] 電圧コントローラ３４は、電源電圧を制御して昇圧回路３５に供給する。昇圧回路３５は、電源電圧を昇圧し、駆動回路４２は制御部３３からの指令を受けた周波数で且つ昇圧回路３５の出力に応じた駆動電圧を生成し、その駆動電圧を圧電素子２２に印加する。これにより、圧電素子２２が駆動し、吸入部１１に外部の流体を吸引させる。

[0035] 圧電素子２２の駆動電圧は、周波数が可聴音の周波数帯域から外れていて、このため圧電素子２２はモータ等に比べて駆動音が静かである。また、圧電素子２２は、図２に示す流路２４を流れる流体の圧力（吸引圧）に応じて、電流電圧位相差が影響を受けるという性質を有している。

[0036] 検出回路３２は、本発明の検出部に相当するものであり、電流検出部３６、電圧検出部３７、位相比較器３８、および抵抗３９を備えている。電流検出部３６は、抵抗値が既知である抵抗３９の両端の電圧から、圧電素子２２に流れる電流を検出する。抵抗３９は、圧電素子２２と駆動回路４２とを接続する電圧線に挿入されている。電圧検出部３７は、圧電素子２２に印加される駆動電圧を検出する。位相比較器３８は、電流検出部３６が検出した電流と電圧検出部３７が検出した電圧との位相差（電流電圧位相差）に対応する出力信号を出力する。

[0037] 記憶部４０は、圧電素子２２の電流電圧位相差と、吸引圧との対応関係がテーブルや演算式として予め記憶されている。制御部３３は、位相比較器３８の出力を記憶部４０で参照し、圧電素子２２の電流電圧位相差に対応する吸引圧を把握する。そして、当該吸引圧に基づいて電圧コントローラ３４を設定する。電圧コントローラ３４は、昇圧回路３５の昇圧比を制御することで、昇圧回路３５が出力する駆動電圧を制御する。インジケータ４１は、制御部３３が把握する吸引圧についての情報を、液晶表示部や表示ランプ等に表示させる機能や、通信回線を介して外部に送信する機能を有している。

[0038] なお、位相比較器３８としては、例えば、ＰＬＬ（Phase Locked Loop）等で用いられる位相周波数比較器（Phase FrequencyComparator）のような回路方式のデジタル型比較器を使用することができる。また、制御部３３および電圧コントローラ３４は、例えば、マイコンに構成することができる。ＰＷＭ制御を行うマイコンを用いる場合には、マイコンのＩ／Ｏ端子を検出回路３２に接続し、マイコンのＰＷＭ出力端子を昇圧回路３５に直接接続する。そして、マイコンでＰＷＭ制御出力のデューティー比を変更することにより、昇圧回路３５の出力する電圧を制御することができる。

[0039] 駆動制御部３１を上記の構成にすることで、駆動電圧の変動や温度変化があるような条件下であっても、検出回路３２と制御部３３とで吸引圧を高精度に検知することができる。したがって、吸引圧を直接検出するような圧力センサを設ける必要が無く、吸引装置１０の構成の複雑化を防ぐことができ

る。

[0040] 次に、電流電圧位相差に基づく駆動電圧および吸引圧の制御例について説明する。まず、圧電素子２２の駆動に伴う自己発熱により圧電素子の出力が上昇して過吸引状態になることを防ぐことができる第１の制御例を示す。

[0041] 図６は、第１の制御例に係る吸引圧の時間変化を例示するグラフである。図６中に示す実線は、駆動電圧を一定振幅で間欠的に出力するように制御し、駆動電圧の出力時間および休止時間を、電流電圧位相差に基づいて制御する場合の吸引圧の時間変化に対応している。図６中に示す破線は、比較のための吸引圧の時間変化に対応しており、駆動電圧を一定の吸引圧および一定の周期で出力するように制御する場合を示している。

[0042] 図６中に破線で示す比較例の場合、実際の吸引圧の大きさを把握することなく、吸引圧が想定の大きさ（口腔内や鼻腔内からの吸引に適切とされる－２０ｋＰａ）になるように、圧電素子２２への駆動電圧の印加時間と休止時間とをそれぞれ一定の時間隔として設定している。このため比較例では、圧電素子２２の駆動に伴う自己発熱によって圧電素子２２に温度上昇が生じ、時間の経過とともに圧電素子２２の出力が上昇する。これにより、実際の吸引圧が当初の想定よりも大きくなって、口腔内や鼻腔内からの吸引に適切とされる－２０ｋＰａを超えてしまう場合がある。吸引圧が－２０ｋＰａを超える過吸引の状態になると、吸入部１１を当接させる鼻腔の皮膚や粘膜を損傷させてしまう恐れがある。

[0043] 一方、図６中に実線で示す第１の制御例の場合、電流電圧位相差に基づいて実際の吸引圧の大きさを把握することができるために、吸引圧が約－２０ｋＰａになるまで駆動電圧を継続して圧電素子２２に印加し、吸引圧が約－２０ｋＰａに到達すると、圧電素子２２への駆動電圧の印加を停止している。このように実際の吸引圧を検知して駆動電圧および吸引圧のパターンを制御することで、吸引装置１０が過吸引状態になることを防ぐことができる。

[0044] 図７は、第１の制御例にかかる駆動制御部３１の動作フローを示すチャート図である。

[0045] 駆動制御部３１は、まず、圧電素子２２に所定振幅に設定された駆動電圧の印加を開始する（Ｓ１１）。これにより、圧電素子２２が駆動し、吸引装置１０は吸入部１１を介した鼻水の吸引動作を開始する。次に、駆動制御部３１は、電流電圧位相差を検出する（Ｓ１２）。そして、駆動制御部３１は、検出した位相差に基づいて、実際の吸引圧の大きさを計測する（Ｓ１３）。

[0046] 次に、駆動制御部３１は、計測した吸引圧を予め登録された第１閾値（－２０ｋＰａ）と比較する（Ｓ１４）。そして、計測した吸引圧が第１閾値未満である場合には（Ｓ１４：Ｙｅｓ）、駆動電圧の印加を継続して駆動を維持し（Ｓ１５）、再び電流電圧位相差の検出ステップに戻る（Ｓ１２）。一方、計測した吸引圧が第１閾値を超える場合には（Ｓ１４：Ｎｏ）、駆動電圧の印加を停止する（Ｓ１６）。そして、所定の時間が経過することを待って（Ｓ１７）、再び駆動電圧の印加を開始するステップに戻る（Ｓ１１）。

[0047] 以上の第１の制御例の動作フローにより、先に図６中の実線で示したように駆動電圧および吸引圧のパターンを設定することができ、吸引装置１０が過吸引状態になることを防ぐことができる。

[0048] 次に、吸入部１１で鼻腔内の鼻水を吸入できていない未吸引状態が長時間続いた場合に、未吸引状態に関する情報の報知と、未吸引状態に対応する駆動電圧および吸引圧の制御を行う第２の制御例を示す。

[0049] 図８は、第２の制御例に係る駆動制御部３１の動作フローを示すチャート図である。

[0050] 駆動制御部３１は、まず、圧電素子２２に所定振幅に設定された駆動電圧の印加を開始する（Ｓ２１）。これにより、圧電素子２２が駆動し、吸引装置１０は吸入部１１を介した鼻水の吸引動作を開始する。次に、駆動制御部３１は、電流電圧位相差を検出する（Ｓ２２）。そして、駆動制御部３１は、検出した位相差に基づいて、実際の吸引圧の大きさを計測する（Ｓ２３）。

[0051] 次に、駆動制御部３１は、計測した吸引圧を予め登録された第２閾値（例

えば－１ｋＰａ）と比較する（Ｓ２４）。そして、計測した吸引圧が第２閾値未満である場合には（Ｓ２４：Ｙｅｓ）、未吸引状態の継続時間の計時を加算する処理を行う（Ｓ２５）。また、インジケータ４１に未吸引状態であることを示す表示や放音を行わせる報知処理を行う（Ｓ２６）。一方、計測した吸引圧が第２閾値を超える場合には（Ｓ２４：Ｎｏ）、未吸引状態の継続時間の計時をリセットする処理を行う（Ｓ２７）。

[0052] 次に、駆動制御部３１は、計時した未吸引状態の継続時間を予め登録された閾時間（例えば１ｓｅｃ）と比較する（Ｓ２８）。そして、計時した未吸引状態の継続時間が閾時間未満である場合には（Ｓ２８：Ｙｅｓ）、駆動電圧の印加を継続して駆動を維持し（Ｓ２９）、再び電流電圧位相差の検出ステップに戻る（Ｓ２２）。一方、計時した未吸引状態の継続時間が閾時間を超える場合には（Ｓ２８：Ｎｏ）、駆動電圧の印加を停止し（Ｓ２９）、全ての処理を終了する。

[0053] 以上の第２の制御例の動作フローにより、利用者がインジケータ４１による未吸引状態の報知を認識することで、吸入部１１が未吸引状態にあることを確認することができる。また、未吸引状態が閾時間を超えて続くような場合に、圧電素子２２への駆動電圧の印加を停止するので、圧電素子２２の消費電力を抑制することができ、例えば電池寿命の伸長を図ることができる。

[0054] なお、以上の説明では、実際の吸引圧が低い場合に電流電圧位相差が小さくなり、実際の吸引圧が高い場合に電流電圧位相差が大きくなるような場合について示したが、圧電ポンプ２１の構成や駆動制御部３１の構成によっては、逆に、実際の吸引圧が低い場合に電流電圧位相差が大きくなり、実際の吸引圧が低い場合に電流電圧位相差が小さくなるような場合もある。そのため、上記の各動作フローにおいて、電流電圧位相差に基づいて吸引圧を計測するステップでの処理は、電流電圧位相差と吸引圧との実際の対応関係に基づいて適宜変更することが好ましい。

[0055] また、以上の説明では、制御部３３で実際の吸引圧を検知して、その吸引圧に基づいて処理を行う場合についてしめしたが、制御部３３で実際の吸引

圧を検知しなくても、電流電圧位相差をそのまま用いて吸引圧に基づく処理を行うこともできる。

[0056] 《第２の実施形態》

次に、本発明の第２の実施形態に係る吸引装置５０について説明する。

[0057] 図９は、吸引装置５０の模式的断面図である。吸引装置５０は、吸入部５１、セパレータ１３、容器１４、および、圧電駆動部１５を備えている。吸引装置５０は搾乳器であり、吸入部５１は、乳房に沿う凹面を有する形状の、いわゆる搾乳カップとして構成されている。その他の構成は、第１の実施形態に係る構成とおよそ同様である。そして、このように吸引装置５０を構成する場合にも、圧電素子２２の電流電圧位相差を検出して、圧電ポンプ２１の吸引圧が－２０ｋＰａを超えないように、圧電素子２２の駆動電圧および吸引圧のパターンを制御することが好ましい。これにより、圧電ポンプ２１が過吸引状態となることを防ぐことができ、吸入部５１が当接することになる胸部の皮膚や粘膜を損傷させることを防ぎながら、母乳を吸引することができる。

[0058] 《第３の実施形態》

次に、本発明の第３の実施形態に係る吸引装置について説明する。

[0059] 図９は、本発明の第３の実施形態に係る吸引装置６０（不図示）が備える吸入部６１の斜視図である。吸引装置６０（不図示）は痰吸引装置であり、吸入部６１は、鼻腔を介して咽喉部に挿入することができるように筒状の、いわゆるカテーテルとして構成されている。その他の構成は、第１の実施形態に係る構成とおよそ同様である。そして、このように吸引装置６０（不図示）を構成する場合にも、圧電素子２２の電流電圧位相差を検出して、圧電ポンプ２１の吸引圧が－２０ｋＰａを超えないように、圧電素子２２の駆動電圧および吸引圧のパターンを制御することが好ましい。これにより、圧電ポンプ２１が過吸引状態となることを防ぐことができ、吸入部６１が当接することになる咽喉部や鼻腔の皮膚や粘膜が吸引圧によって損傷させられることを防ぎながら、咽喉部から痰を吸引することができる。

符号の説明

[0060] １０，５０，６０…吸引装置

１１，５１，６１…吸入部

１３…セパレータ

１４…容器

１５…圧電駆動部

１６…流路

２１…圧電ポンプ

２２…圧電素子

２３…構造体

２４…流路

２５…ポンプ室

２６…吐出口

２７…吸入口

２８…ダイヤフラム

３１…駆動制御部

３２…検出部

３３…制御部

３４…電圧コントローラ

３５…昇圧回路

３６…電流検出部

３７…電圧検出部

３８…位相比較器

３９…抵抗

４０…記憶部

４１…インジケータ

４２…駆動回路

請求の範囲

[請求項1] 外部の流体を吸入する吸入部と、

駆動電圧が印加されて振動する圧電素子を有し、前記圧電素子の振動により前記吸入部を介して流体を吸引する圧電ポンプと、

前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差を検出する検出部と、

前記検出部が検出した位相差に基づいて処理を行う制御部と、

を備える吸引装置。

[請求項2] 前記圧電素子に流れる電流と前記圧電素子の駆動電圧との位相差と前記圧電ポンプの吸引圧との対応関係を予め記憶した記憶部を更に備え、

前記制御部は、前記記憶部を参照することにより、前記検出部が検出した位相差に基づいて処理を行う、

請求項１に記載の吸引装置。

[請求項3] 前記制御部は、前記圧電ポンプの吸引圧が第１閾値を超える場合に、前記圧電ポンプへの駆動電圧の印加を停止させる、

請求項２に記載の吸引装置。

[請求項4] 前記制御部は、前記圧電ポンプの吸引圧が第１閾値を超えて前記圧電ポンプへの駆動電圧の印加を停止させてから所定時間が経過する場合に、前記圧電ポンプへの駆動電圧の印加を開始させる、

請求項３に記載の吸引装置。

[請求項5] 情報を報知する報知部を更に備え、

前記制御部は、前記圧電ポンプの吸引圧に関する情報を前記報知部に報知させる、

請求項２に記載の吸引装置。

[請求項6] 前記制御部は、前記圧電ポンプの吸引圧が第２閾値よりも小さい場合に、未吸引状態であることを示す情報を前記報知部に報知させる、

請求項５に記載の吸引装置。

[請求項7] 前記制御部は、前記圧電ポンプの吸引圧が第２閾値よりも小さい状態が閾時間よりも長く続く場合に、前記圧電ポンプへの駆動電圧の印加を停止させる、

請求項２に記載の吸引装置。

[請求項8] 前記制御部は、前記圧電ポンプの吸引圧が－２０ｋＰａを超える場合に、前記圧電ポンプへの駆動電圧の印加を停止させる、

請求項２に記載の吸引装置。

[請求項9] 前記吸入部は、鼻腔に挿入される形状を有する、

請求項８に記載の吸引装置。

[請求項10] 前記吸入部は、乳房に沿う形状を有する、

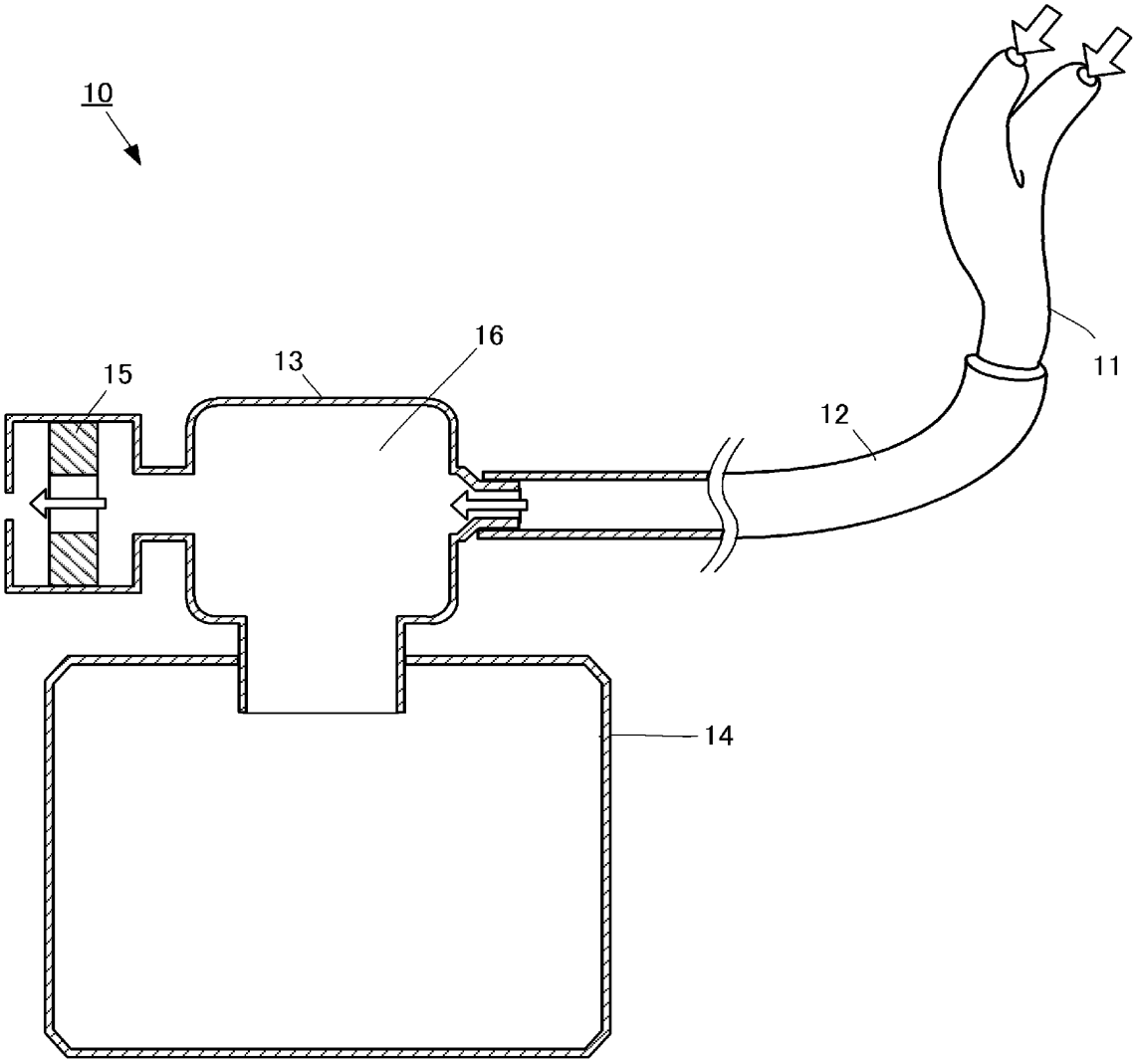
請求項８に記載の吸引装置。

[請求項11] 前記吸入部は、咽頭部に挿入される形状を有する、

請求項８に記載の吸引装置。

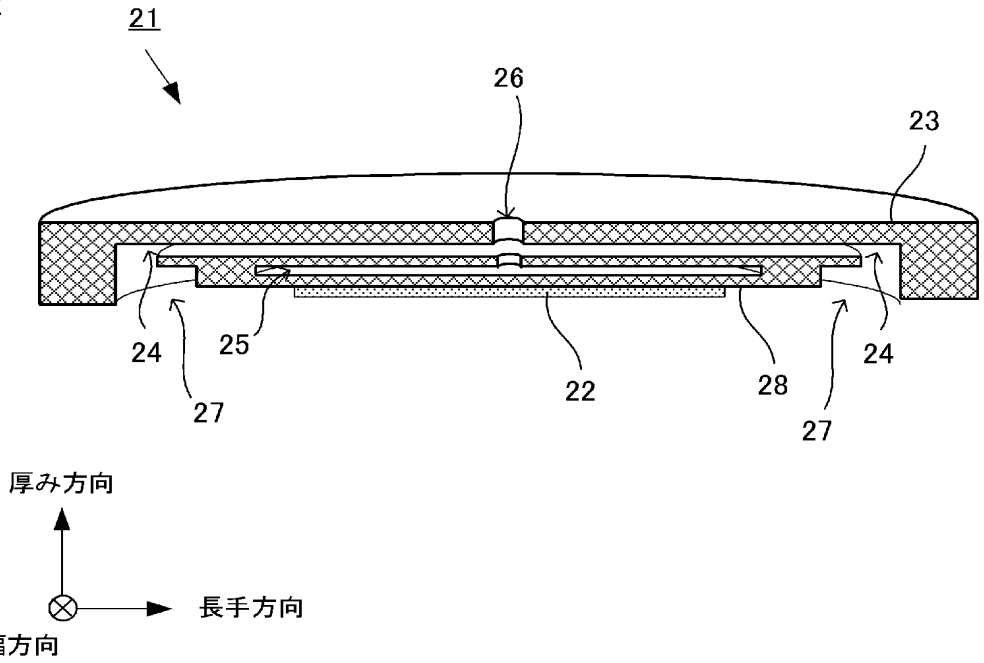
[図1]

図1



[図2]

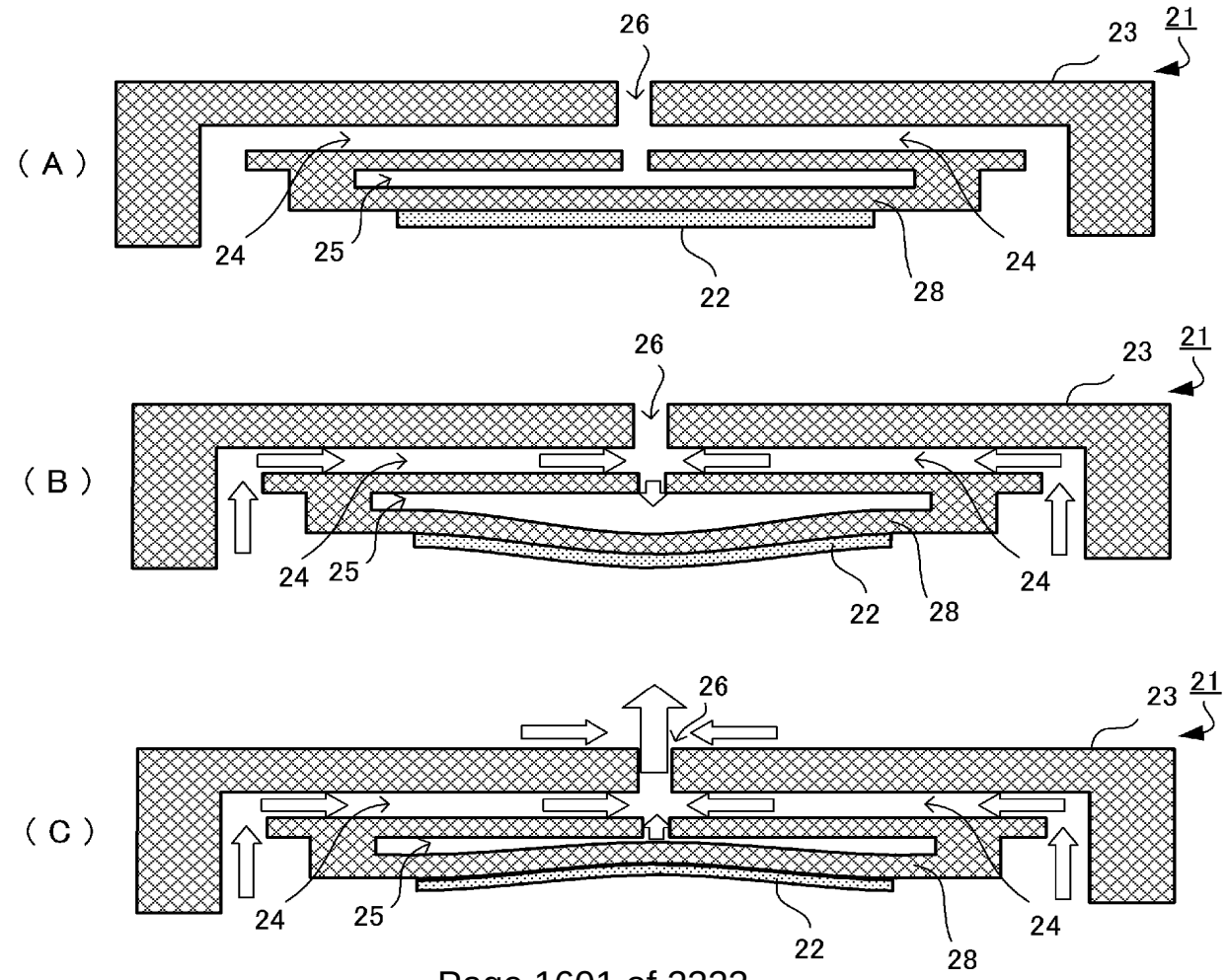
図2


21
26
23
24
25
27
22
28
27
24

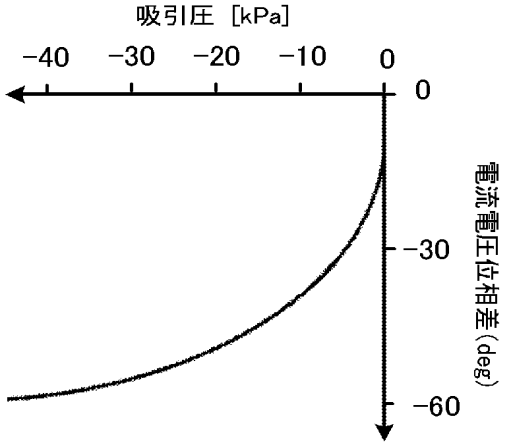
厚み方向
長手方向
幅方向

[図3]

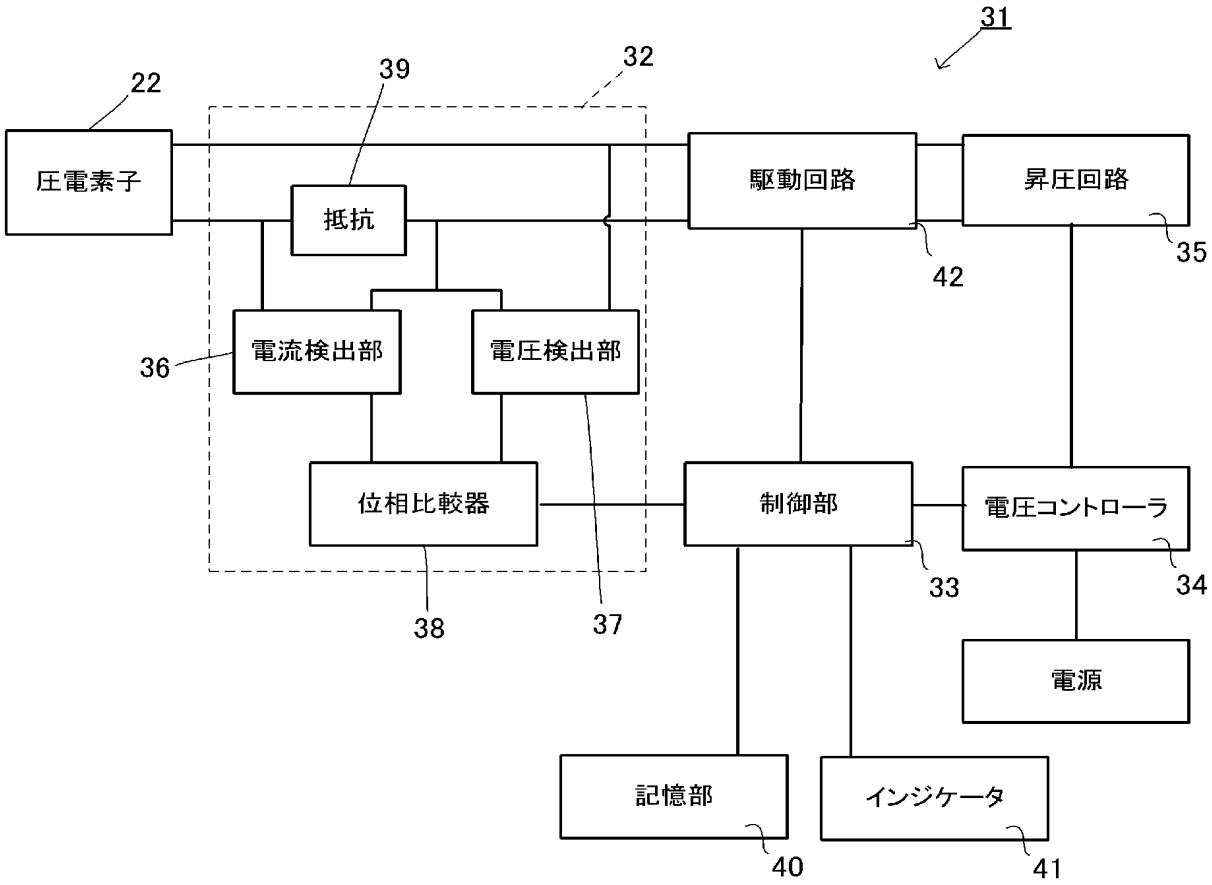
図3


（A）
26
23
21
24
25
22
28
24
（B）
26
23
21
24
25
22
28
24
（C）
26
23
21
24
25
22
28
24

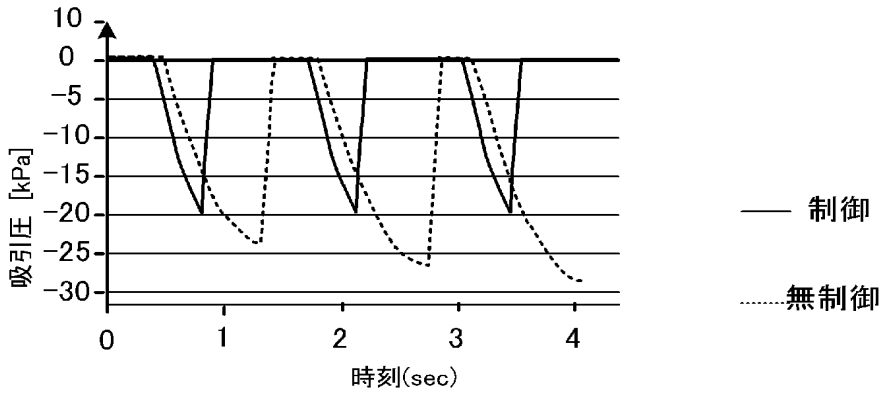
[図4]
図4


吸引圧 [kPa]
−40
−30
−20
−10
0
0
−30
−60
電流電圧位相差(deg)

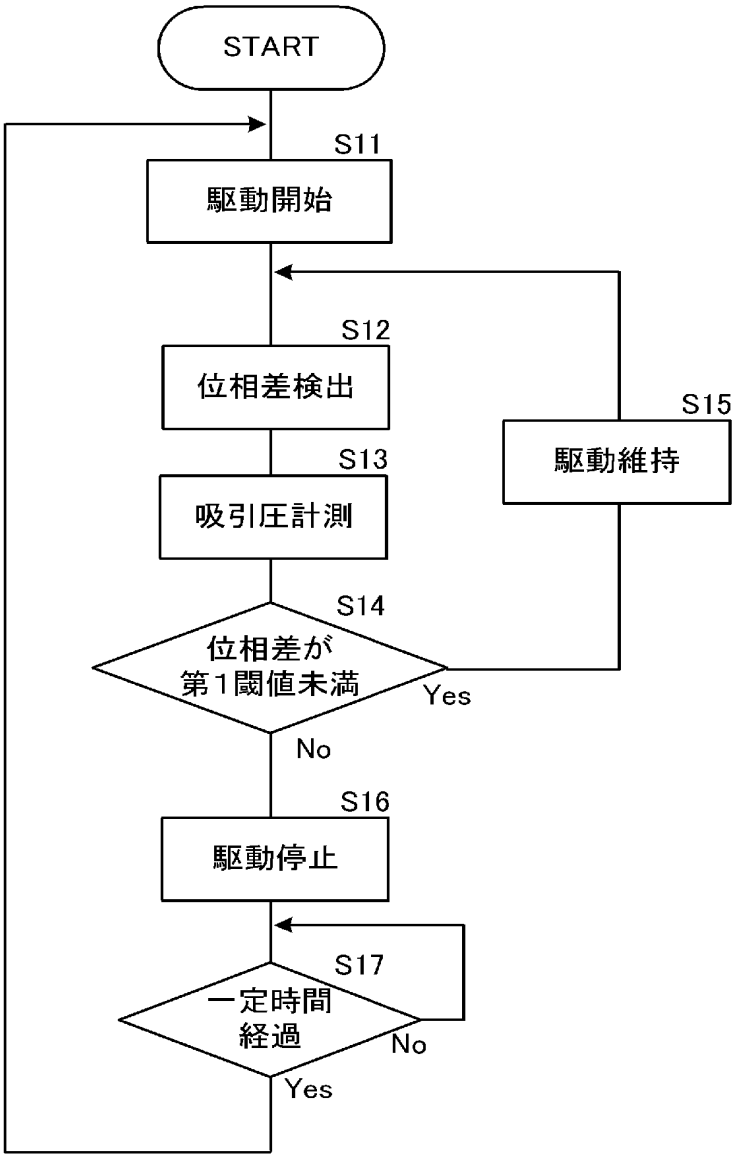
[図5]
図5


31
32
39
22
圧電素子
抵抗
駆動回路
昇圧回路
42
35
36
電流検出部
電圧検出部
位相比較器
制御部
電圧コントローラ
33
34
38
37
電源
記憶部
インジケータ
40
41

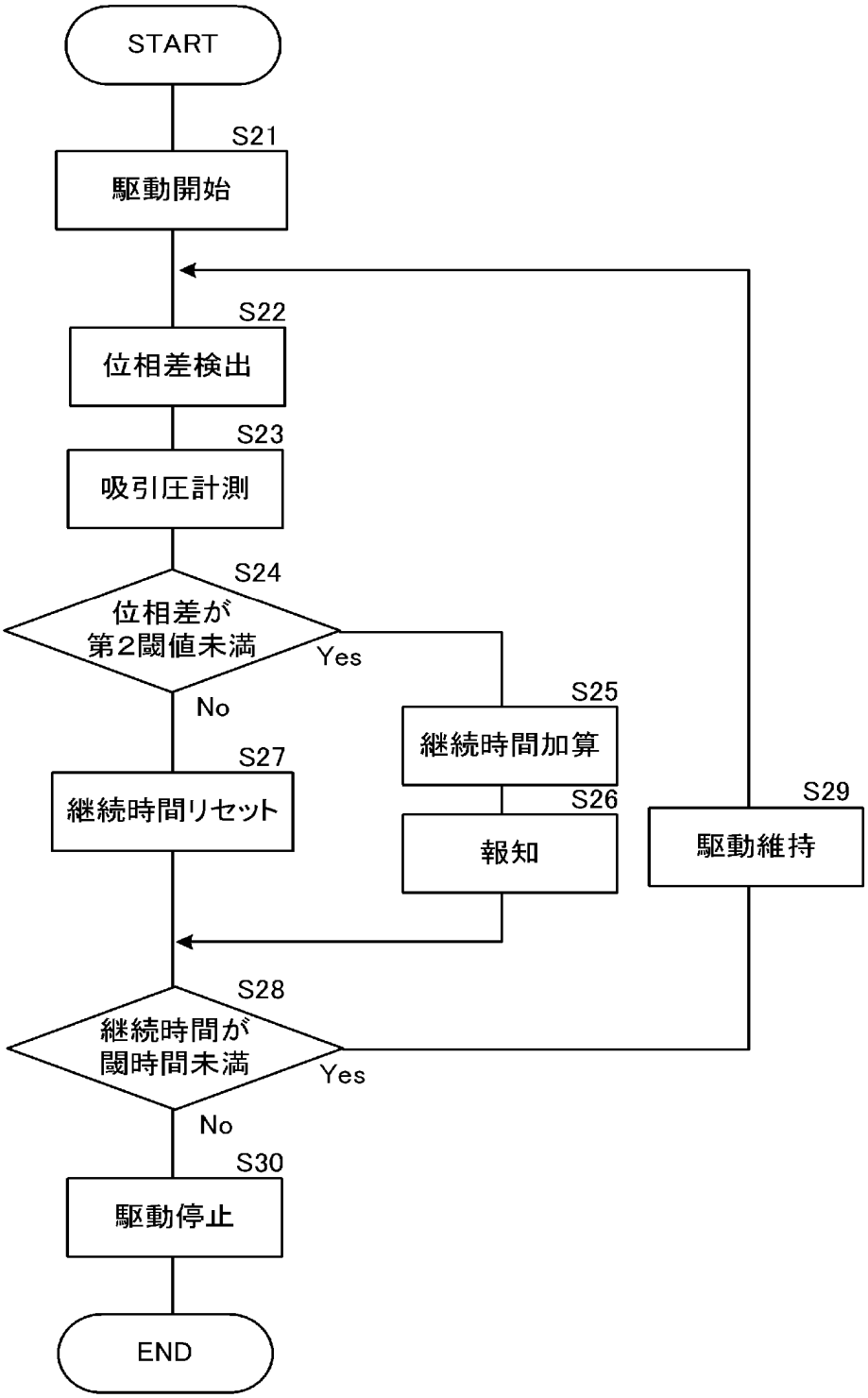
[図6]
図6


10
0
−5
−10
−15
−20
−25
−30
吸引圧 [kPa]
0
1
2
3
4
時刻(sec)
制御
無制御

[図7]
図7

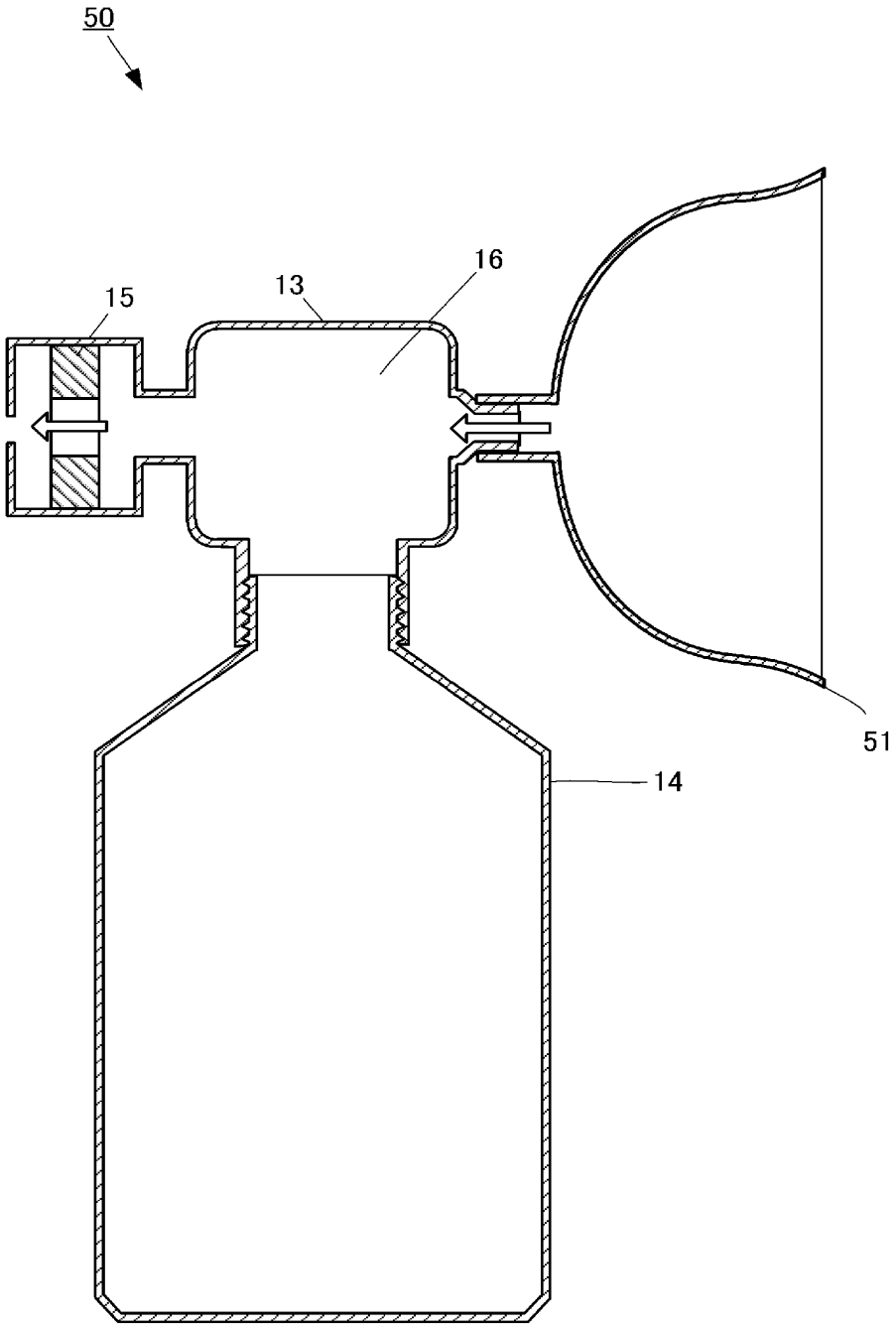

START
S11
駆動開始
S12
位相差検出
S13
吸引圧計測
S14
位相差が
第1閾値未満
Yes
No
S15
駆動維持
S16
駆動停止
S17
一定時間
経過
No
Yes

[図8]
図8

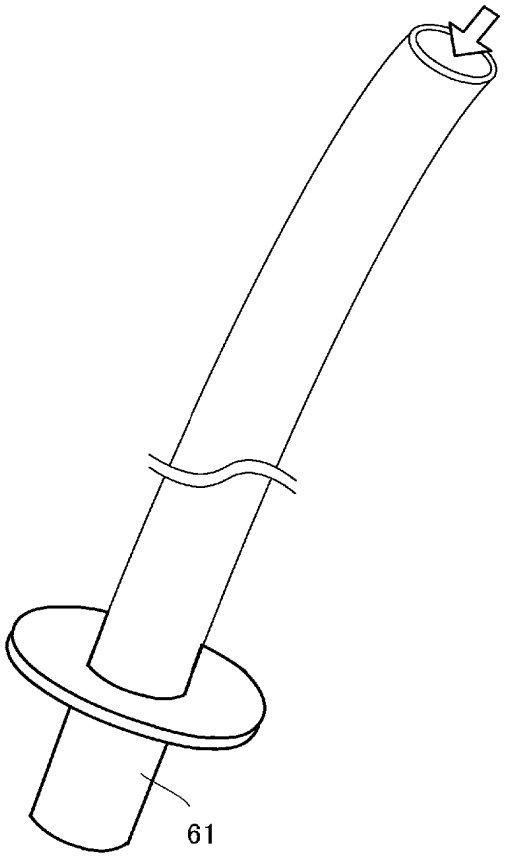

START
S21
駆動開始
S22
位相差検出
S23
吸引圧計測
S24
位相差が
第2閾値未満
Yes
No
S25
継続時間加算
S26
報知
S27
継続時間リセット
S28
継続時間が
閾時間未満
Yes
No
S29
駆動維持
S30
駆動停止
END

[図9]

図9



[図10]
図10



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068749

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	JP 2618685 B2 (TDK Corp.), 11 June 1997 (11.06.1997), column 3, lines 15 to 27; column 5, line 45 to column 6, line 26; fig. 1, 3 & US 4939402 A column 1, lines 11 to 31; column 4, line 47 to column 5, line 54; fig. 1, 3 & EP 343005 A2	1 2-11
A	JP 10-026550 A (Kabushiki Kaisha Nippon Automation), 27 January 1998 (27.01.1998), paragraphs [0004] to [0007] (Family: none)	1-11

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"X" document of particular relevance; the claimed iuvention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 September 2015 (09.09.15)	06 October 2015 (06.10.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068749

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2013-027625 A (Olympus Corp.), 07 February 2013 (07.02.2013), paragraphs [0051] to [0052] & US 2014/0148704 A1 paragraphs [0072] to [0074] & WO 2013/018519 A1	1-11
A	JP 2013-220321 A (Omron Healthcare Co., Ltd., Murata Mfg. Co., Ltd.), 28 October 2013 (28.10.2013), entire text; all drawings & WO 2013/157399 A1	1-11
A	JP 2009-264135 A (Sony Corp.), 12 November 2009 (12.11.2009), entire text; all drawings (Family: none)	1-11

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６８７４９

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X A	JP 2618685 B2 (ティーディーケイ株式会社) 1997.06.11, 第3欄15-27行, 第5欄45行-第6欄26行, 第1, 3図 & US 4939402 A, 第1欄11-31行, 第4欄47行-第5欄54行, 第1, 3図 & EP 343005 A2	1 2-11
A	JP 10-026550 A (株式会社日本オートメーション) 1998.01.27, 段落[0004]-[0007] (ファミリーなし)	1-11

☑ Ｃ欄の続きにも文献が列挙されている。　☐ パテントファミリーに関する別紙を参照。

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「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの
「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）
「Ｏ」口頭による開示、使用、展示等に言及する文献
「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
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「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの
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「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
０９．０９．２０１５	０６．１０．２０１５

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｉ　４１３８
川島　徹
電話番号　０３－３５８１－１１０１　内線　３３８６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
A	JP 2013-027625 A (オリンパス株式会社) 2013.02.07, 段落[0051]-[0052] & US 2014/0148704 A1, 段落[0072]-[0074] & WO 2013/018519 A1	1-11
A	JP 2013-220321 A (オムロンヘルスケア株式会社, 株式会社村田製作所) 2013.10.28, 全文, 全図 & WO 2013/157399 A1	1-11
A	JP 2009-264135 A (ソニー株式会社) 2009.11.12, 全文, 全図 (ファミリーなし)	1-11

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(19) World Intellectual Property Organization
International Bureau

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62/028,219 23 July 2014 (23.07.2014) US

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(72) Inventors: **ALVAREZ, Jeffery, B.**; 412 Lanyard Drive, Redwood City, CA 94065 (US). **ALVAREZ, Janica, B.**; 412 Lanyar Drive, Redwood City, CA 94065 (US).

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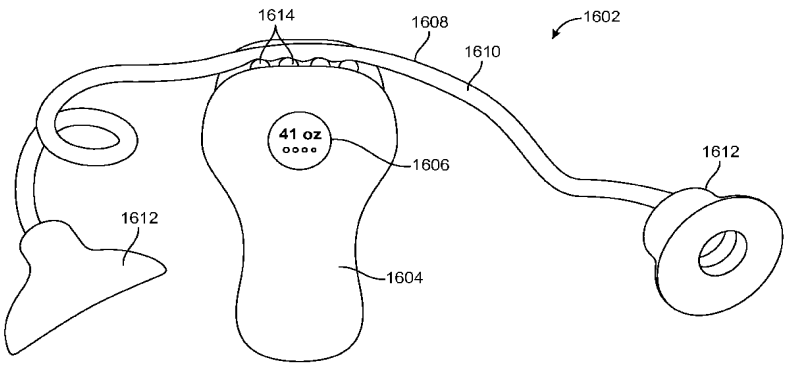


FIG. 16

(57) **Abstract**: Improved devices, systems and methods for the expression of milk from a breast are disclosed herein. A device for expression of milk may comprise a peristaltic pump configured to move a fluid to or from a breast interface, so as to apply pressure at the breast interface and thereby express milk from the breast. The peristaltic pump can be removably coupled to a tube carrying the fluid, so as to maintain a separation between the peristaltic pump and the fluidly coupled components of the device. A device for expressing breast milk may further comprise an adjustable breast interface configured to engage and fluidly seal against the human breast. The adjustable breast interface may be manually or automatically adjustable to fluidly seal against a plurality of sizes or shapes of human breasts.

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PUMP APPARATUS AND METHODS FOR EXPRESSION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 62/021,601, filed July 7, 2014 [Attorney Docket No. 44936-705.101] and U.S. Provisional Application No. 62/028,219, filed July 23, 2014 [Attorney Docket No. 44936-708.101], the full disclosures of which are incorporated herein by reference.

[0002] This application is related to U.S. Patent Application No. 14/221,113, filed on March 20, 2014 [Attorney Docket No. 44936-703.201], U.S. Patent Application No. 14/616,557, filed on February 6, 2015 [Attorney Docket No. 44936-704.201], U.S. Provisional Application No. 62/021,597, filed on July 7, 2014 [Attorney Docket No. 44936-706.101], and U.S. Provisional Application No. 62/021,604, filed July 7, 2014 [Attorney Docket No. 44936-707.101] , the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0004] The exemplary embodiments disclosed herein are preferably directed at expression of breast milk, but one of skill in the art will appreciate that this is not intended to be limiting and that the devices, systems and methods disclosed herein may be used for other treatments requiring application of a differential pressure. The devices, systems and methods disclosed herein may be used for treatments requiring application of a differential pressure to a patient or work surface, with a device having an adjustable flange that can accommodate varying patient anatomy or varying work surfaces.

[0005] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Additionally, current and proposed pump systems may only actuate a single breast pump, and therefore it would be advantageous to provide a pump that can actuate two breast pumps simultaneously.

[0006] Further, currently existing or proposed breast pumps may only provide breast interfaces of limited, fixed sizes, which can result in users having to purchase and return multiple parts as well as contend with poor fit and inefficient pumping. Breast pump users comprise a population with a wide range of size and shape requirements, which may also change over the course of use of the breast pump due to the effects of sustained use of the pump or due to natural changes in user anatomies throughout the course of breastfeeding. Therefore, it would be desirable for a breast pump to provide a breast interface that is adjustable in size or shape. At least some of these objectives will be satisfied by the devices and methods disclosed below.

[0007] 2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: U.S. Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179. U.S. Patent Publication No. 2014/0121593 also relates to expression and collection of breast milk.

SUMMARY OF THE INVENTION

[0008] The present invention generally relates to medical devices, systems and methods, and more particularly relates to devices, systems and methods for expression and collection of human breast milk.

[0009] Disclosed herein are small and highly efficient apparatuses and methods of use for expression and collection of breast milk. An apparatus for expression of milk as described herein may comprise a hydraulic system, wherein movement of a fluid to or from a breast interface can apply pressure at the breast interface and thereby express milk from the breast engaged thereto. The apparatus may comprise a peristaltic pump that is removably coupled to a tube carrying the fluid, so as to move the fluid to or from the breast interface while maintaining a separation between the peristaltic pump and the fluidly coupled components of the apparatus.

[0010] Also disclosed herein are methods and apparatus for providing an adjustable breast interface to accommodate a range of size and shape requirements of the users. The adjustable breast interface may comprise an adjustable flange configured to engage and seal against the breast, wherein the adjustable flange may be adjusted in one or both of the frustoconical portion and the inner diameter of the tubular flange neck. Alternatively or in combination, the adjustable breast interface may comprise an adjustable expression area, whose size and/or shape may be adjusted by adjusting a volume of an expression reservoir of the breast interface. For example, the expression reservoir may be fluidly coupled to an adjustable

reservoir and an actuatable assembly, wherein a volume of the adjustable reservoir may be manually or automatically adjusted to adjust the volume of the expression reservoir and hence the size of the expression area.

[0011] In a first aspect, a device for expression and collection of breast milk comprises a breast interface configured to engage a breast and fluidly seal thereagainst, the breast interface having a movable member disposed within at least a portion thereof. The device further comprises a tube filled with fluid and fluidly coupled with the breast interface, and a peristaltic pump coupled with the tube, wherein actuation of the peristaltic pump moves the fluid in a first direction or a second direction opposite the first direction. Movement of the fluid in the first direction moves the movable member in the breast interface in the first direction and thereby causes the breast interface to apply vacuum pressure at the breast to express milk therefrom. Movement of the fluid in the second direction moves the movable member in the breast interface in the second direction and thereby applies pressure at the breast interface. The peristaltic pump may be removably coupled with the tube.

[0012] The movable member of the breast interface may comprise one or more of a flexible membrane, a deformable portion of a sealing element coupled to a flexible membrane, or an expandable membrane, configured to move in response to actuation of the peristaltic pump. Movement of the movable member in the second direction may return the breast interface to atmospheric pressure, thereby allowing the expressed milk to drain into a collection vessel coupled to the breast interface. The device may further comprise a collection vessel fluidly coupled to the breast interface, and movement of the movable member in the second direction may apply positive pressure at breast interface, thereby forcing the expressed milk out of breast interface into the collection vessel.

[0013] The device may further comprise a collection vessel fluidly coupled to the breast interface, and the breast interface may comprises a first breast interface configured to engage a first breast and a second breast interface configured to engage a second breast. Actuation of the peristaltic pump may simultaneously cause the first breast interface to express milk from the first breast and the second breast interface to collect expressed milk from the second breast into the collection vessel.

[0014] The tube may comprise a central compliant region configured to engage the peristaltic pump. The tube may further comprise a less compliant region that is less compliant relative to the central compliant region and disposed adjacent to the central compliant region. The central compliant region may compress in response to actuation of the peristaltic pump, while the less compliant region may transmit pressure along the tube to the breast interface.

[0015] In another aspect, a method for expressing milk from a breast comprises engaging and fluidly sealing a breast interface with the breast, actuating a peristaltic pump, and expressing milk from the breast. The peristaltic pump may be coupled with a tube filled with a fluid and fluidly coupled to the breast interface, such that actuation of the peristaltic pump can apply vacuum pressure at the breast to express milk from the breast.

[0016] Actuating a peristaltic pump may comprise actuating the peristaltic pump so as to move the fluid in a first direction or in a second direction opposite the first direction. Moving the fluid in the first direction may cause a movable member within the breast interface to move away from the breast and thereby apply vacuum pressure at the breast to express milk therefrom. Moving the fluid in the second direction may cause the movable member to move toward the breast and thereby cause the expressed milk to drain into a collection vessel fluidly coupled to the breast interface. Moving the fluid in the second direction may return the breast interface to atmospheric pressure, thereby allowing the expressed milk to drain into the collection vessel. Alternatively or in combination, moving the fluid in the second direction may apply a positive pressure at breast interface, thereby forcing the expressed milk out of the breast interface into the collection vessel.

[0017] The breast interface may comprise a first breast interface configured to engage a first breast and a second breast interface configured to engage a second breast. Actuating a peristaltic pump may comprise simultaneously moving the fluid away from the first breast interface to express milk from the first breast, and moving the fluid toward the second breast interface to collect expressed milk from the second breast into a collection vessel fluidly coupled to the second breast interface.

[0018] In another aspect, a device for expressing breast milk from a breast comprises a breast interface comprising a flange configured to engage and fluidly seal against the breast, and an expression area where milk is expressed from the breast. The breast interface is manually or automatically adjustable to fluidly seal against a plurality of sizes or shapes of breasts.

[0019] The flange may comprise one or more resilient materials conformable to the breast and adapted to fluidly seal against the plurality of sizes or shapes of breasts. The flange may further comprise a pocket fillable with a filling material, wherein addition of filling material to, or removal of the filling material from the pocket adjusts a size of the flange. The filling material may comprise a plurality of bead-like elements, wherein application of a vacuum to the pocket substantially locks the plurality of bead-like elements and the flange into a fixed configuration for fluidly sealing against a particular size or shape of human breast. Alternatively or in combination, the filling material may comprise a fluid. The breast

interface may further comprise a fluid pump fluidly coupled to the pocket, the fluid pump configured to add or remove the fluid from the pocket.

[0020] The device may further comprise an actuatable assembly operatively coupled to the breast interface, an expression reservoir disposed within the breast interface, and an adjustable reservoir fluidly coupled to the expression reservoir and operatively coupled to the actuatable assembly. The actuatable assembly may be configured to deliver fluid from the adjustable reservoir to the expression reservoir or remove fluid from the expression reservoir and return the fluid to the adjustable reservoir. The adjustable reservoir may comprise a mechanism to adjust a volume thereof, so as to adjust a volume of the expression reservoir and thereby adjust a size of the expression area to fluidly seal against a particular size or shape of breast.

[0021] The mechanism may be manually adjustable. Alternatively or in combination, the mechanism may be automatically adjustable, to adjust the volume of the adjustable reservoir in response to a feedback from the actuatable assembly indicating a degree of fluid seal between the breast interface and the breast. The feedback may comprise a current produced by the actuatable assembly as the volume of the adjustable reservoir is adjusted, wherein an increase in the current indicates an increased degree of fluid seal between the breast interface and the breast. The adjustable reservoir may be integrated with the actuatable assembly, such that the volume of the adjustable reservoir may be adjusted by changing a setting of the actuatable assembly. For example, the actuatable assembly may comprise a piston assembly, and the adjustable reservoir may comprise a reservoir of the piston assembly, such that changing a resting position of the piston assembly adjusts the volume of fluid in the adjustable reservoir.

[0022] In another aspect, a method for expressing breast milk from a breast comprises providing a device for expressing breast milk comprising an adjustable breast interface having a flange and an expression area. The method further comprises engaging the adjustable breast interface with the breast, adjusting a size of the adjustable breast interface, fluidly sealing the breast interface against the breast, and expressing milk from the breast.

[0023] Adjusting the size of the adjustable breast interface may comprise adding a fluid to or removing the fluid from a pocket disposed within the flange. Alternatively or in combination, adjusting the size of the adjustable breast interface may comprise providing a plurality of bead-like elements disposed in a pocket in the flange. The method may further comprise molding the plurality of bead-like elements against the human breast, applying a vacuum to the pocket, and locking the flange into a particular size or shape.

[0024] The breast interface may comprise an expression reservoir fluidly coupled with an actuatable assembly and an adjustable reservoir. Adjusting the size of the adjustable breast interface may comprise actuating the actuatable assembly, thereby delivering a fluid from the adjustable reservoir to the expression reservoir or removing the fluid from the expression reservoir and returning the fluid to the adjustable reservoir. The method may further comprise adjusting a volume of the adjustable reservoir so as to adjust a volume of the expression reservoir, thereby adjusting a size of the expression area. Adjusting a volume of the adjustable reservoir may comprise manually adjusting the volume of the adjustable reservoir. Alternatively or in combination, adjusting a volume of the adjustable reservoir may comprise automatically adjusting the volume of the adjustable reservoir in response to a feedback from the actuatable assembly indicating a degree of fluid seal between the breast interface and the breast. The adjustable reservoir may be integrated with the actuatable assembly, and automatically adjusting the volume of the adjustable reservoir may comprise changing a setting of the actuatable assembly. For example, the actuatable assembly may comprise a piston assembly and the adjustable reservoir may comprise a reservoir of the piston assembly, wherein automatically adjusting the volume of the adjustable reservoir comprises changing a resting position of the piston assembly.

[0025] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0026] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0028] FIG. 1 is a perspective view of an exemplary embodiment of a pumping device.

[0029] FIG. 2 is a perspective view of an exemplary embodiment of a pumping device.

[0030] FIG. 3A is a cross-section of an exemplary embodiment of a pumping device.

[0031] FIG. 3B is a cross-section of an exemplary embodiment of a pumping device.

[0032] FIG. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a driving mechanism.

[0033] FIGS. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit.

[0034] FIG. 6 is a cross-sectional view of an exemplary embodiment of a breast interface.

[0035] FIG. 7 is a cross-sectional view of another exemplary embodiment of a breast interface.

[0036] FIG. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position.

[0037] FIG. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position.

[0038] FIG. 9A is a cross-sectional view of an exemplary embodiment of integrated sensors within a breast interface.

[0039] FIG. 9B is a cross-sectional view of another exemplary embodiment of integrated sensors within a breast interface.

[0040] FIG. 10 illustrates an exemplary embodiment of a pendant unit and a mobile device.

[0041] FIG. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device.

[0042] FIG. 12 is a cross-sectional view of an exemplary embodiment of a breast interface with a mechanical deformable member.

[0043] FIG. 13 is a cross-sectional view of an exemplary embodiment of a mechanical driver for a mechanical deformable member.

[0044] FIG. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device.

[0045] FIG. 15 is a graph illustrating the pumping efficiency of an exemplary embodiment compared to a commercial device.

[0046] FIG. 16 illustrates an exemplary pump.

[0047] FIG. 17 illustrates a cross-section of the pump in FIG. 16.

[0048] FIG. 18 illustrates an alternative embodiment of a pump system.

[0049] FIG. 19A is a cross-sectional view of an exemplary embodiment of an adjustable flange 1600.

[0050] FIGS. 19B and 19C illustrate exemplary embodiments of adjustable flanges of different sizes.

[0051] FIGS. 20A and 20B are perspective views of an exemplary embodiment of an adjustable flange with a sizing element.

[0052] FIGS. 21A, 21B, and 21C are cross-sectional views of an exemplary embodiment of an adjustable flange with a sizing element.

[0053] FIGS. 22A, 22B, and 22C illustrate exemplary embodiments of an adjustable flange that comprises a fillable pocket.

[0054] FIG. 22D is a cross-sectional view of an exemplary embodiment of an adjustable flange with a pocket filled with a fluid.

[0055] FIG. 22E is a cross-sectional view of an exemplary embodiment of an adjustable flange with a pocket filled with a plurality of bead-like elements.

[0056] FIG. 23A and 23B illustrate an exemplary embodiment of an adjustable flange that comprises a fillable pocket.

[0057] FIGS. 24A and 24B illustrate an exemplary embodiment of a device for expressing breast milk comprising an adjustable expression area.

[0058] FIG. 25 illustrates an exemplary embodiment of an automatically adjustable system for adjusting the size of the expression area.

DETAILED DESCRIPTION OF THE INVENTION

[0059] Specific embodiments of the disclosed devices and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. One of skill in the art will appreciate that various features or steps may be substituted or combined with one another.

[0060] The present invention will be described in relation to the expression and collection of breast milk. However, one of skill in the art will appreciate that this is not intended to be limiting, and the devices and methods disclosed herein may be used in other applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea, wound compression, and/or other remote pressure needs, and where it would be desirable to provide an adjustable flange that can fluidly seal against a variety of anatomical shapes and sizes or any other varying work surface.

[0061] FIG. 1 illustrates an exemplary embodiment of a breast pump. Pumping device 100 includes breast interfaces 105, a tube 110, and a controller or pendant unit 115 operatively

coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. The device may optionally only have a single breast interface. Pendant unit 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification and content analysis, and communication with other devices. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from pendant unit 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.

[0062] One of skill in the art will appreciate that components and features of this exemplary embodiment can be combined or substituted with components and features of any of the embodiments of the present invention as described below. Similarly, components and features of other embodiments disclosed herein may be substituted or combined with one another.

Hydraulic pumping device

[0063] Hydraulic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiency. In a preferred embodiment, the pumping device can utilize a hydraulic pumping device to generate a pressure differential against the breast for the expression and collection of milk.

[0064] Exemplary hydraulic pumping devices are depicted in FIGS. 2 and 3. FIG. 2 illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against or away from an expandable member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0065] FIG. 3A illustrates another embodiment of a pumping device 200. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable

portion 270. The drain port 265 is coupled to a collection vessel 275 and includes a one-way valve 280 which may be a flap, duckbill, or ball valve.

[0066] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. The flexible membrane 245 and deformable portion 270 are movable so as to move toward and away from the breast as the actuatable element 215 is actuated. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuatable element 215 in the outward direction away from the breast produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a one-way valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0067] FIG. 3B illustrates another exemplary embodiment of a pumping device 200a. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235a. The breast interface 235a comprises a flange 236, an interface housing 240, an expandable membrane 245a, an expression reservoir 250, an expression area 260, and a drain port 265. The flange 236 comprises a frustoconical portion 237 and a tubular flange neck 238. The flange neck connects to the expression area through the expression mouth 261. The drain port 265 is coupled to a collection vessel 275 and includes a one-way valve 280.

[0068] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies expression reservoir 250 within breast interface 235a and is coupled with expandable membrane 245a. The expandable membrane 245a is movable so as to move toward and away from the breast as the actuatable element 215 is actuated. When a breast is engaged into and fluidly sealed with breast interface 235a by the flange 236, displacement of the actuatable element 215 in the outward direction away from the breast produces substantial vacuum pressure against the breast through expandable membrane 245a, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a one-

way valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0069] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those of skill in the art.

[0070] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the hydraulic pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Peristaltic Pump

[0071] In previous hydraulic pump embodiments, the hydraulic fluid in the pumping mechanism is often the same fluid used in the transmission lines and also in the breast interface. It can be advantageous to separate the fluids to prevent contamination, so that various components of the system may be more easily separated from one another, and also to avoid having to prime the pump or other components with fluid prior to use. An alternative embodiment of a pumping device that addresses some of these challenges uses a peristaltic pump device to move fluid to or from the breast interface device.

[0072] FIG. 16 illustrates an exemplary embodiment of a peristaltic pump system 1602 for expression of breast milk. The system 1602 preferably includes two breast interfaces 1612, a transmission line or tubing 1608 and a peristaltic pump 1604. The breast interfaces 1612 may be any of the embodiments disclosed herein or known in the art. A transmission line or tubing 1608 is coupled to both breast interfaces. A preferably incompressible fluid 1610 is disposed in tubing 1608. This embodiment illustrates two breast interfaces 1612, however one of skill in the art will appreciate that a single breast interface or multiple breast interfaces may be used. The peristaltic pump includes one or more rollers 1614 that engage tubing 1608. When the rollers move in a first direction, fluid 1610 is moved in a first direction toward one of the two breast interfaces and away from the remaining breast interface. This results in actuation of the flexible membrane in the breast interfaces. One membrane is displaced outwardly thereby creating a vacuum in the breast interface and allowing expression of breast milk. The other membrane is displaced inwardly thereby either returning pressure to normal pressure such as atmospheric pressure in the breast interface, or a positive pressure may be applied in the breast interface. When normal atmospheric pressure exists in the breast interface, the expressed milk can then be collected as previously described. Or

when a positive pressure is applied, the expressed milk may be forced out of the breast interface into a collection container. One advantage of using a peristaltic pump with two breast interfaces is that while one side is expressing milk, the other side is collecting the milk in a container. The pump 1604 may include any of the display features or communication features 1606 described elsewhere in this application.

[0073] FIG. 17 illustrates a partial cross-section of the peristaltic pump in FIG. 16. Tubing 1608 is positioned in a tight channel between the rollers 1614 and an outer rim 1710 of pump 1604. As drive wheel 1708 rotates, rollers 1614 compress tubing 1608 thereby displacing fluid 1610 in the direction of rotation. Thus, in the embodiment of FIG. 17, the drive wheel 1708 is rotating in a clock-wise direction and thus fluid 1610 will be displaced from left to right side of the tubing and positive pressure will be formed in breast interface 1612a and expandable membrane 1706 will be pushed outward toward the breast. Fluid 1608 will move away from breast interface 1612b thereby creating a vacuum and membrane 1704 will move inward toward the back of the breast interface. The negative pressure will then permit expression of breast milk. The drive wheel 1708 may be a full circular wheel as indicated in phantom, or it may be a partial circle. One or more rollers 1614 maybe coupled to the wheel.

[0074] FIG. 18 illustrates another exemplary embodiment of a peristaltic pump 1604 with the tubing uncoupled from the rollers 1614. This embodiment of a pump system 1802 is substantially the same as the previous embodiment in FIGS. 16-17 with the major difference being that the tubing 1610 has varying compliance regions. Tubing 1610 may have a central compliant region 1806 designed for engagement with the rollers 1614 and stiffer, less compliant regions 1804 on either side of the compliant region 1806. The compliant region 1804 allows the tubing to be compressed an easily inserted into engagement with the rollers 1614. Additionally, when the rollers roll over the complaint region, the tubing conforms to the rollers and this facilitates transmission of the fluid 1610 along the tubing. The other portions 1804 are more rigid in order to transmit the pressure along the tubing.

Actuation mechanism

[0075] Many actuation mechanisms known to those of skill in the art can be utilized for the actuatable assembly 205. Actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuatable assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0076] FIGS. 3A and 3B illustrate exemplary embodiments in which actuatable assembly 205 is a piston assembly and driving element 215 is a piston. Actuatable assembly 205 includes radial seals 220, such as O-rings, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0077] FIG. 4 illustrates another exemplary embodiment of an actuatable assembly 300 including a pair of pistons 305.

[0078] In preferred embodiments, the actuatable assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in pendant unit 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0079] Referring now to the exemplary embodiment of FIG. 4, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

[0080] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within pendant unit 115.

[0081] FIGS. 5A-5B illustrate an exemplary embodiment of an actuatable assembly 350 that includes releasable coupling 355. FIG. 5A is a perspective view of the embodiment, and FIG. 5B is a cross-sectional view of the embodiment. Preferably, actuatable assembly 350 is releasably coupled to a pendant unit 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens.

Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

[0082] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the actuation mechanism can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Expandable membrane

[0083] In many embodiments such as the embodiment depicted in FIG. 3B, the expandable membrane 245a is located within breast interface 235a and disposed over at least a portion thereof, forming expression reservoir 250 between the interface housing 240 and the expandable membrane 245a. Preferably, the expandable membrane 245a comprises a resilient material that deforms substantially or a more rigid material that is displaced when subject to the negative pressures created when the fluid 230 is displaced from expression reservoir 250 by actuatable assembly 205. The expandable membrane returns to an unbiased position when the negative pressures subside. The amount of deformation of the expandable membrane 245a can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0084] FIG. 6 illustrates an exemplary expandable membrane 370 with a specified thickness and durometer.

[0085] FIG. 7 illustrates another embodiment of expandable membrane 375 with corrugated features 380 for increased surface area. Other configurations of the expandable membrane which may be used in any of the embodiments of breast pumps described herein are disclosed in US Patent Provisional Application No. 62/021,597 (Attorney Docket No. 44936-706.101) filed July 7, 2014; the entire contents of which are incorporated herein by reference.

[0086] Suitable materials for the expandable membrane are known to those of skill in the art. In many embodiments, the expandable membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the expandable membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the expandable membrane without surpassing the yield point of the material.

[0087] FIGS. 8A and 8B illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the expandable membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the expandable membrane 410 is relaxed, as shown in FIG. 8A, and is closed to prevent fluid flow when the expandable membrane 410 is deformed, as shown in FIG. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405 can preferably be configured to also function on the mechanical movement of expandable membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum creation. Furthermore, the implementation of an exit valve integrally formed within the expandable membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

[0088] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the expandable membrane can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Milk collection and quantification system

[0089] With reference to FIG. 3B, expressed milk drains through exit port 265 in expandable membrane 245a into a collection vessel 275. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to expandable membrane 245a. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing.

[0090] In many instances, it can be desirable to track various data related to milk expression and collection, such as the amount of milk production or the chemical and nutritional content of the produced milk. Currently, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Exemplary embodiments of the device described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy.

[0091] FIGS. 9A and 9B illustrate exemplary embodiments of a breast interface 450 with one or more integrated sensors 455. Sensors 455 are preferably located in flap valve 460, but may also be located in exit valve 465, or any other suitable location for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by

fluid flow and detects the length of time that the valve is opened. The sensor signal can be interrogated to quantify the fluid flow. Suitable sensors are known to those of skill in the art, such as accelerometers, Hall effect sensors, and photodiode/LED sensors. The breast interface can include a single sensor or multiple sensors to quantify milk production.

[0092] FIG. 10 illustrates an exemplary embodiment of pendant unit 500 in which milk expression data is shown on a display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data related to milk expression. Preferably, the pendant unit 500 can transmit the data to a second device, such as a mobile phone 510.

[0093] FIG. 11 illustrates data transmission 515 between pendant unit 500 and a mobile phone 510. Suitable methods for communication and data transmission between devices are known to those of skill in the art, such as Bluetooth or near field communication.

[0094] In exemplary embodiments, the pendant unit 500 communicates with a mobile phone 510 to transmit milk expression data, such as expression volume, duration, and date. The mobile phone 510 includes a mobile application to collect and aggregate the expression data and display it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. The mobile application can also include features that allow the user to control aspects of the pump, such as pump power and pump states (e.g., let-down and stimulate modes), adjust expression pressure and speed, and adjust the size of the breast interface 235a or others described herein, where the breast interface is automatically adjustable. The application may also have resources for breastfeeding moms, such as advice or connection to advice, social aspects such as peer comparisons, and an accessory store for acquiring accessories for the pump. Additionally, the pendant unit 500 can send information about the times of pump usage to the mobile phone 510 so that the mobile application can identify when pumping has occurred and set reminders at desired pumping times. Such reminders can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis.

[0095] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the milk collection and quantification system can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Mechanical pumping device

[0096] FIG. 12 illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane 245 or expandable membrane 245a. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible or expandable membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0097] FIG. 13 illustrates the tensile element 610 coupled to driving element 625 of an actuatable assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a pendant unit, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast.

[0098] The tensile element 610 can be any suitable device, such as a wire, coil, or rope, and can be made from any suitable material, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

[0099] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the mechanical pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Adjustable breast interface

[00100] Referring to the exemplary embodiment of FIG. 3B, the breast interface 235a or any other embodiment described herein may be adjustable in size or shape to fluidly seal against and perform efficiently with a plurality of sizes or shapes of human breast. In some embodiments, the flange 236 may be adjustable in one or both of the frustoconical portion 237 and the inner diameter of the tubular flange neck 238, so as to adjust the size or shape of

the breast interface. In some embodiments, the expression area 260 may be adjustable in size or shape, including in the size of the expression mouth 261, so as to adjust the size or shape of the breast interface and improve the efficiency of milk expression. Yet other embodiments may comprise a combination of an adjustable flange and an adjustable expression area.

[00101] FIG. 19A is a cross-sectional view of an exemplary embodiment of an adjustable flange 1900. A flange includes a tapered or frustoconical portion 1905 that engages the breast, and a tubular flange neck 1915 on the opposite end that transitions into expression area 1920 of the breast interface 1910 through the expression mouth 1921. The flange has an exterior surface 1925 and an interior surface 1930 with a wall 1935 defined therebetween. Physical properties and construction of the wall 1935 may vary in different embodiments, allowing the thickness of the wall to be adjusted so as to adjust the size of the flange 1910 to fit a particular size or shape of breast. The flange 1910 may be sized fixedly or adjustably, and flanges of various fixed or adjusted sizes may be detachable from or integrated with the breast interface 1910. The thickness of the wall 1935 may vary in different embodiments.

[00102] FIGS. 19B and 19C illustrate exemplary embodiments of adjustable flanges 1901 and 1902 of different sizes. Whereas the flange 1900 in FIG. 19A has a wall 1935 of a thickness such that the inner diameter of flange neck 1915 is about 30mm, the flange 1901 in FIG. 19B has a wall 1936 thicker than wall 1935 such that the inner diameter of the flange neck 1906 is about 27mm. The flange 1907 in FIG. 19C has a wall 1937 thicker yet than wall 1936, such that the inner diameter of the flange neck 1907 is about 24mm. One of skill in the art will appreciate that these dimensions are not limiting, and that any size is possible.

[00103] FIGS. 20A and 20B are perspective views of an exemplary embodiment of an adjustable flange 2000 with a sizing element 2005. The sizing element 2005 may be a fully closed ring or a partial ring, which encircles the engagement region 2010 disposed on the flange neck 2015, thereby decreasing or increasing the inner diameter of flange neck. The sizing element 2005 may be releasably coupled to the engagement region 2010 by any one of several mechanisms well-known in the art, such as a snap fit, press fit, or magnetic engagement mechanism. The sizing element 2005 may be provided in various sizes, all of which are releasably coupleable to the engagement region 2010 in the same manner. The sizing element 2005 can be coupled to and released from the engagement region 2010 repeatedly, so as to allow the flange 2000 to be adjustable in size throughout the course of a user's use of the breast milk expression device. FIG. 20A shows the sizing element 2005 coupled to the flange 2000, while FIG. 20B shows the sizing element 2005 released from the flange 2000.

[00104] FIGS. 21A, 21B, and 21C are cross-sectional views of an exemplary embodiment of an adjustable flange 2100 with a sizing element. Sizing elements 2105 and 2106 can be releasably coupled to the engagement region 2110, which may comprise a compliant material that is reversibly deformed when a sizing element 2105 or 2106 is coupled. The deformation of the engagement region 2110 can result in the narrowing of the flange neck 2115 so as to adjust the size of the flange 2100 to fluidly seal against a particular size or shape of human breast. The release of a coupled sizing element 2105 or 2106 can reverse the deformation of the engagement region 2110, resulting in the widening of the flange neck 2115. FIG. 21A shows the adjustable flange 2100 with no coupled sizing element, having a flange neck 2115 with an inner diameter of about 30mm. FIG. 21B shows the flange 2100 with sizing element 2105 coupled to the engagement region 2110, resulting in the narrowing of the flange neck 2115 such that the inner diameter of the flange neck decreases to about 27mm. FIG. 21C shows the flange 2100 with sizing element 2106 coupled to the engagement region 2110, resulting in the further narrowing of the flange neck 2115 such that the inner diameter of the flange neck decreases to about 24mm. The sizing element may be a ring, split ring, or other clip such as those previously described.

[00105] FIGS. 22A, 22B, and 22C illustrate exemplary embodiments of an adjustable flange 2200 that comprises a fillable pocket 2205. The pocket 2205 may be disposed between the interior surface 2206 and exterior surface 2207 of the flange 2200 or the pocket may be a discrete reservoir on an interior or exterior surface of the flange. The pocket 2205 comprises a material that prevents any filling material from leaking out. Filling of the pocket 2205 with a filling material displaces the interior surface of the flange 2200 towards the breast to better seal against the surface of the breast and also to narrow the flange neck 2210. The filling of the pocket 2205 can be reversible, such that the removal of a filling material from a filled pocket 2205 results in the widening of the flange neck 2210. Preferably, the pocket 2205 may be filled or emptied repeatedly, so as to allow the flange 2200 to be adjustable in size throughout the course of a user's use of the breast milk expression device. The pocket 2205, whether filled or emptied, does not obstruct the flange 2200 from forming a fluid seal against the breast.

[00106] The pocket 2205 can be accessed for filling with a filling material by various means, depending on the physical and chemical properties of the filling material. As shown in FIG. 22B, the pocket 2205 may comprise a flexible material 2215 that can be punctured without being permanently deformed, such as a butyl rubber or other elastomer, thereby allowing the addition or removal of a filling material through a sharp apparatus such as a needle 2220.

Alternatively, as shown in FIG. 22C, the pocket 2205 may comprise an access port 2225 such as a cap 2230 that can be opened or closed mechanically, disposed on the surface of the pocket 2205, through which the filling material may be added or removed.

[00107] FIG. 22D is a cross-sectional view of an exemplary embodiment of an adjustable flange 2250 with a pocket 2255 filled with a fluid 2260. Filling of the pocket 2255 with the fluid 2260 displaces the interior surface 1956 of the flange 2250 towards the breast to better seal against the surface of the breast and also to narrow the flange neck 2210. The fluid 2260 may comprise any suitable material, such as a saline solution or other fluids including gases. Adding the fluid 2260 to or removing the fluid from the pocket 2255 can adjust the size of the flange 2250 to fit a particular size or shape of human breast.

[00108] FIG. 22E is a cross-sectional view of an exemplary embodiment of an adjustable flange 2280 with a pocket 2285 filled with a plurality of bead-like elements 2290. The plurality of bead-like elements 2290 may comprise any suitable material, such as polystyrene beads or silica nanoparticles. The pocket 2285 can be filled with the plurality of bead-like elements 2290, then molded against the user's breast. Once the pocket 2285 with the bead-like elements 2290 is disposed against the breast and molded therearound, application of a vacuum to the filled pocket 2285 can lock the plurality of bead-like elements 2290 into a fixed configuration for fluidly sealing against a particular size or shape of human breast. This concept is well known in the art and is sometimes referred to as dilatancy.

[00109] FIG. 23A and 23B illustrate another exemplary embodiment of an adjustable flange 2300 comprising a fillable pocket 2305. The pocket 2305 is fluidly coupled to the air pump 2310 and the exhaust valve 2315. The air pump comprises a vault 2320 having an integrated valve, such that the valve closes when the vault is compressed and opens when the vault expands. The air pump also comprises an inlet valve 2325 which fluidly couples the vault 2320 with the pocket 2305. When vault 2320 is depressed, air flows from the vault into the pocket 2305 through the inlet valve 2325. Inlet valve 2325 is a check valve, such as a duckbill valve, that allows air to flow in one direction only, from the vault to the pocket. A secondary relief valve, separate from or integrated with valve 2325, may be configured to release excessive pressure in the pocket 2305. The exhaust valve 2315 is configured to be in a closed position by default, for example by means of a spring mechanism. When depressed, the exhaust valve opens, allowing air to flow out from the pocket 2305, through the exhaust valve. FIG. 23A shows the pocket 2305 in the empty configuration, while FIG. 23B shows the pocket filled with air, whereby the interior surface 2330 of the flange is displaced towards the breast and the flange neck 2335 is narrowed. Adding air to or removing air from the

pocket 2305 can adjust the size of the flange 2300 to fit a particular size or shape of human breast.

[00110] FIGS. 24A and 24B illustrate an exemplary embodiment of a device 2400 for expressing breast milk comprising an adjustable expression area 2402. The device further comprises an adjustable reservoir 2405 in fluid communication with an actuatable assembly 2410, which is operatively coupled by tube 2415 to the breast interface 2420. The breast interface comprises an expandable membrane 2425 and an expression reservoir 2440, which is fluidly coupled by tube 2415 to the adjustable reservoir 2405 and the actuatable assembly 2410.

[00111] The actuation of the actuatable assembly 2410 delivers the fluid 2435 from the adjustable reservoir 2405 through the tube 2415 to the expression reservoir 2440, and returns the fluid 2435 from the expression reservoir through the tube to the adjustable reservoir. The change in the volume of fluid in the expression reservoir causes the expandable membrane 2425 to expand or collapse, thereby adjusting the size of the expression area 2402. The volume of fluid 2435 in the adjustable reservoir can be adjusted so as to adjust the volume of the fluid in the expression reservoir. When the volume of fluid in the expression reservoir decreases, the expandable membrane 2425 expands and moves closer to the interface housing 2421, thereby increasing the size of the expression area 2402. FIG. 24A shows the device whereby the adjustable reservoir 2405 contains a small volume of fluid and the expression reservoir 2440 contains a corresponding larger volume of fluid, thereby resulting in a smaller expression area 2402. FIG. 24B shows the device whereby the adjustable reservoir 2405 contains a large volume of fluid and the expression reservoir 2440 contains a corresponding smaller volume of fluid, thereby resulting in a larger expression area 2402. Adjusting the size of the expression area 2402 can adjust the size of the breast interface 2420 to fluidly seal against a particular size or shape of human breast.

[00112] The volume of fluid in the adjustable reservoir 2405 may be adjusted manually by various means. For example, the adjustable reservoir 2405 may comprise threaded walls 2406 and a threadably engaged plug 2407, such that turning the plug increases or decreases the volume of fluid in the adjustable reservoir.

[00113] The volume of fluid in the adjustable reservoir 2405 may also be adjusted automatically, whereby the device 2400 comprises a closed-loop system that is capable of sensing the engagement of the breast interface with the breast and accordingly adjusting the volume of fluid in the adjustable reservoir to adjust the size of the expression area 2402. FIG. 25 illustrates an exemplary embodiment of an automatically adjustable system for

adjusting the size of the expression area. A mobile phone 2500 may be in communication with a pendant unit 2501 that controls the breast milk expression device. The device may operate in several different states, such as pumping state 2502 and adjustment state 2503. The phone can put the pendant unit into an adjustment state, which drives the motor 2505, disposed within the actuatable assembly, for adjustment of the volume of fluid in the expression reservoir 2510. The adjustable reservoir 2515 may be integrated with and in fluid communication with the actuatable assembly, such that the volume of fluid in the expression reservoir may be adjusted by changing a setting of the actuatable assembly. For example, the actuatable assembly may comprise a piston assembly in fluid communication with the expression reservoir, and the piston may be set at a preset resting position so as to result in a preset volume of fluid in the expression reservoir. Changing the resting position of the piston can accordingly increase or decrease the volume of fluid the expression reservoir. An adjustable reservoir integrated with the actual assembly in this manner, compared to a separate adjustable reservoir, can reduce the number of parts in the system as well as simplify the adjustment operation. The motor may steadily increase the volume of fluid in the expression reservoir, providing motor current feedback to the pendant unit. The motor current feedback may be used to determine when the breast interface has fluidly sealed against the breast, by sensing the timepoint at which the motor current begins to rise in response to greater resistance in the system. When the pendant unit receives feedback that the breast interface has sealed against the breast, it may end the adjustment state. Preferably, the volume of fluid in the adjustable reservoir may be reset to an initial default value at any point, so that a user may readjust the size of the expression area as necessary.

[00114] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the adjustable breast interface can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Experimental data

[00115] FIGS. 14 and 15 illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[00116] FIG. 14 illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were

taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[00117] FIG. 15 illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[00118] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A device for expression and collection of breast milk, said device comprising:

a breast interface configured to engage a breast and fluidly seal thereagainst, the breast interface having a movable member disposed within at least a portion thereof;

a tube filled with fluid and fluidly coupled with the breast interface; and

a peristaltic pump coupled with the tube, wherein actuation of the peristaltic pump moves the fluid in a first direction or a second direction opposite the first direction, and

wherein movement of the fluid in the first direction moves the movable member in the breast interface in the first direction and thereby causes the breast interface to apply vacuum pressure at the breast to express milk therefrom, and

wherein movement of the fluid in the second direction moves the movable member in the breast interface in the second direction and thereby applies pressure at the breast interface.

2. The device of claim 1, wherein the peristaltic pump is removably coupled with the tube.

3. A device as in any one of the preceding claims, wherein the movable member of the breast interface comprises one or more of a flexible membrane, a deformable portion of a sealing element coupled to a flexible membrane, or an expandable membrane, configured to move in response to actuation of the peristaltic pump.

4. A device as in any one of the preceding claims, wherein movement of the movable member in the second direction returns the breast interface to atmospheric pressure, thereby allowing the expressed milk to drain into a collection vessel coupled to the breast interface.

5. A device as in any one of the preceding claims, wherein the device further comprises a collection vessel fluidly coupled to the breast interface, and wherein movement of the movable member in the second direction applies positive pressure at breast interface, thereby forcing the expressed milk out of breast interface into the collection vessel.

6. A device as in any one of the preceding claims, wherein the device further comprises a collection vessel fluidly coupled to the breast interface, and wherein the breast interface comprises a first breast interface configured to engage a first breast and a second breast interface configured to engage a second breast, and wherein actuation of the peristaltic pump simultaneously causes the first breast interface to express milk from the first breast and the second breast interface to collect expressed milk from the second breast into the collection vessel.

7. A device as in any one of the preceding claims, wherein the tube comprises a central compliant region configured to engage the peristaltic pump and a less compliant region that is less compliant relative to the central compliant region disposed adjacent to the central compliant region, such that the central compliant region compresses in response to actuation of the peristaltic pump, while the less compliant region transmits pressure along the tube to the breast interface.

8. A method for expressing milk from a breast, said method comprising:

engaging and fluidly sealing a breast interface with the breast;

actuating a peristaltic pump coupled with a tube filled with a fluid and fluidly coupled to the breast interface, thereby applying vacuum pressure at the breast; and

expressing milk from the breast.

9. The method of claim 8, wherein actuating a peristaltic pump comprises actuating the peristaltic pump so as to move the fluid in a first direction or in a second direction opposite the first direction, wherein moving the fluid in the first direction causes a movable member within the breast interface to move away from the breast and thereby apply vacuum pressure at the breast to express milk therefrom, and wherein moving the fluid in the second direction causes the movable member to move toward the breast and thereby causing the expressed milk to drain into a collection vessel fluidly coupled to the breast interface.

10. The method of claim 9, wherein moving the fluid in the second direction returns the breast interface to atmospheric pressure, thereby allowing the expressed milk to drain into the collection vessel.

11. A method as in any one of claims 8, 9, or 10, wherein moving the fluid in the second direction applies a positive pressure at breast interface, thereby forcing the expressed milk out of the breast interface into the collection vessel.

12. A method as in any one of claims 8, 9, 10, or 11, wherein the breast interface comprises a first breast interface configured to engage a first breast and a second breast interface configured to engage a second breast, and wherein actuating a peristaltic pump comprises simultaneously moving the fluid away from the first breast interface to express milk from the first breast, and moving the fluid toward the second breast interface to collect expressed milk from the second breast into a collection vessel fluidly coupled to the second breast interface.

13. A device for expressing breast milk from a breast, said device comprising:

a breast interface comprising a flange configured to engage and fluidly seal against the breast, and an expression area where milk is expressed from the breast;

wherein the breast interface is manually or automatically adjustable to fluidly seal against a plurality of sizes or shapes of breasts.

14. The device of claim 13, wherein the flange comprises one or more resilient materials conformable to the breast and adapted to fluidly seal against the plurality of sizes or shapes of breasts.

15. A device as in any one of claims 13 or 14, wherein the flange comprises a pocket fillable with a filling material, and wherein addition of filling material to, or removal of the filling material from the pocket adjusts a size of the flange.

16. The device of claim 15, wherein the filling material comprises a plurality of bead-like elements, and wherein application of a vacuum to the pocket substantially locks the plurality of bead-like elements and the flange into a fixed configuration for fluidly sealing against a particular size or shape of human breast.

17. A device as in any one of claims 15 or 16, wherein the filling material comprises a fluid.

18. The device of claim 17, wherein the breast interface further comprises a fluid pump fluidly coupled to the pocket, the fluid pump configured to add or remove the fluid from the pocket.

19. A device as in any one of claims 13, 14, 15, 16, 17, or 18, wherein the device further comprises

an actuatable assembly operatively coupled to the breast interface;

an expression reservoir disposed within the breast interface; and

an adjustable reservoir fluidly coupled to the expression reservoir and operatively coupled to the actuatable assembly;

wherein the actuatable assembly is configured to deliver fluid from the adjustable reservoir to the expression reservoir or remove fluid from the expression reservoir and return the fluid to the adjustable reservoir, and

wherein the adjustable reservoir comprises a mechanism to adjust a volume thereof, so as to adjust a volume of the expression reservoir and thereby adjust a size of the expression area to fluidly seal against a particular size or shape of breast.

20. The device of claim 19, wherein the mechanism is manually adjustable.

21. A device as in any one of claims 19 or 20, wherein the mechanism is automatically adjustable to adjust the volume of the adjustable reservoir in response to a feedback from the actuatable assembly indicating a degree of fluid seal between the breast interface and the breast.

22. The device of claim 21, wherein the feedback comprises a current produced by the actuatable assembly as the volume of the adjustable reservoir is adjusted, wherein an increase in the current indicates an increased degree of fluid seal between the breast interface and the breast.

23. A device as in any one of claims 21 or 22, wherein the adjustable reservoir is integrated with the actuatable assembly, such that the volume of the adjustable reservoir may be adjusted by changing a setting of the actuatable assembly.

24. The device of claim 23, wherein the actuatable assembly comprises a piston assembly and wherein the adjustable reservoir comprises a reservoir of the piston assembly, such that changing a resting position of the piston assembly adjusts the volume of fluid in the adjustable reservoir.

25. A method for expressing breast milk from a breast, said method comprising:

providing a device for expressing breast milk comprising an adjustable breast interface having a flange and an expression area;

engaging the adjustable breast interface with the breast;

adjusting a size of the adjustable breast interface;

fluidly sealing the breast interface against the breast; and

expressing milk from the breast.

26. The method of claim 25, wherein adjusting the size of the adjustable breast interface comprises adding a fluid to or removing the fluid from a pocket disposed within the flange.

27. A method as in any of claims 25 or 26, wherein adjusting the size of the adjustable breast interface comprises:

providing a plurality of bead-like elements disposed in a pocket in the flange;

molding the plurality of bead-like elements against the human breast;

applying a vacuum to the pocket; and

locking the flange into a particular size or shape.

28. A method as in any of claims 25, 26, or 27, wherein the breast interface comprises an expression reservoir fluidly coupled with an actuatable assembly and an adjustable reservoir, and wherein adjusting the size of the adjustable breast interface comprises:

actuating the actuatable assembly, thereby delivering a fluid from the adjustable reservoir to the expression reservoir or removing the fluid from the expression reservoir and returning the fluid to the adjustable reservoir; and

adjusting a volume of the adjustable reservoir so as to adjust a volume of the expression reservoir, thereby adjusting a size of the expression area.

29. The method of claim 28, wherein adjusting a volume of the adjustable reservoir comprises manually adjusting the volume of the adjustable reservoir.

30. A method as in any of claims 28 or 29, wherein adjusting a volume of the adjustable reservoir comprises automatically adjusting the volume of the adjustable reservoir in response to a feedback from the actuatable assembly indicating a degree of fluid seal between the breast interface and the breast.

31. The method of claim 30, wherein the adjustable reservoir is integrated with the actuatable assembly, and wherein automatically adjusting the volume of the adjustable reservoir comprises changing a setting of the actuatable assembly.

32. The method of claim 31, wherein the actuatable assembly comprises a piston assembly and wherein the adjustable reservoir comprises a reservoir of the piston assembly, and wherein automatically adjusting the volume of the adjustable reservoir comprises changing a resting position of the piston assembly.

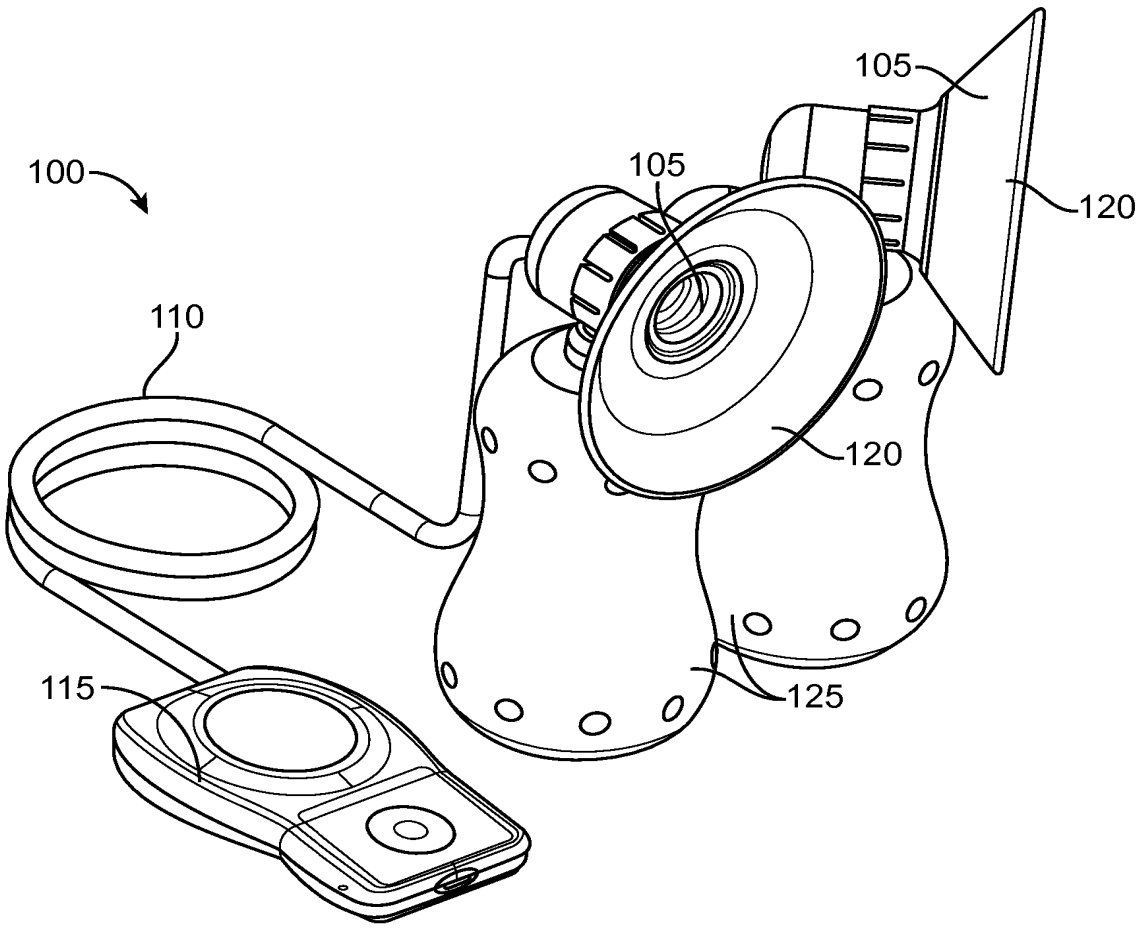


FIG. 1

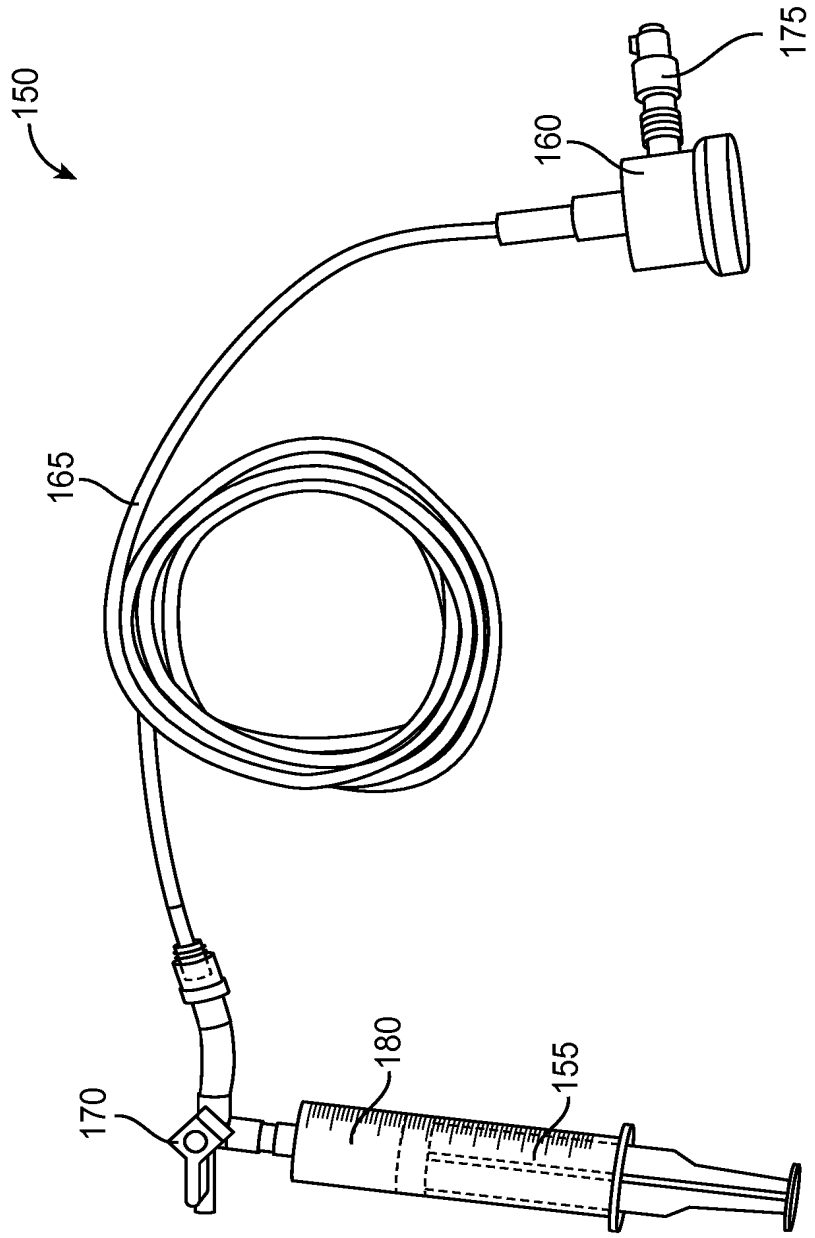


FIG. 2

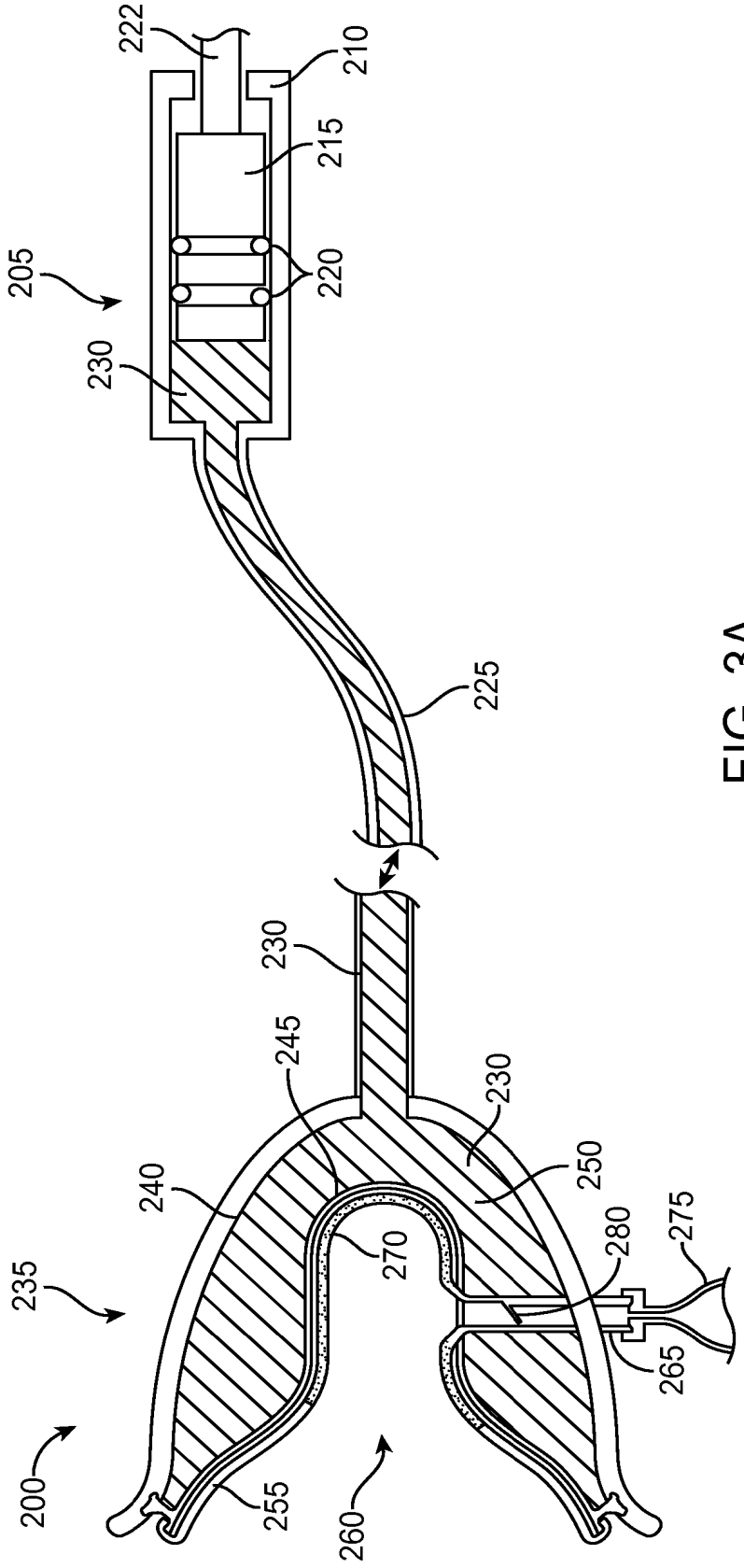

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260

FIG. 3A

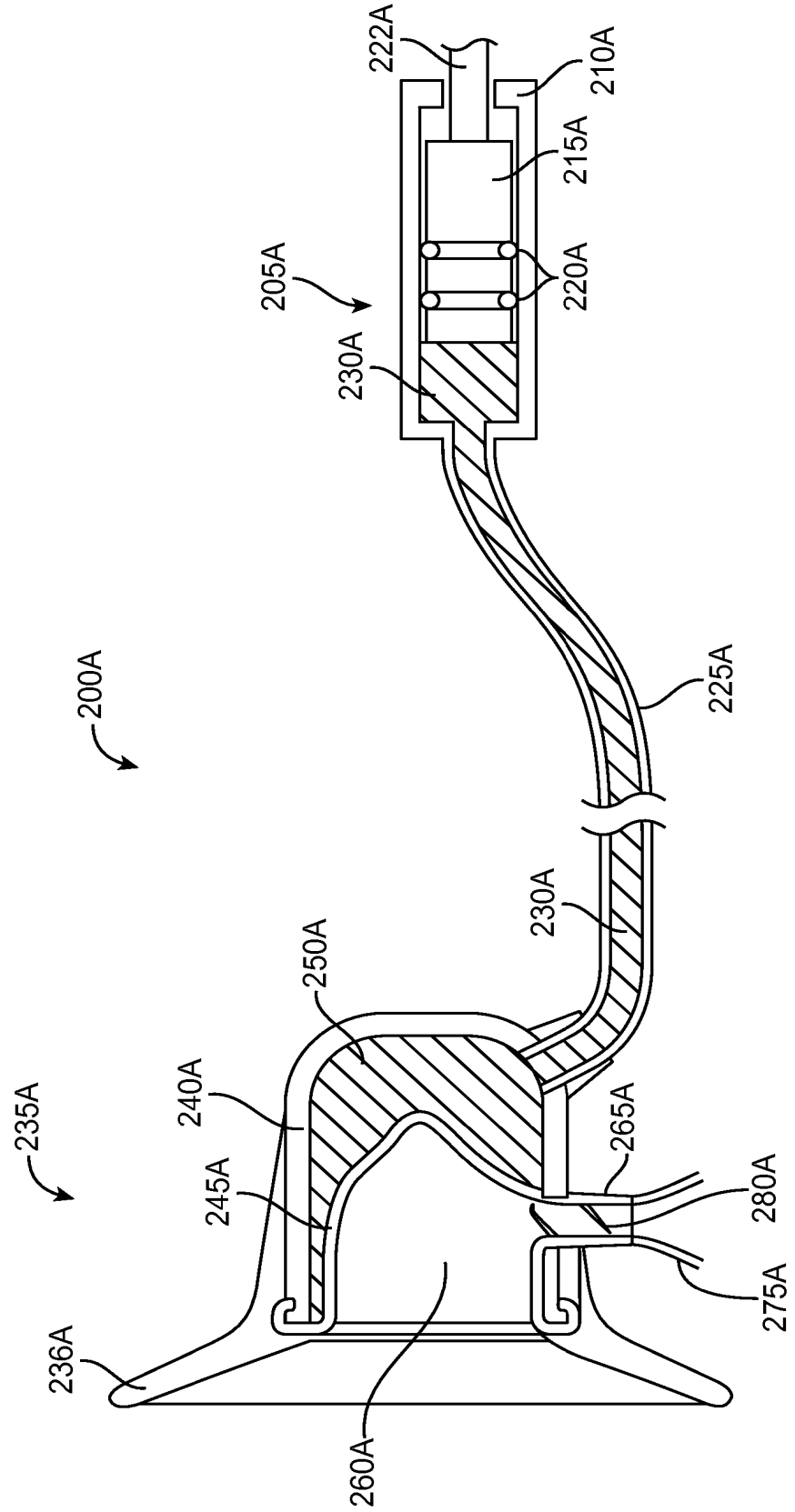

222A
210A
215A
205A
220A
230A
200A
225A
230A
250A
240A
235A
265A
245A
280A
275A
236A
260A

FIG. 3B

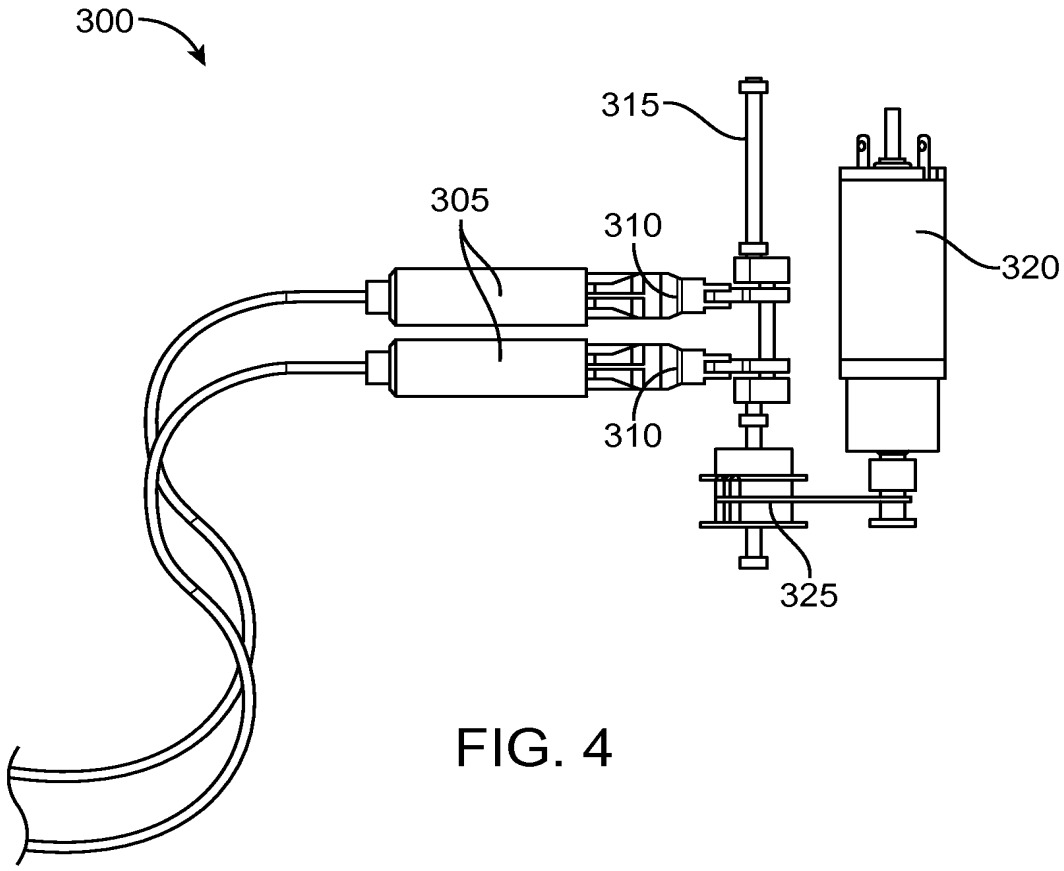


FIG. 4

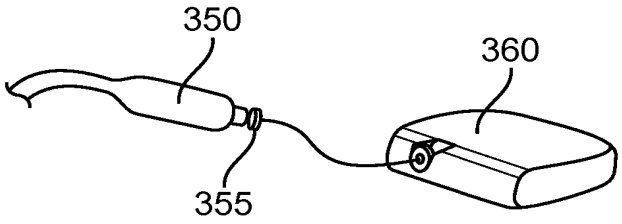


FIG. 5A

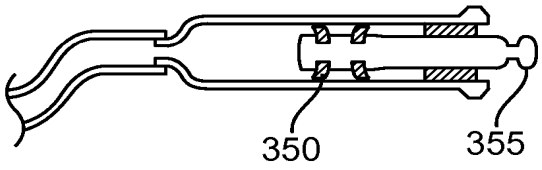


FIG. 5B

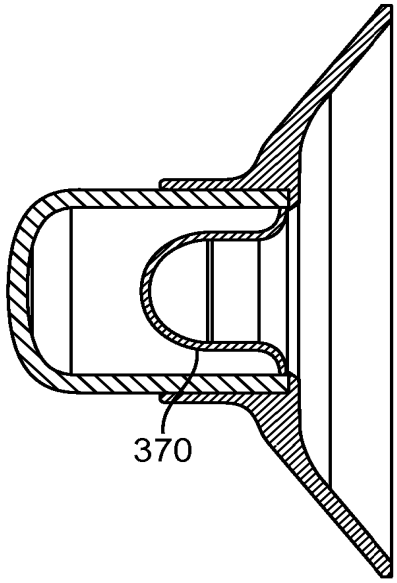


FIG. 6

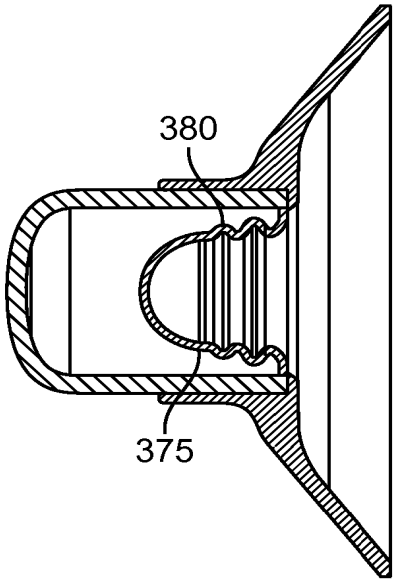


FIG. 7

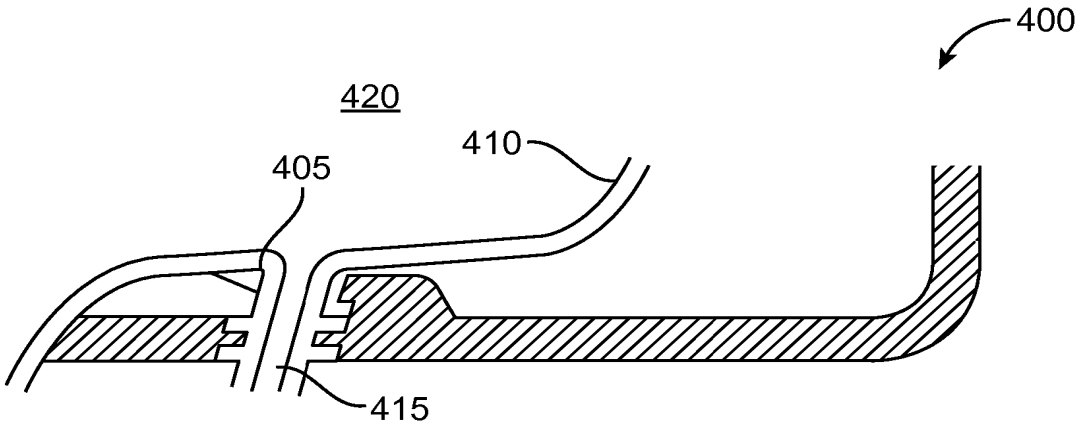


FIG. 8A

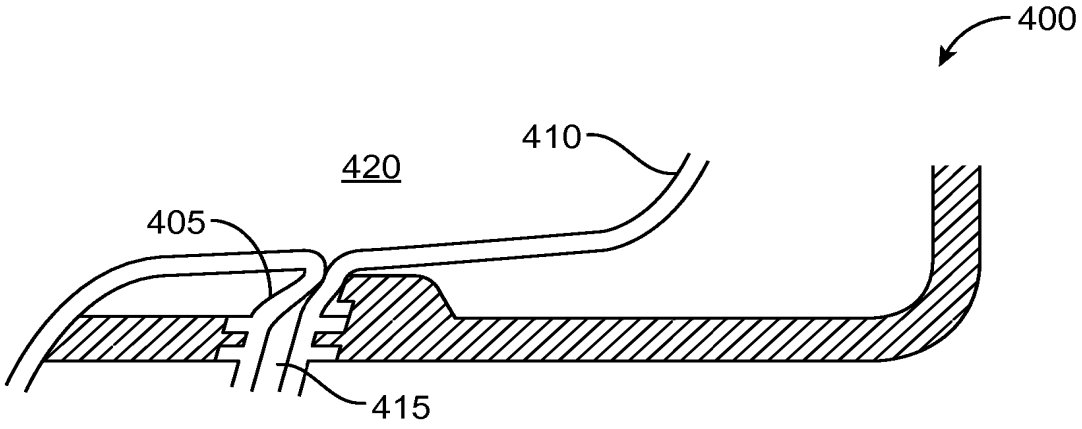


FIG. 8B

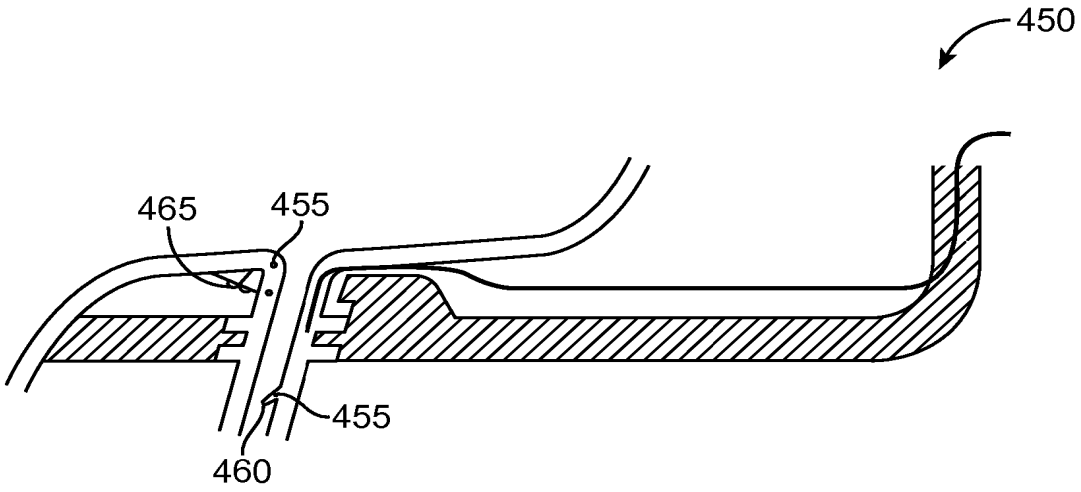


FIG. 9A

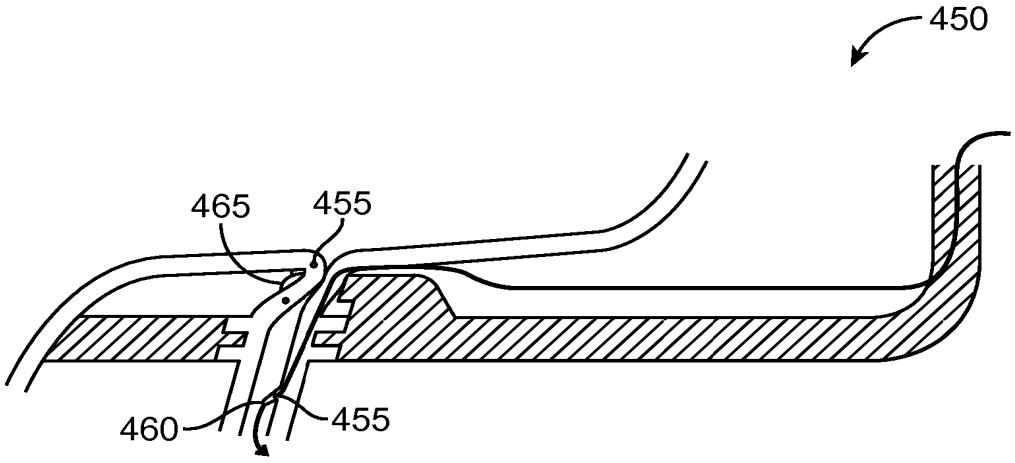


FIG. 9B

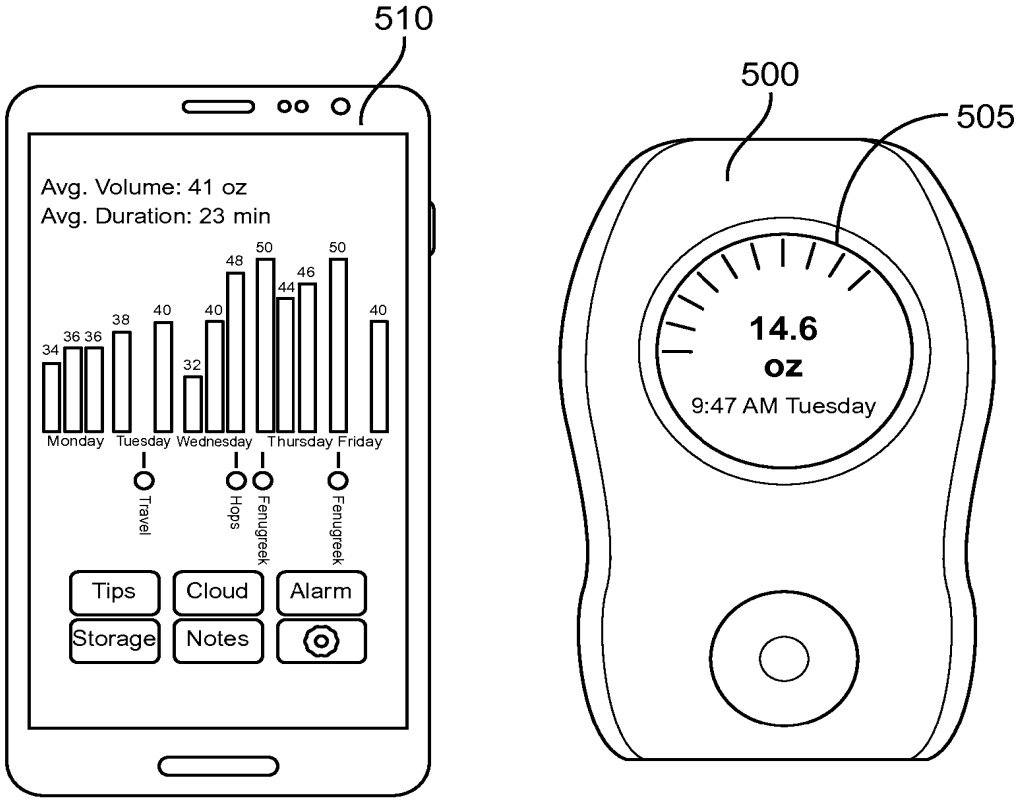

510
500
505
Avg. Volume: 41 oz
Avg. Duration: 23 min
34
36
36
38
40
32
40
48
50
44
46
50
40
Monday
Tuesday
Wednesday
Thursday
Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 10

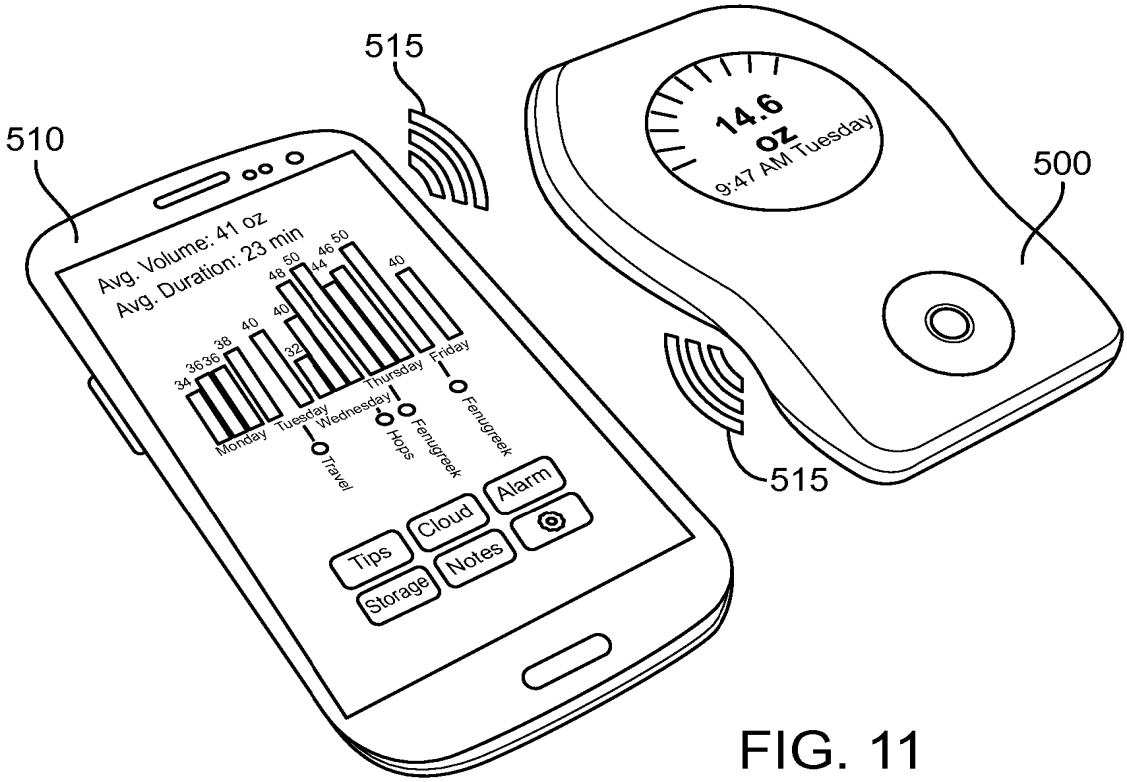

515
510
500
515
Avg. Volume: 41 oz
Avg. Duration: 23 min
34
36
36
38
40
32
40
48
50
44
46
50
40
Monday
Tuesday
Wednesday
Thursday
Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 11

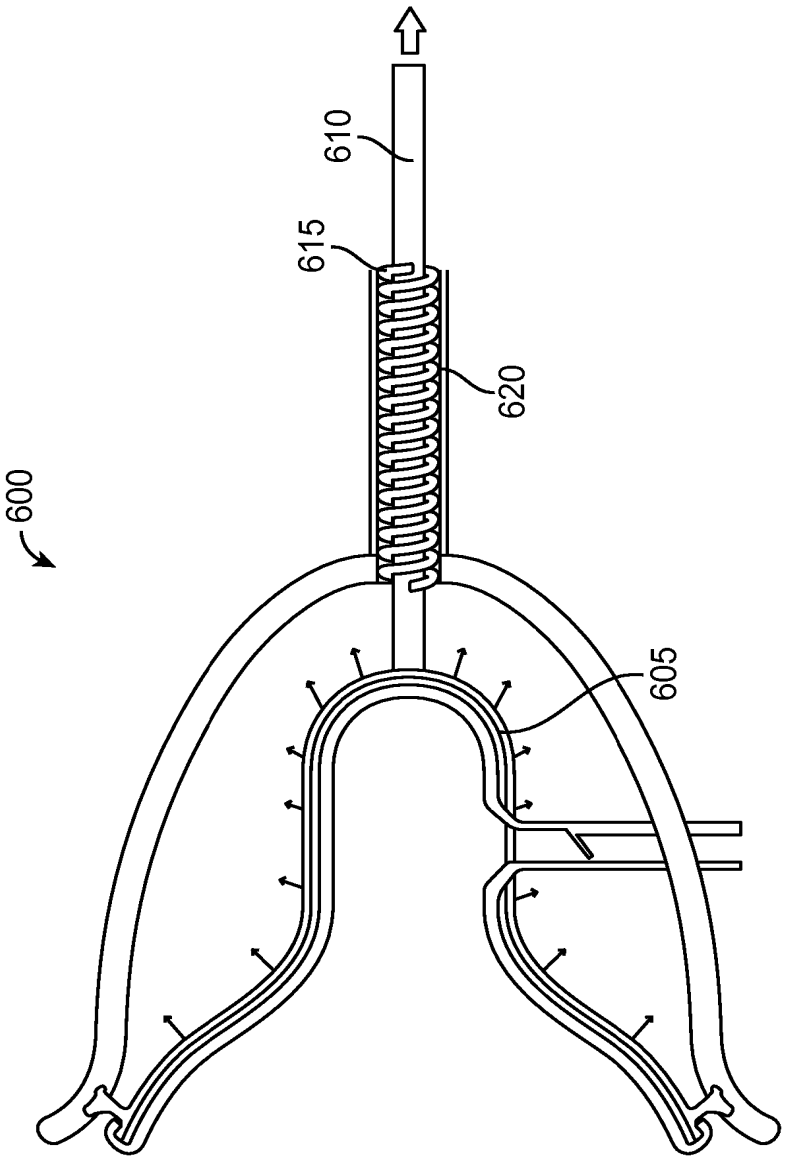


FIG. 12

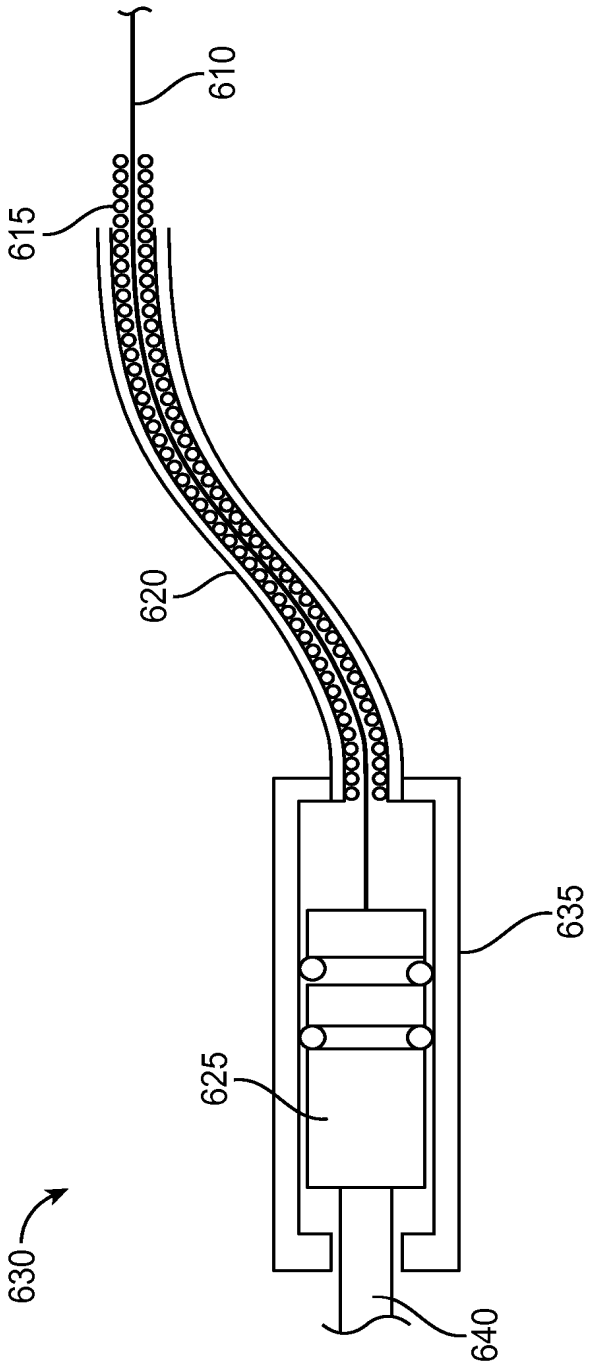


FIG. 13

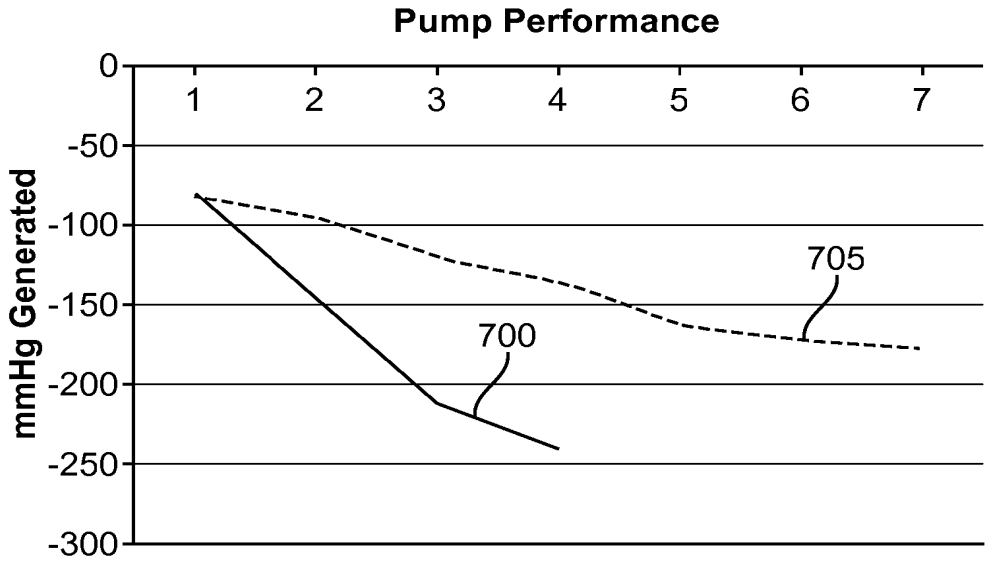

Pump Performance
0
1
2
3
4
5
6
7
-50
-100
-150
-200
-250
-300
mmHg Generated
705
700

FIG. 14

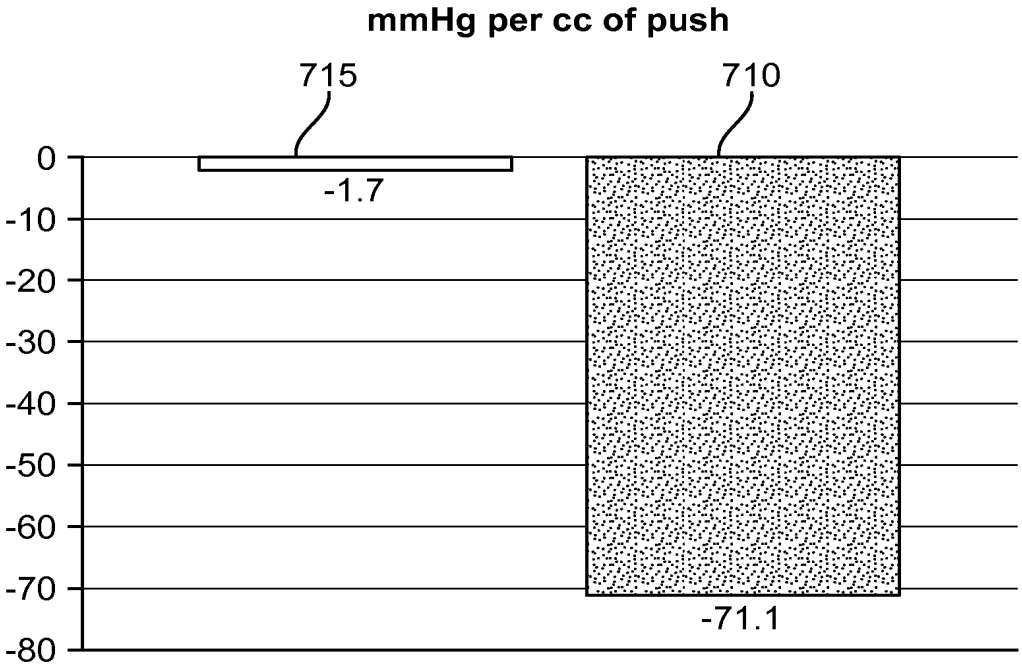


FIG. 15

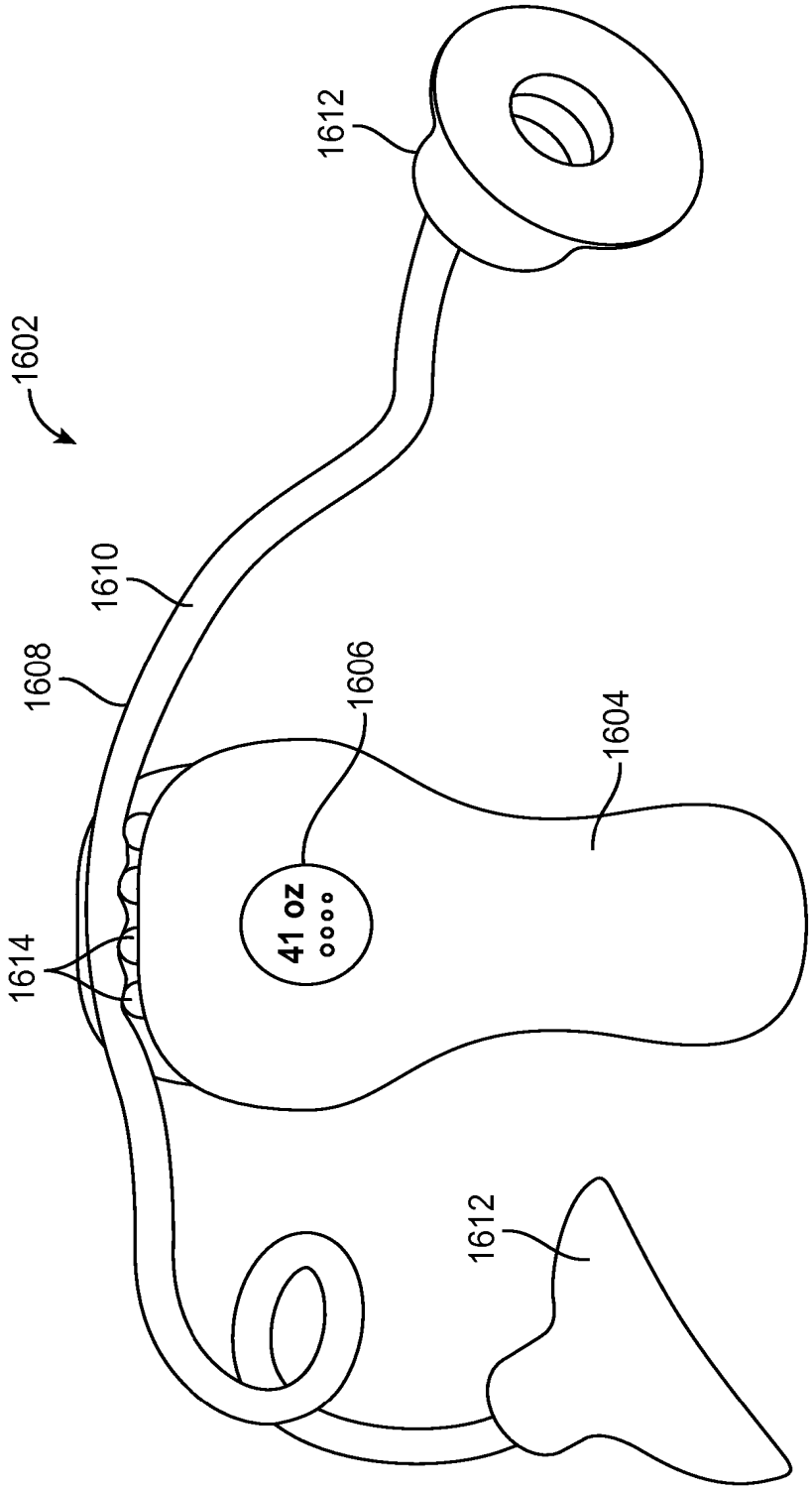


FIG. 16

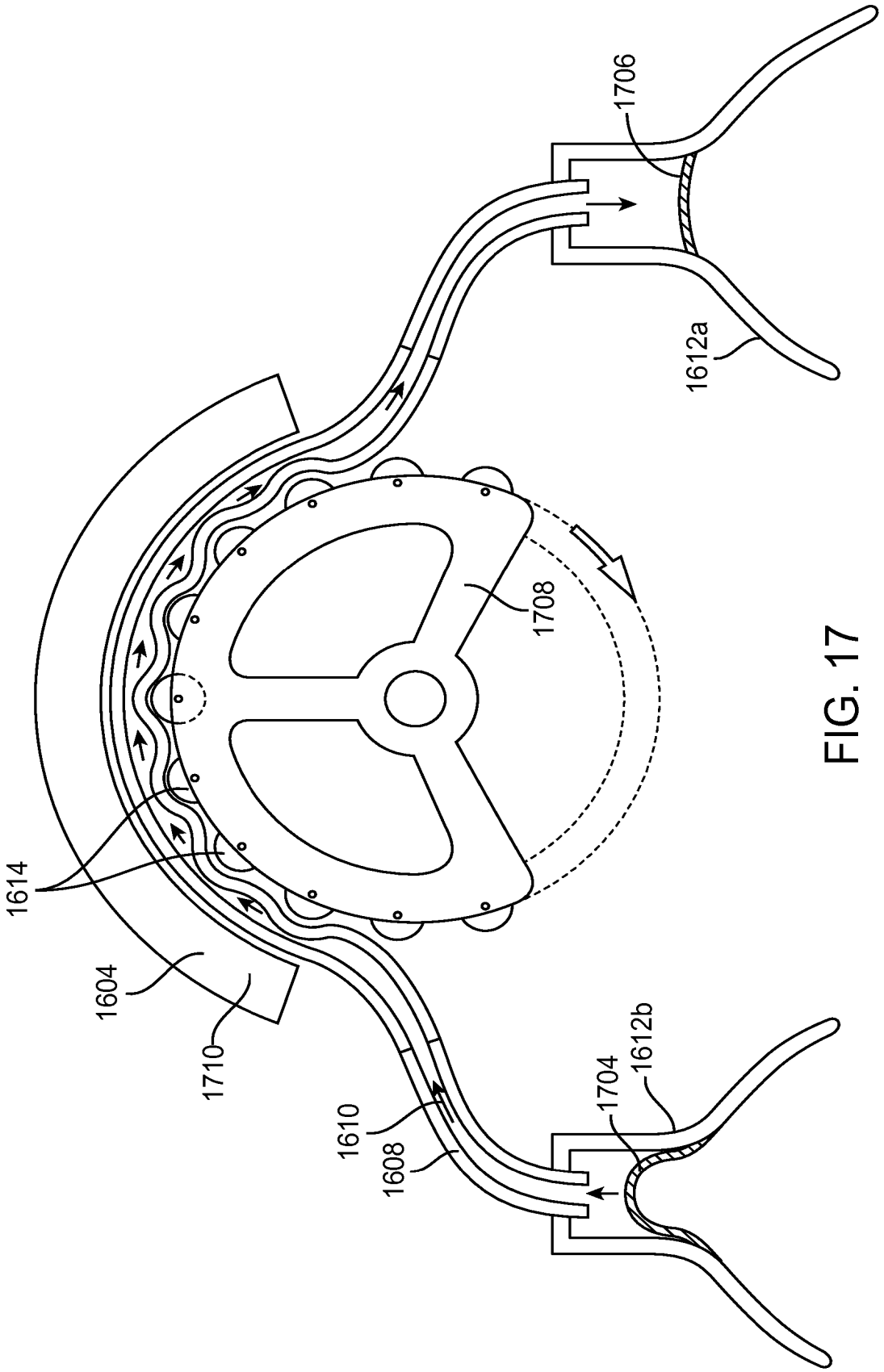


FIG. 17

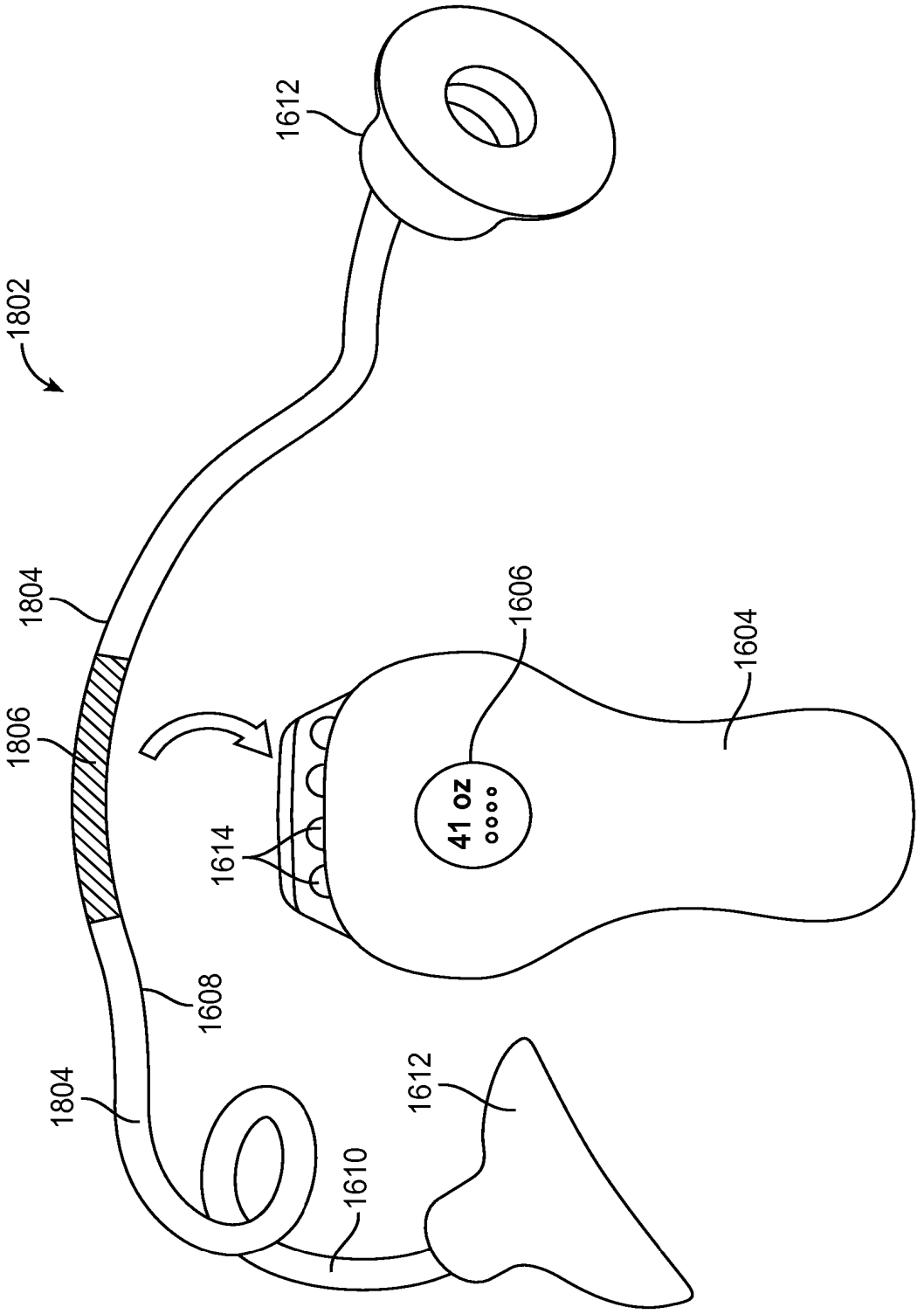


FIG. 18

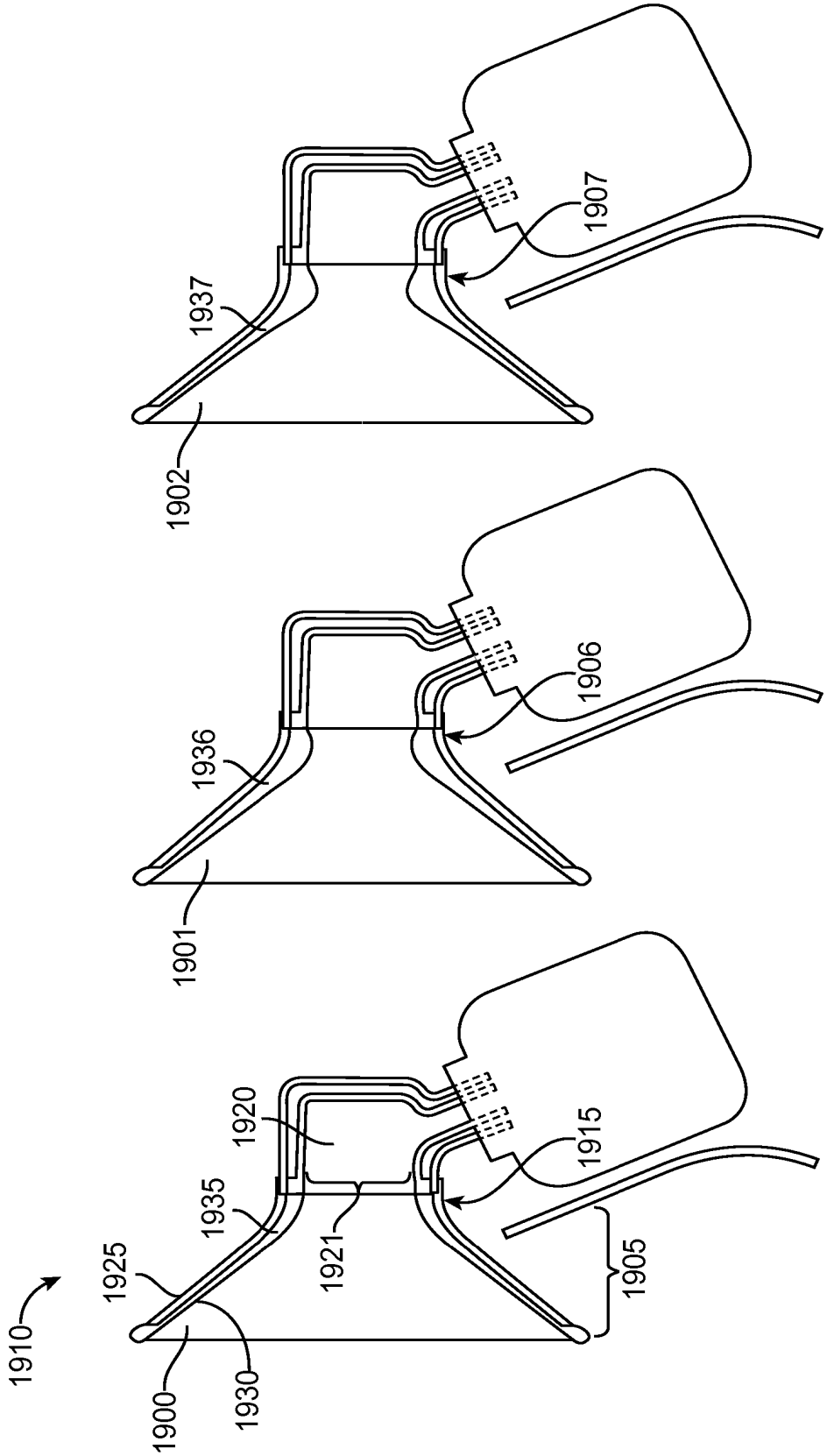


FIG. 19A

FIG. 19B

FIG. 19C

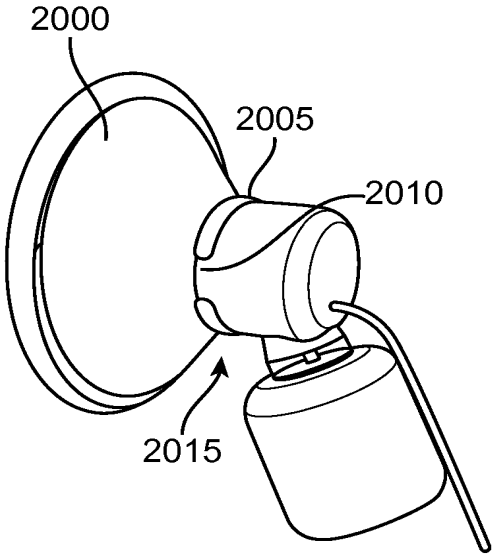


FIG. 20A

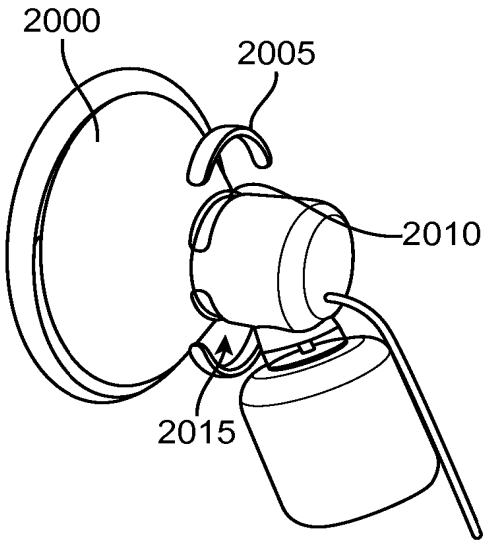


FIG. 20B

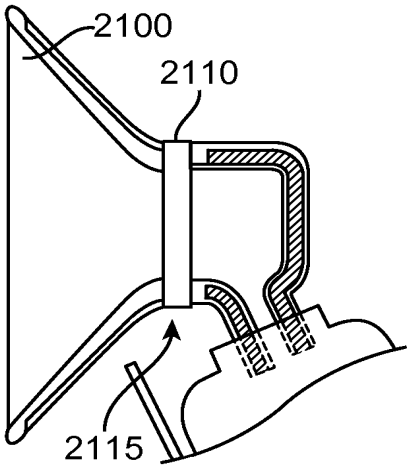


FIG. 21A

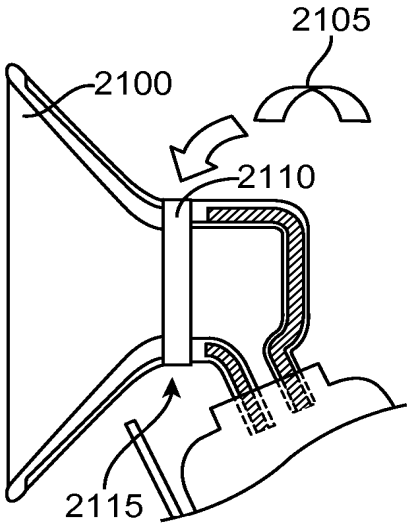


FIG. 21B

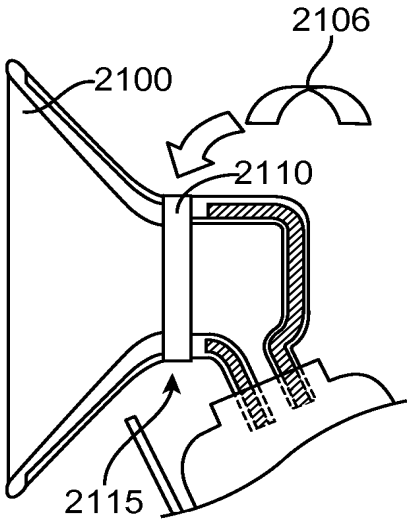


FIG. 21C

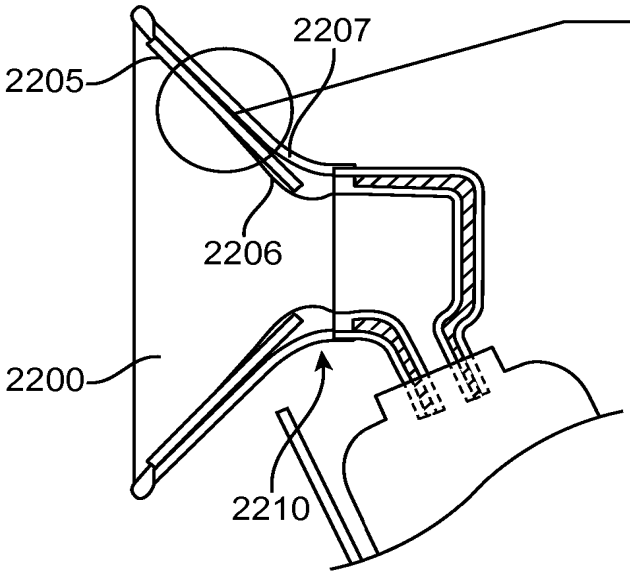


FIG. 22A

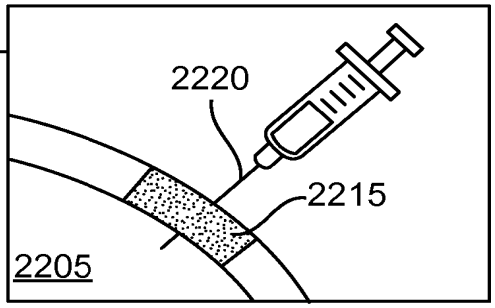


FIG. 22B

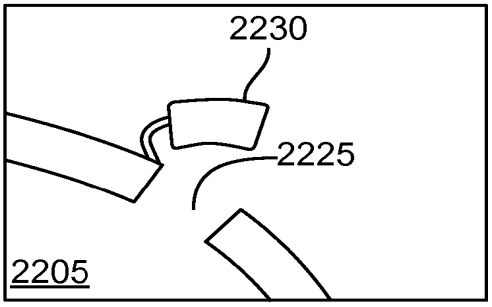


FIG. 22C

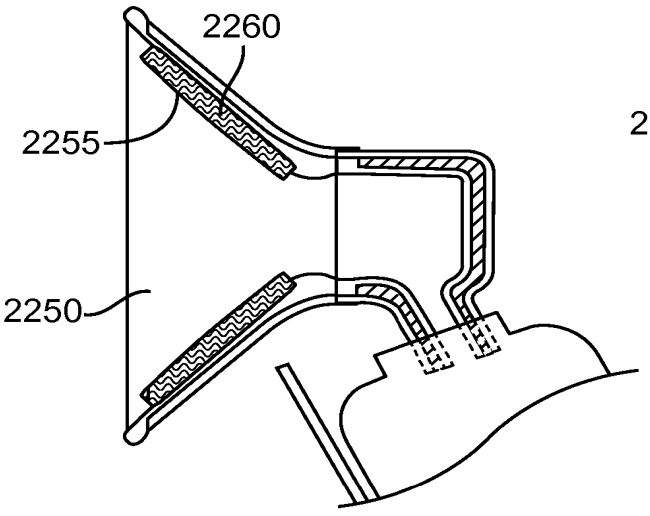


FIG. 22D

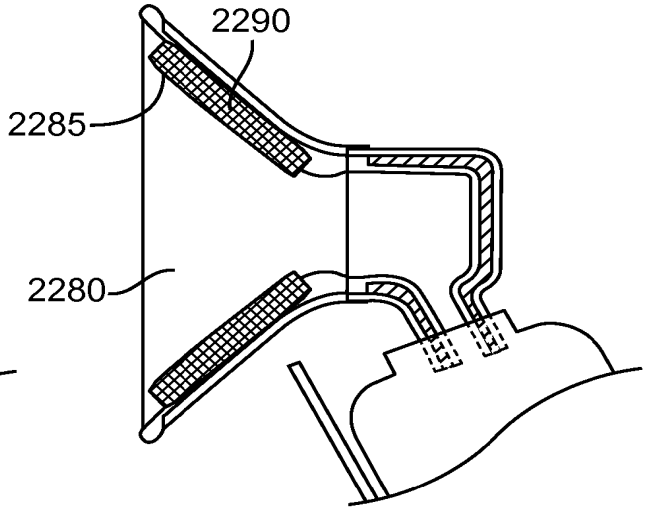


FIG. 22E

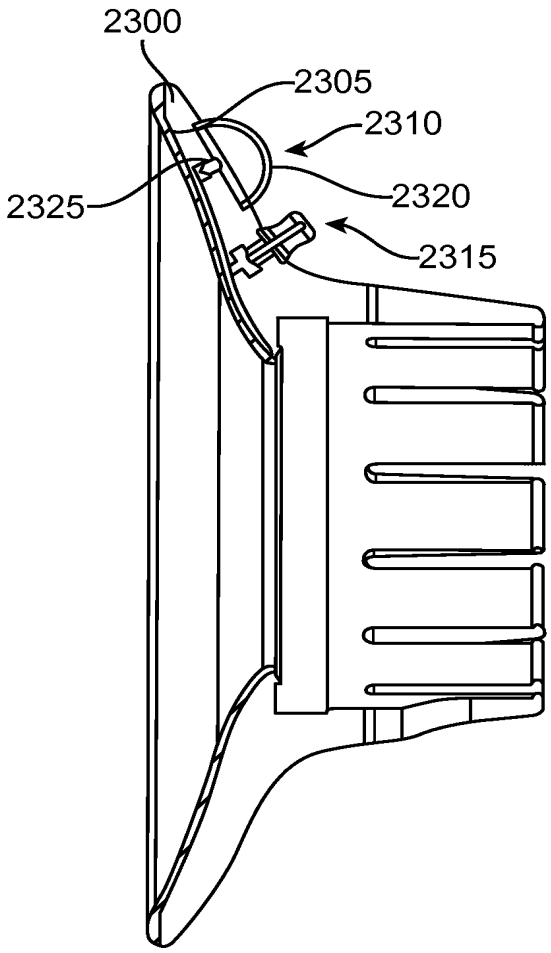


FIG. 23A

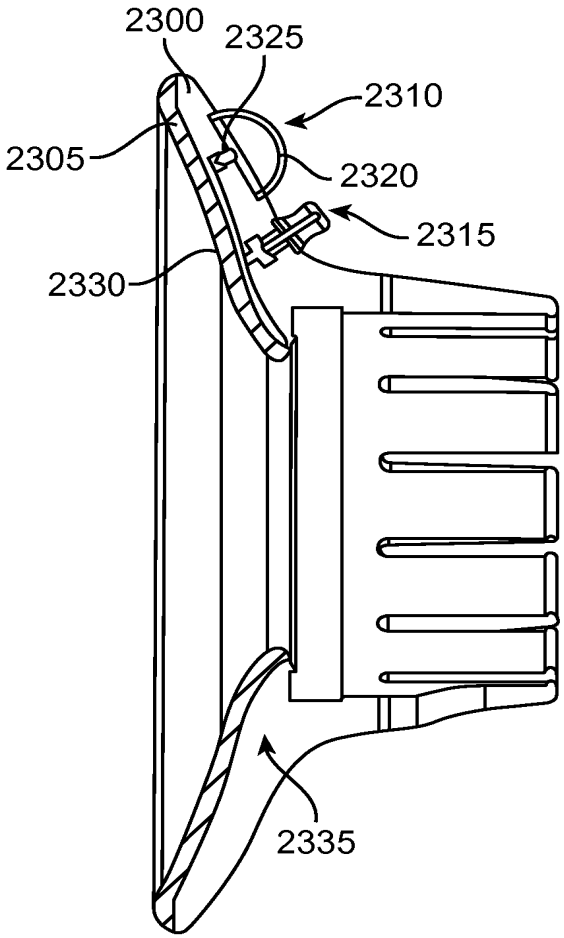


FIG. 23B

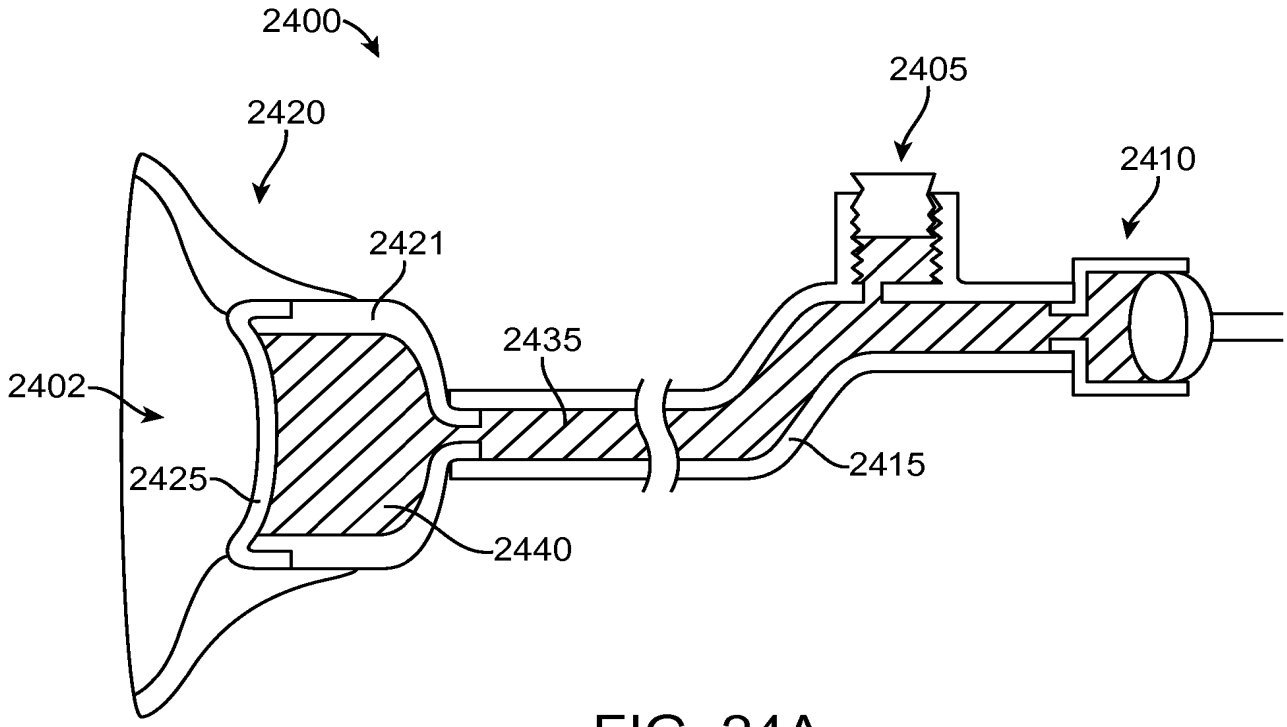


FIG. 24A

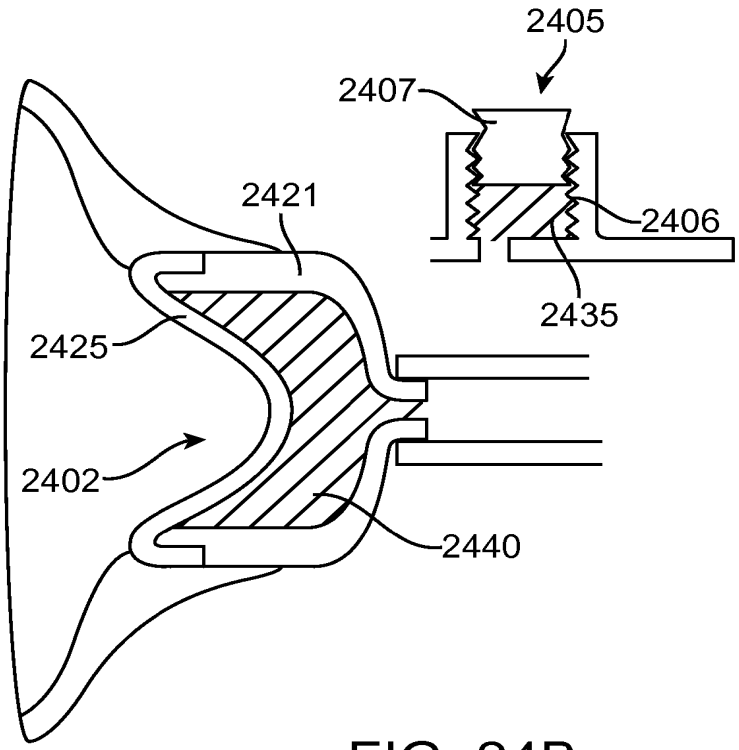


FIG. 24B

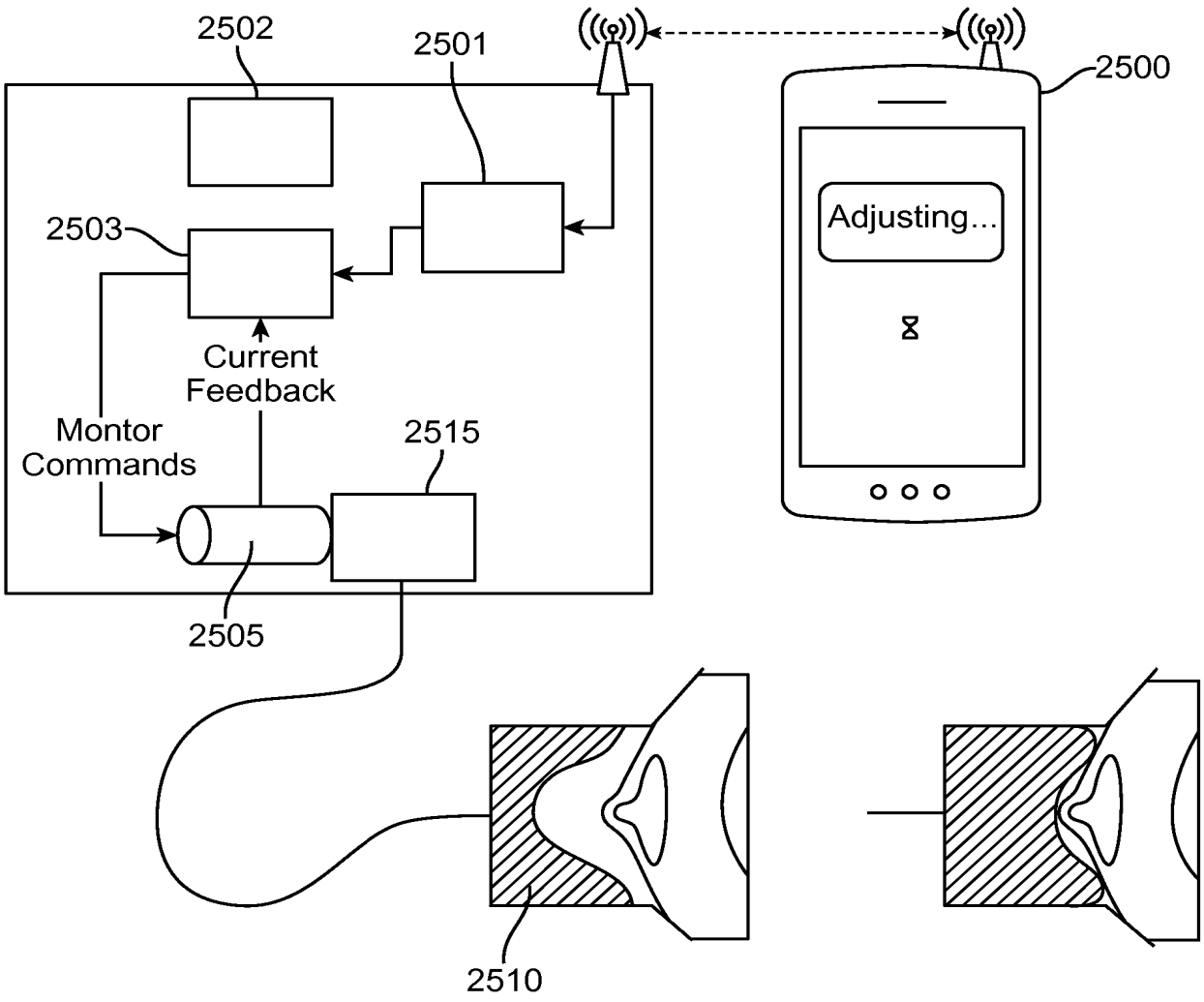

2502
2501
2500
2503
Adjusting...
Current
Feedback
Montor
Commands
2515
2505
2510

FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039452

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2015.01)
CPC - A61M 1/064 (2015.09)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A01J 5/00, 7/00; A61M 1/06 (2015.01)
CPC - A61M 1/064, 1/066 (2015.09) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 119/14.01, 14.08; 417/306, 311; 604/48, 74, 500

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Scholar, Google.
search terms used: collection, breast, milk, pump, peristaltic, tube, interface, adjustable, size, shape, user, flange, frustoconical, seal, movable, member, vacuum, pressure

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0182713 A1 (MORTON et al) 05 December 2002 (05.12.2002) entire document	13-15
A	US 2008/0275386 A1 (MYERS) 06 November 2008 (06.11.2008) entire document	1-3, 8-11, 13-16, 25-27
A	US 2007/0118078 A1 (MCNALLY et al) 24 May 2007 (24.05.2007) entire document	1-3, 8-11, 13-16, 25-27
A	WO 2013/066919 A2 (ZHANG) 10 May 2013 (10.05.2013) entire document	1-3, 8-11, 13-16, 25-27

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2015	28 OCT 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039452

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-7, 12, 17-24, 28-32
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(19)日本国特許庁(JP)　(12)公開特許公報(A)　(11)特許出願公開番号
特開2016-10524
(P2016-10524A)
(43)公開日　平成28年1月21日(2016.1.21)

(51)Int.Cl.			F I			テーマコード（参考）
A61M	1/06	(2006.01)	A61M	1/06		4C077
A41D	1/22	(2006.01)	A41D	1/22	Z	

審査請求 未請求　請求項の数 5　ＯＬ　（全 10 頁）

(21)出願番号　特願2014-133454 (P2014-133454)
(22)出願日　平成26年6月30日 (2014.6.30)

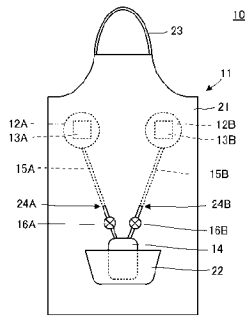
(71)出願人　000006231
株式会社村田製作所
京都府長岡京市東神足１丁目１０番１号
(74)代理人　110000970
特許業務法人　楓国際特許事務所
(72)発明者　田中　伸拓
京都府長岡京市東神足１丁目１０番１号
株式会社村田製作所内

Ｆターム(参考)　4C077 AA22

(54)【発明の名称】搾乳着

(57)【要約】
【課題】使用者が移動しながら搾乳することができる搾乳着を提供する。
【解決手段】搾乳着１０では、搾乳カップ１２Ａ，１２Ｂ、圧電ポンプ１３Ａ，１３Ｂ、搾乳ボトル１４が被服１１に設けられる。搾乳カップ１２Ａ，１２Ｂは、使用者の乳房に対応する位置に配置される。圧電ポンプ１３Ａ，１３Ｂは搾乳カップ１２Ａ，１２Ｂに繋がる。搾乳ボトル１４は、チューブ１５Ａ，１５Ｂにより搾乳カップ１２Ａ，１２Ｂに連通する。チューブ１５Ａ，１５Ｂの流路に逆止弁１６Ａ，１６Ｂが設けられる。
【選択図】図１

図1



【特許請求の範囲】
【請求項１】
搾乳カップ、圧電ポンプ、搾乳ボトルが被服に設けられた搾乳着であって、
前記搾乳カップは、使用者の乳房に対応する位置に配置され、
前記圧電ポンプは、前記搾乳カップに繋がり、
前記搾乳ボトルは、チューブにより前記搾乳カップに連通し、
前記チューブの流路に弁が設けられる、搾乳着。
【請求項２】
前記搾乳カップと前記圧電ポンプとはチューブを介さずに直結される、請求項１に記載の搾乳着。
【請求項３】
２つの前記搾乳カップに同一の前記圧電ポンプが流路を介して繋がる、請求項１に記載の搾乳着。
【請求項４】
前記圧電ポンプ側からそれぞれの前記搾乳カップ側に繋がる流路を切替える弁を備える、請求項３に記載の搾乳着。
【請求項５】
前記圧電ポンプの駆動周波数は２０ｋＨｚ以上である、請求項１ないし４のいずれかに記載の搾乳着。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、搾乳するために着用される搾乳着に関する。
【背景技術】
【０００２】
従来の搾乳着として、例えば、特許文献１に記載のものがある。この搾乳着は、ブラジャー、乳房シールドおよび母乳収集容器を備える。乳房シールドは、ファスナーによりブラジャーに取り付けられている。母乳収集容器は、チャンネルを介して乳房シールドに連通され、乳房シールドの近傍に配置されている。乳房シールドには、チャンネルおよび管を介して真空源が連通されている。この搾乳着では、真空源により乳房シールド内に吸引作用が生じることで、母乳が吸引される。吸引された母乳は、チャンネルを通過し、母乳収集容器に貯留される。
【先行技術文献】
【特許文献】
【０００３】
【特許文献１】特許第３６０９８３２号公報
【発明の概要】
【発明が解決しようとする課題】
【０００４】
特許文献１に記載の搾乳着では、ブラジャーに乳房シールドおよび母乳収集容器が取り付けられているので、手を使わないで搾乳することができる。しかし、真空源が大きくかつ重く、さらに真空源の騒音が大きいので、搾乳着から離れた場所に真空源を置き、搾乳着と真空源とを管で繋いでいる。このため、使用者が移動しながら搾乳することは困難である。
【０００５】
本発明の目的は、使用者が移動しながら搾乳することができる搾乳着を提供することにある。
【課題を解決するための手段】
【０００６】
本発明の搾乳着では、搾乳カップ、圧電ポンプ、搾乳ボトルが被服に設けられている。

搾乳カップは、使用者の乳房に対応する位置に配置される。圧電ポンプは、搾乳カップに繋がる。搾乳ボトルは、チューブにより搾乳カップに連通する。チューブの流路に弁が設けられる。

【０００７】

この構成では、搾乳に必要な構成が全て被服に取り付けられている。また、圧電ポンプは一般的に軽量かつ小型である。このため、使用者は、搾乳時に、両手を自由に使うことができるとともに、自由に移動することができる。また、搾乳着を無理なく着用することができるし、搾乳着の着心地が悪くなることもない。また、搾乳着を着用して体を動かした際に、圧電ポンプが落下することを抑制できる。また、圧電ポンプでは一般的に駆動時に騒音が生じにくいので、搾乳中に周囲に迷惑をかけずに済むとともに、搾乳中であることが周囲に知られにくくなる。

【０００８】

本発明の搾乳着では、搾乳カップと圧電ポンプとはチューブを介さずに直結されてもよい。この構成では、必要なチューブの本数が少ないので、チューブが絡まりにくくなり、延いては、搾乳着を着脱することが容易となる。また、上述のように、必要なチューブの本数が少ないので、搾乳着を軽量にすることができる。

【０００９】

本発明の搾乳着では、２つの搾乳カップに同一の圧電ポンプが流路を介して繋がってもよい。この構成では、各搾乳カップに別の圧電ポンプが繋がる場合に比べて、搾乳着を軽量にすることができるとともに、圧電ポンプの駆動音を小さくすることができる。

【００１０】

本発明の搾乳着は、圧電ポンプ側からそれぞれの搾乳カップ側に繋がる流路を切替える弁を備えてもよい。この構成では、流路の切替を繰り返すことで、右側および左側の乳房から交互に母乳が吸引されるので、乳房に負担をかけず、効率良く搾乳することができる。

【００１１】

また、圧電ポンプは、一度に搾乳カップの両方に負圧を生じさせる必要がない。このため、圧電ポンプとして、性能が低いが、小型かつ軽量であり、駆動音が小さい圧電ポンプを用いることができる。この結果、搾乳着を軽量にすることができるとともに、圧電ポンプの駆動音を小さくすることができる。また、１つの圧電ポンプで一度に両方の乳房から母乳が吸引される場合に比べて、搾乳に必要な電力が小さくなるので、圧電ポンプの温度上昇を小さくすることができる。

【００１２】

本発明の搾乳着では、圧電ポンプの駆動周波数は２０ｋＨｚ以上であることが好ましい。この構成では、圧電ポンプの駆動周波数が可聴域の周波数より高くなるので、圧電ポンプの駆動音を聞えにくくすることができる。

【発明の効果】

【００１３】

本発明によれば、搾乳着を着用することにより移動しながら搾乳することができる。

【図面の簡単な説明】

【００１４】

【図１】第１の実施形態に係る搾乳着１０の平面図である。

【図２】第１の実施形態に係る搾乳着１０のブロック図である。

【図３】チューブ１５Ａ，１７Ａ，２５の模式的断面図である。

【図４】圧電ポンプ１３Ａの断面図である。

【図５】圧電ポンプ１３Ａの振動態様を示す模式図である。

【図６】第１の実施形態の変形例に係る搾乳着４０の平面図である。

【図７】第１の実施形態の変形例に係る搾乳着５０のブロック図である。

【図８】第１の実施形態の変形例に係る搾乳着６０のブロック図である。

【図９】第２の実施形態に係る搾乳着７０のブロック図である。

【図１０】第３の実施形態に係る搾乳着８０のブロック図である。
【図１１】第３の実施形態の変形例に係る搾乳着９０のブロック図である。
【発明を実施するための形態】
【００１５】
《第１の実施形態》
本発明の第１の実施形態に係る搾乳着１０について説明する。図１は搾乳着１０の平面図である。図１には、搾乳着１０を着用したときの搾乳着１０の表側が図示されている。図２は搾乳着１０のブロック図である。搾乳着１０は、エプロン形状の被服１１に、搾乳カップ１２Ａ，１２Ｂ、圧電ポンプ１３Ａ，１３Ｂおよび搾乳ボトル１４を設けてなる。
【００１６】
搾乳カップ１２Ａ，１２Ｂは、使用者が搾乳着１０を着用したとき、搾乳カップ１２Ａ，１２Ｂが使用者の乳房の近くに配置されるように設けられている。すなわち、搾乳カップ１２Ａ，１２Ｂは、使用者の乳房に対応する位置に配置されている。圧電ポンプ１３Ａは、チューブ１７Ａを介して搾乳カップ１２Ａに繋がっている。圧電ポンプ１３Ｂは、チューブ１７Ｂを介して搾乳カップ１２Ｂに繋がっている。圧電ポンプ１３Ａ，１３Ｂは、使用者が搾乳着１０を着用したとき、体の前面に配置されるように設けられている。搾乳ボトル１４は、チューブ１５Ａを介して搾乳カップ１２Ａに連通し、チューブ１５Ｂを介して搾乳カップ１２Ｂに連通している。チューブ１５Ａの流路には、逆止弁１６Ａが設けられている。チューブ１５Ｂの流路には、逆止弁１６Ｂが設けられている。
【００１７】
被服１１は、布２１、ポケット２２および紐２３を備える。布２１は、使用者が被服１１を着用したとき、使用者の前面を被覆する。布２１の表側の下方には、ポケット２２が設けられている。ポケット２２の開口は上方を向いている。布２１の上端には、紐２３の両端が布２１に取り付けられることにより、輪が形成されている。使用者は、この輪に首を通すことで被服１１を着用することができる。
【００１８】
搾乳カップ１２Ａは布２１の裏側の左上方に配置されている。搾乳カップ１２Ｂは布２１の裏側の右上方に配置されている。搾乳カップ１２Ａ，１２Ｂは、先細りになった筒形状を有し、シリコンゴム等を材料とする。搾乳カップ１２Ａ，１２Ｂは、布２１の裏側に設けられたポケット（図示せず）に収納されている。搾乳カップ１２Ａ，１２Ｂが収納されたポケットには、搾乳カップ１２Ａ，１２Ｂが露出するように開口が形成されている。これにより、使用者が搾乳着１０を着用したとき、搾乳カップ１２Ａ，１２Ｂと使用者の乳房とが接する。
【００１９】
圧電ポンプ１３Ａは、平面視で搾乳カップ１２Ａに重なるように、布２１の裏側に配置されている。圧電ポンプ１３Ｂは、平面視で搾乳カップ１２Ｂに重なるように、布２１の裏側に配置されている。圧電ポンプ１３Ａ，１３Ｂは、布２１の裏側に設けられたポケット（図示せず）に収納されている。圧電ポンプ１３Ａ，１３Ｂの駆動周波数は、２０ｋＨｚ以上であり、可聴域の周波数より高くなっている。これにより、圧電ポンプ１３Ａ，１３Ｂの駆動音を聞えにくくすることができる。布２１のポケット２２には、着脱自在に搾乳ボトル１４が保持されている。なお、搾乳カップ１２Ａ，１２Ｂおよび圧電ポンプ１３Ａ，１３Ｂは、被服１１に着脱自在で設けられてもよいし、そうでなくともよい。
【００２０】
チューブ１５Ａは、布２１に形成された孔２４Ａを通って、布２１の裏側から布２１の表側に延伸している。チューブ１５Ｂは、布２１に形成された孔２４Ｂを通って、布２１の裏側から布２１の表側に延伸している。チューブ１５Ａの端部のうち布２１の裏側に配置されたものは、搾乳カップ１２Ａに繋がっている。チューブ１５Ｂの端部のうち布２１の裏側に配置されたものは、搾乳カップ１２Ｂに繋がっている。チューブ１５Ａ，１５Ｂの端部のうち布２１の表側に配置されたものは、搾乳ボトル１４に繋がっている。逆止弁１６Ａ，１６Ｂは布２１の表側に配置されている。逆止弁１６Ａは搾乳ボトル１４側から

搾乳カップ１２Ａ側への流れを制限する。逆止弁１６Ｂは搾乳ボトル１４側から搾乳カップ１２Ｂ側への流れを制限する。

【００２１】

なお、被服１１には、搾乳に必要な構成が全て設けられている。例えば、被服１１には、圧電ポンプを駆動するための駆動回路（図示せず）、駆動回路に電力を供給する電池等の電源（図示せず）、圧電ポンプ１３Ａ，１３Ｂを操作するための操作部（図示せず）等も設けられている。

【００２２】

使用者が搾乳着１０を着用すると、搾乳カップ１２Ａ，１２Ｂが使用者の乳房に接する。圧電ポンプ１３Ａ，１３Ｂを駆動すると、搾乳カップ１２Ａ，１２Ｂ内に負圧が生じることにより母乳が吸引される。吸引された母乳は、チューブ１５Ａ，１５Ｂの流路を通過し、搾乳ボトル１４に貯留される。貯蔵された母乳は、逆止弁１６Ａ，１６Ｂが逆流を防止するので、搾乳カップ１２Ａ，１２Ｂ側に漏れることがない。

【００２３】

図３は、チューブ１５Ａ，１７Ａ，２５の模式的断面図である。チューブ１５Ａ，１７Ａ，２５の第１端部が互いに繋がることにより、Ｔ字状の流路２７が形成されている。チューブ１５Ａの第２端部は搾乳ボトル１４に繋がっている。チューブ１７Ａの第２端部は圧電ポンプ１３Ａに繋がっている。チューブ２５の第２端部は搾乳カップ１２Ａに繋がっている。チューブ１７Ａには、圧電ポンプ１３Ａ側とその反対側とを分離するセパレータ２６が設けられている。セパレータ２６は、例えば、ゴム膜等の膜状弾性体からなる。セパレータ２６は、その主面がチューブ１７Ａの断面に平行になるように配置されている。圧電ポンプ１３Ａは、吸入口３６（図４参照）側がセパレータ２６側を向くように配置されている。

【００２４】

圧電ポンプ１３Ａが駆動すると、圧電ポンプ１３Ａ側に凸となるようにセパレータ２６が弾性変形する。これにより、流路２７の体積が増え、流路２７に負圧が生じる。一方、逆止弁１６Ａ（図１参照）が逆流を制限するので、搾乳ボトル１４側から空気が吸引されることはない。このため、搾乳カップ１２Ａを通って母乳が吸引される。この動作を一定時間毎に繰り返すことにより、継続して母乳を吸引することができる。なお、搾乳カップ１２Ｂ側の構成および動作も搾乳カップ１２Ａ側の構成および動作と同様である。

【００２５】

図４は圧電ポンプ１３Ａの断面図である。圧電ポンプ１３Ａは圧電素子３１および構造体３２を備えている。構造体３２は、概略の外形が厚み方向に薄い円板状である。構造体３２の天面の中央付近には、吐出口３５が開口している。構造体３２の底面の縁付近には、吸入口３６が開口している。構造体３２の内部には、流路３３とポンプ室３４とが設けられている。流路３３は、構造体３２の天面で吐出口３５に通じており、構造体３２の内部で中央付近から外周側に延び、構造体３２の底面で吸入口３６に通じている。ポンプ室３４は、吐出口３５と流路３３との連通部分の底面側に設けられた薄い円筒状の空間であり、吐出口３５と流路３３との連通部分に開口している。

【００２６】

構造体３２におけるポンプ室３４の内底面は、屈曲振動が可能なダイヤフラム（振動板）３７として構成されている。ダイヤフラム３７は円板状であり、天面がポンプ室３４に面していて、底面に圧電素子３１が貼り付けられている。ダイヤフラム３７の天面は、ポンプ室３４を間に介して吐出口３５と対向している。圧電素子３１は、厚み方向に薄い円板状であり、交流電圧が印加されることで主面の面内方向に伸縮しようとする圧電性を有している。

【００２７】

図５は、圧電ポンプ１３Ａの振動態様を示す模式図である。圧電素子３１とダイヤフラム３７とは、互いに貼り付いてユニモルフ構造を構成しており、圧電素子３１の駆動により厚み方向に変位する。具体的には、図５（Ａ）に示すような静止状態から圧電素子３１

が伸びようとする場合には、図５（Ｂ）に示すように、ダイヤフラム３７が圧電素子３１側（底面側）に凸に屈曲してポンプ室３４の体積が増大する。これにより、ポンプ室３４に負圧が生じ、ポンプ室３４に連通する流路３３に負圧が伝わり、流路３３の流体がポンプ室３４に吸引される。

【００２８】

次に、圧電素子３１が縮もうとすると、図５（Ｃ）に示すように、ダイヤフラム３７がポンプ室３４側（天面側）に凸に屈曲してポンプ室３４の体積が減少する。すると、流路３３を間に介してポンプ室３４と吐出口３５とが対向しているために、ポンプ室３４の流体が吐出口３５から外部に吐出されるとともに、その流体の流れに引き込まれて流路３３内の流体が吐出口３５から吐出される。

【００２９】

このように、圧電ポンプ１３Ａでは、圧電素子３１とダイヤフラム３７との屈曲振動に伴い、ポンプ室３４では周期的な体積変動と圧力変動とが繰り返し生じ、気体の流れに慣性力が働くようになる。これにより、流路３３の流体が吐出口３５から吐出される気体の流れが定常的に生じるようになる。なお、圧電ポンプ１３Ｂの構成および動作も圧電ポンプ１３Ａ構成および動作と同様である。

【００３０】

第１の実施形態では、搾乳に必要な構成が全て被服１１に取り付けられている。また、圧電ポンプは一般的に軽量かつ小型である。このため、使用者は、搾乳時に、両手を自由に使うことができるとともに、自由に移動することができる。

【００３１】

また、上述のように、圧電ポンプは一般的に軽量かつ小型である。このため、搾乳着１０を無理なく着用することができるし、搾乳着１０の着心地が悪くなることもない。さらに、搾乳着１０を着用して体を動かした際に、圧電ポンプ１３Ａ，１３Ｂが落下することを抑制できる。

【００３２】

また、使用者が搾乳着１０を着用した際、圧電ポンプ１３Ａ，１３Ｂが体の前面に配置される。すなわち、圧電ポンプ１３Ａ，１３Ｂは、搾乳カップ１２Ａ，１２Ｂの近くに配置される。このため、チューブ１７Ａ，１７Ｂが短くなるので、チューブ１５Ａ，１５Ｂ，１７Ａ，１７Ｂが絡まりにくくなる。延いては、搾乳着１０を着脱することが容易となる。また、圧電ポンプ１３Ａ，１３Ｂと搾乳カップ１２Ａ，１２Ｂとの間の流路が短くなるので、搾乳カップ１２Ａ，１２Ｂ内に確実に負圧が生じ、安定して母乳を吸引することができる。

【００３３】

また、圧電ポンプ１３Ａ，１３Ｂが軽量であることに加え、チューブ１７Ａ，１７Ｂが短くなるので、搾乳着１０を軽量にすることができる。また、圧電ポンプでは一般的に駆動時に騒音が生じにくいので、搾乳中に周囲に迷惑をかけずに済むし、搾乳中であることが周囲に知られにくくなる。また、各乳房から吸引された母乳は１つの搾乳ボトル１４に貯留される。このため、各搾乳カップに別々の搾乳ボトルが繋がり、各搾乳ボトルに母乳が貯留される場合と異なり、貯留された母乳を別の容器に移し替える必要がない。

【００３４】

図６は、第１の実施形態の変形例に係る搾乳着４０の平面図である。図６では、搾乳着４０のうち、搾乳着４０を着用したときに体の前面に配置される側を図示している。搾乳着４０はジャケット形状の被服４１を備える。被服４１には、平面視で中央部に搾乳カップ１２Ａ，１２Ｂ、圧電ポンプ１３Ａ，１３Ｂ、搾乳ボトル１４等が設けられている。被服４１は、本体となる布２８にポケット２２を設けて構成されている。布２８には、平面視で中央部を避けるように開閉部２９が設けられている。使用者は、開閉部２９を開くことにより搾乳着４０を着脱することができる。この際、開閉部２９が平面視で被服４１の中央部を通っていないので、搾乳カップ１２Ａ，１２Ｂやチューブ１５Ａ，１５Ｂ等が邪魔にならない。このため、使用者は搾乳着４０を容易に着脱することができる。開閉部２

９は、ボタンとボタンホール、スナップボタン、ファスナー等により開閉自在となっている。

【００３５】

図７は、第１の実施形態の変形例に係る搾乳着５０のブロック図である。搾乳着５０では、被服１１に２つの搾乳ボトル５４Ａ，５４Ｂが設けられている。搾乳ボトル５４Ａはチューブ１５Ａにより搾乳カップ１２Ａに連通している。搾乳ボトル５４Ｂはチューブ１５Ｂにより搾乳カップ１２Ｂに連通している。チューブ１５Ａの流路には逆止弁１６Ａが設けられ、チューブ１５Ｂの流路には逆止弁１６Ｂが設けられている。搾乳着５０では、貯留することができる母乳量が多くなるので、一度に多くの母乳が搾乳されても、途中で搾乳ボトル５４Ａ，５４Ｂを交換する必要がない。

【００３６】

図８は、第１の実施形態の変形例に係る搾乳着６０のブロック図である。搾乳着６０では、搾乳カップ１２Ａと圧電ポンプ１３Ａとがチューブを介さずに直結し、搾乳カップ１２Ｂと圧電ポンプ１３Ｂとがチューブを介さずに直結している。例えば、搾乳カップ１２Ａ，１２Ｂにセパレータ２６（図３参照）が直接設けられ、セパレータ２６に対して搾乳カップ１２Ａ，１２Ｂ側の反対側に圧電ポンプ１３Ａ，１３Ｂが配置されてもよい。搾乳着６０では、その構成に必要なチューブの本数が少ないので、チューブ１５Ａ，１５Ｂがさらに絡まりにくくなり、また、搾乳着１０をさらに軽量にすることができる。

【００３７】

《第２の実施形態》

本発明の第２の実施形態に係る搾乳着７０について説明する。図９は搾乳着７０のブロック図である。搾乳着７０では、３つに枝分かれするチューブ７７に、搾乳カップ１２Ａ，１２Ｂおよび圧電ポンプ７３が繋がっている。チューブ７７の第１端部に搾乳カップ１２Ａが繋がり、チューブ７７の第２端部に搾乳カップ１２Ｂが繋がり、チューブ７７の第３端部に圧電ポンプ７３が繋がっている。すなわち、２つの搾乳カップ１２Ａ，１２Ｂに同一の圧電ポンプ７３が流路を介して繋がっている。

【００３８】

搾乳着７０では、３つに枝分かれするチューブ７５により、搾乳カップ１２Ａ，１２Ｂおよび搾乳ボトル１４が繋がっている。チューブ７５の第１端部に搾乳カップ１２Ａが繋がり、チューブ７５の第２端部に搾乳カップ１２Ｂが繋がり、チューブ７５の第３端部に搾乳ボトル１４が繋がっている。チューブ７５のうち３つに枝分かれする部分には、逆止弁７６が設けられている。逆止弁７６は、搾乳ボトル１４側から搾乳カップ１２Ａ，１２Ｂ側への流れを制限する。

【００３９】

第２の実施形態では、各搾乳カップに別の圧電ポンプが繋がる場合に比べて、圧電ポンプの個数を減らすことができる。このため、搾乳着７０を軽量にすることができるとともに、圧電ポンプの駆動音を小さくすることができる。

【００４０】

《第３の実施形態》

本発明の第３の実施形態に係る搾乳着８０について説明する。図１０は搾乳着８０のブロック図である。搾乳着８０では、３つに枝分かれするチューブ８７により、搾乳カップ１２Ａ，１２Ｂおよび圧電ポンプ８３が繋がっている。チューブ８７の第１端部に搾乳カップ１２Ａが繋がり、チューブ８７の第２端部に搾乳カップ１２Ｂが繋がり、チューブ８７の第３端部に圧電ポンプ８３が繋がっている。チューブ８７のうち３つに枝分かれする部分には、切替弁８８が設けられている。切替弁８８は、圧電ポンプ８３側から搾乳カップ１２Ａ，１２Ｂ側に繋がる流路を切替える。これにより、搾乳カップ１２Ａ，１２Ｂのうちどちらか一方に負圧を生じさせることができる。

【００４１】

搾乳着８０では、例えば、切替弁８８を１秒毎に切替えることで、搾乳カップ１２Ａ内に負圧を生じさせ、次に搾乳カップ１２Ｂ内に負圧を生じさせることを繰り返す。これに

より、右側および左側の乳房から交互に母乳が吸引されるので、乳房に負担をかけず、効率良く搾乳することができる。

【００４２】

第３の実施形態では，１つの圧電ポンプ８３のみを用いて搾乳する。また、圧電ポンプ８３は、一度に搾乳カップ１２Ａ，１２Ｂの両方に負圧を生じさせる必要がない。このため，圧電ポンプ８３として、性能が低いが、小型かつ軽量であり、駆動音が小さい圧電ポンプを用いることができる。この結果、搾乳着８０を軽量にすることができるとともに、圧電ポンプの駆動音を小さくすることができる。また、搾乳着８０では、１つの圧電ポンプで一度に両方の乳房から母乳が吸引される場合に比べて，搾乳に必要な電力が小さくなるので、圧電ポンプ８３の温度上昇を小さくすることができる。

【００４３】

図１１は、第３の実施形態の変形例に係る搾乳着９０のブロック図である。搾乳着９０では、搾乳カップ１２Ａに搾乳ボトル９４Ａが連通し、搾乳カップ１２Ｂに搾乳ボトル９４Ｂが連通している。搾乳着９０では、貯留することができる母乳量が多くなるので，一度に多くの母乳が搾乳されても，途中で搾乳ボトル９４Ａ，９４Ｂを交換する必要がない。

【００４４】

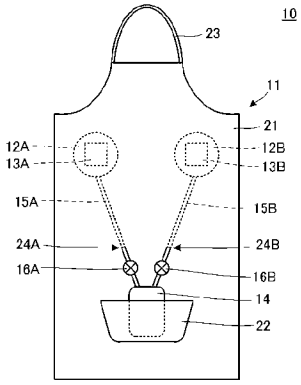
なお、上述の実施形態の被服はエプロン形状またはジャケット形状であったが、本発明の被服は，これに限定されず、例えばブラジャー形状やベスト形状でもよい。また、上述の実施形態では、搾乳ボトル１４、逆止弁１６Ａ，１６Ｂ、チューブ１５Ａ，１５Ｂの一部およびポケット２２は、被服１１，４１の表側に配置されていたが、本発明はこれに限定されない。本発明では，被服の裏側にこれらの構成が配置されてもよい。

【符号の説明】

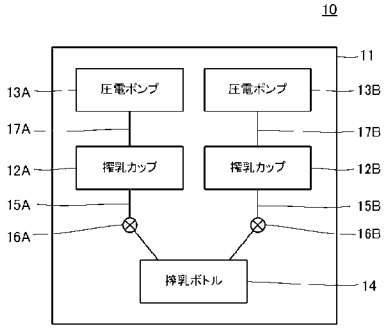
【００４５】

１０，４０，５０，６０，７０，８０，９０…搾乳着
１１，４１…被服
１２Ａ，１２Ｂ…搾乳カップ
１３Ａ，１３Ｂ，７３，８３…圧電ポンプ
１４，５４Ａ，５４Ｂ…搾乳ボトル
１５Ａ，１５Ｂ，１７Ａ，１７Ｂ，２５，７５，７７，８７…チューブ
１６Ａ，１６Ｂ，７６…逆止弁
２１，２８…布
２２…ポケット
２３…紐
２４Ａ，２４Ｂ…孔
２６…セパレータ
２９…開閉部
２７，３３…流路
３１…圧電素子
３２…構造体
３４…ポンプ室
３５…吐出口
３６…吸入口
３７…ダイヤフラム
８８…切替弁

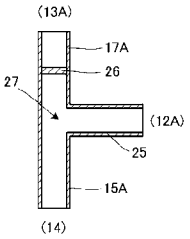
【図１】
図1



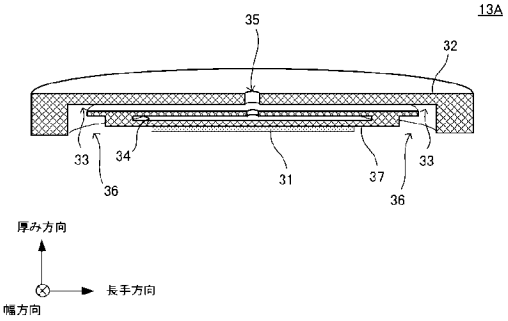
【図２】
図2



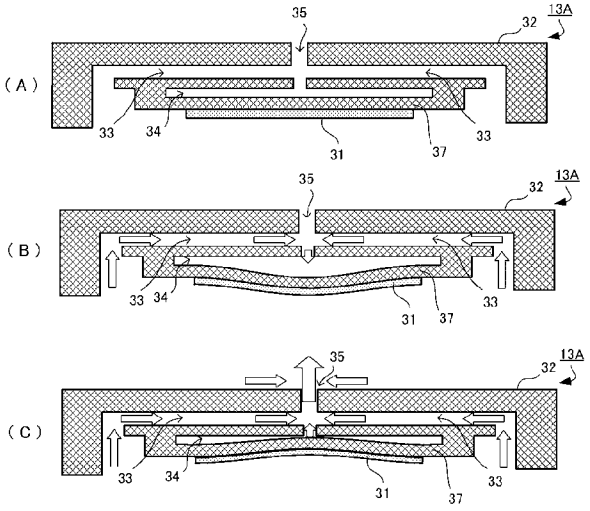
【図３】
図3



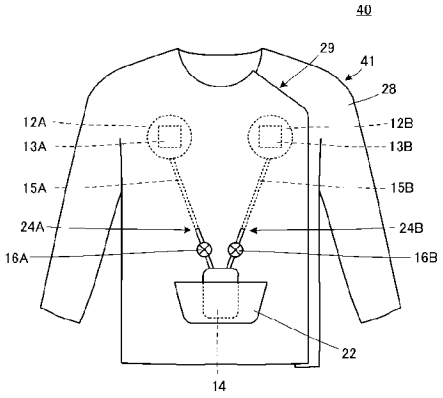
【図４】
図4



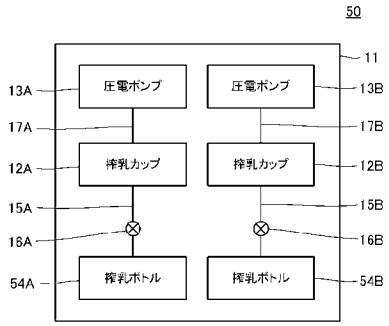
【図５】
図5



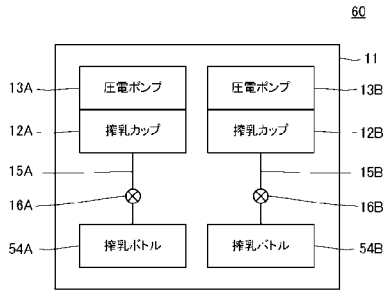
【図６】
図6



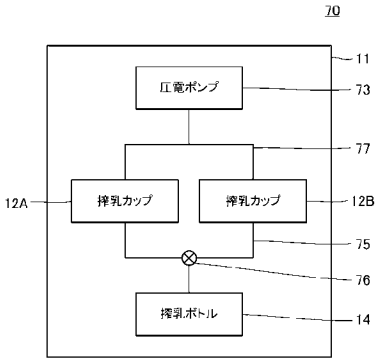
【図７】
図7



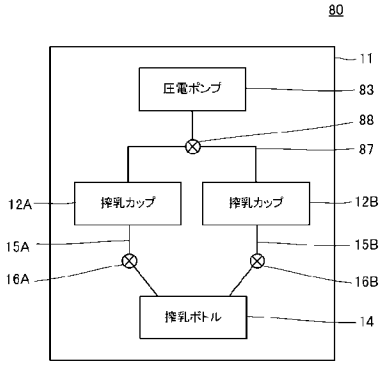
【図８】
図8



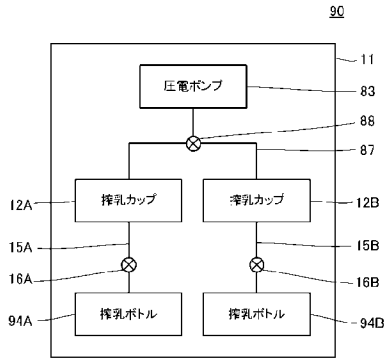
【図９】
図9



【図１０】
図10



【図１１】
図11



(12) 特許協力条約に基づいて公開された国際出願

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(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG, KZ, RU, TJ, TM), ヨーロッパ (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

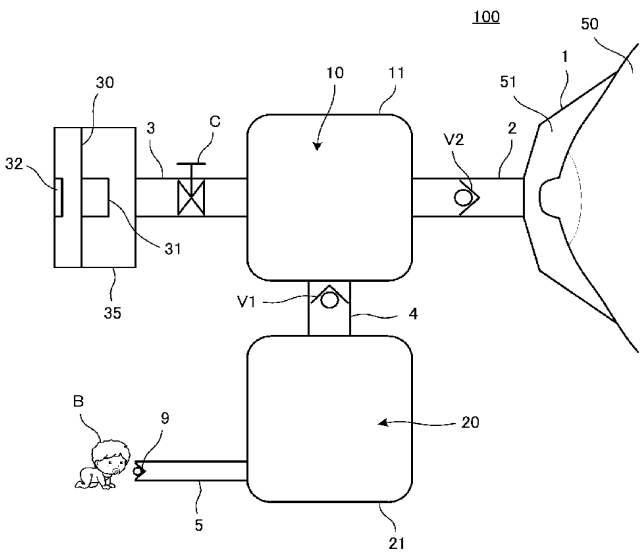
添付公開書類:

— 国際調査報告（条約第 21 条(3)）

(54) **Title**: MILKER

(54) 発明の名称 : 搾乳器

図1



(57) **Abstract**: This milker (100) is provided with: a cup section (1), tubes (2)-(5), a first vessel (11), a second vessel (21), a first duct (10), a second duct (20), a piezoelectric pump (30), a mounting section (35), a first check valve (V1), a second check valve (V2), and an on-off valve (C). The cup section (1) forms a closed space between a breast and the cup section (1). The first duct (10) interconnects with the closed space. The first duct (10) has the first vessel (11), which stores milk. The intake opening (31) of the piezoelectric pump (30) interconnects with the first duct (10). The piezoelectric pump (30) takes in the air within the closed space via the intake opening (31), generating negative pressure in the closed space. The second duct (20) interconnects with the space within the first vessel (11). An artificial nipple (9) is provided to the end of tube (5). The second duct (20) has the second vessel (21), which stores milk flowing in from the first vessel (11) via tube (4).

(57) 要約: 搾乳器（１００）は、カップ部（１）とチューブ（２）～（５）と第１容器（１１）と第２容器（２１）と第１流路（１０）と第２流路（２０）と圧電ポンプ（３０）と装着部（３５）と第１の逆止弁（Ｖ１）と第２の逆止弁（Ｖ２）と開閉弁（Ｃ）とを備える。カップ部（１）は、乳房とカップ部（１）との間に閉鎖空間を形成する。第１流路（１０）は閉鎖空間に連通する。第１流路（１０）は、母乳を貯蔵する第１容器（１１）を有する。圧電ポンプ（３０）の吸引口（３１）は第１流路（１０）に連通する。圧電ポンプ（３０）は、吸引口（３１）から閉鎖空間内の空気を吸引し、閉鎖空間に負圧を生じさせる。第２流路（２０）は、第１容器（１１）内の空間に連通する。チューブ（５）の端部には人工乳首（９）が設けられている。第２流路（２０）は、第１容器（１１）からチューブ（４）を介して流入した母乳を貯蔵する第２容器（２１）を有する。

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明　細　書

発明の名称 ： 搾乳器

技術分野

[0001] この発明は、母乳を搾る搾乳器に関する。

背景技術

[0002] 従来、母親等が母乳を搾るために使用する搾乳器が各種考案されている。

[0003] 例えば、特許文献１には、乳房に当接させるための漏斗部（カップ部）と、このカップ部に乳房を当接することで形成される閉鎖空間に負圧を生じさせるポンプ（負圧形成部）と、を備える搾乳器が開示されている。特許文献１の搾乳器において閉鎖空間とポンプは通気可能に接続されている。

[0004] 特許文献１の搾乳器において、閉鎖空間に吸引された母乳は、流路を介して哺乳瓶に貯蔵される。

先行技術文献

特許文献

[0005] 特許文献1：特表２０１３－５３３４２８号公報

発明の概要

発明が解決しようとする課題

[0006] しかしながら、特許文献１の搾乳器は、乳児に授乳する時、搾乳後に搾乳器から哺乳瓶を外し、人工乳首を哺乳瓶に装着させてからでなければ、授乳できない。

[0007] したがって、特許文献１の搾乳器を含む従来の搾乳器は、搾乳および授乳を同時に行うことができなかった。

[0008] 本発明の目的は、搾乳および授乳を同時に行うことができる搾乳器を提供することにある。

課題を解決するための手段

[0009] 本発明の搾乳器は、乳房に接触させるためのカップ部と、

カップ部を乳房に接触することで形成される閉鎖空間に連通する第１流路

であって、乳房から出た母乳を貯蔵する第１貯蔵部を途中に有する第１流路と、

第１流路に連通する吸引口を有し、吸引口から閉鎖空間内の空気を吸引し、閉鎖空間に負圧を生じさせる負圧生成部と、

第１貯蔵部に連通し、第１貯蔵部とは逆側の端部に人工乳首を有する第２流路と、

第２流路の途中に設けられ、第２流路から第１貯蔵部へ流体が流れることを防ぐ第１の逆止弁と、を備える。

[0010] この構成において、搾乳および授乳を開始する時、母親は、カップ部を乳房に装着し、負圧生成部を駆動する。そして、母親は人工乳首を赤ちゃんに咥えさせる。負圧生成部は例えばポンプである。

[0011] これにより、閉鎖空間内の空気が第１流路へ吸引されて閉鎖空間内が負圧となり、乳房から出た母乳が第１流路へ吸引されて第１貯蔵部に貯蔵されていく。このとき、赤ちゃんが人工乳首を吸うと、第１貯蔵部に貯蔵された母乳が第２流路から人工乳首を介して赤ちゃんの口内に流入する。これにより、赤ちゃんは母乳を飲むことができる。そして、第１の逆止弁は、第２流路から第１貯蔵部へ流体が流れることを防ぐことができる。

[0012] したがって、本発明によれば、搾乳および授乳を同時に行うことができる。

[0013] また、第２流路は途中に、第１貯蔵部から第１の逆止弁を介して流入した母乳を貯蔵する第２貯蔵部を有する、ことが好ましい。

[0014] この構成では、第２貯蔵部は緩衝領域として機能する。詳述すると、赤ちゃんが人工乳首を吸うと、第１貯蔵部から第１の逆止弁を介して流入した母乳が一旦第２貯蔵部に貯蔵される。その後、第２貯蔵部に貯蔵された母乳が第２流路から人工乳首を介して赤ちゃんの口内に流入する。

[0015] また、第２流路における第１貯蔵部と第２貯蔵部との間は、巻回されたチューブで形成される、ことが好ましい。

[0016] この構成では、赤ちゃんが顔を振りまわしても、チューブが伸びるため、

チューブが閉塞したり引っ張られたりすることが無くなる。よって、この構成によれば、常時授乳が可能になる。

[0017] また、第２流路における人工乳首と第２貯蔵部との間は、巻回されたチューブで形成される、ことが好ましい。

[0018] この構成では、赤ちゃんが顔を振りまわしても、チューブが伸びるため、チューブが閉塞したり引っ張られたりすることが無くなる。よって、この構成によれば、常時授乳が可能になる。

[0019] また、第１流路におけるカップ部と第１貯蔵部との間に設けられ、第１貯蔵部からカップ部へ流体が流れることを防ぐ第２の逆止弁を備える、ことが好ましい。

[0020] この構成では、第２の逆止弁は、第１貯蔵部からカップ部へ母乳が流れることを防ぐことができる。

[0021] また、第１流路における第１貯蔵部と負圧生成部との間に設けられ、この間の流路を開閉する開閉弁を備える、ことが好ましい。

[0022] この構成では、授乳中において赤ちゃんの吸う力が弱いとき、母親が開閉弁を閉じる。そして、母親は、例えば第１貯蔵部を圧縮し、第１貯蔵部に貯蔵されている母乳を第１の逆止弁を介して第２流路へ流出させる。

[0023] また、第２流路は、第２貯蔵部から分岐して伸びる複数の端部を有し、各端部には、人工乳首が設けられている、ことが好ましい。

[0024] この構成では、複数の赤ちゃんのそれぞれに人工乳首を咥えさせることで、複数の赤ちゃんに対して同時に授乳することができる。

[0025] また、負圧生成部は、圧電素子を有し、圧電素子により駆動する、ことが好ましい。

[0026] この構成では、駆動時に発生する音や振動が小さい圧電素子を駆動源とすることで、搾乳器の静音化を図ることができる。

発明の効果

[0027] 本発明によれば、搾乳および授乳を同時に行うことができる。

図面の簡単な説明

[0028] [図1]本発明の第１実施形態に係る搾乳器１００の構成を説明する概略図である。

[図2]図１に示す搾乳器１００が搾乳だけを行っている時における母乳の流れを示す説明図である。

[図3]図１に示す搾乳器１００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。

[図4]図１に示す搾乳器１００が授乳だけを行っている時における母乳の流れを示す説明図である。

[図5]本発明の第２実施形態に係る搾乳器２００の構成を説明する概略図である。

[図6]図５に示すチューブ２０５の外観斜視図である。

[図7]本発明の第３実施形態に係る搾乳器３００の構成を説明する概略図である。

[図8]図７に示す搾乳器３００が搾乳だけを行っている時における母乳の流れを示す説明図である。

[図9]図７に示す搾乳器３００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。

[図10]本発明の第４実施形態に係る搾乳器４００の構成を説明する概略図である。

[図11]図１０に示す搾乳器４００が搾乳だけを行っている時における母乳の流れを示す説明図である。

[図12]図１０に示す搾乳器４００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。

[図13]図１０に示す搾乳器４００が授乳だけを行っている時における母乳の流れを示す説明図である。

発明を実施するための形態

[0029] 以下、本発明の第１実施形態に係る搾乳器１００について説明する。

[0030] 図１は、本発明の第１実施形態に係る搾乳器１００の構成を説明する概略

図である。搾乳器１００は、カップ部１と、チューブ２～５と、第１容器１１と、第２容器２１と、第１流路１０と、第２流路２０と、圧電ポンプ３０と、装着部３５と、第１の逆止弁Ｖ１と、第２の逆止弁Ｖ２と、開閉弁Ｃと、を備える。

[0031] なお、圧電ポンプ３０は、本発明の負圧生成部に相当する。第１容器１１は、本発明の第１貯蔵部に相当する。第２容器２１は、本発明の第２貯蔵部に相当する。

[0032] カップ部１は、乳房５０に接触させるためのものである。カップ部１は、乳房５０に接触することで、乳房５０とカップ部１との間に閉鎖空間５１を形成する。

[0033] 第１流路１０は、チューブ２内の空間と、第１容器１１内の空間と、チューブ３内の空間と、圧電ポンプ３０及び装着部３５に挟まれた空間とによって形成されている。第１流路１０は、閉鎖空間５１に連通する。第１流路１０は途中に、第１容器１１を有する。第１容器１１は、チューブ２から流入した母乳と空気をフィルタ等によって分離し、母乳を貯蔵する。

[0034] 圧電ポンプ３０は、圧電素子を有し、圧電素子により駆動する。装着部３５は圧電ポンプ３０に装着している。圧電ポンプ３０は略円柱状であり、装着部３５はコップ状である。圧電ポンプ３０は、空気の吸引口３１と空気の吐出口３２とを有する。圧電ポンプ３０の吸引口３１は、第１流路１０に連通する。圧電ポンプ３０は、吸引口３１から閉鎖空間５１内の空気を吸引し、閉鎖空間５１に負圧を生じさせる。これにより、乳房５０から母乳が出る。

[0035] 第２流路２０は、チューブ４内の空間と、第２容器２１内の空間と、チューブ５内の空間とによって形成されている。第２流路２０は、第１容器１１内の空間に連通する。第２流路２０は、第１容器１１とは逆側の端部（チューブ５の端部）を有する。第１容器１１とは逆側の端部（チューブ５の端部）には、人工乳首９が設けられている。

[0036] 第１の逆止弁Ｖ１は、第２流路２０の途中であるチューブ４内に設けられ

る。第１の逆止弁Ｖ１は、第２流路２０から第１容器１１へ流体が流れることを防ぐ。

[0037] 第２流路２０は途中に、第１容器１１からチューブ４を介して流入した母乳を貯蔵する第２容器２１を有する。

[0038] なお、チューブ２～５、装着部３５、第１容器１１、及び第２容器２１の材料は例えば、ポリプロピレンやポリエチレンなどである。

[0039] 第２の逆止弁Ｖ２は、第１流路１０におけるカップ部１と第１容器１１との間であるチューブ２内に設けられている。第２の逆止弁Ｖ２は、第１容器１１からカップ部１へ流体が流れることを防ぐ。

[0040] 開閉弁Ｃは、第１流路１０における第１容器１１と圧電ポンプ３０との間であるチューブ３内に設けられ、チューブ３内の流路を開閉する。

[0041] 以下、搾乳器１００が搾乳および授乳を同時に行う場面について説明する。

[0042] 図２は、図１に示す搾乳器１００が搾乳だけを行っている時における母乳の流れを示す説明図である。図３は、図１に示す搾乳器１００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。図４は、図１に示す搾乳器１００が授乳だけを行っている時における母乳の流れを示す説明図である。

[0043] なお、図中における矢印は、母乳および空気を含む流体の流れを示す。また、第１の逆止弁Ｖ１及び第２の逆止弁Ｖ２は、〇とＶで示している。〇とＶが離間している場合、弁が開いていることを示す。反対に、〇とＶが接触している場合、弁が閉じていることを示す。

[0044] 搾乳及び授乳を開始する時、母親は、開閉弁Ｃを開いた状態にし、カップ部１を乳房５０に装着し、圧電ポンプ３０を駆動（オン）する。これにより、図２に示すように、閉鎖空間５１内の空気が第１流路１０へ吸引されて閉鎖空間５１内が負圧となり、母乳が第１流路１０へ吸引されて第１容器１１に貯蔵されていく。そして、母親は人工乳首９を赤ちゃんＢに咥えさせる。

[0045] このとき、赤ちゃんＢが人工乳首９を吸うと、図３に示すように、第１の

逆止弁Ｖ１が開き、第１容器１１に貯蔵された母乳が、チューブ４を介して一旦第２容器２１へ流入し、第２容器２１に貯蔵される。その後、第２容器２１に貯蔵された母乳が第２流路２０から人工乳首９を介して赤ちゃんＢの口内に流入する。これにより、赤ちゃんＢは母乳を飲むことができる。第２容器２１は緩衝領域として機能する。

[0046] そして、第１の逆止弁Ｖ１は、第２流路２０から第１容器１１へ流体が流れることを防ぐ。第２の逆止弁Ｖ２は、第１容器１１からカップ部１へ母乳が流れることを防ぐ。

なお、第１の逆止弁Ｖ１が無いと、人工乳首９から空気が第１容器１１および第２容器２１へ流入する為、第１の逆止弁Ｖ１がある時と比較して、第１容器１１は負圧になりにくい。よって搾乳できないこともある。

[0047] したがって、搾乳器１００によれば、搾乳および授乳を同時に行うことができる。

[0048] また、圧電ポンプ３０は、駆動時に発生する音や振動が小さい圧電素子を駆動源としているため、搾乳器１００の静音化を図ることができる。

[0049] なお、赤ちゃんＢの個人差等により、授乳中において赤ちゃんＢの吸う力が弱いことがある。授乳中において赤ちゃんＢの吸う力が弱いとき、母親は開閉弁Ｃを閉じる。このとき、開閉弁Ｃを閉じるとともに圧電ポンプ３０を停止（オフ）してもよいし、圧電ポンプ３０を駆動したままにしておいてもよい。

[0050] そして、母親は、図４に示すように、第１容器１１を圧縮し、第１容器１１に貯蔵されている母乳を第１の逆止弁Ｖ１を介して第２容器２１へ流出させる。このとき、第２の逆止弁Ｖ２は、第１容器１１からカップ部１へ母乳が流れることを防ぐ。

[0051] その後、赤ちゃんＢが人工乳首９を吸うことで、第２容器２１に貯蔵された母乳が第２流路２０から人工乳首９を介して赤ちゃんＢの口内に流入する。これにより、赤ちゃんＢは母乳を飲むことができる。

[0052] 以下、本発明の第２実施形態に係る搾乳器２００について説明する。

[0053] 図５は、本発明の第２実施形態に係る搾乳器２００の構成を説明する概略図である。図６は、図５に示すチューブ２０５の外観斜視図である。

[0054] 第２実施形態に係る搾乳器２００が前述の搾乳器１００と相違する点は、チューブ２０４及びチューブ２０５である。その他の構成は同じであるため、説明を省略する。

[0055] 搾乳器２００において、第２流路２０における人工乳首９と第２容器２１との間は、図６に示すような巻回されたチューブ２０５で形成されている。第２流路２０における第１容器１１と第２容器２１との間も、図６に示すチューブ２０５と同様に、巻回されたチューブ２０４で形成されている。

[0056] この実施形態の搾乳器２００によれば、搾乳器１００と同様、搾乳および授乳を同時に行うことができる。

[0057] また、搾乳器２００では、赤ちゃんＢが顔を振りまわしても、チューブ２０４、２０５が伸びるため、チューブ２０４、２０５が閉塞したり引っ張られたりすることが無くなる。よって、搾乳器２００によれば、常時授乳が可能になる。

[0058] 以下、本発明の第３実施形態に係る搾乳器３００について説明する。

[0059] 図７は、本発明の第３実施形態に係る搾乳器３００の構成を説明する概略図である。図８は、図７に示す搾乳器３００が搾乳だけを行っている時における母乳の流れを示す説明図である。図９は、図７に示す搾乳器３００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。

[0060] なお、図中における矢印は、母乳および空気を含む流体の流れを示す。また、第１の逆止弁Ｖ１及び第２の逆止弁Ｖ２は、〇とＶで示している。〇とＶが離間している場合、弁が開いていることを示す。反対に、〇とＶが接触している場合、弁が閉じていることを示す。

[0061] 第３実施形態に係る搾乳器３００が前述の搾乳器１００と相違する点は、第２流路３２０である。その他の構成は同じであるため、説明を省略する。

[0062] 第２流路３２０は、第２容器２１から分岐して伸びる複数の端部３５１、

３５２、３５３を有する。各端部３５１、３５２、３５３には、人工乳首３９１、３９２、３９３が設けられている。

[0063] この実施形態の搾乳器３００によれば、図８、図９に示すように、搾乳器１００と同様、搾乳および授乳を同時に行うことができる。

[0064] また、搾乳器３００は、図９に示すように、複数の赤ちゃんＢ１、Ｂ２、Ｂ３のそれぞれに人工乳首３９１、３９２、３９３を咥えさせることで、複数の赤ちゃんＢ１、Ｂ２、Ｂ３に対して同時に授乳することができる。

[0065] 以下、本発明の第４実施形態に係る搾乳器４００について説明する。

[0066] 図１０は、本発明の第４実施形態に係る搾乳器４００の構成を説明する概略図である。図１１は、図１０に示す搾乳器４００が搾乳だけを行っている時における母乳の流れを示す説明図である。図１２は、図１０に示す搾乳器４００が搾乳および授乳を同時に行っている時における母乳の流れを示す説明図である。図１３は、図１０に示す搾乳器４００が授乳だけを行っている時における母乳の流れを示す説明図である。

[0067] なお、図中における矢印は、母乳および空気を含む流体の流れを示す。また、第１の逆止弁Ｖ１及び第２の逆止弁Ｖ２は、〇とＶで示している。〇とＶが離間している場合、弁が開いていることを示す。反対に、〇とＶが接触している場合、弁が閉じていることを示す。

[0068] 第４実施形態に係る搾乳器４００が前述の搾乳器１００と相違する点は主に、シリンジ４１２を有する容器４１１である。シリンジ４１２は、容器４１１内の体積を増減させる。シリンジ４１２及び容器４１１で構成される空間は、第１流路４１０の一部を構成する。また、搾乳器４００は搾乳器２００と同様に、チューブ２０５で形成されている。その他の構成は同じであるため、説明を省略する。

[0069] この実施形態の搾乳器４００によれば、図１１、図１２に示すように、搾乳器１００と同様、搾乳および授乳を同時に行うことができる。

[0070] また、授乳中において赤ちゃんＢの吸う力が弱いとき、母親は、圧電ポンプ３０を停止して開閉弁Ｃを閉じる。そして、母親は、図１３に示すように

、シリンジ４１２を可動させて第１容器４１１内を圧縮し、第１容器４１１に貯蔵されている母乳を第１の逆止弁Ｖ１を介して第２容器２１へ流出させる。このとき、第２の逆止弁Ｖ２は、第１容器４１１からカップ部１へ母乳が流れることを防ぐ。

[0071] その後、赤ちゃんＢが人工乳首９を吸うことで、第２容器２１に貯蔵された母乳がチューブ２０５から人工乳首９を介して赤ちゃんＢの口内に流入する。これにより、赤ちゃんＢは母乳を飲むことができる。

[0072] 《その他の実施形態》

なお、前述の実施形態における圧電ポンプ３０は、圧電素子の伸縮によって屈曲振動するアクチュエータを備えるが、これに限るものではない。例えば、電磁駆動で屈曲振動するアクチュエータを備えてもよい。

[0073] 最後に、上述の実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、上述の実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0074] Ｃ…開閉弁

Ｖ１…第１の逆止弁

Ｖ２…第２の逆止弁

１…カップ部

２…チューブ

３…チューブ

４…チューブ

５…チューブ

９…人工乳首

１０…第１流路

１１…第１容器

２０…第２流路

２１…第２容器

３０…圧電ポンプ

３１…吸引口

３２…吐出口

３５…装着部

５０…乳房

５１…閉鎖空間

１００…搾乳器

２００…搾乳器

２０４…チューブ

２０５…チューブ

３００…搾乳器

３２０…第２流路

３５１…端部

３９１…人工乳首

４００…搾乳器

４１０…第１流路

４１１…第１容器

４１２…シリンジ

請求の範囲

[請求項1] 乳房に接触させるためのカップ部と、

前記カップ部を前記乳房に接触することで形成される閉鎖空間に連通する第１流路であって、前記乳房から出た母乳を貯蔵する第１貯蔵部を途中に有する第１流路と、

前記第１流路に連通する吸引口を有し、前記吸引口から前記閉鎖空間内の空気を吸引し、前記閉鎖空間に負圧を生じさせる負圧生成部と、

前記第１貯蔵部に連通し、前記第１貯蔵部とは逆側の端部に人工乳首を有する第２流路と、

前記第２流路の途中に設けられ、前記第２流路から前記第１貯蔵部へ流体が流れることを防ぐ第１の逆止弁と、を備える、ことを特徴とする搾乳器。

[請求項2] 前記第２流路は途中に、前記第１貯蔵部から前記第１の逆止弁を介して流入した前記母乳を貯蔵する第２貯蔵部を有する、ことを特徴とする請求項１に記載の搾乳器。

[請求項3] 前記第２流路における前記第１貯蔵部と前記第２貯蔵部との間は、巻回されたチューブで形成される、ことを特徴とする請求項２に記載の搾乳器。

[請求項4] 前記第２流路における前記人工乳首と前記第２貯蔵部との間は、巻回されたチューブで形成される、ことを特徴とする請求項２又は請求項３に記載の搾乳器。

[請求項5] 前記第１流路における前記カップ部と前記第１貯蔵部との間に設けられ、前記第１貯蔵部から前記カップ部へ前記流体が流れることを防ぐ第２の逆止弁を備える、ことを特徴とする請求項１から請求項４のいずれか１項に記載の搾乳器。

[請求項6] 前記第１流路における前記第１貯蔵部と前記負圧生成部との間に設けられ、この間の流路を開閉する開閉弁を備える、ことを特徴とする

請求項１から請求項５のいずれか１項に記載の搾乳器。

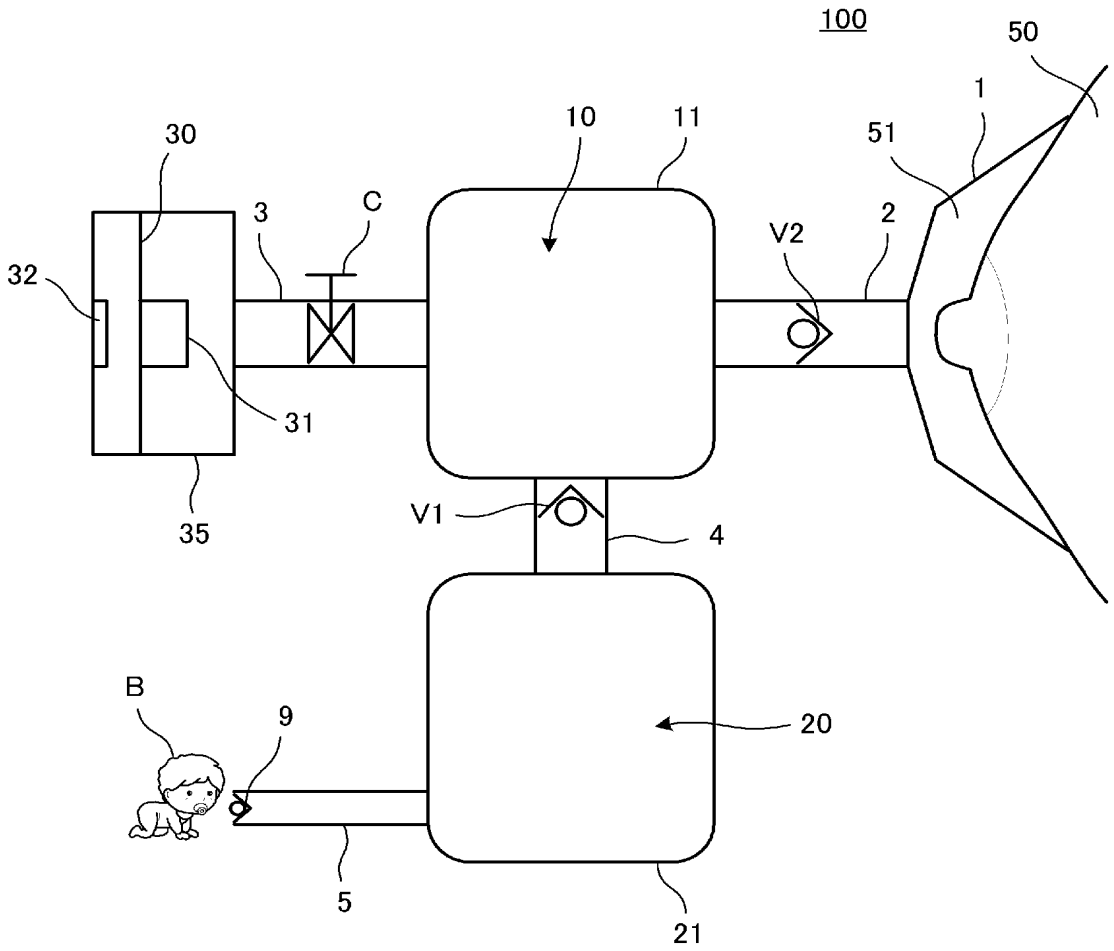
[請求項7] 前記第２流路は、前記第２貯蔵部から分岐して伸びる複数の端部を有し、

各端部には、人工乳首が設けられている、ことを特徴とする請求項１から請求項６のいずれか１項に記載の搾乳器。

[請求項8] 前記負圧生成部は、圧電素子を有し、前記圧電素子により駆動する、ことを特徴とする請求項１から請求項７のいずれか１項に記載の搾乳器。

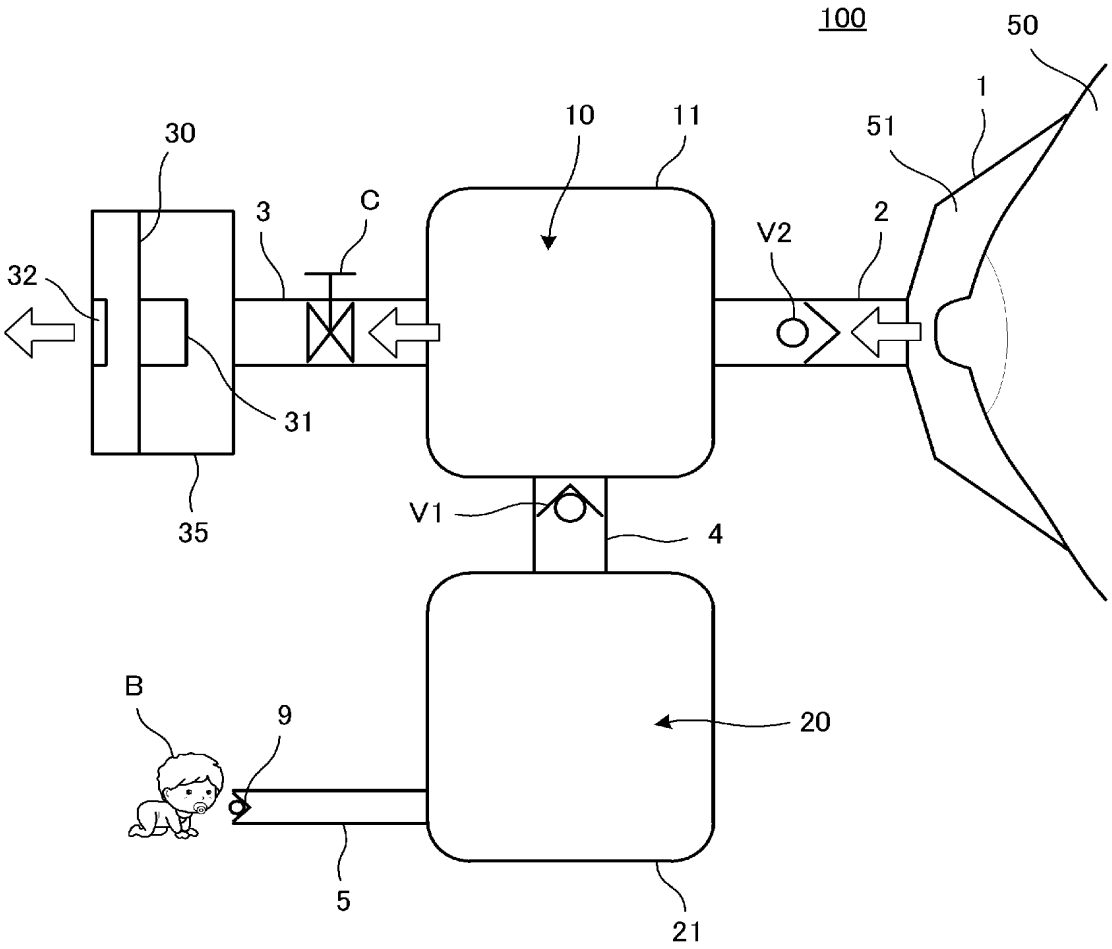
[図1]

図1



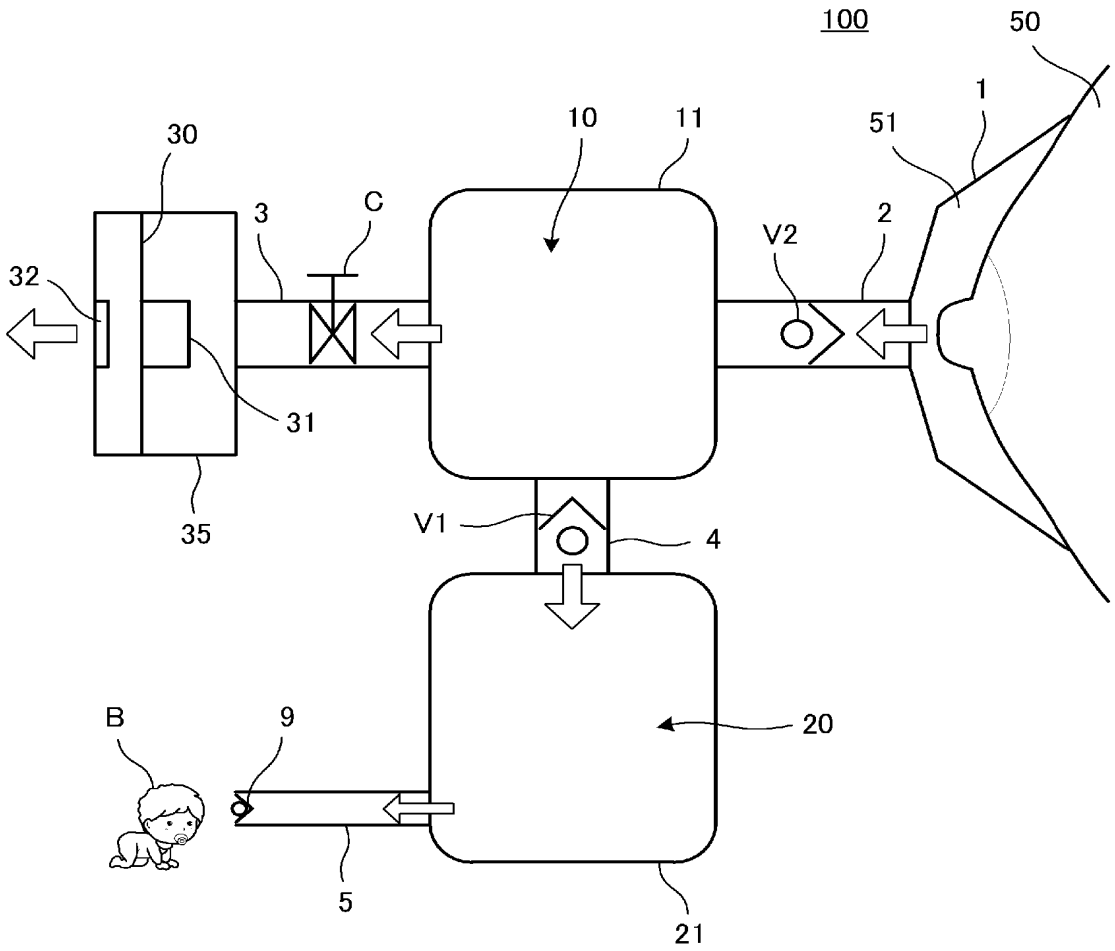
[図2]

図2



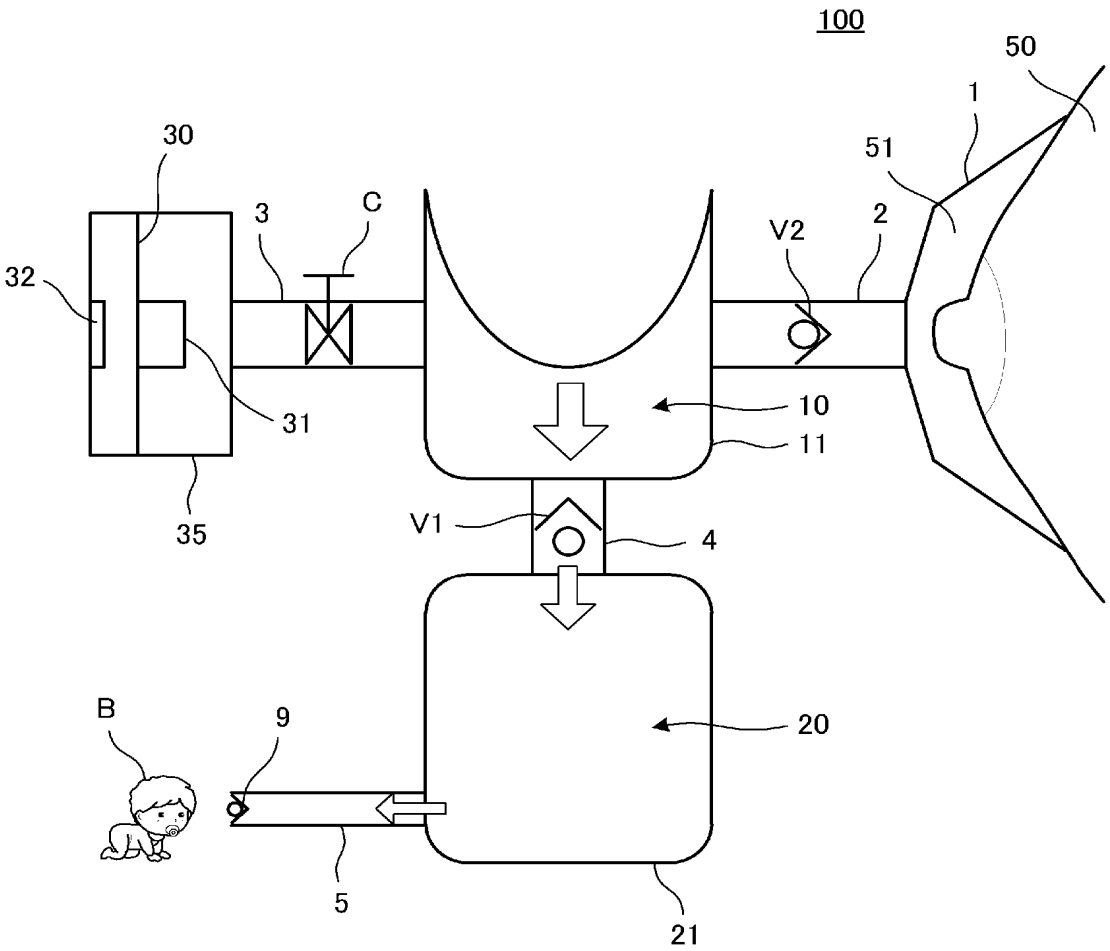
[図3]

図3



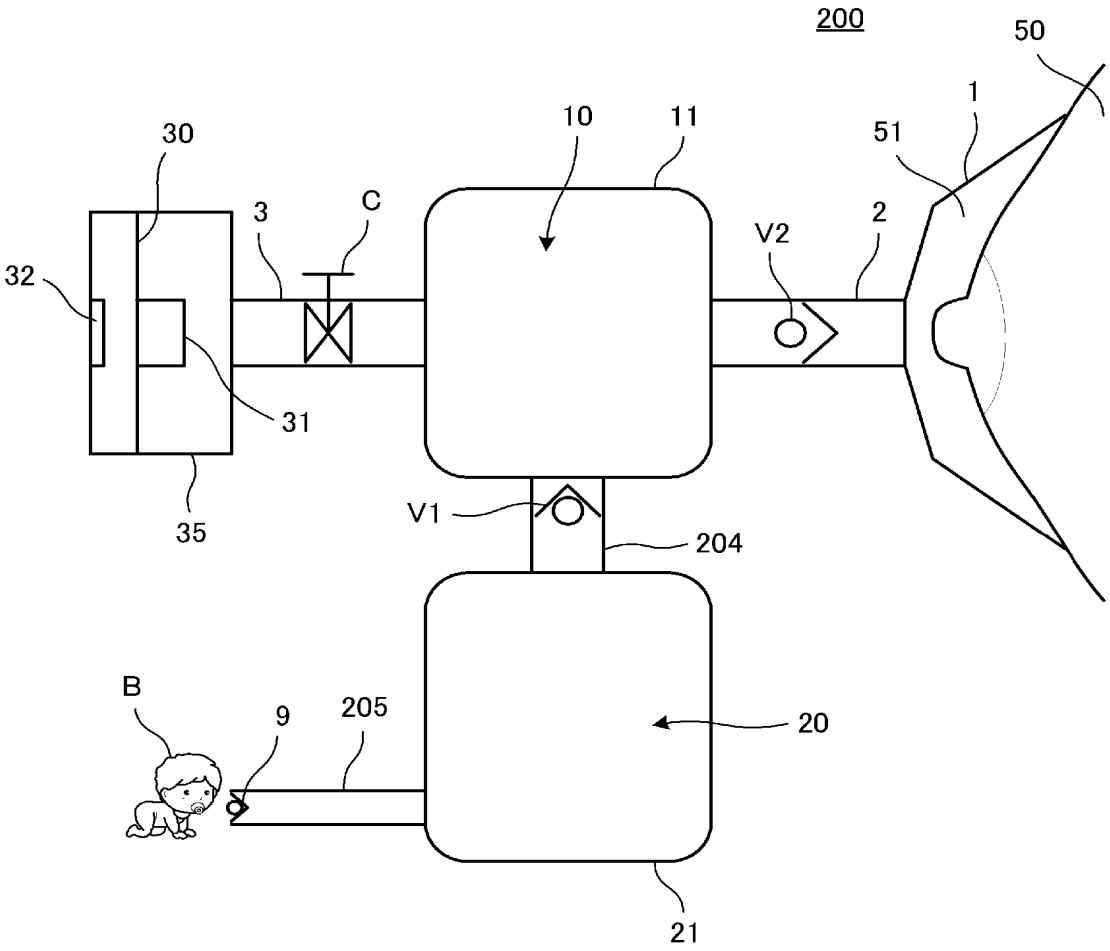
[図4]

図4



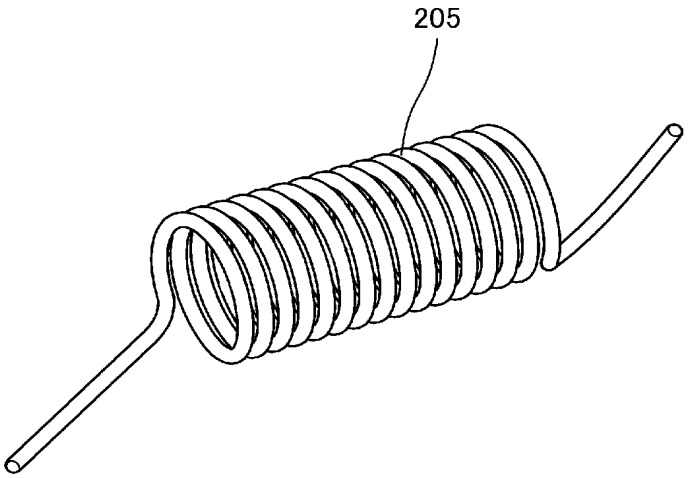
[図5]

図5



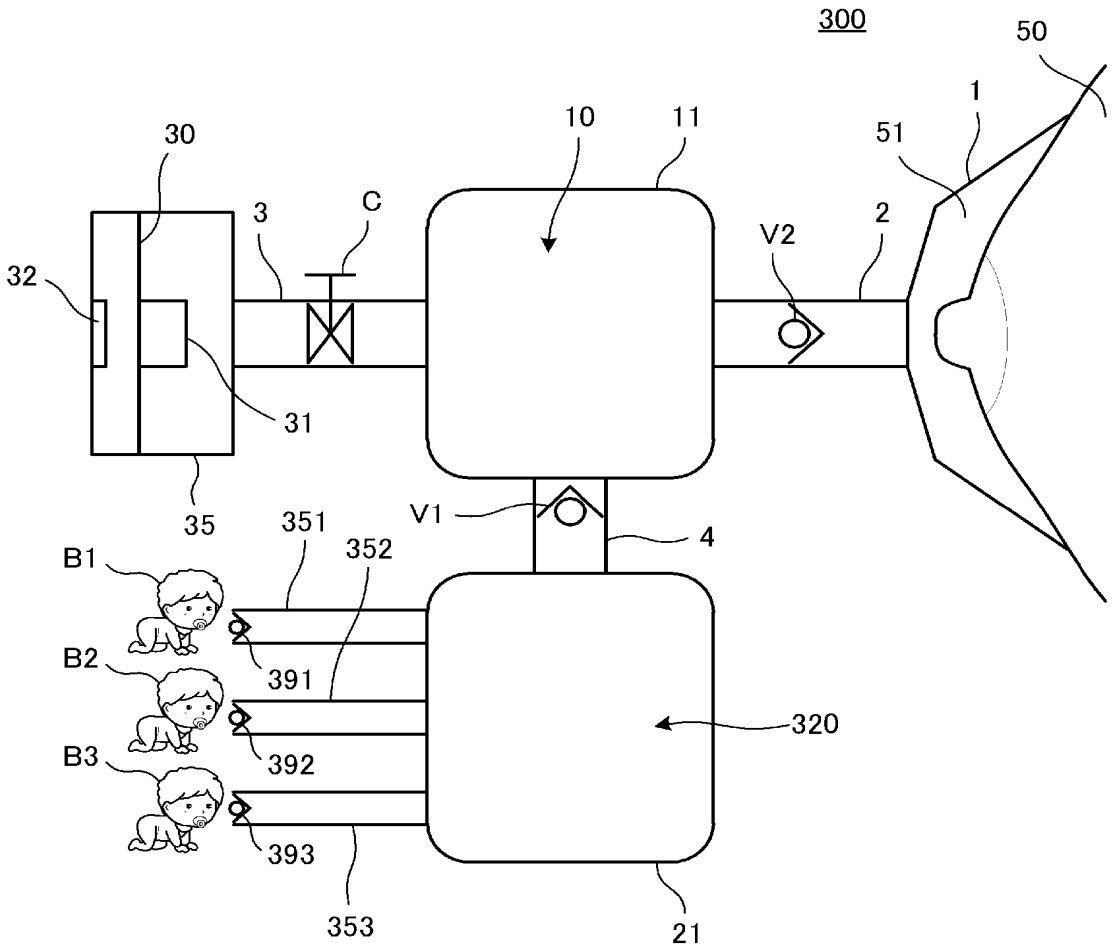
[図6]

図6



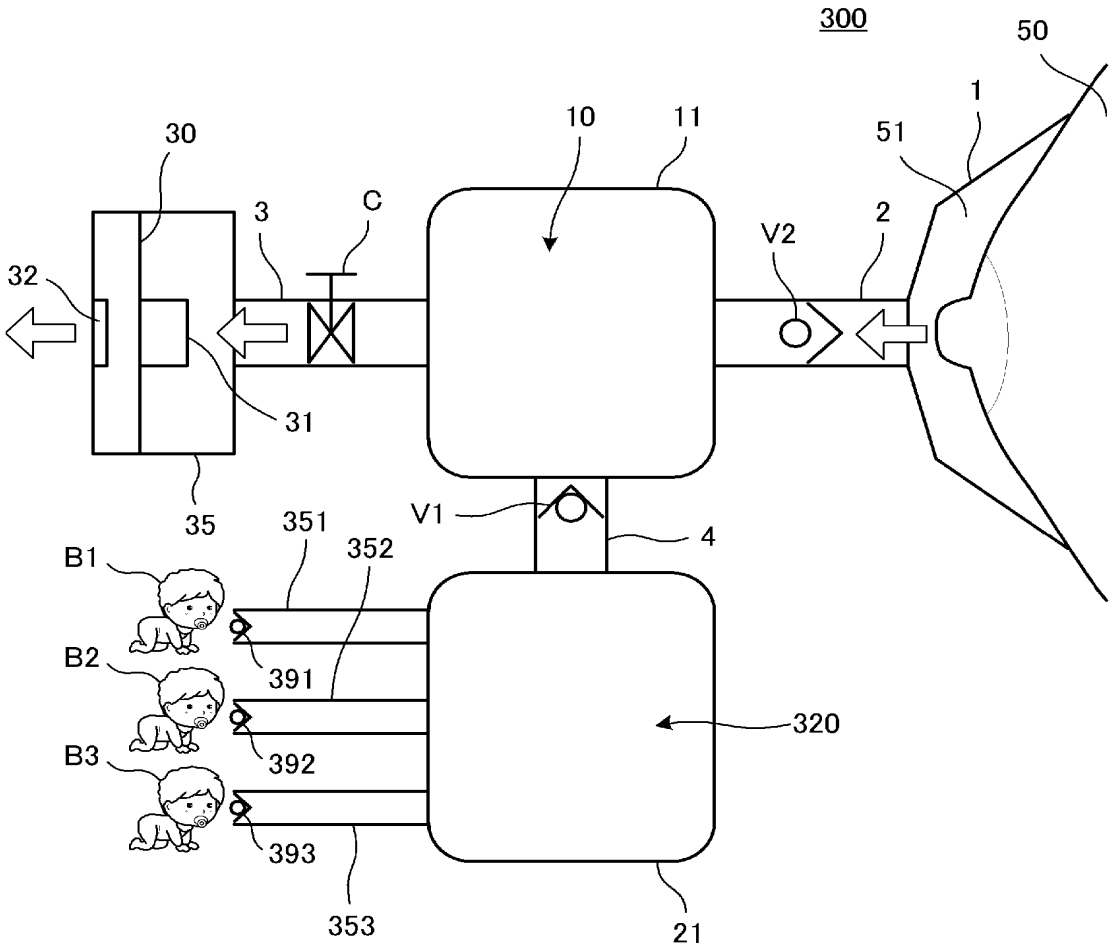
[図7]

図7

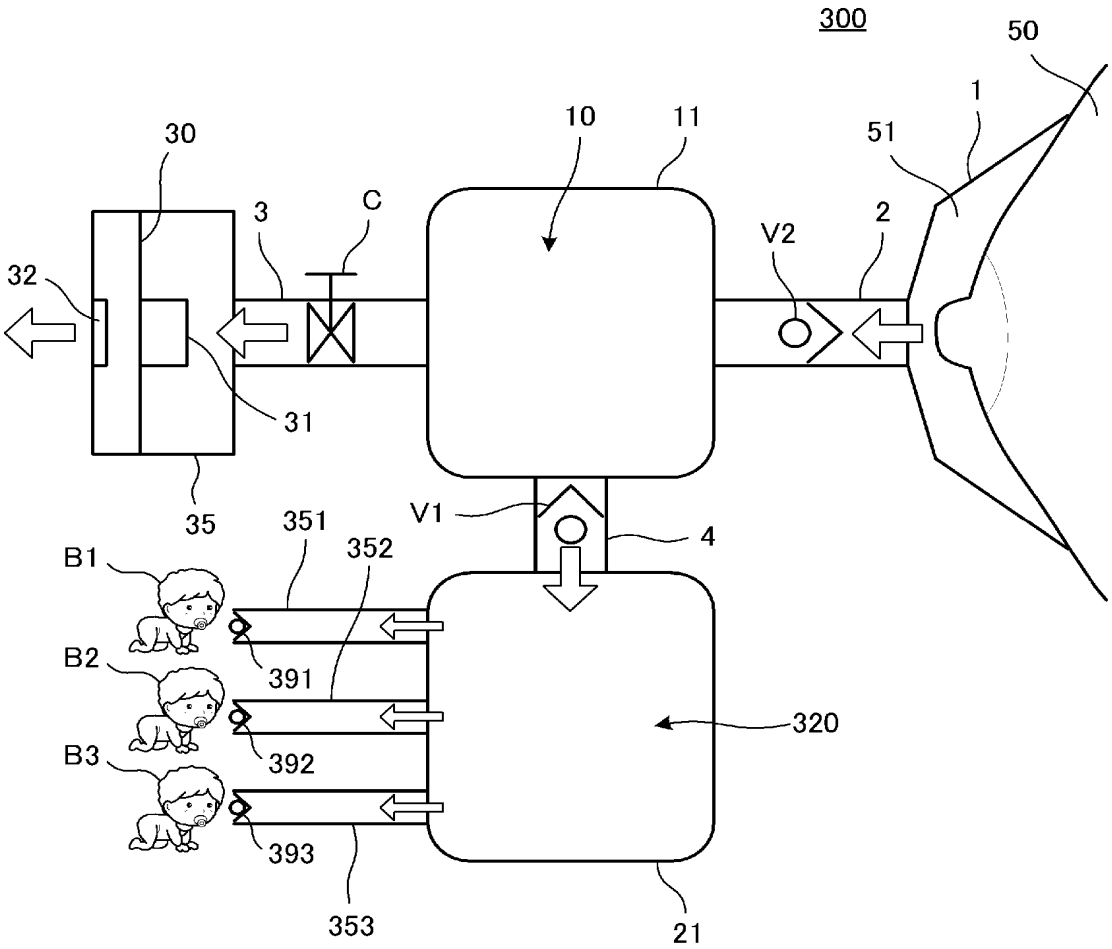

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[図8]

図8

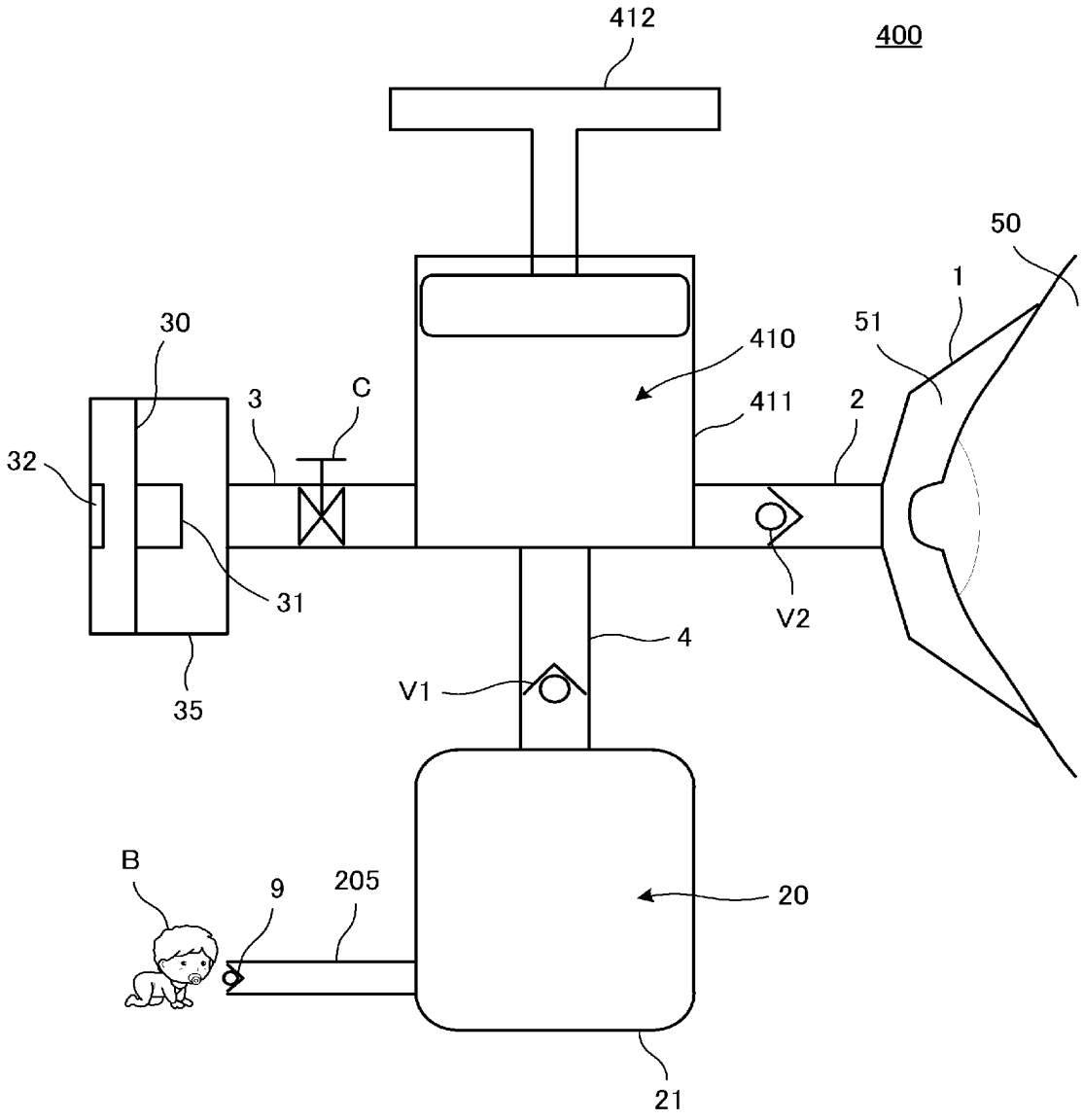

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[図9]
図9

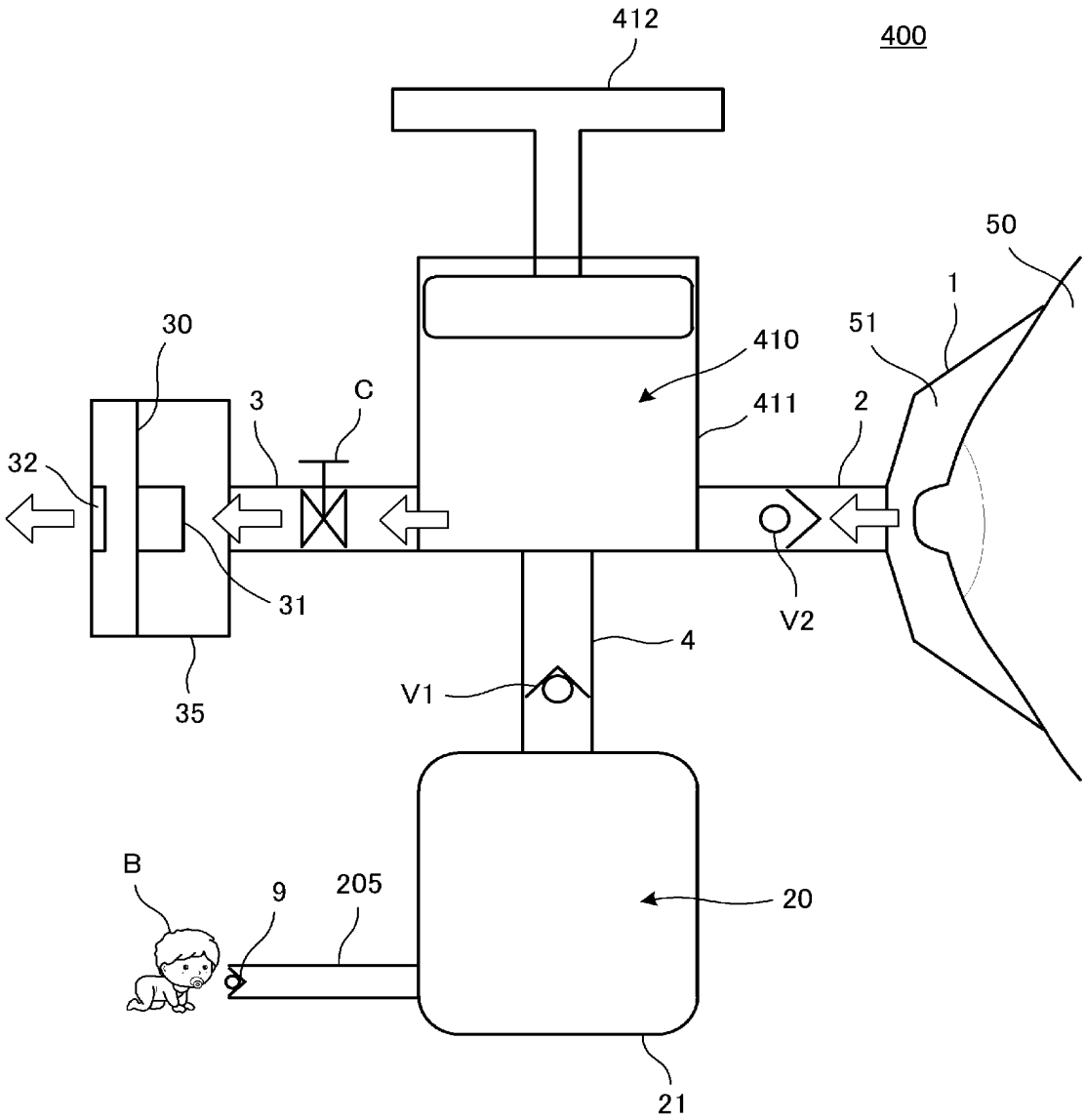

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[図10]

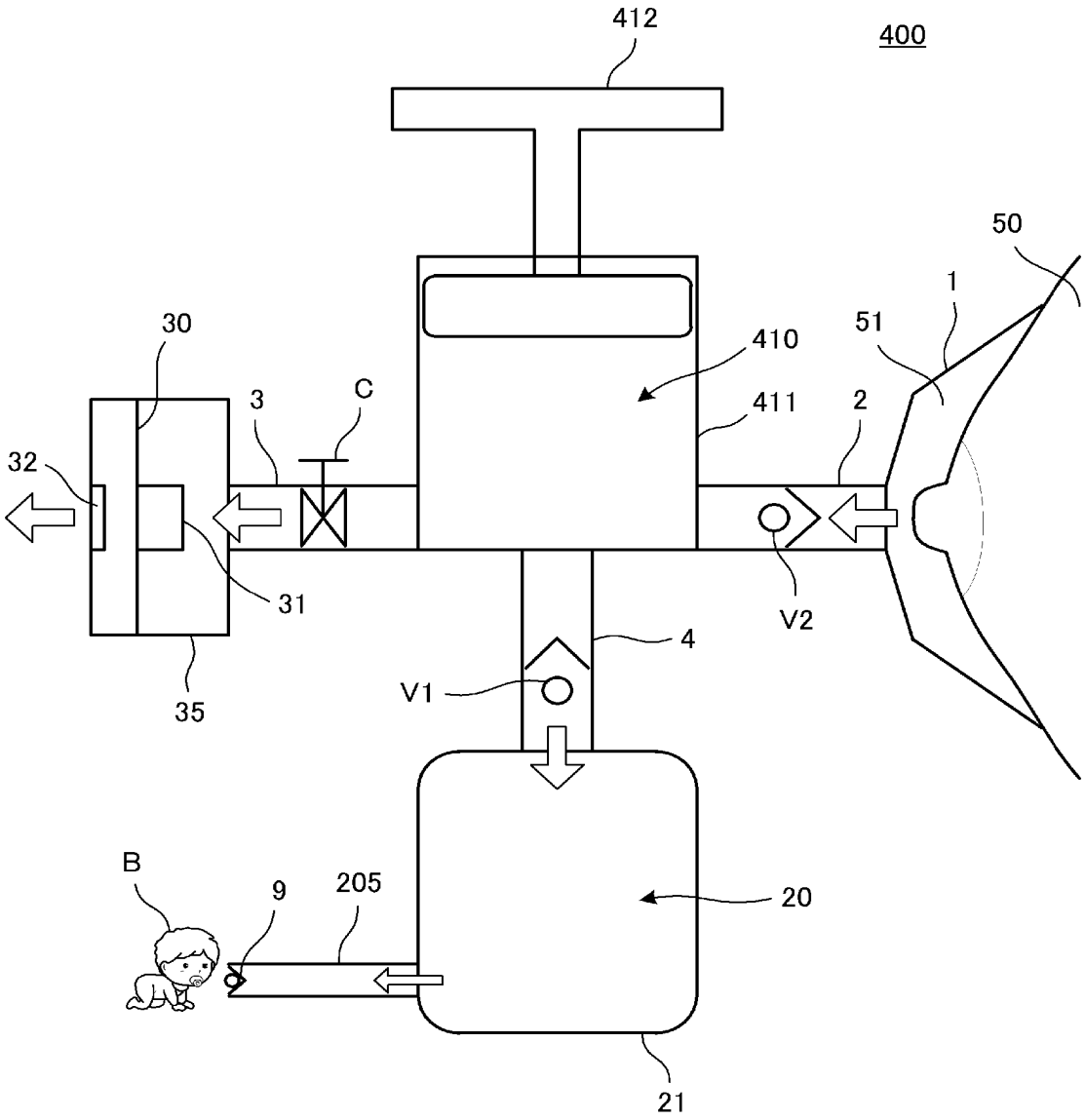
図10



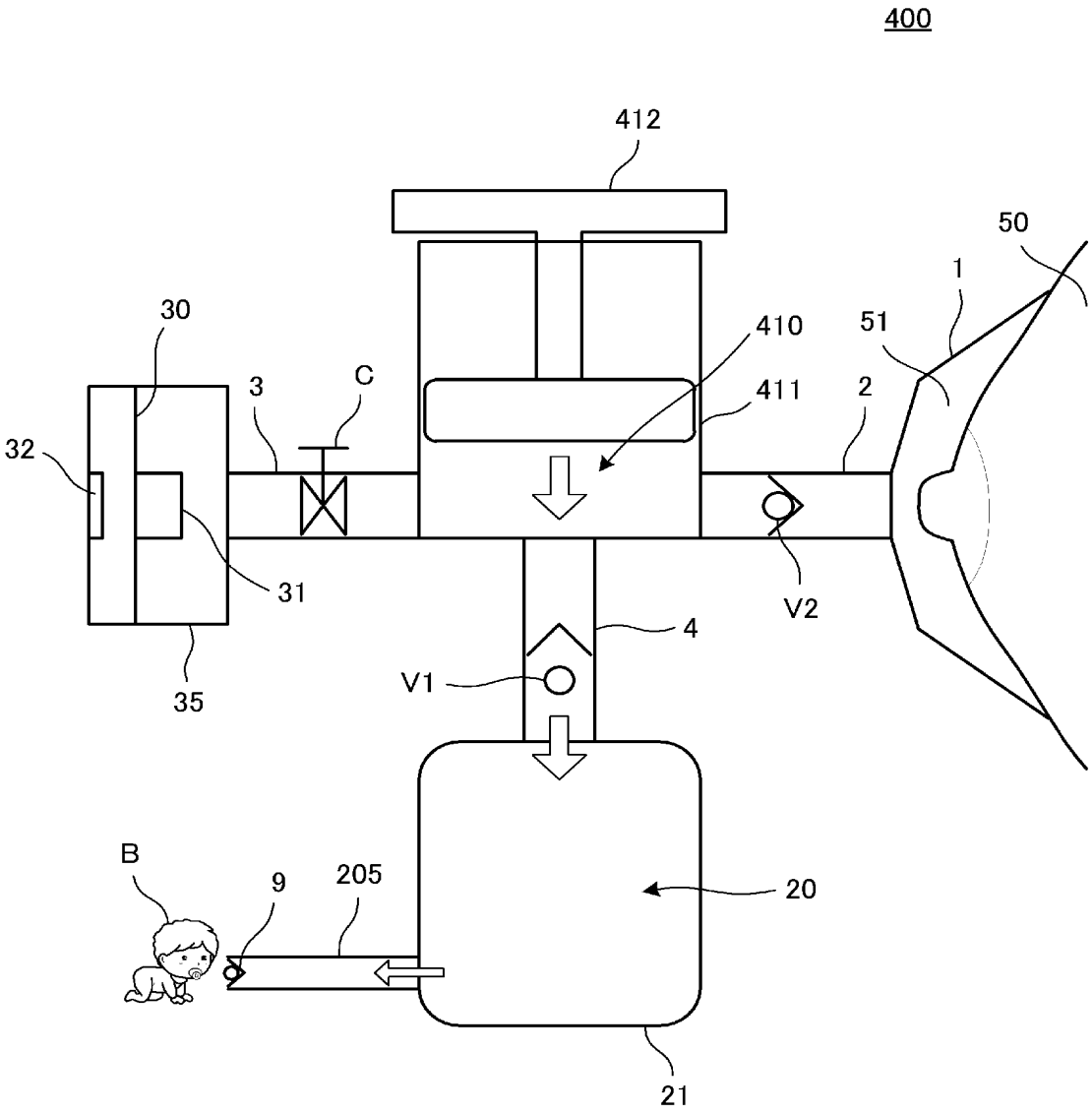
[図11]
図11



[図12]
図12



[図13]
図13



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/072598

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/06(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	JP 48-45096 A (Tomio SUDO), 28 June 1973 (28.06.1973), entire text; all drawings (Family: none)	1-2,5 8 3-4,6-7
Y	JP 2013-533428 A (Koninklijke Philips N.V.), 22 August 2013 (22.08.2013), paragraph [0071] & US 2013/0123689 A1 paragraph [0070] & WO 2012/014135 A1 & EP 2412392 A1 & CN 102343116 A	8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 October 2015 (13.10.15)	27 October 2015 (27.10.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０７２５９８

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X Y A	JP 48-45096 A（須藤　富夫）1973.06.28, 全文, 全図（ファミリーなし）	1-2,5 8 3-4,6-7
Y	JP 2013-533428 A（コーニンクレッカ　フィリップス　エヌ　ヴェ）2013.08.22, 段落【0071】 & US 2013/0123689 A1, [0070] & WO 2012/014135 A1 & EP 2412392 A1 & CN 102343116 A	8

☐　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

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「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
１３．１０．２０１５	２７．１０．２０１５

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｉ　９６２３
寺澤　忠司
電話番号　０３－３５８１－１１０１　内線　３３８６

(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2016 年 3 月 17 日(17.03.2016)

WIPO | PCT

(10) 国際公開番号
WO 2016/039083 A1

(51) 国際特許分類:
A61M 1/06 (2006.01)

(21) 国際出願番号: PCT/JP2015/073077

(22) 国際出願日: 2015 年 8 月 18 日(18.08.2015)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願 2014-183548 2014 年 9 月 9 日(09.09.2014) JP

(71) 出願人: 株式会社村田製作所 (**MURATA MANUFACTURING CO., LTD.**) [JP/JP]; 〒6178555 京都府長岡京市東神足１丁目１０番１号 Kyoto (JP).

(72) 発明者: 田中伸拓 (**TANAKA, Nobuhira**); 〒6178555 京都府長岡京市東神足１丁目１０番１号 株式会社村田製作所内 Kyoto (JP).

(74) 代理人: 特許業務法人 楓国際特許事務所 (**KAEDE PATENT ATTORNEYS' OFFICE**); 〒5400011 大阪府大阪市中央区農人橋１丁目４番３４号 Osaka (JP).

(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

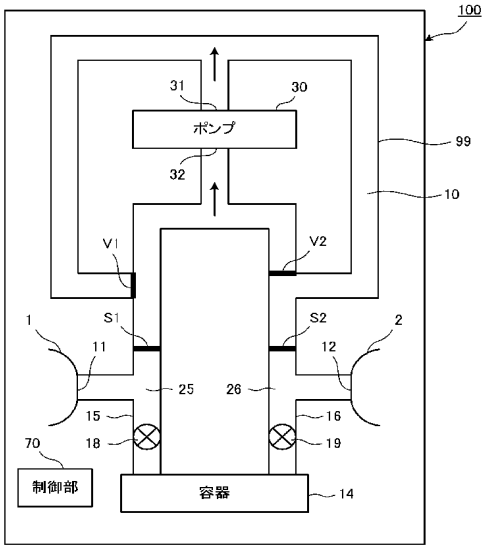
(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG, KZ, RU, TJ, TM), ヨーロッパ (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[続葉有]

(54) **Title**: SUCTION DEVICE

(54) 発明の名称 : 吸引器

図1



14 Container
30 Pump
70 Control unit

(57) **Abstract**: A milking device (100) is provided with: a left cup (1); a right cup (2); tubes (15, 16, 99); a pump (30); a container (14); a first switching valve (V1); a second switching valve (V2); and a control unit (70). The inner space of the tube (99) forms a flow passage (10). The flow passage (10) connects: a first separator (S1) in communication with a closed space (51); a second separator (S2) in communication with a closed space (52); the discharge port (31) of the pump (30); and the suction port (32) of the pump (30). The first switching valve (V1) is provided within the tube (99) located at a position along the length of the flow passage (10). The second switching valve (V2) is provided also within the tube (99) located at the position along the length of the flow passage (10).

(57) 要約: 搾乳器（１００）は、左カップ部（１）と、右カップ部（２）と、チューブ（１５、１６、９９）と、ポンプ（３０）と、容器（１４）と、第１切替弁（Ｖ１）と、第２切替弁（Ｖ２）と、制御部（７０）と、を備える。チューブ（９９）の内部空間は、流路（１０）を形成する。流路（１０）は、閉鎖空間（５１）に連通する第１セパレータ（Ｓ１）と、閉鎖空間（５２）に連通する第２セパレータ（Ｓ２）と、ポンプ（３０）の吐出孔（３１）と、ポンプ（３０）の吸引孔（３２）と、を繋ぐ。第１切替弁（Ｖ１）は、流路（１０）の途中であるチューブ（９９）内に設けられている。第２切替弁（Ｖ２）も、流路（１０）の途中であるチューブ（９９）内に設けられている。

WO 2016/039083 A1

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— 国際調査報告（条約第 21 条(3)）

明　細　書

発明の名称 ： 吸引器

技術分野

[0001] この発明は、流体を吸引する吸引器に関する。

背景技術

[0002] 従来、空気等の流体を吸引する吸引器が各種考案されている。例えば、特許文献１には、母親等が母乳を搾るために使用する搾乳器９００が開示されている。

[0003] 図１６は、特許文献１に係る搾乳器９００の構成を示す外観図である。図１７は、図１６に示す搾乳器９００の流路構成を示す説明図である。図１８は、図１７に示すポンプ９３０が駆動している時における、左カップ部９０１内の気圧の変化と右カップ部９０２内の気圧の変化とを示す図である。

[0004] 搾乳器９００は、図１６に示すように、ポンプ９３０を有する吸引駆動ユニット２４と、左乳房に装着する左カップ部９０１と、右乳房に装着する右カップ部９０２と、チューブ９９２と、を備える。この構成により、搾乳器９００は、図１７に示す流路９１０を構成している。ポンプ９３０は、気体の吸引孔９３２と吐出孔９３１を有する。

[0005] 流路９１０は、流路９１０の外部と繋がる孔部９１８と孔部９１８を開閉する切替弁Ｖ９１とを、ポンプ９３０の吸引孔９３２と左カップ部９０１との間に有する。切替弁Ｖ９１は、さらに、ポンプ９３０の吸引孔９３２と左カップ部９０１との連通または閉塞を行う。ここで、吸引孔９３２と左カップ部９０１とが閉塞した場合、左カップ部９０１は流路９１０の外部と連通する。

[0006] また、流路９１０は、流路９１０の外部と繋がる孔部９１９と孔部９１９を開閉する切替弁Ｖ９２とを、ポンプ９３０の吸引孔９３２と右カップ部９０２との間に有する。切替弁Ｖ９２は、さらに、ポンプ９３０の吸引孔９３２と右カップ部９０２との連通または閉塞を行う。ここで、吸引孔９３２と

右カップ部９０２とが閉塞した場合、右カップ部９０２は流路９１０の外部と連通する。

[0007] 以上の構成において、切替弁Ｖ９１と切替弁Ｖ９２とは、図１７に示すように、流路９１０を第１形態と第２形態とに交互に切替える。第１形態は、吸引孔９３２と左カップ部９０１とが連通し、吸引孔９３２と右カップ部９０２とが連通しない（即ち右カップ部９０２は流路９１０の外部と連通する）形態である。第２形態は、吸引孔９３２と左カップ部９０１とが連通せず（即ち左カップ部９０１は流路９１０の外部と連通し）、吸引孔９３２と右カップ部９０２とが連通する形態である。

[0008] この構成により、搾乳器９００は、１台のポンプ９３０で、左右の乳房を搾乳することができる。

先行技術文献

特許文献

[0009] 特許文献1：特表２０００－５１１４４３号公報

発明の概要

発明が解決しようとする課題

[0010] しかしながら、特許文献１の搾乳器９００は、母乳を吸引する必要があるため、大きな吸引流量を必要とする。そのため、搾乳器９００は、大きな吸引流量を実現することができるよう、大型で高性能なポンプ９３０を備える必要がある。

[0011] したがって、特許文献１の搾乳器９００を含む従来の吸引器は、大きな吸引流量を実現する場合、大型化し、製品コストも高くなる。

[0012] 本発明の目的は、小型・低コストのポンプで、大きな吸引流量を実現することができる吸引器を提供することにある。

課題を解決するための手段

[0013] 本発明の吸引器は、吐出孔および吸引孔を有するポンプと、

第１接続部を有する第１装着部と、

第２接続部を有する第２装着部と、

第１接続部と第２接続部と吐出孔と吸引孔とを繋ぐ流路と、

流路の途中に設けられ、流路を切替える切替機構と、を備え、

切替機構は、流路を、

第１接続部と吸引孔とが連通し、第２接続部と吐出孔とが連通し、第１接続部と第２接続部とが連通しない第１形態と、

第１接続部と吐出孔とが連通し、第２接続部と吸引孔とが連通し、第１接続部と第２接続部とが連通しない第２形態と、

に切替える。

[0014] この構成において、第１装着部及び第２装着部は例えば、左右の乳房に装着する。第１装着部は、左乳房に装着することで、乳房と第１装着部との間に第１閉鎖空間を形成する。第１閉鎖空間は第１接続部に連通する。第２装着部は、右乳房に装着することで、乳房と第２装着部との間に第２閉鎖空間を形成する。第２閉鎖空間は第２接続部に連通する。

[0015] この構成では、ポンプの吐出孔を負圧にした状態で切替機構が流路を第１形態と第２形態とに切替えることで、吸引器は、ポンプの無負荷流量以上の流量を実現できる。

[0016] したがって、本発明の吸引器は、小型・低コストのポンプで、大きな吸引流量を実現することができる。

[0017] また、切替機構は、流路を、第１形態と第２形態とに交互に切替えることが好ましい。

[0018] また、切替機構は、流路を、第１接続部と第２接続部とが連通し、第１接続部および第２接続部の両方と吸引孔とが連通し、第１接続部および第２接続部の両方と吐出孔とが連通しない第３形態、に切替えることが好ましい。

[0019] この構成では、第３形態の間、ポンプの駆動を停止できるため、消費電力を削減できる。

[0020] 流路は、流路の外部に繋がる通気孔と通気孔を開閉する通気弁とを、流路における切替機構と吐出孔との間に有することが好ましい。

[0021] この構成では、吸引器を使用しない時に通気弁を開いて流路内を大気圧にしておけるため、流路、第１装着部、及び第２装着部への負荷が小さい。

[0022] また、通気弁を開いて流路内を大気圧に戻してから、第１装着部及び第２装着部を取り外せるため、人体への負荷が小さい。

[0023] なお、切替機構は、弁で構成されることが好ましい。弁は、電磁弁であることがより好ましい。電磁弁は、３ポート電磁弁であることがより好ましい。

[0024] また、ポンプは、圧電素子を有し、圧電素子により駆動することが好ましい。

[0025] この構成では、駆動時に発生する音や振動が小さい圧電素子を駆動源とすることで、吸引器の静音化を図ることができる。

発明の効果

[0026] 本発明によれば、小型・低コストのポンプで、大きな吸引流量を実現することができる。

図面の簡単な説明

[0027] [図1]本発明の第１実施形態に係る搾乳器１００の構成（第１形態）を示す説明図である。

[図2]図１に示す搾乳器１００において流路１０が第２形態に切り替わったときの構成を示す説明図である。

[図3]図１に示す搾乳器１００において左カップ部１及び右カップ部２を左右の乳房に装着したときの様子を示す説明図である。

[図4]図１に示す第１切替弁Ｖ１及び第２切替弁Ｖ２の具体的な構成の一例を示す説明図である。

[図5]図４に示す第１切替弁Ｖ１の構成を示す断面図である。

[図6]図４に示す第１切替弁Ｖ１の構成を示す断面図である。

[図7]図１、図２に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。

[図8]ポンプの吐出孔および吸引孔の差圧と吐出流量との関係を説明する図で

ある。

[図9]本発明の第２実施形態に係る搾乳器２００の構成を説明する概略図である。

[図10]本発明の第３実施形態に係る搾乳器３００の構成を説明する概略図である。

[図11]図１０に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。

[図12]本発明の第４実施形態に係る搾乳器４００の構成（第１形態）を示す説明図である。

[図13]図１２に示す搾乳器４００において流路１０が第３形態に切り替わったときの構成を示す説明図である。

[図14]図１２に示す搾乳器４００において流路１０が第２形態に切り替わったときの構成を示す説明図である。

[図15]図１２～図１４に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。

[図16]特許文献１に係る搾乳器９００の構成を示す外観図である。

[図17]図１６に示す搾乳器９００の流路構成を示す説明図である。

[図18]図１７に示すポンプ９３０が駆動している時における、左カップ部９０１内の気圧の変化と右カップ部９０２内の気圧の変化とを示す図である。

発明を実施するための形態

[0028] 以下、本発明の第１実施形態に係る搾乳器１００について説明する。

[0029] 図１は、本発明の第１実施形態に係る搾乳器１００の構成（第１形態）を示す説明図である。図２は、図１に示す搾乳器１００において流路１０が第２形態に切り替わったときの構成を示す説明図である。図３は、図１に示す搾乳器１００において左カップ部１及び右カップ部２を左右の乳房に装着したときの様子を示す説明図である。

[0030] なお、図１、図２に示す矢印は、空気の流れを示している。図３に示す矢印は、母乳の流れを示している。

[0031] 搾乳器１００は、左カップ部１と、右カップ部２と、チューブ１５、１６、９９と、ポンプ３０と、容器１４と、第１切替弁Ｖ１と、第２切替弁Ｖ２と、制御部７０と、を備える。

[0032] なお、左カップ部１及びチューブ１５は、本発明の第１装着部に相当する。また、右カップ部２及びチューブ１６は、本発明の第２装着部に相当する。また、第１切替弁Ｖ１及び第２切替弁Ｖ２は、本発明の切替機構を構成する。

[0033] 左カップ部１は、左乳房６１に装着するためのものである。左カップ部１は、チューブ１５と接続する第１流路口１１を有する。左カップ部１は、左乳房６１に装着することで、左乳房６１と左カップ部１との間に閉鎖空間５１を形成する。

[0034] チューブ１５の内部空間は、閉鎖空間５１に流路口１１を介して連通する左流路２５を形成する。チューブ９９、１５の境界には、ポンプ３０側の流路１０と容器１４側の左流路２５とを分離する第１セパレータＳ１が設けられている。チューブ９９、１５は、第１セパレータＳ１が設けられている箇所で接続されている。第１セパレータＳ１は、例えば、ゴム膜等の膜状弾性体からなる。第１セパレータＳ１は、その主面がチューブ１５の断面に平行になるように配置されている。

[0035] 同様に、右カップ部２は、右乳房６２に装着するためのものである。右カップ部２は、チューブ１６と接続する第２流路口１２を有する。右カップ部２は、右乳房６２に装着することで、右乳房６２と右カップ部２との間に閉鎖空間５２を形成する。

[0036] チューブ１６の内部空間は、閉鎖空間５２に流路口１２を介して連通する右流路２６を形成する。チューブ９９、１６の境界には、ポンプ３０側の流路１０と容器１４側の右流路２６とを分離する第２セパレータＳ２が設けられている。チューブ９９、１６は、第２セパレータＳ２が設けられている箇所で接続されている。第２セパレータＳ２は、例えば、ゴム膜等の膜状弾性体からなる。第２セパレータＳ２は、その主面がチューブ１６の断面に平行

になるように配置されている。

[0037] なお、第１セパレータＳ１は、本発明の第１接続部に相当する。また、第２セパレータＳ２は、本発明の第２接続部に相当する。

[0038] 容器１４は、左乳房６１又は右乳房６２から出た母乳を貯蔵する。容器１４は、チューブ１５を介して左カップ部１に接続し、チューブ１６を介して右カップ部２に接続している。これにより、容器１４の内部空間は、左流路２５、２６を介して閉鎖空間５１、５２に連通している。

[0039] なお、チューブ１５には、流体が容器１４から左流路２５へ逆流することを防ぐ逆止弁１８を設けることが好ましい。また、チューブ１６には、流体が容器１４から右流路２６へ逆流することを防ぐ逆止弁１９を設けることが好ましい。

[0040] ポンプ３０は、圧電素子を有し、圧電素子により駆動する。ポンプ３０は、空気が吐出される吐出孔３１と、空気が吸引される吸引孔３２とを有する。ポンプ３０の吸引孔３２と吐出孔３１とは、チューブ９９と接続している。

[0041] チューブ９９の内部空間は、流路１０を形成する。流路１０は、第１セパレータＳ１と、第２セパレータＳ２と、ポンプ３０の吐出孔３１と、ポンプ３０の吸引孔３２と、を繋ぐ。

[0042] なお、チューブ１５、１６、９９の材料は例えば、ポリプロピレンやポリエチレンなどである。

[0043] 第１切替弁Ｖ１は、流路１０の途中であるチューブ９９内に設けられている。第２切替弁Ｖ２も、流路１０の途中であるチューブ９９内に設けられている。

[0044] 制御部７０は、第１切替弁Ｖ１及び第２切替弁Ｖ２の開閉を制御する。制御部７０は、例えばマイクロコンピュータで構成される。

[0045] 以下、第１切替弁Ｖ１及び第２切替弁Ｖ２の具体的な構成の一例について、図４～図６を用いて説明する。図４～図６において第１切替弁Ｖ１の構成と第２切替弁Ｖ２の構成とは同じであるため、第１切替弁Ｖ１及び第２切替

弁Ｖ２を代表して第１切替弁Ｖ１の構成について説明する。

[0046] 図４は、図１に示す第１切替弁Ｖ１及び第２切替弁Ｖ２の具体的な構成の一例を示す説明図である。図５は、図４に示す第１切替弁Ｖ１の構成を示す断面図である。図６は、図４に示す第１切替弁Ｖ１の構成を示す断面図である。

[0047] 第１切替弁Ｖ１は、ポート１２１とポート１２２とポート１２３とが設けられた筐体１２４と、筐体１２４内を摺動する摺動体１２５と、を有する。第１切替弁Ｖ１は、所謂３ポート電磁弁である。

[0048] 第１切替弁Ｖ１は、制御部７０の指示に基づいて、図５、図６に示すように摺動体１２５を摺動させる。これにより、第１切替弁Ｖ１は、流路を切り替える。第２切替弁Ｖ２も同様の方法で、流路を切り替える。

[0049] 以上のようにして、第１切替弁Ｖ１と第２切替弁Ｖ２とは、図１、図２に示すように流路１０を第１形態と第２形態とに交互に切替える。

[0050] ここで、第１形態は、第１セパレータＳ１と吸引孔３２とが連通し、第２セパレータＳ２と吐出孔３１とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0051] また、第２形態は、第１セパレータＳ１と吐出孔３１とが連通し、第２セパレータＳ２と吸引孔３２とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0052] 以下、ポンプ３０が駆動している時の搾乳器１００の動作について説明する。

[0053] 図７は、図１、図２に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。図８は、ポンプの吐出孔および吸引孔の差圧と吐出流量との関係を説明する図である。

[0054] なお、図７中の各形態におけるＡ点、Ｂ点、Ｃ点は、図８中のＡ点、Ｂ点、Ｃ点に対応している。

[0055] まず、図７に示すように、ポンプ３０が駆動を開始する時点では、流路１０は第１形態になっていることとする。さらに、この時点では、左流路２５

の圧力は、大気圧になっていることとし、右流路２６の圧力は、負圧になっていることとする。

[0056] そして、ポンプ３０が駆動を開始すると、ポンプ３０は、吸引孔３２から空気を吸引し、ポンプ３０側に凸となるように第１セパレータＳ１を弾性変形する。これにより、左流路２５の体積が増える。このようにして、ポンプ３０は、図７に示すＣ点、Ｂ点、Ａ点のように、左流路２５及び閉鎖空間５１に負圧を生じさせる。

[0057] このとき、逆止弁１８が逆流を制限するので、容器１４から左流路２５へ空気が吸引されることはない。これにより、左乳房６１から母乳が出る。左乳房６１から左カップ部１を通って出た母乳は、左流路２５に吸引され、容器１４に貯蔵される。

[0058] 一方、ポンプ３０は、吸引孔３２から吸引した空気を吐出孔３１から吐出し、容器１４側に凸となるように第２セパレータＳ２を弾性変形する。これにより、右流路２６の体積が減る。このようにして、ポンプ３０は、図７に示すＡ点、Ｂ点、Ｃ点のように、右流路２６の圧力を高めていく。

[0059] そして、一定時間が経過すると、制御部７０は、流路１０を第１形態から第２形態に切替えるよう、第１切替弁Ｖ１と第２切替弁Ｖ２とに指示する。

[0060] 次に、流路１０に第２形態に切替わると、ポンプ３０は、吸引孔３２から空気を吸引し、ポンプ３０側に凸となるように第２セパレータＳ２を弾性変形する。これにより、右流路２６の体積が増える。このようにして、ポンプ３０は、図７に示すＣ点、Ｂ点、Ａ点のように、右流路２６及び閉鎖空間５２に負圧を生じさせる。

[0061] このとき、逆止弁１９が逆流を制限するので、容器１４から右流路２６へ空気が吸引されることはない。これにより、右乳房６２から母乳が出る。右乳房６２から右カップ部２を通って出た母乳は、右流路２６に吸引され、容器１４に貯蔵される。

[0062] 一方、ポンプ３０は、吸引孔３２から吸引した空気を吐出孔３１から吐出し、容器１４側に凸となるように第１セパレータＳ１を弾性変形する。これ

により、右流路２６の体積が減る。このようにして、ポンプ３０は、図７に示すＡ点、Ｂ点、Ｃ点のように、左流路２５の圧力を高めていく。

[0063] そして、一定時間が経過すると、制御部７０は、流路１０を第２形態から第１形態に切替えるよう、第１切替弁Ｖ１と第２切替弁Ｖ２とに指示する。

[0064] 以後、ポンプ３０が駆動している間、制御部７０は、図７に示すように、流路１０を第１形態と第２形態とに交互に切替える。そのため、ポンプ３０が駆動している間、左流路２５の圧力と右流路２６の圧力とは、図７に示すように、同じ変化を繰り返す。

[0065] 以上の動作では、搾乳器１００は、ポンプ３０の吐出孔３１が負圧となっている。そのため、搾乳器１００は、ポンプ３０の無負荷流量以上の流量を実現できる。

[0066] よって、搾乳器１００は、左流路２５又は右流路２６のいずれか一方の排気時間を短縮できる。また、左流路２５又は右流路２６のいずれか他方も、ポンプ３０の流量を活用できるため、短時間で大気開放できる。

[0067] 以下、ポンプ３０を含むポンプの圧力と流量の関係について詳述する。

[0068] 図８に示すように、ポンプの吐出孔と吸引孔の差圧がΔＰの時の流量をＱとすると、ΔＰとＱは、$Q/Q_0+\Delta P/P_0=1$の関係を満たす。従って、$Q=Q_0(1-\Delta P/P_0)$となる。

[0069] 図１７に示す特許文献１の搾乳器９００の場合、吐出孔９３１の圧力は常に、大気圧Ｐａである。例えば、左カップ部９０１内の圧力（＝吸引孔９３２の圧力）がＰａ－Ｐｃの場合、差圧ΔＰ＝Ｐｃのため、$Q=Q_0(1-Pc/P_0)$となる。

[0070] 一方、本実施形態の搾乳器１００の場合、吸引中の右カップ部２の圧力（＝吸引孔３２の圧力）がＰａ－Ｐｃの時、給気中の左カップ部１の圧力（＝吐出孔３１の圧力）がＰａ－（P_0－Ｐｃ）となるように動作させると、差圧$\Delta P=2Pc-P_0$となり、$Q=Q_0\{1-(2Pc-P_0)/P_0\}=2Q_0(1-Pc/P_0)$となる。

[0071] すなわち、本実施形態の搾乳器１００は、搾乳器９００を含む従来の吸引

器に比べて、２倍の流量を実現できる。したがって、本実施形態の搾乳器１００は、小型・低コストの１台のポンプで、大きな吸引流量を実現することができる。

[0072] また、ポンプ３０は、駆動時に発生する音や振動が小さい圧電素子を駆動源としているため、搾乳器１００の静音化を図ることができる。

[0073] 以下、本発明の第２実施形態に係る搾乳器２００について説明する。

[0074] 図９は、本発明の第２実施形態に係る搾乳器２００の構成を説明する概略図である。

[0075] 第２実施形態に係る搾乳器２００が前述の搾乳器１００と相違する点は、第１切替弁Ｖ１及び第２切替弁Ｖ２の配置である。その他の構成は同じであるため、説明を省略する。

[0076] チューブ２９９の内部空間は、流路２１０を形成する。流路２１０も、閉鎖空間５１に左流路２５を介して連通する第１セパレータＳ１と、閉鎖空間５２に右流路２６を介して連通する第２セパレータＳ２と、ポンプ３０の吐出孔３１と、ポンプ３０の吸引孔３２と、を繋ぐ。

[0077] 第１切替弁Ｖ１は、流路２１０の途中であるチューブ２９９内に設けられている。第２切替弁Ｖ２も、流路２１０の途中であるチューブ２９９内に設けられている。

[0078] したがって、この実施形態の搾乳器２００によれば、搾乳器１００と同様の効果を奏する。

[0079] 以下、本発明の第３実施形態に係る搾乳器３００について説明する。

[0080] 図１０は、本発明の第３実施形態に係る搾乳器３００の構成を説明する概略図である。第３実施形態に係る搾乳器３００が前述の搾乳器１００と相違する点は、通気孔３１９及び通気弁Ｖ３である。その他の構成は同じであるため、説明を省略する。

[0081] チューブ３９９の内部空間は、流路３１０を形成する。流路３１０は、流路３１０の外部と繋がる通気孔３１９と通気孔３１９を開閉する通気弁Ｖ３とを、ポンプ３０の吐出孔３１と第１切替弁Ｖ１及び第２切替弁Ｖ２との間

に有する。

[0082] そして、第１切替弁Ｖ１と第２切替弁Ｖ２とは、ポンプ３０が駆動を開始する前、初期形態に切り替えている。そして、第１切替弁Ｖ１と第２切替弁Ｖ２とは、ポンプ３０が駆動を開始した後、流路１０を第１形態と第２形態とに交互に切替える。

[0083] ここで、初期形態は、図１０に示すように通気弁Ｖ３が開き（大気開放し）、第１セパレータＳ１と吸引孔３２とが連通し、第２セパレータＳ２と吐出孔３１とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0084] また、第１形態は、通気弁Ｖ３が閉じ、第１セパレータＳ１と吸引孔３２とが連通し、第２セパレータＳ２と吐出孔３１とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0085] また、第２形態は、通気弁Ｖ３が閉じ、第１セパレータＳ１と吐出孔３１とが連通し、第２セパレータＳ２と吸引孔３２とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0086] 以下、ポンプ３０が駆動している時の搾乳器３００の動作について説明する。

[0087] 図１１は、図１０に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。

[0088] まず、ポンプ３０が駆動を開始する時点では、流路３１０は、図１０に示すように初期形態になっていることとする。そのため、この時点では、左流路２５の圧力と、右流路２６の圧力とは、大気圧になっている。

[0089] そして、ポンプ３０が駆動を開始すると、ポンプ３０は、吸引孔３２から空気を吸引し、ポンプ３０側に凸となるように第１セパレータＳ１を弾性変形する。これにより、左流路２５の体積が増える。このようにして、ポンプ３０は、図１１に示すように、閉鎖空間５１及び左流路２５に負圧を生じさせる。

[0090] このとき、逆止弁１８が逆流を制限するので、容器１４から左流路２５へ

空気が吸引されることはない。これにより、左乳房６１から母乳が出る。左乳房６１から左カップ部１を通って出た母乳は、左流路２５に吸引され、容器１４に貯蔵される。

[0091] 一方、ポンプ３０は、吸引孔３２から吸引した空気を吐出孔３１から吐出し、通気孔３１９から排出する。

[0092] そして、一定時間が経過すると、制御部７０は、流路３１０を初期形態から第２形態に切替えるよう、第１切替弁Ｖ１と第２切替弁Ｖ２と通気弁Ｖ３とに指示する。

[0093] 以後、ポンプ３０が駆動している間、制御部７０は、図１１に示すように、流路３１０を第１形態と第２形態とに交互に切替える。そのため、ポンプ３０が駆動している間、左流路２５の圧力と右流路２６の圧力とは、図１１に示すように、同じ変化を繰り返す。

[0094] したがって、この実施形態の搾乳器３００によれば、搾乳器１００と同様の効果を奏する。

[0095] また、搾乳器３００を使用しない時に流路３１０内を大気圧にしておけるため、チューブ３９９、左カップ部１、及び右カップ部２への負荷が小さい。

[0096] また、流路３１０内を大気圧に戻してから、左カップ部１及び右カップ部２を取り外せるため、乳房６１、６２への負荷が小さい。

[0097] さらに、駆動中に通気バルブＶ３を開閉することで、左流路２５及び右流路２６の圧力波形制御が容易となる。

[0098] 以下、本発明の第４実施形態に係る搾乳器４００について説明する。

[0099] 図１２は、本発明の第４実施形態に係る搾乳器４００の構成（第１形態）を示す説明図である。図１３は、図１２に示す搾乳器４００において流路１０が第３形態に切り替わったときの構成を示す説明図である。図１４は、図１２に示す搾乳器４００において流路１０が第２形態に切り替わったときの構成を示す説明図である。

[0100] 第４実施形態に係る搾乳器４００が前述の搾乳器１００と相違する点は、

ポンプ３０が駆動している時の動作である。その他の構成は同じであるため、説明を省略する。

[0101] 以下、ポンプ３０が駆動している時の搾乳器４００の動作について説明する。

[0102] 図１５は、図１２～図１４に示すポンプ３０が駆動している時における、左流路２５の気圧の変化と右流路２６の気圧の変化とを示す図である。

[0103] 第１切替弁Ｖ１と第２切替弁Ｖ２とは、ポンプ３０が駆動を開始した後、流路１０を、第１形態と第２形態と第３形態とに交互に切替える。第１切替弁Ｖ１と第２切替弁Ｖ２とは、第３形態が第１形態と第２形態との間に挟まれるよう、流路１０を切替える。

[0104] ここで、第１形態は、第１セパレータＳ１と吸引孔３２とが連通し、第２セパレータＳ２と吐出孔３１とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0105] また、第２形態は、第１セパレータＳ１と吐出孔３１とが連通し、第２セパレータＳ２と吸引孔３２とが連通し、第１セパレータＳ１と第２セパレータＳ２とが連通しない形態である。

[0106] また、第３形態は、第１セパレータＳ１及び第２セパレータＳ２の両方と吸引孔３２とが連通し、第１セパレータＳ１及び第２セパレータＳ２の両方と吐出孔３１とが連通せず、第１セパレータＳ１と第２セパレータＳ２とが連通する形態である。

[0107] そのため、搾乳器４００では、ポンプ３０が駆動している間、左流路２５の圧力と右流路２６の圧力とは、図１５に示すように、同じ変化を繰り返す。

[0108] したがって、この実施形態の搾乳器４００によれば、搾乳器１００と同様の効果を奏する。

[0109] さらに、第３形態の間はポンプ３０の駆動を停止できるため、消費電力を削減できる。

[0110] 《その他の実施形態》

なお、前述の実施形態におけるポンプ３０は、圧電素子の伸縮によって屈曲振動するアクチュエータを備えるが、これに限るものではない。例えば、電磁駆動で屈曲振動するアクチュエータを備えてもよい。

[0111] また、前記実施形態では、流路を通過させる流体として空気を使用しているが、これに限るものでは無い。実施の際、例えば、空気以外の気体でも構わない。

[0112] また、前記実施形態では、圧電駆動のポンプ３０を使用しているが、これに限るものでは無い。実施の際、例えば、電磁駆動のポンプを使用しても構わない。

[0113] また、前記実施形態では、第１装着部および第２装着部を左右の乳房に装着して母乳を吸引しているが、これに限るものでは無い。実施の際、例えば、他の液体（鼻水等）を吸引しても構わない。

[0114] 最後に、上述の実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、上述の実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0115] １…左カップ部
２…右カップ部
１０…流路
１１…第１流路口
１２…第２流路口
１４…容器
１５…チューブ
１６…チューブ
１８…逆止弁
１９…逆止弁

２４…吸引駆動ユニット

２５…流路

２６…流路

３０…ポンプ

３１…吐出孔

３２…吸引孔

５１…閉鎖空間

５２…閉鎖空間

６１…左乳房

６２…右乳房

７０…制御部

９９…チューブ

１００…搾乳器

１２１…ポート

１２２…ポート

１２３…ポート

１２４…筐体

１２５…摺動体

２００…搾乳器

２１０…流路

２９９…チューブ

３００…搾乳器

３１０…流路

３１９…通気孔

３９９…チューブ

４００…搾乳器

９００…搾乳器

９０１…左カップ部

９０２…右カップ部

９１０…流路

９１８…孔部

９１９…孔部

９３０…ポンプ

９３１…吐出孔

９３２…吸引孔

９９２…チューブ

Ｓ１…第１セパレータ

Ｓ２…第２セパレータ

Ｖ１…第１切替弁

Ｖ２…第２切替弁

Ｖ３…通気弁

Ｖ９１…切替弁

Ｖ９２…切替弁

請求の範囲

[請求項1] 吐出孔および吸引孔を有するポンプと、

第１接続部を有する第１装着部と、

第２接続部を有する第２装着部と、

前記第１接続部と前記第２接続部と前記吐出孔と前記吸引孔とを繋ぐ流路と、

前記流路の途中に設けられ、前記流路を切替える切替機構と、を備え、

前記切替機構は、前記流路を、

前記第１接続部と前記吸引孔とが連通し、前記第２接続部と前記吐出孔とが連通し、前記第１接続部と前記第２接続部とが連通しない第１形態と、

前記第１接続部と前記吐出孔とが連通し、前記第２接続部と前記吸引孔とが連通し、前記第１接続部と前記第２接続部とが連通しない第２形態と、

に切替える、ことを特徴とする吸引器。

[請求項2] 前記切替機構は、前記流路を、前記第１形態と前記第２形態とに交互に切替える、ことを特徴とする請求項１に記載の吸引器。

[請求項3] 前記切替機構は、前記流路を、前記第１接続部と前記第２接続部とが連通し、前記第１接続部および前記第２接続部の両方と前記吸引孔とが連通し、前記第１接続部および前記第２接続部の両方と前記吐出孔とが連通しない第３形態、に切替える、ことを特徴とする請求項１に記載の吸引器。

[請求項4] 前記流路は、前記流路の外部に繋がる通気孔と前記通気孔を開閉する通気弁とを、前記流路における前記切替機構と前記吐出孔との間に有する、ことを特徴とする請求項１から請求項３のいずれか１項に記載の吸引器。

[請求項5] 前記切替機構は、弁で構成される、ことを特徴とする請求項１から

請求項４のいずれか１項に記載の吸引器。

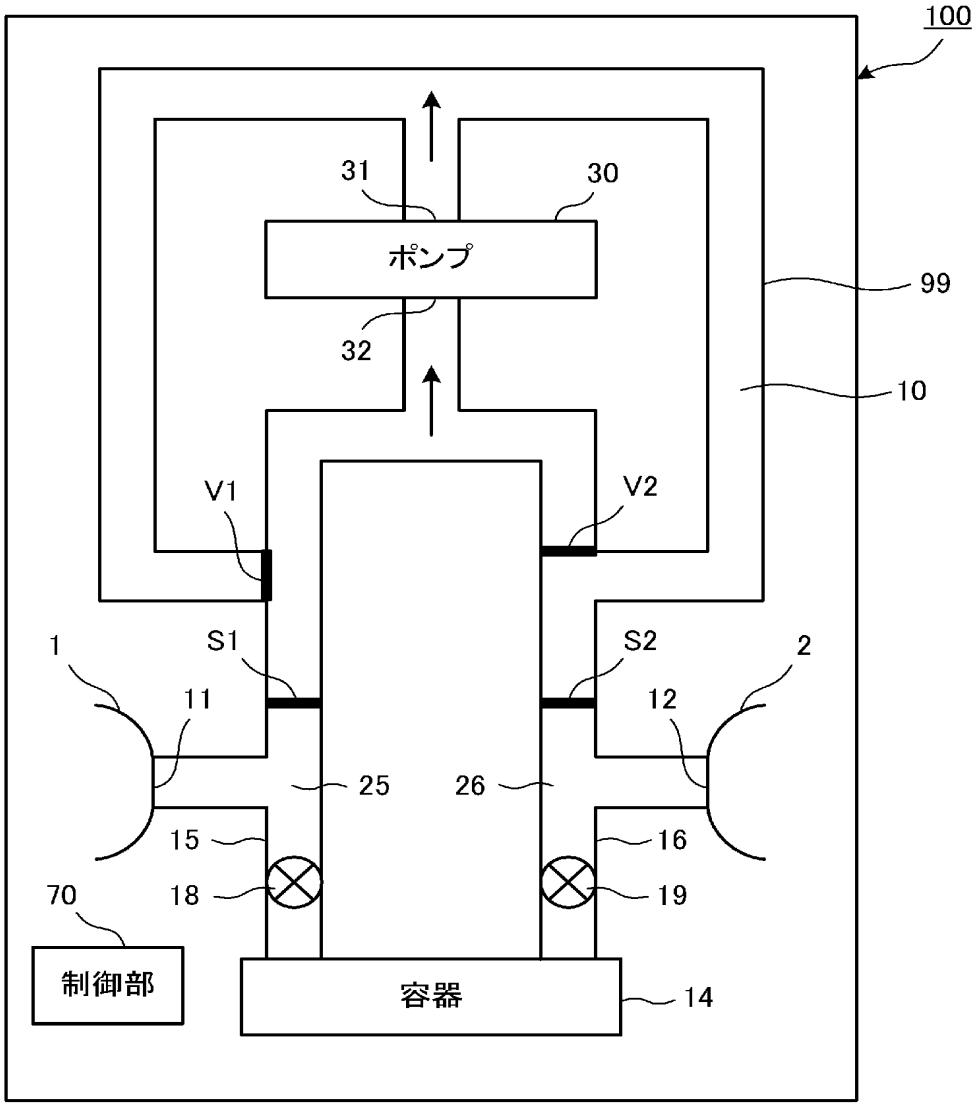
[請求項6] 前記弁は、電磁弁である、ことを特徴とする請求項５に記載の吸引器。

[請求項7] 前記電磁弁は、３ポート電磁弁であることを特徴とする請求項６に記載の吸引器。

[請求項8] 前記ポンプは、圧電素子を有し、前記圧電素子により駆動する、ことを特徴とする請求項１から請求項７のいずれか１項に記載の吸引器。

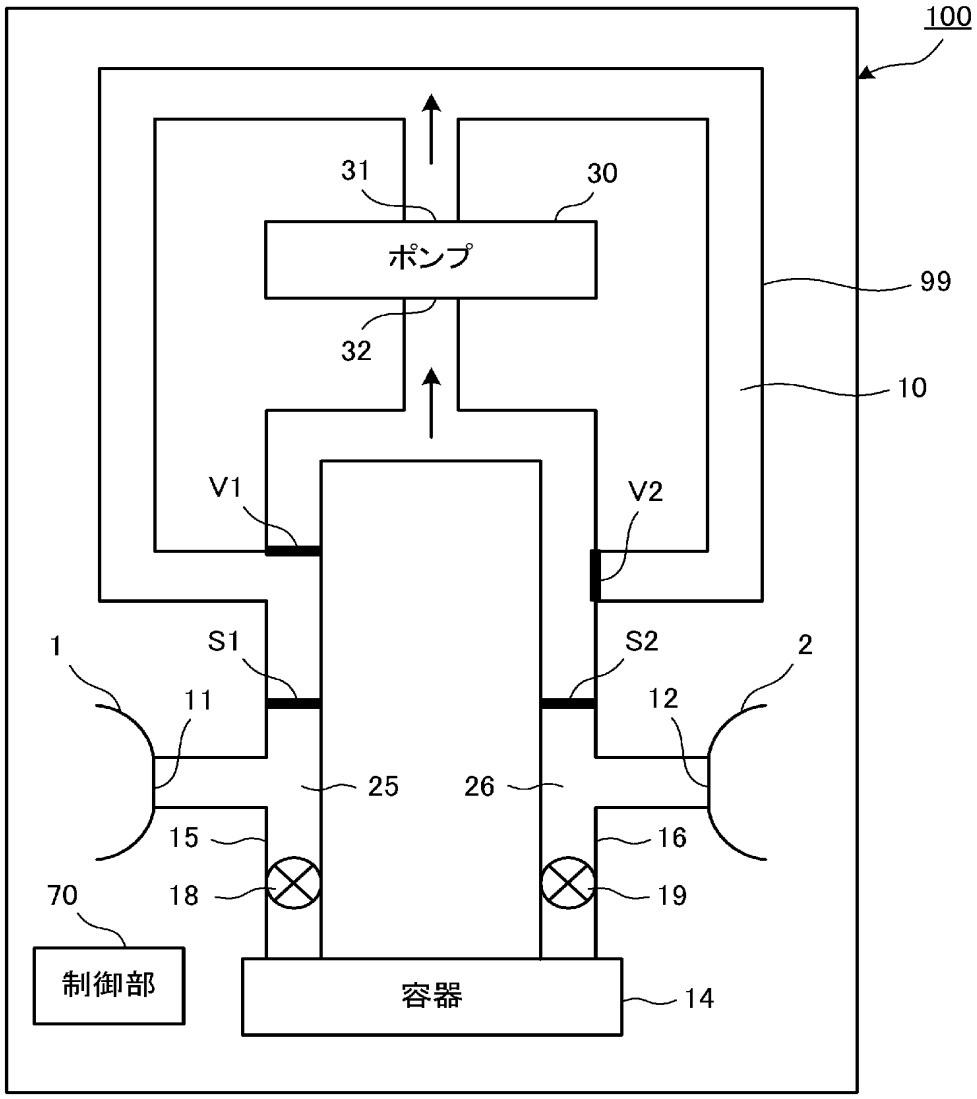
[図1]

図1


100
31
30
ポンプ
99
32
10
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

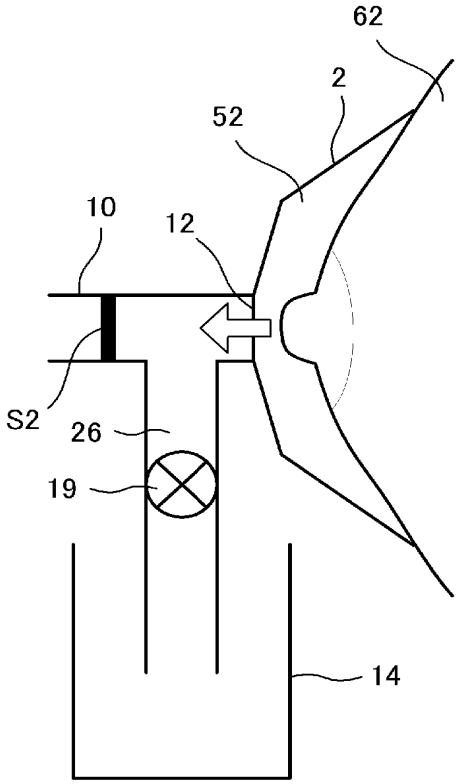
[図2]

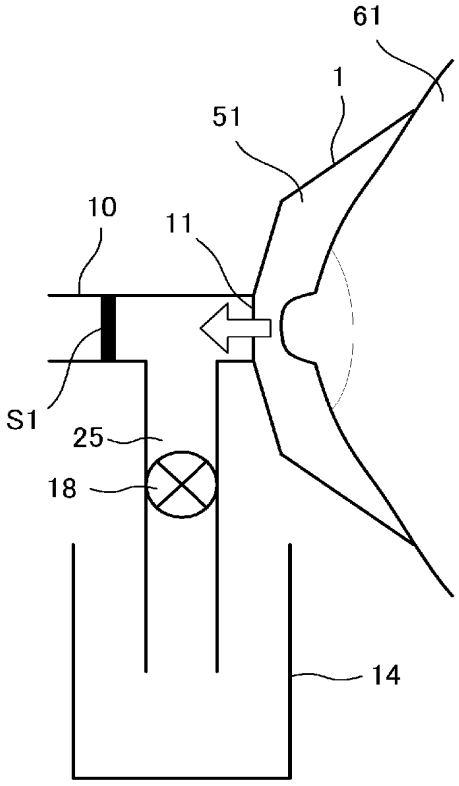
図2


100
31
30
ポンプ
99
32
10
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

[図3]

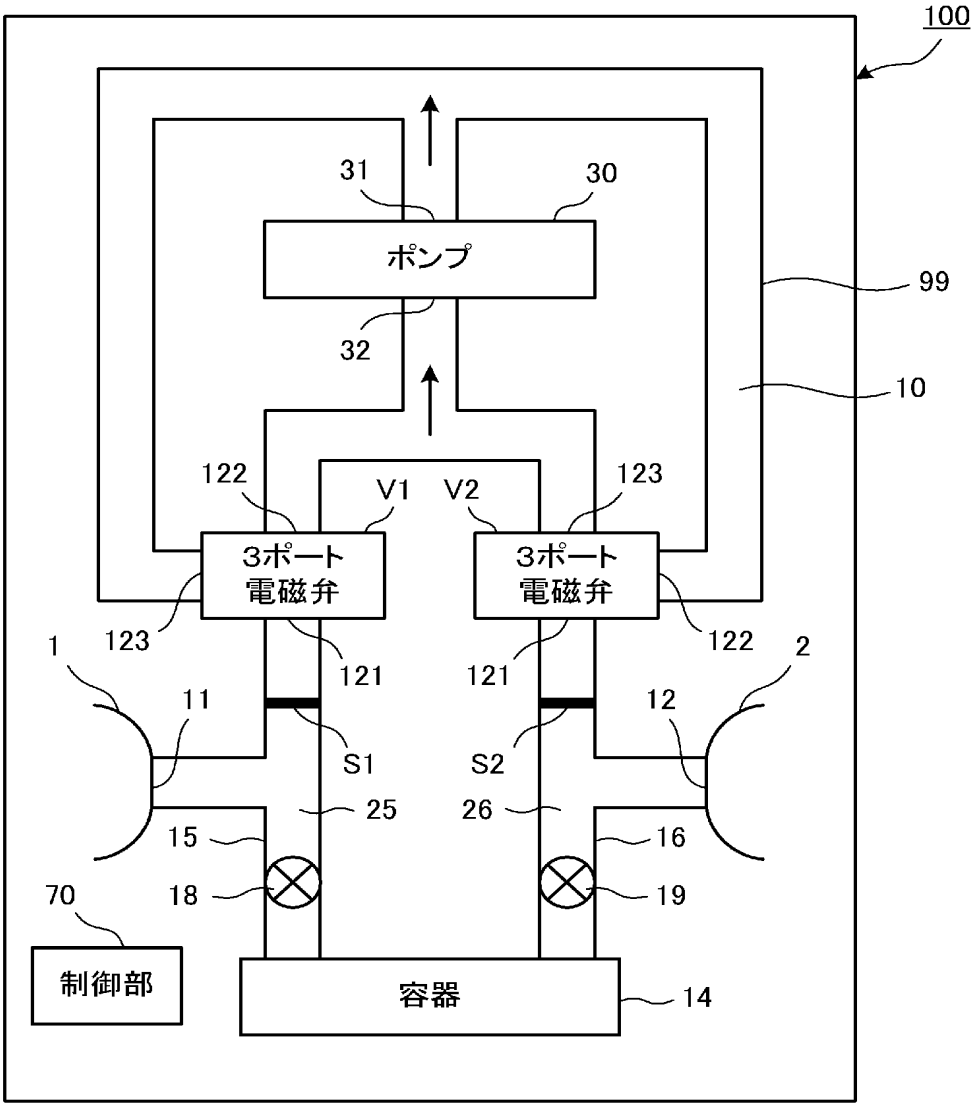
図3





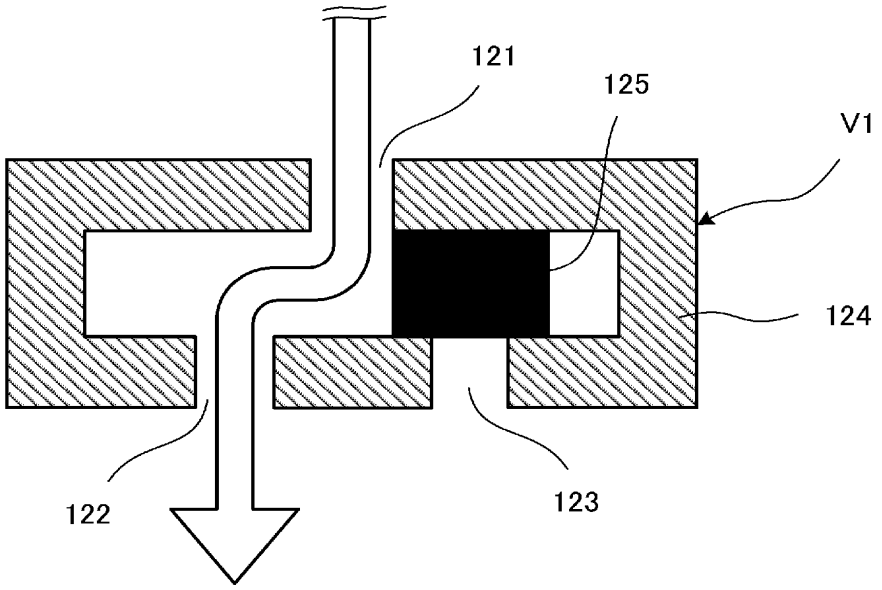
[図4]

図4


100
31
30
ポンプ
99
32
10
122
V1
V2
123
3ポート
電磁弁
3ポート
電磁弁
1
123
121
121
122
2
11
12
S1
S2
25
26
15
16
18
19
70
制御部
容器
14

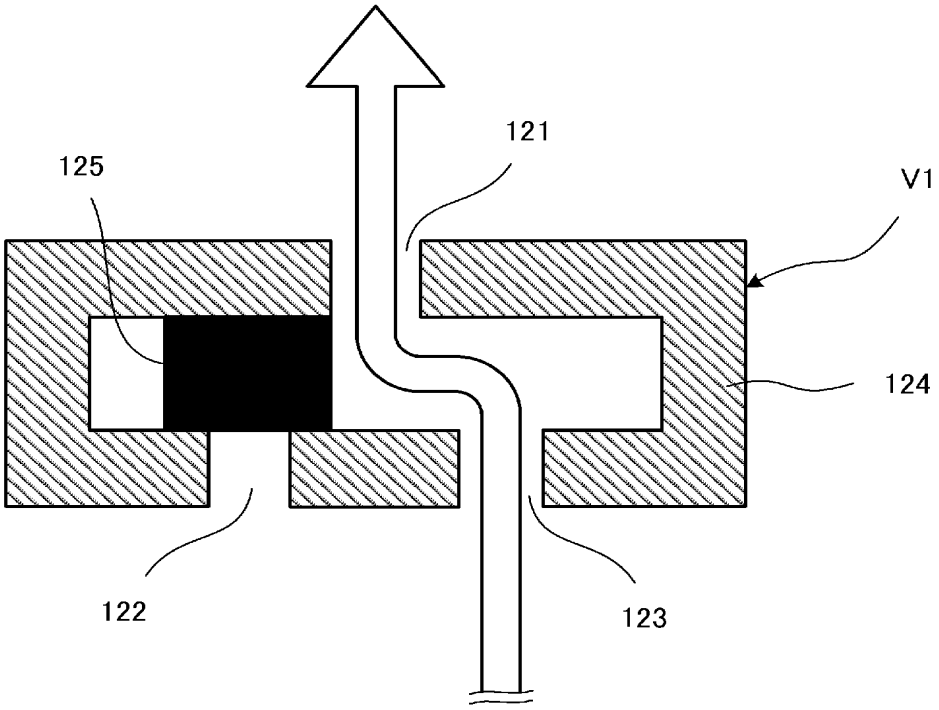
[図5]

図5



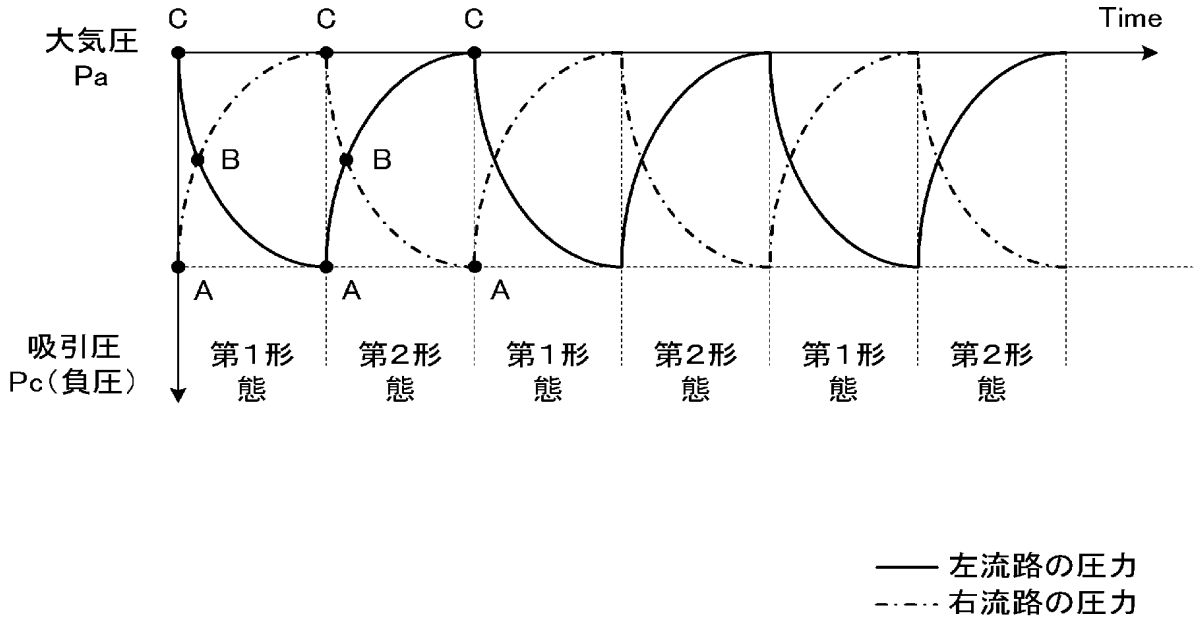
[図6]

図6



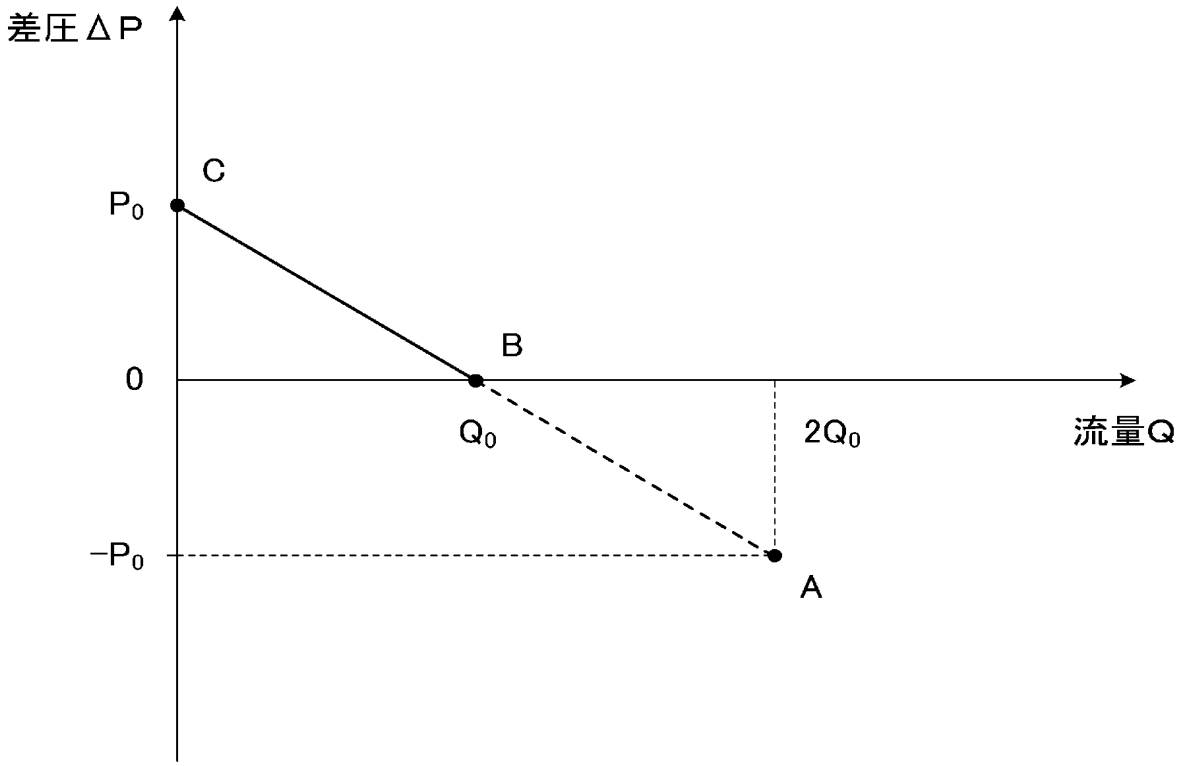
[図7]

図7


C
C
C
Time
大気圧
Pa
B
B
A
A
A
吸引圧
Pc（負圧）
第1形態
第2形態
第1形態
第2形態
第1形態
第2形態
左流路の圧力
右流路の圧力

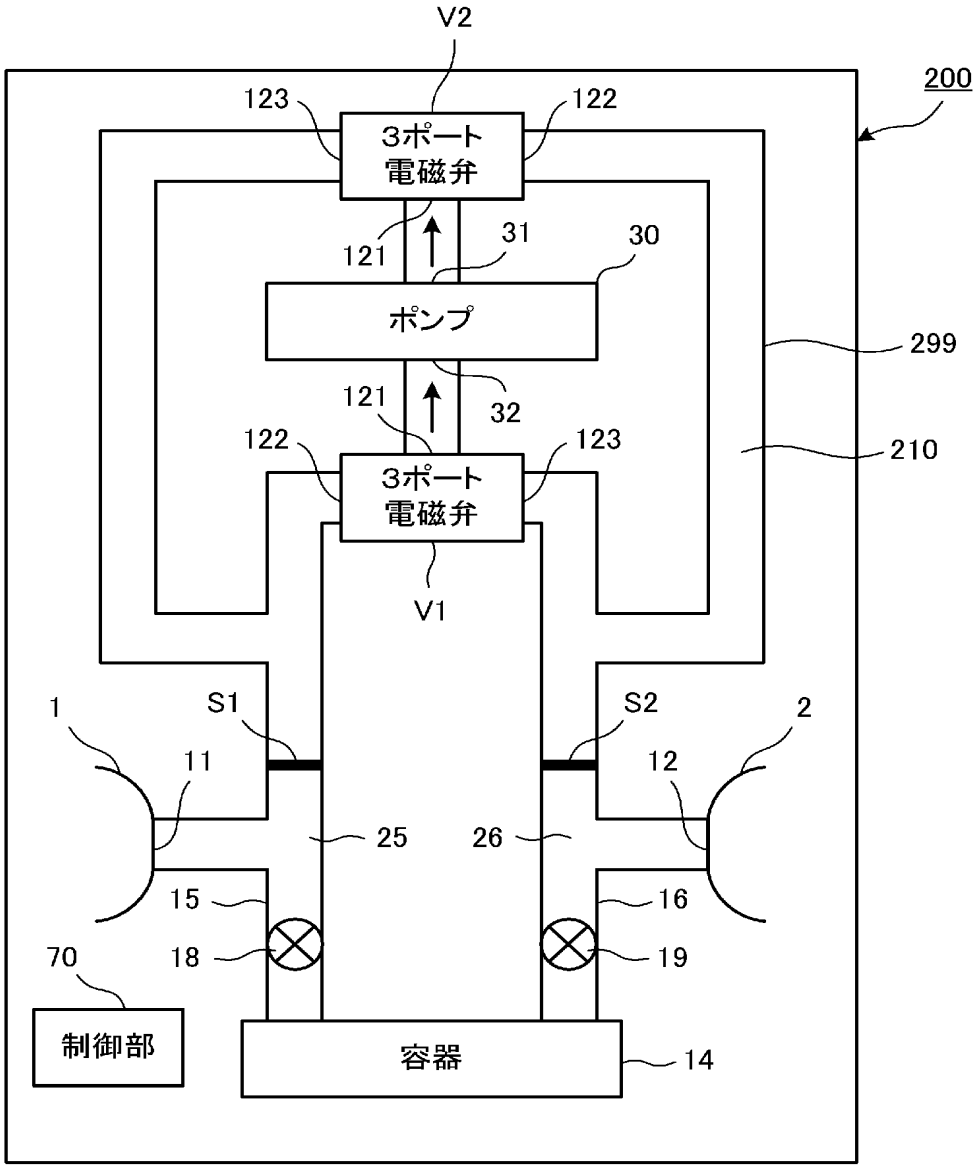
[図8]

図8



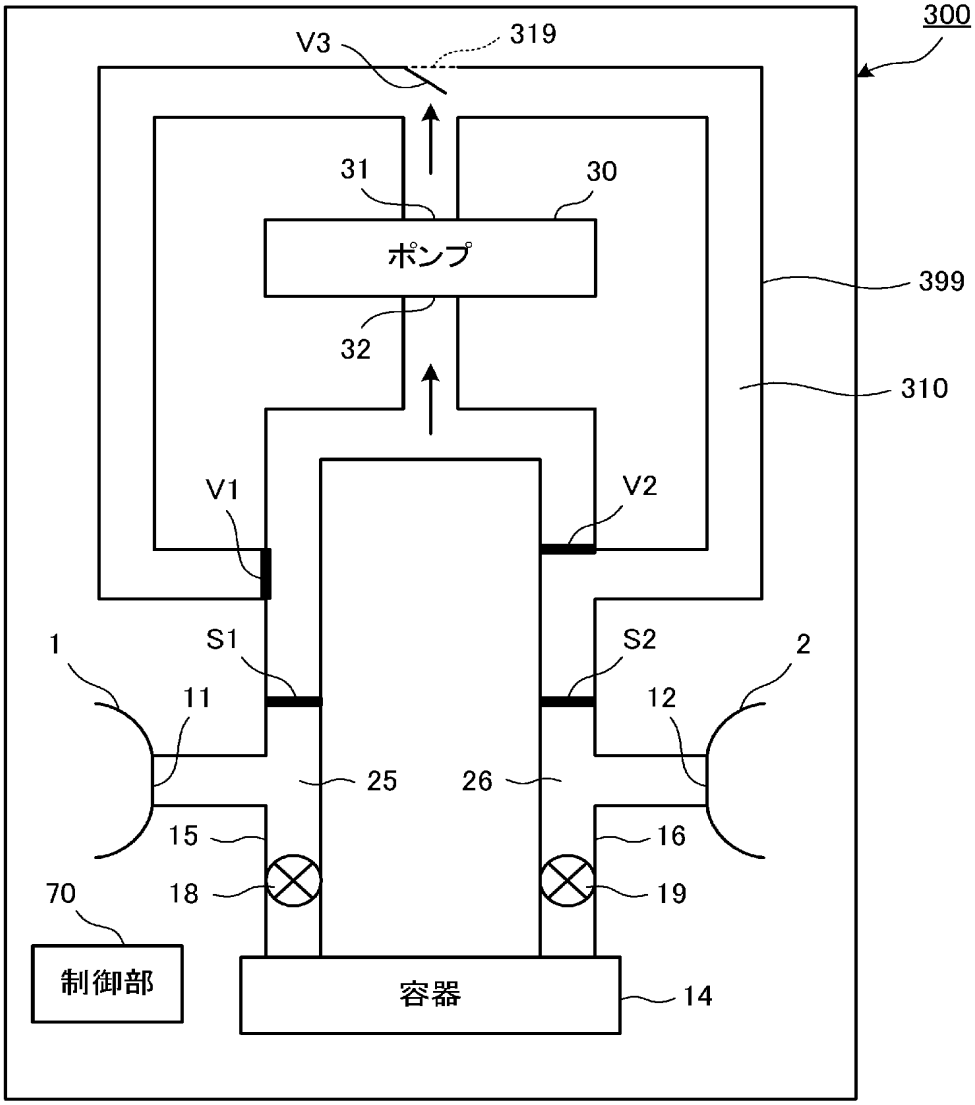
[図9]

図9


V2
200
123
122
3ポート
電磁弁
121
31
30
ポンプ
299
121
32
122
123
210
3ポート
電磁弁
V1
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

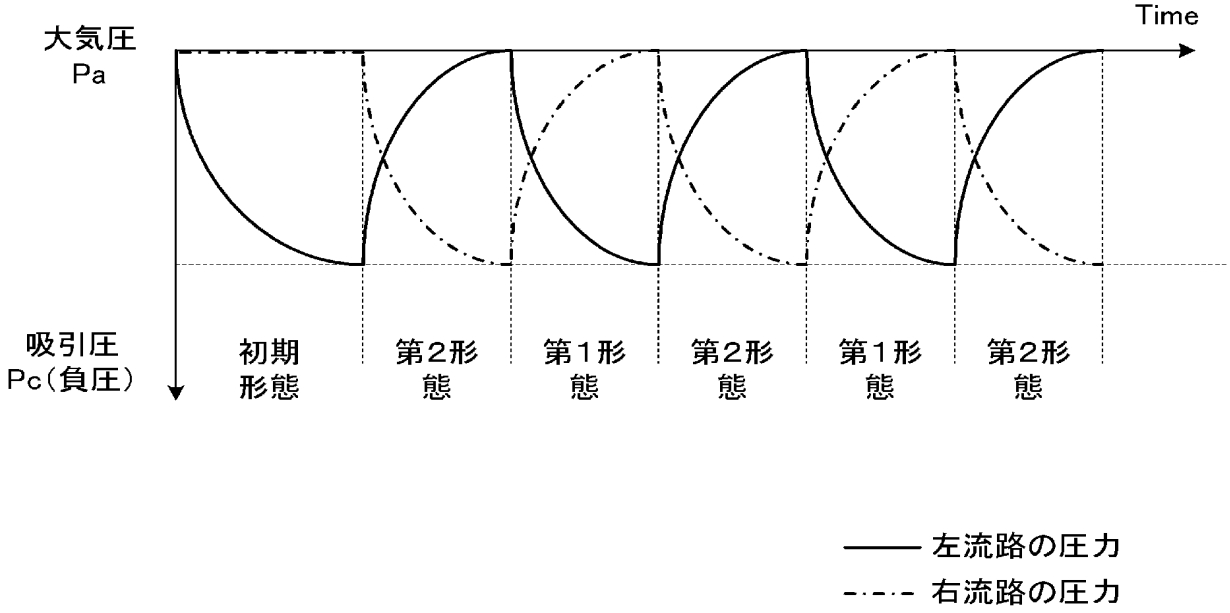
[図10]

図10


300
V3
319
31
30
ポンプ
399
32
310
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

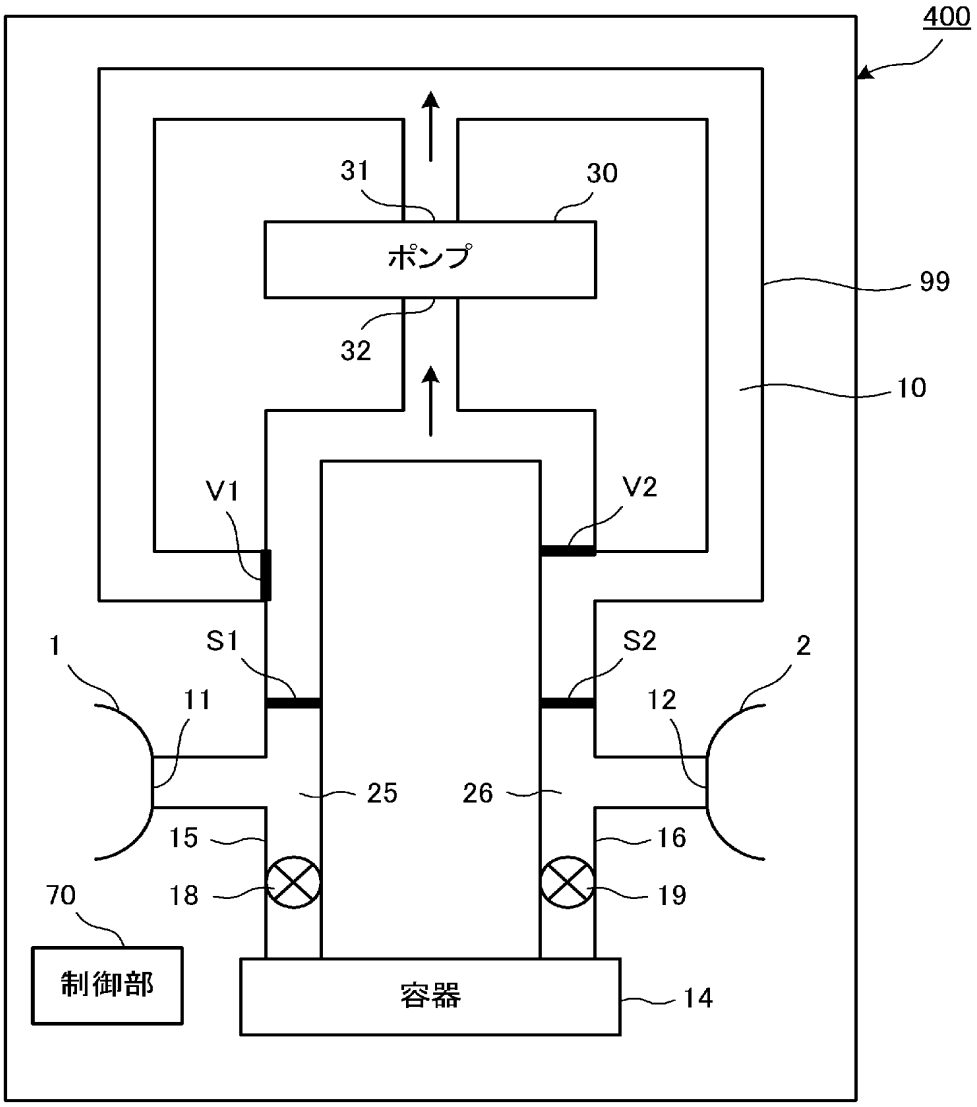
[図11]

図11


Time
大気圧
Pa
吸引圧
Pc(負圧)
初期
形態
第2形
態
第1形
態
第2形
態
第1形
態
第2形
態
左流路の圧力
右流路の圧力

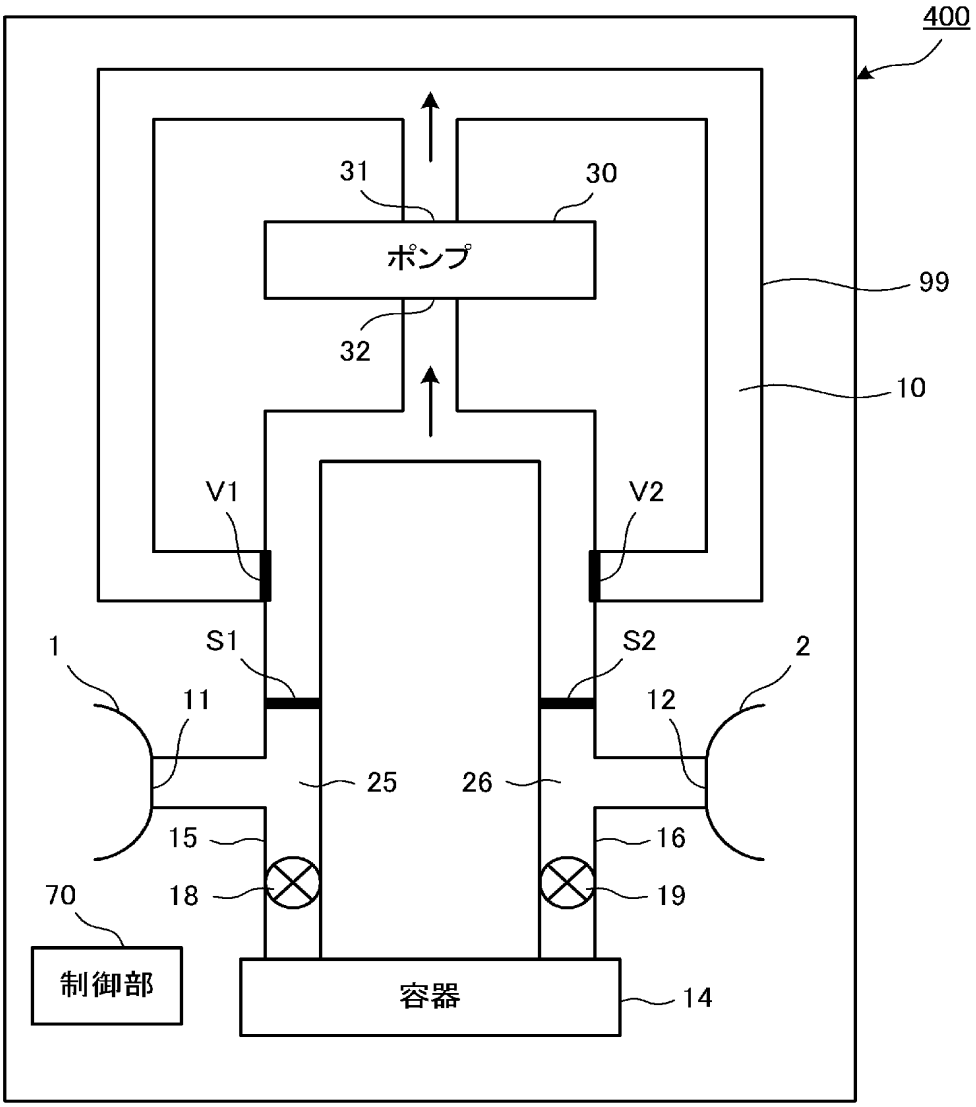
[図12]

図12


400
31
30
ポンプ
99
32
10
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

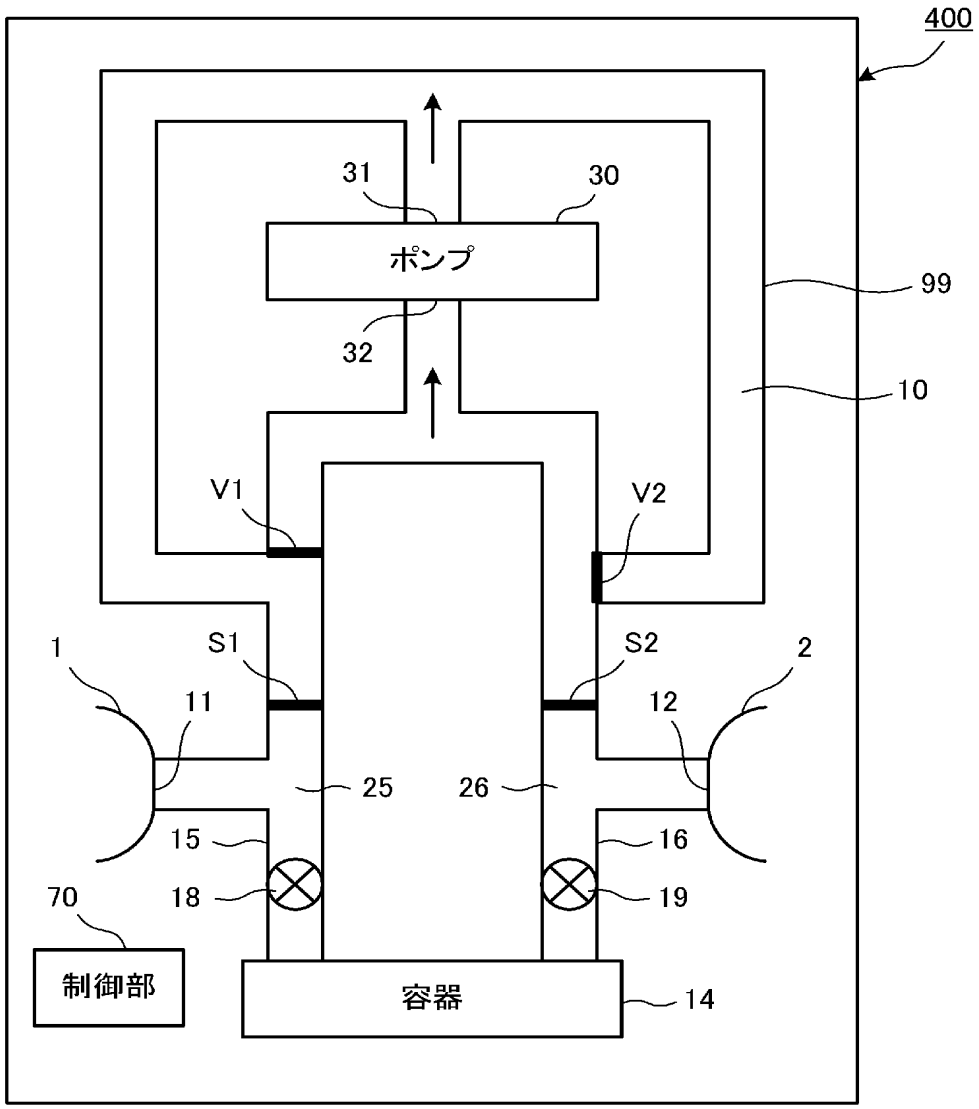
[図13]

図13


400
31
30
ポンプ
99
32
10
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

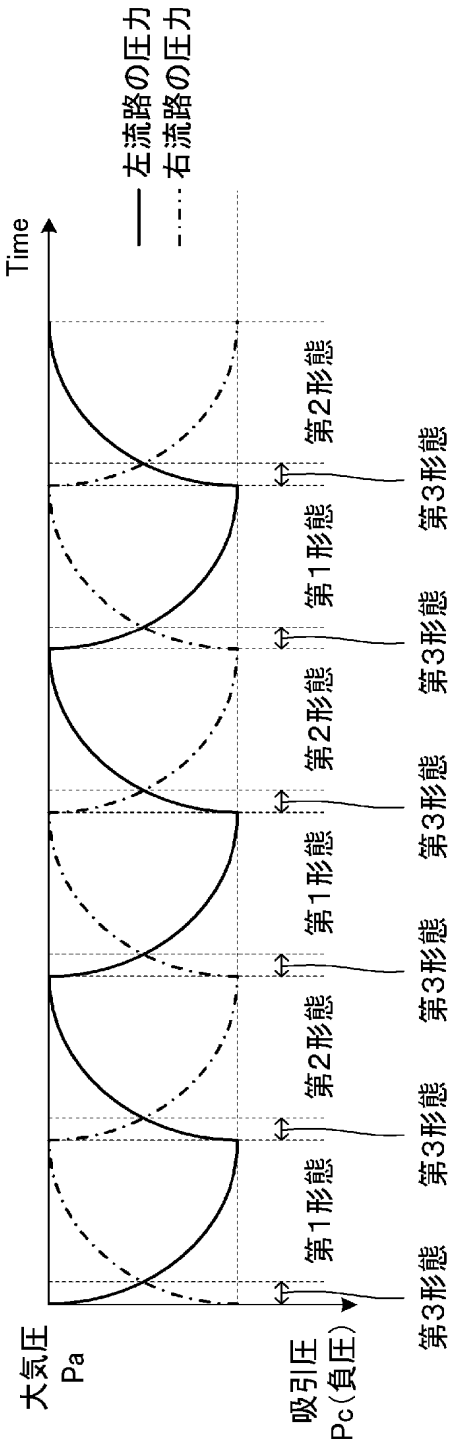
[図14]

図14


400
31
30
ポンプ
99
32
10
V1
V2
1
S1
S2
2
11
12
25
26
15
16
70
18
19
制御部
容器
14

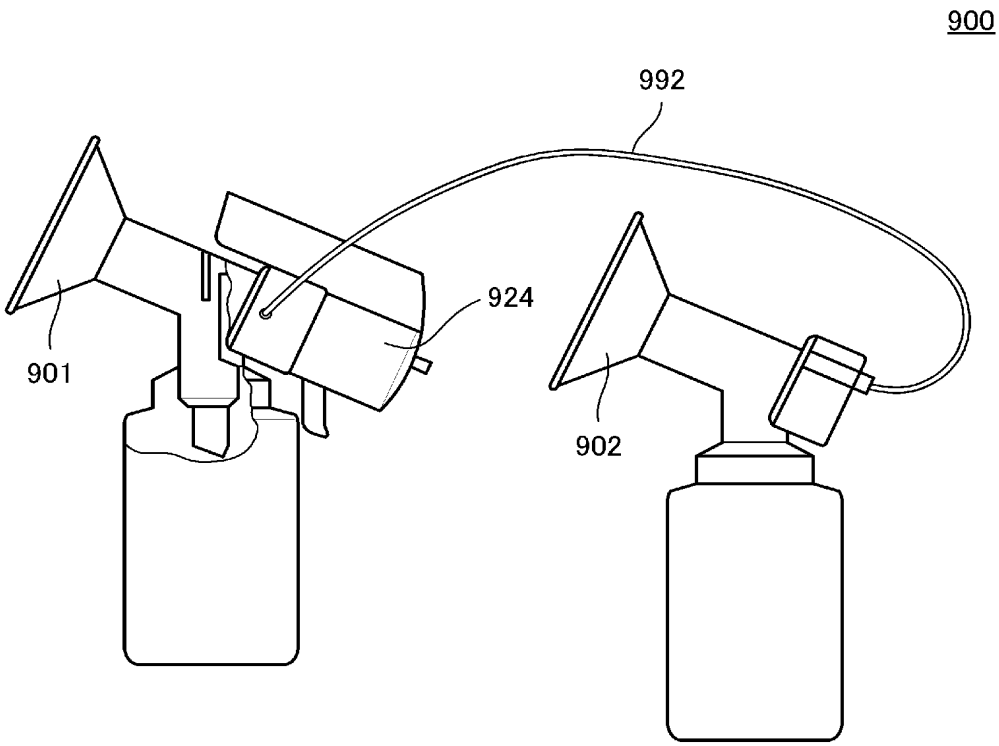
[図15]

図15


左流路の圧力
右流路の圧力
Time
大気圧
Pa
吸引圧
Pc(負圧)
第3形態
第1形態
第3形態
第2形態
第3形態
第1形態
第3形態
第2形態
第3形態
第1形態
第3形態
第2形態

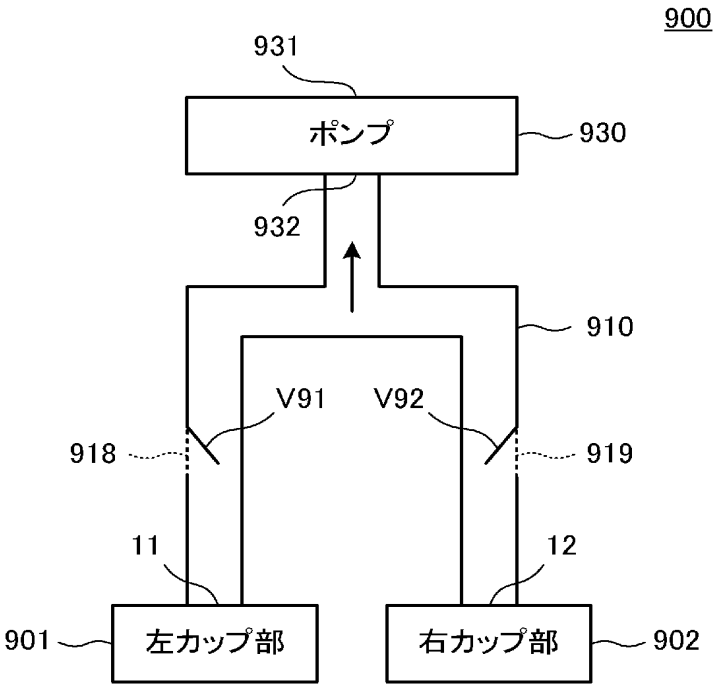
[図16]

図16



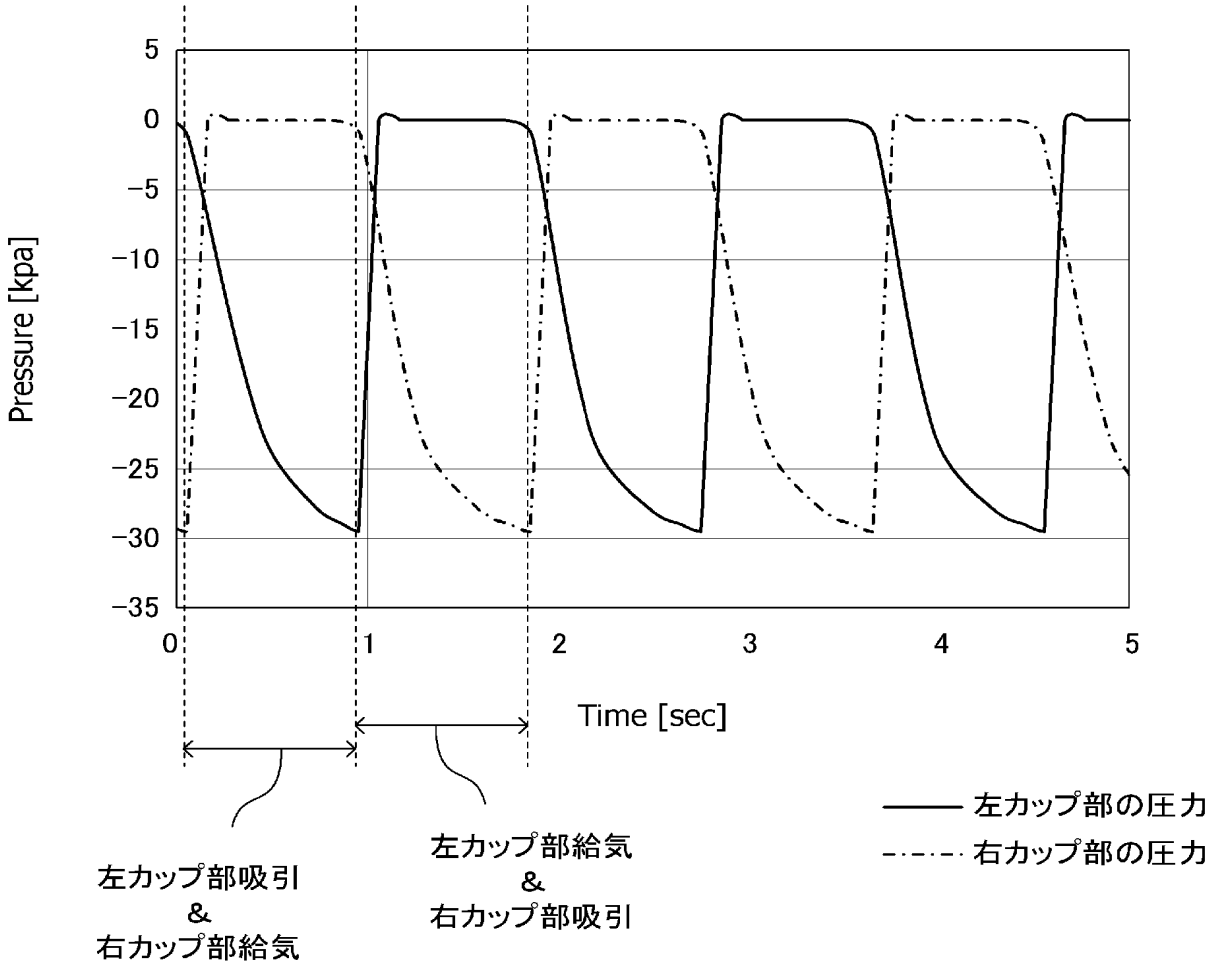
[図17]

図17


900
931
ポンプ
930
932
910
V91
V92
918
919
11
12
901
左カップ部
右カップ部
902

[図18]

図18


5
0
−5
−10
−15
−20
−25
−30
−35
Pressure [kpa]
0
1
2
3
4
5
Time [sec]
左カップ部吸引
&
右カップ部給気
左カップ部給気
&
右カップ部吸引
左カップ部の圧力
右カップ部の圧力

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/073077

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/06(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 2005/0283112 A1 (BRITTO James Joseph), 22 December 2005 (22.12.2005), paragraphs [0036] to [0039]; fig. 5A, 5B & CA 2510385 A1	1-2,5 6-8 3-4
Y	WO 2010/083485 A2 (LEARNING CURVE BRANDS, INC.), 22 July 2010 (22.07.2010), paragraph [0024]; fig. 5 & US 2011/0270163 A1 & US 2013/0102958 A1	6-7
Y	JP 2013-533428 A (Koninklijke Philips N.V.), 22 August 2013 (22.08.2013), paragraph [0071] & US 2013/0123689 A1 & WO 2012/014135 A1 & EP 2412392 A1 & CN 102343116 A	8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 November 2015 (02.11.15)	17 November 2015 (17.11.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０７３０７７

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/06

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X Y A	US 2005/0283112 A1 (BRITTO James Joseph) 2005.12.22, [0036]-[0039], 第5A図, 第5B図 & CA 2510385 A1	1-2,5 6-8 3-4
Y	WO 2010/083485 A2 (LEARNING CURVE BRANDS,INC.) 2010.07.22, [0024], 第5図 & US 2011/0270163 A1 & US 2013/0102958 A1	6-7

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日 ０２．１１．２０１５	国際調査報告の発送日 １７．１１．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｉ　９６２３ 寺澤　忠司 電話番号　０３－３５８１－１１０１　内線　３３８６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	JP 2013-533428 A（コーニンクレッカ　フィリップス　エヌ　ヴェ）2013.08.22, 【0071】 & US 2013/0123689 A1 & WO 2012/014135 A1 & EP 2412392 A1 & CN 102343116 A	8

(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2016 年 6 月 30 日(30.06.2016)

WIPO | PCT

(10) 国際公開番号
WO 2016/104673 A1

(51) 国際特許分類:
F16K 7/17 (2006.01) *A61M 27/00* (2006.01)
A61M 1/06 (2006.01) *F16K 17/164* (2006.01)

(21) 国際出願番号: PCT/JP2015/086169

(22) 国際出願日: 2015 年 12 月 25 日(25.12.2015)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

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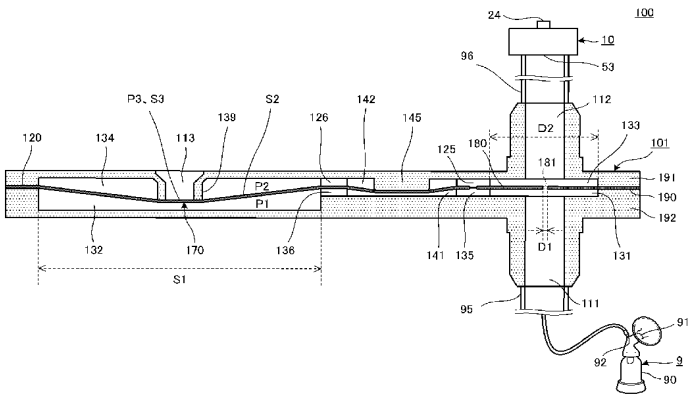
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[続葉有]

(54) **Title**: VALVE AND FLUID CONTROL DEVICE

(54) 発明の名称 : バルブ、流体制御装置

[図1]



(57) **Abstract**: A fluid control device (100) is provided with a piezoelectric pump (10), an inspirator (9), and a valve (101). The piezoelectric pump (10) has a gas intake hole (53) and a gas discharge hole (24). The inspirator (9) has a container (90), an intake port (91), and a connecting hole (92). The valve (101) has a first aeration hole (111), a second aeration hole (112), a third aeration hole (113), a first valve casing (191), a second valve casing (192), and a valve body (190). The first aeration hole (111) of the valve (101) is connected to the connecting hole (92) of the inspirator (9). The second aeration hole (112) of the valve (101) is connected to the intake hole (53) of the piezoelectric pump (10). The third aeration hole (113) of the valve (101) is open to the atmosphere. The valve body (190) is held between the first valve casing (191) and the second valve casing (192), constituting a first area and a second area.

(57) 要約:

[続葉有]

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流体制御装置（１００）は、圧電ポンプ（１０）と吸入器（９）とバルブ（１０１）とを備える。圧電ポンプ（１０）は、気体の吸引孔（５３）と気体の吐出孔（２４）とを有する。吸入器（９）は、容器（９０）と吸入口（９１）と接続孔（９２）とを有する。バルブ（１０１）は、第１通気孔（１１１）と第２通気孔（１１２）と第３通気孔（１１３）と第１弁筐体（１９１）と第２弁筐体（１９２）と弁体（１９０）とを有する。バルブ（１０１）の第１通気孔（１１１）は吸入器（９）の接続孔（９２）に接続する。バルブ（１０１）の第２通気孔（１１２）は圧電ポンプ（１０）の吸引孔（５３）に接続する。バルブ（１０１）の第３通気孔（１１３）は大気開放されている。弁体（１９０）は、第１弁筐体（１９１）及び第２弁筐体（１９２）に挟持され、第１領域と第２領域を構成する。

明　細　書

発明の名称 ： バルブ、流体制御装置

技術分野

[0001] この発明は、気体の流れを切り替えるバルブ、及び当該バルブを備える流体制御装置に関する。

背景技術

[0002] 従来、気体の流れをバルブによって制御する流体制御装置が各種考案されている。例えば特許文献１には、ポンプとバルブとを備える流体制御装置が開示されている。

[0003] ポンプは、空気の吸引孔と空気の吐出孔とを有している。

[0004] バルブは、ダイヤフラムと第１弁筐体と第２弁筐体とを備え、それらが順に積層された構造を有している。さらに、バルブには、通気孔と排気口とカフ接続口とが設けられている。通気孔には、ポンプの吐出孔が接続されている。排気口は大気開放されている。

[0005] バルブのダイヤフラムは、ダイヤフラムの両面にかかる圧力差に基づいて排気口を閉塞または開放する。カフの腕帯ゴム管がバルブのカフ接続口に接続されることにより、流体制御装置がカフに接続されている。

[0006] 以上の構成において、特許文献１の流体制御装置は、ポンプを駆動し、空気をポンプの吐出孔からバルブ内へ吐出する。ダイヤフラムは、バルブ内へ吐出された空気の圧力によって排気口を閉塞する。そのため、バルブ内へ吐出された空気は、カフ接続口からカフ内へ流入する。これにより、特許文献１の流体制御装置は、カフ内に圧縮空気を充填する。

[0007] この後、ポンプが駆動を停止すると、ダイヤフラムは、カフの圧力によって排気口を開放する。そのため、カフ内の圧縮空気は、排気口から排気される。よって、特許文献１のバルブは、カフ（流路）内の圧力を受動的に大気開放することができる。

先行技術文献

特許文献

[0008] 特許文献1：特許第５１８５４７５号公報

発明の概要

発明が解決しようとする課題

[0009] しかしながら、特許文献１のバルブは、容器内から気体を吸引して、容器内の圧力を負圧にする吸引動作には対応していない。

[0010] また、患者の体内に挿入されたチューブ（流路）を介して、体液や空気などの流体を体内から容器内へ吸引する吸引装置がある。吸引装置では吸引中、チューブの吸入口が体内の組織に密着した場合、チューブが閉塞するという問題がある。この問題を回避するため、吸引装置は、圧力センサや流量計などを使ってチューブの閉塞状態を検知し、電磁バルブなどを使ってチューブ（流路）内の圧力を能動的に大気開放させる安全機能を備える。

[0011] しかし、この安全機能を備えるためには、圧力センサや流量計や電磁バルブなどの部品が必要となる。そのため、従来の吸引装置には、装置本体が大型化したり装置本体のコストが高価になったりするという問題がある。

[0012] 本発明の目的は、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができるバルブ、及び当該バルブを備える流体制御装置を提供することにある。

課題を解決するための手段

[0013] 本発明のバルブは、前記課題を解決するために以下の構成を備えている。

[0014] （１）第１通気孔、第２通気孔、及び第３通気孔を有する弁筐体と、

第１通気孔に連通する第１領域と第２通気孔に連通する第２領域とを弁筐体内に構成する弁体と、を備え、

弁体は、第１領域と第２領域とを連通させる第１貫通孔を有する固定部と、第２通気孔と第３通気孔との連通状態を切替える可動部と、を有し、

弁体は、

第１領域の圧力が第２領域の圧力よりも高い場合、第２通気孔と第３通気

孔との連通を遮断するとともに、第１貫通孔を介して第１通気孔と第２通気孔とを連通させ、

第１領域の圧力が第２領域の圧力以下の場合、第２通気孔と第３通気孔とを連通させるとともに、第１貫通孔を介して第１通気孔と第２通気孔とを連通させるよう、

弁筐体に固定されている。

[0015] この構成では、例えば、吸入口を有する吸入器を第１通気孔に接続し、ポンプの吸引孔を第２通気孔に接続し、第３通気孔を大気開放する。この場合においてポンプが駆動すると、第２領域の空気が第２通気孔及び吸引孔を介してポンプ内に吸引される。そして、ポンプ内の空気が吐出孔から吐出される。

[0016] 弁体の固定部では、第１領域と第２領域とが第１貫通孔を介して連通するものの、第１貫通孔によって圧力損失（流路抵抗）が生じる。そのため、バルブでは、第１領域の圧力が第２領域の圧力より高くなる。

[0017] このため、可動部は、第１領域と第２領域の圧力差を利用して第３通気孔を閉塞し、第２通気孔と第３通気孔との連通を遮断することができる。

[0018] よって、この構成のバルブでは、第１領域の圧力が第２領域の圧力より高い場合、空気は、第１通気孔から第１貫通孔を通って第２通気孔へ流れる。

[0019] この結果、吸入器の容器内の気体が第１通気孔を介してバルブの第１領域へ排出され、第２通気孔及び吸引孔を介してポンプ内に吸引される。これにより、容器内の圧力（気体の圧力）が大気圧から低下し、負圧になる。そのため、吸入器は、容器外部の液体（例えば母乳、血液、胸水、痰など）を吸入口から容器内へ吸入することができる。

[0020] 次に、ポンプが駆動を停止した時、容器内の圧力がポンプの最大吸引圧力に達した時、又はチューブ等の流路が閉塞した時、第１領域の圧力が第１貫通孔によって第２領域の圧力と等しくなる。ただし、この時点における第１領域の圧力と第２領域の圧力とは、大気圧以下である。

[0021] そのため、可動部は、大気圧を利用して第３通気孔を開放し、第２通気孔

と第３通気孔とを連通させることができる。

[0022] これにより、空気は、第３通気孔から第１貫通孔を通って第１通気孔へ流れる。そして、第１通気孔から流出した空気は、チューブを介して容器内へ流入する。これにより、容器内の圧力（空気圧）が上昇し、大気圧に戻る。

[0023] したがって、この構成のバルブは、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。

[0024] （２）可動部は、第１領域と第２領域との圧力差により、弁筐体の一部である第１部分に対して接触または離間し、連通状態を切り替えることが好ましい。

[0025] この構成において、可動部は、第１領域の圧力が第２領域の圧力よりも高い場合、弁筐体の第１部分に対して接触し、第２通気孔と第３通気孔との連通を遮断する。

[0026] 一方、可動部は、第１領域の圧力が第２領域の圧力以下の場合、弁筐体の第１部分に対して離間し、第２通気孔と第３通気孔とを連通させる。

[0027] （３）弁筐体は、第３通気孔と、第２領域において第３通気孔の周囲から可動部側へ突出した弁座と、を第１部分に有し、

弁体は、可動部が弁座に接触するよう、弁筐体に固定されていることが好ましい。

[0028] この構成において、可動部は、第１領域の圧力が第２領域の圧力よりも高い場合、弁座に対して接触し、第２通気孔と第３通気孔との連通を遮断する。

[0029] 一方、可動部は、第１領域の圧力が第２領域の圧力以下の場合、弁座に対して離間し、第２通気孔と第３通気孔とを連通させる。

[0030] （４）可動部は、第２通気孔と第１通気孔及び第３通気孔とが連通しているとき、第１領域と第２領域とを連通させる第２貫通孔を有することが好ましい。

[0031] （５）可動部は、弁筐体の一部である第２部分に対して接触または離間することにより第２貫通孔を閉塞または開放し、

弁体は、

第１領域の圧力が第２領域の圧力よりも高い場合、第２貫通孔を閉塞し、

第１領域の圧力が第２領域の圧力以下の場合、第２貫通孔を開放し、第１貫通孔および第２貫通孔を介して第１通気孔と第２通気孔と第３通気孔とを連通させるよう、

弁筐体に固定されていることが好ましい。

[0032] この構成において、可動部は、第１領域の圧力が第２領域の圧力よりも高い場合、弁筐体の第２部分に対して接触し、第２貫通孔を閉塞する。

[0033] 一方、可動部は、第１領域の圧力が第２領域の圧力以下の場合、弁筐体の第２部分から離間し、第２貫通孔を開放する。この場合、空気は、第３通気孔から第２貫通孔を通って第１通気孔へ流れる。

[0034] すなわち、この構成では、空気は、第３通気孔から第１貫通孔および第２貫通孔の両方を通って第１通気孔へ流れる。

[0035] そのため、空気は、第３通気孔から容器内へ急速に流入する。これにより、容器内の圧力（空気圧）が上昇し、大気圧に速やかに戻る。

[0036] したがって、この構成のバルブは、流路内の圧力を短時間で、受動的に大気開放することができる。

[0037] （６）弁筐体は、第１領域に連通する第４通気孔を有することが好ましい。

[0038] この構成のバルブは、ポンプが駆動し続ける間、容器の減圧状態を維持することができる。

[0039] （７）第４通気孔の断面積は、第１通気孔の断面積より小さいことが好ましい。

[0040] （８）第４通気孔の断面積は、第１貫通孔の断面積より大きいことが好ましい。

[0041] （９）弁筐体は、気体を通過させ、液体の通過を阻止するフィルタを有することが好ましい。

[0042] この構成のバルブでは、吸引時に液体が付着してフィルタの通気抵抗が増加すると、第１領域と第２領域の圧力差が無くなり、可動部が第３通気孔を

開放する。この大気開放によって空気が通過する際に音が発生する。

[0043] したがって、この構成では、看護師等が大気開放時の音によりフィルタが目詰まりしたことを容易に検出できる。

[0044] また、本発明の流体制御装置は、前記課題を解決するために以下の構成を備えている。

[0045] （１０）上記（１）～（９）のいずれかに記載のバルブと、

吸引孔を有し、吸引孔から気体を吸引するポンプと、

流体を吸入する吸入口を有する吸入器と、を備え、

バルブの第１通気孔は、吸入器の一部に連通し、

バルブの第２通気孔は、ポンプの吸引孔に連通している。

[0046] この構成により、上記（１）～（９）のいずれかのバルブを用いることで、当該バルブを備える流体制御装置も同様の効果を奏する。

[0047] （１１）吸入器は、吸入口から母乳を吸入することが好ましい。

[0048] この構成では、流体制御装置は搾乳機として用いられる。吸入口から吸入された母乳は、容器に貯蔵される。

[0049] （１２）吸入器は、

吸入口に接続し、吸入口から吸入された液体を貯蔵する第１容器と、

第１容器に接続し、気体を通過させて液体の通過を阻止する第２容器と、

第２容器およびポンプの吸引孔に接続し、ポンプが吸引する気体の吸引圧力を調整する第３容器と、を有することが好ましい。

[0050] この構成では、流体制御装置はドレナージとして用いられる。吸入口から吸入された血液や胸水等は、第１容器に貯蔵される。

発明の効果

[0051] 本発明は、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。

図面の簡単な説明

[0052] [図1]本発明の第１実施形態に係る流体制御装置１００の断面図である。

[図2]図１に示すバルブ１０１の外観斜視図である。

[図3]図１に示すバルブ１０１の側面図である。

[図4]図１に示すバルブ１０１の分解斜視図である。

[図5]図１に示すバルブ１０１の分解斜視図である。

[図6]図１に示す圧電ポンプ１０の外観斜視図である。

[図7]図６に示す圧電ポンプ１０の分解斜視図である。

[図8]図６に示す圧電ポンプ１０のＳ－Ｓ線の断面図である。

[図9]図９は、図６に示す圧電ポンプ１０を１次モードで動作させた時における圧電ポンプ１０のＳ－Ｓ線の断面図である。図９（Ａ）はポンプ室の容積が増大したときの図、図９（Ｂ）はポンプ室の容積が減少したときの図である。

[図10]圧電ポンプ１０が駆動している間における流体制御装置１００の空気の流れを示す説明図である。

[図11]圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又は流路が閉塞した時における、流体制御装置１００の空気の流れを示す説明図である。

[図12]圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．２５ｍｍであるバルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。

[図13]圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．４０ｍｍであるバルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。

[図14]圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．７０ｍｍであるバルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。

[図15]本発明の第２実施形態に係る流体制御装置２００の断面図である。

[図16]圧電ポンプ１０が駆動している間における流体制御装置２００の空気の流れを示す説明図である。

[図17]圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又は流路が閉塞した時における、流体制御装置２００の空気の流れを示す説明図である。

[図18]本発明の第３実施形態に係る流体制御装置３００の外観図である。

[図19]図１８に示すバルブ３０１の断面図である。

[図20]本発明の第４実施形態に係る流体制御装置４００の断面図である。

[図21]本発明の第４実施形態の変形例に係る流体制御装置４５０の断面図である。

[図22]本発明の第５実施形態に係る流体制御装置５００の断面図である。

[図23]圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置５００の空気の流れを示す説明図である。

[図24]容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置５００の空気の流れを示す説明図である。

[図25]圧電ポンプ１０が駆動を停止した直後における、流体制御装置５００の空気の流れを示す説明図である。

[図26]本発明の第６実施形態に係る流体制御装置６００の断面図である。

[図27]圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置６００の空気の流れを示す説明図である。

[図28]容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置６００の空気の流れを示す説明図である。

[図29]圧電ポンプ１０が駆動を停止した直後における、流体制御装置６００の空気の流れを示す説明図である。

発明を実施するための形態

[0053] 以下、本発明の第１実施形態に係る流体制御装置１００について説明する

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[0054] 図１は、本発明の第１実施形態に係る流体制御装置１００の断面図である。流体制御装置１００は、圧電ポンプ１０と吸入器９とバルブ１０１とを備える。流体制御装置１００は、液体（例えば母乳など）を吸引する装置である。図１に示すバルブ１０１は、後述の図２に示すＴ－Ｔ線の断面に相当する。

[0055] 圧電ポンプ１０は、詳細を後述するが、気体を吸引するための吸引孔５３と気体を吐出するための吐出孔２４とを有する。

[0056] 吸入器９は、容器９０と吸入口９１と接続孔９２とを有する。吸入器９は、例えば搾乳器である。吸入口９１は、例えばヒトや動物の乳房に装着する。容器９０は、液体（例えば母乳など）を貯蔵する。

[0057] バルブ１０１は、詳細を後述するが、第１通気孔１１１と第２通気孔１１２と第３通気孔１１３とを有する。バルブ１０１の第１通気孔１１１は、吸入器９の接続孔９２に接続する。バルブ１０１の第２通気孔１１２は、圧電ポンプ１０の吸引孔５３に接続する。バルブ１０１の第３通気孔１１３は、大気開放されている。

[0058] なお、図１において、バルブ１０１の第１通気孔１１１と吸入器９の接続孔９２とは、チューブ９５を介して接続されている。同様に、図１において、バルブ１０１の第２通気孔１１２と圧電ポンプ１０の吸引孔５３とも、チューブ９６を介して接続されている。実施の際、これらの接続は、任意の接続方法を採用すればよい。

[0059] 次に、バルブ１０１と圧電ポンプ１０との構造について詳述する。まず、図１～図５を用いてバルブ１０１の構造について詳述する。

[0060] 図２は、図１に示すバルブ１０１の外観斜視図である。図３は、図１に示すバルブ１０１の側面図である。図４、図５は、図１に示すバルブ１０１の分解斜視図である。図４は、当該バルブ１０１を上面側から見た分解斜視図であり、図５は、当該バルブ１０１を底面側から見た分解斜視図である。

[0061] バルブ１０１は、図２～図５に示すように、第２弁筐体１９２と、弁体１

９０と、第１弁筐体１９１とを備え、それらが順に積層された構造を有している。

[0062] 第１弁筐体１９１は、図１～図５に示すように、圧電ポンプ１０の吸引孔５３に連通する第２通気孔１１２と、流体制御装置１００外部に連通する第３通気孔１１３と、第３通気孔１１３の周囲から弁体１９０側へ突出した弁座１３９と、弁体１９０側へ突出した円柱状の弁座１４５と、第２上バルブ室１４２及び第１上バルブ室１３３を連通させる連通路１２５と、第２上バルブ室１４２及び第３上バルブ室１３４を連通させる連通路１２６と、を有する。第１弁筐体１９１は、例えば樹脂からなる。弁座１３９は中央部に第３通気孔１１３を有する円筒形状である。

[0063] なお、第１弁筐体１９１は、弁座１４５を有しているが、必ずしも有する必要は無い。また、第２上バルブ室１４２、第２下バルブ室１４１を、必ずしも有する必要はない。連通路１２５と連通路１２６、連通路１３５と連通路１３６が連通していればよい。

[0064] 第２弁筐体１９２は、図１～図５に示すように、吸入器９の接続孔９２に連通する第１通気孔１１１と、第２下バルブ室１４１及び第１下バルブ室１３１を連通させる連通路１３５と、第２下バルブ室１４１及び第３下バルブ室１３２を連通させる連通路１３６と、を有する。第２弁筐体１９２は、例えば樹脂からなる。

[0065] 弁体１９０は、固定部１８０と可動部１２０とを有する。固定部１８０は、例えば樹脂からなる。可動部１２０は、長方形状のダイヤフラムで構成される。可動部１２０の材料は、例えばＥＰＤＭ（エチレンプロピレンジエンゴム）やシリコーンなどのゴムである。固定部１８０と可動部１２０とは、接着剤等で接着されている。

[0066] 第１上バルブ室１３３及び第１下バルブ室１３１に接触する固定部１８０の領域の中心部には、図１～図５に示すように、円形の第１貫通孔１８１が設けられている。第１貫通孔１８１は、第１上バルブ室１３３及び第１下バルブ室１３１を連通させる。

[0067] 弁体１９０は、例えば両面テープや接着剤等を介して第１弁筐体１９１及び第２弁筐体１９２に挟持されている。

[0068] 弁体１９０は、図１に示すように、可動部１２０の一部が弁座１３９、１４５に接触するよう、第１弁筐体１９１および第２弁筐体１９２に固定されている。

[0069] 弁体１９０は、第１弁筐体１９１及び第２弁筐体１９２に固定されることにより、第１弁筐体１９１及び第２弁筐体１９２内を分割する。

[0070] これにより、弁体１９０は、図１～図５に示すように、第１弁筐体１９１及び第２弁筐体１９２内に、円柱状の第１下バルブ室１３１と、円柱状の第２下バルブ室１４１と、円柱状の第３下バルブ室１３２と、円柱状の第１上バルブ室１３３と、円環状の第２上バルブ室１４２と、円環状の第３上バルブ室１３４と、を構成する。

[0071] ここで、第１下バルブ室１３１は、第１通気孔１１１に連通する。第１下バルブ室１３１は、連通路１３５を介して第２下バルブ室１４１に連通する。第３下バルブ室１３２は、連通路１３６を介して第２下バルブ室１４１に連通する。

[0072] また、第１上バルブ室１３３は、第２通気孔１１２に連通する。第１上バルブ室１３３は、連通路１２５を介して第２上バルブ室１４２に連通する。第３上バルブ室１３４は、連通路１２６を介して第２上バルブ室１４２に連通する。

[0073] なお、第１下バルブ室１３１、連通路１３５、第２下バルブ室１４１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」の一例に相当する。第１上バルブ室１３３、連通路１２５、第２上バルブ室１４２、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」の一例に相当する。弁座１３９が本発明の「弁座」の一例に相当する。

[0074] また、弁体１９０は、図１に示すように、排気弁１７０を、第１弁筐体１９１及び第２弁筐体１９２とともに構成する。排気弁１７０は、第３下バルブ室１３２と第３上バルブ室１３４と弁座１３９と第３下バルブ室１３２及

び第３上バルブ室１３４に面する弁体１９０の領域とで構成される。

[0075] 排気弁１７０では、図１に示すように、第３下バルブ室１３２に面する弁体１９０の部分の面積をＳ１、第３下バルブ室１３２の圧力をＰ１、第３上バルブ室１３４に面する弁体１９０の部分の面積をＳ２、第３上バルブ室１３４の圧力をＰ２、第３通気孔１１３に面する弁体１９０の部分の面積をＳ３、第３通気孔１１３の圧力（本実施形態では大気圧）をＰ３、としたとき、弁体１９０の可動部１２０が以下の状態となる。

[0076] すなわち、Ｓ１×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）の関係を満たす場合、可動部１２０は弁座１３９に接触する。Ｓ１×（Ｐ１－Ｐ２）≦Ｓ３×（Ｐ３－Ｐ１）の関係を満たす場合、可動部１２０は弁座１３９から離間する。

[0077] 次に、図６、図７、図８を用いて圧電ポンプ１０の構造について詳述する。

[0078] 図６は、図１に示す圧電ポンプ１０の外観斜視図である。図７は、図６に示す圧電ポンプ１０の分解斜視図である。図８は、図６に示す圧電ポンプ１０のＳ－Ｓ線の断面図である。

[0079] 圧電ポンプ１０は、上から順に、外筐体１７、天板３７、側板３８、振動板３９、圧電素子４０、及びキャップ４２を備え、それらを順に積層した構造を有している。天板３７、側板３８、及び振動板３９は、ポンプ室３６を構成している。圧電ポンプ１０は、幅２０ｍｍ×長さ２０ｍｍ×ノズル１８以外の領域の高さ１．８５ｍｍの寸法となっている。

[0080] 外筐体１７は、空気が吐出される吐出孔２４が中心に形成されたノズル１８を有する。このノズル１８は、外形の直径２．０ｍｍ×内形（即ち吐出孔２４）の直径０．８ｍｍ×高さ１．６ｍｍの寸法となっている。外筐体１７の四角には、ネジ穴５６Ａ～５６Ｄが形成されている。

[0081] 外筐体１７は、下方が開口した断面コ字状に形成されており、外筐体１７は、ポンプ室３６の天板３７、ポンプ室３６の側板３８、振動板３９及び圧電素子４０を収納する。外筐体１７は、例えば樹脂から構成される。

[0082] ポンプ室３６の天板３７は、円板状であり、例えば金属から構成されている。天板３７には、中央部６１と、中央部６１から水平方向に突出し、外筐体１７の内壁に当接する鍵状の突出部６２と、外部回路に接続するための外部端子６３とが形成されている。

[0083] また、天板３７の中央部６１には、ポンプ室３６の内部と外部とを連通させる通気孔４５が設けられている。この通気孔４５は、外筐体１７の吐出孔２４と対向する位置に形成されている。天板３７は、側板３８の上面に接合する。

[0084] ポンプ室３６の側板３８は、円環状であり、例えば金属から構成されている。側板３８は、振動板３９の上面に接合する。そのため、側板３８の厚みは、ポンプ室３６の高さとなる。

[0085] 振動板３９は、円板状であり、例えば金属から構成されている。振動板３９は、ポンプ室３６の底面を構成する。

[0086] 圧電素子４０は、円板形状であり、例えばチタン酸ジルコン酸鉛系セラミックスから構成されている。圧電素子４０は、振動板３９のポンプ室３６とは逆側の主面に接合されており、印加された交流電圧に応じて屈曲する。圧電素子４０及び振動板３９は、アクチュエータを構成する。

[0087] そして、天板３７、側板３８、振動板３９、及び圧電素子４０の接合体は、天板３７に設けられている４個の突出部６２によって外筐体１７に対して弾性的に支持されている。

[0088] 電極導通用板７０は、圧電素子４０に接続するための内部端子７３と、外部回路に接続するための外部端子７２とで構成されている。内部端子７３の先端は圧電素子４０の平板面にはんだ付けされている。はんだ付け位置を圧電素子４０の屈曲振動の節に相当する位置とすることにより、内部端子７３の振動がより抑制できる。

[0089] キャップ４２には、円板形状の吸引孔５３が形成されている。吸引孔５３の直径は、圧電素子４０の直径より長い。また、キャップ４２には、外筐体１７のネジ穴５６Ａ～５６Ｄに対応する位置に切欠き５５Ａ～５５Ｄが形成

されている。

[0090] また、キャップ４２は、外周縁に、天板３７側へ突出する突出部５２を有する。キャップ４２は、突出部５２で外筐体１７を挟持し、ポンプ室３６の天板３７、ポンプ室３６の側板３８、振動板３９及び圧電素子４０を、外筐体１７とともに収納する。キャップ４２は、例えば樹脂から構成されている。

[0091] そして、図８に示すように、天板３７、側板３８、振動板３９及び圧電素子４０の接合体と外筐体１７及びキャップ４２との間には通気路３１が形成されている。

[0092] 次に、駆動している時の圧電ポンプ１０の動作について説明する。

[0093] 図９（Ａ）（Ｂ）は、図３に示す圧電ポンプ１０を１次モードの周波数（基本波）で動作させた時における圧電ポンプ１０のＳ－Ｓ線の断面図である。ここで、図中の矢印は、空気の流れを示している。

[0094] 図８に示す状態において、１次モードの周波数（基本波）の交流駆動電圧が外部端子６３，７２から圧電素子４０に印加されると、振動板３９は同心円状に屈曲振動する。同時に、天板３７は、振動板３９の屈曲振動に伴うポンプ室３６の圧力変動により、振動板３９の屈曲振動に伴って（この実施形態では振動位相が１８０°遅れて）同心円状に屈曲振動する。

[0095] これにより、図９（Ａ）（Ｂ）に示すように、振動板３９及び天板３７が屈曲変形してポンプ室３６の体積が周期的に変化する。

[0096] 図９（Ａ）に示すように、圧電素子４０に交流電圧を印加して振動板３９を圧電素子４０側へ屈曲させると、ポンプ室３６の容積が増大する。これに伴い、圧電ポンプ１０の外部の空気が吸引孔５３、通気路３１、及び通気孔４５を介してポンプ室３６内に吸引される。ポンプ室３６からの空気の流出は無いものの、吐出孔２４から圧電ポンプ１０の外部への空気の流れの慣性力が働いている。

[0097] 図９（Ｂ）に示すように、圧電素子４０に交流電圧を印加して振動板３９をポンプ室３６側へ屈曲させると、ポンプ室３６の容積が減少する。これに

伴い、ポンプ室３６内の空気が通気孔４５、通気路３１を介して吐出孔２４から吐出する。

[0098] このとき、ポンプ室３６から吐出される空気が，圧電ポンプ１０の外部の空気を吸引孔５３及び通気路３１を介して引き込みながら吐出孔２４から吐出する。そのため、圧電ポンプ１０では、吐出孔２４から吐出される空気の流量が、引き込まれる空気の流量分増大する。

[0099] 次に、流体制御装置１００の空気の流れについて説明する。

[0100] 図１０は、圧電ポンプ１０が駆動している間における流体制御装置１００の空気の流れを示す説明図である。図１０中の矢印は、空気の流れを示している。

[0101] なお、前述したように、第１下バルブ室１３１、連通路１３５、第２下バルブ室１４１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」に相当する。第１上バルブ室１３３、連通路１２５、第２上バルブ室１４２、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」に相当する。弁座１３９が本発明の「弁座」に相当する。

[0102] まず、ユーザが、吸入器９の吸入口９１を例えばヒトや動物の乳房に装着する。圧電ポンプ１０が駆動する前における容器９０内の圧力は大気圧となっている。流体制御装置１００は、吸入器９による液体の吸入を開始するとき、圧電ポンプ１０をオンする。

[0103] 圧電ポンプ１０が駆動すると、第１上バルブ室１３３の空気が第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引される。そして、圧電ポンプ１０内の空気が吐出孔２４から吐出される。

[0104] しかし、弁体１９０の固定部１８０では、第１下バルブ室１３１と第１上バルブ室１３３とが第１貫通孔１８１を介して連通するものの、第１貫通孔１８１によって圧力損失（流路抵抗）が生じる。そのため、第１下バルブ室１３１の圧力が第１上バルブ室１３３の圧力より高くなる。

[0105] また、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より高くなる。このため、可動部１２０は、第３下バルブ室１

３２と第３上バルブ室１３４との圧力差を利用して第３通気孔１１３を閉塞する。これにより、可動部１２０は第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0106] 即ち、弁体１９０は、第１領域の圧力が第２領域の圧力より高い場合、第２通気孔１１２と第３通気孔１１３との連通を遮断するとともに、第１貫通孔１８１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0107] よって、空気は、第１通気孔１１１から第１貫通孔１８１を通って第２通気孔１１２へ流れる。第２通気孔１１２から流出した空気は、吸引孔５３を介して圧電ポンプ１０内に吸引され、吐出孔２４から吐出される。

[0108] この結果、吸入器９の容器９０内の空気が接続孔９２から第１通気孔１１１を介してバルブ１０１の第２下バルブ室１４１へ排出される。これにより、容器９０内の圧力（空気圧）が大気圧より低下し、負圧になる。

[0109] そのため、吸入器９は、容器９０外部の液体（例えば母乳など）を吸入口９１から容器９０内へ吸入することができる。吸入器９は、液体を容器９０内に貯蔵し、容器９０内の空気を接続孔９２から排出する。

[0110] 図１１は、圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又は流路が閉塞した時における、流体制御装置１００の空気の流れを示す説明図である。図１１中の矢印は、空気の流れを示している。

[0111] 圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又はチューブ等の流路が閉塞した時、第１下バルブ室１３１の圧力が第１貫通孔１８１によって第１上バルブ室１３３の圧力と等しくなる。

[0112] ただし、第１下バルブ室１３１の圧力と第１上バルブ室１３３の圧力とは、大気圧以下である。そのため、排気弁１７０では可動部１２０が、弁座１３９から離間して第３通気孔１１３を開放する。

[0113] 即ち、弁体１９０は、第１領域の圧力が第２領域の圧力以下の場合、第２通気孔１１２と第３通気孔１１３とを連通させるとともに、第１貫通孔１８

１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0114] そのため、空気は、図１１に示すように、第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第２上バルブ室１４２、第１上バルブ室１３３、第１貫通孔１８１、及び第１下バルブ室１３１を経由して第１通気孔１１１へ流れる。そして、第１通気孔１１１から流出した空気は、チューブを介して容器９０内へ流入する。

[0115] これにより、容器９０内の圧力（空気圧）が上昇し、大気圧に戻る。そのため、吸入器９は、吸入口９１を、ヒトや動物の乳房から容易に取り外すことができる。

[0116] 以上より、この実施形態のバルブ１０１は、第１貫通孔１８１の流路抵抗による第１領域及び第２領域の圧力差によって第３通気孔１１３を開閉している。

[0117] 従って、この実施形態のバルブ１０１は、圧力センサや流量計や電磁バルブなどの特別な部品を設けることなく、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。

[0118] また、電磁バルブと異なり、バルブ１０１は、前述したように受動的に弁を開閉する。そのため、バルブ１０１は、電磁バルブより消費電力を削減できる。よって、バルブ１０１は、少ない消費電力で駆動することが求められる搾乳器に好適である。

[0119] また、この実施形態のバルブ１０１を備える流体制御装置１００も同様の効果を奏する。

[0120] 次に、第１貫通孔１８１の直径Ｄ１を変化させた３つのバルブ１０１を比較する。

[0121] 図１２は、圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．２５ｍｍであるバルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。図１３は、圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．４０ｍｍであるバルブ１０１の第

１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。図１４は、圧電ポンプ１０を駆動している間における、第１貫通孔１８１の直径Ｄ１が０．７０ｍｍであるバルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差と第２通気孔１１２から流出する空気の流量とを測定した結果を示す図である。

[0122] まず、第１貫通孔１８１の直径Ｄ１が０．２５ｍｍ、０．４０ｍｍ、又は０．７０ｍｍである３つのバルブ１０１を用意する。そして、各バルブ１０１の第２通気孔１１２に圧電ポンプ１０を接続し、圧電ポンプ１０を駆動した条件で、各バルブ１０１の第１通気孔１１１及び第２通気孔１１２の圧力差（ｋＰａ）と第２通気孔１１２から流出する空気の流量（Ｌ／ｍｉｎ）とを測定した結果を表１～表３に示す。

[0123] [表1]

流量 L/min	圧力差 （理論値） kPa	圧力差 （実験値） kPa
0.2	2.9	3.5
0.3	6.7	9.0
0.4	11.9	14.5
0.5	18.6	19.5

[0124]

[表2]

流量 L/min	圧力差 （理論値） kPa	圧力差 （実験値） kPa
0.35	1.4	1.6
0.5	2.8	2.8
0.65	4.8	4.0
0.8	7.3	5.2

[0125] [表3]

流量 L/min	圧力差 （理論値） kPa	圧力差 （実験値） kPa
0.35	0.1	0.4
0.5	0.3	0.7
0.65	0.5	1.0
0.8	0.8	1.3

[0126] なお、表１～表３では、圧力差（実験値）は、第１通気孔１１１の圧力と第２通気孔１１２の圧力とを実際に測定し、両圧力の差を計算した値を示している。また、圧力差（理論値）は、シミュレーターで当該両圧力の差を算出した値を示している。

[0127] また、表１の圧力差（実験値）及び流量は図１２のグラフに対応する。同様に、表２の圧力差（実験値）及び流量は図１３のグラフに対応する。表１３の圧力差（実験値）及び流量は図１４のグラフに対応する。

[0128] 実験により、バルブ１０１では第１貫通孔１８１の直径Ｄ１が大きくなっていくにつれて、流量が増加し、圧力差が小さくなっていくことが明らかと

なった。

[0129] 以上の結果になった理由は、第１貫通孔１８１の直径Ｄ１が大きくなっていくにつれて、第１貫通孔１８１の流路抵抗が小さくなっていくためであると考えられる。

[0130] ここで、第１貫通孔１８１の断面積をｓ１、第１貫通孔１８１を通過する空気の流速をｖ１、第１貫通孔１８１を通過する空気の流量をｑ１、第１貫通孔１８１を通過する空気の圧力をｐ１、第１上バルブ室１３３の断面積をｓ２、第１上バルブ室１３３を通過する空気の流速をｖ２、第１上バルブ室１３３を通過する空気の流量をｑ２、第１上バルブ室１３３を通過する空気の圧力をｐ２、空気密度をρとしたとき、

ベルヌーイの定理「$p_1/\rho+v_1^2/2=p_2/\rho+v_2^2/2$」が成立する。そして、ベルヌーイの定理から、以下に示す圧力差「$p_1-p_2=\rho\cdot v_1^2/2=\rho\cdot(q_1/s_1)^2/2$」を求めることができる。

[0131] なお、ｓ１に比べ、十分に広いところではｖ２≒０と考えてよい。

[0132] また、第１上バルブ室１３３及び第１下バルブ室１３１の直径Ｄ２に対して第１貫通孔１８１の直径Ｄ１は十分に小さいことが、ベルヌーイの定理では必要である。そのため、第１貫通孔１８１の直径Ｄ１は、第１上バルブ室１３３及び第１下バルブ室１３１の直径Ｄ２の１／３以下であれば、誤差は１０％以下と計算できる。

[0133] また、第１貫通孔１８１の長さＬは、第１貫通孔１８１を流れる際の空気抵抗（損失）が十分小さいと考えることのできる範囲の長さであることが必要である。第１貫通孔１８１の長さＬは、固定部１８０の厚みに等しい。第１貫通孔１８１を空気が流れる際の損失は、ポアズイユの式から概算できる。その式から第１貫通孔１８１の長さＬは第１貫通孔１８１の直径Ｄ１の倍の長さ以下であれば、誤差は１０％以下と計算できる。

[0134] したがって、例えば、図１に示す直径Ｄ２が１０ｍｍであれば、直径Ｄ１が０．２５ｍｍから０．７ｍｍまでの長さである場合、前述のＤ１＜Ｄ２／３の関係を満たす。さらに、第１貫通孔１８１の長さＬが０．１ｍｍである

場合、前述のＬ＜２Ｄ１の関係を満たす。

[0135] 以下、本発明の第２実施形態に係る流体制御装置２００について説明する。

[0136] 図１５は、本発明の第２実施形態に係る流体制御装置２００の断面図である。流体制御装置２００が流体制御装置１００と相違する点は、バルブ２０１が第２貫通孔１２２を有する点である。弁体２９０の可動部２２０には、弁座１４５に対向する領域の中心部に円形の第２貫通孔１２２が設けられている。その他の構成は同じであるため、説明を省略する。

[0137] 第２貫通孔１２２の直径は、可動部２２０に当接する弁座１４５の面の直径よりも小さい。

[0138] 弁体２９０は、図１５に示すように、可動部２２０の一部が弁座１３９に接触し、可動部２２０における第２貫通孔１２２の周囲が弁座１４５に接触するよう、第１弁筐体１９１および第２弁筐体１９２に固定されている。このとき、弁座１４５は、弁体２９０における第２貫通孔１２２の周囲を与圧する。

[0139] 弁体２９０は、図１５に示すように、逆止弁１４０を、第１弁筐体１９１及び第２弁筐体１９２とともに構成する。逆止弁１４０は、第２下バルブ室１４１と第２上バルブ室１４２と弁座１４５と第２下バルブ室１４１及び第２上バルブ室１４２に面する弁体２９０の領域とで構成される。

[0140] 逆止弁１４０では、第２下バルブ室１４１と第２上バルブ室１４２との圧力差によって弁体２９０における第２貫通孔１２２の周囲が弁座１４５に対して当接または離間する。これにより、逆止弁１４０は、第２上バルブ室１４２から第２下バルブ室１４１への空気の流れを許可し、第２下バルブ室１４１から第２上バルブ室１４２への空気の流れを遮断する。

[0141] 次に、流体制御装置２００の空気の流れについて説明する。

[0142] 図１６は、圧電ポンプ１０が駆動している間における流体制御装置２００の空気の流れを示す説明図である。

[0143] 圧電ポンプ１０が駆動している間における流体制御装置２００の空気の流

れは、図１０に示す流体制御装置１００の空気の流れと同じである。逆止弁１４０では、第２下バルブ室１４１の圧力が第２上バルブ室１４２の圧力より高くなる。このため、可動部２２０における第２貫通孔１２２の周囲が弁座１４５に接触したままの状態を維持する。

[0144] 図１７は、圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又は流路が閉塞した時における、流体制御装置２００の空気の流れを示す説明図である。

[0145] 圧電ポンプ１０が駆動を停止した時、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達した時、又はチューブ等の流路が閉塞した時、第１下バルブ室１３１の圧力が第１貫通孔１８１によって第１上バルブ室１３３の圧力と等しくなる。

[0146] ただし、第１下バルブ室１３１の圧力と第１上バルブ室１３３の圧力とは、大気圧以下である。そのため、排気弁１７０では可動部２２０が、弁座１３９から離間して第３通気孔１１３を開放する。

[0147] 即ち、弁体２９０は、第１領域の圧力が第２領域の圧力以下の場合、第２通気孔１１２と第３通気孔１１３とを連通させるとともに、第１貫通孔１８１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0148] そのため、空気は、第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第２上バルブ室１４２、連通路１２５、第１上バルブ室１３３、第１貫通孔１８１、及び第１下バルブ室１３１を経由して第１通気孔１１１へ流れる（図１７参照）。

[0149] さらに、逆止弁１４０では、排気弁１７０が開いた後、第２下バルブ室１４１の圧力が第２上バルブ室１４２の圧力より低下する。このため、可動部２２０における第２貫通孔１２２の周囲が弁座１４５から離間し、第１通気孔１１１と第２領域とを連通させる。そのため、空気は、第３通気孔１１３から第２貫通孔１２２を通って第１通気孔１１１へ流れる。

[0150] すなわち、バルブ２０１では空気は、第３通気孔１１３から第１貫通孔１８１および第２貫通孔１２２の両方を通って第１通気孔１１１へ流れる。

[0151] そのため、バルブ２０１では空気は、第１通気孔１１１から容器９０内へ急速に流入する。これにより、バルブ２０１では容器９０内の圧力（空気圧）が上昇し、大気圧に速やかに戻る。

[0152] したがって、バルブ２０１は、流体の吸引動作に対応し、流路内の圧力を短時間で、受動的に大気開放することができる。また、電磁バルブと異なり、バルブ２０１は、前述したように受動的に弁を開閉する。そのため、バルブ２０１は、電磁バルブより消費電力を削減できる。よって、バルブ２０１は、少ない消費電力で駆動することが求められる搾乳器に好適である。また、この実施形態のバルブ２０１を備える流体制御装置２００も同様の効果を奏する。

[0153] 以下、本発明の第３実施形態に係る流体制御装置３００について説明する。

[0154] 図１８は、本発明の第３実施形態に係る流体制御装置３００の外観図である。図１９は、図１８に示すバルブ３０１の断面図である。流体制御装置３００は、液体（例えば痰など）を吸引する装置である。流体制御装置３００は、ポンプ３１０と吸入器３０９とバルブ３０１とを備える。

[0155] ポンプ３１０は、空気を吸引するための吸引孔３５３と、空気を吐出するための吐出孔（不図示）と、空気の吸引圧力を示す圧力計３１５と、を有する。

[0156] 吸入器３０９は、容器３９０と接続孔３９２とチューブ３９４とを有する。チューブ３９４の先端である吸入口３９１は、例えばヒトや動物の口腔内に挿入される。容器３９０は、液体（例えば痰など）を貯蔵する。

[0157] バルブ３０１がバルブ１０１と相違する点は、フィルタ３５０を筐体３９３内に有する点である。フィルタ３５０は、気体を通過させ、液体の通過を阻止する。フィルタ３５０は、感染や汚染防止のため、例えばバクテリアを吸着する。フィルタ３５０は、筐体３９３の内壁に接着剤等で接合されている。その他のバルブ３０１の構成はバルブ１０１と同じであるため、説明を省略する。

[0158] 以上の構成において、吸入口３９１は、チューブ３９４を介して容器３９０に接続する。バルブ３０１の第１通気孔１１１は、チューブ３９５を介して吸入器３０９の接続孔３９２に接続する。バルブ３０１の第２通気孔１１２は、チューブ３９６を介してポンプ３１０の吸引孔３５３に接続する。バルブ３０１の第３通気孔１１３は、大気開放されている。

[0159] 次に、ポンプ３１０が駆動している間における流体制御装置３００の空気の流れは、図１０に示す流体制御装置１００の空気の流れとほぼ同じである。流体制御装置３００において空気は、フィルタ３５０を通過しながら流れる。

[0160] ポンプ３１０が駆動を停止した時、容器３９０内の圧力がポンプ３１０の最大吸引圧力に達した時、又は流路が閉塞した時における流体制御装置３００の空気の流れも、図１１に示す流体制御装置１００の空気の流れとほぼ同じである。流体制御装置３００において空気は、フィルタ３５０を通過しながら流れる。

[0161] 例えば、吸入口３９１は、吸着対象物がない状態で人体の組織を吸引すると、閉塞する。吸入口３９１の閉塞により流量が低下し、第１領域と第２領域との圧力差が０になる。これにより、可動部１２０が自動的に第３通気孔１１３を開放し、吸入口３９１が大気解放される。

[0162] したがって、バルブ３０１は、バルブ１０１と同様の効果を奏する。すなわち、バルブ３０１は、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。また、バルブ３０１を備える流体制御装置３００も同様の効果を奏する。

[0163] ここで、ポンプ３１０が駆動している間、フィルタ３５０に液体が付着した場合、フィルタ３５０が詰り、フィルタ３５０の流路抵抗（通気抵抗）が増加する。すなわち、流体制御装置３００は、空気を適切に吸引できなくなる。

[0164] 一般的な従来の吸引装置もフィルタを備えるが、フィルタが詰まったことを検出することができない。従来の吸引装置では看護師等が、フィルタの外

観を確認したりフィルタの使用時間を管理したりして、フィルタを交換している。すなわち、従来の吸引装置では、フィルタの定量的な管理が難しかった。

[0165] 一方、流体制御装置３００のバルブ３０１では、フィルタ３５０の流路抵抗が増加すると、第１領域と第２領域の圧力差が無くなり、可動部１２０が第３通気孔１１３を開放する。この大気開放によって空気が通過する際に音が発生する。

[0166] したがって、バルブ３０１及び流体制御装置３００では、看護師等が大気開放時の音によりフィルタ３５０が詰まったことを容易に検出できる。

[0167] 以下、本発明の第４実施形態に係る流体制御装置４００について説明する。

[0168] 図２０は、本発明の第４実施形態に係る流体制御装置４００の断面図である。図２０中に示す矢印は、流体の流れを示している。流体制御装置４００は、液体（例えば胸水や血液など）を吸引するドレナージである。流体制御装置４００は、ポンプ４１０と吸入器４０９とバルブ１０１とを備える。

[0169] ポンプ４１０は、任意のポンプであり、空気を吸引するための吸引孔（不図示）と、空気を吐出するための吐出孔（不図示）と、を有する。

[0170] 吸入器４０９は、所謂胸腔ドレーンバックである。吸入器４０９は、第１容器４９０Ａと第２容器４９０Ｂと第３容器４９０Ｃとチューブ４３０と接続孔４９２とチューブ４３７とを有する。チューブ４３０の先端である吸入口４９１は、患者４０８の胸腔内に挿入される。患者４０８は、例えばヒトや動物である。

[0171] 第１容器４９０Ａは、所謂排液ボトルである。第１容器４９０Ａは、吸入口４９１に接続する。第１容器４９０Ａは、吸入口４９１から吸入された患者４０８の液体Ｂ（例えば胸水や血液など）を貯蔵する。

[0172] 第２容器４９０Ｂは、所謂水封ボトルである。第２容器４９０Ｂは、第１容器４９０Ａに接続する。第２容器４９０Ｂ内には、水Ｗ１が入れられている。第２容器４９０Ｂは、空気を水Ｗ１の中で通過させて、空気の流れを可

視化する。

[0173] 第３容器４９０Ｃは、は、所謂吸引圧制御ボトルである。第３容器４９０Ｃは、第２容器４９０Ｂおよびポンプ４１０の吸引孔に接続する。第３容器４９０Ｃ内には、水Ｗ２が入れられている。第３容器４９０Ｃ内には、管４３６が挿入され、管４３６の先端は水Ｗ２に浸かっている。第３容器４９０Ｃは、水Ｗ２の水位と管４３６の先端から流入する空気とによって、ポンプ４１０が吸引する空気の吸引圧力を調整する。

[0174] バルブ１０１は、第３容器４９０Ｃの出口である接続孔４９２を塞ぐよう、第３容器４９０Ｃの内面に装着されている。バルブ１０１における第１通気孔１１１又は第２通気孔１１２のいずれか一方は、第３容器４９０Ｃの接続孔４９２に接続している。

[0175] 以上の構成において、吸引口４９１は、チューブ４３０を介して容器４９０Ａの内部に連通し、バルブ１０１の第１通気孔１１１は容器４９０Ｃの接続口４９３に連通し、バルブ１０１の第２通気孔１１２は、チューブ４３７を介して、ポンプ４１０の吸引孔（不図示）に連通する。バルブ１０１の第３通気孔１１３は大気解放されている。

[0176] 次に、ポンプ４１０が駆動している間における流体制御装置４００の空気の流れは、図１０に示す流体制御装置１００の空気の流れと同じである。

[0177] ポンプ４１０が駆動を停止した時、容器４９０Ａ内の圧力がポンプ４１０の最大吸引圧力に達した時、又は流路が閉塞した時における流体制御装置４００の空気の流れも、図１１に示す流体制御装置１００の空気の流れと同じである。

[0178] 例えば、吸入口４９１は、吸着対象物がない状態で人体の組織を吸引すると、閉塞する。吸入口４９１の閉塞により流量が低下し、第１領域と第２領域との圧力差が０になる。これにより、可動部１２０が自動的に第３通気孔１１３を開放し、吸入口４９１が大気解放される。

[0179] したがって、流体制御装置４００においてもバルブ１０１は、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。

[0180] また、肺気胸では傷口が小さくなり、流量が低下してきた場合、吸引を止めた方が治癒期間を短縮できるといわれている。そのため、自動的に吸入口４９１を開放するバルブ１０１は、肺気胸の治療に用いることが好適である。

[0181] また、バルブ１０１の構造が簡単で安価である事から、吸入器４０９及びバルブ１０１の使い捨て使用が可能となる。そのため、バルブ１０１は、病院のメンテナンス費用を削減できる。

[0182] また、バルブ１０１を備える流体制御装置４００も同様の効果を奏する。

[0183] 以下、本発明の第４実施形態の変形例に係る流体制御装置４５０について説明する。

図２１は、本発明の第４実施形態の変形例に係る流体制御装置４５０の断面図である。流体制御装置４５０が流体制御装置４００と相違する点は、バルブ１０１が、第３容器４９０Ｃの接続孔４９２を塞ぐよう第３容器４９０Ｃの外側に設けられている点である。

[0184] 詳述すると、バルブ１０１の第１通気孔１１１は、第３容器４９０Ｃの接続孔４９２に連通している。バルブ１０１の第２通気孔１１２は、チューブ４３７を介して、ポンプ４１０の吸引孔（不図示）に連通している。その他の構成に関しては同じであるため、説明を省略する。

[0185] また、ポンプ４１０が駆動している間における流体制御装置４５０の空気の流れは、図２０に示す流体制御装置４００の空気の流れと同じである。すなわち、ポンプ４１０が駆動を停止した時、容器４９０Ａ内の圧力がポンプ４１０の最大吸引圧力に達した時、又は流路が閉塞した時における流体制御装置４５０の空気の流れも、図２０に示す流体制御装置４００の空気の流れと同じである。

[0186] したがって、流体制御装置４５０においてもバルブ１０１は、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。また、バルブ１０１を備える流体制御装置４５０も同様の効果を奏する。

[0187] なお、図２０に示す流体制御装置４００と図２１に示す流体制御装置４５

０とでは、患者４０８がくしゃみなどをした場合、吸入器４０９内の圧力が大きく負圧になる。そのため、流体制御装置４００及び流体制御装置４５０は、吸入器４０９内の圧力をすぐに吸引圧まで戻すことが求められるが、吸入器４０９内の圧力は患者４０８が通常の呼吸を行うことによっても、微小に減圧される。

[0188] しかし、患者４０８が通常の呼吸を行う度に、バルブ１０１が頻繁に開いて吸入器４０９内の圧力が吸引圧まで戻ることは、患者４０８の負担になる。

[0189] そこで、バルブ１０１は、突起１３９と突起１４５の寸法を調整することで、バルブ１０１が開く圧力を調整することができる。そのため、流体制御装置４００及び流体制御装置４５０のそれぞれは、患者４０８の通常の呼吸によってバルブ１０１を開かず、くしゃみなどにより吸入器４０９内の圧力が大きく減圧した場合にのみバルブ１０１を開くように調整することができる。

[0190] 以下、本発明の第５実施形態に係る流体制御装置５００について説明する。

[0191] 図２２は、本発明の第５実施形態に係る流体制御装置５００の断面図である。流体制御装置５００が図１に示す流体制御装置１００と相違する点は、バルブ５０１である。バルブ５０１がバルブ１０１と相違する点は、第２弁筐体５９２が第４通気孔１１４を有する点である。第４通気孔１１４は第１領域に連通する。第４通気孔１１４の直径は、第１通気孔１１１の直径に比べて小さい。また、第４通気孔１１４の直径は、第２通気孔１１２の直径に比べて小さい。その他の流体制御装置５００の構成に関しては、流体制御装置１００の構成と同じであるため、説明を省略する。

[0192] なお、前述したように、第１下バルブ室１３１、連通路１３５、第２下バルブ室１４１、連通路１３６及び第３下バルブ室１３２が、本発明の「第１領域」に相当する。第１上バルブ室１３３、連通路１２５、第２上バルブ室１４２、連通路１２６及び第３上バルブ室１３４が、本発明の「第２領域」

に相当する。弁座１３９が本発明の「弁座」に相当する。

[0193] 次に、流体制御装置５００の空気の流れについて説明する。流体制御装置５００の空気の流れは、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達するまでの第１段階と、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの第２段階と、圧電ポンプ１０が駆動を停止した直後における第３段階と、に分かれている。

[0194] まず、第１段階における空気の流れについて説明する。

図２３は、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置５００の空気の流れを示す説明図である。なお、図中の矢印は、空気の流れを示している。

[0195] まず、ユーザが、吸入器９の吸入口９１を例えばヒトや動物の乳房に装着する。圧電ポンプ１０が駆動する前における容器９０内の圧力は大気圧となっている。流体制御装置５００は、吸入器９による液体の吸入を開始するとき、圧電ポンプ１０をオンする。

[0196] 圧電ポンプ１０が駆動すると、第２上バルブ室１３３の空気が第２通気孔１１２及び吸引孔５３を介して圧電ポンプ１０内に吸引される。そして、圧電ポンプ１０内の空気が吐出孔２４から吐出される。

[0197] しかし、弁体１９０の固定部１８０では、第１下バルブ室１３１と第１上バルブ室１３３とが第１貫通孔１８１を介して連通するものの、第１貫通孔１８１によって圧力損失（流路抵抗）が生じる。そのため、第１下バルブ室１３１の圧力が第１上バルブ室１３３の圧力より高くなる。

[0198] また、排気弁１７０では、第３下バルブ室１３２の圧力が第３上バルブ室１３４の圧力より高くなる。このため、可動部１２０は、第３下バルブ室１３２と第３上バルブ室１３４との圧力差を利用して第３通気孔１１３を閉塞する。これにより、可動部１２０は第２通気孔１１２と第３通気孔１１３との連通を遮断する。

[0199] 即ち、弁体１９０は、第１領域の圧力が第２領域の圧力より高い場合、第

２通気孔１１２と第３通気孔１１３との連通を遮断するとともに、第１貫通孔１８１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0200] よって、空気は、第１通気孔１１１から第１貫通孔１８１を通って第２通気孔１１２へ流れる。第２通気孔１１２から流出した空気は、吸引孔５３を介して圧電ポンプ１０内に吸引され、吐出孔２４から吐出される。

[0201] この結果、吸入器９の容器９０内の空気が接続孔９２から第１通気孔１１１を介してバルブ５０１の第１下バルブ室１４１へ排出される。これにより、容器９０内の圧力（空気圧）が大気圧より低下し、負圧になる。

[0202] そのため、吸入器９は、容器９０外部の液体（例えば母乳など）を吸入口９１から容器９０内へ吸入することができる。吸入器９は、液体を容器９０内に貯蔵し、容器９０内の空気を接続孔９２から排出する。

[0203] ここで、流体制御装置５００では、第４通気孔１１４を介して、少量の空気がバルブ５０１の外部からバルブ５０１の内部へ吸引される。そのため、流体制御装置５００では流体制御装置１００に比べて、容器９０から吸引される空気の流量が減る。

[0204] しかし、第４通気孔１１４の直径は第１通気孔１１１の直径に比べて微小であるため、影響が小さい。そのため、空気は主に第１通気孔１１１からバルブ５０１の内部へ吸引され、容器９０から圧電ポンプ１０へ空気が流れる。これにより、排気弁１７０では、Ｐ２＜Ｐ１の関係と（Ｓ１－Ｓ３）×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。

[0205] ところで、図１０に示す流体制御装置１００において圧電ポンプ１０が長時間駆動し続けた場合、容器９０内の空気が十分に減少し、容器９０内の圧力が最大吸引圧力に達する。これによりＰ１とＰ２の圧力差が無くなる。この結果、第３通気孔１１３が開き、空気が第３通気孔１１３から第２領域へ流入し、Ｐ２＜Ｐ１の関係を維持できなくなる可能性がある。すなわち、流体制御装置１００は、十分な吸引力を維持することができなくなる可能性がある。

[0206] そこで、流体制御装置５００の第２段階における空気の流れについて説明

する。

図２４は、容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置５００の空気の流れを示す説明図である。なお、図中の矢印は、空気の流れを示している。

[0207] 流体制御装置５００の第２段階では、空気が第４通気孔１１４から吸引され、第１貫通孔１８１を通って圧電ポンプ１０に空気が流れる。そのため、バルブ５０１は、第４通気孔１１４によって吸引時のＰ１とＰ２の差を一定値以上に保つことができる。排気弁１７０では、Ｐ２＜Ｐ１の関係と（Ｓ１－Ｓ３）×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）関係とが維持される。

[0208] 以上により、バルブ５０１は、第３通気孔１１３が閉じた状態を維持することができる。すなわちバルブ５０１は、圧電ポンプ１０が駆動し続ける間、容器９０の減圧状態を維持することができる。

[0209] 次に、第３段階における空気の流れについて説明する。

図２５は、圧電ポンプ１０が駆動を停止した直後における、流体制御装置５００の空気の流れを示す説明図である。なお、図中の矢印は、空気の流れを示している。

[0210] 吸入器９による液体の吸入を終了するとき、流体制御装置５００は、圧電ポンプ１０をオフし、圧電ポンプ１０の駆動を停止する。このとき、第１下バルブ室１３１の圧力が第１貫通孔１８１によって第１上バルブ室１３３の圧力と等しくなる。ただし、バルブ５０１の内部が大気圧より低くなっている。そのため、第４通気孔１１４を介して、少量の空気がバルブ５０１の外部からバルブ５０１の内部へ吸引される。

[0211] しかし、第４通気孔１１４の直径は第２通気孔１１２の直径に比べて微小であるため、影響が小さい。そのため、主に、圧電ポンプ１０の吐出孔２４から微量の空気が圧電ポンプ１０内へ流入し、吸引孔５３及び第２通気孔１１２を介して第２領域に流入する。

[0212] この結果、排気弁１７０では、第３下バルブ室１３２の圧力と第３上バルブ室１３４の圧力とが等しくなる。即ち排気弁１７０では、圧力Ｐ２＝Ｐ１

の関係と（Ｓ１－Ｓ３）×（Ｐ１－Ｐ２）＜Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。そのため、排気弁１７０では可動部１２０が、弁座１３９から離間して第３通気孔１１３を開放する。

[0213] 即ち、バルブ５０１では弁体１９０は、第１領域の圧力が第２領域の圧力以下の場合、第２通気孔１１２と第３通気孔１１３とを連通させるとともに、第１貫通孔１８１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0214] そのため、空気は、図２５に示すように、第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第２上バルブ室１４２、第１上バルブ室１３３、及び第１貫通孔１８１を経由して、第１下バルブ室１３１へ流れる。

[0215] このとき、第１下バルブ室１３１から第２下バルブ室１４１へ流れた少量の空気が、第４通気孔１１４を介してバルブ５０１の内部からバルブ５０１の外部へ流出する。しかし、第４通気孔１１４の直径は第１通気孔１１１の直径に比べて微小であるため、影響が小さい。そのため、第１下バルブ室１３１に流れた空気は主に、第１通気孔１１１からチューブを介して容器９０内へ流入する。

[0216] これにより、容器９０内の圧力（空気圧）が上昇し、大気圧に戻る。そのため、吸入器９は、吸入口９１を、ヒトや動物の乳房から容易に取り外すことができる。

[0217] 以上より、この実施形態のバルブ５０１は、第１貫通孔１８１の流路抵抗による第１領域及び第２領域の圧力差によって第３通気孔１１３を開閉している。

[0218] 従って、この実施形態のバルブ５０１は、圧力センサや流量計や電磁バルブなどの特別な部品を設けることなく、流体の吸引動作に対応し、流路内の圧力を受動的に大気開放することができる。

[0219] また、電磁バルブと異なり、バルブ５０１は、前述したように受動的に弁を開閉する。そのため、バルブ５０１は、電磁バルブより消費電力を削減で

きる。よって、バルブ５０１は、少ない消費電力で駆動することが求められる搾乳器に好適である。また、この実施形態のバルブ５０１を備える流体制御装置５００も同様の効果を奏する。

[0220] 以下、本発明の第６実施形態に係る流体制御装置６００について説明する。

[0221] 図２６は、本発明の第６実施形態に係る流体制御装置６００の断面図である。流体制御装置６００が図１５に示す流体制御装置２００と相違する点は、バルブ６０１である。バルブ６０１がバルブ２０１と相違する点は、第２弁筐体５９２が前述の第４通気孔１１４を有する点である。その他の流体制御装置６００の構成は流体制御装置２００の構成と同じであるため、説明を省略する。

[0222] また、流体制御装置６００が図２２に示す流体制御装置５００と相違する点は、バルブ６０１に備えられる弁体２９０の可動部２２０が前述の第２貫通孔１２２を有する点である。逆止弁１４０は前述したように、第２下バルブ室１４１と第２上バルブ室１４２と弁座１４５と第２下バルブ室１４１及び第２上バルブ室１４２に面する弁体２９０の領域とで構成される。その他の流体制御装置６００の構成は流体制御装置５００の構成と同じであるため、説明を省略する。

[0223] 次に、流体制御装置６００の空気の流れについて説明する。流体制御装置６００の空気の流れは、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達するまでの第１段階と、容器９０内の圧力が圧電ポンプ１０の最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの第２段階と、圧電ポンプ１０が駆動を停止した直後における第３段階と、に分かれている。

[0224] まず、第１段階における空気の流れについて説明する。

図２７は、圧電ポンプ１０が駆動を開始してから容器９０内の圧力が最大吸引圧力に達するまでの間における流体制御装置６００の空気の流れを示す説明図である。

[0225] 流体制御装置６００における第１段階の空気の流れは、流体制御装置５００における第１段階の空気の流れ（図２３参照）と同じである。逆止弁１４０では、第２下バルブ室１４１の圧力が第２上バルブ室１４２の圧力より高くなる。このため、可動部２２０における第２貫通孔１２２の周囲が弁座１４５に接触したままの状態を維持する。

[0226] 次に、第２段階における空気の流れについて説明する。

図２８は、容器９０内の圧力が最大吸引圧力に達してから圧電ポンプ１０が駆動を停止する前までの流体制御装置６００の空気の流れを示す説明図である。

[0227] 流体制御装置６００における第２段階の空気の流れは、流体制御装置５００における第２段階の空気の流れ（図２４参照）と同じである。逆止弁１４０では、第２下バルブ室１４１の圧力が第２上バルブ室１４２の圧力より高くなる。このため、可動部２２０における第２貫通孔１２２の周囲が弁座１４５に接触したままの状態を維持する。

[0228] 流体制御装置６００の第２段階においても、空気が第４通気孔１１４から吸引され、第１貫通孔１８１を通って圧電ポンプ１０に空気が流れる。そのため、バルブ５０１は、第４通気孔１１４によって吸引時のＰ１とＰ２の差を一定値以上に保つことができる。排気弁１７０では、Ｐ２＜Ｐ１の関係と（Ｓ１－Ｓ３）×（Ｐ１－Ｐ２）＞Ｓ３×（Ｐ３－Ｐ１）関係とが維持される。

[0229] 以上により、バルブ６０１は、第３通気孔１１３が閉じた状態を維持することができる。すなわちバルブ６０１は、圧電ポンプ１０が駆動し続ける間、容器９０の減圧状態を維持することができる。

[0230] 次に、第３段階における空気の流れについて説明する。

図２９は、圧電ポンプ１０が駆動を停止した直後における、流体制御装置６００の空気の流れを示す説明図である。

[0231] 吸入器９による液体の吸入を終了するとき、流体制御装置６００は、圧電ポンプ１０をオフし、圧電ポンプ１０の駆動を停止する。このとき、第１下

バルブ室１３１の圧力が第１貫通孔１８１によって第１上バルブ室１３３の圧力と等しくなる。ただし、バルブ６０１の内部が大気圧より低くなっている。そのため、第４通気孔１１４を介して、少量の空気がバルブ６０１の外部からバルブ６０１の内部へ吸引される。

[0232] しかし、第４通気孔１１４の直径は第２通気孔１１２の直径に比べて微小であるため、影響が小さい。そのため、主に、圧電ポンプ１０の吐出孔２４から微量の空気が圧電ポンプ１０内へ流入し、吸引孔５３及び第２通気孔１１２を介して第２領域に流入する。

[0233] この結果、排気弁１７０では、第３下バルブ室１３２の圧力と第３上バルブ室１３４の圧力とが等しくなる。即ち排気弁１７０では、圧力Ｐ２＝Ｐ１の関係と（Ｓ１－Ｓ３）×（Ｐ１－Ｐ２）＜Ｓ３×（Ｐ３－Ｐ１）関係とが成立する。そのため、排気弁１７０では可動部１２０が、弁座１３９から離間して第３通気孔１１３を開放する。

[0234] 即ち、バルブ６０１では弁体１９０は、第１領域の圧力が第２領域の圧力以下の場合、第２通気孔１１２と第３通気孔１１３とを連通させるとともに、第１貫通孔１８１を介して第１通気孔１１１と第２通気孔１１２とを連通させる。

[0235] そのため、空気は、図２９に示すように、第３通気孔１１３から流入し、第３上バルブ室１３４、連通路１２６、第２上バルブ室１４２、第１上バルブ室１３３、及び第１貫通孔１８１を経由して、第１下バルブ室１３１へ流れる。

[0236] さらに、逆止弁１４０では、排気弁１７０が開いた後、第２下バルブ室１４１の圧力が第２上バルブ室１４２の圧力より低下する。このため、可動部２２０における第２貫通孔１２２の周囲が弁座１４５から離間し、第１通気孔１１１と第２領域とを連通させる。そのため、空気は、第３通気孔１１３から第２貫通孔１２２及び第２下バルブ室１４１を通って第１下バルブ室１３１へ流れる。

[0237] すなわち、バルブ６０１では空気は、第３通気孔１１３から第１貫通孔１

８１および第２貫通孔１２２の両方を通って第１通気孔１１１へ流れる。

[0238] そのため、空気は、第１通気孔１１１から容器９０内へ急速に流入する。これにより、容器９０内の圧力（空気圧）が上昇し、大気圧に速やかに戻る。そのため、吸入器９は、吸入口９１を、ヒトや動物の乳房から速やかに取り外すことができる。

[0239] したがって、バルブ６０１は、流体の吸引動作に対応し、流路内の圧力を短時間で、受動的に大気開放することができる。また、電磁バルブと異なり、バルブ６０１は、前述したように受動的に弁を開閉する。そのため、バルブ６０１は、電磁バルブより消費電力を削減できる。よって、バルブ６０１は、少ない消費電力で駆動することが求められる搾乳器に好適である。また、この実施形態のバルブ６０１を備える流体制御装置６００も同様の効果を奏する。

[0240] なお、第３段階における空気の流れでは、第３通気孔１１３から第２貫通孔１２２を介して第２下バルブ室１４１へ流れた空気の一部が、第４通気孔１１４を介してバルブ６０１の内部からバルブ６０１の外部へ流出する。しかし、第４通気孔１１４の直径は第１通気孔１１１の直径に比べて微小であるため、影響が小さい。そのため、第１下バルブ室１３１に流れた空気は主に、第１通気孔１１１からチューブを介して容器９０内へ流入する。

[0241] 《その他の実施形態》

なお、前記実施形態では流体の一部として空気を用いているが、これに限るものではなく、当該流体が、空気以外の気体や液体であっても適用できる。

[0242] また、前述の実施形態においては、液体を吸入器で吸入する例を示したが、吸入する対象物は液体以外のもの（例えばゲル状の物質）であってもよい。

[0243] また、前述の実施形態においては、貫通孔の数は１つであるが、これに限るものではない。実施の際、貫通孔の数は２つ以上あってもよい。

[0244] また、前述の実施形態における圧電ポンプ１０は、圧電素子４０の伸縮に

よって屈曲振動するアクチュエータを備えるが、これに限るものではない。例えば、電磁駆動で屈曲振動するアクチュエータを備えてもよい。

[0245] また、前述の実施形態における圧電ポンプ１０は、ユニモルフ型で屈曲振動するアクチュエータを備えるが、振動板の両面に圧電素子を貼着してバイモルフ型で屈曲振動するアクチュエータを備えてもよい。

[0246] また、前述の実施形態において、圧電素子４０はチタン酸ジルコン酸鉛系セラミックスからなるが、これに限るものではない。例えば、ニオブ酸カリウムナトリウム系及びアルカリニオブ酸系セラミックス等の非鉛系圧電体セラミックスの圧電材料などからなってもよい。

[0247] 最後に、上述の実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、上述の実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0248] ９…吸入器

１０…圧電ポンプ

１７…外筐体

１８…ノズル

２４…吐出孔

３１…通気路

３６…ポンプ室

３７…天板

３８…側板

３９…振動板

４０…圧電素子

４２…キャップ

４５…通気孔

５２…突出部

５３…吸引孔

５５Ａ～Ｄ…切欠き

５６Ａ～Ｄ…ネジ穴

６１…中央部

６２…突出部

６３，７２…外部端子

７０…電極導通用板

７３…内部端子

９０…容器

９１…吸入口

９２…接続孔

９５、９６…チューブ

１００、２００、３００、４００、４５０、５００、６００…流体制御装置

１０１、２０１、３０１、５０１、６０１…バルブ

１１１…第１通気孔

１１２…第２通気孔

１１３…第３通気孔

１１４…第４通気孔

１２０…可動部

１２２…第２貫通孔

１２５、１２６…連通路

１３１…第１下バルブ室

１３２…第３下バルブ室

１３３…第１上バルブ室

１３４…第３上バルブ室

１３５、１３６…連通路

１３９…弁座

１４０…逆止弁

１４１…第２下バルブ室

１４２…第２上バルブ室

１４５…弁座

１７０…排気弁

１８０…固定部

１８１…第１貫通孔

１９０…弁体

１９１…第１弁筐体

１９２…第２弁筐体

２２０…可動部

２９０…弁体

３０９…吸入器

３１０…ポンプ

３１５…圧力計

３５０…フィルタ

３５３…吸引孔

３９０…容器

３９１…吸入口

３９２…接続孔

３９３…筐体

３９４、３９５、３９６…チューブ

４０８…患者

４０９…吸入器

４１０…ポンプ

４３０…チューブ

４３６…管

４３７…チューブ

４９０Ａ…第１容器

４９０Ｂ…第２容器

４９０Ｃ…第３容器

４９１…吸入口

４９２…接続孔

４９３…接続口

５９２…第２弁筐体

請求の範囲

[請求項1] 第１通気孔、第２通気孔、及び第３通気孔を有する弁筐体と、

前記第１通気孔に連通する第１領域と前記第２通気孔に連通する第２領域とを前記弁筐体内に構成する弁体と、を備え、

前記弁体は、前記第１領域と前記第２領域とを連通させる第１貫通孔を有する固定部と、前記第２通気孔と前記第３通気孔との連通状態を切替える可動部と、を有し、

前記弁体は、

前記第１領域の圧力が前記第２領域の圧力よりも高い場合、前記第２通気孔と前記第３通気孔との連通を遮断するとともに、前記第１貫通孔を介して前記第１通気孔と前記第２通気孔とを連通させ、

前記第１領域の圧力が前記第２領域の圧力以下の場合、前記第２通気孔と前記第３通気孔とを連通させるとともに、前記第１貫通孔を介して前記第１通気孔と前記第２通気孔とを連通させるよう、

前記弁筐体に固定されている、バルブ。

[請求項2] 前記可動部は、前記第１領域と前記第２領域との圧力差により、前記弁筐体の一部である第１部分に対して接触または離間し、前記連通状態を切り替える、請求項１に記載のバルブ。

[請求項3] 前記弁筐体は、前記第３通気孔と、前記第２領域において前記第３通気孔の周囲から前記可動部側へ突出した弁座と、を前記第１部分に有し、

前記弁体は、前記可動部が前記弁座に接触するよう、前記弁筐体に固定されている、請求項２に記載のバルブ。

[請求項4] 前記可動部は、前記第２通気孔と前記第１通気孔及び前記第３通気孔とが連通しているとき、前記第１領域と前記第２領域とを連通させる第２貫通孔を有する、請求項１から請求項３のいずれか１項に記載のバルブ。

[請求項5] 前記可動部は、前記弁筐体の一部である第２部分に対して接触また

は離間することにより、前記第２貫通孔を閉塞または開放し、

前記弁体は、

前記第１領域の圧力が前記第２領域の圧力よりも高い場合、前記第２貫通孔を閉塞し、

前記第１領域の圧力が前記第２領域の圧力以下の場合、前記第２貫通孔を開放し、前記第１貫通孔および前記第２貫通孔を介して前記第１通気孔と前記第２通気孔と前記第３通気孔とを連通させるよう、

前記弁筐体に固定されている、請求項４に記載のバルブ。

[請求項6] 前記弁筐体は、前記第１領域に連通する第４通気孔を有する、請求項１から請求項５のいずれか１項に記載のバルブ。

[請求項7] 前記第４通気孔の断面積は、前記第１通気孔の断面積より小さい、請求項６に記載のバルブ。

[請求項8] 前記第４通気孔の断面積は、前記第１貫通孔の断面積より大きい、請求項６に記載のバルブ。

[請求項9] 前記弁筐体は、気体を通過させ、液体の通過を阻止するフィルタを有する、請求項１から請求項８のいずれか１項に記載のバルブ。

[請求項10] 請求項１から請求項９のいずれか１項に記載のバルブと、

吸引孔を有し、前記吸引孔から気体を吸引するポンプと、

流体を吸入する吸入口を有する吸入器と、を備え、

前記バルブの前記第１通気孔は、前記吸入器の一部に連通し、

前記バルブの前記第２通気孔は、前記ポンプの前記吸引孔に連通している、流体制御装置。

[請求項11] 前記吸入器は、前記吸入口から母乳を吸入する、請求項１０に記載の流体制御装置。

[請求項12] 前記吸入器は、

前記吸入口に接続し、前記吸入口から吸入された液体を貯蔵する第１容器と、

前記第１容器に接続し、前記気体を通過させて前記液体の通過を阻

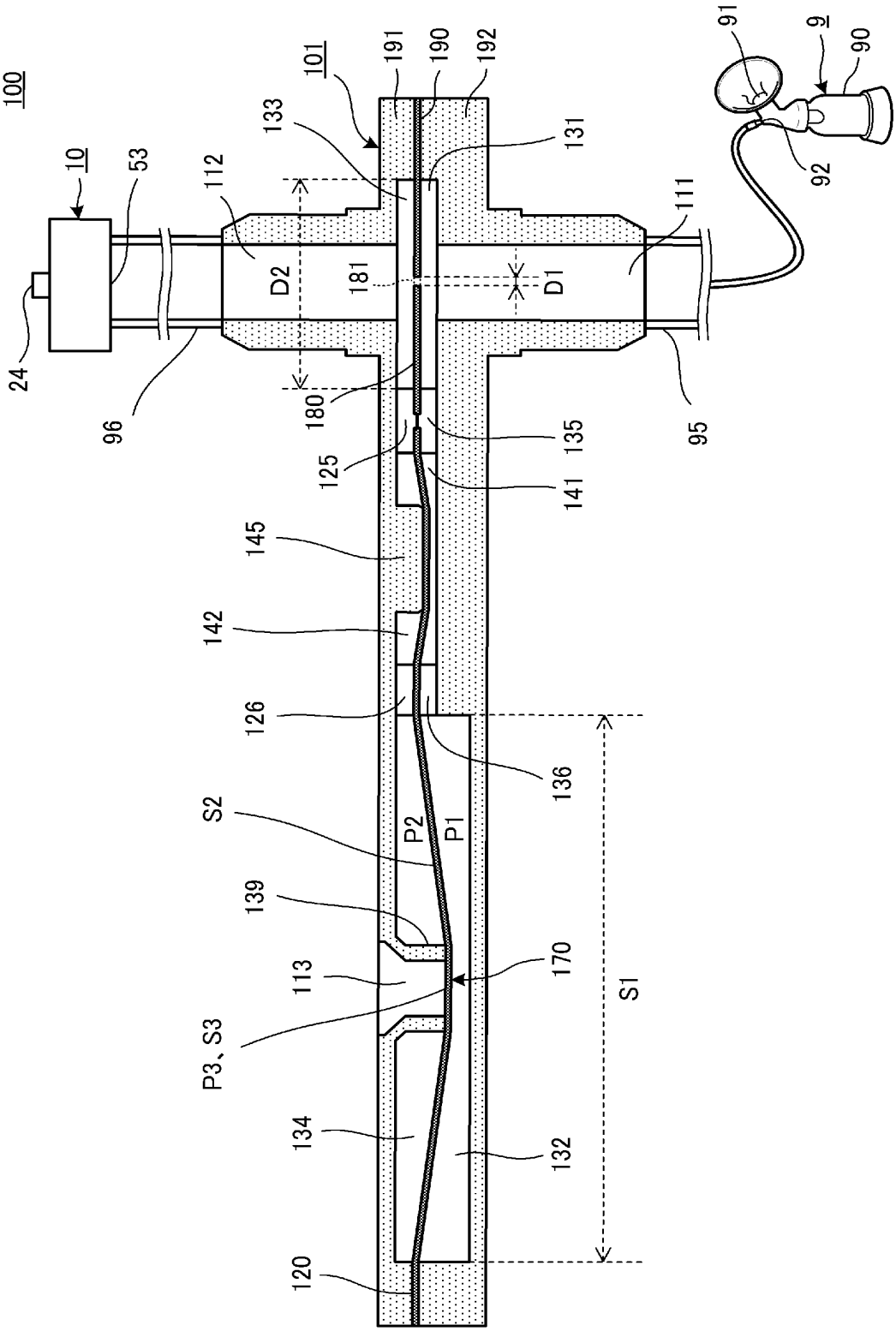
止する第２容器と、

前記第２容器および前記ポンプの前記吸引孔に接続し、前記ポンプが吸引する前記気体の吸引圧力を調整する第３容器と、

を有する、請求項１０に記載の流体制御装置。

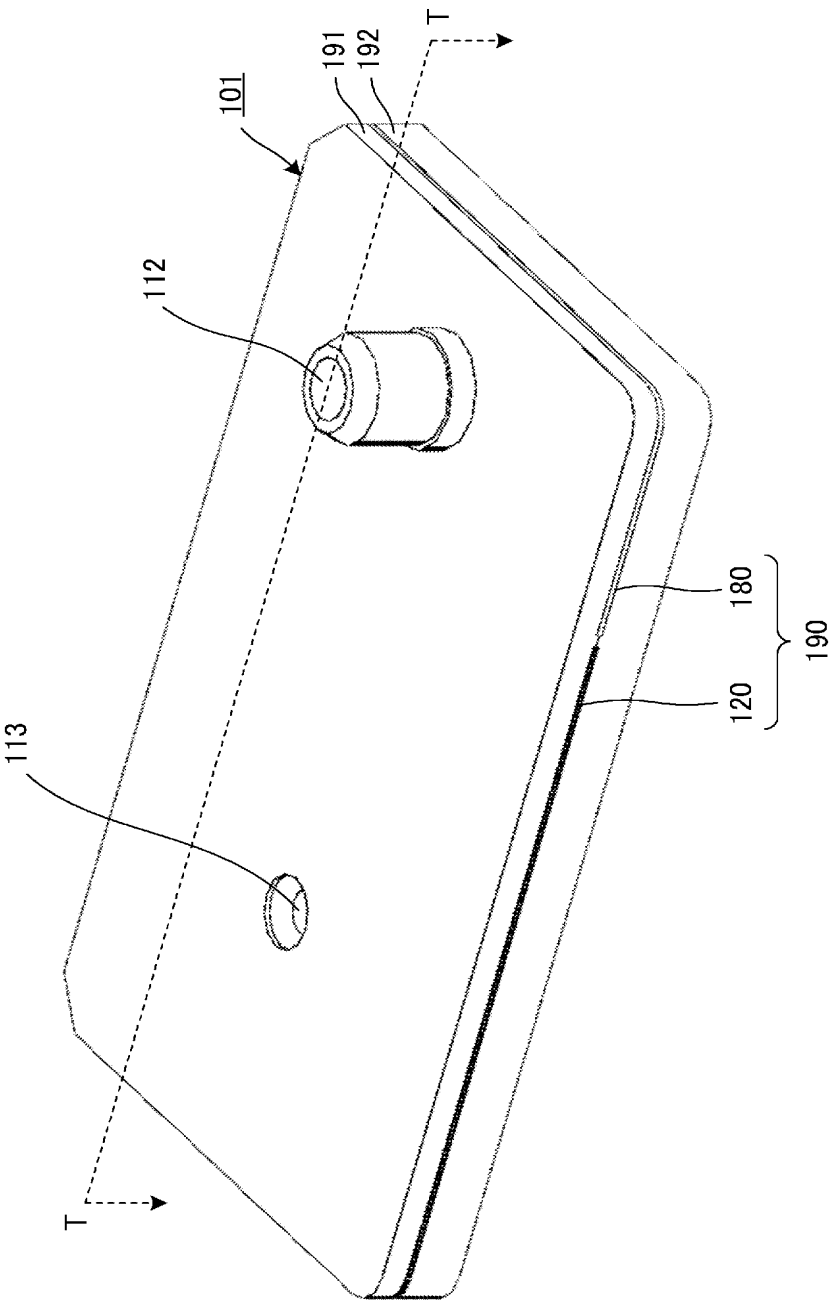
[図1]

図1


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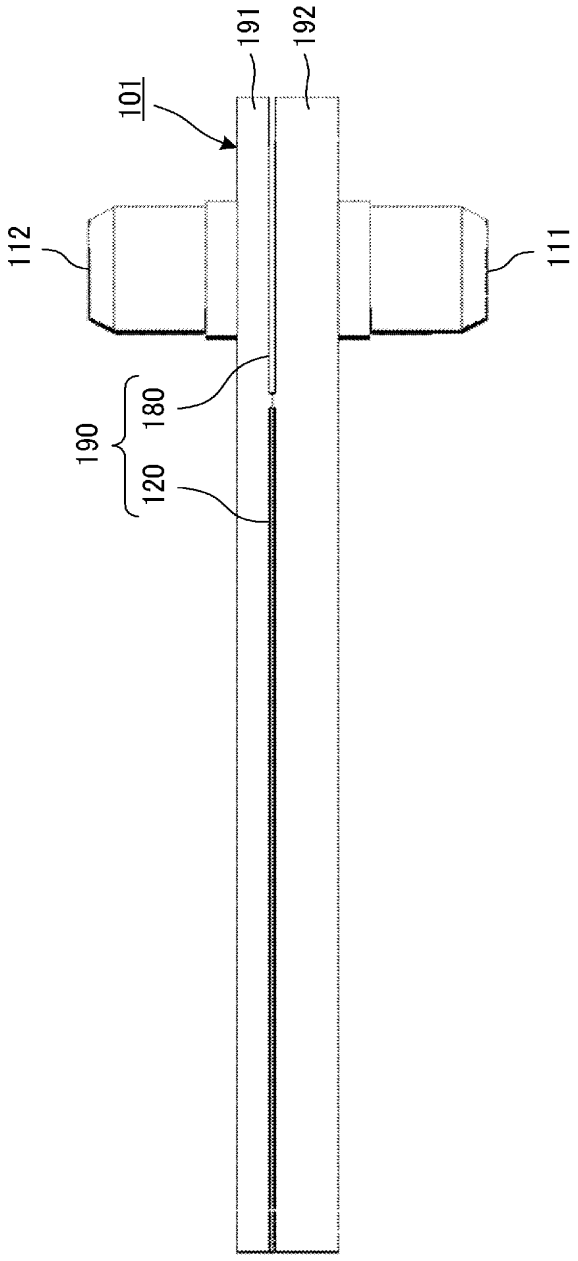
[図2]

図2

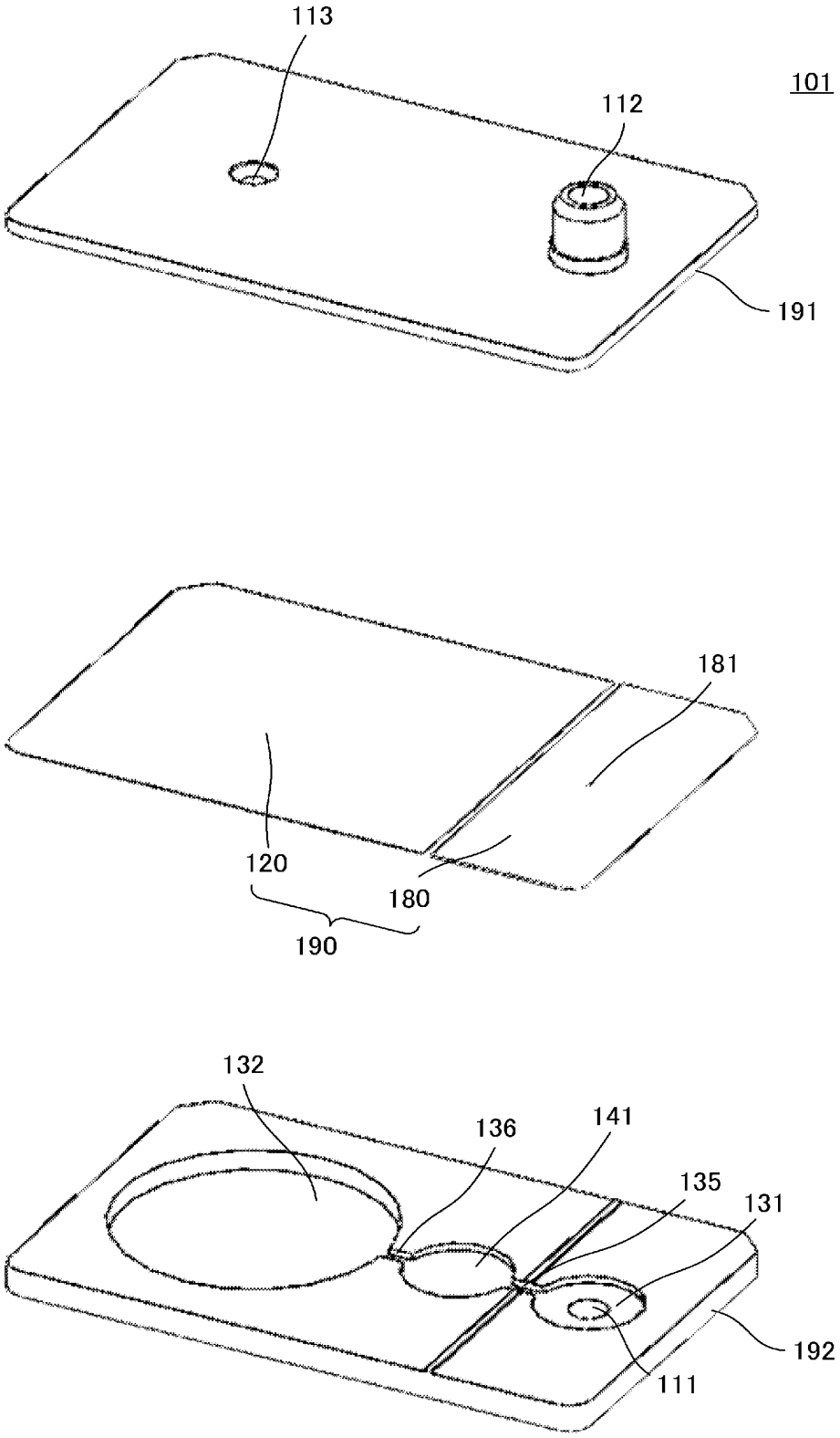


[図3]

図3

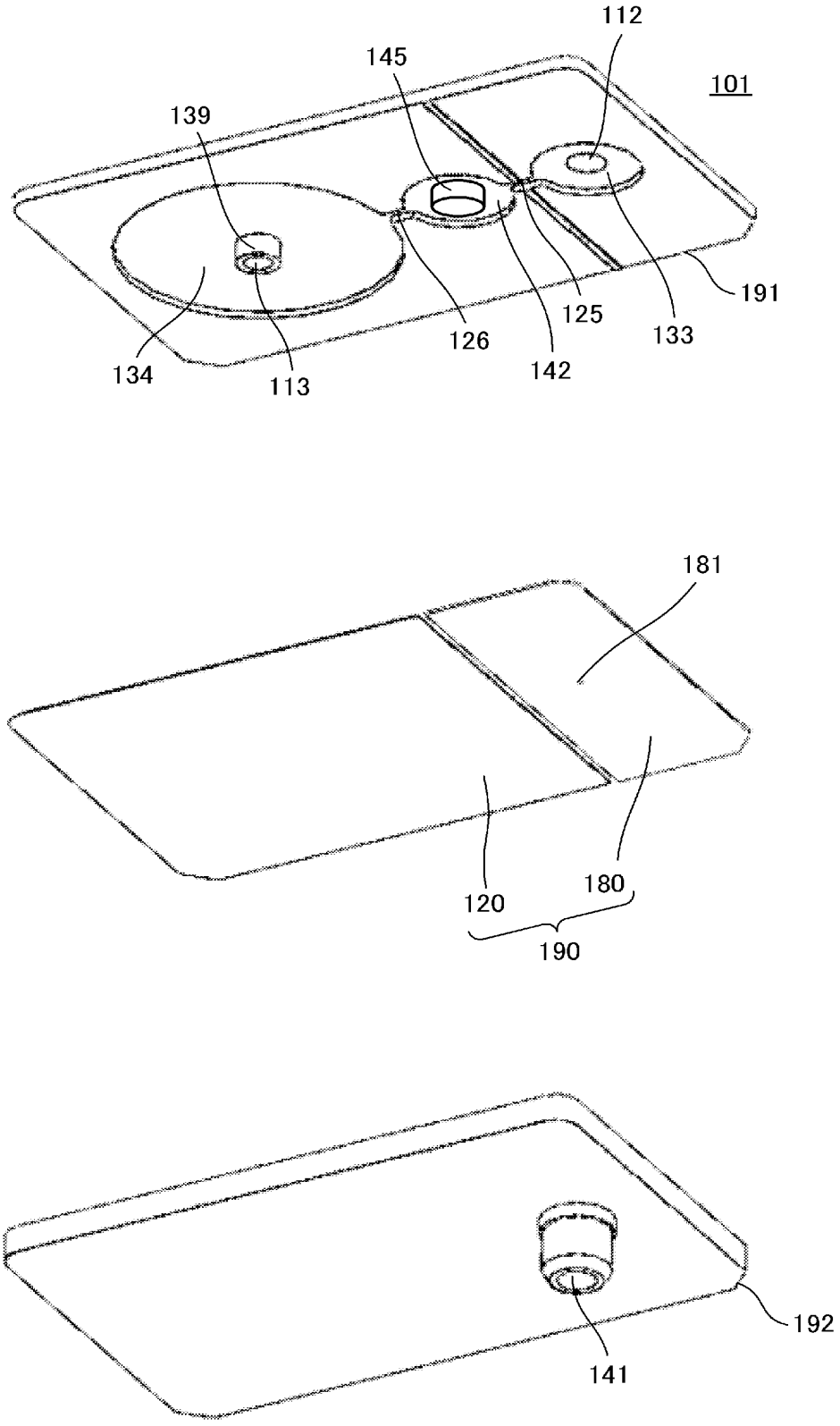


[図4]
図4

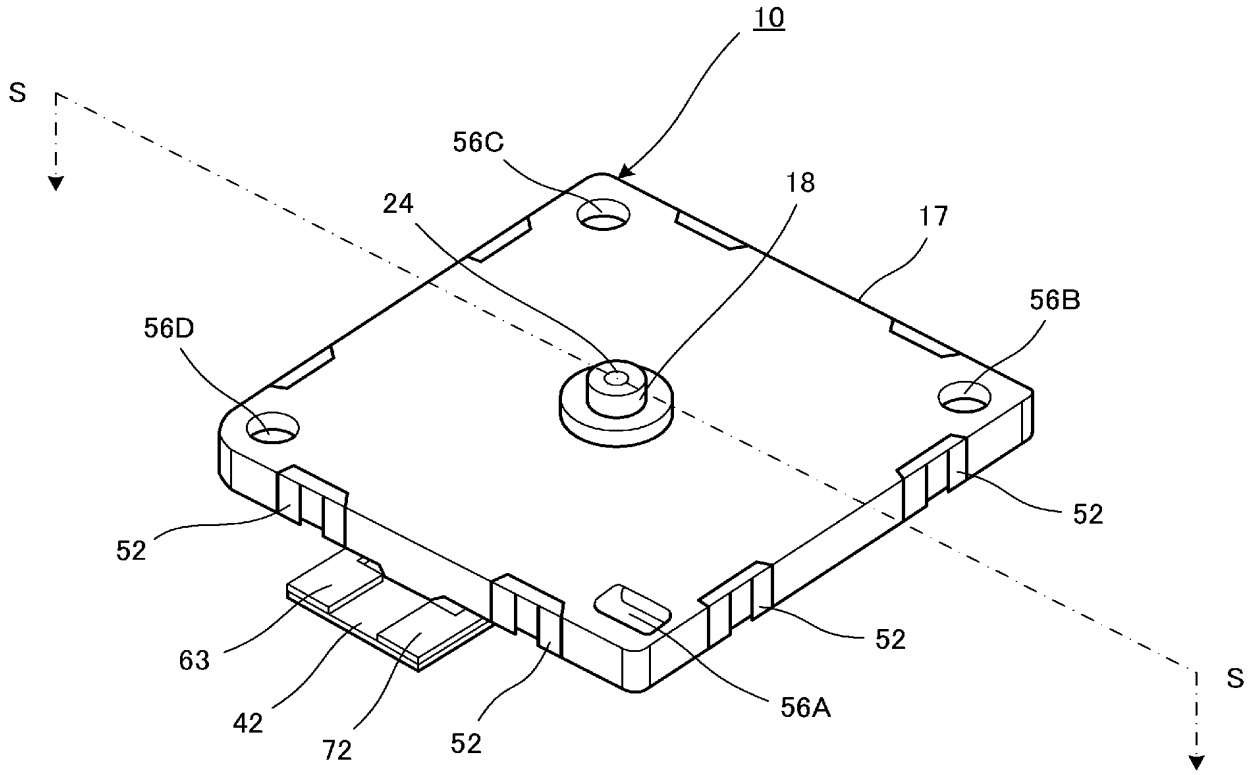


[図5]

図5

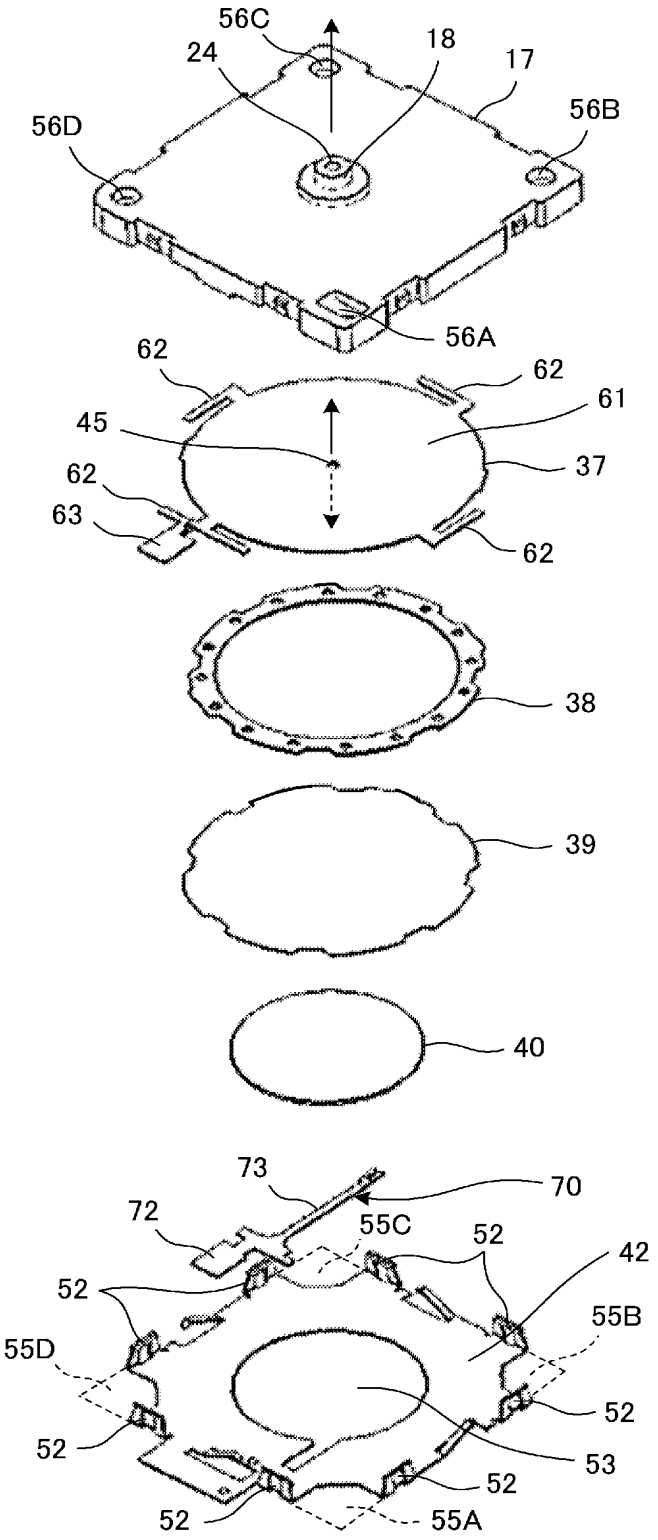

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[図6]
図6

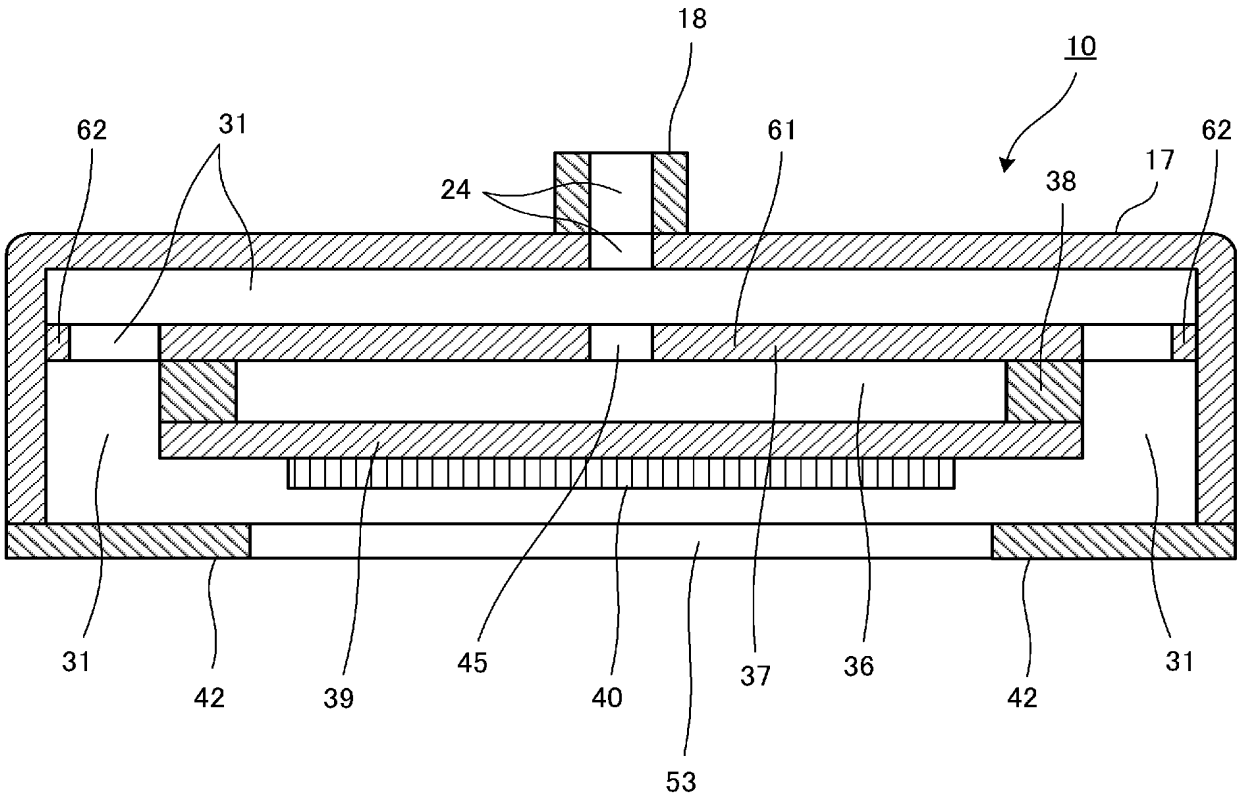


[図7]

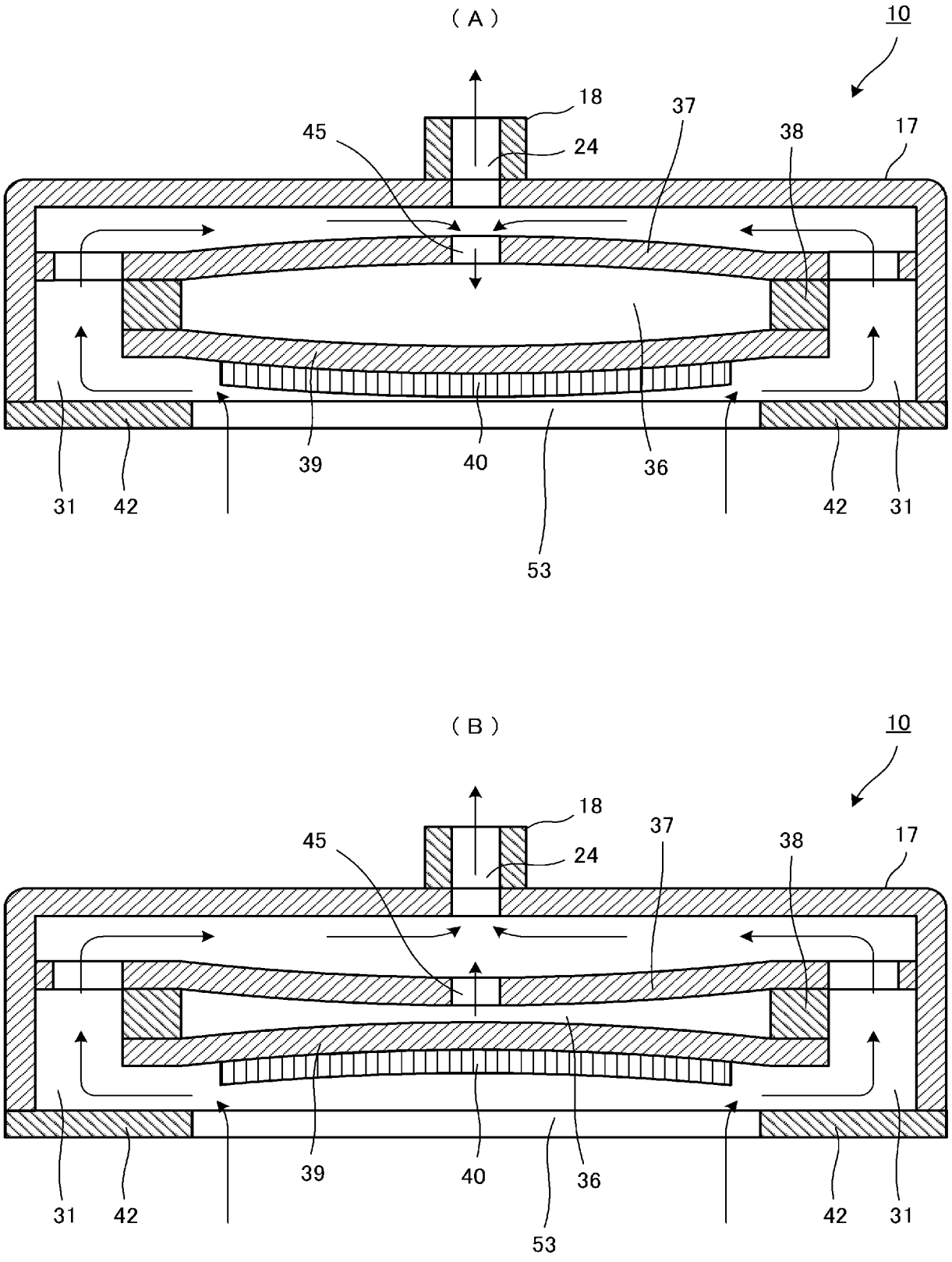
図7


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56B
56D
56A
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55C
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55A

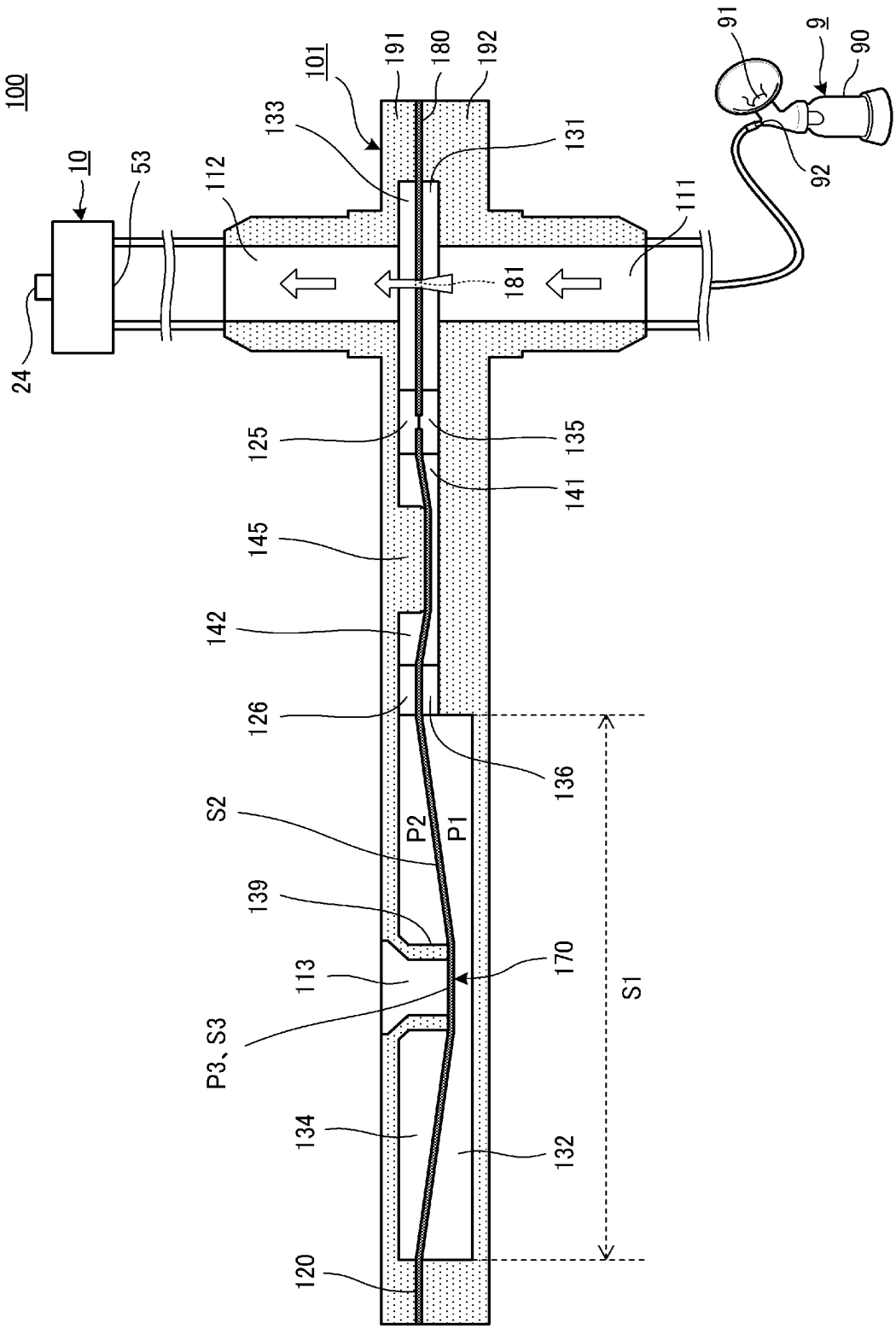
[図8]
図8



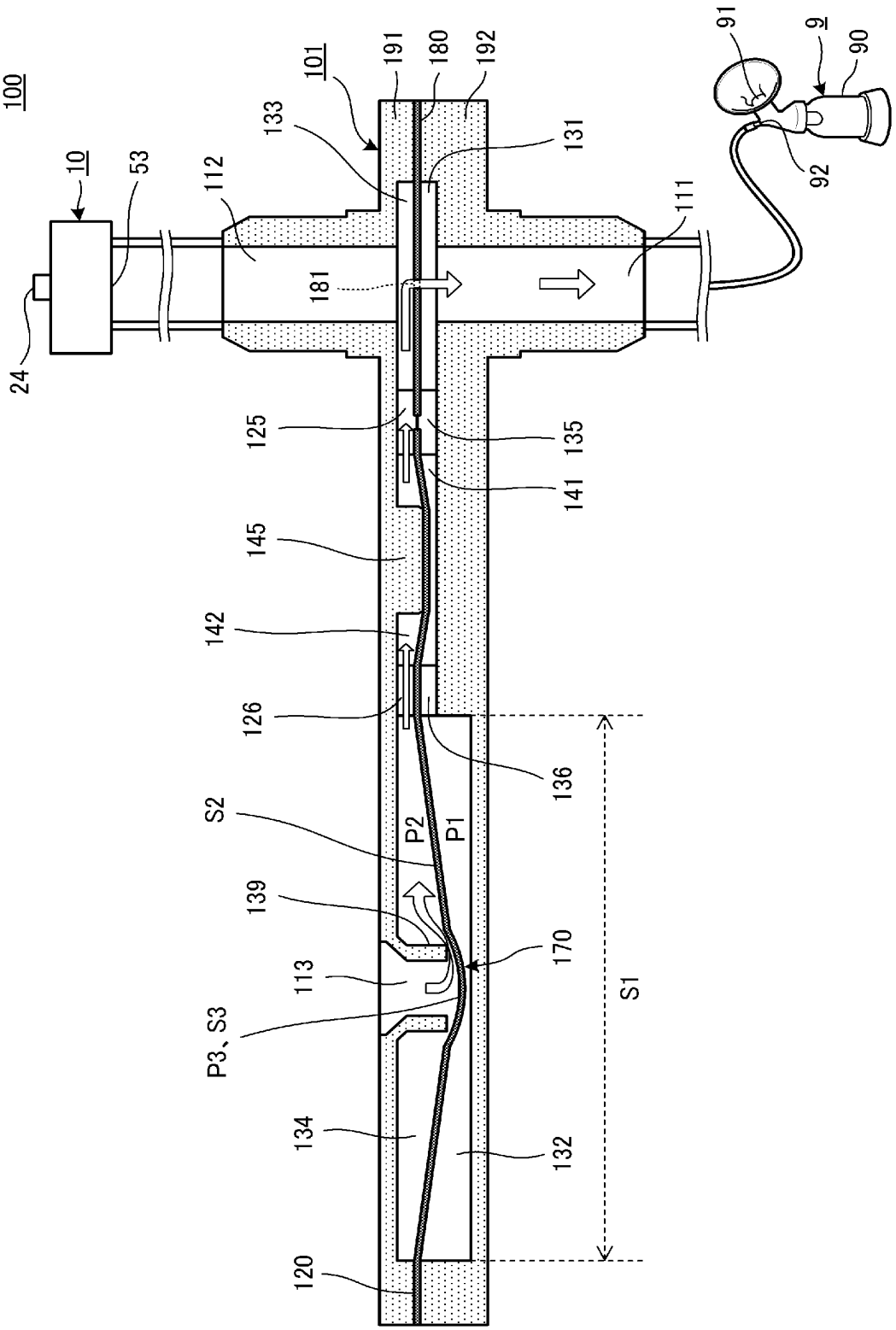
[図9]
図9


(A)
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(B)
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[図10]
図10

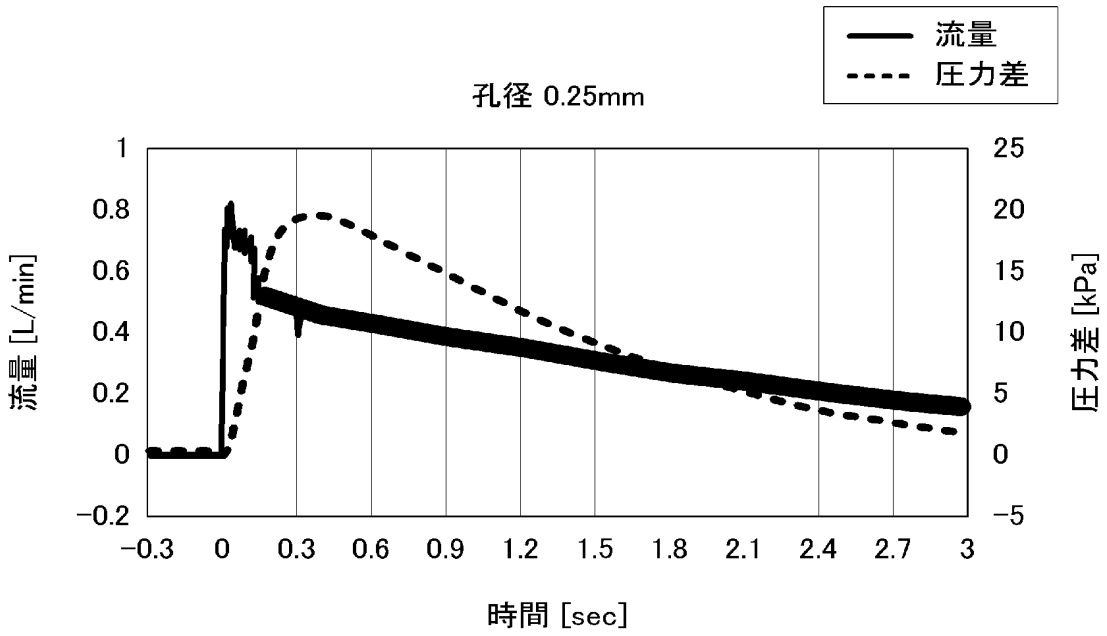

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[図11]
図１１


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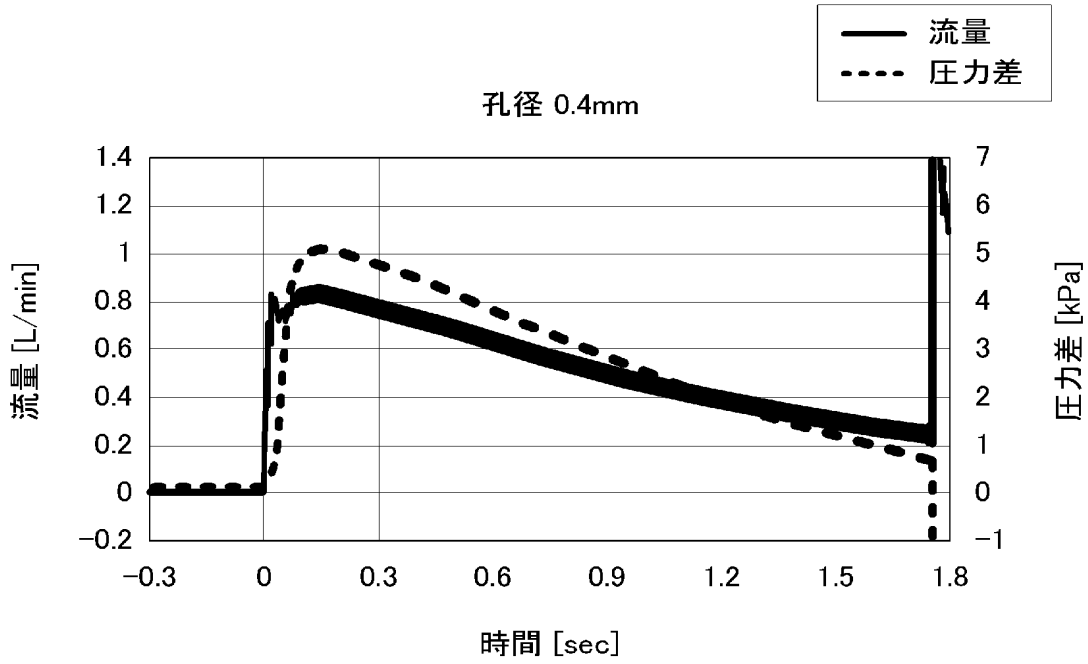
[図12]

図１２


流量
圧力差
孔径 0.25mm
流量 [L/min]
圧力差 [kPa]
時間 [sec]
1
0.8
0.6
0.4
0.2
0
−0.2
25
20
15
10
5
0
−5
−0.3
0
0.3
0.6
0.9
1.2
1.5
1.8
2.1
2.4
2.7
3

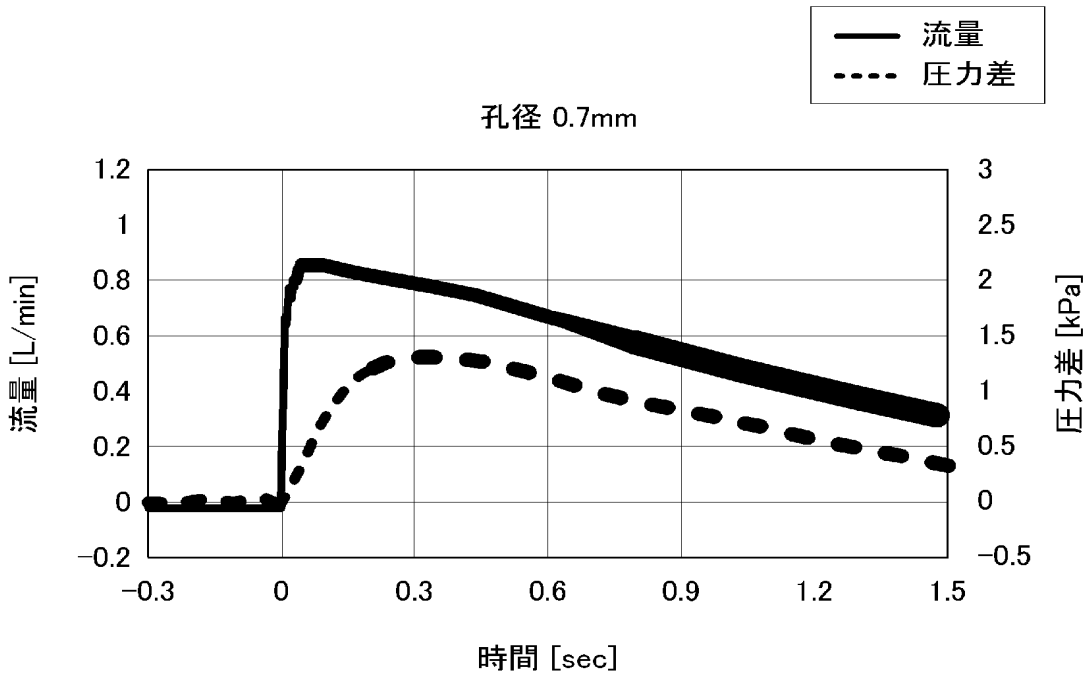
[図13]

図１３

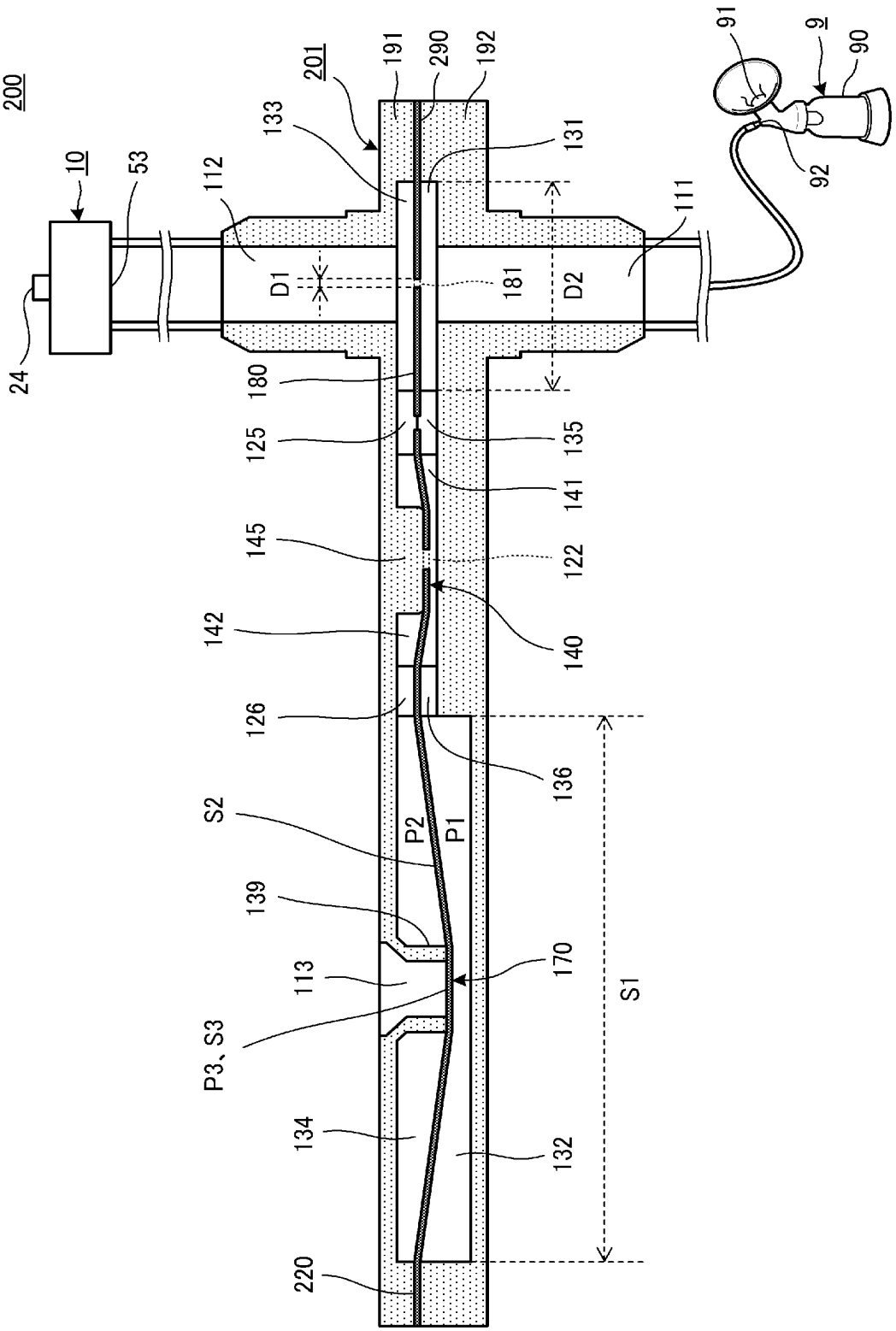

流量
圧力差
孔径 0.4mm
流量 [L/min]
圧力差 [kPa]
時間 [sec]
1.4
1.2
1
0.8
0.6
0.4
0.2
0
−0.2
7
6
5
4
3
2
1
0
−1
−0.3
0
0.3
0.6
0.9
1.2
1.5
1.8

[図14]

図１４

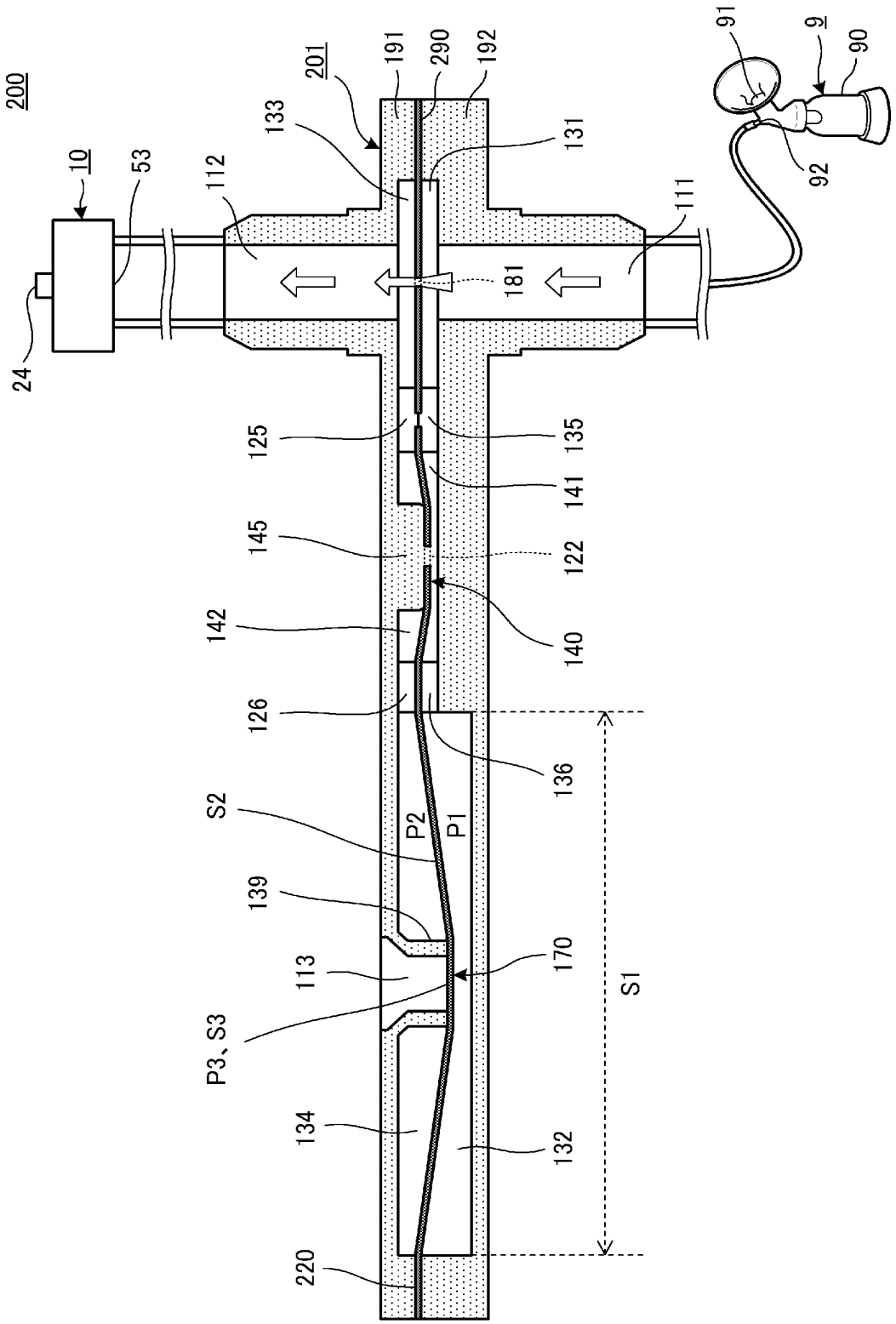

流量
圧力差
孔径 0.7mm
流量 [L/min]
圧力差 [kPa]
時間 [sec]
1.2
1
0.8
0.6
0.4
0.2
0
−0.2
3
2.5
2
1.5
1
0.5
0
−0.5
−0.3
0
0.3
0.6
0.9
1.2
1.5

[図15]
図15

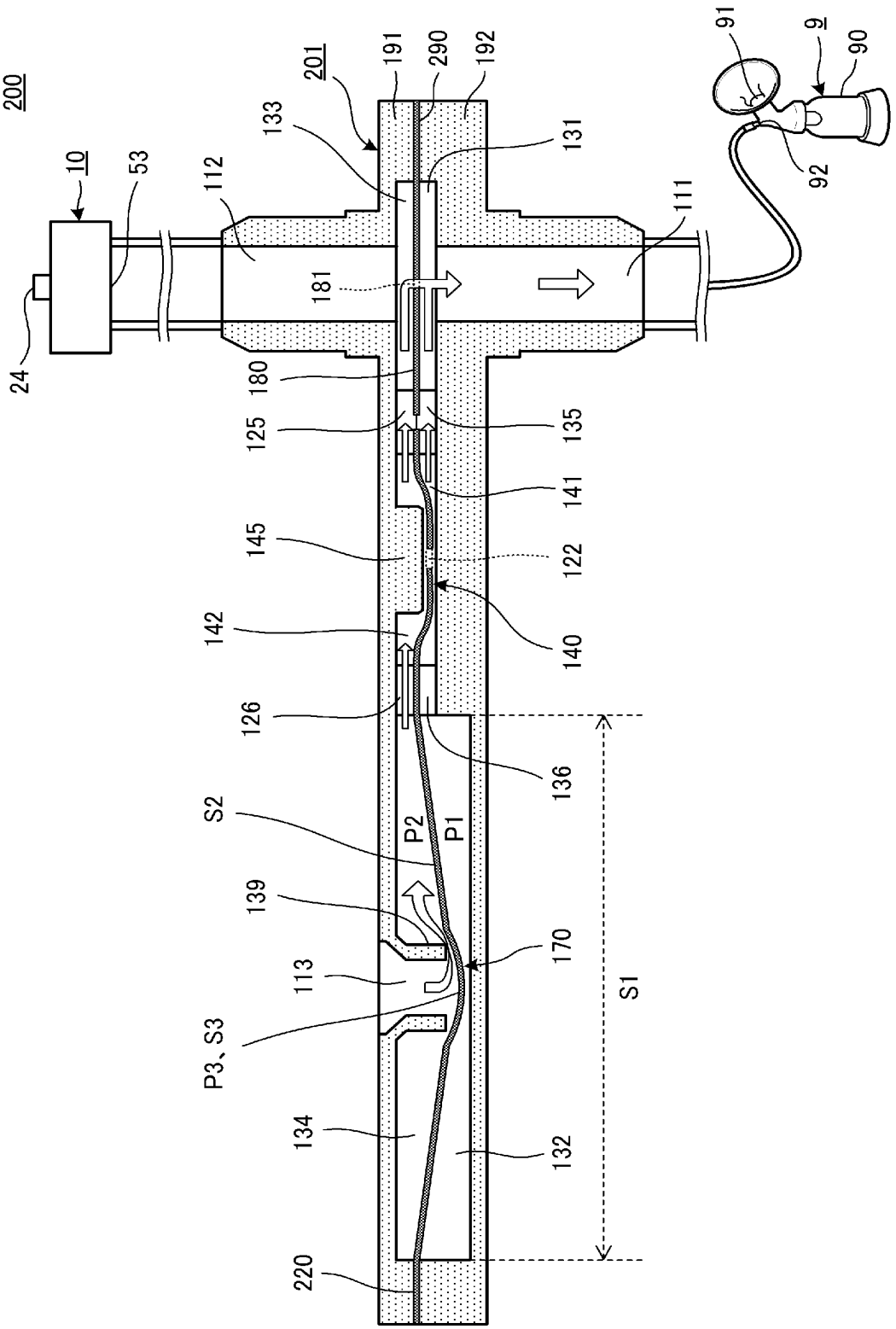

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[図16]

図16

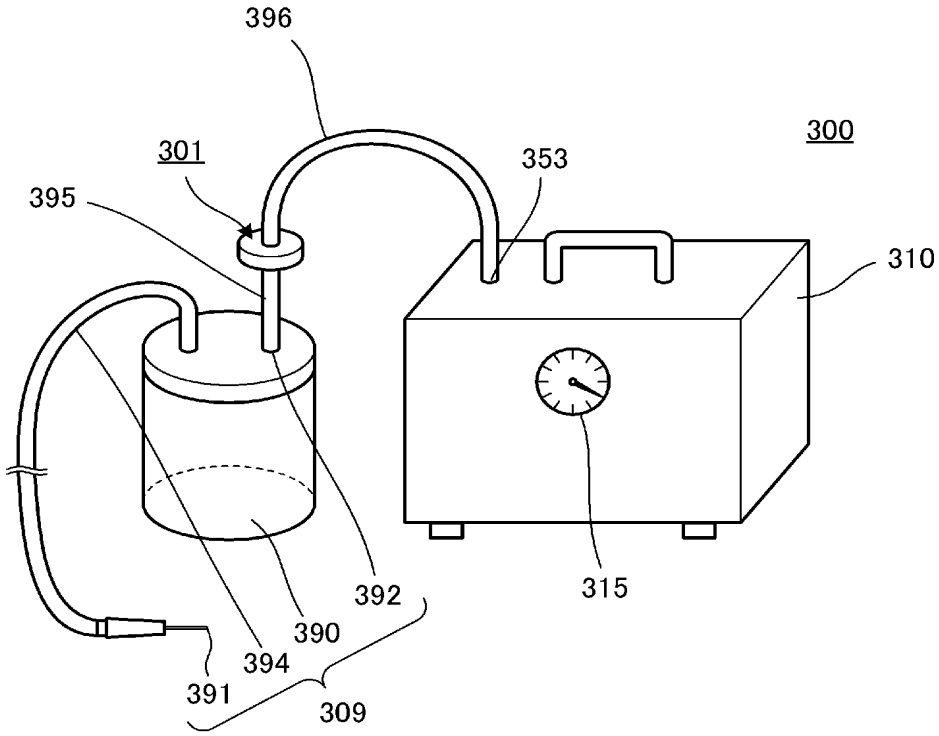

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[図17]
図17


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P3、S3
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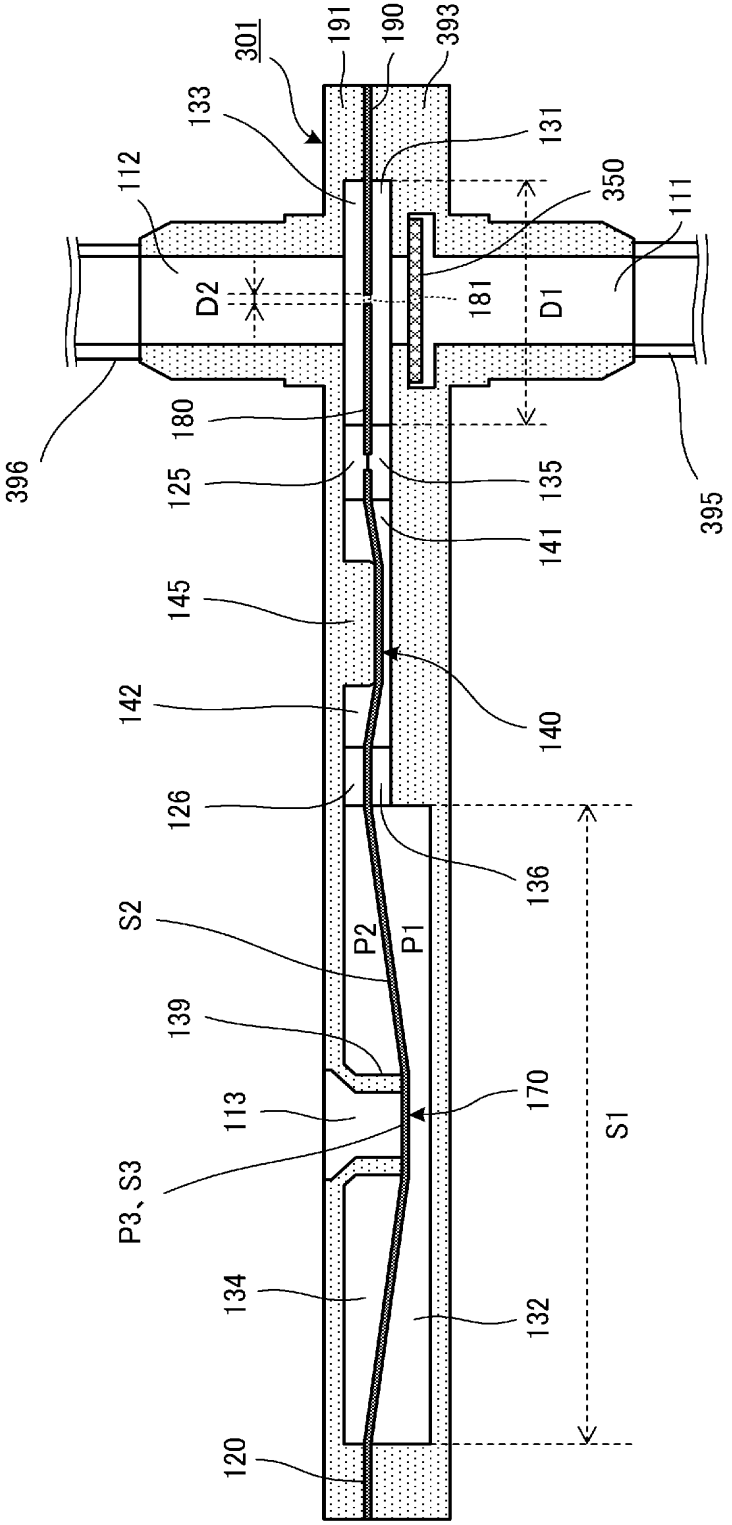
[図18]

図１８

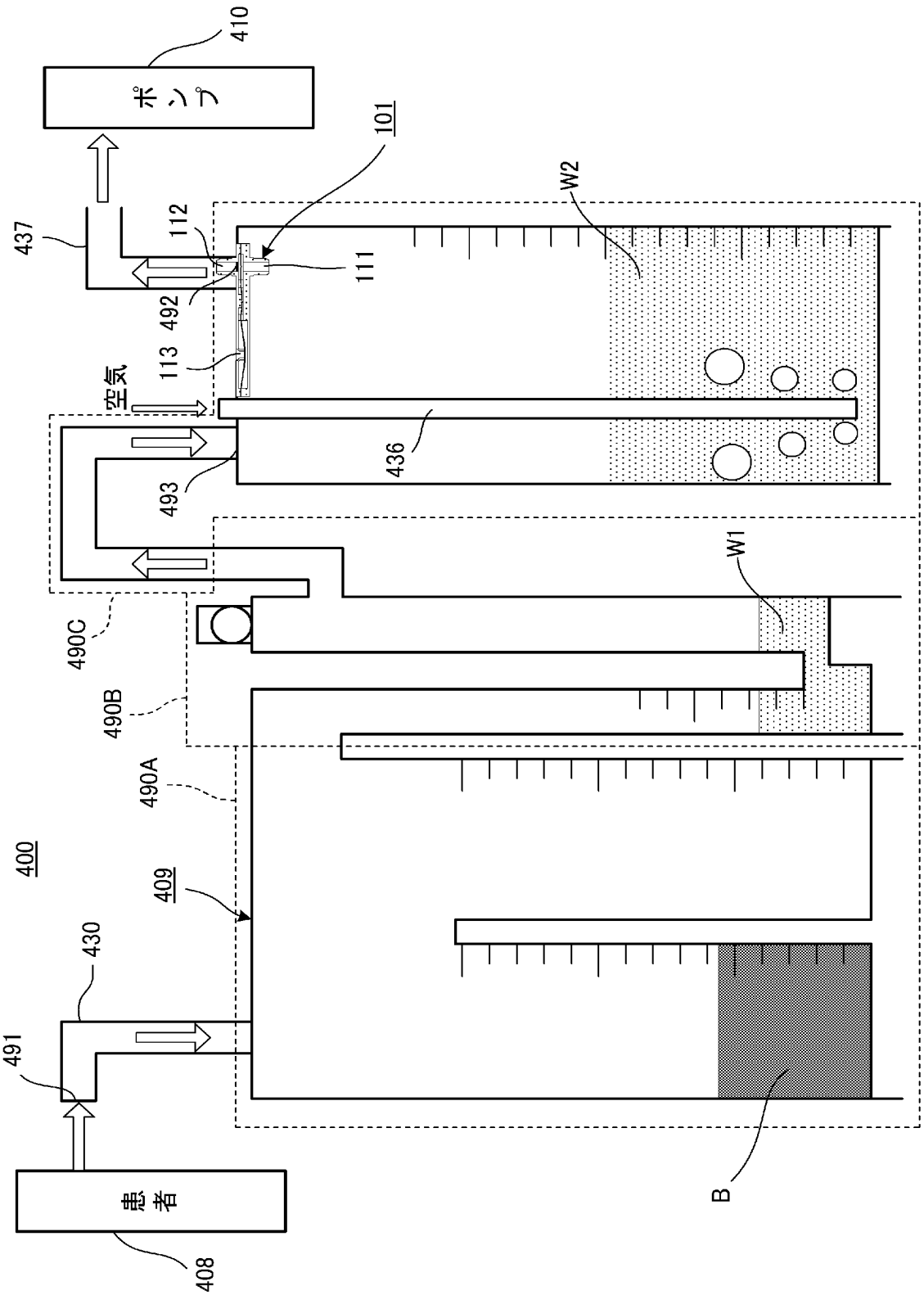


[図19]

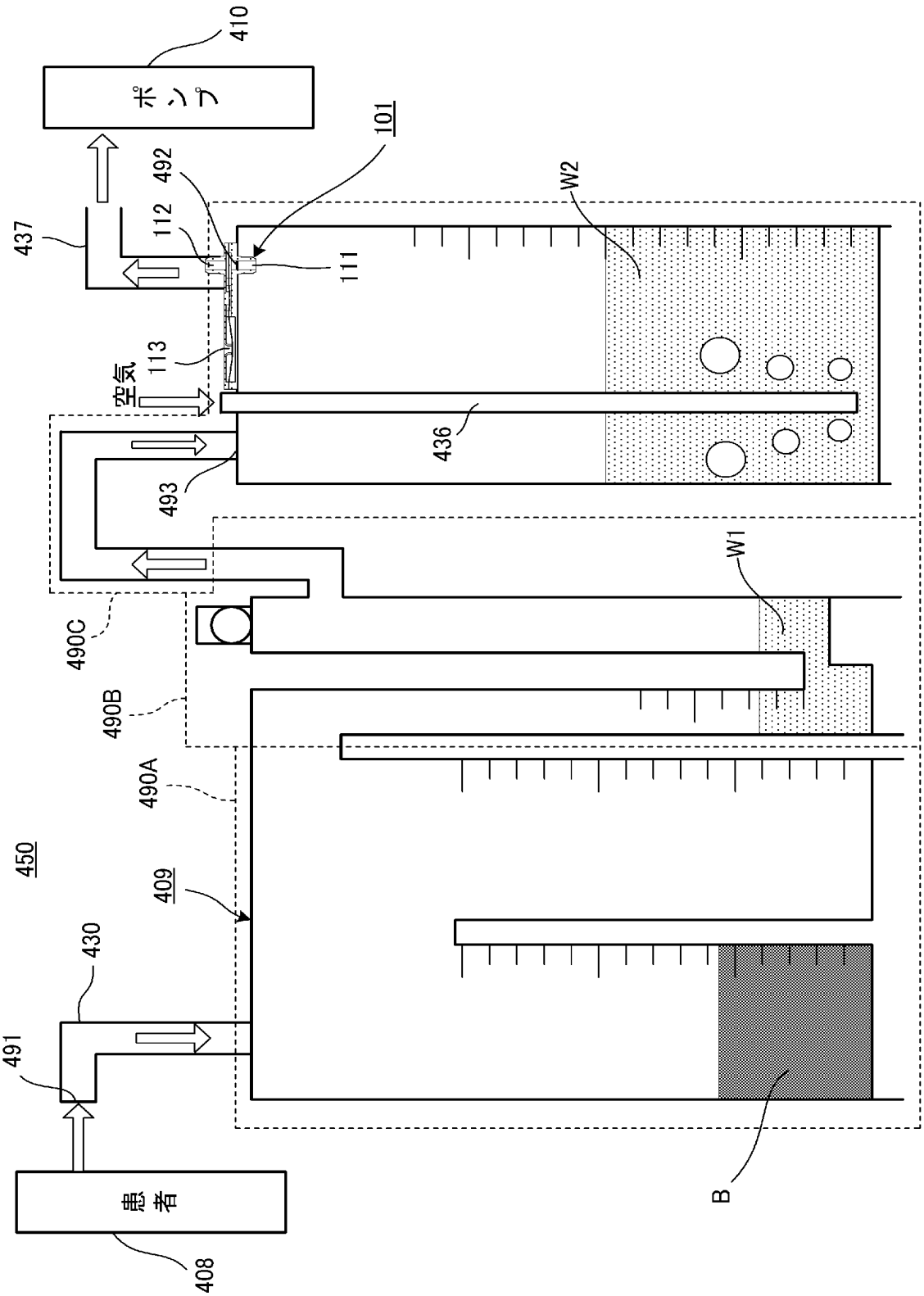
図19


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[図20]
図20

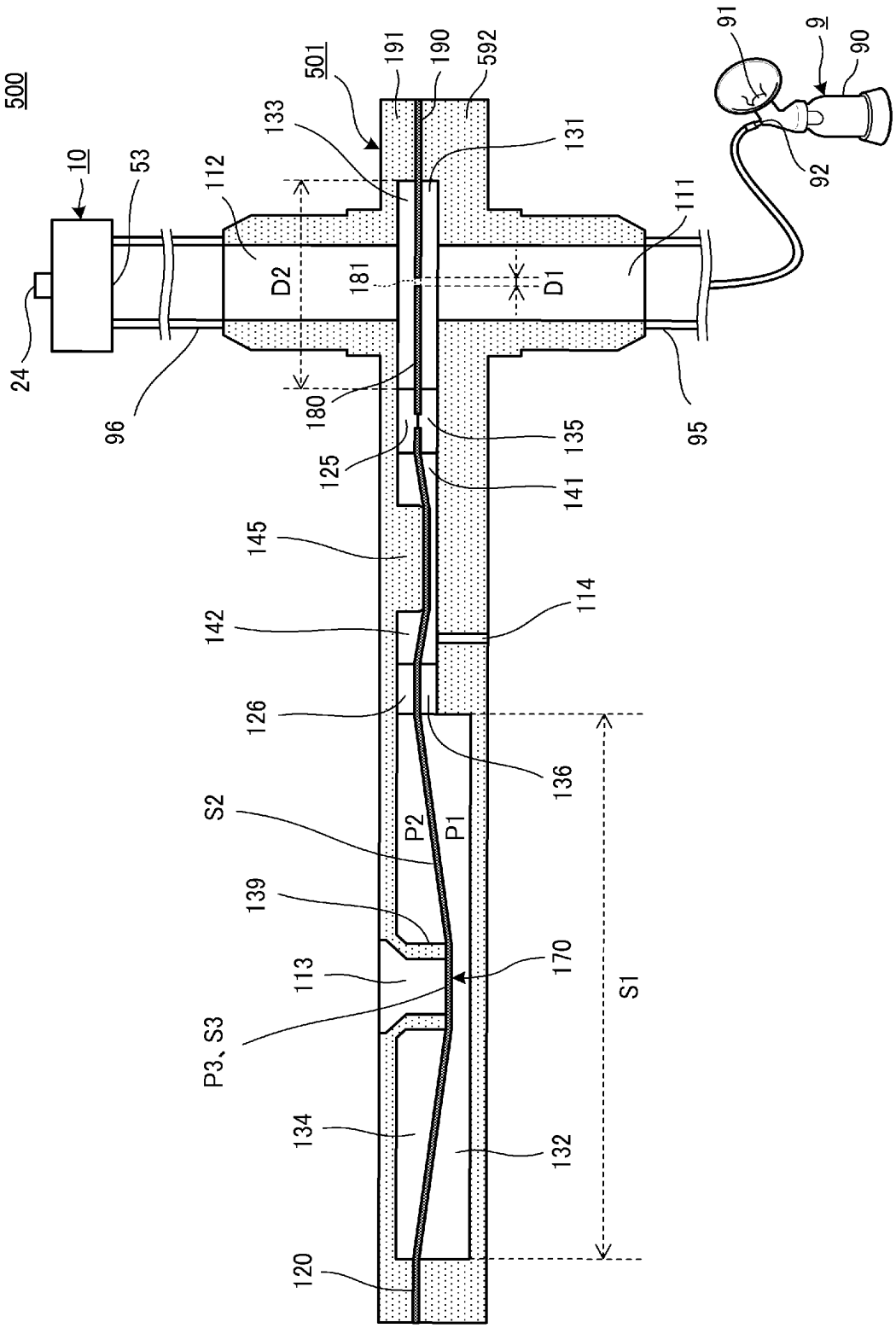

410
ポンプ
101
W2
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112
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492
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空気
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493
W1
490C
490B
490A
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491
患者
408
B

[図21]
図21


410
ポンプ
101
492
112
437
111
W2
113
空気
436
493
W1
490C
490B
490A
450
409
430
491
B
患者
408

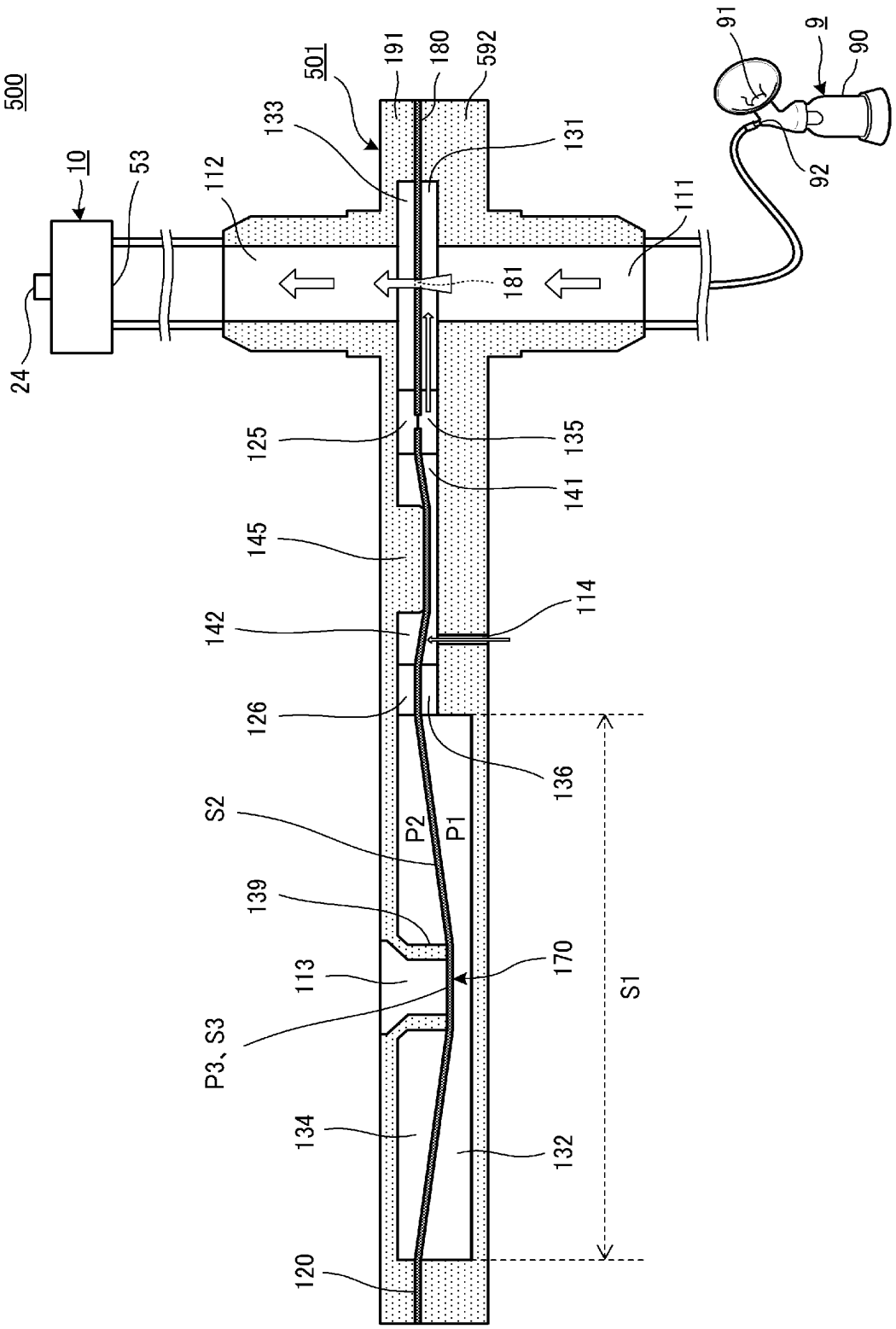
[図22]

図22


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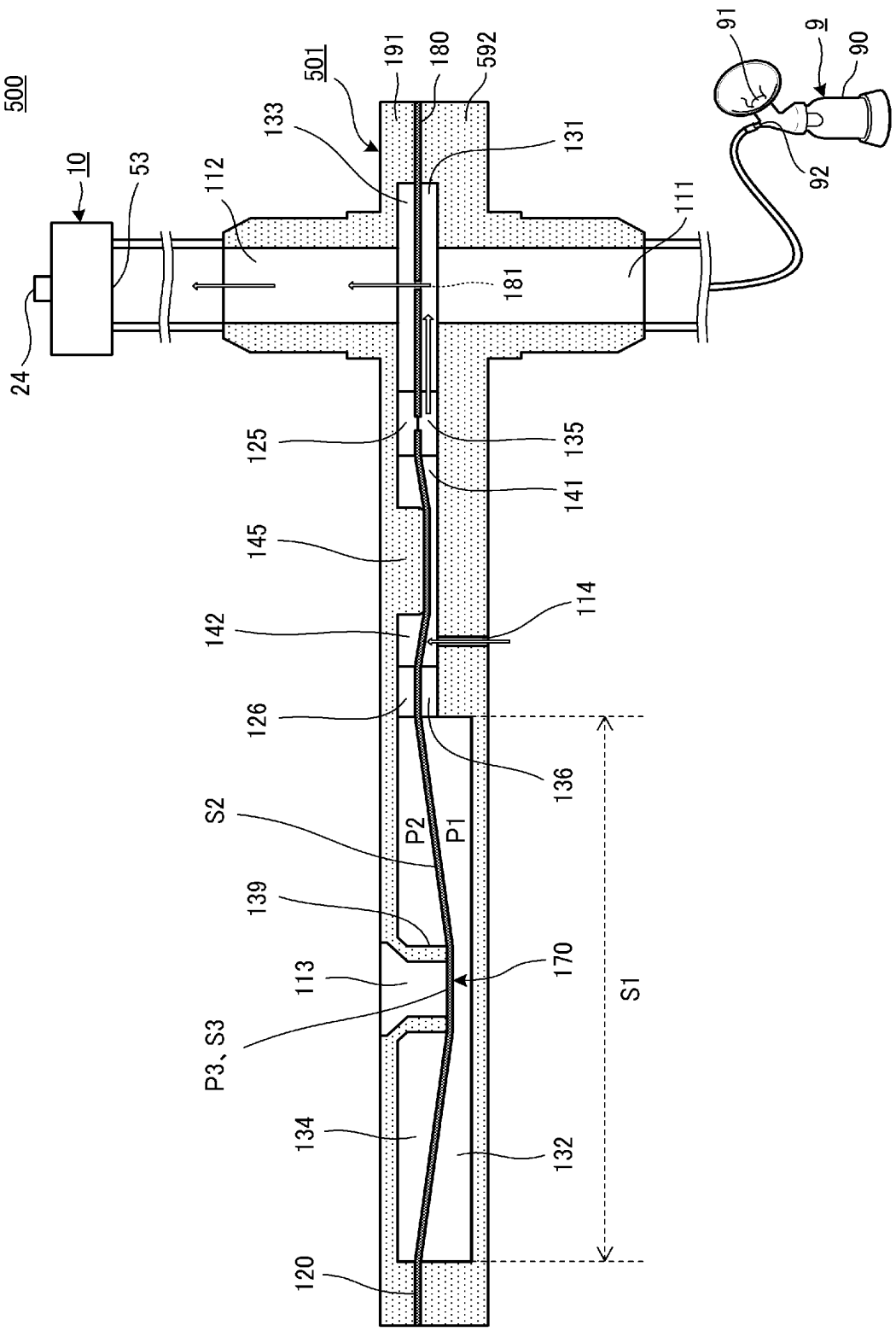
[図23]

図23


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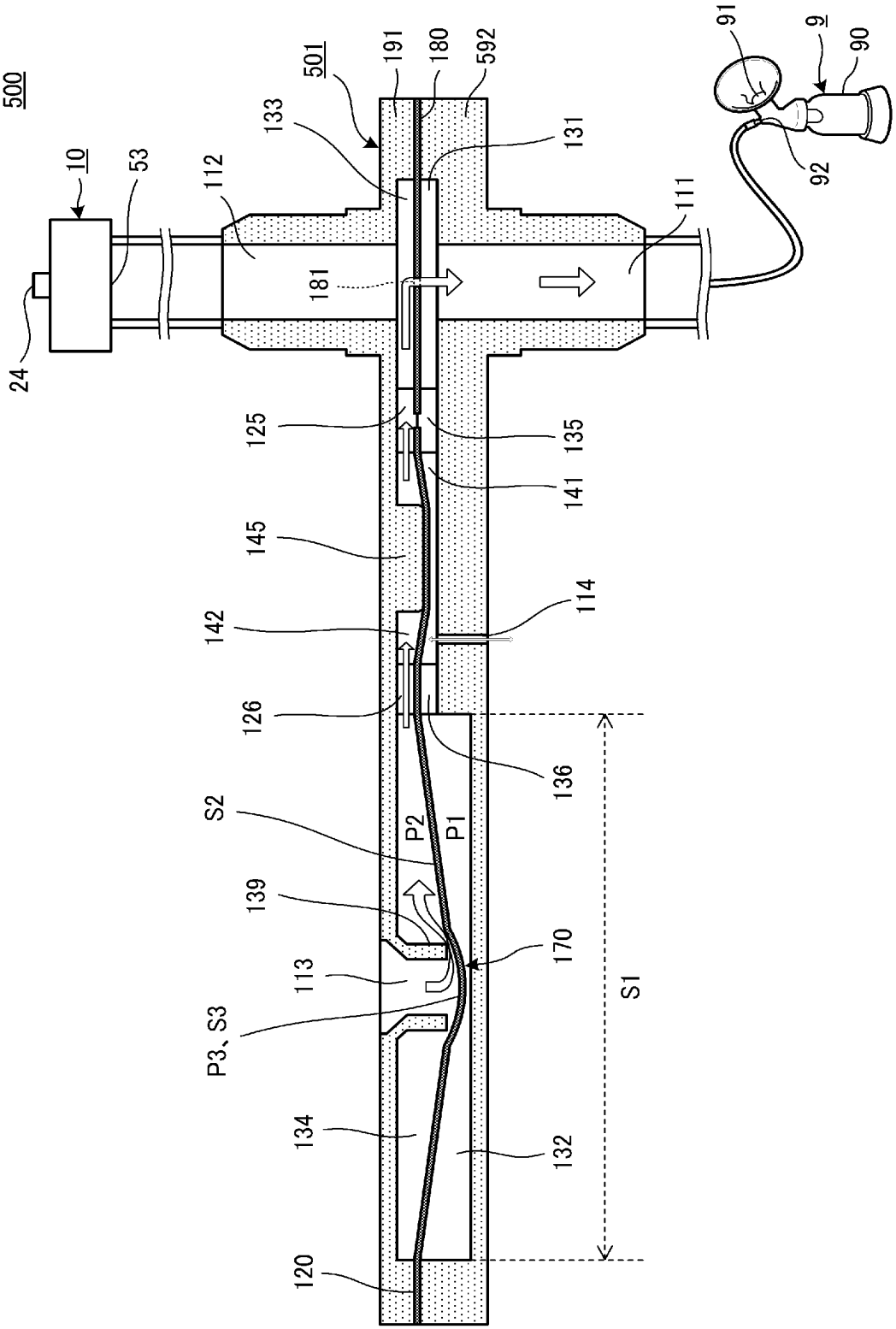
[図24]

図24

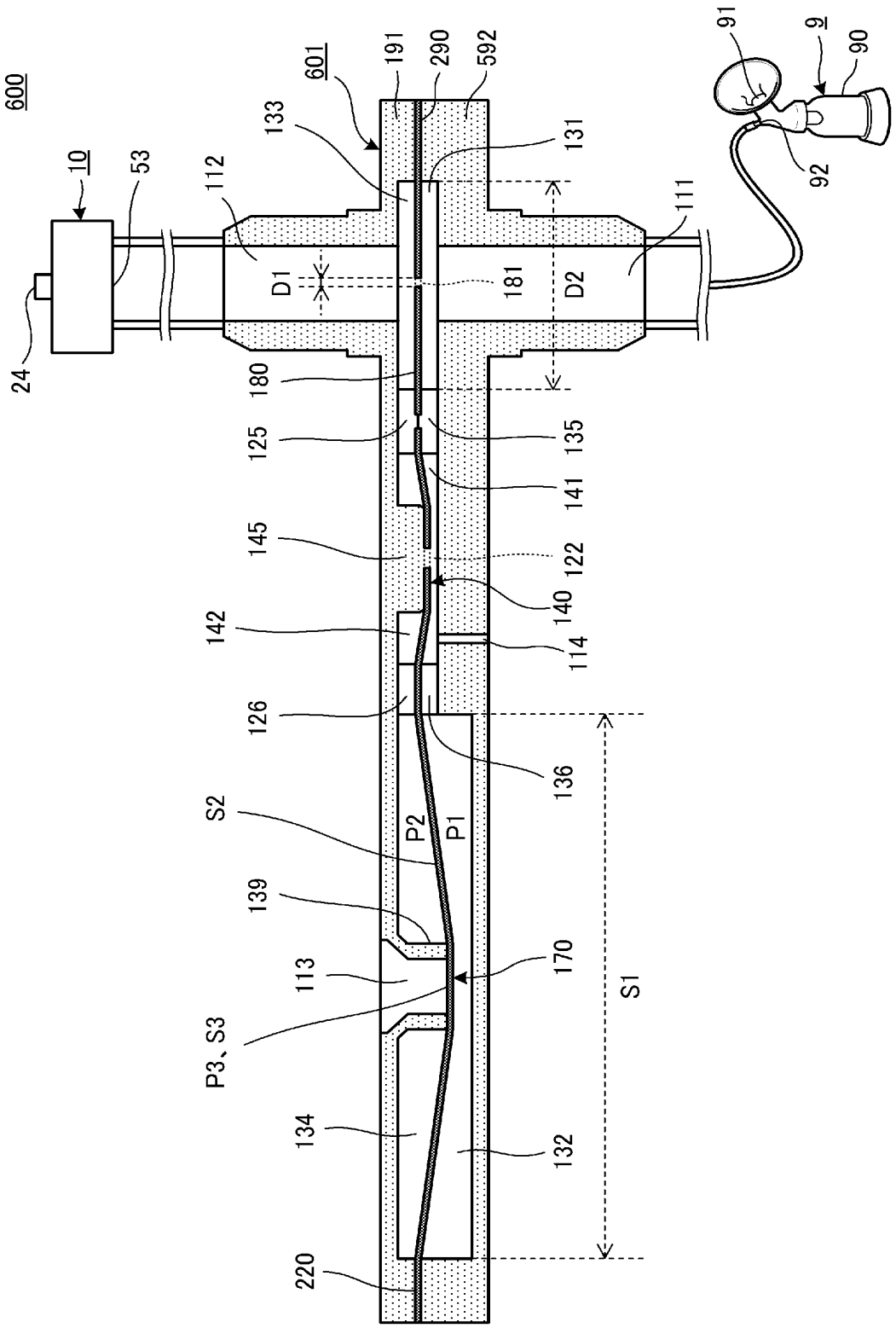

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[図25]

図25

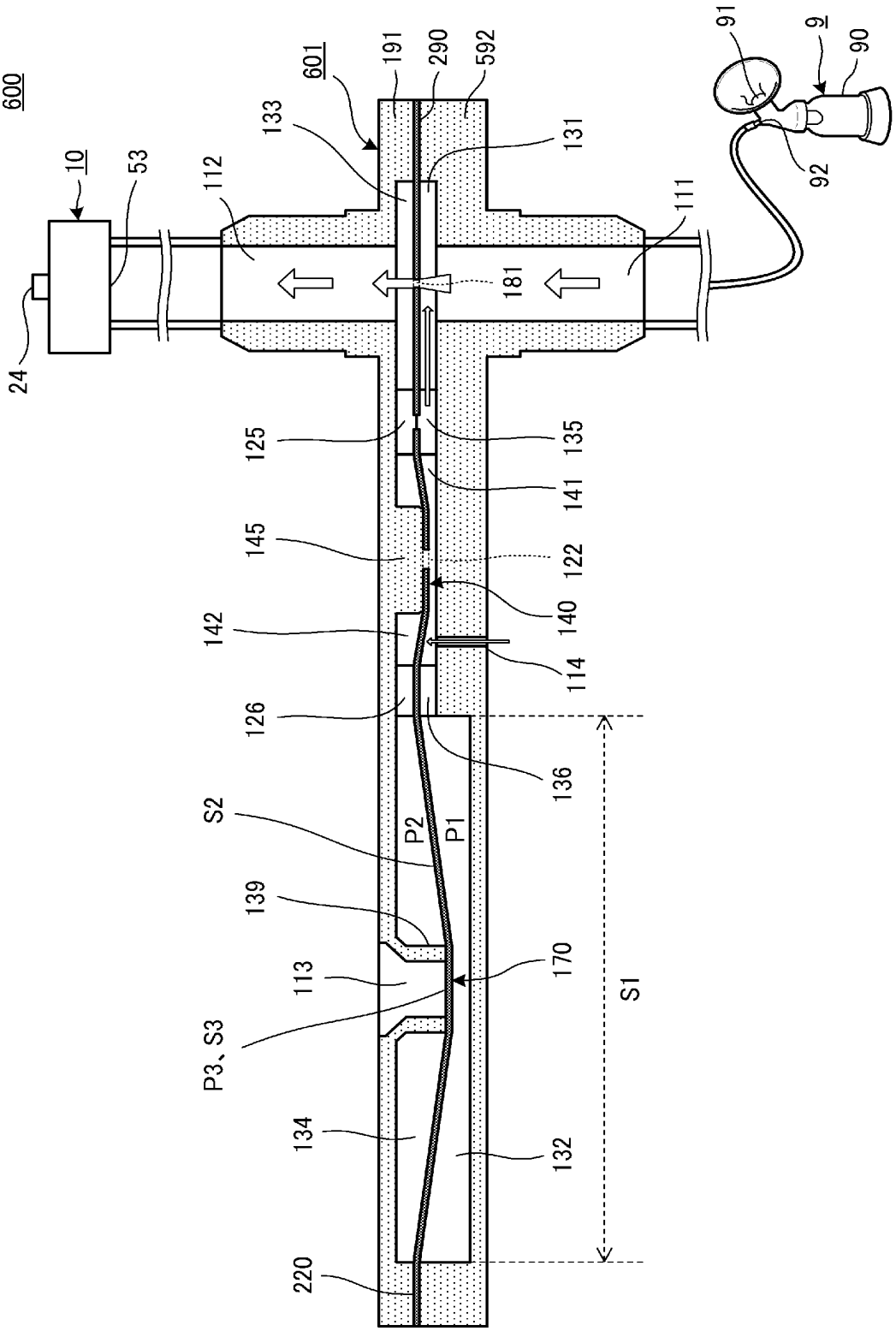

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[図26]
図26


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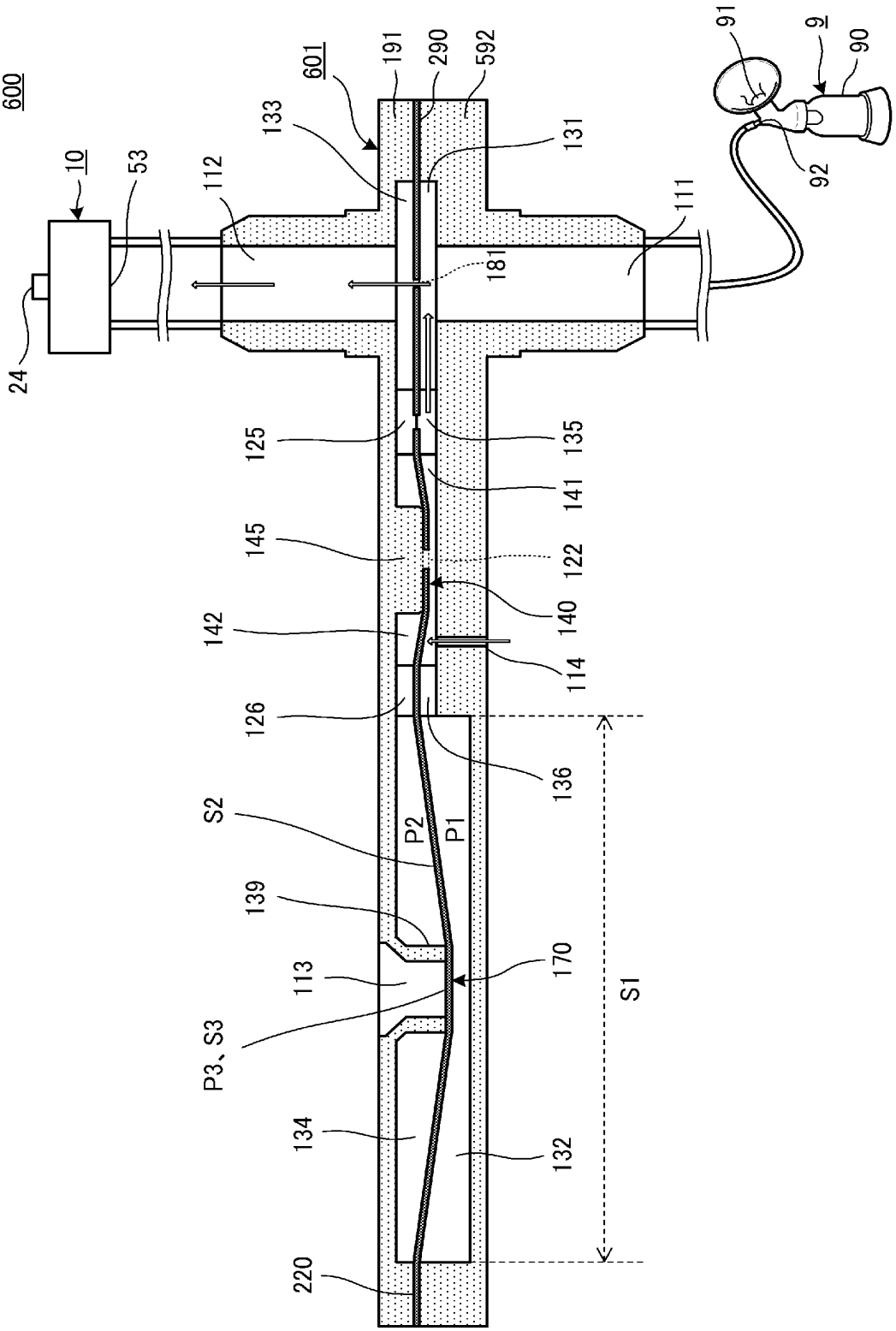
[図27]

図27


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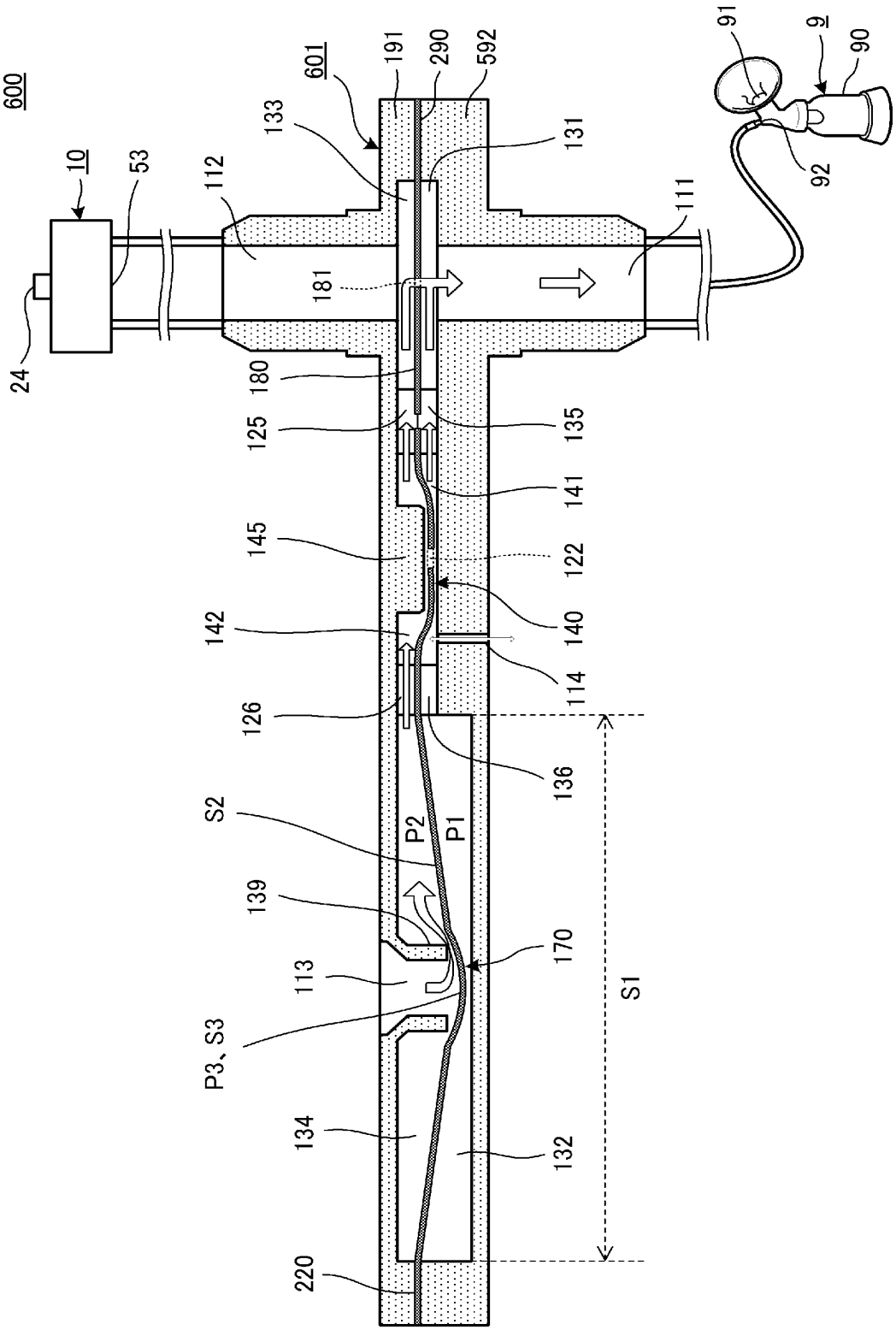
[図28]

図28


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図29


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INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/086169

A. CLASSIFICATION OF SUBJECT MATTER
F16K7/17(2006.01)i, *A61M1/06*(2006.01)i, *A61M27/00*(2006.01)i, *F16K17/164*(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
F16K7/17, A61M1/06, A61M27/00, F16K17/164

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2016
Kokai Jitsuyo Shinan Koho 1971-2016 Toroku Jitsuyo Shinan Koho 1994-2016

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 5185475 B2 (Murata Mfg. Co., Ltd., Omron Healthcare Co., Ltd.), 17 April 2013 (17.04.2013), paragraphs [0100] to [0109]; fig. 16 to 18 & US 2013/0178752 A1 paragraphs [0144] to [0153]; fig. 16 to 18 & US 2015/0096638 A1 paragraphs [0144] to [0153]; fig. 16 to 18 & WO 2012/141113 A1 paragraphs [0100] to [0109]; fig. 16 to 18 & EP 2698107 A1 paragraphs [0099] to [0108]; fig. 16 to 18 & CN 103140166 A paragraphs [0170] to [0182]; fig. 16 to 18	1-12

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 March 2016 (04.03.16)	15 March 2016 (15.03.16)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/086169

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 3-9764 A (Pigeon Corp.), 17 January 1991 (17.01.1991), page 5, lower right column, line 12 to page 6, upper left column, line 19; fig. 7 to 9 (Family: none)	11

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０８６１６９

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　F16K7/17(2006.01)i, A61M1/06(2006.01)i, A61M27/00(2006.01)i, F16K17/164(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　F16K7/17, A61M1/06, A61M27/00, F16K17/164

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１６年
日本国実用新案登録公報	１９９６－２０１６年
日本国登録実用新案公報	１９９４－２０１６年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Ａ	JP 5185475 B2 (株式会社村田製作所, オムロンヘルスケア株式会社) 2013.04.17, 段落［０１００］－［０１０９］, 図１６－１８ & US 2013/0178752 A1 , 段落［０１４４］－［０１５３］, 図１６－１８ & US 2015/0096638 A1 , 段落［０１４４］－［０１５３］, 図１６－１８ & WO 2012/141113 A1 , 段落［０１００］－［０１０９］, 図１６－１８ & EP 2698107 A1 , 段落［００９９］－［０１０８］, 図１６－１８ & CN 103140166 A , 段落［０１７０］－［０１８２］, 図１６－１８	１－１２

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

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「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

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「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
０４．０３．２０１６	１５．０３．２０１６

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｏ　４１３０
加藤　一彦

電話番号　０３－３５８１－１１０１　内線　３３５８

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Ａ	JP 3-9764 A（ピジョン株式会社）1991.01.17，第５頁右下欄第１２行－第６頁左上欄第１９行，第７－９図（ファミリーなし）	１１

(12) UK Patent (19) GB (11) 2473022 (13) B

(45) Date of B Publication 14.12.2011

(54) Title of the Invention: Maternity brassieres

(51) INT CL: ***A41C 3/04*** (2006.01)

(21) Application No: **0914965.9**

(22) Date of Filing: **27.08.2009**

(43) Date of A Publication **02.03.2011**

(56) Documents Cited:

DE 020210029 U1 **JP 2005187955 A**
US 4390024 A **US 2888729 A**
US 2317664 A **US 1616267 A**

(58) Field of Search:
As for published application 2473022 A viz:
INT CL **A41C, A41F, A44B**
Other: **Online: WPI & EPODOC**
updated as appropriate

(72) Inventor(s):
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GB 2473022 B

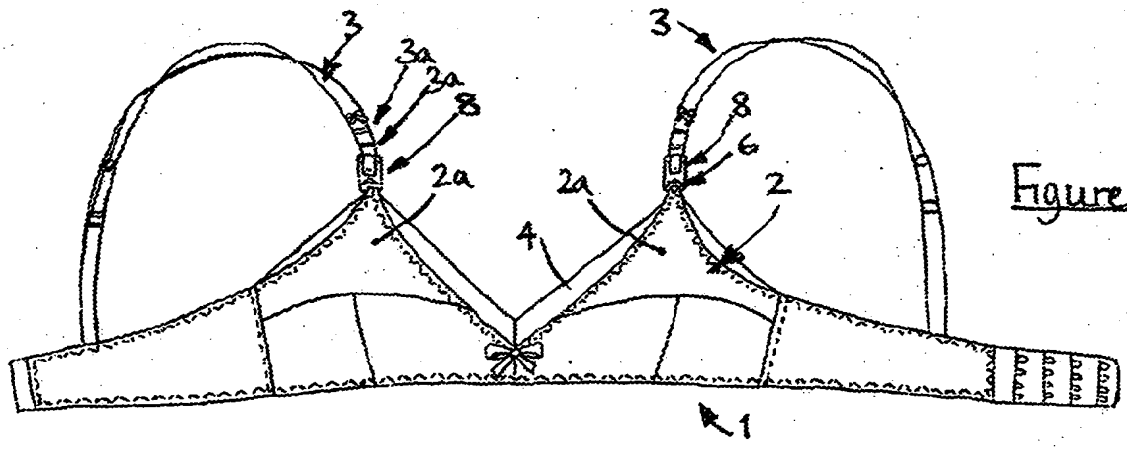


Figure 1

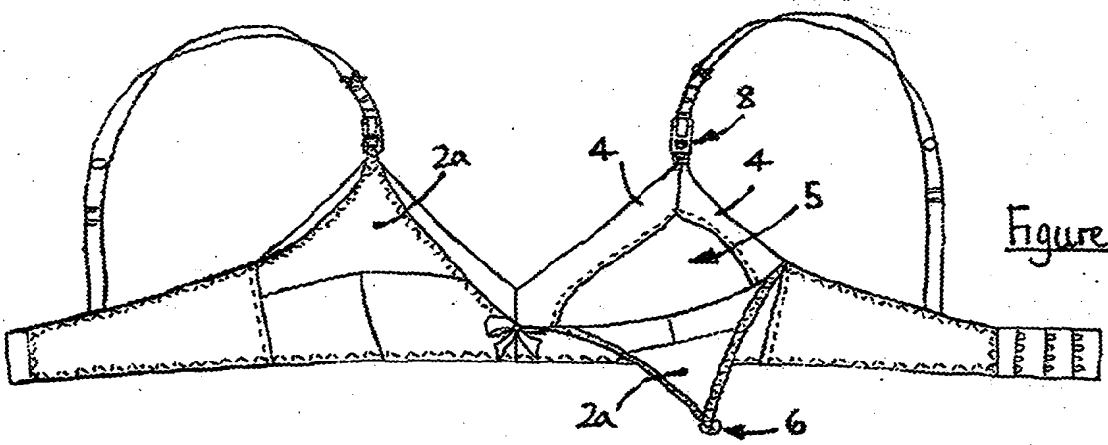


Figure 2

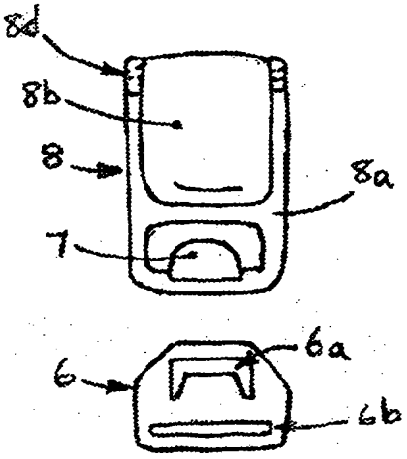


Figure 3

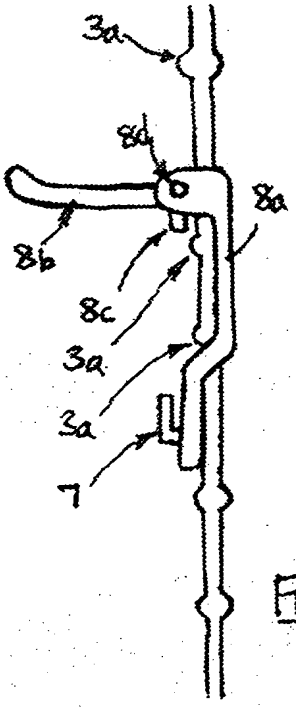


Figure 4

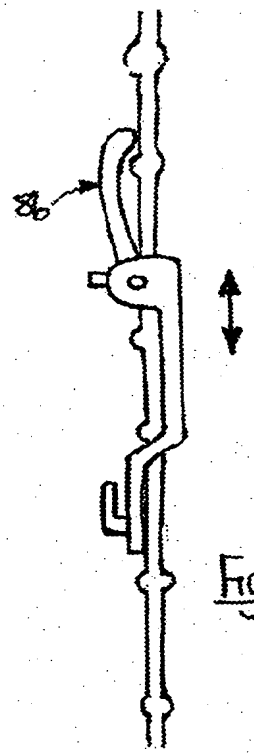


Figure 5

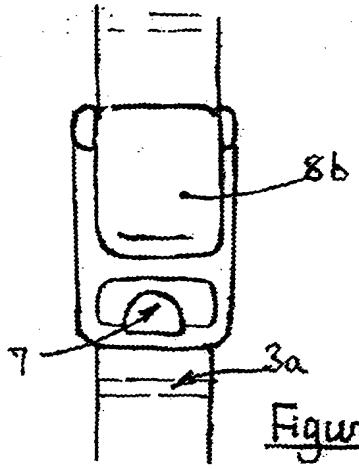


Figure 6

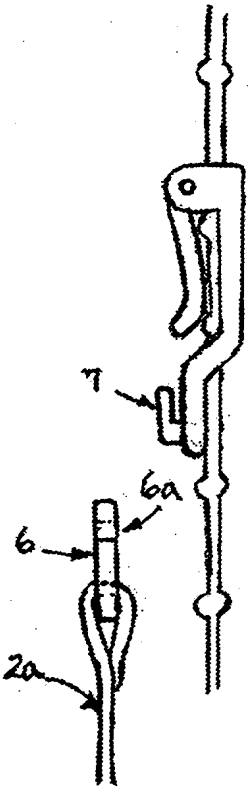
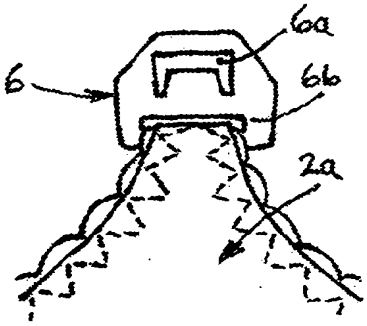


Figure 7



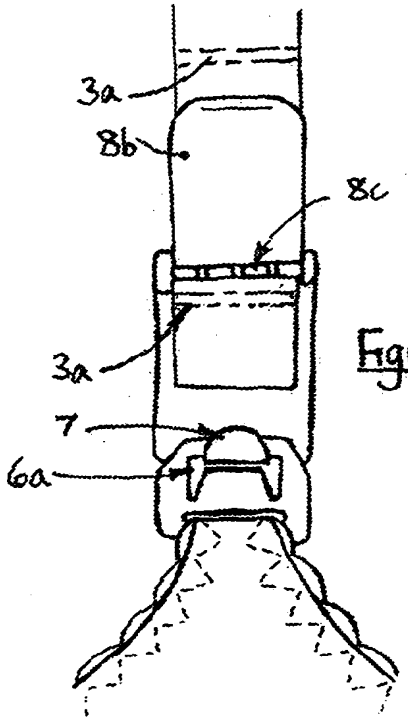


Figure 8

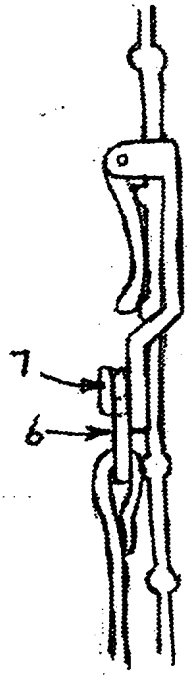


Figure 9

Maternity Brassieres

Field of the Invention

The present invention concerns improvements in and relating to brassieres of the type where the cups are openable such as in maternity and nursing brassieres or medical brassieres.

Background to the Invention

Maternity, nursing and some pre/post-operative surgical/ medical brassieres generally share the feature of having a central panel in one or both of the brassiere cups that is in the form of a flap that may be peeled back at an edge to expose the wearer's corresponding breast. For maternity and nursing brassieres this facilitates suckling of the infant and for surgical/ medical brassieres this facilitates treatment of the breast whether preceding or following biopsy, partial mastectomy or other procedure.

In maternity brassieres simple clips have been used for many years to detachably secure the apex/ leading edge of the panel closed. These clips are generally of hook and eye type with a hook at the apex of the panel to engage in an eye on the bra's shoulder strap. A problem common to the majority of such brassieres is that they do not have flexibility to accommodate for the substantial changes in breast size and shape that occur in lactating mothers or as a result of surgery or other breast tissue damage/ trauma. In mothers who breastfeed their babies the breast expands substantially when full with milk, swelling to even go up a whole cup size, and then shrinking again once the mother has fed her baby. In essence half of the time these mothers are wearing the wrong cup size of bra - either the bra is too big or too small, since there is no way to adjust the size of the cups.

Proposals have been made in the past to try to address this problem, including multi-point fastening arrangements as set out in US patents numbers US 2,317,664 and US 4,390,024. Each of these patents proposes use of several eyes arranged in a line up the shoulder strap of the brassiere to be selectively engaged by a hook at the apex of the central panel/ flap. The choice of eye gives the user the ability to raise or lower the point at which the apex of the flap is secured to the strap and hence adjusts for enlargement or diminution of the breast. The perimeter of the cups in US 4,390,024 is defined by wide stretchable bands to give greater elastic accommodation for the flux in breast size.

It is an objective of the present invention to provide an improved brassiere of the type where the cups are openable/ adjustable and which substantially alleviates the problems of fluctuating breast size. It is a further object to provide a brassiere which gives the user control over adjustment for fluctuating breast size independently of attaching the opening flap/ panel of the brassiere cup to the brassiere shoulder strap. It is a further object to provide a brassiere which gives the user a relatively fine control over adjustment. The improved brassiere is to have an adjust-to-fit component to raise the bra cup up and down the bra strap and which may provide a better quality, continually supportive, and more comfortable maternity bra to the market.

Summary of the Invention

According to a first aspect of the present invention there is provided a brassiere comprising one or a pair of breast supporting cups and of the type where at least one of the breast-supporting cups has a frontal opening to expose the breast, the breast-supporting cup comprising a panel/flap that covers the opening and a part of which is releasably attachable to the shoulder strap of the brassiere to support the breast-supporting cup and so that on release the opening may be uncovered, characterized in that the means by which the panel/flap is releasably attachable to the shoulder strap comprises a clasp on the shoulder strap

that is movable up and down the shoulder strap to a selected position and having a clamping part so that it may be clamped at the selected position, thereby providing adjustment of the breast-supporting cup, the clasp incorporating co-operative engagement means thereon for the releasable attachment of the panel/ flap.

Preferably the shoulder strap has a plurality of transverse ribs thereon each serving as an abutment on the shoulder strap for the clamping part of the clasp to stop against.

Suitably the co-operative engagement means on the clasp comprises a hook and the cup panel/flap has a tab with an aperture to engage with the hook.

The brassieres allows the user to raise the bra cup up and down the bra strap and provides a better quality, continually supportive, and more comfortable maternity bra. Moreover it gives the user control over adjustment for fluctuating breast size independently of attaching the opening flap/ panel of the brassiere cup to the brassiere shoulder strap and the user can have a much finer control over adjustment than is afforded by the prior art.

The brassiere may not only be used by nursing mothers. For medical brassieres the adjustment of the present invention is useful since after any breast surgery the straps can be adjusted to allow for any post surgery swelling and the cups can be adjusted individually. Therefore, if only one breast is operated on both breasts can be perfectly supported even if they are of different sizes due to removal of tissue or due to swelling.

Brief Description of the Drawings

A preferred embodiment of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a front elevation view of a brassiere embodying the invention

and **Figure 2** is a corresponding view showing the panel/ flap of the left cup of the brassiere hanging down for exposure of the breast ;

Figure 3 is a front elevation view of the clasp showing the clasp in the closed state and, below the clasp, the co-operating eye tab that fits on the apex of the flap/panel;

Figure 4 is a side elevation view of the clasp in part-opened state, the clasp being shown installed upon the lower front end of the bra's shoulder strap and **Figure 5** is a corresponding view of the clasp in fully opened state and shifted one 'rung' down the shoulder strap;

Figure 6 is a front elevation view of the shut state of the clasp installed on the shoulder strap and, below the clasp, the co-operating eye tab is shown installed on the apex of the flap/panel being brought up to the hook on the clasp to be hooked in place;

Figure 7 is a side elevation view of the Figure 6 arrangement;

Figure 8 is a front elevation view of the clasp installed on the shoulder strap and with the co-operating eye tab hooked onto the hook of the clasp, the clasp being open for upward or downward adjustment of the clasp's position on the shoulder strap; and

Figure 9 is a side elevation view of the Figure 8 arrangement but with the clasp shut to lock it at its selected position on the strap.

Description of the Preferred Embodiment

Referring to Figures 1 and 2, these show a maternity brassiere 1 with its characteristic fold-down central panels/ flaps 2a at the front of the cups 2.

The panels 2a have an approximately triangular form and when they are in the closed state the apex of each triangle is uppermost and detachably fastens to the lower end of the front length of a respective one of the shoulder straps 3 of the brassiere 1.The perimeter of each cup 2 is defined by bands 4 of a material that suitably is an elasticated fabric that

can adjust somewhat to breast size fluctuation and the bands 4 of each cup form an aperture/opening 5 at the centre that exposes the underlying wearer's breast for breast-feeding. The central cup openings 5 are covered over by the central panel/ flap 2a until access is needed for breast-feeding at which point the panel 2a apex is detached from the shoulder strap 3 and the flap is folded down as shown on the right of Figure 2.

The releasable attachment of the central panel/ flap 2a to the shoulder strap 3 has a unique arrangement. The apex of each central panel/ flap 2a carries a tab 6, suitably of moulded plastics or of metal, which incorporates an eyehole 6a. A second aperture 6b in the tab 6 receives a length of the fabric of the panel/flap 2a passing through it and looped and stitched to secure the tab 6 on the panel/flap 2a. The eyehole 6a of the tab 6 is designed to co-operatively engage in use with a corresponding hook formation 7 that is formed on the lower front end of a clasp structure 8 that is mounted on the brassiere strap 3.

The clasp structure 8 is adapted to have one of the brassiere's shoulder straps 3 passing through it and to be moved up and down the shoulder strap 3 with the clasp in its opened state and secured to the strap 3 at a selected location by closing of the clasp 8. The clasp structure 8 is suitably of moulded plastics or of metal and has a body part 8a that fits on and is movable up and down the shoulder strap 3 and a clamp part 8b with teeth 8d, the clamp part 8b being pivotally mounted 8c to the body part 8a to pivot between open and closed states to bite into and lock on the strap 3 when the chosen position on the strap 3 has been selected.

The teeth 8d of the clasp structure 8 effectively close down on the strap 3 behind one of a number of ribs 3a that are provided on the strap 3. The ribs 3a are in the region of the strap 3 where the apex of the flap is to attach and the ribs 3a extend transversely of the longitudinal axis of the strap 3 and can be many and at very close-spaced intervals down the strap 3 to allow for a fine and extensive degree of control over the position

of attachment and hence over cup-size adjustment.

The ribs 3a of the bra shoulder strap 3 may be formed by insertion of short lengths of wire in the strap or may be formed by stitching, folding or addition of other material to that area of the strap 3a. Although illustrated in the side elevation views as bulging to both front and rear of the strap 3, each rib 3a might suitably be provided bulging only forwardly/ in the direction facing the clamping part 8b of the clasp 3 so that the rear of the strap 3 is smooth, aiding upward and downward adjustment. Notably, the ribs 3a are generally of such small scale that they do not affect the wearer's comfort.

Referring to Figures 4 to 9, the clasp structure 8 may be adjusted to the desired position by the wearer independently of the step of hooking attachment of the central panel 2a and thus may be done before, during or after the central panel 2a is hooked to it. The clasp 8 installed on the bra shoulder strap 3 with the clamping part 8b raised, as in Figures 4 and 5, is able to be moved up and down to then be clamped at any chosen position. The step of hooking the eyelet 6a of the tab 6 at the apex of central panel 2a to the hook 7 on the clasp 8 is shown in Figures 7 to 9. For this the state of the clasp clamping part 8a does not matter and it may be in its raised/ opened state as in Figure 8 or lowered/ closed state as in Figure 9 while hooking to suit the wearer's preference in how they fit and adjust the brassiere cup.

Claims

1. A brassiere comprising one or a pair of breast supporting cups and of the type where at least one of the breast-supporting cups has a frontal opening to expose the breast, the breast-supporting cup comprising a panel/flap that covers the opening and a part of which is releasably attachable to the shoulder strap of the brassiere when closing the opening and so that on release the opening may be uncovered, characterized in that the means by which the panel/flap is releasably attachable to the shoulder strap comprises a clasp mounted on the shoulder strap with the strap extending through it and which is movable up and down the shoulder strap to any of a number of selected positions and having a clamping part so that it may be clamped at the selected position, thereby providing adjustment of the breast-supporting cup, the clasp incorporating co-operative engagement means thereon for the releasable attachment of the panel/ flap.

2. A brassiere as claimed in claim 1, wherein the shoulder strap has a plurality of transverse ribs thereon each serving as an abutment on the shoulder strap for the clamping part of the clasp to stop against.

3. A brassiere as claimed in claim 1 or 2, wherein the co-operative engagement means on the clasp comprises a hook and the panel/flap of the cup has a tab with an aperture to engage with the hook.

4. A brassiere as claimed in claim 3, wherein the tab has an aperture that receives material of the panel/flap therethrough to secure the tab to the panel/flap.

5. A brassiere as claimed in claim 2, wherein the ribs incorporate plastic or metal wire.

6. A brassiere as claimed in claim 2 or 5, wherein the ribs are provided on the front length of the strap at the lower end thereof.

(12) UK Patent (19) GB (11) 2499248 (13) B

(45) Date of B Publication 02.04.2014

(54) Title of the Invention: Breast feeding reminder bra strap clasp

(51) INT CL: ***A41C 3/04*** (2006.01)

(21) Application No: **1202384.2**

(22) Date of Filing: **13.02.2012**

(43) Date of A Publication **14.08.2013**

(56) Documents Cited:
GB 2394884 A **FR 002761238 A1**
Design no. 4019903 (MORANA) See whole document.

(58) Field of Search:
As for published application 2499248 A viz:
INT CL **A41C, A41D, A44B**
Other: **EPODOC WPI INTERNET**
updated as appropriate

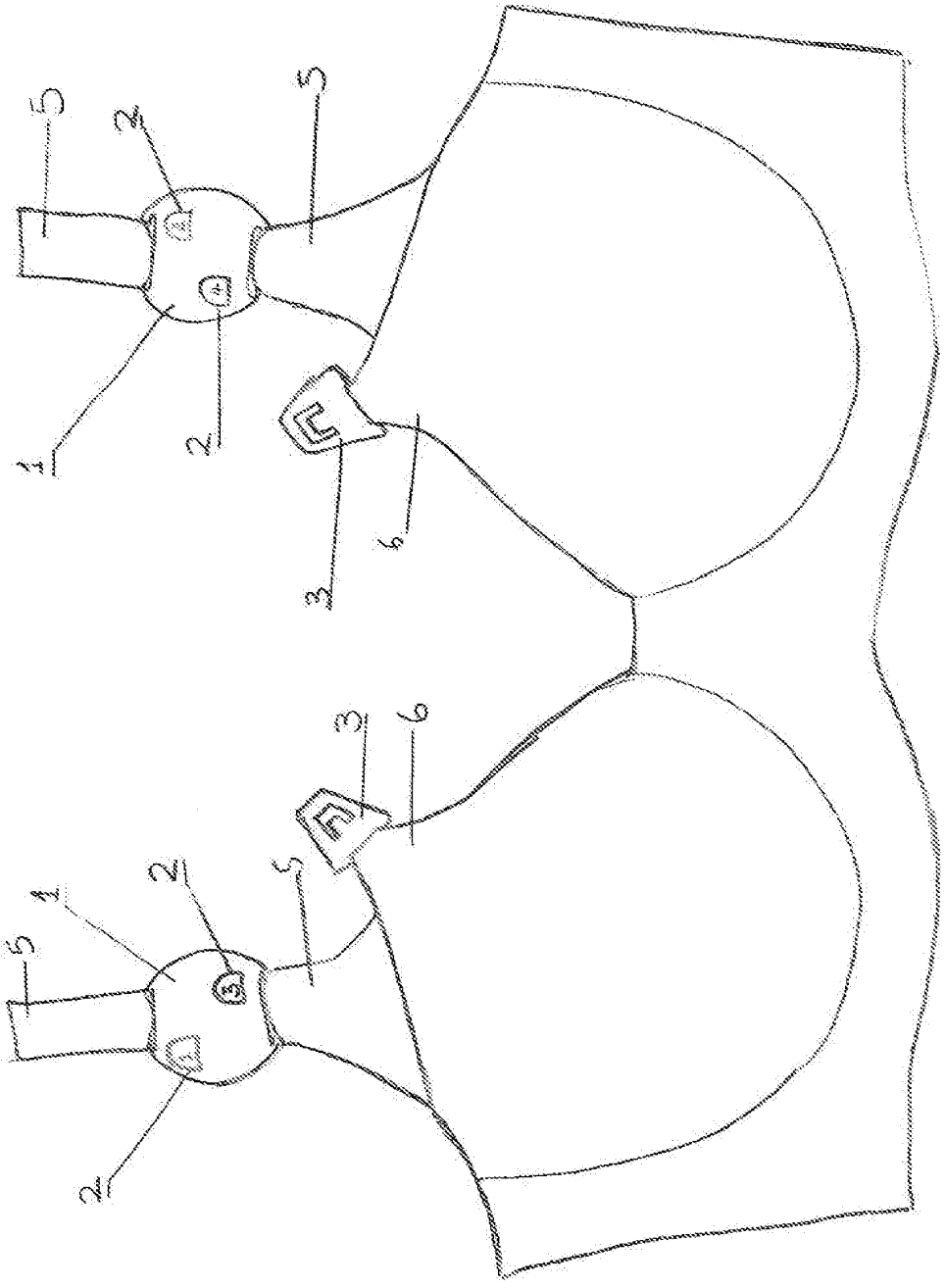
(72) Inventor(s):
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Figure 1



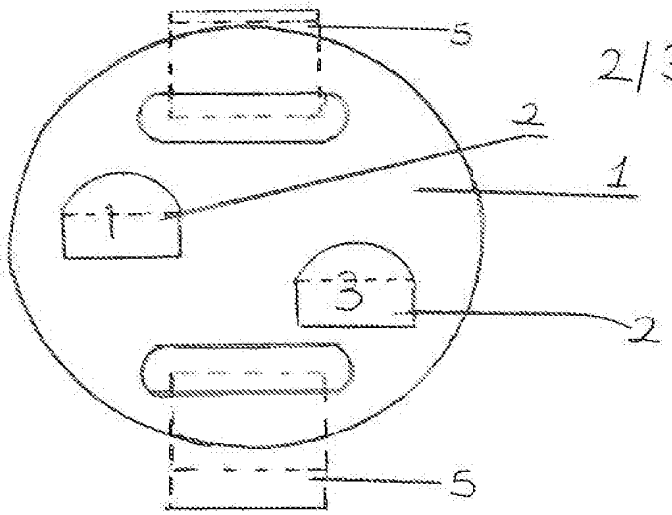


Figure 2

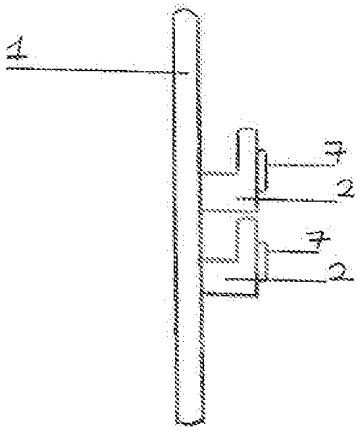


Figure 3

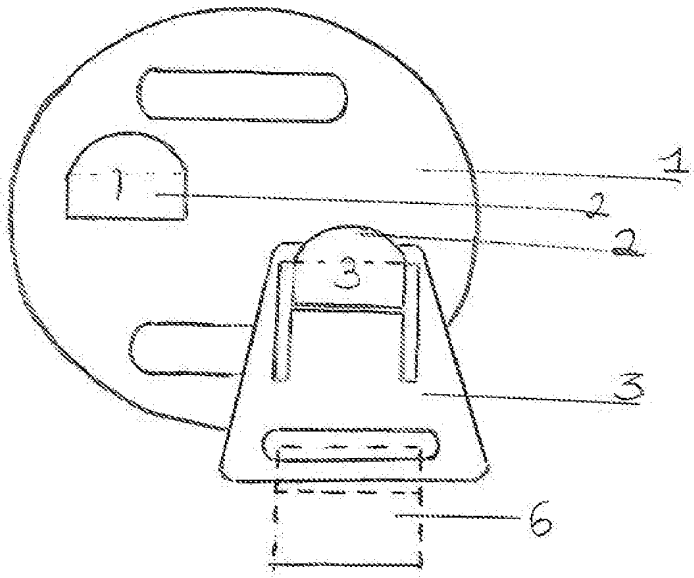


Figure 4

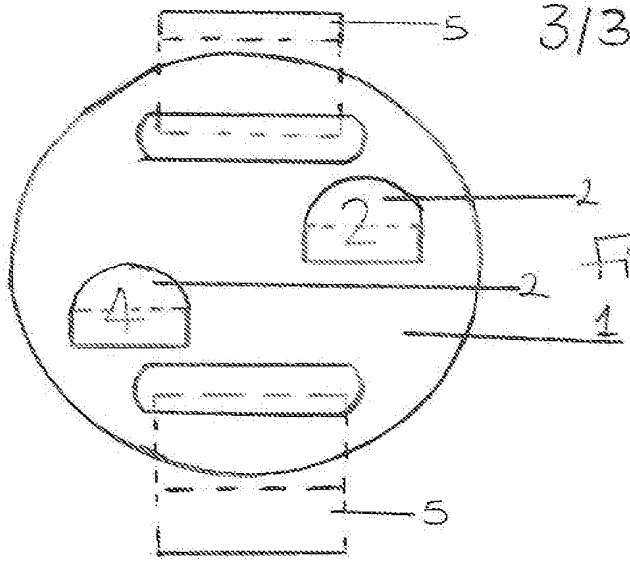


Figure 5

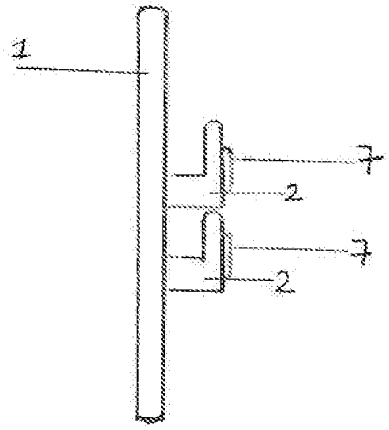


Figure 6

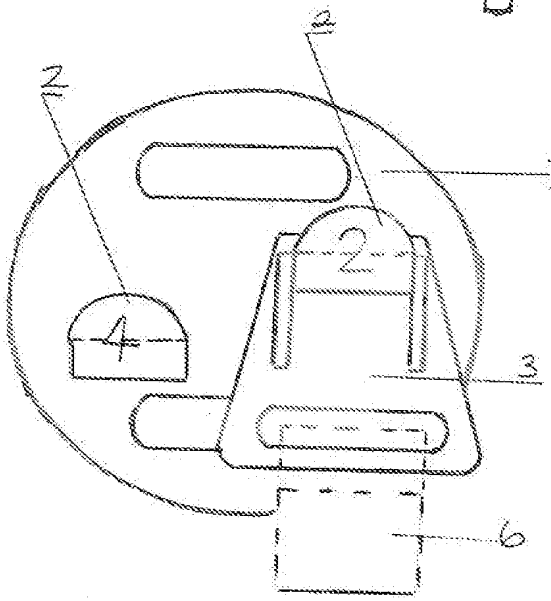


Figure 7

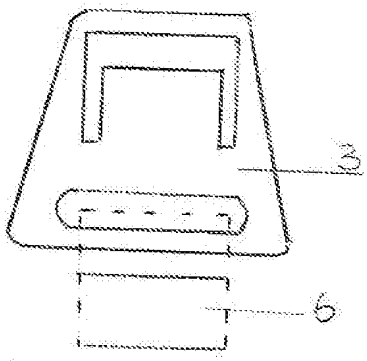


Figure 8

DESCRIPTION

Breast feeding reminder bra strap clasp

This invention helps breastfeeding mothers overcome a known problem of forgeting which breast to give to their baby to feed on next.
Most times as a new mother, experienced or not, everything can be overwhelming. Women can feel so overwhelmed; they tend to forget what can seem like a simple thing, "what breast do I feed my baby with this time?" and "what side did I use the last time?"
It is important to alternate between breasts while you nurse. As this will prevent painful breast engorgement and maintain the milk supply in both breasts, which is important in the beginning days of a baby's birth.
Current breast feeding reminder products, which include necklaces, clips and bracelets are all accessories that either need to be attached to the nursing bra, or moved from one side of the body to the other. They therefore only work, as long as you remember to switch them to the other side of the body and constantly remember to carry them with you.

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The invention provides a method of aiding a breast feeding mother to remember which breast to feed their baby on next as defined by claim 1.

To overcome the problem, the invention reminder feature works by using the clasp on a nursing bra, which mothers will always have to open and close, when feeding their baby ordinarily. With the use of two hooks and numbers on the clasps. The number reminds the user (mother) which breast to feed the baby from next, and/or which breast they fed their baby from last.

The use of numbers is preferable as the means of following a sequence for the reminder function. Although the number means may also be represented in other formats, such as letters, A, B, C, D. Roman numerals, I, II, III, IV. Dots, **./../.../....** etc Anything that can form a sequence.

When using the breast feeding reminder clasp, when the user chooses to feed her baby, she will look for the LOWEST number on the clasp hooks that the eyes are set on, to understand which side to feed the baby from. After finishing a feed, she will look for the HIGHEST CONSECUTIVE number on the clasp hook, to understand where to replace the eye.
When the lower hooks are reached, the user just repeats the process again by going back to the top hook.

The important 3 STEPS for use are summarised as follows:

1. Always *select the LOWEST number hook that the eye is on to understand which side to feed the baby from next.*

2. *Always select the HIGHEST CONSECTUTIVE number to the opposite hook, once finished feeding*

3. *When the eyes are on hooks numbers 1 and 4 always follow on to number 2*

The invention will now be described solely by way of example and with reference to the accompanying drawings in which:

Figure 1 shows a pair of breast feeding reminder bra strap clasps, permanently attached to a nursing bra. One fitted to the right bra strap and the other to the left.

Figure 2 shows the right breast feeding reminder bra strap clasp, front view.

Figure 3 shows the right breast feeding reminder bra strap clasp, side view.

Figure 4 shows the right breast feeding reminder bra strap clasp, front view. With eye fitting attached to the lower clasp hook

Figure 5 shows the left breast feeding reminder bra strap clasp, front view.

Figure 6 shows the left breast feeding reminder bra strap clasp, side view.

Figure 7 shows the left breast feeding reminder bra strap clasp, front view. With eye fitting attached to the upper clasp hook

Figure 8 shows the eye fitting

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Figure 1, shows the use of numbers on the breast feeding reminder bra strap clasp 1, hooks 2 as reminders. There are two hooks on each breast feeding reminder bra strap clasp.
The breast feeding reminder bra strap clasps are permanently fixed to the bra strap 5. The eye 3 fittings are permanantly affixed to the breast cup 6 section of the bra. The eye allows the breast cup to open, when it is realeased from the clasp hook and close, when attached to the clasp hook

Figure 2 shows the right clasp 1 attached to the bra strap 5. With the use of numbers on the hooks 2 as reminders.

Figure 3 shows the right clasp 1, on a side view. With the numbers raised 7 onto the hooks 2. As this is a way that the numbers could be made visable on the plastic hooks. Although alternative methods such as being printed to the hooks may be used.

Figure 4 shows the eye 3 fitting attached to the lower hook 2 of the right clasp 1

Figure 5 shows the left clasp 1 attached to the bra strap 5. With the use of numbers on the hooks 2 as reminders.

Figure 6 shows the left clasp 1, on a side view. With the numbers raised 7 onto the hooks 2. As this is a way that the numbers could be made visable on the plastic hooks. Although alternative methods such as being printed to the hooks may be used.

Figure 7 shows the eye 3 fitting attached to the upper hook 2 of the left clasp 1.

Figure 8 shows the eye 3 fitting attached to the breast cup 6 section of the bra.

Example of use.
The user is wearing the nursing bra, and the eye fixings of the breast cup are attached to number 1 on the right clasp hook and number 2 on the left clasp hook

- She opens up the right cup, by releasing the eye from hook number 1 on the right side.
- She then begins to feeds her baby.
- Once finished with the feeding, the reminder function kicks in. As the wearer would look to the the opposite clasp, (left clasp) to observe which number hook the eye is on.
- The eye would be on hook number 2.
- Complying with the STEPS for use. The user would then replace the eye on the feeding side (right side) on the HIGHER CONSECUTIVE number. (There is only a choice of number 1 and 3 on the feeding side) Therefore number chosen would be 3. As 3 is higher than 2, and is consecutive to number 2

This now allows the user when returning to feed her baby the next time, to recognise which breast (left or right) she fed her baby on last but most importantly which breast (left of right) to start feeding her baby with next.

So in this instance, when the user would go to feed her baby for the next feed that day. Simply by observing which number hook, the eye on the right and left clasp are attached to, she will undertsand which side to feed from.

In this case, she would see that the eye on the left clasp was attached to hook number 2 and the eye on the right clasp was attached to hook number 3. By complying with the STEPS for use, the LOWER number would be chosen.

Number 2 is the lower number between numbers 2 and 3. So she would understand that the the left breast was where to start feeding her baby from next.

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- She opens up the left cup, by releasing the eye from hook number 2 on the left side.
- She then begins to feeds her baby.

- Once finished with the feeding, the reminder function kicks in again. As the wearer would look to the the opposite clasp, (right clasp) to observe which number hook the eye is on.
- The eye would be on hook number 3.
- Complying with the STEPS for use. The user would then replace the eye on the feeding side (left side) on the HIGHER CONSECUTIVE number. (There is only a choice of number 2 and 4 on the feeding side) Therefore number chosen would be 4. As 4 is higher than 3, and is consecutive to number 3

When the user returns again to feed her baby next, she will observe which number hook, the eye on the right and left clasp are attached to. She will notice that the right was on hook number 3 and the eye on the left was on hook number 4. She would again:-

- Select the LOWER number, to understand which is the next breast to feed from.
- The LOWER number between 3 and 4 is number 3
- The user would select the right breast to feed the baby from, by releasing the eye from hook number 3.
- Once finished, she would look to the opposite clasp, (left clasp) to observe which number hook, the eye is on.
- This would advise her where to place the eye, of the breast that she has just fed from.
- As the left eye is on hook number 4. There is no hook number HIGHER than number 4, so she would return back to the top hook on the feeding side, which is number 1.
- When she returns for her next feed, she will again observe which number hook the eye on the right and left clasp are attached to.
- In this case she will see that the right clasp is attached to number 1 and the left number 4
- Complying with the three STEPS for use. When the eyes are attached to hooks number 1 and 4. The user should always follow on to number 2.
- So she would open up the bra cup of left breast and when finished feeding, would replace it on hook number 2. Hook number 2 is HIGHER and CONSECUTIVE to the opposite hook, number 1.

These steps are then continued and repeated at each feed.

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The clasp will be produced in plastic, by using the injection moulding process. The clasp will be produced in a variety of colours to match and contrast with the fabric and colours of the nursing bra.

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CLAIMS

1. A method of aiding a breast feeding mother to remember which breast to feed their baby on next wherein said method comprises the mother wearing a bra comprising a first clasp attached to a first side of the bra and a second clasp attached to a second side of the bra, wherein each said clasp comprises two hooks for attaching an eye connected to the bra cup of each side, said hooks being labelled in sequence to indicate a feeding order and wherein the feeding order is determined by identifying the eye that is attached to the hook having a value lower than the highest consecutive value of the hook in use on the opposite side of the bra and feeding from the side on which said eye has been identified and then, after feeding, replacing said eye onto the hook bearing the highest consecutive value to the hook in use on the opposite side of the bra.

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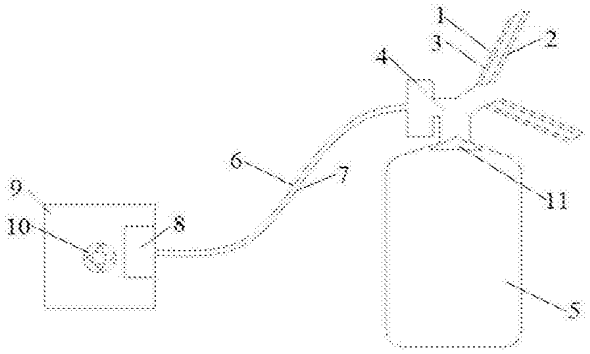
权利要求书2页 说明书6页 附图1页

(54)发明名称

基于柔性压力传感器进行压力反馈控制的电动吸乳器

(57)摘要

本发明涉及一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，包括吸乳护罩、主体、吸气管、真空泵及控制主机，吸乳护罩与主体连接，主体通过吸气管与真空泵连接，真空泵设置在控制主机内，主体下端用于连接接收容器，还设置有压电薄膜传感器与反馈单元，压电薄膜传感器设置在吸乳护罩的内侧，反馈单元设置在控制主机内部，压电薄膜传感器与反馈单元连接，压电薄膜传感器检测乳房体表组织所承受的负压，并传递给反馈单元，反馈单元根据反馈信息控制真空泵的吸力大小。与现有技术相比，本发明电动吸乳器可以实时监控吸乳器使用者的乳房所承受的压力，动态调节吸乳器真空吸力，避免真空吸力过大导致的乳房损伤，保护使用者乳房健康。



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1. 一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，包括吸乳护罩 (3)、主体 (4)、吸气管 (6)、真空泵 (8) 及控制主机 (9)，所述的吸乳护罩 (3) 与主体 (4) 连接，所述的主体 (4) 通过吸气管 (6) 与真空泵 (8) 连接，所述的真空泵 (8) 设置在控制主机 (9) 内，所述的主体 (4) 下端用于连接接收容器 (5)，其特征在于，还设置有压电薄膜传感器 (1) 与反馈单元，所述的压电薄膜传感器 (1) 设置在吸乳护罩 (3) 的内侧，所述的反馈单元设置在控制主机 (9) 内部，所述的压电薄膜传感器 (1) 与反馈单元连接，所述的压电薄膜传感器 (1) 检测乳房体表组织所承受的负压，并传递给反馈单元，反馈单元根据反馈信息控制真空泵 (8) 的吸力大小。

2. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的反馈单元包括电荷放大器 (12)、低通滤波器 (13)、比例放大器 (14) 及微控制器 (15)，所述的压电薄膜传感器 (1) 两个电极通过导线 (7) 依次与电荷放大器 (12)、低通滤波器 (13)、比例放大器 (14) 及微控制器 (15) 连接，所述的微控制器 (15) 还与真空泵 (8) 连接，

所述的真空泵 (8) 产生负压，压电薄膜传感器 (1) 检测乳房体表组织所承受的负压，并产生电压输出，电信号顺序传输给电荷放大器 (12)、低通滤波器 (13)、比例放大器 (14) 及微控制器 (15)，微控制器 (15) 将真空泵 (8) 产生的负压与压电薄膜传感器 (1) 输出的电压对应成比例关系，并根据压电薄膜传感器 (1) 输出的电压来调节真空泵 (8) 吸力的大小。

3. 根据权利要求 2 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的微控制器 (15) 内装有相应的乳房受压变化动态数学模型，即 $P(u)(k) = \Sigma a_i P(u)(k-i) + \Sigma b_j u(k-j)$，

其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为乳房承受的压力，量纲为帕斯卡，Σ 表示求和运算，a_i 和 b_j 为加权系数，i 和 j 分别是加权系数 a_i 和 b_j 的序号指标，

在开始吸乳时，由微控制器 (15) 控制真空泵 (8) 发出一组随机试探控制电压，使得乳房承受随机变化的负压压力，其峰值压力 $P_m < P_0$，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，根据这组测得的压力和控制电压，微控制器 (15) 采用递推最小二乘法辨识出动态数学模型中的参数 a_i 和 b_j。

4. 根据权利要求 2 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的微控制器 (15) 内装有多种吸乳负压变化的波形模式，包括正弦波、变幅正弦波、变频正弦波、变频和变幅正弦波，用户根据 P_0 压力上限的约束，可选择任一种波形模式，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，微控制器 (15) 根据客户选择的波形模式而生成吸乳负压变化给定曲线，并控制真空泵 (8) 按照吸乳负压变化给定曲线提供负压。

5. 根据权利要求 4 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的微控制器 (15) 根据压电薄膜传感器 (1) 实时测量到的乳房承受压力 P 与吸乳负压变化给定曲线不同时刻的给定负压 P_r，按下式实时计算出微控制器 (15) 的输出电压值 u(k)，其中 $\alpha > 0$，α 为调节控制稳定度的系数：

$$u(k) = (P_r(k+1) - \Sigma a_i P(u)(k-i+1) + \Sigma_{j \neq 1} b_j u(k-j+1)) b_1 / (b_1^2 + \alpha)$$

其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为

乳房承受的压力，量纲为帕斯卡，Σ 表示求和运算，a_i和 b_j为加权系数，i 和 j 分别是加权系数 a_i和 b_j的序号指标。

6. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的压电薄膜传感器 (1) 外侧紧贴在吸乳护罩 (3) 内侧，所述的压电薄膜传感器 (1) 内侧设有用于与乳房体表接触的硅胶 (2)。

7. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的压电薄膜传感器 (1) 为 PVDF 压电薄膜传感器。

8. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的主体 (4) 上用于连接接收容器 (5) 处设有防逆流组件 (11)。

9. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的控制主机 (9) 上设有用于对真空泵 (8) 吸力进行手动调节的手动调节按键 (10)。

10. 根据权利要求 1 所述的一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，其特征在于，所述的控制主机 (9) 上还设有报警器，当压电薄膜传感器 (1) 检测的压力小于设定压力值时，报警器报警。

基于柔性压力传感器进行压力反馈控制的电动吸乳器

技术领域

[0001] 本发明涉及一种电动吸乳器，尤其是涉及一种基于柔性压力传感器进行压力反馈控制的电动吸乳器。

背景技术

[0002] 母乳喂养是一种国际公认的健康哺乳方式，而孕期妇女一般都是职业女性，哺乳时间有限，当决定母乳喂养之后便需要借助专业设备挤出母乳并储藏。目前国际知名的吸乳器厂商有美德乐、飞利浦等，它们生产的吸乳器分为电动型与手动型。针对电动吸乳器，均使用开环控制，在刺激泌乳阶段，利用微控制器控制高频率 PWM 波，使得真空泵的负压变化频率高，幅度小；在吸乳阶段，利用控制器控制低频率 PWM 波，使得真空泵的负压变化频率低，幅度大。

[0003] 然而电动吸乳器开环设计的明显缺陷是在电压突变、电机故障或者误操作按键的情况下导致吸乳真空力度的突然变化超出用户乳房组织承受的压力，造成用户乳腺及乳房组织受到伤害；此外部分用户由于对痛觉不敏感，因在使用吸乳器时，较长期使用不合适的吸乳压力，也导致乳房的乳腺或乳房组织受伤。

[0004] 中国专利CN 103182103 A公布了一种具有负压调节机构的电动吸乳器，其包括机体、机罩、负压生成机构、负压调节机构和压力显示机构，以及通过软管与负压生成机构相连的吸乳集乳机构。负压生成机构包括步进电机和气缸。负压调节机构包括负压调节橡皮圈、指令器和接收器，负压调节橡皮圈活动套装在气缸上可径向转动，指令器的外端固定套装在负压调节橡皮圈上可带动负压调节橡皮圈转动，接收器嵌套在指令器的内与气缸之间并与气缸固定连接。通过选用步进电机，设置负压调节机构，能够生成稳定负压，通过步进电机控制活塞频率，更加贴近婴儿吮吸频率，提高吸乳时的舒适度；压力显示机构能够让使用者更加直观的调节负压的大小，但是上述反馈装置采用步进气缸来调节气缸吸力大小，导致反应不够灵敏，准确性较差，此外，该专利电动吸乳器结构设置较为复杂。

发明内容

[0005] 本发明的目的就是为了克服上述现有技术存在的缺陷而提供一种基于柔性压力传感器进行压力反馈控制的电动吸乳器。

[0006] 根据人体的体表组织受外力产生的形变变化可由胡克定律近似表示的假设，设所检测的体表组织受压时产生的形变量 X = S*h(S 为所检测的体表组织受压部分的表面积，h 为体表组织受压产生的形变位移）与所产生的形变压力 P 之间的关系可以近似为 P = K*X，其中 K 为体表组织的形变系数，设 K_0为乳房组织的形变系数值，该值可以通过实验测得。因此，在对应的形变位移区间 h 中，总会对应一个形变压力 P，由于乳房组织的体积和形变位移 h 是有限的，当吸乳器施加的压力 P 过大，使得 K = P/(S*h) 增大到大于乳房组织的形变系数值 K_0时便有可能对乳腺造成伤害。

[0007] 为了克服现有电动吸乳器开环设计可能造成的乳腺伤害，本发明引入柔性压力传

感器，通过该柔性压力传感器对乳房体表组织所承受的负压进行实时检测反馈，并对吸乳器的负压实时进行闭环控制，防止开环控制存在的由于装置故障或电压波动造成压力失控进而给乳腺造成伤害的问题，将吸乳器的最大真空负压控制在安全的范围内，确保用户乳腺的安全。

[0008] 本发明的目的可以通过以下技术方案来实现：

[0009] 一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，包括吸乳护罩、主体、吸气管、真空泵及控制主机，所述的吸乳护罩与主体连接，所述的主体通过吸气管与真空泵连接，所述的真空泵设置在控制主机内，所述的主体下端用于连接接收容器，还设置有压电薄膜传感器与反馈单元，所述的压电薄膜传感器设置在吸乳护罩的内侧，所述的反馈单元设置在控制主机内部，所述的压电薄膜传感器与反馈单元连接，所述的压电薄膜传感器检测乳房体表组织所承受的负压，并传递给反馈单元，反馈单元根据反馈信息控制真空泵的吸力大小。

[0010] 所述的反馈单元包括电荷放大器、低通滤波器、比例放大器及微控制器，所述的压电薄膜传感器两个电极通过导线依次与电荷放大器、低通滤波器、比例放大器及微控制器连接，所述的微控制器还与真空泵连接，所述的真空泵产生负压，压电薄膜传感器检测乳房体表组织所承受的负压，并产生电压输出，电信号顺序传输给电荷放大器、低通滤波器、比例放大器及微控制器，电荷放大器对信号进行放大，由于吸乳操作的频率接近 1Hz，因此采用低通滤波器对信号进行低通滤波，然后比例放大器对信号进行比例放大后，输送给微控制器，微控制器对信号进行非线性标定校正后，将真空泵产生的负压与压电薄膜传感器输出的电压对应成比例关系，根据压电薄膜传感器输出的电压即可判断真空泵产生的负压是否超过阈值，据此动态调节输出电压占空比，从而自动调节真空泵产生的负压大小。在吸乳过程中，微控制器实时监控乳房与吸乳护罩之间的压力变化，当压力过大时，微控制器降低占空比，动态减小真空泵的真空吸力，使其不会超过乳房承受压力的最大阈值。

[0011] 其中导线与吸气管绑定在一起。

[0012] 1) 乳房承受压力动态模型的在线辨识：

[0013] 所述的微控制器内装有相应的乳房受压变化动态数学模型，即 $P(u)(k) = \Sigma a_i P(u)(k-i) + \Sigma b_j u(k-j)$，

[0014] 其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为乳房承受的压力，量纲为帕斯卡，P 可由柔性压力传感器实时测得，Σ 表示求和运算，a_i 和 b_j 为加权系数，i 和 j 分别是加权系数 a_i 和 b_j 的序号指标。

[0015] 在开始吸乳时，由微控制器控制真空泵发出一组随机试探控制电压，使得乳房承受随机变化的负压压力，其峰值压力 $P_m < P_0$，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，根据这组测得的压力和控制电压，微控制器采用递推最小二乘法辨识出动态数学模型中的加权系数 a_i 和 b_j。

[0016] 2) 乳房吸乳负压给定曲线的自动生成

[0017] 所述的微控制器内装有多种吸乳负压变化的波形模式，包括正弦波、变幅正弦波、变频正弦波、变频和变幅正弦波，用户根据 P_0 压力上限的约束，可选择任一种波形模式，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，微控制器根据客户选择的波形模式而生成吸乳负压变化给定曲线，并控制真空泵按照吸乳负压变化给定曲线提供

负压。

[0018] 3) 自动吸乳负压反馈控制

[0019] 所述的微控制器根据压电薄膜传感器实时测量到的乳房承受压力 P 与吸乳负压变化给定曲线不同时刻的给定负压 P_r，按下式实时计算出微控制器的输出电压值 u(k)，其中 α >0，α 为调节控制稳定度的系数：

[0020] $u(k) = (P_r(k+1) - \Sigma a_i P(u)(k-i+1) + \Sigma_{j\neq 1} b_j u(k-j+1)) b_1/(b_1^2+\alpha)$

[0021] 其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为乳房承受的压力，量纲为帕斯卡，Σ 表示求和运算，a_i和 b_j为加权系数，i 和 j 分别是加权系数 a_i和 b_j的序号指标。

[0022] 4) 特殊情况和故障自动处理

[0023] 在吸乳时，微控制器实时监控乳房与吸乳护罩之间的压力变化，当压力过大时，即 $P>P_0$或 $P = P_0$时，微控制器会降低 PWM 波的占空比，动态减小真空吸力，使其不会超过乳房承受压力的阈值 P_0；如果乳房与吸乳器护罩之间松落，此时压力会低于正常吸乳的阈值 P_s，处于低效率吸乳模式，微控制器会报警提示使用者重新固定吸乳器。当真空泵发生故障导致负压压力超过阈值 P_0而微控制器的控制无效时，微控制器将自动切断真空泵电源，以保护用户的乳腺不受伤害。

[0024] 所述的压电薄膜传感器外侧紧贴在吸乳护罩内侧，所述的压电薄膜传感器内侧设有用于与乳房体表接触的硅胶，通过设置硅胶以对乳房进行保护。

[0025] 所述的压电薄膜传感器为 PVDF 压电薄膜传感器，其是一种柔性的传感器，能够实时监控吸乳护罩与使用者乳房之间的压力变化。

[0026] 所述的主体上用于连接接收容器处设有防逆流组件，作用是防止由于失误导致乳汁逆回流主机，导致电机或微控制器损毁。

[0027] 所述的控制主机上设有用于对真空泵吸力进行手动调节的手动调节按键。当自动调节失效或需要紧急手动调节使，通过手动调节按键来调节真空泵的吸力大小。

[0028] 所述的控制主机上还设有报警器，当压电薄膜传感器检测的压力小于设定压力值，即低于最小阈值时，乳房与吸乳器护罩之间松落，此时处于低效率吸乳模式，报警器报警提示使用者进行调节。

[0029] 与现有技术相比，本发明具有以下优点及有益效果：

[0030] 1、本发明采用柔性压力传感器安装在吸乳器与乳房相贴部分，对乳房的乳腺在吸乳过程所承受的负压大小进行实时检测，并根据测量的压力值，对吸乳压力进行实时反馈控制，确保乳腺和乳房组织所能承受的压力在安全阈值范围内，如果一旦出现因吸乳器装置故障、电压波动等因素引起压力增大，达到安全阈值，便自动进行泄压操作，确保用户的乳腺和乳房组织不受伤害。

[0031] 2、本发明装置在微控制器中安装有多种波形模式，用户可以根据需要自行选择。

[0032] 3、控制主机上设置有手动调节按键，可以通过手动调节按键来调节真空泵的吸力大小，手动调节按键的设置为本发明装置提供了双重安全保障。

[0033] 4、本电动吸乳器可以实时监控吸乳器使用者的乳房所承受的压力，动态调节吸乳器真空吸力，避免真空吸力过大导致的乳房损伤，保护使用者乳房健康。

[0034] 5、本发明装置结构简单，易于实现，防止由于吸乳器使用过程中的故障导致的对

使用者乳房的伤害。

附图说明

[0035] 图 1 为本发明电动吸乳器结构示意图；

[0036] 图 2 为反馈单元的结构原理图。

[0037] 图中，1 为压电薄膜传感器，2 为硅胶，3 为吸乳护罩，4 为主体，5 为接收容器，6 为吸气管，7 为导线，8 为真空泵，9 为控制主机，10 为手动调节按键，11 为防逆流组件，12 为电荷放大器，13 为低通滤波器，14 为比例放大器，15 为微控制器。

具体实施方式

[0038] 下面结合附图和具体实施例对本发明进行详细说明。

[0039] 实施例

[0040] 如图 1 所示，一种基于柔性压力传感器进行压力反馈控制的电动吸乳器，包括吸乳护罩 3、主体 4、吸气管 6、真空泵 8 及控制主机 9，吸乳护罩 3 与主体 4 连接，主体 4 通过吸气管 6 与真空泵 8 连接，真空泵 8 设置在控制主机 9 内，主体 4 下端用于连接接收容器 5，还设置有压电薄膜传感器 1 与反馈单元，压电薄膜传感器 1 设置在吸乳护罩 3 的内侧，反馈单元设置在控制主机 9 内部，压电薄膜传感器 1 与反馈单元连接，压电薄膜传感器 1 检测乳房体表组织所承受的负压，并传递给反馈单元，反馈单元根据反馈信息控制真空泵 8 的吸力大小。

[0041] 压电薄膜传感器 1 外侧紧贴在吸乳护罩 3 内侧，压电薄膜传感器 1 内侧设有用于与乳房体表接触的硅胶 2，通过设置硅胶 2 以对乳房进行保护。

[0042] 压电薄膜传感器 1 为 PVDF 压电薄膜传感器，其是一种柔性的传感器，能够实时监控吸乳护罩与使用者乳房之间的压力变化。

[0043] 主体 4 上用于连接接收容器 5 处设有防逆流组件 11，作用是防止由于失误导致乳汁逆回流主机，导致电机或微控制器损毁。

[0044] 控制主机 9 上设有用于对真空泵 8 吸力进行手动调节的手动调节按键 10。当自动调节失效或需要紧急手动调节使，通过手动调节按键 10 来调节真空泵 8 的吸力大小。

[0045] 控制主机 9 上还设有报警器，当压电薄膜传感器 1 检测的压力小于设定压力值，即低于最小阈值时，乳房与吸乳器护罩之间松落，此时处于低效率吸乳模式，报警器报警提示使用者进行调节。

[0046] 参考图 2，反馈单元包括电荷放大器 12、低通滤波器 13、比例放大器 14 及微控制器 15，压电薄膜传感器 1 两个电极通过导线 7 依次与电荷放大器 12、低通滤波器 13、比例放大器 14 及微控制器 15 连接，微控制器 15 还与真空泵 8 连接，真空泵 8 产生负压，压电薄膜传感器 1 检测乳房体表组织所承受的负压，并产生电压输出，电信号顺序传输给电荷放大器 12、低通滤波器 13、比例放大器 14 及微控制器 15，电荷放大器 12 对信号进行放大，由于吸乳操作的频率接近 1Hz，因此采用低通滤波器 13 对信号进行低通滤波，然后比例放大器 14 对信号进行比例放大后，输送给微控制器 15，微控制器 15 对信号进行非线性标定校正后，将真空泵 8 产生的负压与压电薄膜传感器 1 输出的电压对应成比例关系，根据压电薄膜传感器 1 输出的电压即可判断真空泵 8 产生的负压是否超过阈值，据此动态调节输出电压占

空比，从而自动调节真空泵 8 产生的负压大小。在吸乳过程中，微控制器 15 实时监控乳房与吸乳护罩之间的压力变化，当压力过大时，微控制器降低占空比，动态减小真空泵 8 的真空吸力，使其不会超过乳房承受压力的最大阈值。

[0047] 本实施例中，导线 7 与吸气管 6 绑定在一起。

[0048] 本实施例中的吸乳器具备以下功能：

[0049] 1、乳房承受压力动态模型的在线辨识：

[0050] 微控制器 15 内装有相应的乳房受压变化动态数学模型，即 $P(u)(k) = \Sigma a_i P(u)(k-i) + \Sigma b_j u(k-j)$，

[0051] 其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为乳房承受的压力，量纲为帕斯卡，P 可由柔性压力传感器实时测得，Σ 表示求和运算，a_i 和 b_j 为加权系数，i 和 j 分别是加权系数 a_i 和 b_j 的序号指标。

[0052] 在开始吸乳时，由微控制器 15 控制真空泵 8 发出一组随机试探控制电压，使得乳房承受随机变化的负压压力，其峰值压力 $P_m < P_0$，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，根据这组测得的压力和控制电压，微控制器 15 采用递推最小二乘法辨识出动态数学模型中的参数 a_i 和 b_j。

[0053] 2、乳房吸乳负压给定曲线的自动生成

[0054] 微控制器 15 内装有多种吸乳负压变化的波形模式，包括正弦波、变幅正弦波、变频正弦波、变频和变幅正弦波，用户根据 P_0 压力上限的约束，可选择任一种波形模式，P_0 即经过大量统计试验获得的使乳房产生形变的安全压力的平均值，微控制器 15 根据客户选择的波形模式而生成吸乳负压变化给定曲线，并控制真空泵 8 按照吸乳负压变化给定曲线提供负压。

[0055] 3、自动吸乳负压反馈控制

[0056] 微控制器 15 根据压电薄膜传感器 1 实时测量到的乳房承受压力 P 与吸乳负压变化给定曲线不同时刻的给定负压 P_r，按下式实时计算出微控制器 (15) 的输出电压值 u(k)，其中 $\alpha > 0$，α 为调节控制稳定度的系数：

[0057] $u(k) = (P_r(k+1) - \Sigma a_i P(u)(k-i+1) + \Sigma_{j \neq 1} b_j u(k-j+1)) b_1 / (b_1^2 + \alpha)$

[0058] 其中 u 为微控制器给出的控制电压信号，量纲为伏特，k 为采样时间，单位为毫秒，P 为乳房承受的压力，量纲为帕斯卡，Σ 表示求和运算，a_i 和 b_j 为加权系数，i 和 j 分别是加权系数 a_i 和 b_j 的序号指标。

[0059] 4、特殊情况和故障自动处理

[0060] 在吸乳时，微控制器 15 实时监控乳房与吸乳护罩之间的压力变化，当压力过大时，即 $P > P_0$ 或 $P = P_0$ 时，微控制器会降低 PWM 波的占空比，动态减小真空吸力，使其不会超过乳房承受压力的阈值 P_0；如果乳房与吸乳器护罩之间松落，此时压力会低于正常吸乳的阈值 P_s，处于低效率吸乳模式，微控制器会报警提示使用者重新固定吸乳器。当真空泵发生故障导致负压压力超过阈值 P_0 而微控制器的控制无效时，微控制器将自动切断真空泵电源，以保护用户的乳腺不受伤害。

[0061] 上述的对实施例的描述是为便于该技术领域的普通技术人员能理解和使用发明。熟悉本领域技术的人员显然可以容易地对这些实施例做出各种修改，并把在此说明的一般原理应用到其他实施例中而不必经过创造性的劳动。因此，本发明不限于上述实施例，本领

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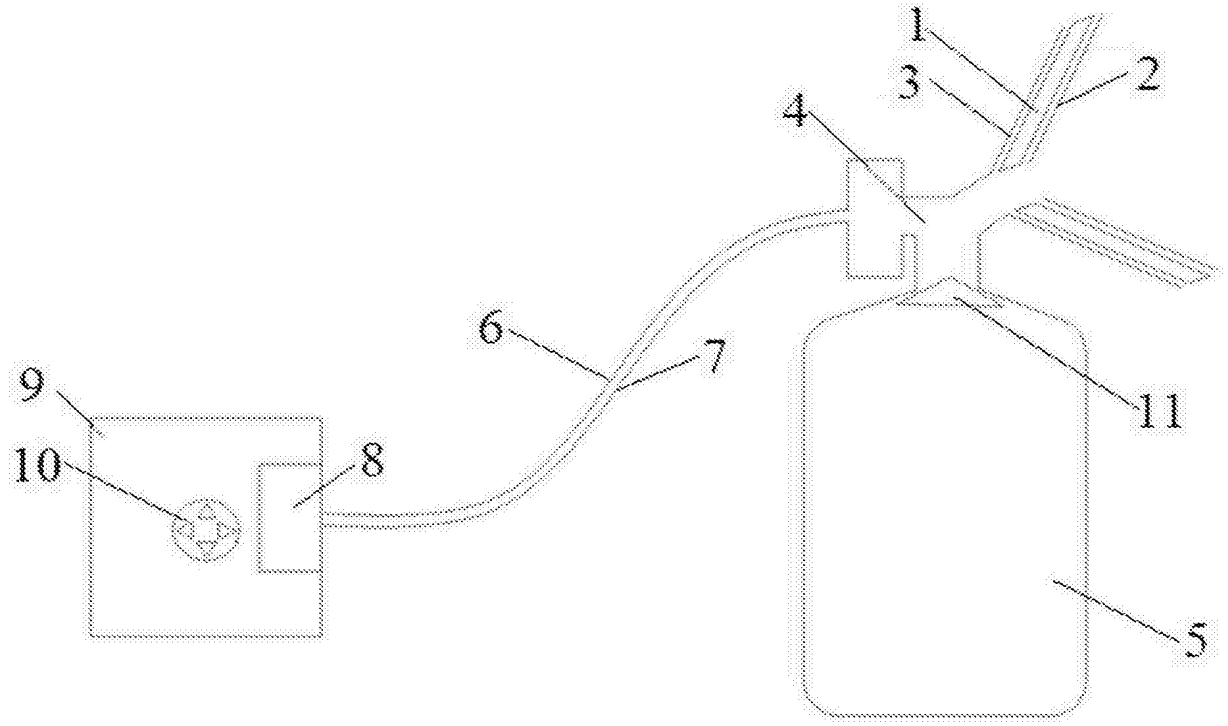


图 1

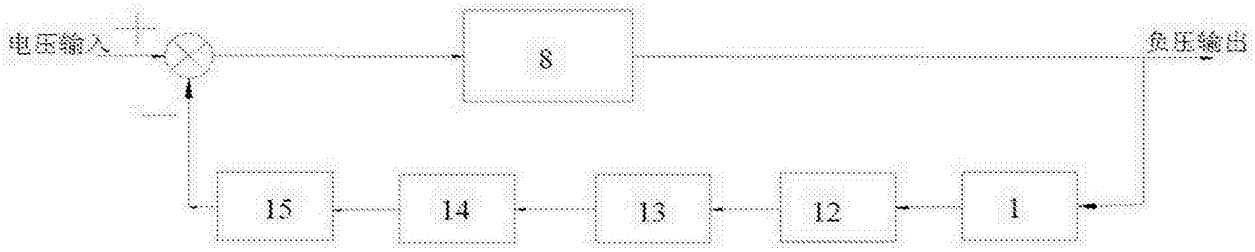


图 2

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(54) **SYSTEM FOR A PORTABLE HANDS-FREE BREAST PUMP**

SYSTEM FÜR EINE FREIHÄNDIG TRAGBARE BRUSTPUMPE

SYSTEME DESTINE A UN TIRE-LAIT MAINS LIBRES, PORTATIF

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(56) References cited:
US-A- 5 358 476
US-A- 5 680 978
US-A- 5 776 098
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US-B1- 6 427 475

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EP 1 404 393 B1

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The invention generally relates to a portable, hands-free, and visually friendly breast pump system and method for collecting milk from a breast of a nursing mother which may be hidden from view when in use. In particular, the invention may be hidden underneath the clothing of a nursing mother, which provides privacy and avoids any attention and the awkwardness experienced by the nursing mother using existing breast pumps.

Description of the Related Art

[0002] Breastfeeding is the best source of nutrition for a baby, and it also offers health benefits to the nursing mother. Often, the nursing mother needs to use a breast pump to collect milk. A variety of breast pumps are available. The basic types of breast pumps include manual (hand operated) pumps and electric pumps. The electric pumps may be battery and/or AC powered. Further, the electric pumps may be self-cycling or require some manual user control. U.S. Pat. No. 6,213,840 combines a manual hand pump with a breast pump support bra which supports the weight of the breast. While most hand pumps are inexpensive and portable, they are typically uncomfortable, inefficient, and difficult to clean.

[0003] Some electric pumps are not battery-operated such that the nursing mother has to be near a power outlet. Other electric pumps, such as the diaphragm pump disclosed in U.S. Pat. Nos. 6,257,847 and 6,090,065, are assembled from many parts (hoses, gaskets, valves, etc.) which are difficult to clean, wash and carry. Figure 27 illustrates such a prior art system from the '065 patent having many parts which makes it cumbersome and difficult to use. In particular, in such a traditional breast pump, the milk has to pass through a plurality of components, such as a funnel P20, a cylindrical guiding means P22, a cap assembly P30, a reservoir P40, an inlet P62 connected to the suction assembly, etc., just to get to a container.

[0004] The website at http://www.epinions.com/kifm-Health-Nursing_and_Feeding-Breast_Pumps-All/tk~PR001.1.5 lists many commercially available breast pumps. Most of the electric breast pumps, such as Hollister's Purely Yours™ Kit, are cumbersome and noisy, and thus very stressful for the nursing mother to use. In addition, while the nursing mother is using these breast pumps to collect milk, she cannot take care of the baby or do anything else.

[0005] Even more, these pumps share the disadvantage that the mother's breast is exposed during use (lack of privacy) and that their motors are noisy. The breast pump vest described in U.S. Pat. No. 5,571,084, although covering most of the breast, is heavy and inconvenient to wear.

[0006] Currently, there are no portable and user-friendly breast pumps capable of achieving private, quiet, easy, efficient, and effective breast-feeding.

SUMMARY OF THE INVENTION AS CLAIMED

[0007] It is a purpose of this invention to provide a portable and hands-free breast pump system that facilitates hands-free, private, quiet, easy, efficient, and effective breast-pumping.

[0008] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump hidden from view beneath clothing.

[0009] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump while nursing a baby or doing something else at the same time.

[0010] It is another purpose of this invention to provide a breast pump that has very few parts, and is easy to assemble and clean.

[0011] It is another purpose of this invention to provide a breast pump that is cost-effective and easy to transport.

[0012] It is another purpose of this invention to provide a breast pump with a vacuum chamber which also functions as a part of the vacuum mechanism.

[0013] It is still another purpose of this invention to reduce the contamination of the milk during the processing, such as collection and storage, by a breast pump system.

[0014] It is still another purpose of this invention to accurately emulate the suckling action of a baby when breast-feeding so as to facilitate the numerous benefits of breast-feeding to the mother and to the baby.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The foregoing and additional features and characteristics of the present invention will become more apparent from the following detailed description considered with reference to the accompanying drawings in which like reference numerals designate like elements and wherein:

Figure 1A is a perspective view showing the front side of the breast pump according to a preferred embodiment of the invention; and Figure 1B is a perspective view showing the rear side of the breast pump according to the first embodiment of the invention.

Figure 2 is a rear view of a top housing cover of the breast pump according to the first embodiment of the invention shown in Figure 1.

Figure 3 is side view showing the breast pump according to a second embodiment of the invention.

Figure 4 shows the details of the slide button according to the second embodiment of the invention.

Figure 5 is an exploded view showing the breast pump of the first embodiment of the invention.

Figure 6 is an exploded view showing the breast pump of the second embodiment in conjunction with a one-way valve and a splint.

Figure 7 is an enlarged inset view of a positive connect pin of the breast pump according to the second embodiment of the present invention.

Figure 8A shows an adapter for connecting a positive contacting pin to an external power supply of the invention, while Figure 8B shows an example of a tethered drive configuration of the present invention.

Figure 9 is an enlarged inset view showing the connection between the external power supply of Figure 8A and a positive contacting pin.

Figures 10A and 10B show cross-sectional views of different embodiments of the flange of the invention.

Figures 11A-C show a rear-piston lever-arm system of the breast pump according to the second embodiment that communicates with the servomotor mechanism so as to move linearly.

Figure 12 shows a second embodiment of a rear-piston lever-arm system in conjunction with a servomotor mechanism of the breast pump according to the first embodiment.

Figure 13 show a third embodiment of the rear-piston lever-arm system in conjunction with another embodiment of the servomotor mechanism according to the invention.

Figure 14 is an exploded view showing the servomotor mechanism illustrated in Figure 13.

Figure 15 shows a second embodiment of the linear movement mechanism according to the present invention.

Figure 16 shows a third embodiment of the linear movement mechanism according to the present invention.

Figure 17 shows a one-way valve for use with the breast pump of the invention.

Figure 18A shows a splint for use with the breast pump of the invention, while Figure 18B shows an outer sleeve according to the present invention.

Figures 19A and 19B show a collection bag for use with the breast pump of the invention.

Figures 20A and 20B show cross-sectional views of the pump along with splint and the bag bent to conform with the contour of the user's breast and body.

Figures 21A-C depict the actual suckling profiles of a seven-month-old baby boy.

Figures 22A and 22B depict the suckling profiles of the present invention.

Figure 23 depict the suckling profiles of a conventional, mass-retail double pump set.

Figures 24A and 24B depict the suckling profiles of a conventional high-end double pump set.

Figures 25A and 25B depict the suckling profiles of a conventional battery powered portable pump.

Figure 26 shows a carrying case for a breast pump system according to the present invention.

Figure 27 is an exploded view showing the breast pump of the prior art (U.S. Pat. No. 6,090,065).

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] With reference to the figures, like reference characters will be used to indicate like elements throughout the several embodiments and views thereof. In particular, referring to Figures 1A and 1B, the breast pump 10 of the invention is embodied as a volume-displacement-type pump. Figure 1A is a perspective view of a preferred embodiment of the present invention showing the front side of the breast pump 10 with a dome-shaped housing shell 12. The housing shell 12 gives a natural appearance of the shape of a breast when the pump 10 is concealed underneath the user's clothing. Figure 1B is a perspective view showing the rear side of the breast pump 10.

[0017] The pumping action generated by the breast pump 10 depends upon a cycle rate and a vacuum level which are controlled via an adjusting means 14. In one implementation, a user may use one finger to slide button 16 in an axial direction along the groove 18 so as to adjust the vacuum level (or range). Figure 2 depicts the open top housing cover 12a of breast pump showing the rear side of the slide button 16 shown in Figure 1.

[0018] In a second embodiment shown in Figure 3, the slide button 16 is configured to slide in a circumferential direction along the groove 18 so as to adjust the pumping action to continuously vary the vacuum level. A push button 20 is used to control the cycling rate by incrementally increasing the rate with each push of the button 20 up to the fastest cycling rate designed into the pump. A further push of the button 20 then rolls the increment back to the slowest cycling rate for a continuous loop operation. Fig-

ure 4 depicts that the slide button 16 is connected to an electrical contacting base 21 with an arm 16a so as to slide the electrical contacting base 21 and vary the vacuum level.

[0019] Referring to Figure 5, each breast pump 10 includes a housing shell 12, a central deck 22 with a servomotor mechanism 24 integrated therewith, and a straw-hat shaped breast "flange" 30 having a flange top 35. The servomotor mechanism 24 is a servomotor mechanism powered by at least one power source 26, such as two AA batteries. The central deck 22 includes a pump seat 28 for receiving the servomotor mechanism 24, two battery seats 32, 32' for receiving the batteries 26, and a tunnel 34 extending toward the housing shell 12 for guiding and receiving a piston cylinder 25 of a rear-piston lever-arm system 100 (See Figures 11A - 11C). A central deck cover 22' is used to fixedly encase the servomotor mechanism 24 and the two batteries 26 in the central deck 22.

[0020] A second embodiment of the breast pump 10 as shown in Figure 6 is designed for a breast larger than that to which the first embodiment shown in Figure 5 is applied. Therefore, the central deck 22 of this second embodiment of the breast pump has a larger space that allows the two batteries 26 to be positioned parallel to one another. In addition, the central deck 22 of the second embodiment incorporates other parts for other parts, such as motor cover 40, rather than the fewer integral pieces as in the first embodiment.

[0021] Specifically, the breast pump 10 of the second embodiment includes the housing shell 12, the cycling rate button 20, the vacuum level slide button 16, the central deck 22, the flange 30, the servomotor mechanism 24, and the batteries 26. In addition, the second embodiment includes a flange support 36 placed between the flange top 35 and the piston cylinder 25, a servomotor cover 40, a battery cover 38, a printed circuit assembly("PCA")/microprocessor 90, a PCA compartment 41, a DC power jack pin 42 (positive), a DC power jack tab 43 (negative), a battery contact 52, and a pair of screws 49 (Figure 6).

[0022] The first embodiment of the breast pump uses traditional positive and negative contact plates with springs for receiving each battery. In the second embodiment of the breast pump, one positive contact pin 42 (Figure 7 inset view) is used instead. Both of these configurations would be known in the art for purposes of connecting to batteries held in small compartments.

[0023] The second embodiment of the breast pump (Figure 6) has an additional flange support 36 designed to protect against any overshooting of the strokes towards the flange top 35. The flange support 36 is fixed in place with the control deck 22, such as via a rotating lock mechanism, and then fitted around the exterior of the vacuum chamber 60 so as to have an interference fit at least around the base of the flange 30 (i.e., the 'bellows' area of the flange which creates the air displacement). The flange support 36 is an individual part of the unit assembly designed to be attached onto the flange 30. The flange support 36 not only holds the flange 30 in place during the pumping action (prevents over-pressure on the flange top 35) but also supports the vacuum chamber 60 from collapsing.

[0024] Unlike most other breast pumps which have their pump mechanisms situated outside of their breast interface elements or even at a remote distance from the breast interface element, the servomotor mechanism 24 of the invention is integrated inside the pump 10. The servomotor mechanism 24 is designed to be lightweight (for example, 0.4 oz. making each entire pump 10 weigh only 2.4 oz. without batteries or 4.2 oz. with batteries) such that it sits directly inside the pump 10 and is supported by the housing without any additional components. The pump 10 in turn is exclusively supported by the bra and the negative pressure created between the breast and the flange 30 by the servomotor mechanism 24 and the lever arm system 100. In variations of the present invention, the servomotor mechanism 24 may be substituted with an external driving mechanism, such as an electrical motor or a tethered manual pumping device, to provide the negative pressure for pumping. The implementations of such substitute devices would have those devices modularized such that they could be substituted for one another and be easy to replace.

[0025] In a third embodiment of the breast pump, power for the external servomotor mechanism 24 is located outside the housing. As shown in Figure 8A, an adapter 46 is used to connect a positive contacting pin to the external power supply 26 via a wire 26a. Figure 9 shows an inset view of how the adapter 46 is attached to the positive contacting pin 44. This embodiment has the advantage of a longer-lasting power supply that can be used, for example, in an institutional setting (i.e., a hospital) or even a home setting where a more limited range of mobility is acceptable or even desired.

[0026] Alternatively, as shown in Figure 8B, the servomotor mechanism 24 may be replaced by a servomechanism 24' that may be just a mechanical or pneumatic linkage 101 connected to the lever arm 21 for implementing the pumping action of the vacuum chamber 60. The linkage 101 is connected to a remote control 103 that acts as the user's control for pumping via a linkage element 103. For example, in a mechanical implementation, the linkage element 103 is a wire in a sleeve similar to that used in bicycle handbrake controls, while the control 103 is a hand- or foot-pedal that the user manipulates to move the lever arm 21 in the pump 10. Alternatively, in a pneumatic implementation, the linkage element 103 is a flexible pipe that feeds air or fluid into the linkage 101. The control 102 is also a hand- or foot-pedal that controls the flow of control air/fluid to the linkage 101 to then operate the pumping motion of the lever arm 21. The specific details for implementing either of the above-discussed alternative embodiments would be within the knowledge of those skilled in the art.

[0027] Various components of the system are formed

from resiliently plastic or other resin-type materials to accomplish various purposes. For example, in order that the splint 110 be flexible so as to conform with the shape of the user's breast, and so that the overall structure of the pump 10 is lightweight, including but not limited to the housing shell 12, the housing cover 12a, the lever arm 21 and the central deck 22, these various parts are formed from plastic. Other components in the system would be formed from materials appropriate to their function as would be understood by those skilled in the art. Other materials for the various components may also be used as would be known in the art so long as the selection of such materials is not inconsistent with the structure, operation and purpose of each such component and of the present invention as a whole.

[0028] In the general operation and use of the present invention, as shown in Figures 20B, the pump 10 contacts the breast only with the breast flange 30, and the dome-shaped housing shell 12 does not contact the breast. A vacuum chamber 60 is defined between the breast flange 30 and the breast, and is completely isolated from the working components of the breast pump 10; the servomotor mechanism 24 is only in contact with the exterior surface of the breast flange 30. This allows the vacuum chamber 60 to be maintained at a negative air pressure while keeping the breast milk from contacting any other parts of the breast pump 10. The invention significantly reduces the number of parts that can come in contact with the milk so as to make the system easy to clean and sanitary. Further, the invention eliminates the potential of the milk co-mingling with any room air contaminants.

[0029] The breast flange 30 is made from silicone or other soft elastic material for interfacing directly with a breast and situated on the breast with an inlet hole 50 (See Figures 5,10A and 10B). The inlet hole 50 is designed for seating a nipple and areola in a vacuum chamber 60 which is defined between the breast pump 10 and the breast. The soft breast flange 30 allows the wearer to pump milk quickly and painlessly by mimicking the baby's suckling movements when the servomotor mechanism 24 moves the flange 30, thereby triggering the female body's natural reaction to produce milk.

[0030] A health benefit for the user or mother derived from the invention is that, as the nerves in the nipple and areola are stimulated by the action of the invention, the pituitary gland receives a signal to release prolactin and oxytocin into mother's blood stream. Prolactin relaxes the mother and stimulates the alveoli to produce more milk. Oxytocin causes the alveoli to contract and squeezes milk into the ducts. In contrast, the traditional hard funnel breast pumps (See Figure 27) simply pull the nipple into the rigid shaft to obtain milk. The hard shaft of the funnel is rigid and unyielding so that the suction concentrates on the nipple and creates a stinging sensation.

[0031] Varying thicknesses in the silicone flange 30 helps the breast pump 10 to attach to the breast and be compressed towards the nipple by the rear-piston lever-arm system 100 shown in Figures 6, 11A-11C and 13. Pumping sessions become faster by using the soft flange 30 since the milk is being removed in a more natural way than with a traditional hard funnel. As such, the milk is also better extracted from the breast to avoid any decrease of milk production due to the remaining breast milk in the breast. The milk residuals reduce hormone stimulation for milking.

[0032] As shown in Figure 10A, the flange 30 includes an outlet 62 through which the milk drawn from the breast flows out of the flange 30. As will be discussed further herein, the milk is then directed away from the breast pump 10 and stored. In a variation of the flange 30, as shown in Figure 10B, the outlet 62 is funnel-shaped so as to direct the milk flow out of the flange 30 and prevent the milk from flowing back towards the breast.

[0033] In at least one of the embodiments of the invention, the nipple is well seated at the back of the breast pump 10 (inside the chamber 60), where only air is directly in contact with the nipple. When the nipple is placed inside the flange 30, the nipple rests within the vacuum chamber 60 with the surface of the surrounding area of the breast in contact with the surface of the flange 30. Air compression and suction is then controllably generated to occur by virtue of the cap-shaped piston cylinder 25 being cyclically pushed toward the breast so as to physically push on the top 35 of the flange 30 (see Figure 11A), and then released. The top 35 is formed with a relatively thin and soft side wall which has an accordion-style, contour-shape with alternating convex and concave edges formed on its surface for transferring and converting the contact pressure from the cap-shaped piston cylinder 25 to air compression and suction on the nipple. In order to strengthen the top 35 and to help in uniformly compressing the vacuum chamber 60, the top 35 may be formed with a circular, reinforcing plate 35a fixedly imbedded therein. The reinforcing plate 35a is formed with a dome-shaped alignment stub or nipple 35b on a top center portion of the plate that aligns with the alignment dome 25b of the piston cylinder 25 so as to center the vacuum chamber 60 within the piston cylinder 25. This centered alignment is especially important in keeping the vacuum chamber 60 from floating or misaligning within the piston cylinder 25 during the pumping operation.

[0034] In a first embodiment of the rear-piston lever-arm system 100, as shown in the exploded view of Figure 11A, the top of the piston cylinder 25 is shaped like a yo-yo or a doughnut without a hole. The lever arm 21 has a protrusion 21 a on the top that contacts with the alignment dome 25b of the piston cylinder 25. The lever arm 21 is a projecting handle used to adjust or operate the piston cylinder 25. In particular, the-rear piston lever-arm system 100 mechanically communicates with the servomotor mechanism 24 so as to be activated by the mechanism and thereby pivotally move the lever arm 21 which then linearly moves the piston cylinder 25 along a line generally parallel with the centerline of the pump 10. Such a linear movement is depicted, wherein the start or "up-

stroke" position of the piston cylinder's linear movement is shown in Figure 11B.

[0035] Figure 11C shows the lever arm 21 pivoted forward thereby linearly pushing the piston cylinder toward the flange 30 in a "downstroke" motion. The lever arm 21 pushes the protrusion 21a against the alignment dome 25b of the piston cylinder 25 to move the piston cylinder 25 toward the nipple. As mentioned, the nipple is insulated by the vacuum chamber 60 of the flange 30 from direct contact with other components such as the piston cylinder 25. The motion of the piston cylinder 25 is controlled by the level arm 21 which sets the default position of the piston cylinder 25 within the tunnel 34 such that the piston cylinder 25 rests away from the breast when the pump is not in action. During operation, in the "upstroke" motion, the lever arm 21 pivots back thereby releasing the piston cylinder 25 and the top 35 of the flange 30. The movement of the piston cylinder 25 is rather short, delicate and efficient in comparison with the pumping action of other breast pumps.

[0036] The servomotor mechanism 24 activates the rear-piston lever-arm system 100 embodied in the lever arm 21 and the piston cylinder 25 to create the "downstroke" action inward (toward the breast). This downstroke action displaces the air in the flange 30 which exits via a one-way valve 140 (See Figure 17) that is inserted into the outlet 62, thereby releasing the vacuum and actively stimulating the breast for further expression of milk. In addition, milk expressed by the breast flows out also through the one-way valve 140 and into a collection bag 300 (as will be explained further herein). The "upstroke" action not only moves the lever arm 21 and the piston cylinder 25 back into their start positions, but also generates the vacuum pressure against the breast. The upstroke and downstroke action of the system 100 alternatingly generates and releases the volume displacement vacuum in the chamber 60, and in particular in the flange 30. Among the features of this construction, the "upstroke" passively maintains or creates the vacuum via the vacuum chamber 60 of the flange 30 elastically returning to its normal state, and not by any energy expended by the servomotor mechanism 24. However, in other embodiments, the protrusion 21 a may be linked to piston cylinder 25 and the top 35 so as to actively generate both the "upstroke" and "downstroke" motions of the vacuum chamber 60.

[0037] In order to further simulate the suckling motion of an infant, the preferred suckling time to releasing time is , for example, approximately 3:1 in a cycle of a second. Namely, the suckling stage takes 3/4 second, and the releasing stage takes 1/4 second for each cycle. However, other cycling ratios may be used based on individual user preferences or breastfeeding requirements. The combination of the servomotor mechanism 24, the lever arm 21 and the piston cylinder 25 provides precision control of the air compression inside the chamber 60 which allows the precise controlling of the cycle rate and the vacuum level.

[0038] In a second embodiment of the rear-piston lever-arm system 100, as shown in Figure 12, the lever arm 21 is formed to surround the side wall of the cylinder piston 25 and connect to the piston via a protrusion 25c formed on the side wall. When the lever arm 21 pivots, it rotatively pushes on the protrusion 25c (rather than push on the top 35 of the piston cylinder 25) thereby linearly moving the cylinder piston 25. Otherwise, the operation and effects of this second embodiment are the same as those of the first embodiment.

[0039] As shown throughout the drawings, the present invention includes various embodiments for the servomotor mechanism 24. Figures 11A-C depict using a first embodiment of servomotor mechanism 24, while Figures 5 and 12 illustrate a second embodiment of the servomotor mechanism 24 that is used with the rear piston 25 and the modified lever arm 21. Figures 6 and 13 shows a third (preferred) embodiment of the servomotor mechanism 24 applied to a third variation of the lever arm 21.

[0040] Figure 14 illustrates an exploded view of the third embodiment of the servomotor mechanism 24 so as to provide an example of the internal structure for a servomotor mechanism that would be applicable to the present invention. That embodiment is implemented via a structure that includes a potentiometer 201, an output gear 202, cluster gears 203-206, a DC motor 207, an arm 208, a motor housing 209, a screw 210, a rotary pot contact 211, a power contact 212, a gear train motor shaft 213, a front cover 214, a rear cover 215, and a pinion gear 216. Essentially, a servomotor mechanism for the present invention is implemented via mechanical or electromechanical system that pivotally moves a lever arm that then linearly moves a piston (in this case, a cylindrical piston 25) that then creates the pumping motion in the flange 30. The electric motor structure of the third embodiment (even of the first and second embodiments) as described above is one such system. Otherwise, given this disclosure of the invention, one of skill in the art should be able to devise other structures for a servomotor mechanism that would serve the purposes of the present invention and within the scope and intent of the claims.

[0041] Figures 15 and 16 illustrate other systems for providing the above-mentioned linear movements for the cylindrical piston 25, and thus the pumping operation of the flange 30. For example, Figure 15 shows a lead screw mechanism with a rotary motor. The motor 240 oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The rotation of a lead screw 250 pushes a plunger 260 so as to push the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 rotates the lead screw 250 away from the breast so as to move the plunger 260 away from the breast. This allows the flange 30 to return to its natural state so as to create a negative pressure in the vacuum chamber 60.

[0042] In Figure 16, the lead screw 250 is substituted

with a rack and pinion 270, wherein the motor 240 again oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The linear movement of the rack and pinion 270 pushes the plunger 260 pushing the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 linearly moves the rack and pinion 270 away from the breast so as to move the plunger 260 away from the breast. Again, this allows the flange 30 to return to its natural state and create a negative pressure in the vacuum chamber 60.

[0043] The one-way valve 140 shown in Figure 17 is used in conjunction with the outlet 62 of the flange 30. The valve is generally implemented as a one-piece element that is inserted into the outlet 62. Alternatively, the one-way valve may be constructed as an integral part of the flange 30. Its main function is to help maintain the vacuum in the chamber 60 during operation and to help draw the expressed milk away from the chamber 60 in the flange 30 so as to flow to a collection bag 300. However, other embodiments as those of skill in the art would understand may be accomplished used to implement the one-way valve 140.

[0044] The splint 110 shown in Figure 18A guides the milk from the pump to a collection bag 300. The splint 110 has a cup 115 and a wave-form portion 117. The cup 115 and the wave-form portion 117 of the splint 110 are inserted into the neck of the collection bag 300, extending downward to ensure the neck walls do not collapse due to the pressure from the bra at the point where the collection bag exits at the bottom edge of the bra (as will be discussed further hereinbelow). The cup 115 is formed to pressure fit into the outlet 70 of the housing shell 12 when inserted using an upward sliding force. The cup 115 is intended to have at least a liquid-tight fit within the outlet 70 while guiding the milk out of in the chamber 60. Preferably, the cup 115 has an air-tight fit when positioned in the outlet 70. Such a pressure fit is intended to hold the bag 300 tightly to the cup 115 so as to avoid any milk spillage and any air contaminants therebetween. At the bottom of the cup 115, there are holes 116 through which the milk is intended to flow out of the cup 115 and onto the wave-form portion 117 of the splint 110. In a preferred embodiment, the cup 115 has an extruded rim which will contact the outer edge of the neck of a collection bag 300 so as to further seal the neck. The splint may be formed integrally with the bag by incorporating the extruded tube in the construction of the collection bags. In such a case, a hot-pressed tear-off line is set between the end of the splint and the end of the bag neck.

[0045] Also, in another variation as shown in Figure 18B, an outer sleeve 111 is used to surround the neck 310 of the bag 300. The outer sleeve serves to protect the neck of the bag 300 as it extends from the pump to the body 305 of the bag 300. In this implementation, the neck 310 of the bag connects directly to the one-way valve 140 with the sleeve 111 surrounding the connection. In one form, the outer sleeve 111 is C-shaped in cross-section and also formed of a resiliently plastic material, which allows the sleeve to have some flexibility. Other cross-sectional shapes or configurations as would be understood by one of skill in the art to perform the same function as the C-shaped sleeve may be used.

[0046] When viewed along its longitudinal axis, the wave-form portion 117 has a substantially sinusoidal contour, wherein the peaks and valleys of the sinusoidal contour form channels along which the milk flows downward to the collection bag 300. The use of the wave form portion 117 enjoys several benefits over using a conventional tube form. First, it avoids any obstruction caused by air bubbles stuck in a tube. Second, a splint having a wave-form portion is more easily bent than a tube so as to conform with the contour of the breast and the bra to in order to reach the collection bag or a bottle. Third, the wave-form portion is easier to clean and keep sanitized than a tube. Plastic tubing needs to be cleaned each use. If washed, it has to be hung to allow it to drain and dry thoroughly. In contrast, the wave-form splint dries out more easily than a tube form. Lastly, a wave-form structure confronts less air resistance than a tube when it is inserted into either a regular container or the collection bag 300. As will be discussed further hereinbelow, the sub-assembly of the one-way valve 140 and the splint 110 provides further support for the vacuum chamber 60 so as to prevent it from collapsing.

[0047] As shown in Figures 19A and 19B, the collection bag 300 is made of plastic and substantially deflated so as to be maintained in a substantially vacuum state for receiving the splint 110 and the milk. In one embodiment, the collection bag 300 is made by hot-pressing two thin plastic sheets to form a square bag body 305 with sealed edges 301, 301', 302, 303, 303' and a neck 310 with sealed edges 311 and 311'. Meanwhile, each perforation line 312 is punched with holes for easily separating the bags with a slight force. At the same time, graduations are printed on the surface of one plastic sheet to indicate ounces or milliliters. The sequentially hot-pressed bags are rolled into one roll to reduce storage space and make them easy to transport. Alternatively, the bags may be made using other conventional methods for fabricating plastic bags known in the art. Also, the bags may be formed into other shapes or with additional features (i.e., resealable tops, adhesive surfaces) or using other different materials that have the same manufacturing, sanitary and liquid-proof characteristics.

[0048] The sealed edges 311 and 311' of the neck extend into the bag body 305 so that the splint 110, including the cup 115, can be fully inserted inside the neck 310 to completely seal the splint inside the collection bag 300 thereby avoiding any milk spillage outside of the collection bag 300 during use. After the collection bag 300 is filled, a user can remove the splint 110 and roll the neck 310 so as to seal the bag. Further, adhesive tape or an adhesive surface formed on the neck 310 or the body

305 may be used to fixedly secure the rolled neck to the body of the bag.

[0049] In another embodiment, an additional pair of sealed edges 306, 306' in a V-shape are hot-pressed next to the neck 310 to provide additional pressure on the neck after the neck has been pressed from the top-down to expel any residual milk in the neck of the bag. In addition, the sealed edges 311, 311' include lower extensions that promote the sealing of the neck 310 when the neck is pressed, so as to function as a simple, one-way valve to prevent milk spillage after the neck is press-sealed. The neck of the collection bag with the sealed edges in a V-shape effectively becomes spill-proof after being pressed shut. This structure of the bag 300 solves the common problem encountered by mothers that use conventional plastic collection bags when they pump for breast milk. The plastic collection bags of the prior art have not been able to provide any effective means for sealing closed so as to allow the mother to put down the bags without spilling.

[0050] In a further embodiment of the invention, an additional tear notch 304 is hot-pressed at a corner of the bag so that a user may tear off the bag at the line to release the milk into another container to feed a baby. Additional tear notches are hot-pressed at the neck of the bag so that a user may alter the length of the neck by tearing off the bag at any one of the notches.

[0051] In a preferred implementation, each bag 300 is a freezer grade bag made of FDA rated plastic and intended only for single use so as to keep the milk from contamination caused by any residuals of old milk and eliminate laborious cleaning. The preferred dimensions of the bag body are 4.25 inches by 3 inches, and the dimension of the neck is 5.0 inches in length. The capacity of each bag is 4-8 ounces, which is the average production amount for a nursing mother. However, other dimensions may be used as one of skill in the art would understand.

[0052] Like breastfeeding, pumping is a learned skill. Most mothers are able to express only a few drops of milk when they first try a breast pump. Sometimes if mothers don't see milk immediately after beginning pumping, they start to pump harder or increase the suction with the mistaken idea that more pressure will "pull" the milk out. Doing this can cause discomfort and anxiety and actually discourage the let-down response. The invention is simple and easy to use so that the mother will intuitively become efficient at pumping without much practice and knowledge of how the breast works. In addition, many working mothers have no option but to pump in their offices or in a restroom. The privacy of using a conventional breast pump and the effect of the ambient air on the safety of the breast milk are at issue.

[0053] As generally illustrated in Figures 20A and 20B, a user just inserts a one-way valve 140 (if made as a separate component) into the hole in the flange 30 as a cap on the splint/bag. Otherwise, if the valve 140 is manufactured to be an integral part of the flange 30, then the user just then proceeds with inserting the "splint" 110 (the wave-shape guiding means) into neck 310 of a disposable collection bag 300. The splint 110 serves to keep the neck 310 of the bag fluid-passable as it passes underneath the bottom edge of the bra. The sub-assembly is inserted into the outlet 70 of the housing 12 at the bottom of the flange 30 and the breast pump 10. With the sub-assembly in place, the cup 115 of the splint 110 fixedly connects to the outlet of the one-way valve 140.

[0054] There is no need for the mother to undress herself in order to use the breast pump of the invention. In contrast, all the prior art requires a user to undress herself so as to use the pump.

[0055] After inserting the splint 110 into the housing shell 12, the user can insert the entire pump 10 with the sub-assembly of the splint 110 and collection bag 300 underneath her clothing and against the her breast. The inlet hole 50 is positioned over the breast so as to cover and surround the nipple and thereby catch the expressed breast milk. Alternatively, the user can insert the pump 10 underneath the clothing first, then insert the sub-assembly of the splint 110 and the collection bag 300.

[0056] In at least one embodiment, the insertion of the sub-assembly may be designed to act as an activation switch for the operation of the pump 10. Alternatively, either the slide button 16 or the push button 20 may be used as the activation switch, or a combination of the slide button 16 or the push button 20 in conjunction with the insertion of the sub-assembly. In an even further embodiment, the servomotor mechanism 24 may be activated by an initial movement of the switch 16 resulting from the insertion of the sub-assembly.

[0057] When a collection bag is filled or when the user is finished using the pump 10, the splint 110 along with the bag 300 is removed from the pump 10, but with the one-way valve 140 left in place to keep the outlet 70 plugged thereby prevent any milk from dripping out of the outlet 70. Upon removal of the sub-assembly, in one embodiment, contact between the sub-assembly and a switch of the servomotor mechanism 24 is severed which turns off the pump 10. As mentioned, the vacuum chamber 60 is air-tight and isolated from outside air turbulence. Such a design not only maintains the privacy of the user but keeps the pump from contacting any outside air contaminants.

[0058] With respect to the adjusting means 14 (See Figure1A, 1B and 3), the pumping rate is controlled via a microprocessor 90 which reads the user inputs from the switch slide button 16 and the push button 20 for the vacuum level and the cycling rate, respectively, so as to power the servomotor mechanism 24 accordingly. The servomotor mechanism 24 in turn activates the rear-piston lever-arm system 100 to create a stroke action toward and away from the breast in accordance with the desired settings. When the appropriate time has passed, the microprocessor 90 will reverse the motor system to allow the flange 30 to return to its natural state. As noted above, the stroke action is programmed to mimic the natural

suck-hold-release-relax cycling of a nursing baby according to the age of the baby. The present invention applies mimicking the baby's suckling movements to trigger a nursing mother's natural reaction to produce milk. The pumping rate in the present invention may be controlled and/or programmed to mimic both the nutritive and non-nutritive suckling actions of the a baby, which have distinctly different cycling characteristics.

[0059] According to a controlled study of a seven-month-old baby boy, the suck-hold-release-relax cycle starts with a series of non-nutritive sucks at low vacuum levels with a high suckling rate as the suckling pulses depicted in Figure 21A. The non-nutritive suckling rate typically is higher than nutritive suckling; in this example, the non-nutritive suckling exceeded 100 cycles/min while nutritive suckling was 30 - 60 cycles/min. The peak vacuum level of each suck increases until reaching a threshold for milk expression (the first and second nutritive sucks) then holds longer on the threshold (152 mmHg, in this case) than non-nutritive sucks with no plateau but mere a peak. The plateaus exhibit distinct flatness to hold the threshold vacuum level of each cycle. The holding period (in the plateau) is about 2-3 times of the relax period (drop from the plateau).

[0060] Figure 21B shows a second example illustrating a steady-state post-ejection reflex action. Essentially, the baby has achieved a rhythm in suckling. Figure 21C illustrates the threshold vacuum level decreasing with the cycle rate increasing. In this example, the baby is finishing feeding and/or tiring. Overall, the study reveals that the holding and releasing timing of a baby suckling is not symmetrical. Depending on the baby, there may be rapid transitions between holding and releasing periods. In the present invention, the microprocessor 90 is programmed to mimic the natural suck-hold-release-relax cycling of a nursing baby along the lines of the results of the study.

[0061] The microprocessor 90 may be programmed to suggest or control the vacuum level and the cycle rate. In one preferred embodiment, the microprocessor 90 is programmed with artificial intelligence so as to mimic the natural suck-hold-release-relax cycling of a nursing baby as discussed. Each stroke of the breast pump of the present invention has a definite holding period, which is about 2 - 3 times the relaxation period. As depicted in Figures 22A and 22B, the cycle profile is designed to be consistent regardless of the maximum vacuum level or the cycle rate settings.

[0062] In particular, the suction level starts at a minimum at the beginning for a new nursing mother, and then some quick, short pulses at the start of the pumping to especially stimulate and imitate more closely the way a baby initiates breastfeeding. Once the milk is flowing freely, long steadier strokes are initiated so as to be effective and less tiring. Since each woman has a different comfort level, the level may then be gradually increased to what is comfortable for her. The pumping mechanism supports a cycle rate up to 80 cycles per minute, which is higher than most of the other portable breast pumps (25-60 cycles/minute). However, the preferred cycle rates range from 35-60 cycles per minute which balances the efficiency and the comfort of the user. The most preferred cycle rate (45 cycles/minute) takes less than one-quarter second to fully vacuum the chamber 60 and incurs minimum noise.

[0063] This stroke action creates a vacuum on the order of 200 mmHg in the flange 30 while the one-way valve 140 seals off the opening. As shown in Figures 22A and 22B, when the maximum vacuum level is set at 136 mmHg, the matching cycle rate is 39 cycles/min. when the maximum vacuum level is set at 204 mmHg, the matching cycle rate is 36 cycles/min. Vacuum control circuitry is provided for allowing manual adjustment of the level of vacuum generated by the electric pump means. This is accomplished by controlling the stroke length of the servomotor mechanism. In another embodiment of the invention, some residual vacuum is programmed in the stroke profile.

[0064] In another variation of the invention, a flow sensor may be connected with the adjusting means 14 to monitor the suckling results of the stroke actions.

[0065] In contrast, the commercially available products simply operate under mathematics profiles rather than a natural baby suckling profile as the present invention. For example, the characteristics of one inexpensive, mass-produced double pump set allows manual control as well as residual vacuum as shown in Figure 23. However, it operates with excessive tissue stress due to its slow vacuum rise profile. In addition, it operates terribly inefficient at 7 cycles/minute, which takes 8 seconds to reach the full vacuum level of 220 mmHg. Other conventional high-end double pump sets operate according to the profiles such as those shown in Figures 24A and 24B which are within appropriate vacuum levels (180-200 mmHg) at an appropriate cycle rate range of 47-53 cycles/ min. Nevertheless, such systems have no holding periods, but instead release their vacuums immediately upon reaching full vacuum. One popular battery powered portable pump as shown in Figures 25A and 25B operates with appropriate holding periods (1-1.4 seconds) and releasing periods (0.9 second), but dragging along a slowly increasing profile from vacuum levels 100 to 270 mmHg at inefficient cycle rate range of 27-29 cycles/ min. Such a profile yields long periods of stress on the breast to reach a excessively high vacuum level of 270 mmHg.

[0066] Studies and experience have shown that young breastfed babies usually need to nurse every 2-3 hours, and that it is best to pump on the same schedule. The more the breasts are stimulated, the more milk is produced. A good time for many mothers to pump is about one hour after the baby's first morning feeding. Most women tend to have more milk earlier in the day. The length of time spent pumping varies with each woman and with each day. When pumping one side at a time, alternating breasts several times during expression is more stimulating and can result in a higher volume of milk. Pumping at one side of the breast and nursing on

the other side has the advantage of using the body's natural response to let down the milk for the baby.

[0067] The microprocessor 90 of the present invention may be programmed to suggest or control the timing for pumping. For example, using two pumps 10 simultaneously can cut the total pumping time in half. Double pumping may also result in better stimulation of prolactin due to its sense of balance provided to a nursing mother. In a double pump arrangement, the adjusting mechanism 14 of each pump may be linked by hardwire connection or by wireless link to coordinate or synchronize their strokes via the microprocessor 90.

[0068] A commercial implementation of the portable breast pump system of the invention as shown would include two breast pumps 10, a pair of valves 140 and splints 110, and a roll of collection bags. All of those components would be stored in a soft sided black shoulder bag 400 (Figure 26) having two storage compartments, the upper compartment 403 includes a working surface for storage of the pumps on its breast pump holders 409, 409', the accessories, and complete instructions; and the lower compartment 405 includes heat-insulating side walls and at least one cooling element 407. The cooling element 407 is formed with concave seats for receiving collection bottles or bags. The closeness of the walls hold the collection bags next to the cooling element surfaces. The portable breast pump system of the invention would weigh only about 2 lbs., rather than the 8 - 10 lbs. of other commercially available portable breast pump system, or even then 25-40 lbs. of those used in hospitals. The cooler is available from Rubbermaid® (Blue ICE Model No. 1056). The shoulder bag 400 may be manufactured by companies such as California Innovation® with synthetic fabric surfaces which are easy to wipe clean. The aggregate weight of the cooler and the shoulder bag is approximately 2.5 lbs.

[0069] Parts of the pump such as the collection bags 300 are sterilized to FDA's hygienic standard for rubber articles before the first use, while other parts that come into contact with the mother's skin or the milk will need to be sterilized before first use. After initial use, only the flange 30, the valve 140 and the splint 110 need to be washed in warm, soapy water, rinsed with hot water and drained on a clean towel. However, periodic boiling for sterilization may be desirable, depending on the individual needs of the baby.

[0070] In summary, the breast pump of the present invention provides several unique features. As noted above, various parts of the system are made of plastic materials so as to be lightweight, easy to clean/maintain and easily conform with the contour of the user's breast (Figures 20A and 20B). Working moms can thus easily pump their milk and save it for the babysitter or daycare. The breast pump of the invention has very few parts so as to be easily assembled and cleaned. The overall system of the present invention also results in a breast pump smaller than commercially available breast pumps such as Hollister's Purely Yours™ Kit, i.e. about 1/4 size of other portable (the shoulder bag actually is 70% smaller) and Medela's Pump in Style system.

[0071] The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However, the invention which is intended to be protected is not limited to the particular embodiments disclosed. The embodiments described herein are illustrative rather than restrictive. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the scope of the present invention as defined in the claims, be embraced thereby.

Claims

1. A portable, hands-free and visually friendly breast pump (10) for facilitating breast-pumping, comprising: a housing (12) having a servomotor mechanism (24); a flange (30) having a chamber portion, a brim portion and an outlet, (62) the chamber portion being formed so as to be placed over a nipple on a breast so as to define a chamber (60) between the flange (30) and the breast, and the brim portion being formed to surround the nipple and thereby form a suction seal therebetween; and a one-way venting element (140) formed to operatively communicate with the chamber (60) so as to vent pumped milk from the chamber (60) via the outlet (62), **characterized in that** the housing (12) is dome-shaped and the flange (20) is hat-shaped and **in that** the servomotor mechanism (24) is operatively connected to the chamber portion of the flange (30) so as to induce a pumping motion onto the chamber portion and create vacuum in the chamber (60) to thereby pump milk from the breast, the chamber (60) being sealed via the vacuum except at the outlet (62), and the housing (12), the flange (30) and the venting element (140) are connected into an integral device held against the breast and underneath clothing so as to keep the integral device hidden.

2. The portable, hands-free and visually friendly breast pump according to claim 1, further comprising a guiding means (110) operatively connected to the one-way venting element (140) for guiding the pumped milk into a container (300).

3. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the outlet (62) of the flange (30) has the funnel shape.

4. The portable, hands-free and visually friendly, breast pump according to claim 1, further comprising a flange support (35) for preventing overshooting of strokes towards the flange (30), said flange support (35) is fixed in place by fitting snuggly around a base of the flange (30).

5. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the hat-shaped flange (30) is integrally formed from an elastic material.

6. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the dome-shaped housing (12) further includes therein a portable power supply (26).

7. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism (24) of the housing (12) is operatively connected to the chamber portion of the flange (30) so as to impart an alternating stroking action onto the chamber portion, whereby the chamber portion generates an air displacement and vacuum alternating motion that mimics suckling movement of a baby.

8. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the guide means includes a flexible guide element (110) that extends from the integral device to a container (300) and that is flexibly positionable so as to operatively connect the integral device to the container (300) whereby the integral device, the guide element (110) and the container (300) are maintained against the breast and under the clothes.

9. The portable, hands-free and visually friendly breast pump system according to claim 8, wherein the guide element (110) includes an elongated, flexible splint (117) having a wave-form shape in a transverse direction of the splint (110).

10. The portable, hands-free and visually friendly breast pump system according to claim 9, wherein the guide means (110) further include a cup head (115) to be connected to the outlet (62), said cup head (115) is connected with the wave- form splint (117) with at least one hole (116) at the bottom of the cup head (115) for the milk to leak through to the wave-form splint (117).

11. The portable, hands-free and visually friendly breast pump system according to claim 10, wherein the cup (115) fits snugly into the outlet (62) under an upward sliding force so as to be air-tight while guiding the milk out of in the chamber.

12. The portable, hands-free and visually friendly breast pump system according to claim 2, wherein the container is a collection bag (300).

13. The portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag (300) is formed from a thin, synthetic, leak proof material.

14. The portable, hands-free and visually friendly breast pump system according to claim 12, wherein the container is a collection bag (300) having a neck (310) for snugly receiving the guiding means (110) so as to allow leakproof flow of milk via the guiding means (110) into the bag (300) while maintaining operative contact with the guiding means (110).

15. The portable, hands-free and visually friendly breast pump system according to claim 14, wherein the neck (310) of the collection bag (300) has two sealed edges (311, 311") in a V shape to make the neck spell-proof after being pressed.

16. The portable, hands-free and visually friendly breast pump system according to claim 11, wherein the container is a collection bag (300) having a neck (310), and the cup (115) has an extruded rim for covering on an edge of the neck (310) thereby sealing the neck (310) and going against pressure created by any clothing covering the breast pump.

17. The portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag (300) is printed with a graduation scale to show the amount of milk collected in the bag (300).

18. The portable, hands-free and visually friendly breast pump according to claim 1, further comprising a control means (90) for controlling operation of the servomotor mechanism (24).

19. The portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means (90) includes means for controlling at least one of a cycle rate and a vacuum level of the servomotor mechanism (24).

20. The portable, hands-free and visually friendly breast pump according to claim 19, wherein the control means (90) includes at least one variable switch (14) on the housing (12).

21. The portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means includes a microprocessor (90).

22. The portable, hands-free and visually friendly breast pump according to claim 21, wherein the microprocessor (90) controls the pump to mimic the natural suck hold- release-relax cycling and force of a nursing baby.

23. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism (24) is formed from one of an electric motor and a tethered hand pump device.

24. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism (24) is located outside the housing (12).

25. The portable, hands-free and visually friendly breast pump according to claim 24, wherein the servomotor mechanism (24) is connected to the housing (12) with an adapter (46).

26. The portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism (24) includes an electric motor, a lever arm (21) operatively connected to the electric motor, and a rear piston operatively positioned to move linearly by the lever arm so as to press on a top of the flange (30) toward the breast thereby pressing the air out of the chamber (60) to create the vacuum on withdrawal.

Patentansprüche

1. Eine tragbare, freihändige und optisch ansprechende Brustpumpe (10) zur Erleichterung des Abpumpens, aufweisend: ein Gehäuse (12) mit einem Servomotormechanismus (24); einen Flansch (30) mit einem Kammerteil, einem Randteil und einem Auslass (62), wobei der Kammerteil zur Platzierung über einer Brustwarze ausgebildet ist um eine Kammer (60) zwischen dem Flansch (30) und der Brust zu definieren und wobei der Randteil zum Umfassen der Brustwarze und dabei zur Ausbildung einer Saugdichtung dazwischen ausgebildet ist; und ein Einweg-Lüftungselement (140), welches zur operativen Kommunikation mit der Kammer (60) ausgebildet ist, um abgepumpte Milch von der Kammer (60) über den Auslass (62) auszulassen, **dadurch gekennzeichnet, dass** das Gehäuse (12) domförmig ist und der Flansch (30) Hut-förmig ist und dass der Servormotormechanismus (24) mit dem Kammerteil des Flansches (30) wirkverbunden ist, um eine Pumpbewegung auf den Kammerteil zu induzieren und um Unterdruck in der Kammer (60) zu erzeugen, um dabei Milch von der Brust abzupumpen, wobei die Kammer (60) mit Ausnahme des Auslasses (62) durch den Unterdruck abgedichtet ist, und wobei das Gehäuse (12), der Flansch (30) und das Lüftungselement (140) in einer gegen die Brust und zwecks Verbergung unter der Kleidung gehaltenen Einheit verbunden sind.

2. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, welche des Weiteren ein Führungsmittel (110) aufweist, welches mit dem Einweg-Lüftungselement (140) wirkverbunden ist, um die abgepumpte Milch in einen Behälter (300) zu leiten.

3. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Auslass (62) des Flansches (30) eine Trichterform aufweist.

4. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, welche des Weiteren einen Flanschträger (35) aufweist um ein Überschiessen von Hüben in Richtung Flansch (30) zu vermeiden, wobei dieser Flanschträger (35) durch genaue Passung um eine Basis des Flansches (30) lagefixiert ist.

5. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Hut-förmige Flansch (30) einstückig aus einem elastischen Material geformt ist.

6. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei das domförmige Gehäuse (12) ferner eine tragbare Energieversorgung beinhaltet.

7. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Servomotormechanismus (24) des Gehäuses (12) mit dem Kammerteil des Flansches (30) wirkverbunden ist, um eine alternierende Hubbewegung auf den Kammerteil zu übermitteln, wodurch der Kammerteil eine Luftverschiebung und eine alternierende Unterdruckbewegung generiert, welche eine Saugbewegung eines Baby's imitiert.

8. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei das Führungsmittel ein flexibles Führungselement (110) aufweist, welches sich von der Einheit zu einem Behälter (3009 erstreckt und welches flexibel positionierbar ist, um die Einheit mit dem Behälter (300) in Wirkverbindung zu bringen, wodurch die Einheit, das Führungselement (110) und der Behälter (300) gegen die Brust und unter der Kleidung gehalten sind.

9. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 8, wobei das Führungselement (110) einen länglichen, flexiblen Splint (117) beinhaltet, wobei der Splint (117) in einer Querrichtung des Splints (117) eine Wellenform aufweist.

10. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 9, wobei das Führungsmittel (110) ferner einen Becherkopf (115) aufweist zur Verbindung mit dem Auslass (62), wobei dieser Becherkopf (115) mit mindestens einem Loch (116) am Boden des Becherkopfes (115) mit dem wellenförmigen Splint (117) verbunden ist, damit die Milch durch den wellenförmigen Splint (117) entweicht.

11. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 10, wobei der Becher (115) genau in den Auslass (62) passt mit einer nach oben gerichteten Gleitkraft, um bei der Führung der Milch aus der Kammer luftdicht zu sein.

12. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 1, wobei der Behälter ein Sammelbeutel (300) ist.

13. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 12, wobei der Sammelbeutel (300) aus einem dünnen, synthetischen, dichten Material gebildet ist.

14. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 12,wobei der Behälter ein Sammelbeutel (300) ist mit einem Hals (310) zur passenden Aufnahme des Führungsmittels (110), um einen dichten Fluss der Milch durch das Führungsmittel (110) in den Beutel (300) zu erlauben bei Aufrechterhaltung des operativen Kontakts mit dem Führungsmittel (110).

15. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 14, wobei der Hals (310) des Sammelbeutels (300) zwei dichte Kanten (311, 311") in V-Form aufweist, um den Hals nach einem Zusammenpressen dicht zu machen.

16. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 11, wobei der Behälter ein Sammelbeutel (300) ist mit einem Hals (310), und wobei der Becher (115) einen extrudierten Rand aufweist, um eine Kante des Halses (310) zu bedecken, wodurch der Hals (310) gedichtet ist und einem von einem die Brust bedeckenden Kleidungsstück erzeugten Druck stand hält.

17. Das tragbare, freihändige und optisch ansprechende Brustpumpensystem gemäss Anspruch 12, wobei der Sammelbeutel (300) mit einer Einteilungsskala bedruckt ist, um die Menge der im Beutel (300) gesammelten Milch anzuzeigen.

18. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, ferner aufweisend ein Steuerungsmittel (90), um den Betrieb des Servomotormechanismus (24) zu steuern.

19. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 18, wobei das Steuerungsmittel (90) ein Mittel zur Steuerung einer Zyklusrate und/oder eines Vakuumlevels des Servomotormechanismus (24) beinhaltet.

20. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 19, wobei das Steuerungsmittel (90) mindestens einen variablen Schalter (14) auf dem Gehäuse (12) beinhaltet.

21. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 18, wobei das Steuerungsmittel einen Mikroprozessor (90) beinhaltet.

22. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 21, wobei der Mikroprozessor (90) die Pumpe steuert, um einen natürlichen Saugen-Halten-Loslassen-Entspannen-Zyklus und Kraft eines saugenden Baby's zu imitieren.

23. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Servomotormechanismus (24) aus einem Elektromotor oder einer angebundenen Handpumpeneinrichtung gebildet ist.

24. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Servomotormechanismus (24) ausserhalb des Gehäuses (12) angeordnet ist.

25. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 24, wobei der Servomotormechanismus (24) mittels eines Adapters (46) mit dem Gehäuse (12) verbunden ist.

26. Die tragbare, freihändige und optisch ansprechende Brustpumpe gemäss Anspruch 1, wobei der Servomotormechanismus (24) einen Elektromotor, einen mit dem Elektromotor wirkverbundenen Hebelarm (21) und einen hinteren Kolben aufweist, wobei der hintere Kolben operativ angeordnet ist, um sich mittels des Hebelarms linear zu bewegen so dass er auf eine Oberseite des Flansches (30) in Richtung der Brust drückt und dabei Luft aus der Kammer (60) drückt, um den Unterdruck beim Rückzug zu erzeugen.

Revendications

1. Tire-lait (10) visuellement convivial, mains libres et portatif destiné à faciliter le tirage de lait maternel, comportant : un logement (12) pourvu d'un mécanisme (24) de servomoteur ; une coupelle (30) pourvue d'une partie chambre, une partie rebord et un orifice de sortie (62), la partie chambre étant formée de façon à être placée sur le mamelon du sein de façon à délimiter une chambre (60) entre la coupelle (30) et le sein, et la partie rebord étant formée pour entourer le mamelon et former ainsi un joint étanche de succion entre les deux, et un élément (140) d'évacuation à sens unique formé pour communiquer

fonctionnellement avec la chambre (60) de façon à évacuer le lait tiré de la chambre (60) vers l'orifice de sortie (62), **caractérisé en ce que** le logement (12) est en forme de dôme et la coupelle (30) est en forme de chapeau et **en ce que** le mécanisme (24) de servomoteur est relié fonctionnellement à la partie chambre de la coupelle (30) de façon à induire un mouvement de tirage sur la partie chambre et à créer un vide dans la chambre (60) pour tirer ainsi le lait du sein, la chambre (60) étant fermée de manière étanche par le vide excepté au niveau de l'orifice de sortie (62), et le logement (12), la coupelle (30) et l'élément (140) d'évacuation sont reliés en un dispositif intégré maintenu contre le sein et situé sous les vêtements de façon à maintenir le dispositif intégré caché.

2. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, comportant en outre un moyen (110) de guidage relié fonctionnellement à l'élément (140) d'évacuation à sens unique destiné à guider le lait tiré dans un contenant (300).

3. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel l'orifice de sortie (62) de la coupelle (30) est en forme d'entonnoir.

4. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, comportant en outre un support (35) de coupelle destiné à empêcher le dépassement des frappes vers la coupelle (30), ledit support (35) de coupelle étant fixé en place par un ajustement étroit autour d'une base de la coupelle (30) .

5. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel la coupelle (30) en forme de chapeau est intégralement formée d'une matière élastique.

6. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le logement (12) en forme de dôme comprend en outre à l'intérieur de ce dernier une alimentation (26) électrique portative.

7. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le mécanisme (24) de servomoteur du logement (12) est relié fonctionnellement à la partie chambre de la coupelle (30) de façon à impartir une action de frappe alternative sur la partie chambre, la partie chambre produisant un déplacement d'air et un mouvement alternatif de vide qui imite le mouvement de tétée d'un bébé.

8. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le moyen de guidage comprend un élément (110) de guidage souple qui s'étend du dispositif intégré à un contenant (300) et qui est positionnable de manière souple de façon à relier fonctionnellement le dispositif intégré au contenant (300), le dispositif intégré, l'élément (110) de guidage et le contenant (300) étant maintenus contre le sein et sous les vêtements.

9. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 8, dans lequel l'élément (110) de guidage comprend une éclisse (117) allongée souple qui a une forme d'onde dans une direction transversale par rapport à l'éclisse (110).

10. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 9, dans lequel le moyen (110) de guidage comprend en outre une tête (115) de cupule devant être reliée à l'orifice de sortie (62), ladite tête (115) de cupule étant reliée à l'éclisse (117) en forme d'onde avec au moins un orifice (116) à la partie inférieure de la tête (115) de cupule pour que le lait fuie le long de l'éclisse (117) en forme d'onde.

11. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 10, dans lequel la cupule (115) est étroitement ajustée dans l'orifice de sortie (62) sous une force de glissement vers le haut de façon à être hermétique tout en guidant le lait hors de la chambre.

12. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 2, dans lequel le contenant est un sac (300) collecteur.

13. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 12, dans lequel le sac (300) collecteur est formé d'une matière synthétique mince antifuite.

14. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 12, dans lequel le contenant est un sac (300) collecteur présentant un col (310) destiné à recevoir de manière étroitement ajustée le moyen (110) de guidage de façon à permettre un écoulement sans fuite du lait par le moyen (110) de guidage dans le sac (300) tout en maintenant un contact fonctionnel avec le moyen (110) de guidage.

15. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 14, dans lequel le col (310) du sac (300) collecteur présente deux bords (311, 311") fermés de manière étanche en forme de V pour rendre le col imperméable aux déversements une fois pressé.

16. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 11, dans lequel le contenant est un sac (300) collecteur pourvu d'un col (310), et la cupule (115) présente un pourtour extrudé pour recouvrir un bord du col (310), rendant ainsi le col (310) étanche et contrecarrant la pression créée par les vêtements recouvrant le tire-lait.

17. Système pour tire-lait visuellement convivial, mains libres et portatif selon la revendication 12, dans lequel le sac (300) collecteur a une échelle de graduation imprimée sur ce dernier pour indiquer la quantité de lait collectée dans le sac (300).

18. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, comportant en outre un moyen (90) de commande pour commander le fonctionnement du mécanisme (24) de servomoteur.

19. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 18, dans lequel le moyen (90) de commande comprend un moyen destiné à commander au moins un rythme cyclique et/ou un niveau de vide du mécanisme (24) de servomoteur.

20. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 19, dans lequel le moyen (90) de commande comprend au moins un interrupteur (14) variable sur le logement (12).

21. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 18, dans lequel le moyen de commande comprend un microprocesseur (90).

22. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 21, dans lequel le microprocesseur (90) commande la pompe pour imiter le cycle naturel de maintien-libération-détente de tétée et la force d'un bébé s'allaitant.

23. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le mécanisme (24) de servomoteur est constitué d'un moteur électrique et d'un dispositif de tirage manuel attaché.

24. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le mécanisme (24) de servomoteur est situé à l'extérieur du logement (12).

25. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 24, dans lequel le mécanisme (24) de servomoteur est relié au logement (12) avec un adaptateur (46).

26. Tire-lait visuellement convivial, mains libres et portatif selon la revendication 1, dans lequel le mécanisme (24) de servomoteur comprend un moteur électrique, un bras (21) de levier relié fonctionnellement au moteur électrique, et un piston arrière positionné fonctionnellement de manière à être déplacé linéairement par le bras de levier de façon à appuyer sur le haut de la coupelle (30) vers le sein, ce qui fait sortir l'air de la chambre (60) par pression pour créer le vide au moment du retrait.

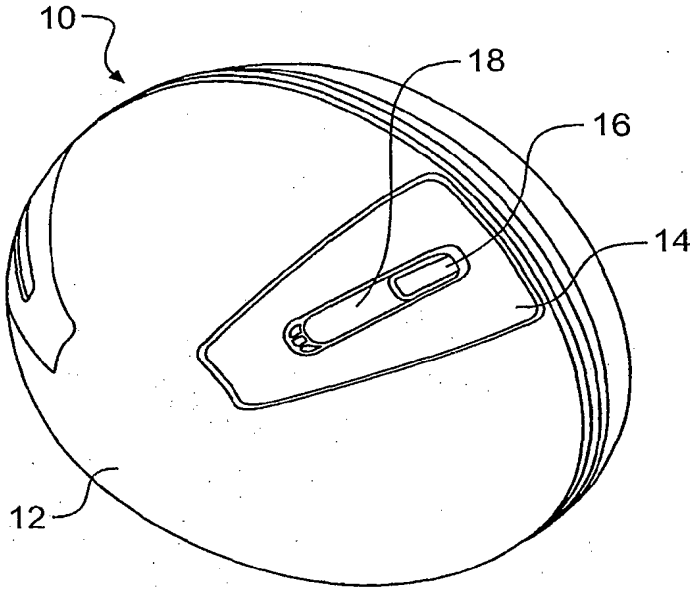


FIG. 1A

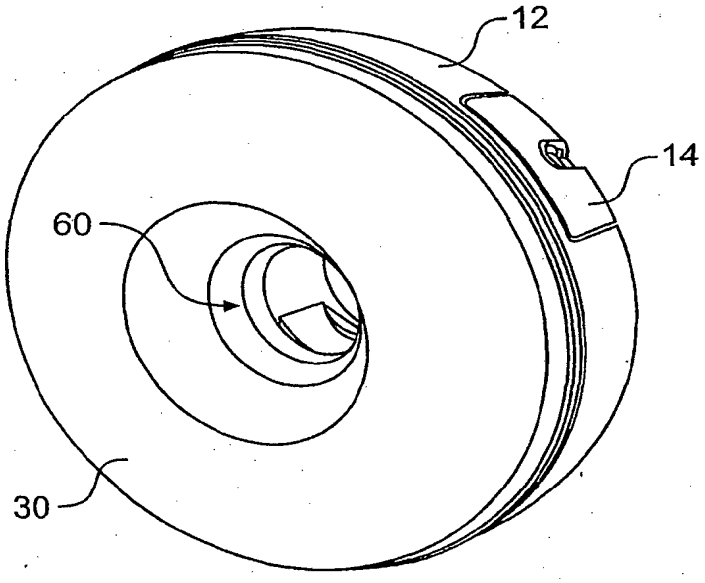


FIG. 1B

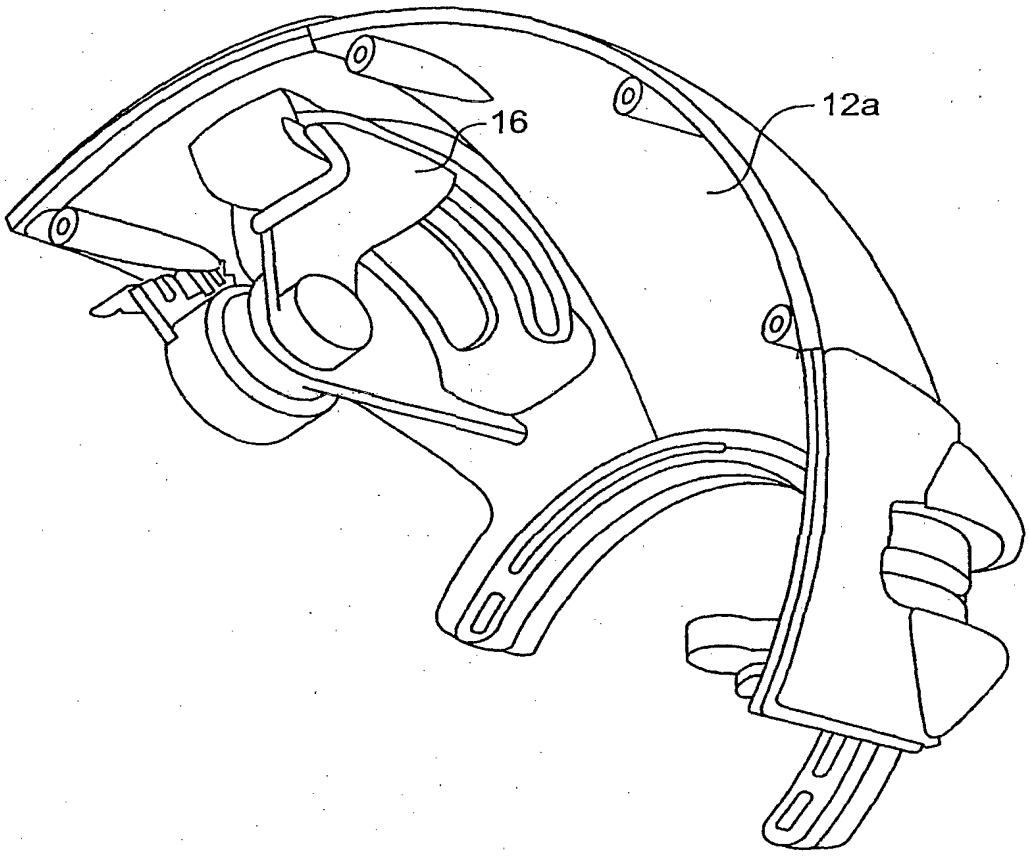


FIG. 2

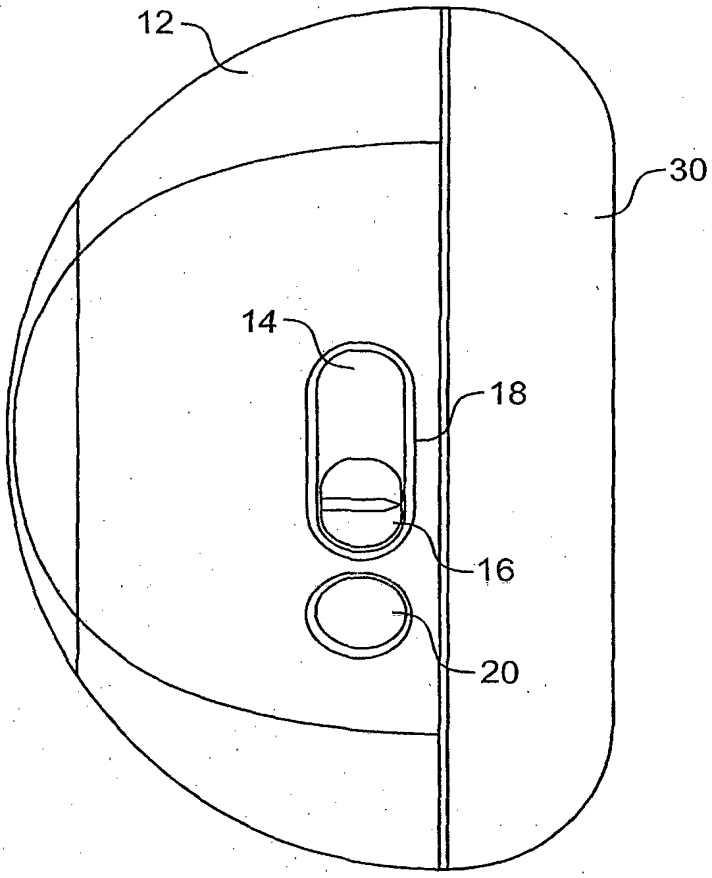


FIG. 3

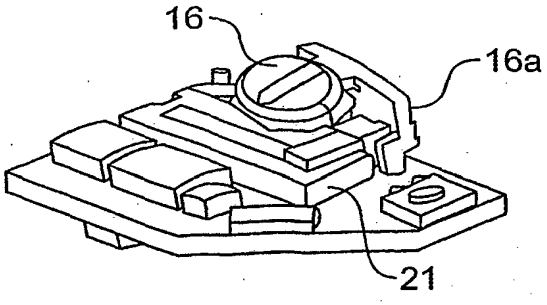


FIG. 4

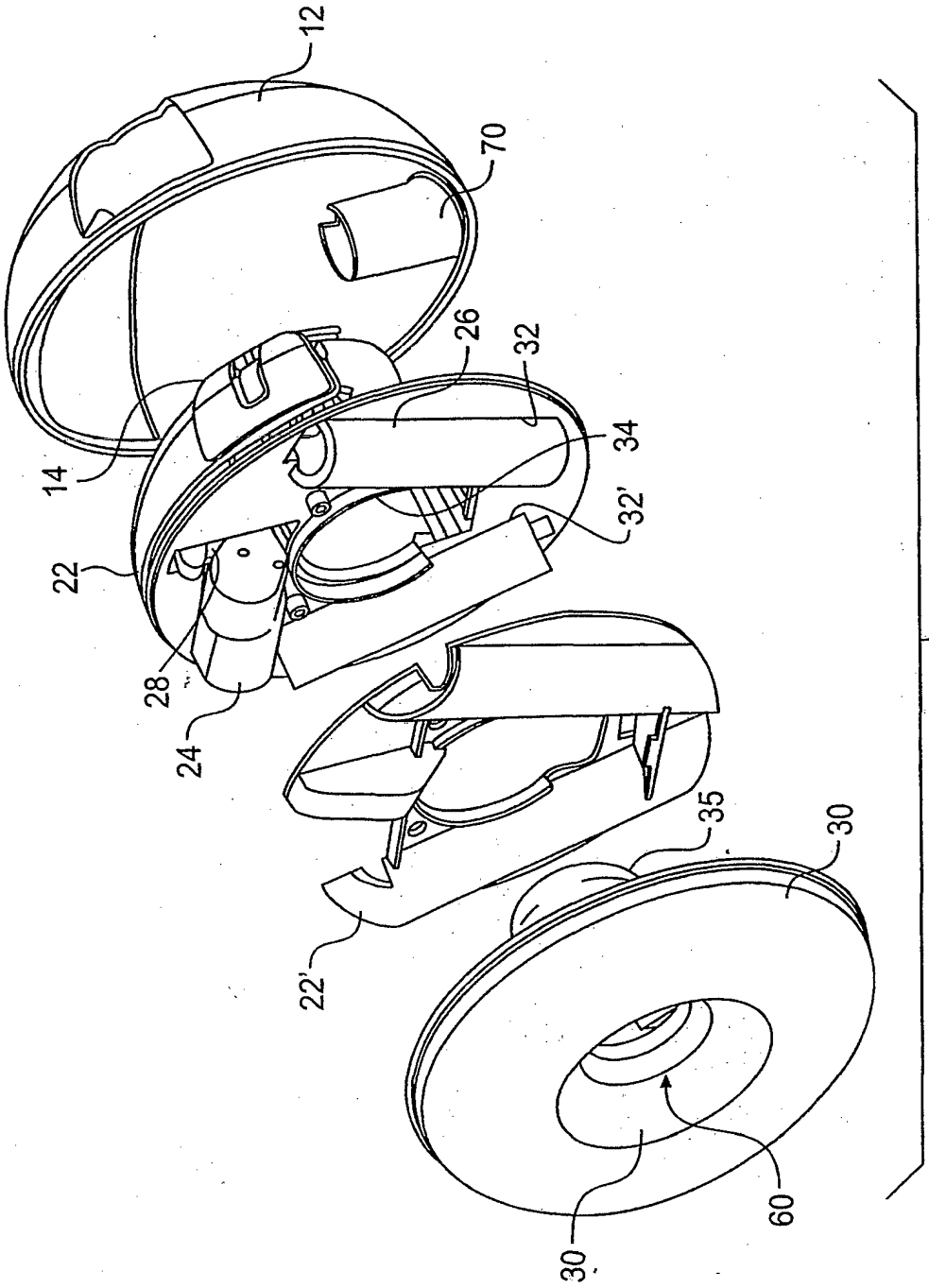


FIG. 5

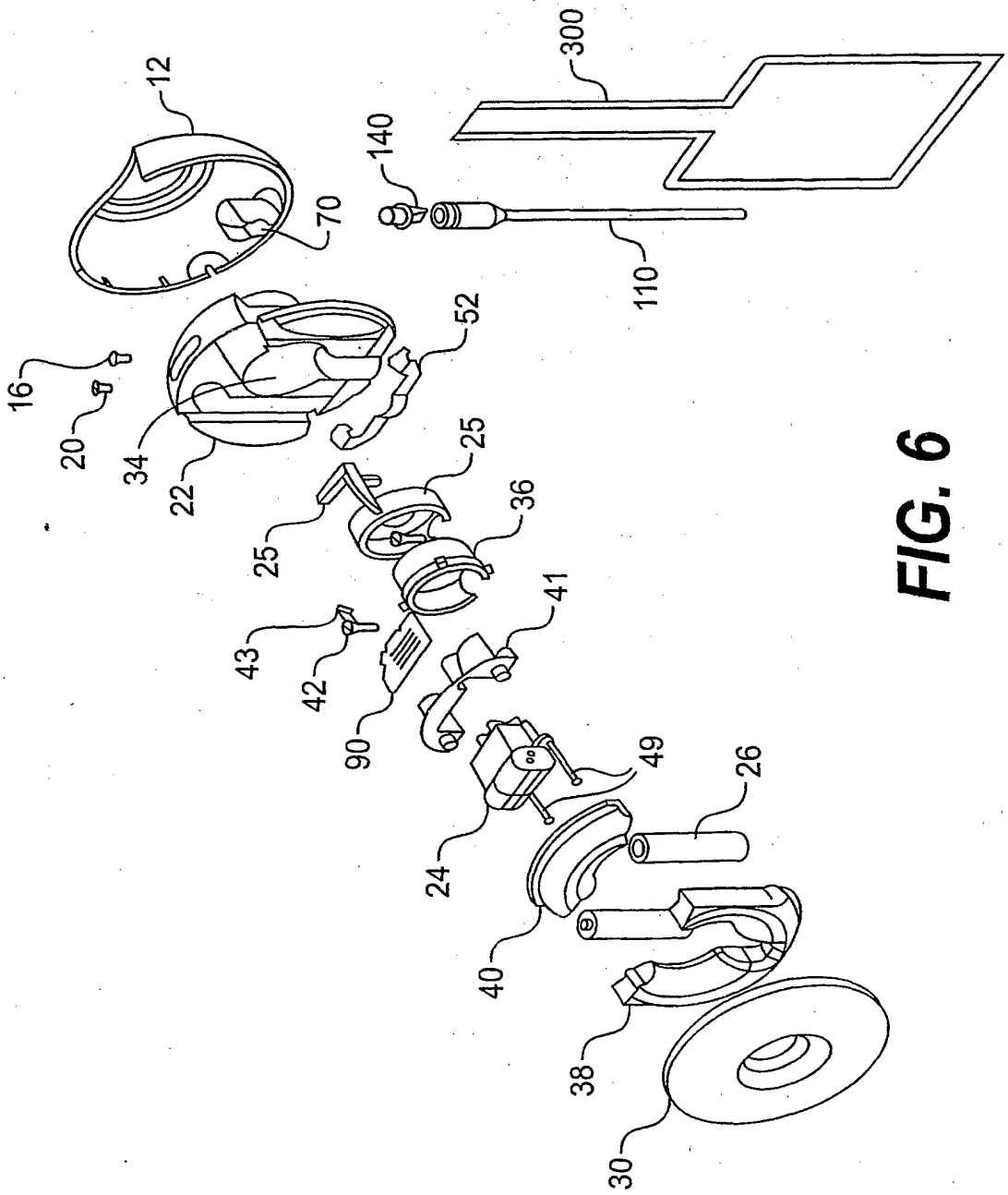


FIG. 6

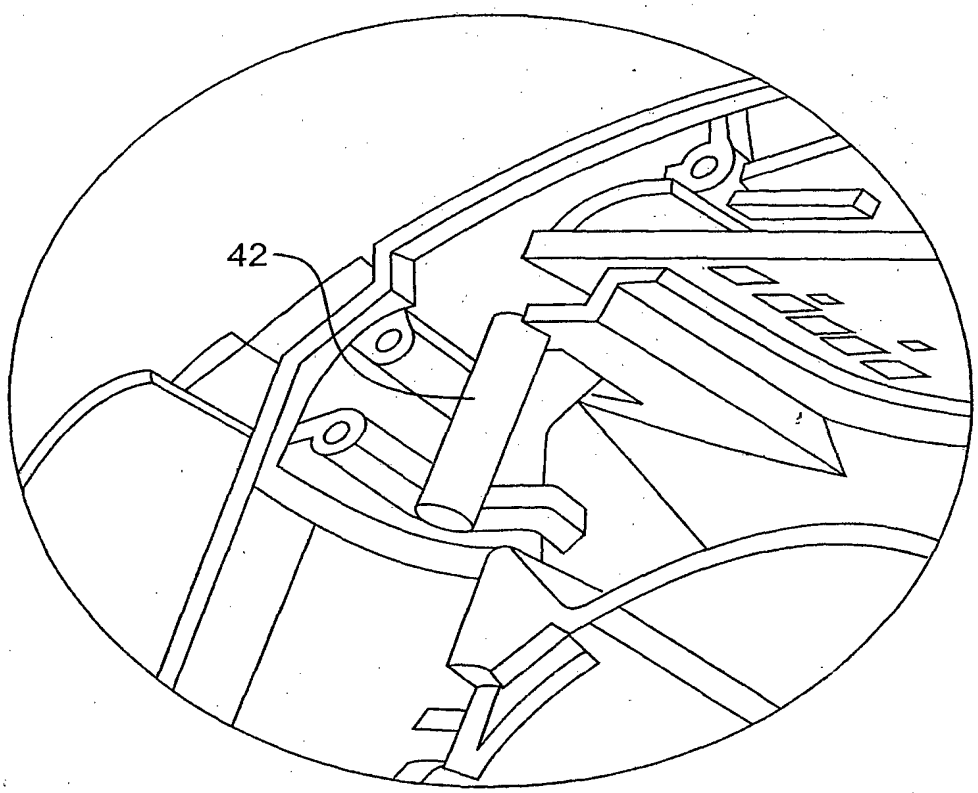


FIG. 7

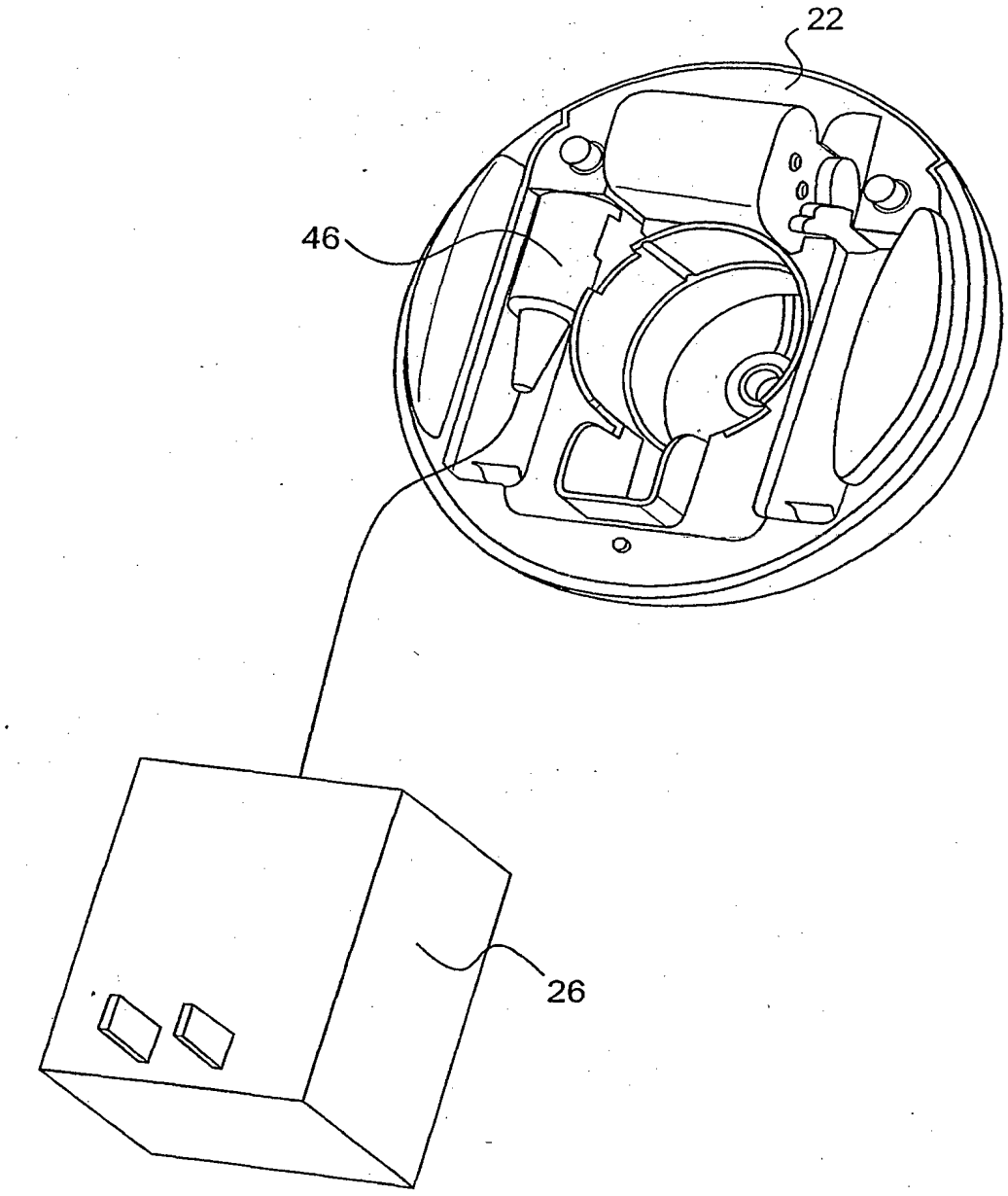


FIG. 8A

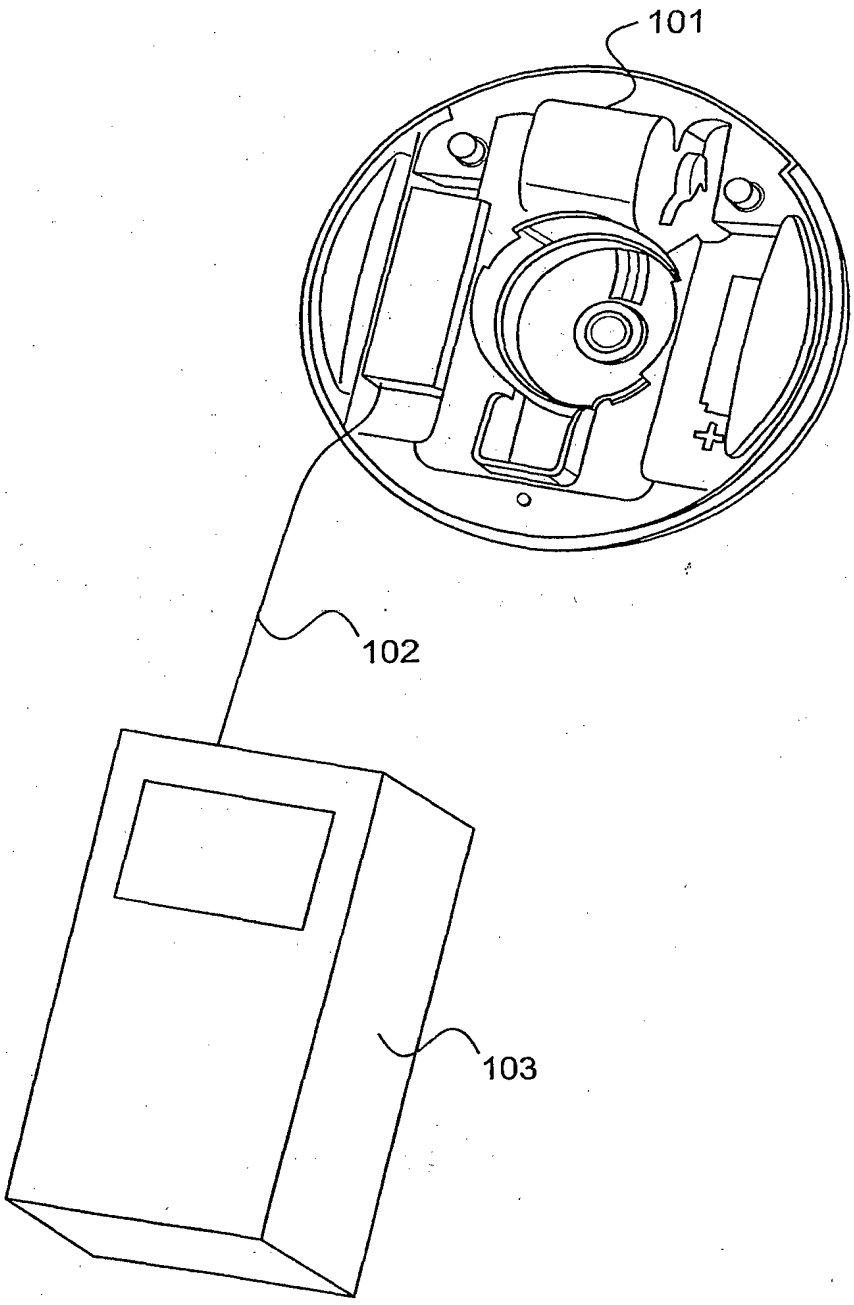


FIG. 8B

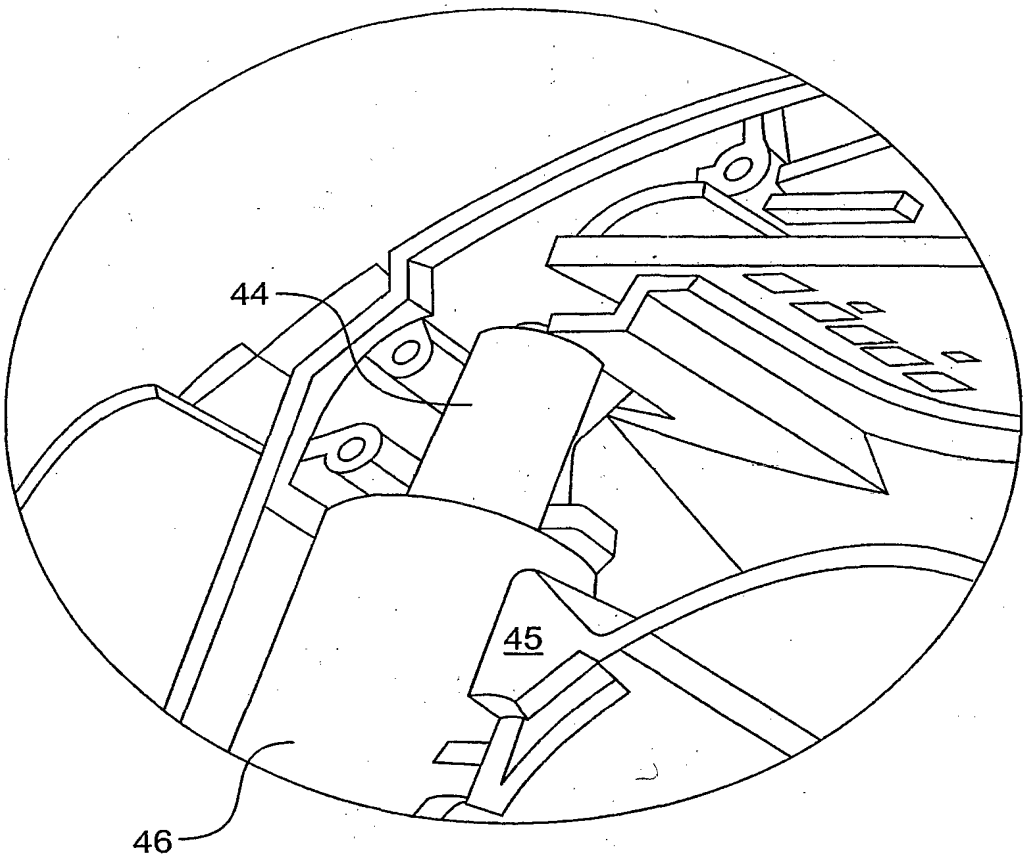


FIG. 9

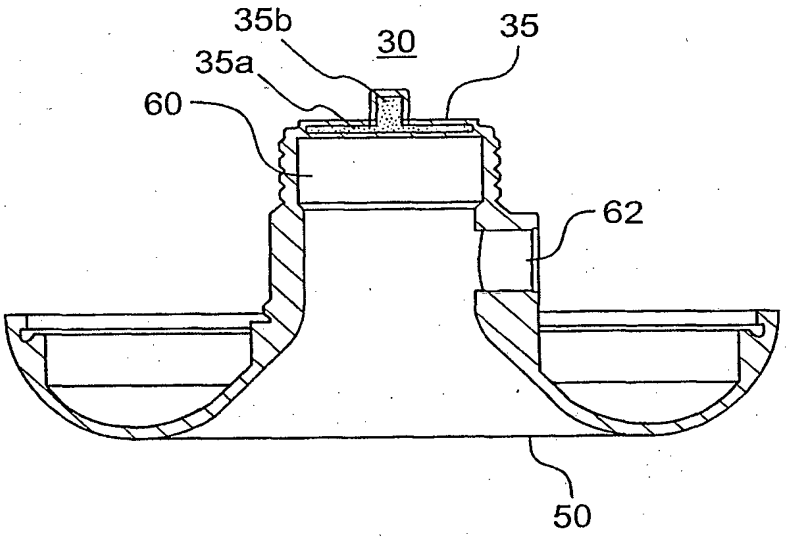


FIG. 10A

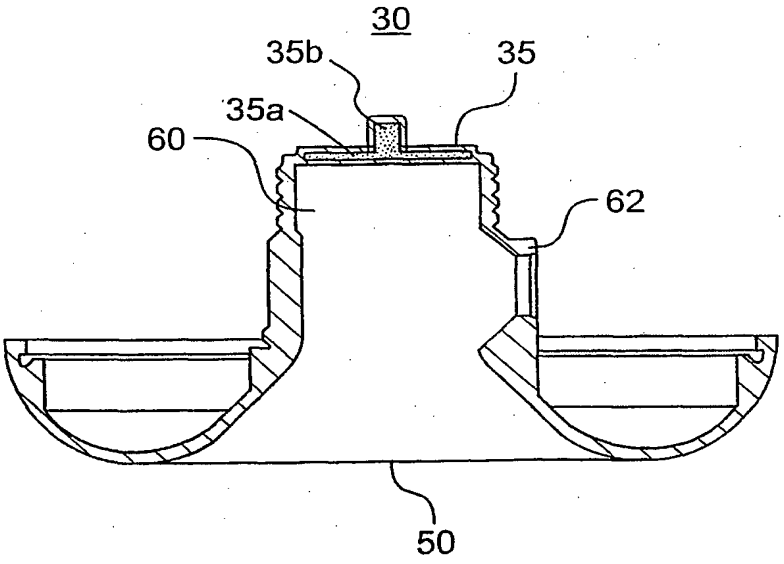


FIG. 10B

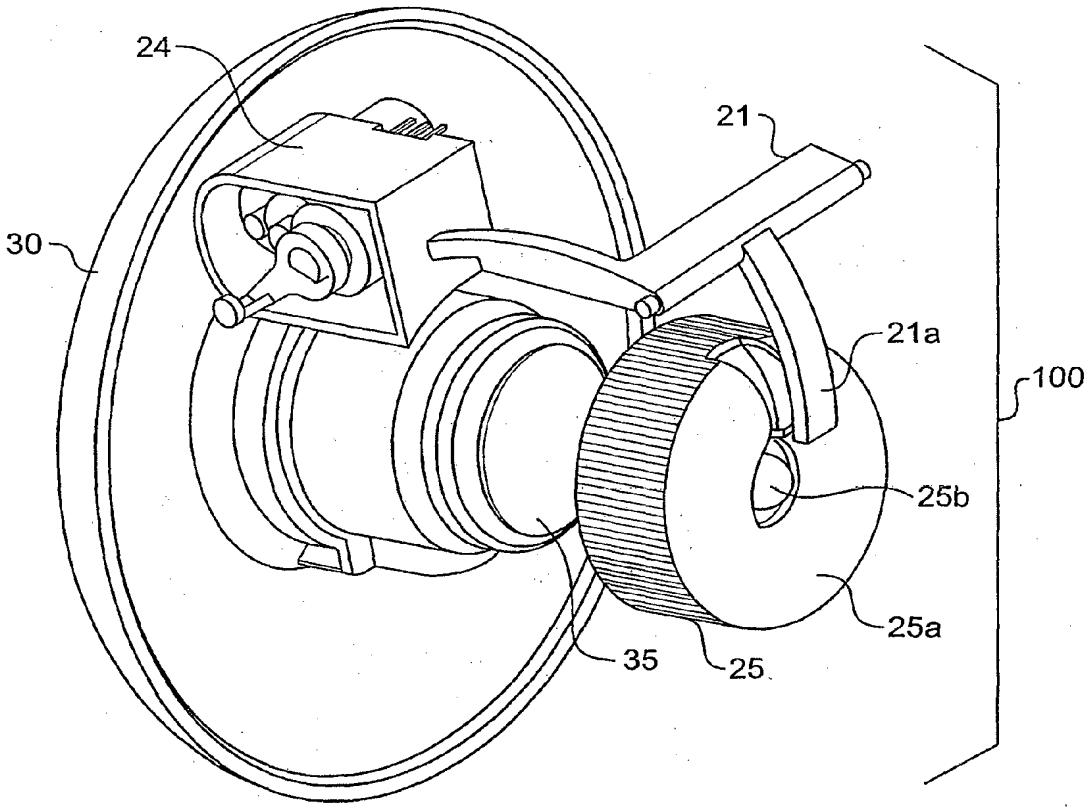


FIG. 11A

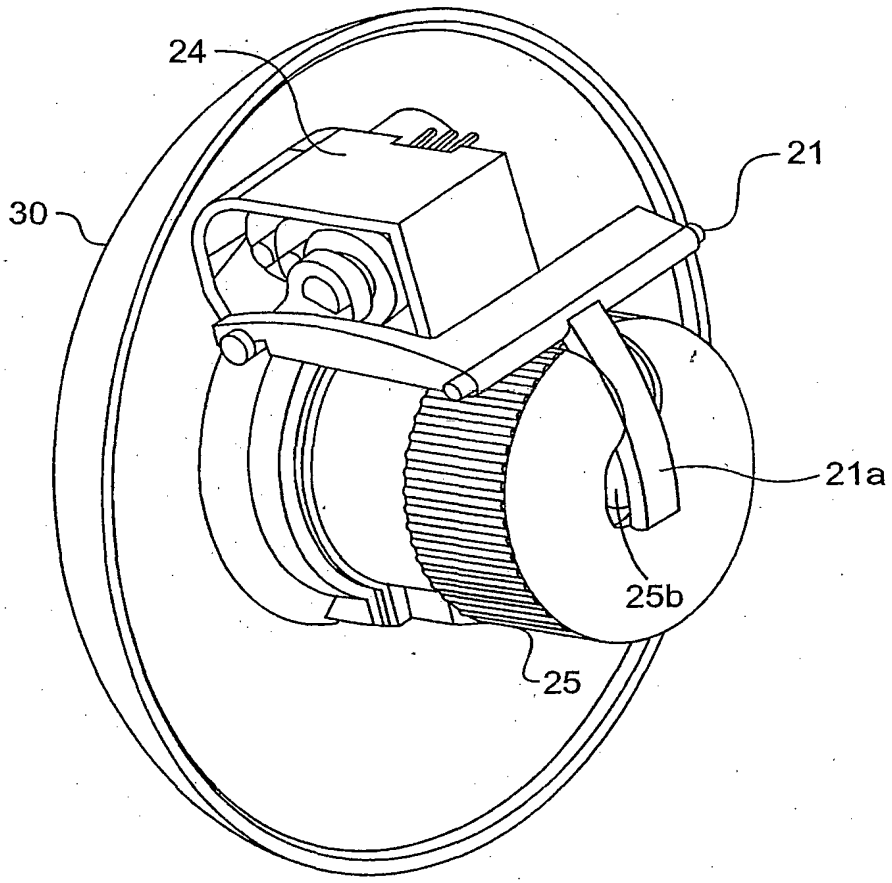


FIG. 11B

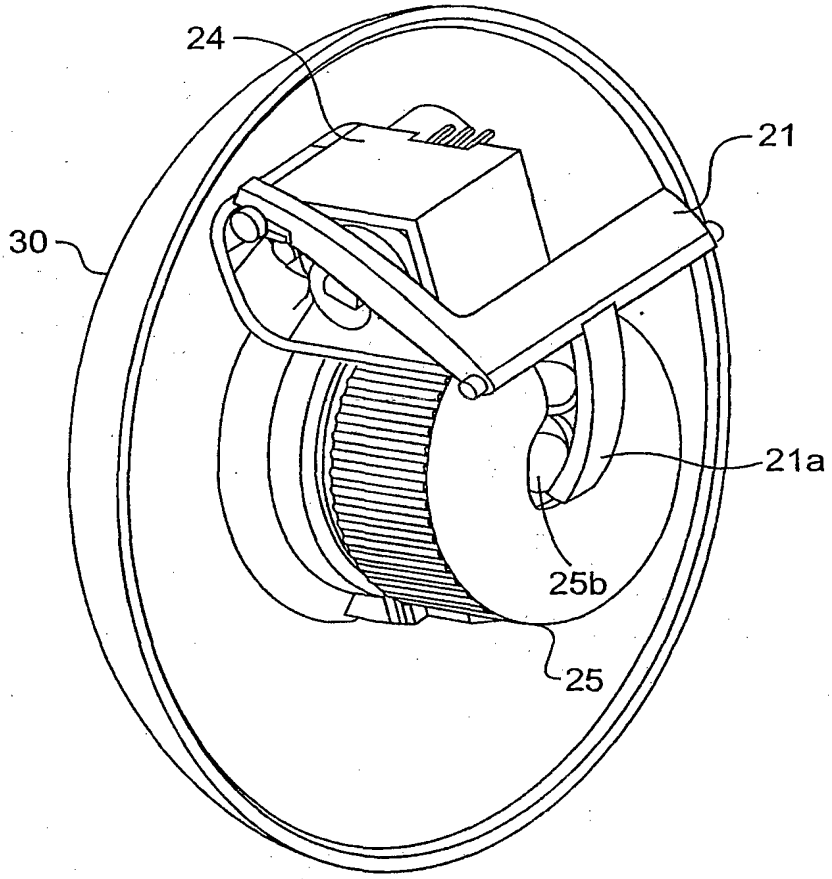


FIG. 11C

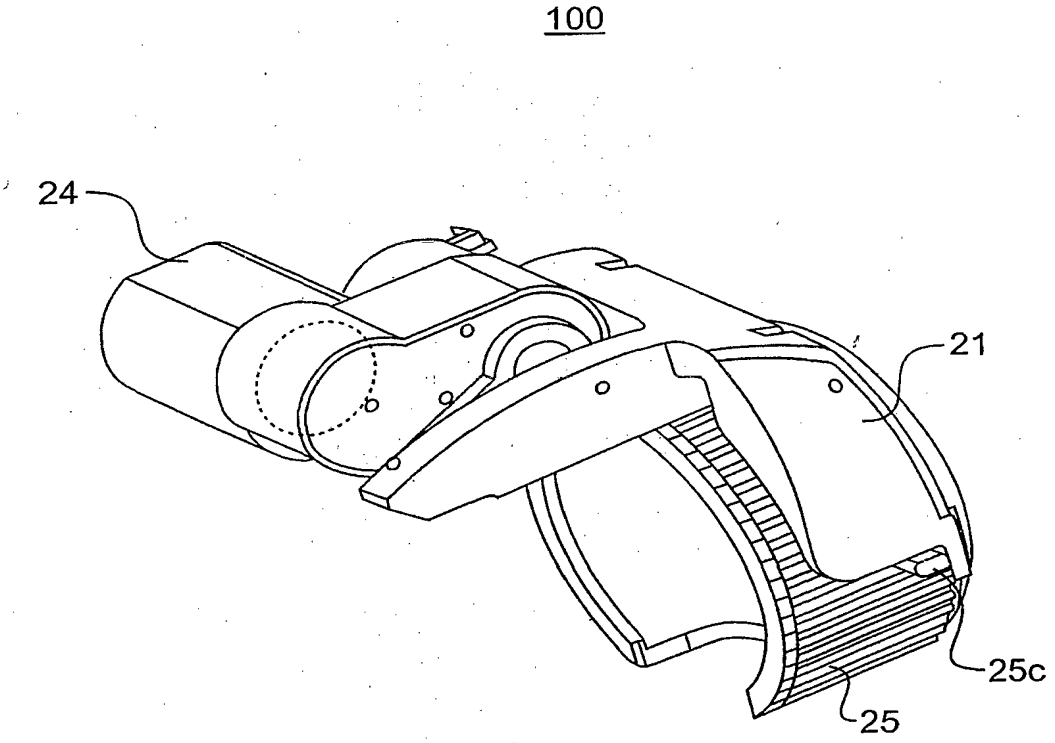


FIG. 12

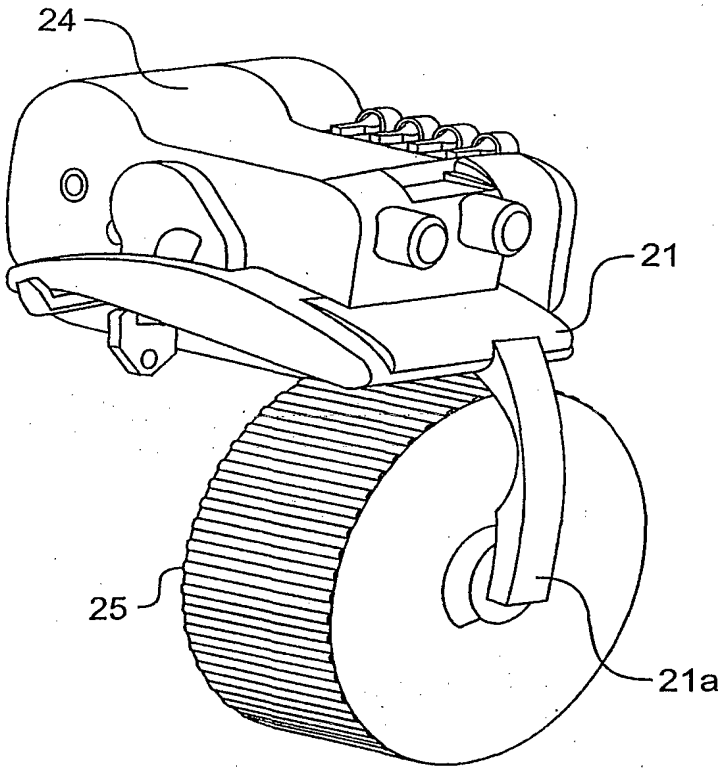


FIG. 13

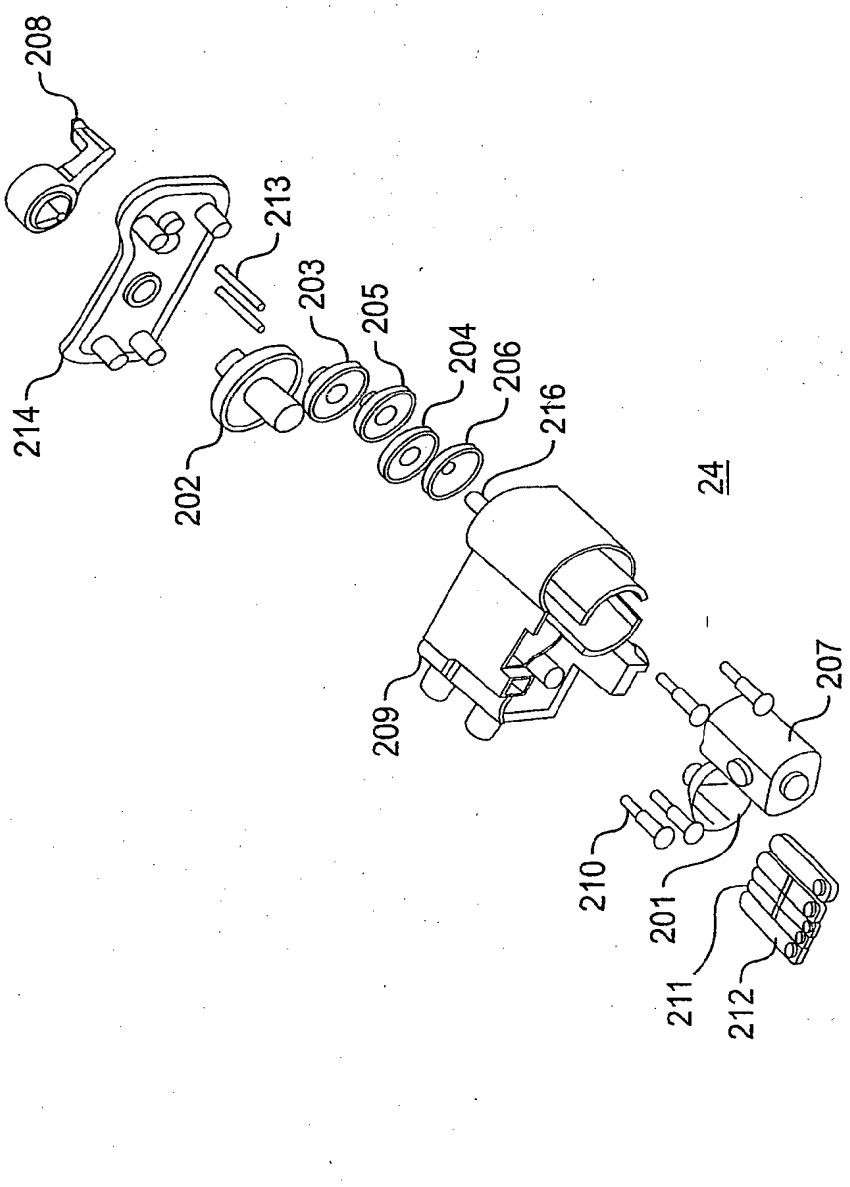

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FIG. 14

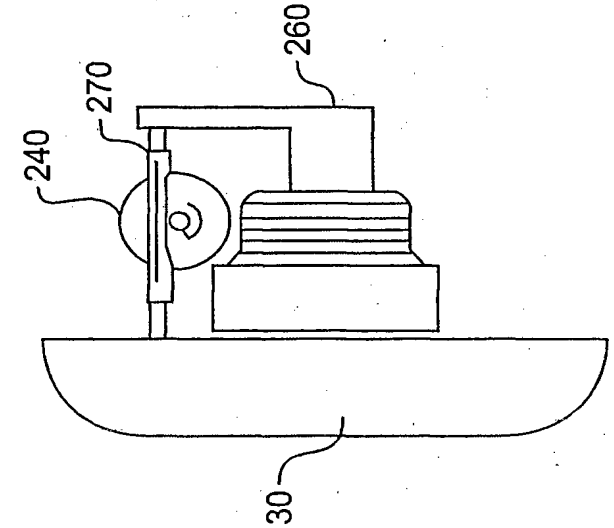


FIG. 16

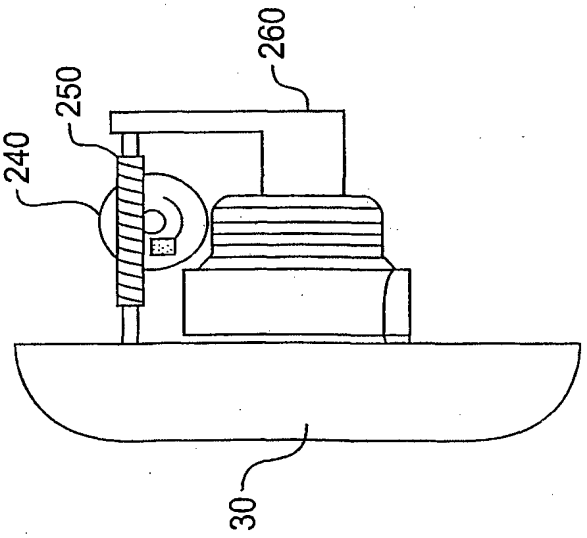


FIG. 15

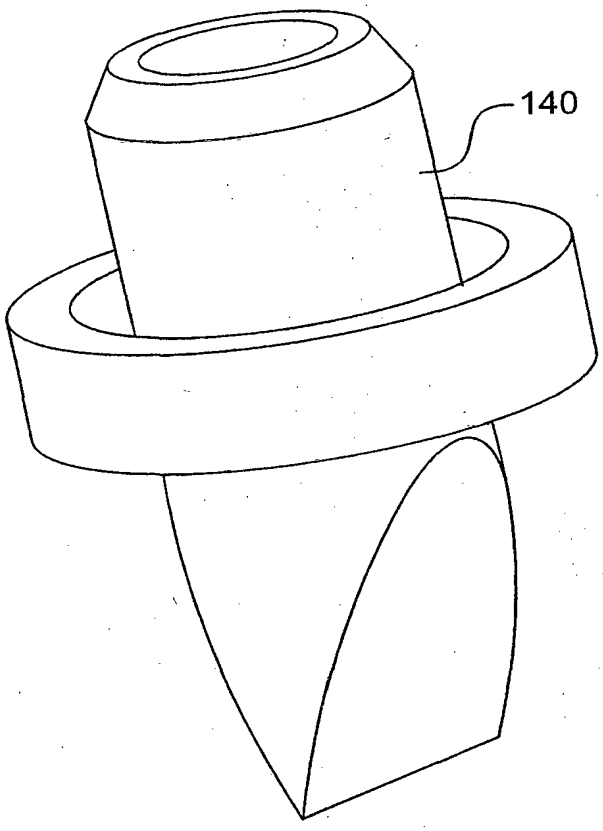


FIG. 17

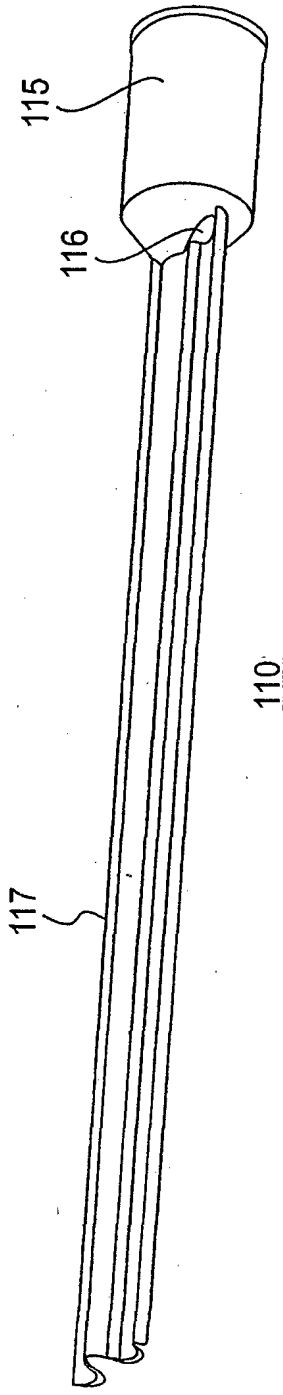


FIG. 18A

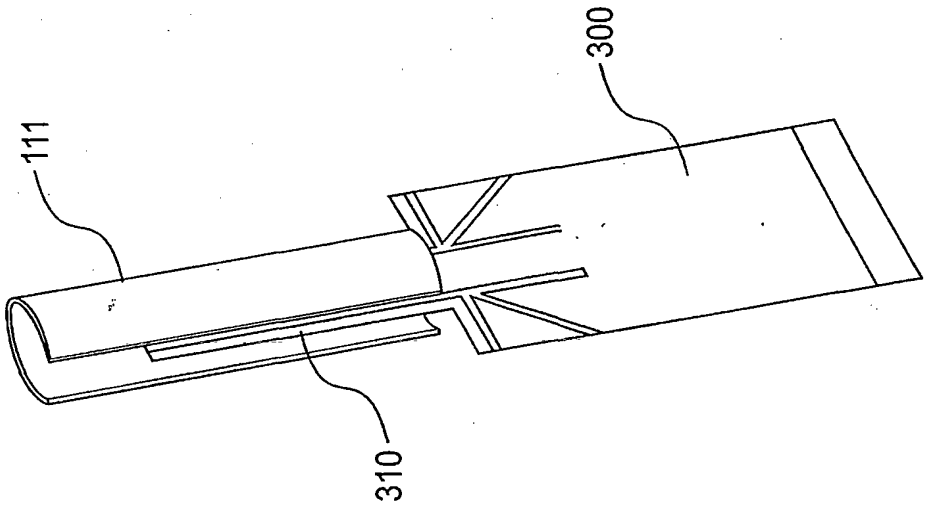


FIG. 18B

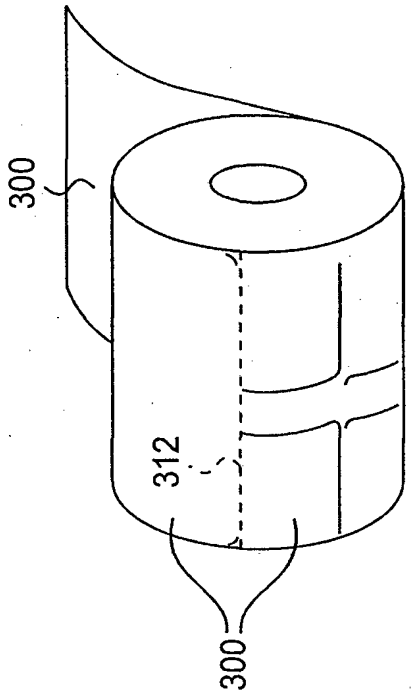


FIG. 19B

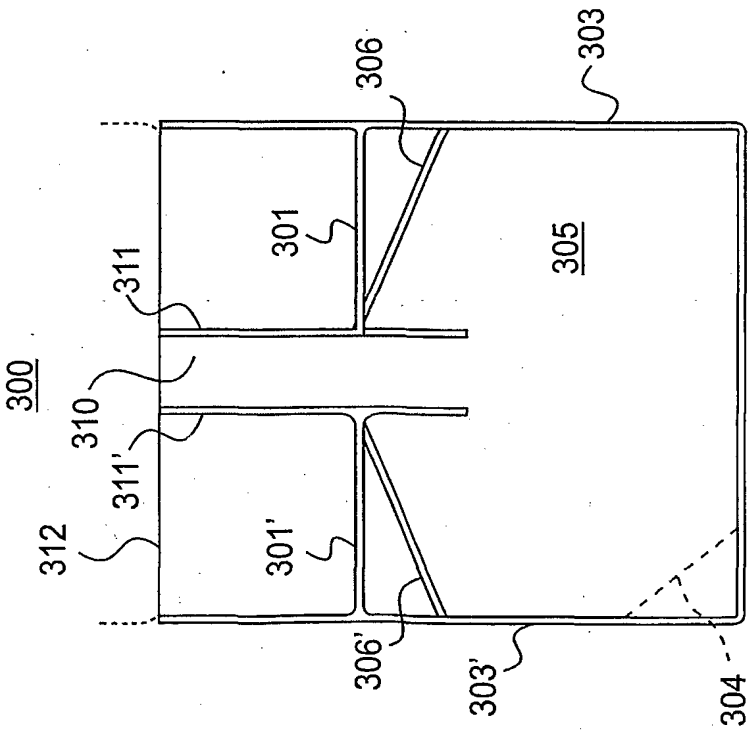


FIG. 19A

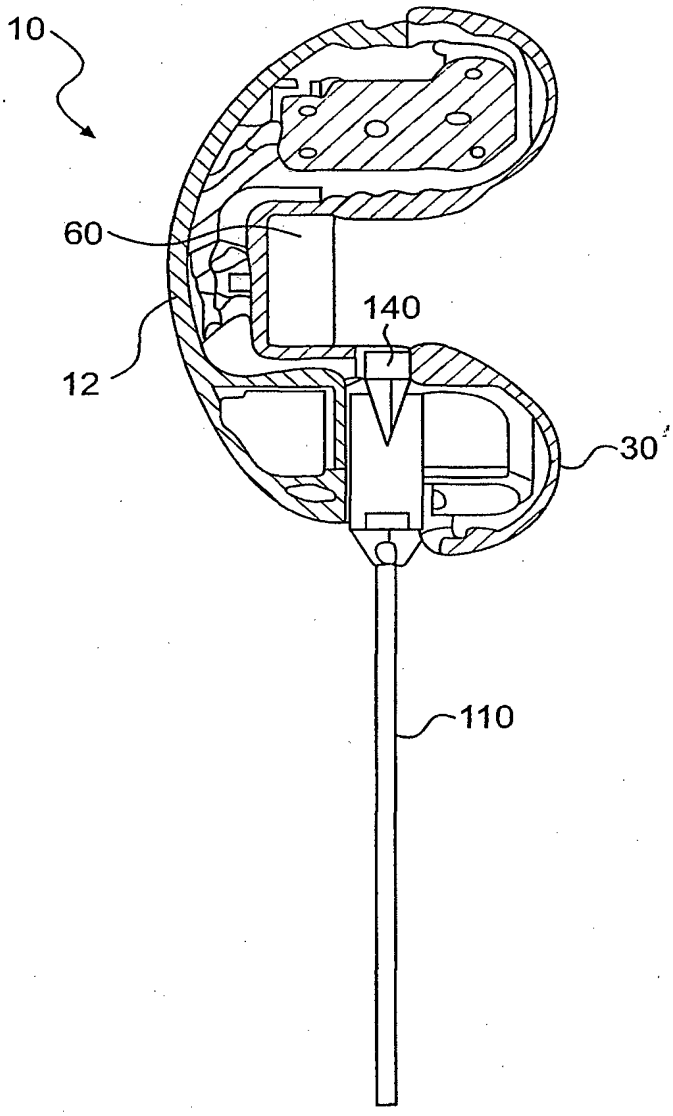


FIG. 20A

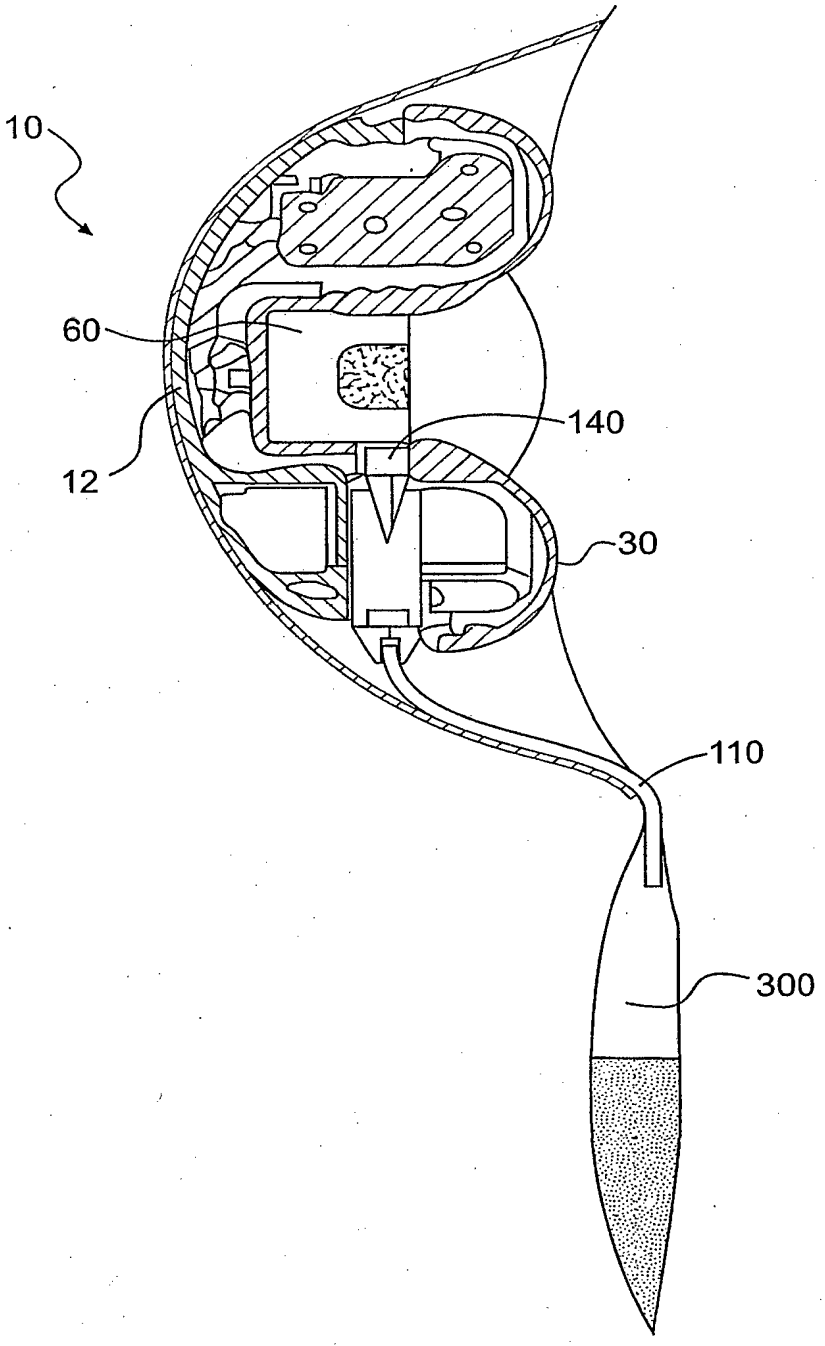


FIG. 20B

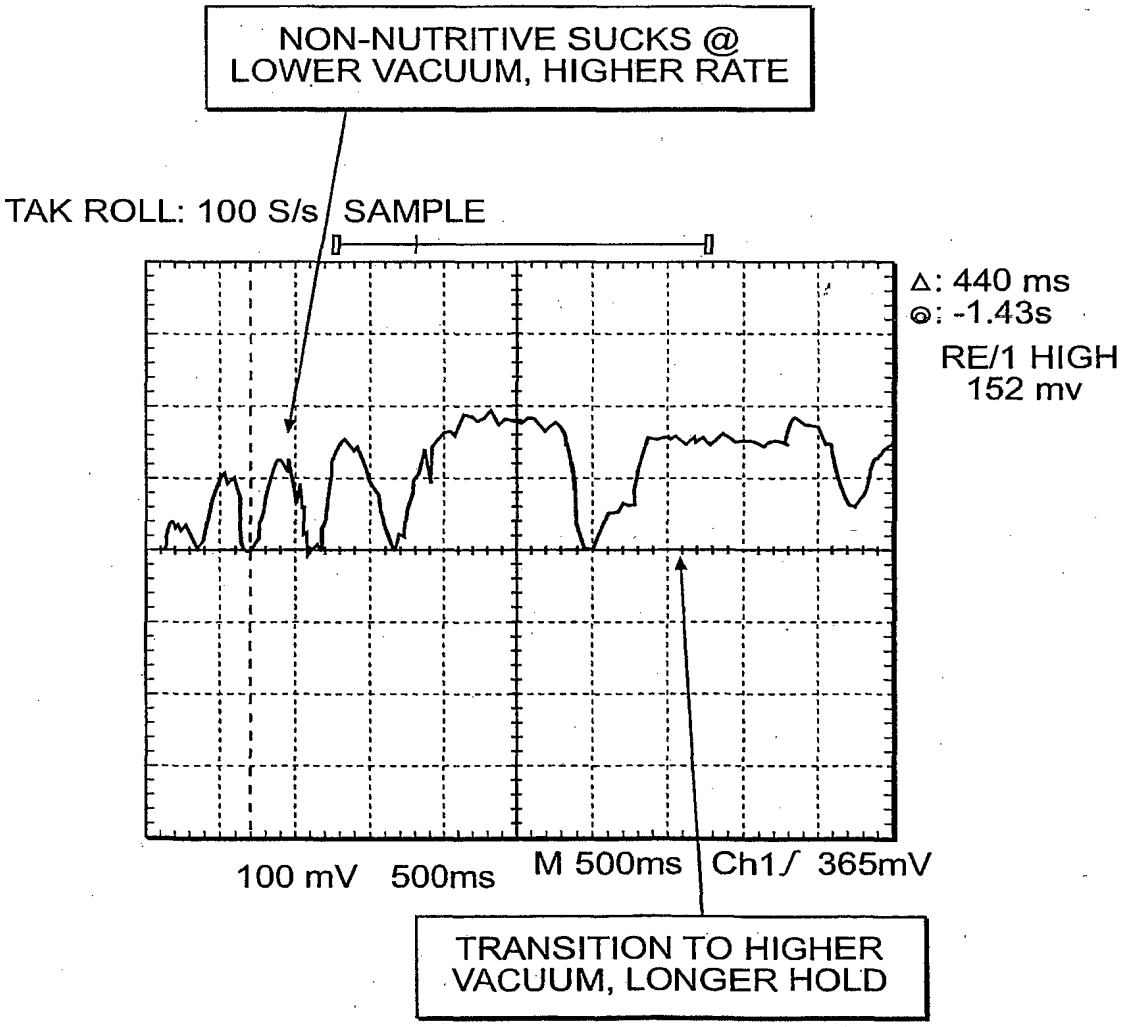

NON-NUTRITIVE SUCKS @
LOWER VACUUM, HIGHER RATE
TAK ROLL: 100 S/s SAMPLE
Δ: 440 ms
@: -1.43s
RE/1 HIGH
152 mv
100 mV
500ms
M 500ms
Ch1 365mV
TRANSITION TO HIGHER
VACUUM, LONGER HOLD

FIG. 21A

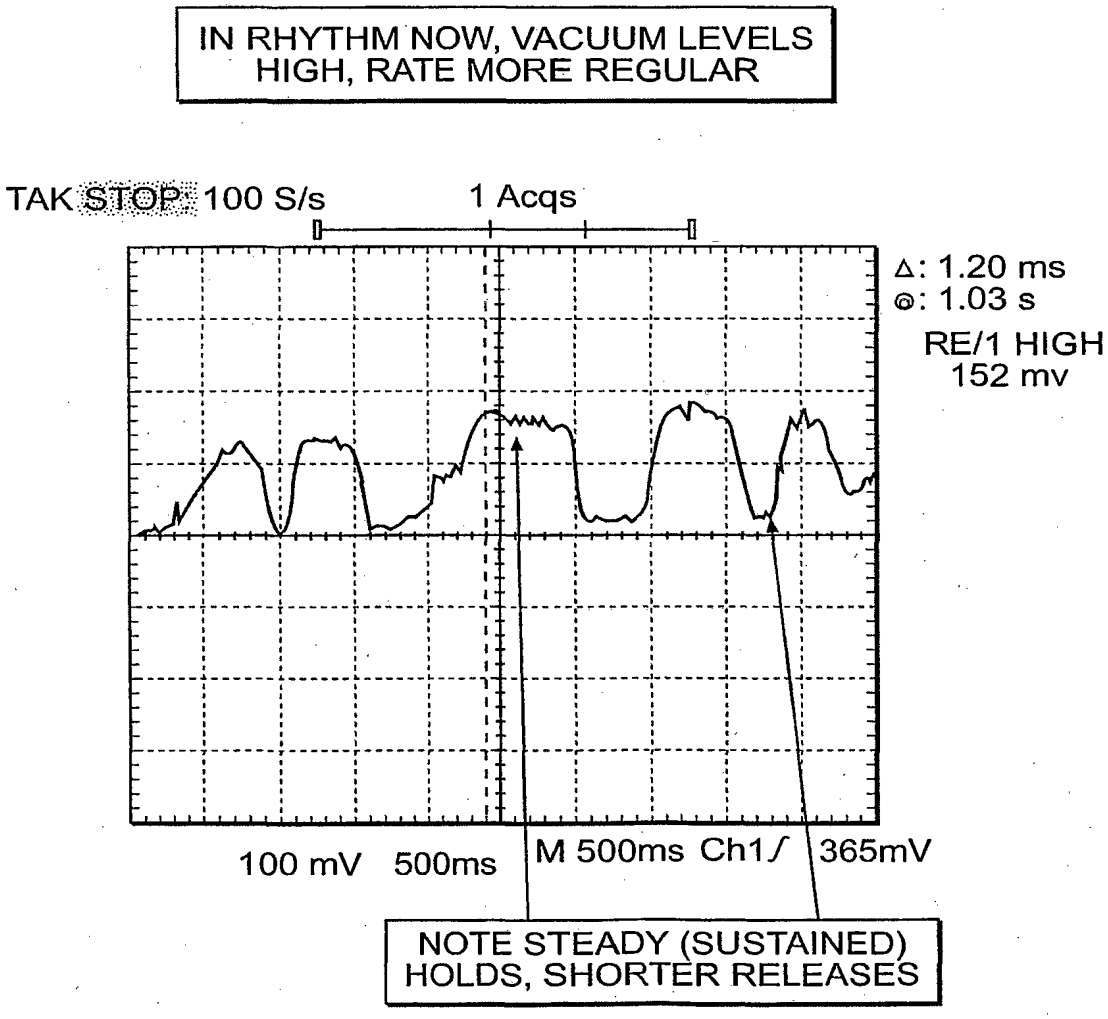

IN RHYTHM NOW, VACUUM LEVELS HIGH, RATE MORE REGULAR
TAK STOP 100 S/s
1 Acqs
Δ: 1.20 ms
@: 1.03 s
RE/1 HIGH
152 mv
100 mV 500ms
M 500ms Ch1 365mV
NOTE STEADY (SUSTAINED) HOLDS, SHORTER RELEASES

FIG. 21B

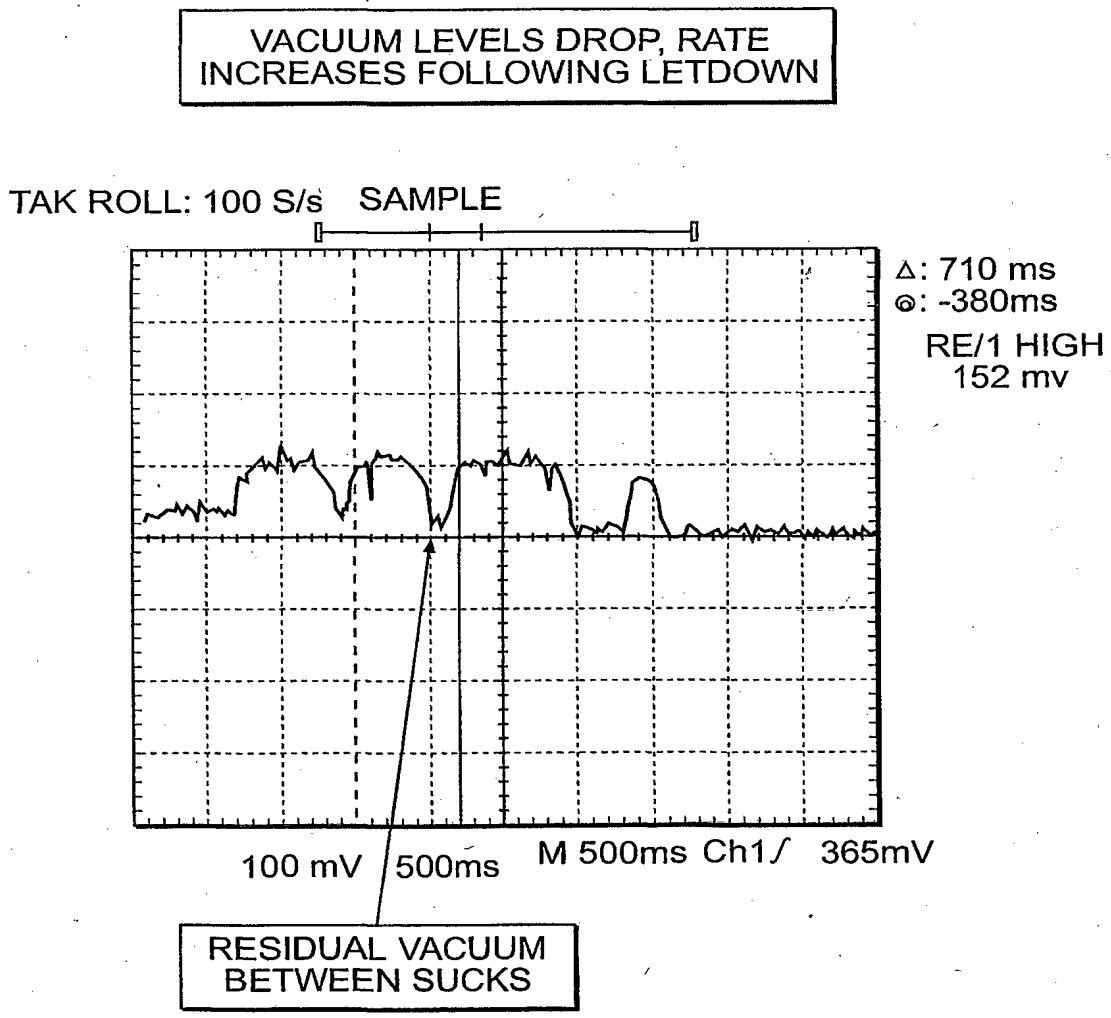
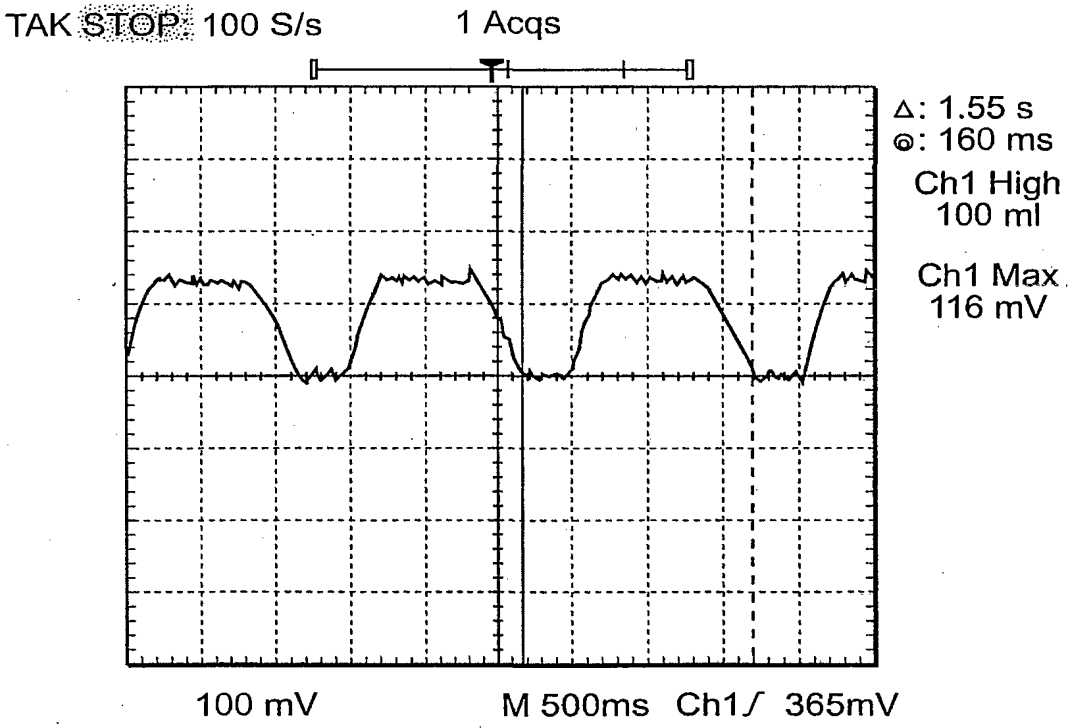

VACUUM LEVELS DROP, RATE INCREASES FOLLOWING LETDOWN
TAK ROLL: 100 S/s SAMPLE
Δ: 710 ms
@: -380ms
RE/1 HIGH
152 mv
100 mV
500ms
M 500ms Ch1 365mV
RESIDUAL VACUUM BETWEEN SUCKS

FIG. 21C



Max Vacuum (mmHg):	136
Rate (cyc/min):	39

FIG. 22A

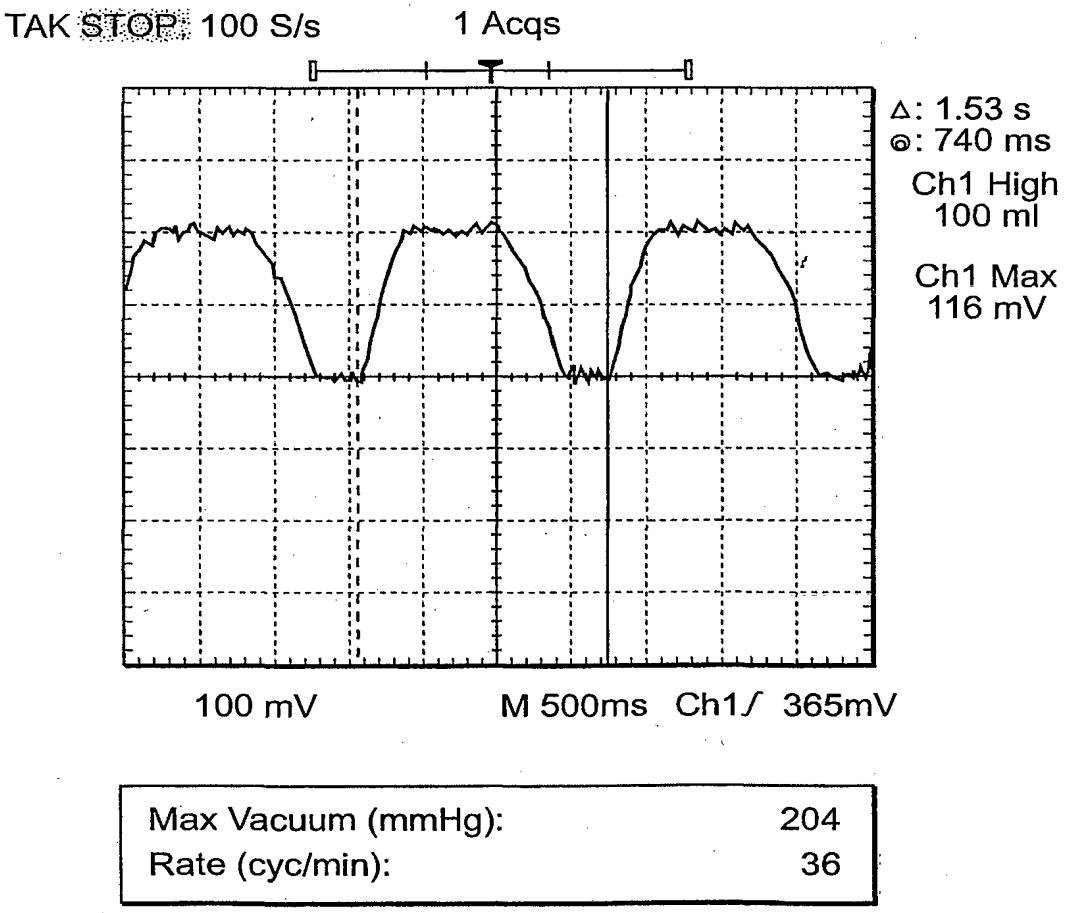

TAK STOP: 100 S/s
1 Acqs
Δ: 1.53 s
@: 740 ms
Ch1 High
100 ml
Ch1 Max
116 mV
100 mV
M 500ms Ch1ƒ 365mV
Max Vacuum (mmHg): 204
Rate (cyc/min): 36

FIG. 22B

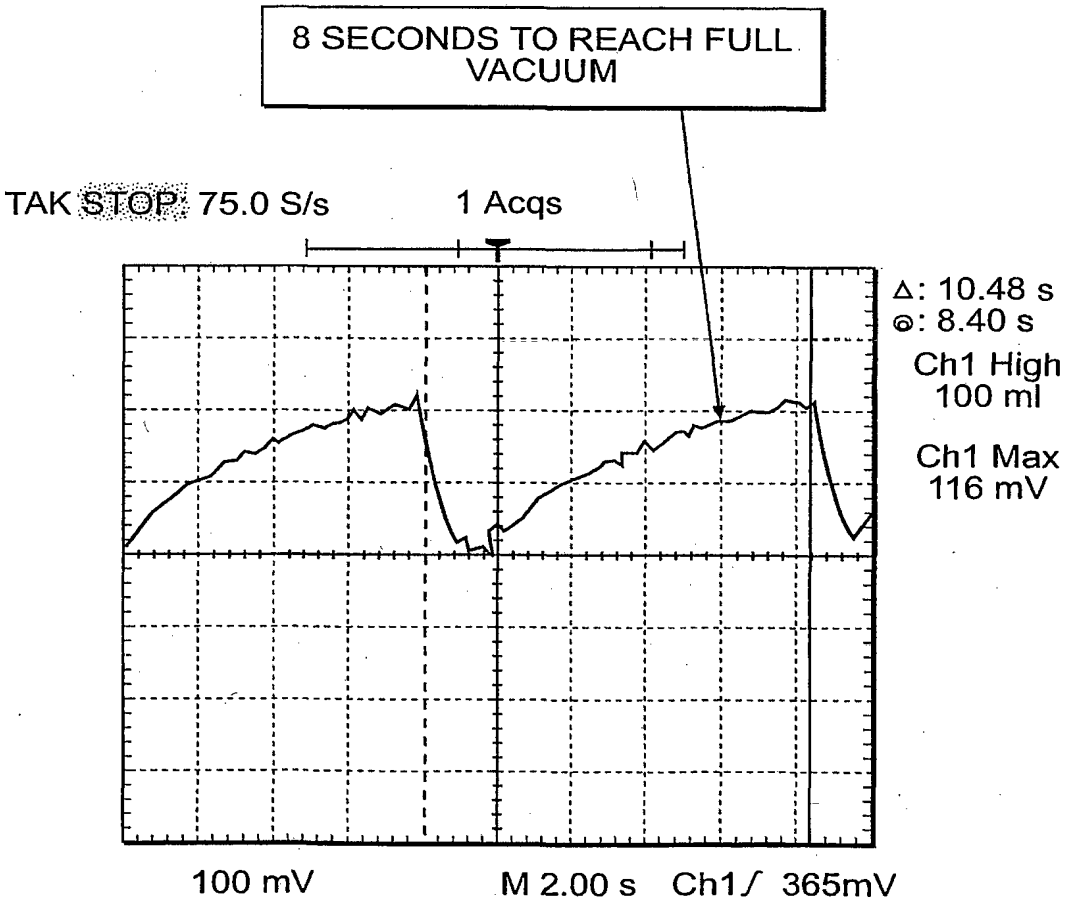


FIG. 23
PRIOR ART

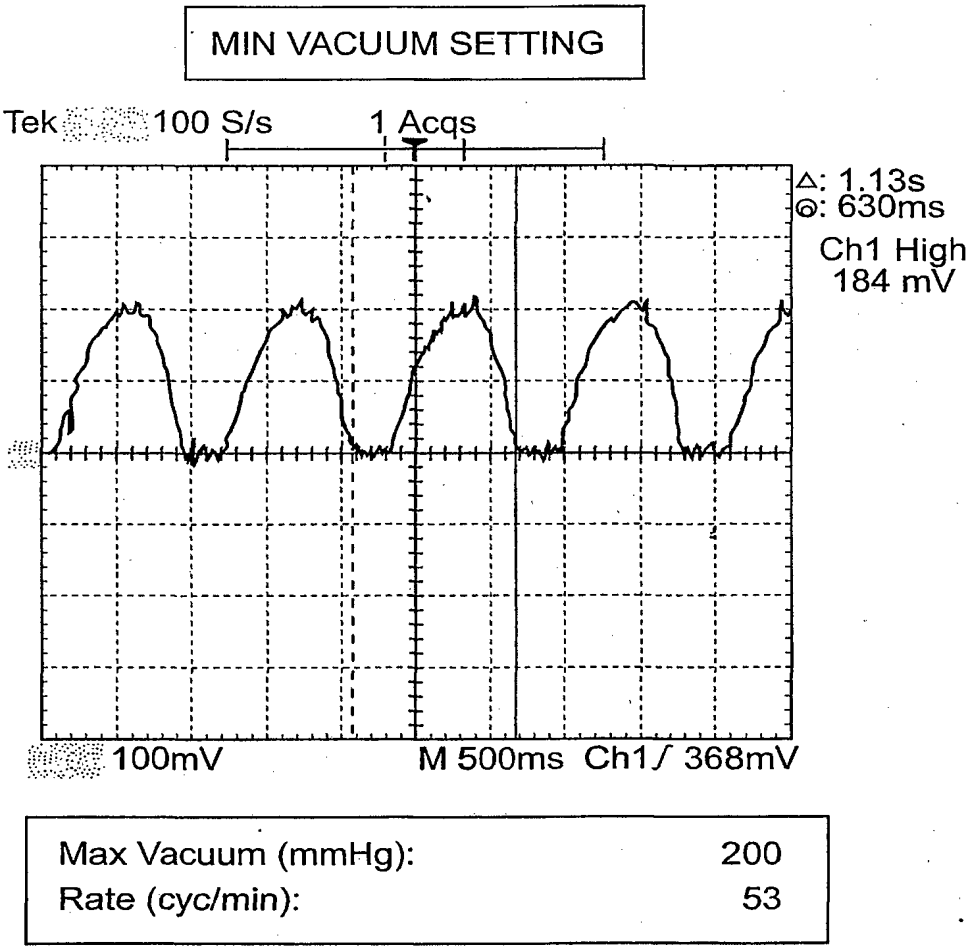


FIG. 24A
PRIOR ART

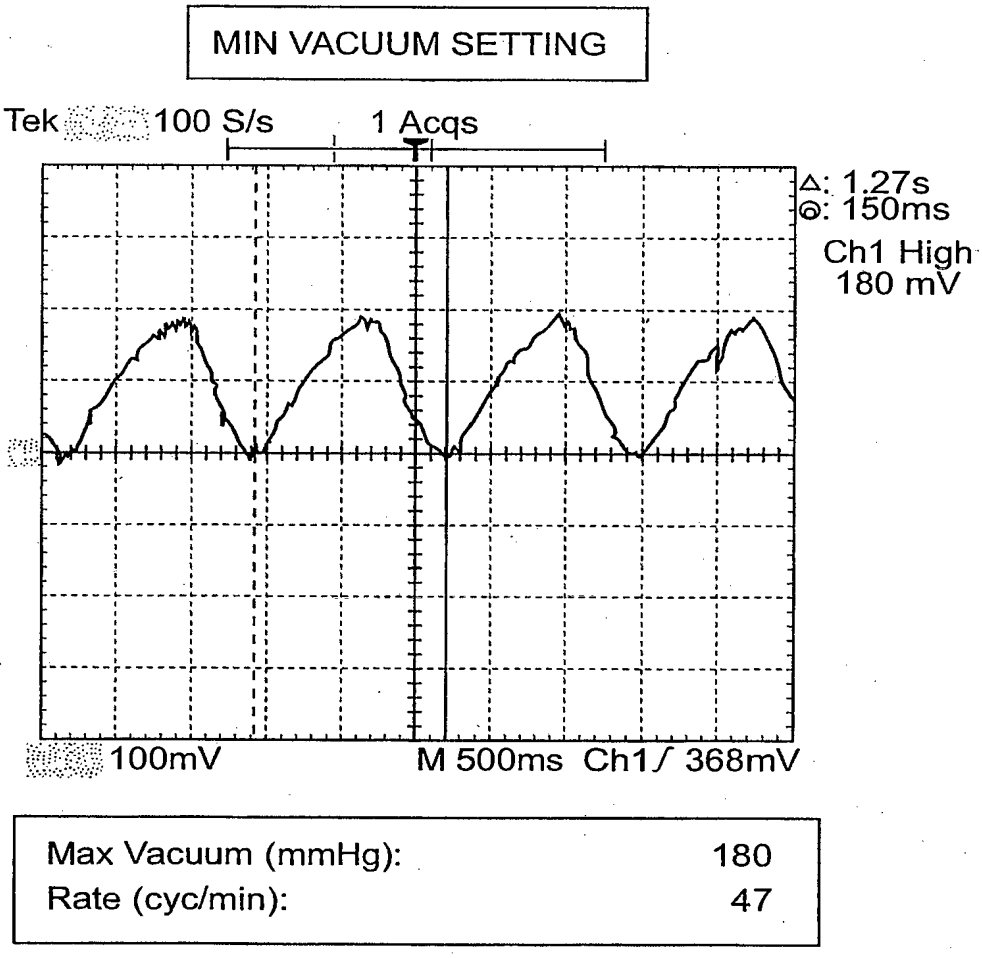
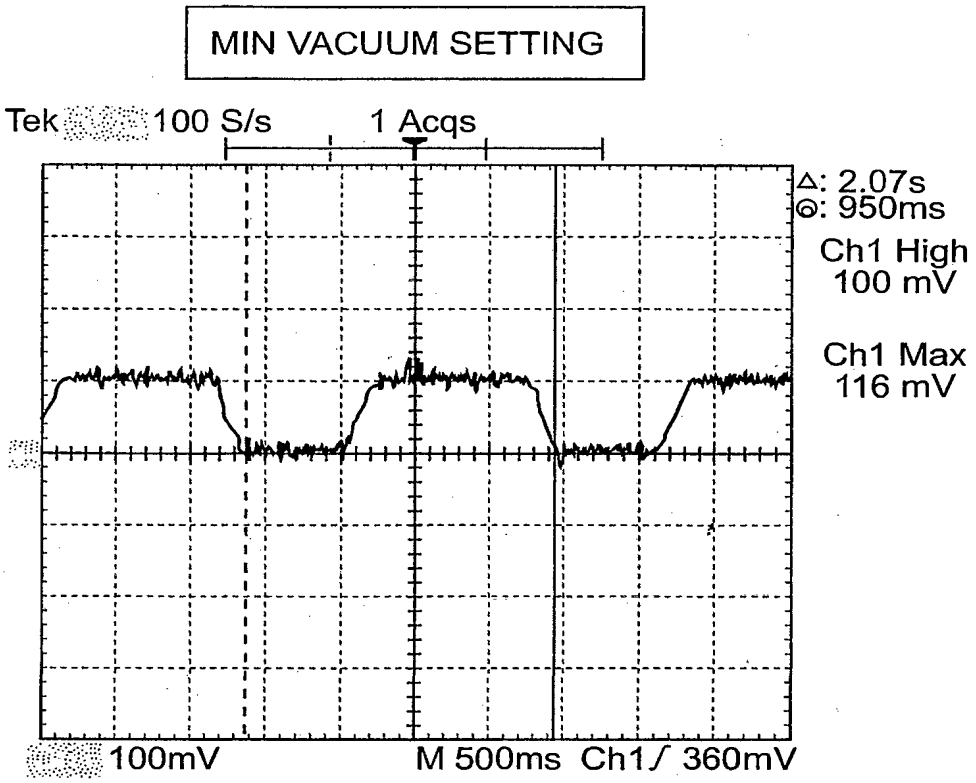


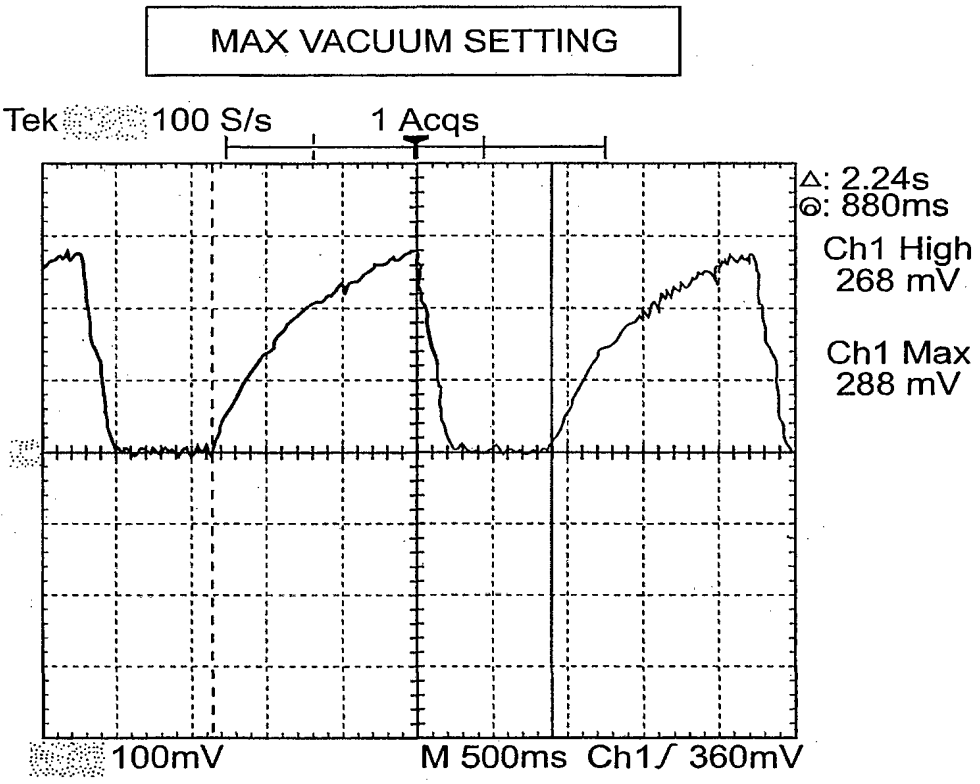
FIG. 24B
PRIOR ART



Max Vacuum (mmHg):	100
Rate (cyc/min):	29
>100 mmHg Hold (sec):	1
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Min
Cycles:	N/A

FIG. 25A
PRIOR ART



Max Vacuum (mmHg):	270
Rate (cyc/min):	271
>100 mmHg Hold (sec):	1.4
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Max
Cycles:	N/A

FIG. 25B
PRIOR ART

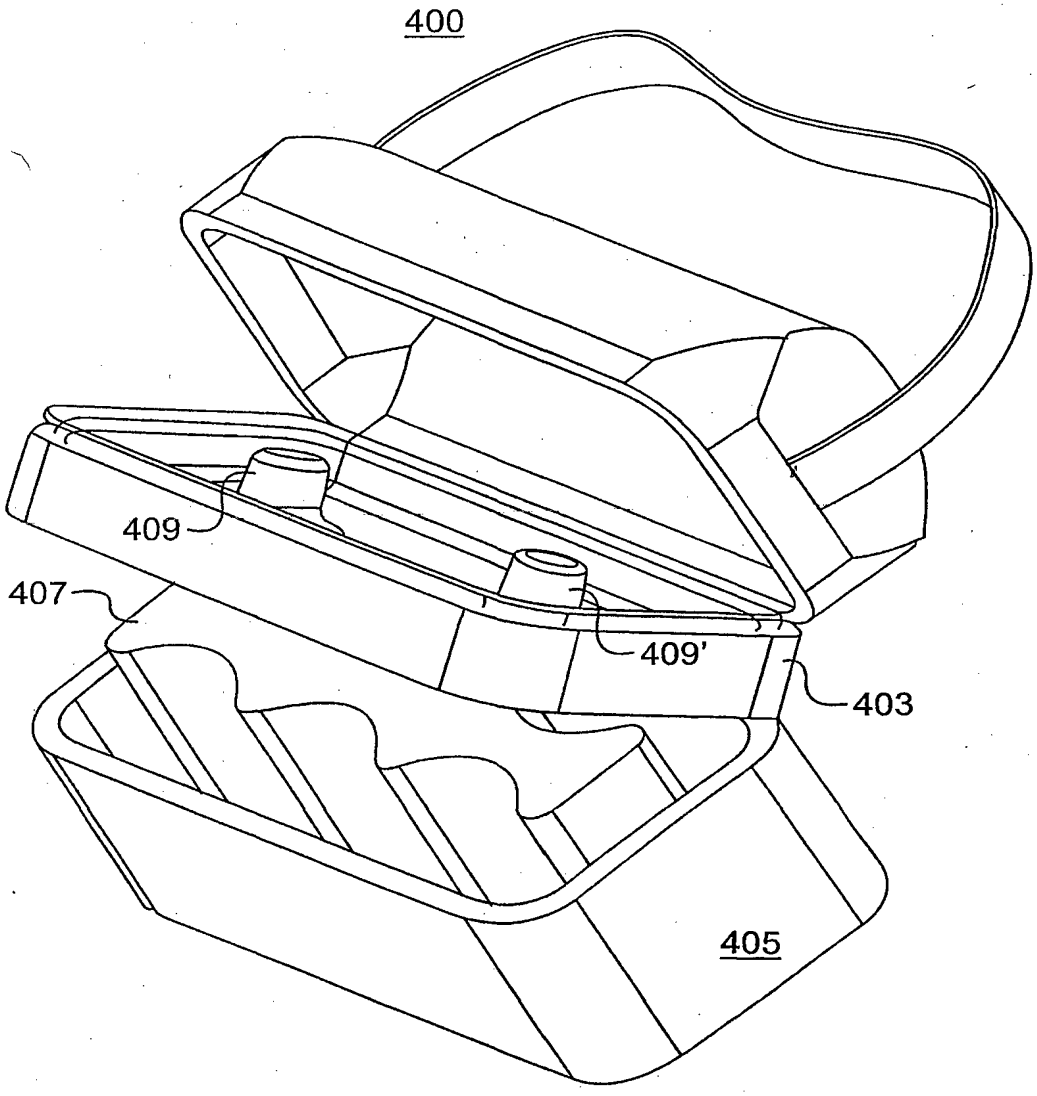


FIG. 26

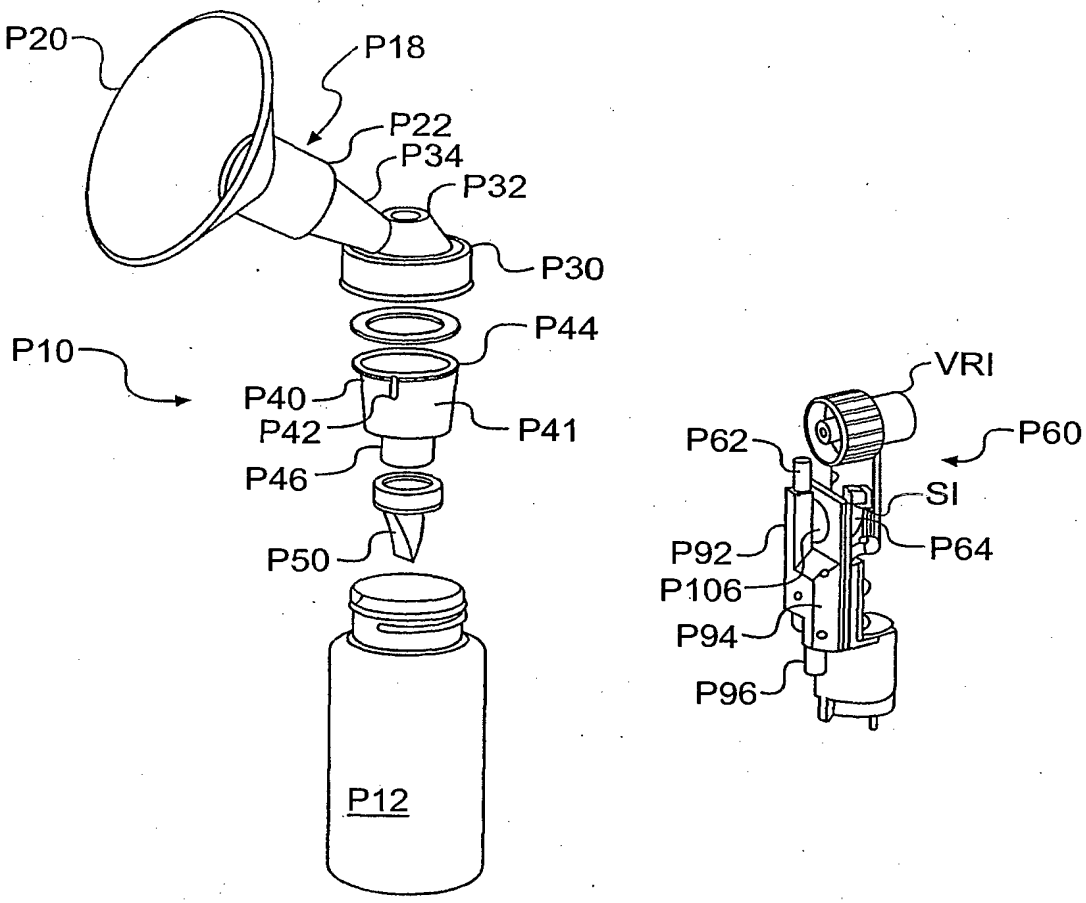


FIG. 27
PRIOR ART

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6213840 B **[0002]**
- US 6257847 B **[0003]**
- US 6090065 B **[0003]**
- US 5571084 A **[0005]**
- US 6090065 A **[0015]**

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(81) 指定国 (除另有指明，要求每一种可提供的国家保护): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW。

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[见续页]

(54) **Title**: CUP AND BREAST PUMP COMPRISING SAME

(54) **发明名称** : 一种罩杯及含有这种罩杯的吸奶器

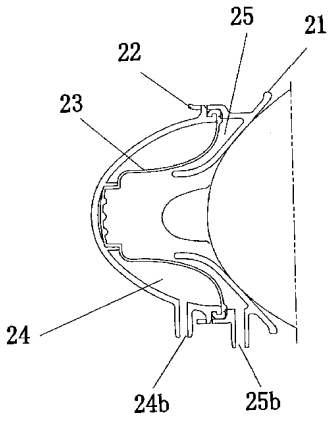


图 3 / Fig. 3

(57) **Abstract**: A cup (2) and breast pump comprising same; the cup (2) comprises a guard (21) made of thermoplastic material and having a flared opening, and a hemispherical guard casing (22) made of thermoplastic material; the throat of the guard (21) is located in the guard casing (22); the abutting edges of the guard (21) and the guard casing (22) enclose the guard (21) and the guard casing (22) to form a detachable fixing structure; the cup (2) further comprises an airbag (23) made of soft rubber material located in the cup (2); the airbag (23) covers the throat of the guard (21); the edge of the airbag (23) is clamped within the abutting gaps between the guard (21) and the guard casing (22); the airbag (23) divides the cup (2) into a negative pressure cavity (24) at the front and a milk chamber (25) at the rear; the negative pressure cavity (24) is provided with a negative pressure inlet (24b); and a milk outlet (25b) is provided in the lower part of the milk chamber (25). The cup (2) is suitable to be covered in a brassiere for privacy, has a simple structure, is easy to disassemble and clean, and prevents backflow of breast milk into a negative pressure pump (1).

(57) **摘要**:

[见续页]

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IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG)。

本国际公布:

— 包括国际检索报告(条约第 21 条(3))。

一种罩杯（2）以及含有这种罩杯（2）的吸奶器，所述罩杯（2）包括一个由热塑性材料制成的开口呈喇叭状的护罩（21）以及一个由热塑性材料制成的呈半球状的护罩壳体（22），其中，护罩（21）的缩口位于护罩壳体（22）内，由护罩（21）与护罩壳体（22）的对接边沿将两者封闭，构成可拆卸的固定结构；还包括一个由软胶材料制成的气囊（23），气囊（23）位于罩杯（2）中，气囊（23）罩在护罩（21）的缩口处，气囊（23）的边沿夹持于护罩（21）与护罩壳体（22）对接的缝隙中，由气囊（23）将罩杯（2）分隔为位于前端的负压腔室（24）和位于后端的出奶腔室（25），于负压腔室（24）开有负压输入口（24b），而出奶腔室（25）于下部开有出奶口（25b）。所述罩杯（2）适合隐藏于乳罩内，具有结构简单、可隐蔽使用、便于拆卸清洗、并杜绝乳汁逆流进入负压泵（1）的特点。

一种罩杯及含有这种罩杯的吸奶器

技术领域

本发明属于一种利用负压帮助哺乳期的女性将乳汁导出的装置，具体地说，是一种改良的罩杯和吸奶器。

背景技术

中国实用新型 200520065795.0 公开了一种吸奶器，该吸奶器包括负压泵、三通吸取器以及贮奶瓶组成，其中，由三通吸取器的一端与负压泵连通，以便在其中形成负压；另一端连通罩杯，该罩杯以吻合乳房形状的特点而制造，以便于乳房对接，将乳汁导入；同时，再一端与贮奶瓶连接，使由负压导入的乳汁经贮奶瓶收集起来。它可帮助产妇将乳汁导出，其存在缺点是：使用暴露、麻烦，又不方便清洗。

中国发明专利申请 201310138498.3 公开了一种带有配套母乳储存器的吸奶器，它将罩杯与贮奶容器结合起来，使罩杯和贮奶容器适合隐藏在乳罩内。它具有使用隐藏以及免手操作的优点，其存在问题是：使用过程中，尤其是产妇奶水较多或当产妇不留意弯腰时，乳汁极易被负压吸入到负压泵中，无法排除乳汁在负压的作用下经软管进入负压泵的可能。

中国实用新型 201220625761.2 公开了一种吸奶器，它将三通吸取器与罩杯、奶瓶分离开来，且各部分由软管连接，适合隐藏在身体上，并由膜片将乳汁与负压泵隔离，杜绝乳汁经软管进入负压泵的可能，其存在的不足是：部件较多且各部件连接、携带在身体上较为零散，使用中仍然存在不便。

综上所述，上述吸奶器在帮助将乳汁导出、解决使用中身体暴露以及满足人们边吸奶边工作上，均能发挥着不同的作用，但是，对于采用负压吸取乳汁可能产生的乳汁粘连在吸取器上、在吸奶器的清洗问题上、吸奶器的方便使用上以及乳汁进入负压泵的问题上，均未能得到很好的解决。

发明内容

本发明创造的罩杯和吸奶器，它的气囊将乳房护罩与护罩壳体完全隔开

来，使得乳汁不可能从负压输入口进入负压泵中，从根本上杜绝了乳汁逆流对负压泵产生不利的影响而呈现出它新的特点。

本发明的罩杯和吸奶器，它的三通吸取器结合在罩杯中，从而使传统产品的结构得以改良，它更便于隐藏在身体上，携带在身体上也更加简单而显示出它创新的特点。

本罩杯和吸奶器，其气囊通过其翻边被夹持在可拆卸的护罩与护罩壳体的对接缝隙中，不仅可以通过拆卸，将气囊分离出来，以便清洗，而且在用户装配时能够保证气囊与护罩壳体之间、气囊与护罩之间的封闭，其构造具有更加简单的优点。

因此，本发明的目的是要提供一种将气液管路的分离结构结合在其中，适合隐藏在产妇乳罩内，并杜绝乳汁逆流进入负压泵，便于拆卸清洗的罩杯和吸奶器。

本发明的罩杯由下列方案实现：

一种罩杯，包括一个由热塑性材料制成的开口呈喇叭状的护罩以及一个由热塑性材料制成的呈半球状的护罩壳体，其中，护罩的缩口位于护罩壳体内，由护罩与护罩壳体的对接边沿将两者封闭，构成可拆卸的固定结构，其特点是，还包括一个由软胶材料制成的气囊，气囊位于罩杯中，气囊罩在护罩的缩口处，且由气囊边沿夹持于护罩与护罩壳体对接边沿的缝隙中，由气囊将罩杯分隔为位于前端的负压腔室和位于后端的出奶腔室，于负压腔室开有负压输入口，而出奶腔室于下部开有出奶口。

本发明的吸奶器由下列方案实现：

一种吸奶器，包括有负压泵和奶袋，其特点是，还包括有与负压泵、奶袋连接的上述罩杯。

上述罩杯可固定隐藏在乳房与乳罩之间，上述罩杯由软管通过其负压输入口、出奶口分别与负压泵、奶袋相连接。

这样，当负压泵工作时，通过负压输入口抽气，可在上述罩杯的负压腔

室中产生负压，从而使气囊往外膨胀，进而在护罩中产生负压，可从乳头导出乳汁，这时，乳汁可通过气囊与护罩之间的间隙流向出奶腔室下部的出奶口，从出奶口流入奶袋。

本发明创造的罩杯和吸奶器，罩杯可藏在乳房与乳罩之间，且在身体其他部位带上负压泵和奶袋，则可隐蔽使用，且在吸奶的过程中，几乎无须再借助手的扶持便可完成，于是，手被解放出来，可以进行其他工作。

本发明的罩杯和吸奶器，气囊将负压腔室与出奶腔室完成分开出来，于是，使用中乳汁不可能进入负压腔室而流入负压泵，从而杜绝乳汁逆流对负压泵产生不利的影响。

本罩杯和吸奶器由于护罩与护罩壳体可以拆卸，使气囊也能够容易地分离开来，随后装配也方便，这样，各个部件均可以得到彻底清洗和消毒，避免残余奶液而滋生细菌。

该罩杯和吸奶器的负压吸奶和气液分离过程在罩杯内同时完成，因此，无须设置三通吸取器之类的部件，使吸奶器在部件数量上得以减少，更有利于方便使用和携带。

图面说明

图 1 是本发明吸奶器一种具体实施方式的示意图；

图 2 是图 1 吸奶器中的罩杯的分离结构示意图；

图 3 是图 1 吸奶器中的罩杯的剖面结构示意图；

图 4 是图 3 罩杯工作过程中的剖面结构示意图。

具体实施方式

下面结合附图对本发明作出具体详述：

参照图 1，本吸奶器包括负压泵 1、罩杯 2 以及奶袋 3，由负压泵 1 在罩杯 2 中产生负压，将乳头分泌的乳汁导入罩杯 2 中，并从罩杯 2 的出奶口 25b 送入奶袋 3。

参照图 1 或图 2，罩杯 2 可罩在乳房上，可再戴上乳罩，使罩杯固定隐

藏在乳房与乳罩之间，由软管通过负压输入口 24b、出奶口 25b 分别与负压泵 1、奶袋 3 相连接。

参照图 2 和图 3，罩杯 2 包括一个由热塑性材料制成的护罩 21，护罩 21 的开口呈喇叭状；以及一个由热塑性材料制成的护罩壳体 22，护罩壳体 22 呈类似半球状；同时，护罩 21 的缩口位于护罩壳体 22 内部，由护罩 21 与护罩壳体 22 的对接边沿将两者的内部封闭，并构成可拆卸的固定结构，罩杯 2 中还设置一个由软胶材料制成的气囊 23，气囊 23 罩在护罩 21 的缩口处，且由气囊 23 的边沿夹持于护罩 21 与护罩壳体 22 的对接边沿之间的间隙中，由气囊 23 将罩杯 2 分隔为位于前端的负压腔室 24 和位于后端的出奶腔室 25，于负压腔室 24 开有负压输入口 24b，而出奶腔室于下部开有出奶口 25b。

这样，参照图 1 至图 4，由护罩 21 的敞口罩于乳房上，可让乳头从护罩 21 的缩口伸出，当打开负压泵 1 使其工作，负压泵 1 将通过负压输入口 24b 抽气，并在负压腔室 24 中产生负压，这时，气囊 23 将向外膨胀，使出奶腔室 25 的空间变大，从而也在出奶腔室 25 中产生负压，于是，乳头受到出奶腔室 25 负压的作用，可将乳汁导出，这时，乳汁可被从气囊 23 与护罩 21 之间的缝隙流向下部，并从出奶口 25b 流入奶袋 3。

权 利 要 求

1、一种罩杯，包括一个由热塑性材料制成的开口呈喇叭状的护罩以及一个由热塑性材料制成的呈半球状的护罩壳体，其中，护罩的缩口位于护罩壳体内，由护罩与护罩壳体的对接边沿将两者封闭，构成可拆卸的固定结构，其特点是，还包括一个由软胶材料制成的气囊，气囊位于罩杯中，气囊罩在护罩的缩口处，且由气囊边沿夹持于护罩与护罩壳体对接边沿的缝隙中，由气囊将罩杯分隔为位于前端的负压腔室和位于后端的出奶腔室，于负压腔室开有负压输入口，而出奶腔室于下部开有出奶口。

2、一种吸奶器，包括有负压泵和奶袋，其特点是，还包括有与负压泵、奶袋连接的权利要求 1 所述的罩杯。

3、依据权利要求 2 所述的吸奶器，其特点是，所述罩杯可安置在乳房与乳罩之间，所述罩杯由软管通过其负压输入口、出奶口分别与负压泵、奶袋相连接。

1/2

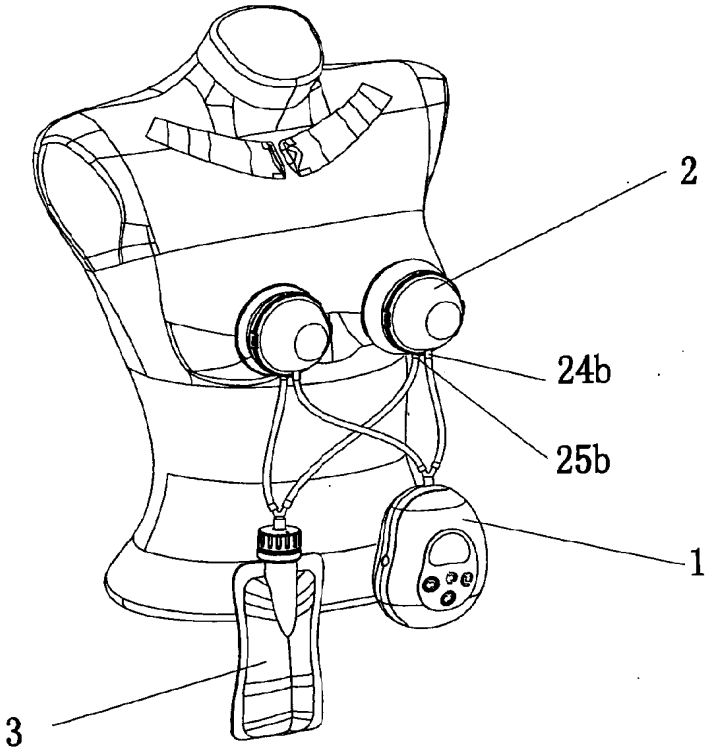


图 1

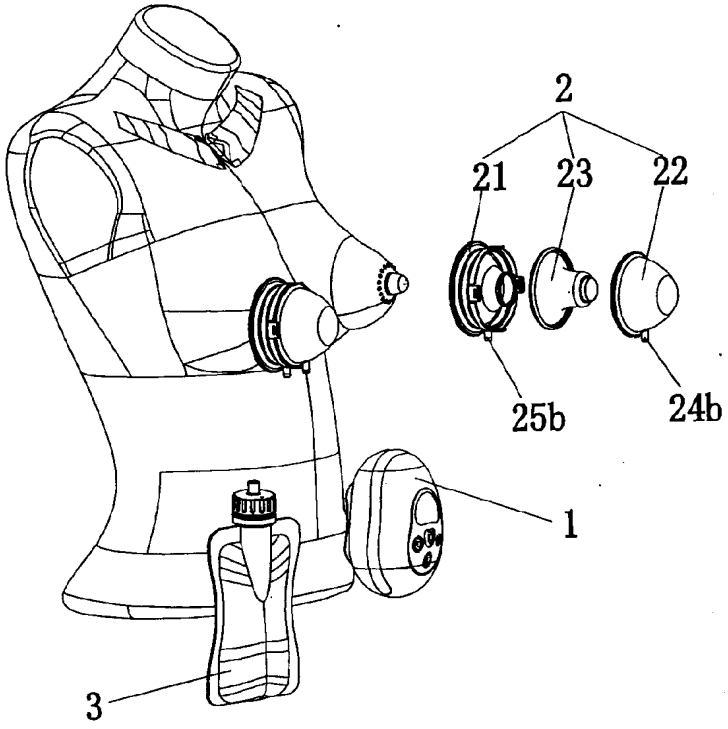


图 2

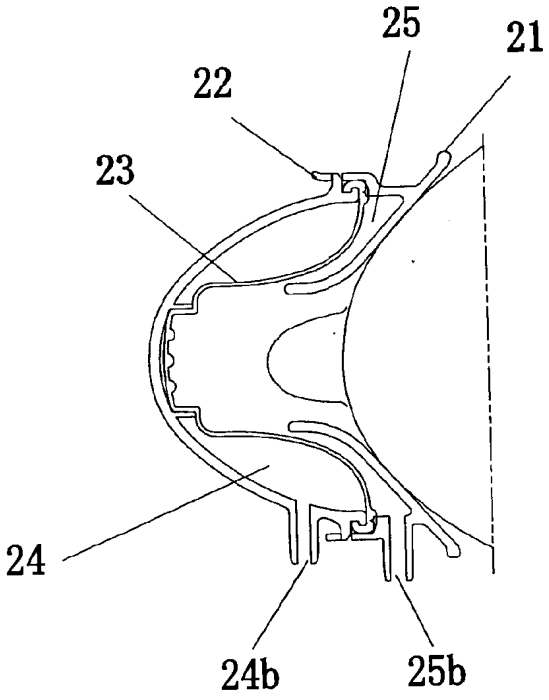


图 3

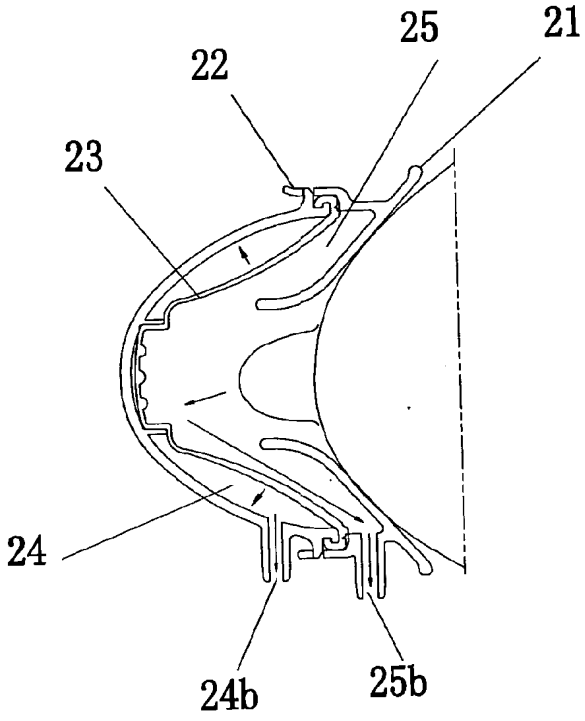


图 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2013/001571

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 (2006.01) i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CNABS, CNTXT, WPI, EPODOC, USTXT, cap, air bag, film, membrane, layer, separate

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 203090023 U (CHEN, Junbo) 31 July 2013 (31.07.2013) description, paragraphs [0029]-[0031] and figures 3 and 4	1-3
Y	CN 201418903 Y (CHENG, Keyong) 10 March 2010 (10.03.2010) description, pages 1 and 2 and figures 1-3	1-3
A	CN 203001530 U (JIANG, Fengjun) 19 June 2013 (19.06.2013) the whole document	1-3
A	CN 1799436 A (ZHU, Yunyuan) 12 July 2006 (12.07.2006) the whole document	1-3
A	WO 2013010286 A1 (MEDELA HOLDING AG et al.) 24 January 2013 (24.01.2013) the whole document	1-3
A	JP 2001259023 A (JEX INC.) 25 September 2001 (25.09.2001) the whole document	1-3
A	US 4263912 A (ADAMS FRANK H) 28 April 1981 (28.04.1981) the whole document	1-3

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 September 2014	11 September 2014
Name and mailing address of the ISA State Intellectual Property Office of the P. R. China No. 6, Xitucheng Road, Jimenqiao Haidian District, Beijing 100088, China Facsimile No. (86-10) 62019451	Authorized officer ZHANG, Liping Telephone No. (86-10) 62085609

Form PCT/ISA /210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2013/001571

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN 203090023 U	31 July 2013	None	
CN 201418903 Y	10 March 2010	None	
CN 203001530 U	19 June 2013	None	
CN 1799436 A	12 July 2006	CN 100367888 C	13 February 2008
WO 2013010286 A1	24 January 2013	AU 2012286462 A1	13 February 2014
		CH 705296 A1	31 January 2013
		TW 201304827 A	01 February 2013
		US 2013023821 A1	24 January 2013
		KR 20140040232 A	02 April 2014
		EP 2734250 A1	28 May 2014
		CN 103687634 A	26 March 2014
JP 2001259023 A	25 September 2001	None	
US 4263912 A	28 April 1981	None	

Form PCT/ISA /210 (patent family annex) (July 2009)

国际检索报告

国际申请号
PCT/CN2013/001571

A. 主题的分类

A61M 1/06(2006.01)i

按照国际专利分类(IPC)或者同时按照国家分类和IPC两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

A61M

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用）)

CNABS, CNTXT, WPI, EPODOC, USTXT, 罩，气囊，膜，层，隔，分离，film, membrane, separate

C. 相关文件

类 型*	引用文件，必要时，指明相关段落	相关的权利要求
Y	CN 203090023 U (陈俊波) 2013年 7月 31日 (2013-07-31) 说明书第[0029]-[0031]段，附图3、4	1-3
Y	CN 201418903 Y (程克勇) 2010年 3月 10日 (2010-03-10) 说明书第1、2页，附图1-3	1-3
A	CN 203001530 U (蒋凤军) 2013年 6月 19日 (2013-06-19) 全文	1-3
A	CN 1799436 A (朱允元) 2006年 7月 12日 (2006-07-12) 全文	1-3
A	WO 2013010286 A1 (MEDELA HOLDING AG 等) 2013年 1月 24日 (2013-01-24) 全文	1-3
A	JP 2001259023 A (JEX INC) 2001年 9月 25日 (2001-09-25) 全文	1-3
A	US 4263912 A (ADAMS FRANK H) 1981年 4月 28日 (1981-04-28) 全文	1-3

☐ 其余文件在C栏的续页中列出。

☑ 见同族专利附件。

* 引用文件的具体类型：

“A” 认为不特别相关的表示了现有技术一般状态的文件

“E” 在国际申请日的当天或之后公布的在先申请或专利

“L” 可能对优先权要求构成怀疑的文件，或为确定另一篇引用文件的公布日而引用的或者因其他特殊理由而引用的文件（如具体说明的）

“O” 涉及口头公开、使用、展览或其他方式公开的文件

“P” 公布日先于国际申请日但迟于所要求的优先权日的文件

“T” 在申请日或优先权日之后公布，与申请不相抵触，但为了理解发明之理论或原理的在后文件

“X” 特别相关的文件，单独考虑该文件，认定要求保护的发明不是新颖的或不具有创造性

“Y” 特别相关的文件，当该文件与另一篇或者多篇该类文件结合并且这种结合对于本领域技术人员为显而易见时，要求保护的发明不具有创造性

“&” 同族专利的文件

国际检索实际完成的日期	国际检索报告邮寄日期
2014年 9月 02日	2014年 9月 11日

ISA/CN的名称和邮寄地址	受权官员
中华人民共和国国家知识产权局(ISA/CN) 北京市海淀区蓟门桥西土城路6号 100088 中国	张莉平
传真号 (86-10)62019451	电话号码 (86-10)62085609

表 PCT/ISA/210 (第2页) (2009年7月)

国际检索报告
关于同族专利的信息

国际申请号
PCT/CN2013/001571

检索报告引用的专利文件			公布日（年/月/日）	同族专利			公布日（年/月/日）
CN	203090023	U	2013年 7月 31日	无			
CN	201418903	Y	2010年 3月 10日	无			
CN	203001530	U	2013年 6月 19日	无			
CN	1799436	A	2006年 7月 12日	CN	100367888	C	2008年 2月 13日
WO	2013010286	A1	2013年 1月 24日	AU	2012286462	A1	2014年 2月 13日
				CH	705295	A1	2013年 1月 31日
				TW	201304827	A	2013年 2月 01日
				US	2013023821	A1	2013年 1月 24日
				KR	20140040232	A	2014年 4月 02日
				EP	2734250	A1	2014年 5月 28日
				CN	103687634	A	2014年 3月 26日
JP	2001259023	A	2001年 9月 25日	无			
US	4263912	A	1981年 4月 28日	无			

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A01J 5/007 (2006.01)

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PCT/US2015/014901

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6 February 2015 (06.02.2015)

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(30) Priority Data:
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(71) Applicant: **NAIA HEALTH, INC.** [US/US]; 412 Lanyard Drive, Redwood City, CA 94065 (US).

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(74) Agents: **PORTNOW, Douglas** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: METHODS, APPARATUS, AND SYSTEM FOR EXPRESSION OF HUMAN BREAST MILK

(57) Abstract: Systems, methods, and devices for milk expression are provided. In one aspect, a system includes an expression apparatus having an interface configured to engage a breast and an actuation assembly operably coupled to the interface. Actuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express milk from the breast. The system also includes a computing device configured to communicate with the expression apparatus via a data connection.

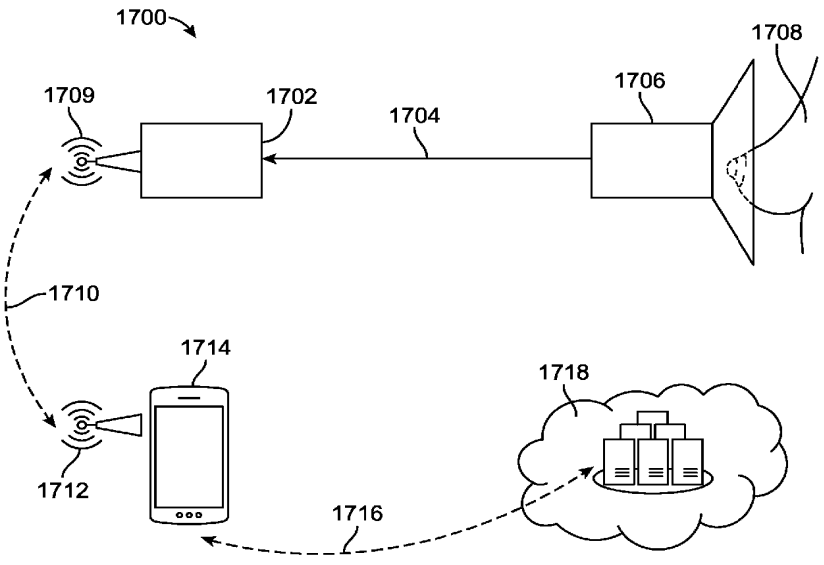


FIG. 17

WO 2015/120321 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

METHODS, APPARATUS, AND SYSTEM FOR EXPRESSION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] The present application is a non-provisional of, and claims the benefit of U.S. Provisional Patent Application No. 61/937,027, filed on February 7, 2014 [attorney docket no. 44936-704.101], the entire contents of which are incorporated herein by reference.

[0002] The subject matter of the present application is related to U.S. Patent Application No. 14/221,113, filed on March 20, 2014, [attorney docket no. 44936-703.201], U.S. Provisional Patent Application No. 62/021,601, filed on July 7, 2014 [attorney docket no. 44936-705.101], U.S. Provisional Patent Application No. 62/021,597, filed on July 7, 2014 [attorney docket no. 44936-706.101], U.S. Provisional Patent Application No. 62/028,219, filed on July 23, 2014 [attorney docket no. 44936-708.101], and U.S. Provisional Patent Application No. 62/052,941, filed on September 19, 2014 [attorney docket no. 44936-709.101], the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Additional features such as milk production quantification, milk characterization, and communication with mobile devices are further desirable for enhanced user convenience. At least some of these objectives will be satisfied by the devices and methods disclosed below.

[0005] 2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0006] The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0007] In a first aspect of the present invention, a system for expression of milk from a breast is provided. The system may comprise an expression apparatus having an interface configured to engage a breast and an actuation assembly operably coupled to the interface. Actuation of the actuation assembly can cause the interface to apply vacuum pressure against the breast to express milk from the breast. The system further comprises a computing device configured to communicate with the expression apparatus via a data connection.

[0008] In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast.

[0009] In many embodiments, the data connection utilizes wireless communication, near field communication, or a USB cable to transmit data between at a least a portion of the expression apparatus and the computing device. The computing device may be a smartphone, tablet, or personal computer.

[0010] In many embodiments, the expression apparatus further includes a sensing unit configured to generate measurement data indicative of one or more characteristics of milk expression. The measurement data can be transmitted to the computing device via the data connection. The computing device can include an application configured to analyze the measurement data. The computing device can transmit the measurement data to a server. The expression apparatus can further include a processing unit configured to analyze the measurement data to generate an analysis result, and a display unit configured to display the analysis result to a use. The analysis result can be displayed in a graph, chart, or table. The analysis result can be transmitted to a computing device via the data connection, and the computing device can display the analysis result to the user.

[0011] In many embodiments, the computing device can control at least one functionality of the expression apparatus via the data connection. The functionality can comprise one or more of power of the expression apparatus, vacuum pressure applied by the expression apparatus, or cycles per minute of the expression apparatus.

[0012] In many embodiments, a notification reminding a user to express milk may be transmitted to the computing device via the data connection. The notification can be transmitted to at least a portion of the expression apparatus via the data connection.

Firmware updates can be transmitted to at least a portion of the expression apparatus via the data connection.

[0013] In many embodiments, the computing device can comprise a communication module in communication with a server via a network. A notification reminding a user to express milk may be transmitted from the server to the computing device. The computing device may comprise a cellular phone associated with a cellular phone number, and the notification may be transmitted by short message service (SMS) via the network to the cellular phone number.

[0014] In another aspect of the present invention, a method for measuring expression of milk from a breast is provided. The method comprises providing a breast milk expression apparatus having an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The method further comprises engaging the interface with a breast, and actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast. The method further comprises expressing milk from the breast. The method may further comprise measuring a characteristic of milk expression using the sensing unit, in order to generate measurement data. The measurement data may be transmitted from the sensing unit to a computing device via a data connection.

[0015] In many embodiments, the measurement data may be stored in one or more data stores of the computing device. The measurement data can be analyzed via an application of the computing device to generate an analysis result, and the analysis result can be displayed to a user via the computing device. The analysis result can be displayed in a graph, chart, table, or any other visual, audible, or tactile indicator.

[0016] In another aspect of the present invention, a method for controlling expression of milk from a breast is provided. The method comprises providing a breast milk expression apparatus having an interface and an actuation assembly operably coupled to the interface. The method further comprises engaging the interface with a breast. A control signal may be received from a computing device via a data connection. The method may further comprise actuating the actuation assembly based on the control signal, causing the interface to apply vacuum pressure against the breast. The method further comprises expressing milk from the breast.

[0017] In another aspect of the present invention, an apparatus for expression of milk from a breast is provided. The apparatus comprises an interface configured to engage a breast and an actuation assembly operably coupled to the interface. Actuation of the actuation assembly can cause the interface to apply vacuum pressure against the breast to

express milk from the breast. The apparatus can also include a communication module in communication with a server via a network.

[0018] In many embodiments, the network includes an Internet network. The apparatus can further include a sensing unit configured to generate measurement data indicative of one or more characteristics of milk expression, and the measurement data can be transmitted to the server via the network. The server can include an application configured to analyze the measurement data.

[0019] In many embodiments, the apparatus further includes a processing unit configured to analyze the measurement data to generate an analysis result, and a display unit configured to display the analysis result to a user. The analysis result can be transmitted to the server via the network. The analysis result can be displayed on a computing device in communication with the server.

[0020] In many embodiments, at least one functionality of the actuation assembly is controlled by an application on the server via the network. The functionality can include power of the actuation assembly, vacuum pressure applied by the actuation assembly, or cycles per minute of the actuation assembly.

[0021] In many embodiments, a notification reminding a user to express milk may be transmitted via the network to an email address. The notification reminding the user to express milk can be transmitted by short message service (SMS) via the network to a cellular phone number, such as by SMS from the server to a smartphone associated with the cellular phone number. The notification reminding the user to express milk can be transmitted to the communication module via the network. Firmware updates can be transmitted to the communication module via the network.

[0022] In another aspect, the present invention provides a method for measuring expression of milk from a breast. The method comprises providing a breast milk expression apparatus including an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface may be engaged with a breast. The actuation assembly can be actuated, causing the interface to apply vacuum pressure against the breast. Milk is expressed from the breast. The sensing unit may be used to measure a characteristic of milk expression to generate measurement data. The measurement data may be transmitted to a server via a network.

[0023] In many embodiments, the server is a distributed computing server. The characteristic of milk expression can be measured by the sensing unit as the milk moves from the interface to a collection reservoir in fluid communication with the interface. The

measurement data can be stored in one or more data stores associated with the server. The measurement data can be analyzed via an application on the server to generate an analysis result. The analysis result can be transmitted from the server to a computing device and displayed to a user via the computing device.

[0024] In another aspect of the present invention, a method for remotely controlling expression of milk from a breast is provided. The method comprises providing a breast milk expression apparatus comprising an interface and an actuation assembly operably coupled to the interface. The interface may be engaged with a breast. A control signal can be received from a server via a network. The actuation assembly may be actuated based on the control signal, causing the interface to apply vacuum pressure against the breast. Milk may be expressed from the breast.

[0025] In another aspect of the present invention, an apparatus for measuring expression of fluid from a breast is provided. The apparatus includes an interface configured to engage a breast and an actuation assembly operably coupled to the interface. Actuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express milk from the breast. The apparatus includes a sensing unit configured to generate measurement data indicative of volume of expressed fluid from the breast.

[0026] In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast. The fluid can be breast milk or colostrum. The measurement data can be indicative of the volume per unit time, volume per stroke of the pump, or volume per pump power cycle of the expressed fluid.

[0027] In many embodiments, the interface includes a valve permitting the passage of the expressed fluid and the sensing unit comprises an accelerometer measuring motion of the valve. The measurement data can be generated based on the motion of the valve.

[0028] In many embodiments, the apparatus can further include a second interface configured to engage a second breast. Actuation of the actuation assembly may cause vacuum pressure to be applied alternatingly against the breast and the second breast to alternatingly express fluid from the breasts. The second interface can include a second valve permitting the passage of expressed fluid from the second breast and the sensing unit can include a second accelerometer measuring position of the second valve. The sensing unit can determine user motion based on motion detected by both the accelerometer and the second accelerometer. The user motion can be subtracted from motion detected by at least one of the accelerometer or the second accelerometer when determining position of at least one of the first or second valves.

[0029] In many embodiments, the interface may comprise an interface housing and a valve permitting passage of the expressed fluid. The sensing unit may comprise a first accelerometer coupled to the interface housing, and a second accelerometer coupled to the valve. The first accelerometer may be configured to measure a position of the interface housing. The second accelerometer may be configured to measure a position of the valve. The measurement data may be generated based on a position of the interface housing and a position of the valve. The sensing unit can determine background motion, based on motion detected by the first accelerometer. The background motion may be subtracted from motion detected by the second accelerometer when determine a position of the valve.

[0030] In many embodiments, the interface may be coupled to a reservoir configured to collect the expressed fluid. The sensing unit may be coupled to the reservoir. The reservoir may comprise a processing unit in communication with the sensing unit, and the processing unit may be configured to receive the measurement data generated by the sensing unit. The processing unit may further comprise a communication module configured to transmit the measurement data to a computing device via a data connection. The communication module of the processing unit may be configured to transmit the measurement data to a server via a network.

[0031] In many embodiments, the sensing unit includes a beam-break sensor configured to detect passage of the expressed fluid near one or more sensor components of the beam-break sensor. The measurement data can be generated based on a length of time the expressed fluid passes between the sensor components.

[0032] In many embodiments, the interface includes a valve permitting the passage of the expressed fluid and the sensing unit includes a charge-coupled device (CCD) configured to count drops of the expressed fluid passing through the valve. The measurement data can be generated based on one or more CCD images of the drops.

[0033] In many embodiments, the interface includes a tube permitting passage of the expressed fluid and the sensing unit includes a capacitive sensor configured to sense the expressed fluid contained in the tube. The interface can be coupled to a reservoir configured to collect the expressed fluid and the sensing unit can include a capacitive sensor configured to measure volume of the expressed fluid contained in the reservoir.

[0034] In many embodiments, the sensing unit includes a strain gauge configured to measure the volume of the expressed fluid. The interface can include a valve permitting the passage of the expressed fluid, and the strain gauge can be coupled to the valve and configured to determine displacement of the valve over time. The interface can be coupled to

a reservoir configured to collect the expressed fluid, and the strain gauge can be coupled to the reservoir and configured to measure volume of the expressed fluid contained in the reservoir. The reservoir may comprise a bottom interior surface having a bellows element. The bellows element can be configured to minimize absorption by the bottom interior surface of a load placed on the bottom interior surface by the expressed fluid.

[0035] In many embodiments, the sensing unit includes a camera coupled to the interface and configured to capture one or more images of the expressed fluid. The apparatus can further include a processing unit configured to analyze the one or more images to determine the volume of the expressed fluid or other characteristics of the expressed fluid. The one or more images can be transmitted to a computing device configured to analyze the one or more images to determine the volume of the expressed fluid. The computing device can be a smartphone. The camera can be situated on a mobile device.

[0036] In many embodiments, the apparatus further comprises a processing unit and a control unit operably coupled to the actuation assembly to control at least one functionality of the actuation assembly. At least a subset of the measurement data may be transmitted as feedback to at least one of the processing unit and the control unit. The actuation assembly can include a pump, and the feedback can be used to adjust a vacuum stroke of the pump or cycles per minute of the pump to maintain optimal fluid expression.

[0037] In another aspect of the present invention, a method for measuring the volume of fluid expressed from a breast is provided. The method includes providing a breast fluid expression apparatus including an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface is engaged with a breast. The actuation assembly is actuated, causing the interface to apply vacuum pressure against the breast. Fluid is expressed from the breast. Measurement data indicative of volume of the expressed fluid is generated via the sensing unit.

[0038] In many embodiments, the method further comprises changing an actuation parameter of the actuation assembly based on at least a subset of the measurement data. The actuation assembly is actuated based on the changed actuation parameter.

[0039] Other objects and features of the present invention will become apparent by a review of the specification, claims, and appended figures.

INCORPORATION BY REFERENCE

[0040] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication,

patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0042] **FIG. 1** is a perspective view of a pumping device, in accordance with embodiments;

[0043] **FIG. 2** is a perspective view of a hydraulic pumping device, in accordance with embodiments;

[0044] **FIG. 3** is a cross-section of a hydraulic pumping device, in accordance with embodiments;

[0045] **FIG. 4** illustrates an actuation assembly coupled to a driving mechanism, in accordance with embodiments;

[0046] **FIG. 5A-5B** illustrate an actuation assembly coupled to a controller, in accordance with embodiments;

[0047] **FIG. 6** is a cross-sectional view of a breast interface, in accordance with embodiments;

[0048] **FIG. 7** is a cross-sectional view of another a breast interface, in accordance with embodiments;

[0049] **FIG. 8A** is a cross-sectional view of an integrated valve within a flexible membrane in an open position, in accordance with embodiments;

[0050] **FIG. 8B** is a cross-sectional view of an integrated valve within a flexible membrane in a closed position, in accordance with embodiments;

[0051] **FIG. 9** is a cross-sectional view of a breast interface with a mechanical deformable member, in accordance with embodiments;

[0052] **FIG. 10** is a cross-sectional view of a mechanical driver for a mechanical deformable member, in accordance with embodiments;

[0053] **FIGS. 11A-11Q** illustrate exemplary embodiments of sensors for detecting fluid;

[0054] **FIG. 12** illustrates a controller and a mobile device, in accordance with embodiments;

[0055] **FIG. 13** illustrates short range communication between a controller and a mobile device, in accordance with embodiments;

[0056] **FIG. 14** is a schematic illustration of a pumping device in communication with a computing device and a server, in accordance with embodiments;

[0057] **FIG. 15** is a graph illustrating the pump performance of an exemplary pumping device compared to a commercial device, in accordance with embodiments; and

[0058] **FIG. 16** is a graph illustrating the pumping efficiency of an exemplary pumping device compared to a commercial device, in accordance with embodiments.

[0059] **FIG. 17** illustrates a schematic diagram of a system for expression of milk;

[0060] **FIG. 18** illustrates another exemplary embodiment of a system for expression of milk;

[0061] **FIGS. 19A-19C** illustrate exemplary displays on a computing device;

[0062] **FIGS. 20A-20B** illustrate exemplary displays in a milk expression system;

[0063] **FIG 21** illustrates the use of a feedback control loop to control a milk expression device; and

[0064] **FIG 22** illustrates a dual expression system.

DETAILED DESCRIPTION OF THE INVENTION

[0065] Specific embodiments of the disclosed systems, devices, and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. Although the present invention primarily relates to breast milk, any description herein of expression and collection of breast milk can also be applied to other types of fluids expressed from the breast, such as colostrum. Furthermore, the disclosed embodiments may be used in other applications, particularly applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea and/or other remote pressure needs.

[0066] The systems, devices, and methods of the present invention provide improved pumping devices for the expression and collection of breast milk, such as human breast milk. Contrary to existing devices, the mechanisms described herein enable the development of smaller and more efficient electrical pumping devices, thereby enhancing convenience and ease of use. Additionally, at least some of the exemplary embodiments disclosed herein incorporate sensors for measuring characteristics of milk expression. The resultant data can be used, for instance, as feedback for improving pumping efficiency, as well as to provide information and/or analytics relevant to milk expression to the user. Furthermore, in preferred

embodiments, the data can be transmitted to another device in communication with the pumping device, thereby enabling control, display, and/or analysis of milk expression to be performed remotely.

[0067] **FIG. 1** illustrates an exemplary embodiment of the present invention. Pumping device 100 (also known as an "expression apparatus") includes breast interfaces 105, a tube 110, and a controller 115 (sometimes also referred to as a "pendant unit") operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. Controller 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices, as described in further detail herein. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from controller 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125. The device 100 may further comprise one or more sensors configured to track various characteristics of the collected fluid, as described in further detail herein. Power may be provided to the one or more sensors via a connection to the controller 115, or to another source of power. In embodiments in which the one or more sensors are coupled to one or more portions of the breast interfaces 105 or collection vessels 125, the sensors may be further coupled to the controller 115 via one or more communication lines configured to transmit signals between the sensors and the controller.

Hydraulic pumping device

[0068] Hydraulic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiencies. In a preferred embodiment, the pumping device can utilize a hydraulic system to generate a pressure differential against the breast for the expression and collection of milk.

[0069] Exemplary hydraulic pumping devices are depicted in **FIGS. 2** and **3**. **FIG. 2** illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against a flexible member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0070] **FIG. 3** illustrates another embodiment of a pumping device 200. The actuation assembly 205 includes an assembly housing 210, a driving element 215, seals 220, and a shaft 222. Driving element 215 is operatively coupled to a controller, such as controller 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuation assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable portion 270. Alternatively, the flexible membrane 245 may comprise a sealing element 255 having a deformable portion 270, the flexible membrane 245 configured to function as a sealing element by fluidly sealing against the breast engaged into the breast interface 235. The drain port 265 is coupled to a collection vessel 275 and includes a flap valve 280.

[0071] Actuation assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Preferably, the couplings between the flexible membrane 245, sealing element 255, and interface housing 240 are fluid-tight couplings, such that the fluid 230 is contained within the reservoir 250 and cannot infiltrate into the expression area 260. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuation element 215 produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. Alternatively, the flexible membrane 245 may comprise the sealing element 255 having a deformable portion 270, such that the flexible membrane 245 forms a fluid seal against the breast engaged into the breast interface 235, and transmits vacuum pressure from fluid 230 to a deformable portion of the flexible membrane 245. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a flap valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing. Preferably, the collection vessel can be quickly decoupled from the other components of the pumping device 200 (e.g., for milk storage, cleaning, etc.).

[0072] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be a liquid, such as

water or oil. In many embodiments, the fluid can be a fluid having properties such that the vacuum pressure exerted on the fluid by the pumping device does not result in outgassing of the fluid. Alternatively, the fluid can be any suitable gas, such as air. Any liquid or gas suitable for use with hydraulic systems can be used for the hydraulic pumping devices described herein.

Actuation mechanism

[0073] Many actuation mechanisms known to those of skill in the art can be utilized for the actuation assembly 205. Actuation assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuation assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0074] **FIG. 3** illustrates an exemplary embodiment in which actuation assembly 205 is a piston assembly and driving element 215 is a piston. Actuation assembly 205 includes seals 220, such as O-rings, rolling diaphragm seals, or wiper seals, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0075] **FIG. 4** illustrates another exemplary embodiment of an actuation assembly 300 including a pair of pistons 305.

[0076] In preferred embodiments, the actuation assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in controller 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0077] Referring now to the exemplary embodiment of **FIG. 4**, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

Alternating or offset stroke cycles can have the benefit of reducing the power requirement of the motor 320.

[0078] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within controller 115.

[0079] **FIG. 22** illustrates another embodiment of an alternating pump system 2200. The system 2200 includes dual expression devices with an interface 2212 sized and shaped to conform to the target tissue, here a breast 2220. A reservoir 2214 is threadably or otherwise coupled to the expression device. A hydraulic line 2210 fluidly couples each expression device to a hydraulic piston assembly 2204 which has an incompressible fluid such as oil in a piston chamber and an actuatable piston 2206. One hydraulic line 2210 is coupled to the high pressure side 2208 of the hydraulic piston, and the other hydraulic line is coupled to the lower pressure side 2208 of the piston. A motor 2202 actuates the piston 2206. Thus, in operation, as the piston is actuated the high pressure side creates a higher pressure in one of the expression devices and a lower pressure in the other expression device. The lower pressure expression device results in a vacuum which causes milk expression, while the high pressure side does not express milk. Then, as the piston reaches the end of its stroke, and reciprocates in the opposite direction, the high and low pressure sides are reversed, thereby causing expression of milk on the opposite side and no expression on the original side. This process allows milk to be collected in an alternating fashion. The expression devices, reservoirs in this system may be any of the components disclosed elsewhere in this disclosure.

[0080] **FIGS. 5A-5B** illustrate an exemplary embodiment of an actuation assembly 350 that includes releasable coupling 355. **FIG. 5A** is an isometric view of the actuation assembly 350 and controller 360 coupled via a releasable coupling 355. **FIG. 5B** is a cross-sectional view of the actuation assembly 350 comprising a releasable coupling 355. Preferably, actuation assembly 350 is releasably coupled to a controller 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens. Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

Flexible membrane

[0081] In many embodiments, such as the embodiment depicted in **FIG. 3**, the flexible membrane 245 is located within breast interface 235 and disposed over at least portion thereof, forming reservoir 250 between the interface housing 240 and the flexible membrane 245. Preferably, the flexible membrane 245 deforms substantially when subject to the negative pressures created when the fluid 230 is displaced from reservoir 250 by actuation assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0082] **FIG. 6** illustrates an exemplary flexible membrane 370 with a specified thickness and durometer.

[0083] **FIG. 7** illustrates another embodiment of flexible membrane 375 with corrugated features 380 for increased surface area.

[0084] Suitable materials for the flexible membrane are known to those of skill in the art. In many embodiments, the flexible membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the flexible membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the flexible membrane without surpassing the yield point of the material.

[0085] **FIGS. 8A** and **8B** illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the flexible membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the flexible membrane 410 is relaxed, as shown in Fig. 8A, and is closed to prevent fluid flow when the flexible membrane 410 is deformed, as shown in Fig. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405 can preferably be configured to also function on the mechanical movement of flexible membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum

creation. Furthermore, the implementation of an exit valve integrally formed within the flexible membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

Mechanical pumping device

[0086] **FIG. 9** illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0087] **FIG. 10** illustrates the tensile element 610 coupled to driving element 625 of an actuation assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a controller, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast. The driving element 625 can be actuated by a suitable driving mechanism, such as the embodiments previously described herein.

[0088] The tensile element 610 can be any suitable device, such as a wire, coil, tube, braid, rope, or any combination thereof. For example, with tensile element 610 can be a small nitinol wire with stainless steel braid disposed around it. The tensile element 610 can be made from any suitable material having high tensile strength, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

Fluid collection and quantification system

[0089] In many instances, it can be desirable to measure and track various characteristics of the collected fluid such as milk expression and collection, such as the amount of milk production (e.g., volume, weight), expression frequency (e.g., time, date), and/or expression duration. In existing approaches, the tracking of milk production is commonly accomplished

by manual measurements and record-keeping. Exemplary embodiments of the devices described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy. For example, sensors can be used to measure the volume of expressed milk. In preferred embodiments, the volume can be measured as volume per unit time, volume per pump stroke (e.g., stroke of the actuation assembly), or volume per pump power cycle (e.g., power cycle of the actuation assembly).

[0090] In exemplary embodiments, the pumping devices described herein include one or more sensors for generating measurement data indicative of one or more characteristics of milk expression, such as the volume of expressed milk. Any description herein pertaining to measurement of volume can also be applied to measurements of other characteristics, and vice-versa. Any suitable type of sensor can be used, such as accelerometers, Hall effect sensors, photodiode/LED sensors, CCD sensors, cameras and other imaging devices, capacitive sensors, strain gauges, etc., and such sensors can be used in any number and combination. The sensors can be positioned at any location suitable for monitoring fluid flow from the breast, such as on or near a breast interface (e.g., the expression area 260, drain port 265, collection vessel 275). In embodiments where milk is concurrently expressed from a pair of breasts via a pair of breast interfaces, sensors can be located on or near both breast interfaces, or on or near only one of the breast interfaces. The sensors may be integrally formed with or permanently affixed to the pumping device. Alternatively, the sensors may be provided separately and coupled to the pumping device prior to use.

[0091] **FIGS. 11A** and **11B** illustrate exemplary embodiments of a breast interface 450 with valve-integrated sensors 455. Sensors 455 are preferably located in a valve, such as the flap valve 460, but may also be located in exit valve 465, or any other valve (e.g., on or near the collection vessel) that is opened by fluid flow. In exemplary embodiments, the sensor 455 includes an accelerometer measuring the position and/or motion of the valve, such as a length of time that the valve is opened, and the resultant measurement data can be interrogated to quantify the fluid flow. Preferably, the breast interface 450 is used in conjunction with a second, identical breast interface to concurrently express milk from a pair of breasts (e.g., simultaneously, alternatingly, or sequentially). A pair of accelerometers can be used to detect the position and/or motion of the corresponding valve in each interface. In some instances, movements of the user may cause the accelerometers to produce motion signals that are erroneously interpreted as valve motion. Accordingly, in preferred embodiments, suitable approaches are used to distinguish between signals resulting from motion of the user and signals generated by motion of the valves. For example, the pumping

device can be configured to alternatingly express milk from each breast, such that the corresponding valves are also opened alternatingly. Consequently, motion detected simultaneously from both accelerometers can be regarded as resulting from user motion, rather than from valve motion. The user motion can be subtracted from the total motion signal obtained by the accelerometers in order to obtain the valve motion, and thereby determine the position of each valve. Alternatively or in combination, the sensor 455 may comprise a set of background motion accelerometers in addition to the set of valve accelerometers, wherein the background motion accelerometers are configured to measure background motion including motion of a user, as described in further detail herein. The background motion measured by the background motion accelerometers may be subtracted from the motion measured by the valve accelerometers, in order to obtain the isolated valve motion.

[0092] **FIG. 11C** illustrates an embodiment with an accelerometer 470 more clearly. The accelerometer 470 is coupled to a valve 476 on the output of the expression device 472 which has a breast interface 474 (sometimes also referred to as a distal assembly in this specification). The valve 476 may be a flap valve, a duckbill valve, or the like. The expression device and breast interface may be any of the embodiments disclosed herein. As breast milk 468 is expressed, it collects at the output of the device. When enough fluid is collected, flap valve 470 opens, and the milk 468 drains into reservoir 462 and collects in a layer 464 therein. The reservoir 462 is preferably threadably connected to the expression device 472 so that it may easily be attached and detached. Movement of the valve 476 is tracked using accelerometer 470. Data from the accelerometer is then processed, transmitted or displayed using any of the methods or means disclosed herein.

[0093] **FIGS. 11L-11N** illustrate an exemplary embodiment having a background motion accelerometer 473 and a valve motion accelerometer 478. **FIG. 11L** is an isometric view of the exemplary embodiment. **FIG. 11M** is an side cross-sectional view of the exemplary embodiment. The background motion accelerometer 473 may be coupled to a portion of the breast interface 235, for example to the housing 240 of the breast interface. The valve motion accelerometer 478 may be coupled to a valve 471, wherein the valve 471 may be a flap valve, a duckbill valve, or any other valve configured to open in response to pressure or weight exerted by the expressed milk 468. The background motion accelerometer 473 and valve motion accelerometer 478 may be coupled to a power source, for example the controller 115, through a power line 482. The background motion accelerometer 473 and valve motion accelerometer 478 may be further coupled to a processing device or a communication module

of a pump control unit, such as the controller 115, through a communication line 480. Alternatively or in combination, the accelerometers may be coupled to a communication module disposed on a portion of the breast interface or of a reservoir, wherein the communication module is configured to communicate wirelessly with the controller or a computing device. The power line 482 and communication line 480 may comprise one or more wires, and may be disposed within different channels or within the same channel 484 of the flexible tubing 110, coupling the breast interface 235 to an actuation assembly of the pumping device. The background motion accelerometer 473 may be disposed on a surface of the housing 240 so as to be positioned close to the power line 482 and communication line 480. Similarly, the valve motion accelerometer 478 may be disposed on a surface of the valve 471 so as to be positioned close to the power and communication lines. The valve 471 may be arranged in a configuration such that the valve accelerometer 478 disposed thereon can be positioned close to the power and communication lines. Preferably, the background motion accelerometer 473 may be disposed in a location and orientation that align its sensing axes to the axes of the valve accelerometer 471, so as to optimize the consistency of the positional data generated by the accelerometers.

[0094] As shown in **FIG. 11M**, the expressed milk 468 can enter the expression area 260 of the breast interface 235, and subsequently enter the drain port 265 coupled to a collection vessel. The fluid flow of the milk 468 can create pressure against the valve 471, causing the valve 471 to open. For example, the valve 471 may be displaced in the direction shown by arrow 485, to the configuration 486. The movement of the valve 471 may be tracked by the valve motion accelerometer 478. The valve motion accelerometer 478 may often measure background motion unrelated to the motion of the valve 471, such as user motion, in addition to the motion of the valve 471. In order to normalize the measurement of the valve motion accelerometer 478 against the background motion, the background motion accelerometer 473 can be configured to track the overall movement of the pumping device in space, so as to measure the background motion of the device unrelated to the motion of the valve 471. Data generated by the accelerometers 473 and 478 may be transmitted via the communication line 480 to a communication module of a pump control unit, wherein the communication module may be configured to transmit the data to a processing device, either of the pump control unit or of another computing device, for data analysis and/or display. Alternatively or in combination, the data generated by the accelerometers may be transmitted wirelessly, via a communication module integrated with a portion of the breast interface or of the reservoir.

[0095] **FIG. 11N** shows an exemplary graph of motion signals generated by the background motion accelerometer 473 and valve motion accelerometer 478. As shown in the graph, the valve signal 487 generated by the valve motion accelerometer 478 differs from the background signal 488 generated by the background motion accelerometer 473. In order to exclude or minimize the contribution of background motion to the measured valve motion, the background signal 488 may be subtracted from the valve signal 487 to generate a normalized valve signal 489.

[0096] In other exemplary embodiments, the pumping devices described herein can utilize one or more beam-break sensors (e.g., infrared-based, laser-based, etc.) situated at a suitable location in the pumping device (e.g., in or near a valve, an exit port, or other component permitting fluid passage). The beam-break sensor can include a plurality of sensor components and can be configured to detect passage of fluid between or near one or more of the components. Preferably, the sensor can be configured to generate a signal when the expressed fluid breaks a beam by passing between a beam emitter and a beam detector. The resultant signal can be used to produce measurement data indicative of the volume of expressed fluid. For example, the measurement data can be based on the length of time the fluid passes between or near the sensor components.

[0097] **FIG. 11D** illustrates an exemplary embodiment of a milk expression device that employs a beam break sensor 477. The expression device 472 includes a breast interface 474 and a reservoir 462. The reservoir is threadably or otherwise coupled 466 to the expression device. Any of the exemplary embodiments of expression devices, interfaces, reservoirs, etc. disclosed in this specification may be used in this exemplary system. A beam-break sensor 477 is disposed adjacent the output of the expression device, and thus as droplets 468 of milk drain from the expression device outlet into reservoir 462, they break the light beam 477a, allowing measurement of the fluid expressed. The fluid collects in a layer 464 in reservoir 462. The data from the sensor can then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

[0098] In another exemplary embodiment, the pumping devices described herein can include one or more image sensors for capturing images of the fluid in order to quantify the expression volume, such as a charge-coupled device (CCD), active pixel sensors in complementary metal–oxide–semiconductor (CMOS), or a camera. The image sensors may be integrated with or coupled to a suitable portion of the pumping device. Conversely, the image sensors can be located on another device separate from the pumping device, such as a smartphone or other mobile device. In exemplary embodiments, the breast interface includes

a valve permitting the passage of expressed fluid, as previously described herein, and a suitable image sensor is positioned on or near the valve in order to capture images of fluid passing through the valve. Preferably, the image sensor is operably coupled to a processing unit configured to analyze the image data (e.g., using a suitable image analysis algorithm) in order to determine the fluid volume. For example, the image sensors can be used to capture images of drops of fluid, and the images can be analyzed to count the number of drops. In some instances, the image data can be transmitted to a computing device (e.g., a smartphone) for analysis, as described in further detail below.

[0099] **FIG. 11E** illustrates an exemplary embodiment having a CCD or CMOS device 479 adjacent an outlet of the expression device. The expression device 472 includes interface 474 and reservoir 462, either of which may be any of the embodiments disclosed herein. As milk 468 is expressed, it passes through the outlet of the expression device past CCD or CMOS 479 which detects the fluid and allows quantification thereof as previously described. The milk 468 then accumulates in a layer 464 in reservoir 462. Data from the device 479 may then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

[00100] **FIG. 11F** illustrates an exemplary embodiment that uses an image of the reservoir to characterized the expressed milk. Once milk 468 has been collected in reservoir 462, the reservoir may optionally be detached from the expression device. A mobile phone may then be used to take a photo 463a of the reservoir which has a suitable application for analyzing the photo and determining how much milk has been expressed, as well as optionally providing other details about the expressed milk. The data is processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

[00101] **FIG. 11G** illustrates an alternative embodiment of a photo sensor system. After milk 468 has been expressed and collected in a reservoir 462, a camera in the pump control unit 465 may be used to obtain an image of the milk in the reservoir and analyze it for quantity or other characteristics. The pump control 465 may be any of the pump controls described elsewhere in this applications, and the data may be processed, transmitted, or displayed using any of the methods disclosed herein.

[00102] In some exemplary embodiments, the pumping devices described herein can employ one or more capacitive sensors for measuring fluid volume. The capacitive sensors can be configured to detect the volume of fluid contained in any suitable portion of the pumping device, such as fluid contained within a collection reservoir and/or within a breast

interface (e.g., expression area 260, a component permitting passage of fluid from the interface such as a valve, exit port, or tube).

[00103] **FIGS. 11H-11I** illustrate exemplary embodiments of expression devices that use capacitive sensors. The expression device 472 may be any of the expression devices disclosed herein and they have an interface 474 that also may be any of the interfaces disclosed in this specification. A reservoir 462 is threadably 466 or otherwise coupled to the expression device and the reservoir may be any of the reservoirs described herein. As milk 468 is expressed and collected at the outlet of the expression device, it passes through the capacitive sensor 475 which is then able to measure fluid volume. **FIG. 11I** is similar to the embodiment in **FIG 11H**, with the major difference being that the capacitive sensor 475a is disposed in the reservoir 462 near the bottom, rather than in the outlet of the expression device. The data from the sensor in either embodiment may then be processed, transmitted, or displaying using any of the techniques described herein.

[00104] In other exemplary embodiments, one or more strain gauges can be used to measure the volume of expressed fluid. The strain gauges can be situated at any suitable position in the pumping device. For example, a strain gauge can be coupled to a flap valve (or any other valve permitting passage of expressed fluid) and configured to determine the volume based on the displacement of the valve over time. Alternatively or in addition, a strain gauge can be coupled to a collection reservoir and configured to measure the volume of expressed fluid contained within the reservoir.

[00105] **FIG. 11J** illustrates an exemplary embodiment of a strain gauge. The expression device 472 includes an interface 474 and reservoir 462 threadably 466 or otherwise coupled thereto. Any portion of this system may be any of the components described elsewhere in this specification. As milk is expressed 468 it accumulates in the outlet of the expression device. Eventually, the weight of the accumulated milk is sufficient to actuate and open valve 476. A strain gauge 481 is coupled to the flap valve and this sensor is then used to collect data on movement of the valve and therefore this correlates to the collected fluid. The fluid accumulates in a layer 464 in reservoir 462. The data from the sensor is then processed, transmitted, or displayed using any of the methods disclosed herein.

[00106] **FIG. 11K** illustrates an alternative embodiment of a strain gauge. This embodiment generally takes the same form as the previous embodiment with the major difference being that the collected fluid layer 464 is disposed over a plate 483 which bears the weight of the collected fluid. Thus, as the weight increases or decreases, a strain gauge 481a disposed under the plate 483 detects the weight change and this can be correlated to the

collected fluid volume. Data from the sensor is then processed, transmitted, or displayed according to any of the methods disclosed herein.

[00107] **FIGS. 11O-11Q** illustrate an exemplary embodiment of a strain gauge or force sensitive resistor (FSR) comprising an integrated processing unit. **FIG. 11O** is a cross-sectional view the embodiment. The strain gauge 490 may be integrated into the bottom of a reservoir, such as reservoir 462 or any reservoir described herein, in such a configuration as to place the load 469 of the expressed milk 468 onto the sensor area of the strain gauge or FSR 490. The strain gauge 490 may comprise a small, force sensitive resistor that adjusts its resistance based on the compressive force it is under. In order to maximize the sensitivity of the strain gauge 490 to the load 469, the bottom interior surface 491 of the reservoir 462 may be designed in such a way as to minimize the absorption of the load 469 as the load is transmitted to the strain gauge. For example, the bottom interior surface 491 may comprise a bellows element 492 to allow the surface 491 to move up and down, thereby minimizing absorption of the load 469 by stretching the surface 491. Preferably, the reservoir 462 comprises self-contained electronics to collect, process, and communicate the data generated using the strain gauge 490. As shown in **FIG. 11P**, which is an exploded view of the embodiment in **FIG. 11O**, the strain gauge 490 may be mounted on a support 493, and coupled to a processing unit 494. Power may be supplied to the processing unit 494 via battery or a direct contact connection such as a cable or pad connectors, or, preferably, via an inductive charging system. The inductive charging system may comprise a battery 495 coupled to the processing unit, and a wireless charger 496 coupled to the battery, which may be charged using an inductive charging method as known in the art. **FIG. 11Q** is a detailed view of the processing unit 494. The processing unit 494 may comprise a printed circuit board (PCB) housing one or more of a microcontroller 494a, a communication module 494b, a strain gauge connection 494c, a power connection 494d, and a timer 494e. The processing unit 494 may receive signals from the strain gauge 490 through the strain gauge connection 494c, and the signals may be transmitted to the microcontroller 494a. The microcontroller 494a may comprise a non-transitory computer readable medium comprising instructions to collect and process the signals received from the strain gauge 490. The microcontroller 494a may further comprise instructions to transmit the collected and/or processed signals to the communication module 494b. The communication module 494b may comprise wireless transmitter/receiver such as a Blue Tooth module, for example. The communication module 494b may be configured to transmit the strain gauge data to a pump control unit of the

expression device or to another computing device, such as a mobile phone, for data analysis and/or display.

[00108] The integrated processing unit of the embodiment of **FIGS. 11O-11Q** may also be suitably combined with any other sensor described herein. An expression device with a reservoir having an integrated sensor and processing unit as described can help automate the management and monitoring of milk production, thus reducing the need for manually maintaining records related to milk production. For example, the strain gauge system as described can monitor the quantity of milk produced, and automatically process and send the data to a computing device, from which the user may easily access the information. Such a system can greatly improve convenience for the users, and also help reduce human errors related to manual record maintenance.

[00109] In exemplary embodiments, some or all of the measurement data collected by the sensors can be fed back to the pumping device in order to optimize fluid expression. Preferably, the feedback can be transmitted to a processing unit and/or control unit of the pumping device (e.g., suitable hardware located in the controller 115) configured to control one or more functionalities of the actuation assembly. Based on the feedback, the processing unit can determine changes to actuation parameters of the actuation assembly in order to achieve and/or maintain optimal fluid expression. For example, the feedback can be used to determine adjustments to a vacuum stroke or the cycles per minute of a pump, piston assembly, or any other suitable actuation assembly.

[00110] **FIG. 21** illustrates an exemplary expression system with feedback control. The system includes a pump unit 2100 preferably including a controller and processor 2104 as well as a motor 2102 for actuating the device, and a distal assembly 2110 which is sized and shaped to mate with the target anatomy, here a breast 2112. Any of the elements in this exemplary system may be any of the components disclosed elsewhere in this specification in other exemplary embodiments. In this embodiment, feedback 2106 from the sensor which monitors expressed milk in the expression device 2110 is transmitted from the distal assembly (expression device with interface) to the controller and processor 2104. The data is processed and this information is used to provide instructions to motor 2102 which increases or decreases actuation of the expression device which is then transmitted by communication 2108 back to the expression device or distal assembly 2110. The feedback information may also be used to provide instructions to motor 2012 to change the stroke or number of cycles per minute of the expression device. Any of the embodiments in this specification may include such a feedback loop.

[00111] **FIG. 12** illustrates an exemplary embodiment of a controller 500 for a pumping device including a display screen 505. The controller 500 can include suitable hardware for collecting, processing, and storing the milk expression data described herein, as well as analysis results obtained from processing the expression data. In preferred embodiments, this information is displayed to a user of the pumping device via the display screen 505. Furthermore, as shown in **FIG. 13**, information can also be transmitted from the controller 500 and displayed on a separate computing device, such as a mobile device 510, as described in further detail below. The information can be presented in any suitable format, including graphs, charts, tables, images, or other visual elements, such as one or more lights of different colors. Alternatively or in combination, the information may be provided via an audible indicator. The information may be presented in a format that is static or dynamic (e.g., updated in real time, etc.). Additionally, the controller 500 can include input devices enabling users to interact with the displayed information, such as the button 515, as well as keyboards, joysticks, touchscreens, switches, or knobs, or suitable combinations thereof.

Communication with computing devices

[00112] In any of the embodiments disclosed herein, the pumping devices described herein can be configured to communicate with another entity, such as one or more computing devices and/or servers. Exemplary computing devices include personal computers, laptops, tablets, and mobile devices (e.g., smartphones, cellular phones). The servers described herein can be implemented across physical hardware, virtualized computing resources (e.g., virtual machines), or any suitable combination thereof. In preferred embodiments, the servers are distributed computing servers (also known as cloud servers) utilizing any suitable combination of public and/or private distributed computing resources. The computing devices and/or servers may be in close proximity to the pumping device (short range communication), or may be situated remotely from the pumping device (long range communication). Any description herein relating to communication between a computing device and a pumping device can also be applied to communication between a server and a pumping device, and vice-versa.

[00113] **FIG. 13** illustrates short range communication 515 between the controller 500 of a pumping device and mobile device 510. The communication 515 can utilize wireless communication methods, as described below. In many embodiments, the controller 500 and mobile device 510 are also capable of long range communication.

[00114] **FIG. 14** is a schematic illustration of a pumping device 800 in communication with a computing device 805 and a server 810. The pumping device 800 includes one or more breast interfaces 815, an actuation assembly 820, a sensing unit 825, and a communication module 835. Preferably, the communication module 830 is implemented across suitable hardware within a controller of the pumping device (e.g., controller 500). The pumping device 800 can communicate with the computing device 805 and server 810 via the communication module 830. In many embodiments, the communication module 830 is communicably coupled to the computing device 805 and server 810 via first and second data connections 835, 840. Furthermore, the server 810 can be communicably coupled to the computing device 805 via a third data connection 845. Although the pumping device 800 is depicted herein as communicating directly with the computing device 805 and the server 810, other configurations are also possible. For example, the pumping device 800 may communicate with the server 810 indirectly via the computing device 805, or vice-versa. Conversely, the server 810 may communicate with the pumping device 800 indirectly via the computing device 805, and the computing device 805 may communicate with the pumping device 800 via the server 810. Any description herein related to communication between the pumping device 800, the computing device 805, or server 810 can be applied to direct communication as well as indirect communication between these entities.

[00115] The data connections 835, 840, and 845 can utilize any communication method suitable for transmitting data between the pumping device 800, the computing device 805, and server 810. Such communication methods can include wired communication (e.g., wires, cables such as USB cables, fiber optics) and/or wireless communication (Bluetooth®, WiFi, near field communication). In many embodiments, data can be transmitted over one or more networks, such as local area networks (LANs), wide area networks (WANs), telecommunications networks, the Internet, or suitable combinations thereof.

[00116] In exemplary embodiments, the pumping device 800 transmits milk expression data to the computing device 805 or server 810 (directly or indirectly). The milk expression data can include measurement data generated by the sensing unit 825 of the pumping device 800, as previously described herein. In many embodiments, the pumping device 800 analyzes the measurement data (e.g., using suitable onboard hardware and/or software) and transmits the analysis results to the computing device 805 or server 810. Alternatively, the measurement data can be analyzed by the computing device 805 or server 810, such as using one or more applications. The computing device 805 or server 810 may be associated with data stores for storage of the measurement data and/or analysis results.

[00117] The applications (of the computing device 805 or server 810) can also collect and aggregate the measurement data and/or analysis results and display them in a suitable format to a user (e.g., charts, tables, graphs, images, etc.), as previously described herein. Preferably, the application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. The analysis and display functionalities described herein may be performed by a single entity, or by any suitable combination of entities. For example, in many embodiments, data analysis can be carried out by the server 810, and the analysis results transmitted to the pumping device 800 or computing device 805 for display to the user.

[00118] Additionally, the computing device 805 or server 810 can include an application configured to control at least one functionality of the pumping device 800 or a portion thereof (e.g., the actuation assembly 820), such as power, vacuum pressure applied (via the interfaces 815), or cycles per minute. For example, the communication module 830 can receive control signals from the computing device 805 and/or sever 810, and transmit the control signals to the actuation assembly 820 to produce the desired actuation. In preferred embodiments, the control signals can be generated using feedback provided by the pumping device 800, such as feedback based on measurement data provided by the sensing unit 825, as previously described herein. Additionally, the computing device 805 or server 810 may implement machine learning techniques with regards to control of the pumping device 800, in order to improve and optimize pumping performance over time.

[00119] Furthermore, the pumping device 800, computing device 805, and/or server 810 can be configured to provide notifications reminding the user to express milk. Such notifications can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis. The notifications can be generated based on previously collected milk expression data, such as data relating to expression frequency and/or the timing of previous pumping sessions, as well as based on user preferences. Preferably, the notification functionality is included in a suitable application running on the computing device 805 or server 810. For example, the pumping device 800 can send information about the times of pump usage to the computing device 805 or server 810, so that the application can identify when pumping has occurred and set reminders at desired pumping times.

[00120] The notifications can be provided using any suitable method and in any suitable format. For example, the notifications can be generated by the computing device 805 or

server 810, transmitted to the pumping device 800 (e.g., to the communication module 830), and displayed to the user (e.g., on a display of the pumping device 800, such as the display screen 505). Conversely, the notifications can be generated by the pumping device 800 and transmitted to the computing device 805 and/or server 810. In many embodiments, the notifications are displayed to the user by the computing device 805. Alternatively, the pumping device 800, computing device 805 and/or sever 810 can provide the notifications to the user using other methods. For example, the notifications can be sent to an email address, via short message service (SMS) to a smartphone or other mobile device associated with a cellular phone number, or to a web page accessible by the user.

[00121] Other types of data can also be transmitted between the pumping device 800, computing device 805, and/or server 810. For example, in many embodiments, firmware updates for one or more components of the pumping device 800 can be transmitted to the pumping device 800 from the computing device 805 and/or server 810.

[00122] **FIG. 17** illustrates another exemplary embodiment of a system for expression of milk or for monitoring other fluids. The system 1700 includes a pump unit 1702, a distal assembly 1706 (sometimes also referred to as an interface in this specification), wireless communication transmitters and receivers 1709, 1712, a computing device 1714 and a remote server 1718. The pump unit 1702 may be any of the pump units described in this specification or known in the art, and the distal assembly 1708 also may be any of those described herein or known in the art. The distal assembly 1706 is preferably sized and shaped to conform to the target anatomy, which in this exemplary embodiment is a breast 1708. The pump unit 1702 actuates 1704 the distal assembly 1706 to cause expression of milk from breast 1708 using any of the actuation mechanism disclosed herein. A transmitter 1709 is preferably disposed on the pump unit or adjacent thereto and is configured to transmit data 1710 from the pump unit to a receiver 1712 on the computing device 1714. The data may be transmitted wirelessly using methods known in the art such as those disclosed in this specification. In alternative embodiments, a hard connection such as with a USB cable may be used to operably couple the pump 1702 and computing device 1714 together. The computing device may be a smart phone, tablet, personal computer, or any other electronic computing device that can display the data transmitted from the pump unit 1702. The computing device may also transmit information back to the pump unit to help control operation of the distal assembly. The computing device 1714 may also communicate 1716 with a remote server 1718 which may store or display the data. Access to the remote service

1718 may be by the Internet or by other means known in the art and thus the cloud based data may be readily accessed from any other device with Internet access.

[00123] **FIG. 18** illustrates another exemplary embodiment of a system 1800 for expression of milk. In this embodiment, the system 1800 includes a pump unit 1802, a distal assembly 1806 and a cloud based or remote server 1812. The pump unit 1802 may be any of the pumps disclosed herein and it is operably coupled with the distal assembly 1806 which is sized and shaped to conform to the target, such as breast 1808. The distal assembly may be any of the distal assemblies described herein. The pump unit 1802 actuates 1804 the distal assembly using any of the mechanisms disclosed herein to cause expression of milk from breast 1808. The pump unit 1802 also includes a transmitter and receiver 1809 for transmitting pump data 1810 to a remove server 1812, which in this embodiment is a cloud based server. Thus, the data may be transmitted to the remote service via the Internet, and accessed from the cloud based server by the pump 1802 or any other computing device via the Internet. Preferably communication with the cloud based server is by wireless communication.

[00124] **FIGS. 19A-19C** illustrate exemplary computing device displays 1904. For example, **FIG. 19A** illustrates an exemplary display on a mobile phone 1902 and graphically illustrates milk production, the time of the last pumping session, a graphic of goal attainment, and a graphic illustrating the fluid consumption of the user. Additionally, the display 1904 may also provide user encouragement or user feedback based on the amount of milk production. **FIG. 19B** is an enlarged view of the display 1904 in **FIG. 19A**. **FIG. 19C** illustrates additional information that the display 1904 may show when a touch screen is actuated (e.g. by swiping or touching the screen). For example, the volume of the milk expressed is indicated after the "Last Pumping Session" section of the display is selected. Some or all items may be expanded, as also indicated in **FIG. 19C**. Additional information, or in some situations, less information may be displayed as desired.

[00125] **FIGS. 20A-20B** illustrate other exemplary displays which may be used in a milk expression system. For example, **FIG. 20A** is an exemplary display 2002 on any of the computing devices disclosed herein and operably coupled with any of the pump units described herein. The display may indicate an average volume of milk expressed over any time period, along with an average duration of the expression session during that same time period. Graphics may be used (e.g. bar chart, pie chart, x-y plot, etc.) to show volume expressed during individual sessions over the course of several days, here Monday through Friday. The display may allow a user to annotate the display so that missed sessions may be

accounted for, for example if a session is omitted due to traveling, the display may show travel during that time period. Other annotations may also be made, such as when certain foods or nutritional supplements are taken, here hops or fenugreek. This allows the user to recall when expressed milk samples were obtained relative to the consumption of the food or nutritional supplements. The display may have other functional buttons such as for obtaining tips, accessing the cloud, setting an alarm, making notes, storing data, or establishing system preferences. Communication between the computing device and the pump unit in **FIGS. 20A-20B** is discussed more thoroughly above in relation to **FIG. 13**.

[00126] **FIG. 20B** illustrates an exemplary display 2004 that may be on a computing device in the system, or more preferably that is on any of the pumps disclosed herein. The display 2004 is similar to a dashboard style gauge and indicates the volume of fluid expressed and collected and the time. Other information may also be displayed.

Experimental data

[00127] **FIGS. 15** and **16** illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[00128] **FIG. 15** illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[00129] **FIG. 16** illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary

embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[00130] The various techniques described herein may be partially or fully implemented using code that is storable upon storage media and computer readable media, and executable by one or more processors of a computer system. Storage media and computer readable media for containing code, or portions of code, can include any appropriate media known or used in the art, including storage media and communication media, such as but not limited to volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage and/or transmission of information such as computer readable instructions, data structures, program modules, or other data, including RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disk (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, solid state drives (SSD) or other solid state storage devices, or any other medium which can be used to store the desired information and which can be accessed by the a system device. Based on the disclosure and teachings provided herein, a person of ordinary skill in the art will appreciate other ways and/or methods to implement the various embodiments.

[00131] It shall be understood that different aspects of the invention can be appreciated individually, collectively, or in combination with each other. Suitable elements or features of any of the embodiments described herein can be combined or substituted with elements or features of any other embodiment.

[00132] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A system for expression of milk from a breast, the system comprising:

an expression apparatus comprising an interface configured to engage a breast, and an actuation assembly operably coupled to the interface, wherein actuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express milk therefrom; and

a computing device configured to communicate with the expression apparatus via a data connection.

2. The system of claim 1, wherein the interface is configured to fluidly seal against the breast.

3. The system of claim 1, wherein the data connection utilizes one or more of a wireless communication, near field communication, and a USB cable to transmit data between at least a portion of the expression apparatus and the computing device.

4. The system of claim 1, wherein the computing device is selected from a smartphone, a tablet, and a personal computer.

5. The system of claim 1, wherein the expression apparatus further comprises a sensing unit configured to generate measurement data indicative of one or more characteristics of milk expression.

6. The system of claim 5, wherein the measurement data is transmitted to the computing device via the data connection.

7. The system of claim 6, wherein the computing device comprises an application configured to analyze the measurement data.

8. The system of claim 6, wherein the computing device transmits the measurement data to a server.

9. The system of claim 5, wherein the expression apparatus further comprises a processing unit configured to analyze the measurement data and thereby generate an analysis result.

10. The system of claim 9, wherein the expression apparatus further comprises a display unit configured to display the analysis result to a user.

11. The system of claim 10, wherein the analysis result is displayed in a graph, chart, or table.

12. The system of claim 9, wherein the analysis result is transmitted to the computing device via the data connection.

13. The system of claim 12, wherein the computing device displays the analysis result to a user.

14. The system of claim 1, wherein the computing device controls at least one functionality of the expression apparatus via the data connection.

15. The system of claim 14, wherein the functionality comprises one or more of power of the expression apparatus, vacuum pressure applied by the expression apparatus, and cycles per minute of the expression apparatus.

16. The system of claim 1, wherein a notification reminding a user to express milk is transmitted to the computing device via the data connection.

17. The system of claim 1, wherein a notification reminding a user to express milk is transmitted to at least a portion of the expression apparatus via the data connection.

18. The system of claim 1, wherein firmware updates are transmitted to at least a portion of the expression apparatus via the data connection.

19. The system of claim 1, wherein the computing device comprises a communication module in communication with a server via a network.

20. The system of claim 19, wherein a notification reminding a user to express milk is transmitted from the server to the computing device.

21. The system of claim 20, wherein the computing device comprises a cellular phone associated with a cellular phone number, and the notification is transmitted by short message service (SMS) via the network to the cellular phone number.

22. A method for measuring expression of milk from a breast, the method comprising:

providing a breast milk expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;

engaging the interface with a breast;

actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast;

expressing milk from the breast;

measuring a characteristic of milk expression using the sensing unit, thereby generating measurement data; and

transmitting the measurement data from the sensing unit to a computing device via a data connection.

23. The method of claim 22, further comprising storing the measurement data in one or more data stores of the computing device.

24. The method of claim 22, further comprising analyzing the measurement data via an application of the computing device to generate an analysis result.

25. The method of claim 24, further comprising displaying the analysis result to a user via the computing device.

26. The method of claim 25, wherein the analysis result is displayed in a graph, chart, or table.

27. A method for controlling expression of milk from a breast, the method comprising:

providing a breast milk expression apparatus comprising an interface and an actuation assembly operably coupled to the interface;

engaging the interface with a breast;

receiving a control signal from a computing device via a data connection,;

actuating the actuation assembly based on the control signal, thereby causing the interface to apply vacuum pressure against the breast; and

expressing milk from the breast.

28. An apparatus for expression of milk from a breast, the apparatus comprising:

an interface configured to engage a breast;

an actuation assembly operably coupled to the interface, wherein actuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express milk therefrom; and

a communication module in communication with a server via a network.

29. The apparatus of claim 28, wherein the interface is configured to fluidly seal against the breast.

30. The apparatus of claim 28, wherein the network comprises an Internet network.

31. The apparatus of claim 28, further comprising a sensing unit configured to generate measurement data indicative of one or more characteristics of milk expression.

32. The apparatus of claim 31, wherein the measurement data is transmitted to the server via the network.

33. The apparatus of claim 32, wherein the server comprises an application configured to analyze the measurement data.

34. The apparatus of claim 31, further comprising a processing unit configured to analyze the measurement data and thereby generate an analysis result.

35. The apparatus of claim 34, further comprising a display unit configured to display the analysis result to a user.

36. The apparatus of claim 34, wherein the analysis result is transmitted to the server via the network.

37. The apparatus of claim 36, wherein the analysis result is displayed on a computing device in communication with the server.

38. The apparatus of claim 28, wherein at least one functionality of the actuation assembly is controlled by an application on the server via the network.

39. The apparatus of claim 38, wherein the functionality comprises one or more of power of the actuation assembly, vacuum pressure applied by the actuation assembly, and cycles per minute of the actuation assembly.

40. The apparatus of claim 28, wherein a notification reminding a user to express milk is transmitted via the network to an email address.

41. The apparatus of claim 28, wherein a notification reminding a user to express milk is transmitted by short message service (SMS) via the network to a cellular phone number.

42. The apparatus of claim 41, wherein the notification is transmitted by SMS from the server to a smartphone associated with the cellular phone number.

43. The apparatus of claim 28, wherein a notification reminding a user to express milk is transmitted to the communication module via the network.

44. The apparatus of claim 28, wherein firmware updates are transmitted to the communication module via the network.

45. A method for measuring expression of milk from a breast, the method comprising:

providing a breast milk expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;

engaging the interface with a breast;

actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast;

expressing milk from the breast;

measuring a characteristic of milk expression using the sensing unit, thereby generating measurement data; and

transmitting the measurement data to a server via a network,.

46. The method of claim 45, wherein the server is a distributed computing server.

47. The method of claim 45, wherein the characteristic of milk expression is measured by the sensing unit as the milk moves from the interface to a collection reservoir in fluid communication with the interface.

48. The method of claim 45, further comprising storing the measurement data in one or more data stores associated with the server.

49. The method of claim 45, further comprising analyzing the measurement data via an application on the server to generate an analysis result.

50. The method of claim 49, further comprising:

transmitting the analysis result from the server to a computing device; and

displaying the analysis result to a user via the computing device.

51. A method for remotely controlling expression of milk from a breast, the method comprising:

providing a breast milk expression apparatus comprising an interface and an actuation assembly operably coupled to the interface;

engaging the interface with a breast;

receiving a control signal from a server via a network,;

actuating the actuation assembly based on the control signal, thereby causing the interface to apply vacuum pressure against the breast; and

expressing milk from the breast.

52. An apparatus for measuring expression of fluid from a breast, the apparatus comprising:

an interface configured to engage a breast;

an actuation assembly operably coupled to the interface, wherein actuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express fluid therefrom; and

a sensing unit configured to generate measurement data indicative of volume of expressed fluid from the breast.

53. The apparatus of claim 52, wherein the interface is configured to fluidly seal against the breast.

54. The apparatus of claim 52, wherein the fluid is one or more of breast milk and colostrum.

55. The apparatus of claim 52, wherein the measurement data is indicative of the volume per unit of time of the expressed fluid.

56. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data is indicative of the volume per stroke of the pump of the expressed fluid.

57. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data is indicative of the volume per pump power cycle of the expressed fluid.

58. The apparatus of claim 52, wherein the interface comprises a valve permitting the passage of the expressed fluid and the sensing unit comprises an accelerometer measuring motion of the valve.

59. The apparatus of claim 58, wherein the measurement data is generated based on the motion of the valve.

60. The apparatus of claim 58, further comprising a second interface configured to engage a second breast, wherein actuation of the actuation assembly causes vacuum pressure to be applied alternatingly against the breast and the second breast to alternatingly express fluid therefrom, and wherein the second interface comprises a second valve permitting the passage of expressed fluid from the second breast and the sensing unit comprises a second accelerometer measuring motion of the second valve.

61. The apparatus of claim 60, wherein the sensing unit determines user motion based on motion detected by both the accelerometer and the second accelerometer.

62. The apparatus of claim 61, wherein the user motion is subtracted from motion detected by at least one of the accelerometer or the second accelerometer when determining motion of at least one of the first or second valves.

63. The apparatus of claim 52, wherein the interface comprises a valve permitting passage of the expressed fluid, and the sensing unit comprises a first accelerometer coupled to the interface and a second accelerometer coupled to the valve.

64. The apparatus of claim 63, wherein the first accelerometer is configured to measure a motion of the interface.

65. The apparatus of claim 63, wherein the second accelerometer is configured to measure a motion of the valve.

66. The apparatus of claim 63, wherein the measurement data is generated based on a motion of the interface and a motion of the valve.

67. The apparatus of claim 63, wherein the sensing unit determines background motion based on motion detected by the first accelerometer.

68. The apparatus of claim 67, wherein the background motion is subtracted from motion detected by the second accelerometer when determining a motion of the valve.

69. The apparatus of claim 52, wherein the interface is coupled to a reservoir configured to collect the expressed fluid and the sensing unit is coupled to the reservoir, and wherein the reservoir comprises a processing unit in communication with the sensing unit, the processing unit configured to receive the measurement data generated by the sensing unit.

70. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a computing device via a data connection.

71. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a server via a network.

72. The apparatus of claim 52, wherein the sensing unit comprises a beam-break sensor configured to detect passage of the expressed fluid near one or more sensor components of the beam-break sensor.

73. The apparatus of claim 72, wherein the measurement data is generated based on a length of time the expressed fluid passes between the sensor components.

74. The apparatus of claim 52, wherein the interface comprises a valve permitting the passage of the expressed fluid and the sensing unit comprises a charge-coupled device (CCD) configured to count drops of the expressed fluid passing through the valve.

75. The apparatus of claim 74, wherein the measurement data is generated based on one or more CCD images of the drops.

76. The apparatus of claim 52, wherein the interface comprises a tube permitting passage of the expressed fluid and the sensing unit comprises a capacitive sensor configured to sense the expressed fluid contained in the tube.

77. The apparatus of claim 52, wherein the interface is coupled to a reservoir configured to collect the expressed fluid and the sensing unit comprises a capacitive sensor configured to measure volume of the expressed fluid contained in the reservoir.

78. The apparatus of claim 52, wherein the sensing unit comprises a strain gauge configured to measure the volume of the expressed fluid.

79. The apparatus of claim 78, wherein the interface comprises a valve permitting the passage of the expressed fluid, and the strain gauge is coupled to the valve and is configured to determine displacement of the valve over time.

80. The apparatus of claim 78, wherein the interface is coupled to a reservoir configured to collect the expressed fluid, and the strain gauge is coupled to the reservoir and is configured to measure volume of the expressed fluid contained in the reservoir.

81. The apparatus of claim 80, wherein the reservoir comprises a bottom interior surface having a bellows element, the bellows element configured to minimize absorption by the bottom interior surface of a load placed on the bottom interior surface by the expressed fluid.

82. The apparatus of claim 52, wherein the sensing unit comprises a camera coupled to the interface and configured to capture one or more images of the expressed fluid.

83. The apparatus of claim 82, further comprising a processing unit configured to analyze the one or more images to determine the volume of the expressed fluid.

84. The apparatus of claim 82, wherein the one or more images are transmitted to a computing device configured to analyze the one or more images to determine the volume of the expressed fluid.

85. The apparatus of claim 84, wherein the computing device is a smartphone.

86. The apparatus of claim 82, wherein the camera is situated on a mobile device.

87. The apparatus of claim 52, further comprising:

a processing unit; and

a control unit operably coupled to the actuation assembly to control at least one functionality thereof;

wherein at least a subset of the measurement data is transmitted as feedback to at least one of the processing unit and the control unit.

88. The apparatus of claim 87, wherein the actuation assembly comprises a pump, and the feedback is used to adjust a vacuum stroke of the pump to maintain optimal fluid expression.

89. The apparatus of claim 87, wherein the actuation assembly comprises a pump, and the feedback is used to adjust cycles per minute of the pump to maintain optimal fluid expression.

90. A method for measuring the volume of fluid expressed from a breast, the method comprising:

providing a breast fluid expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;

engaging the interface with a breast;

actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast;

expressing fluid from the breast; and

generating, via the sensing unit, measurement data indicative of volume of the expressed fluid.

91. The method of claim 90, further comprising:

changing an actuation parameter of the actuation assembly based on at least a subset of the measurement data; and

actuating the actuation assembly based on the changed actuation parameter.

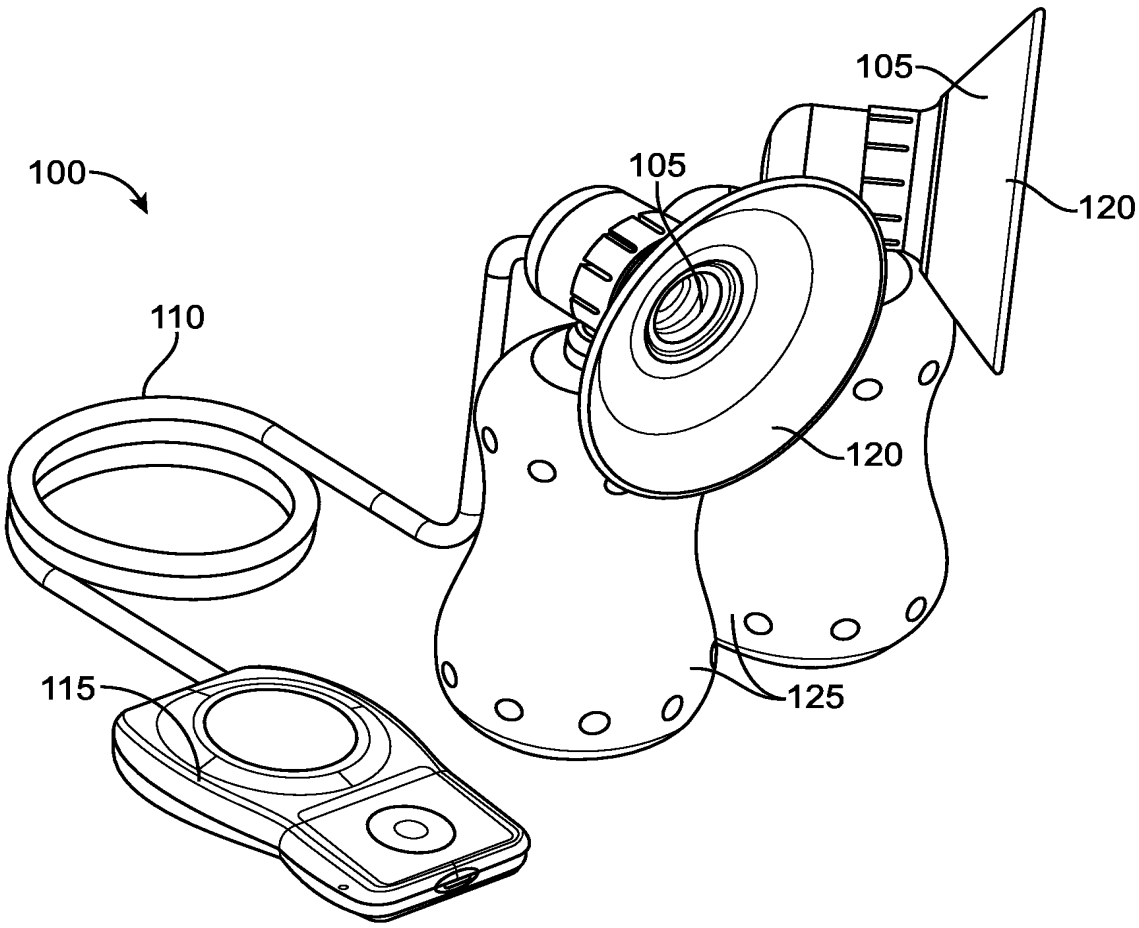


FIG. 1

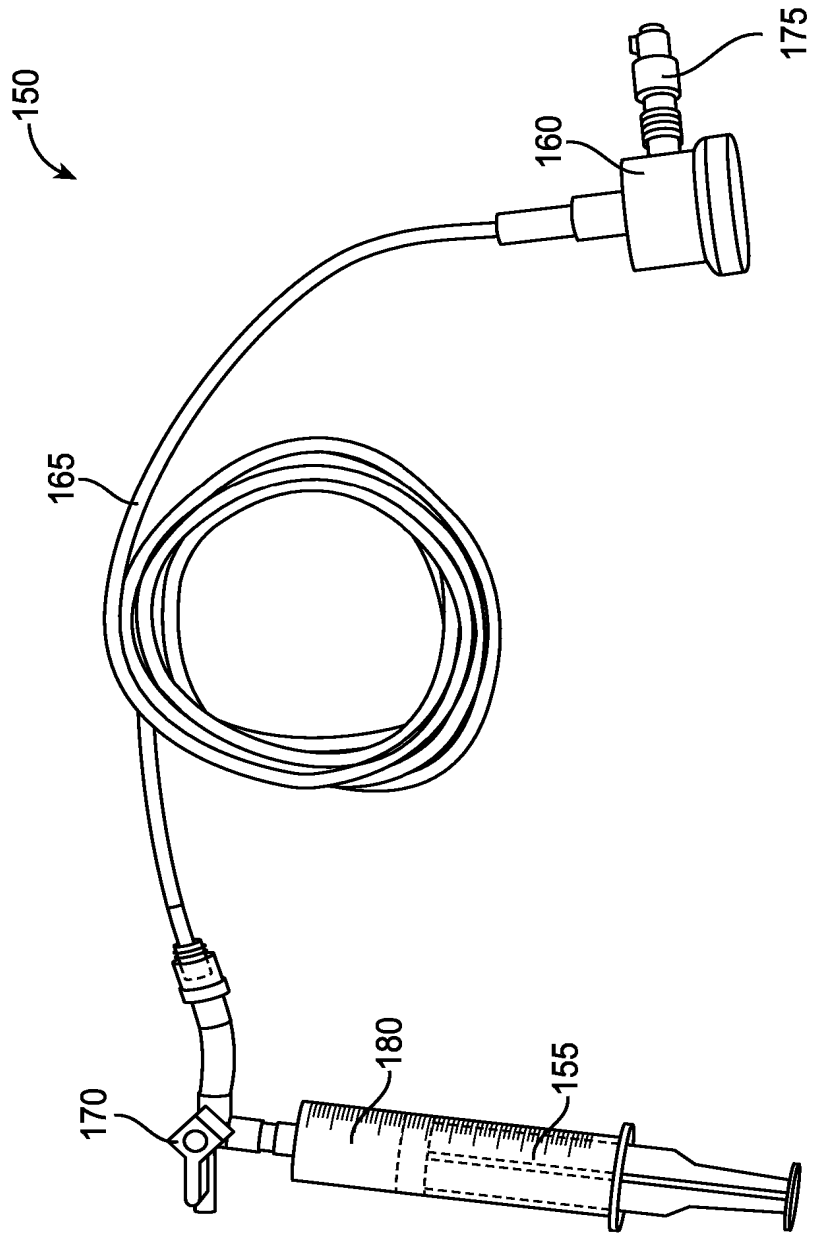


FIG. 2

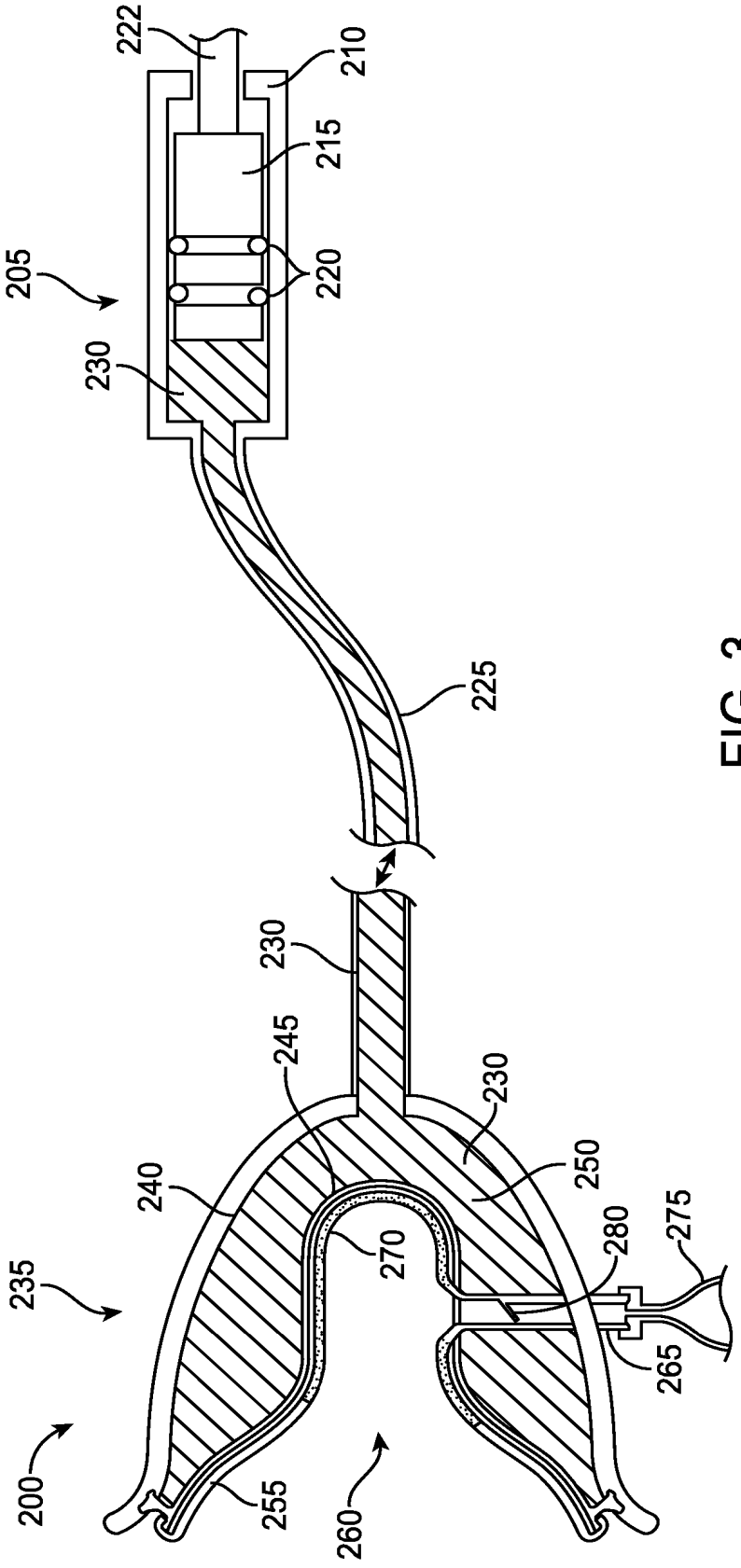

222
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260

FIG. 3

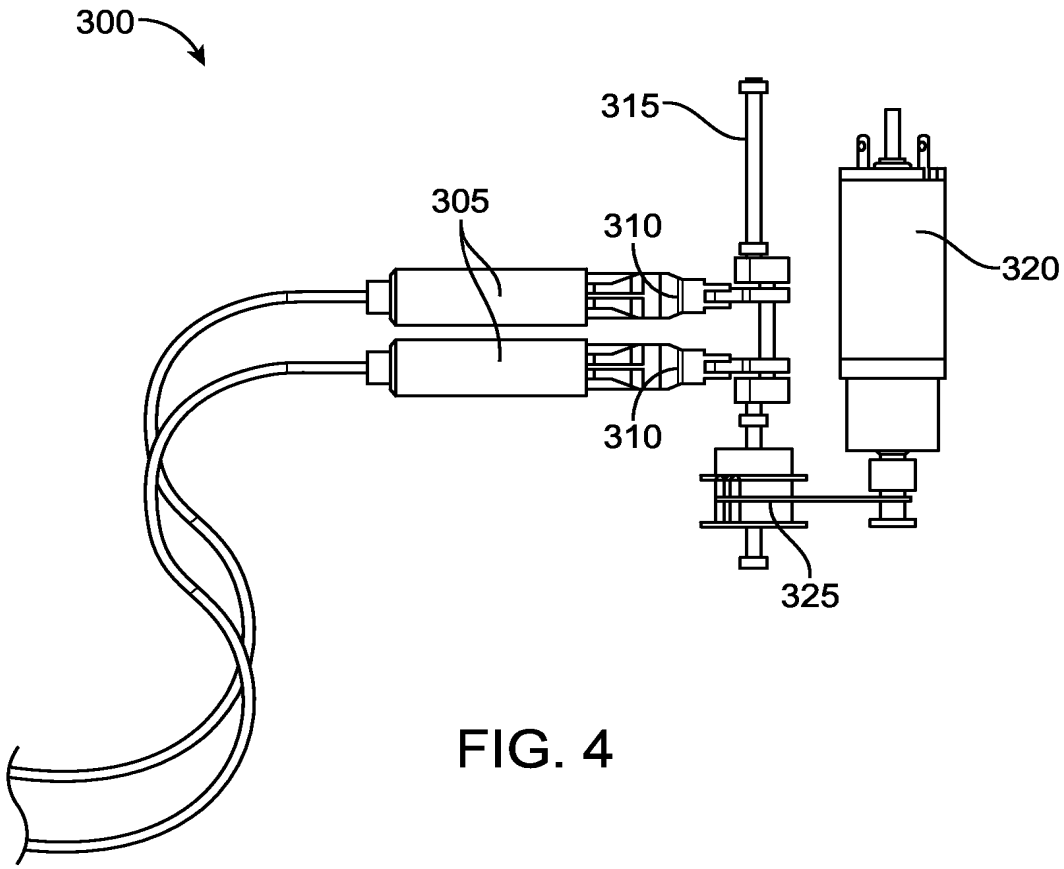


FIG. 4

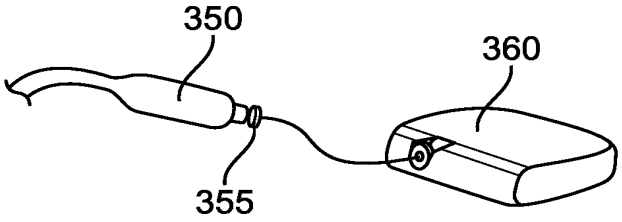


FIG. 5A

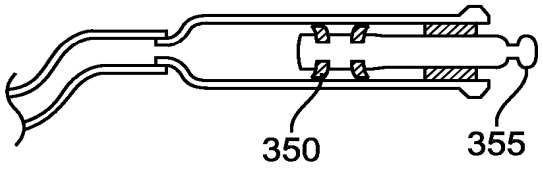


FIG. 5B

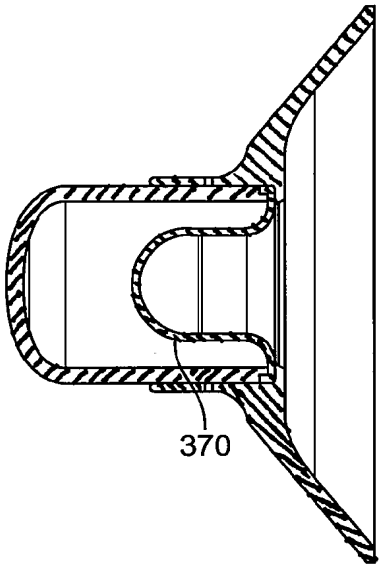


FIG. 6

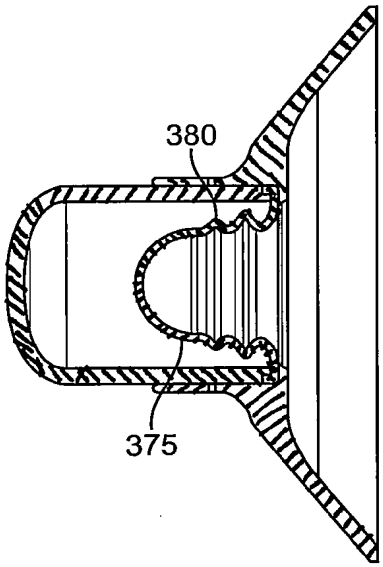


FIG. 7

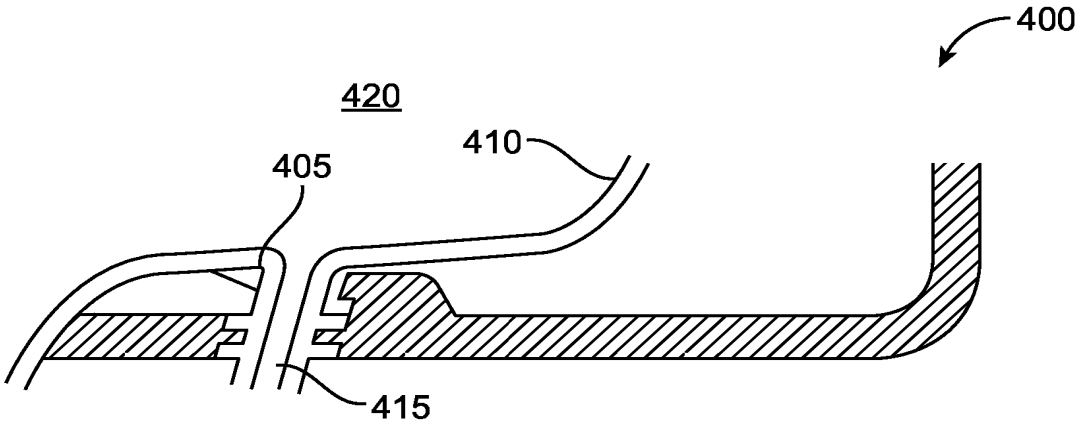


FIG. 8A

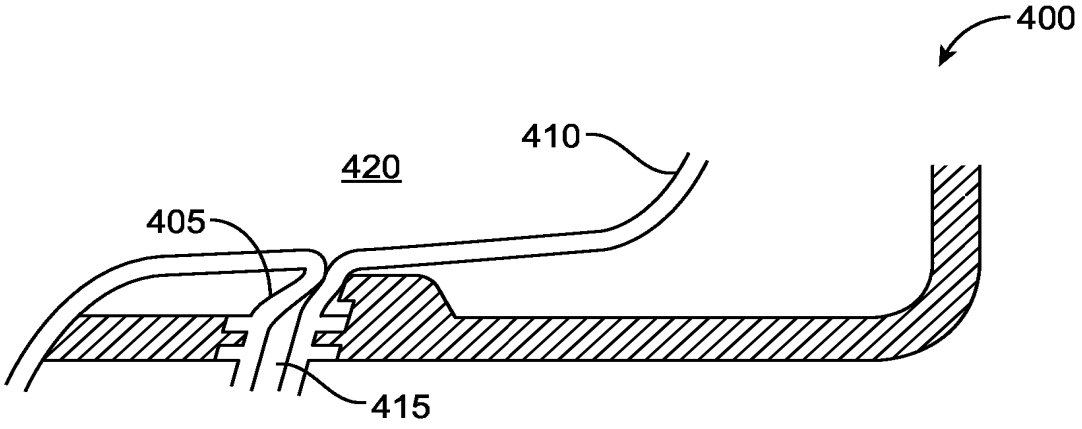


FIG. 8B

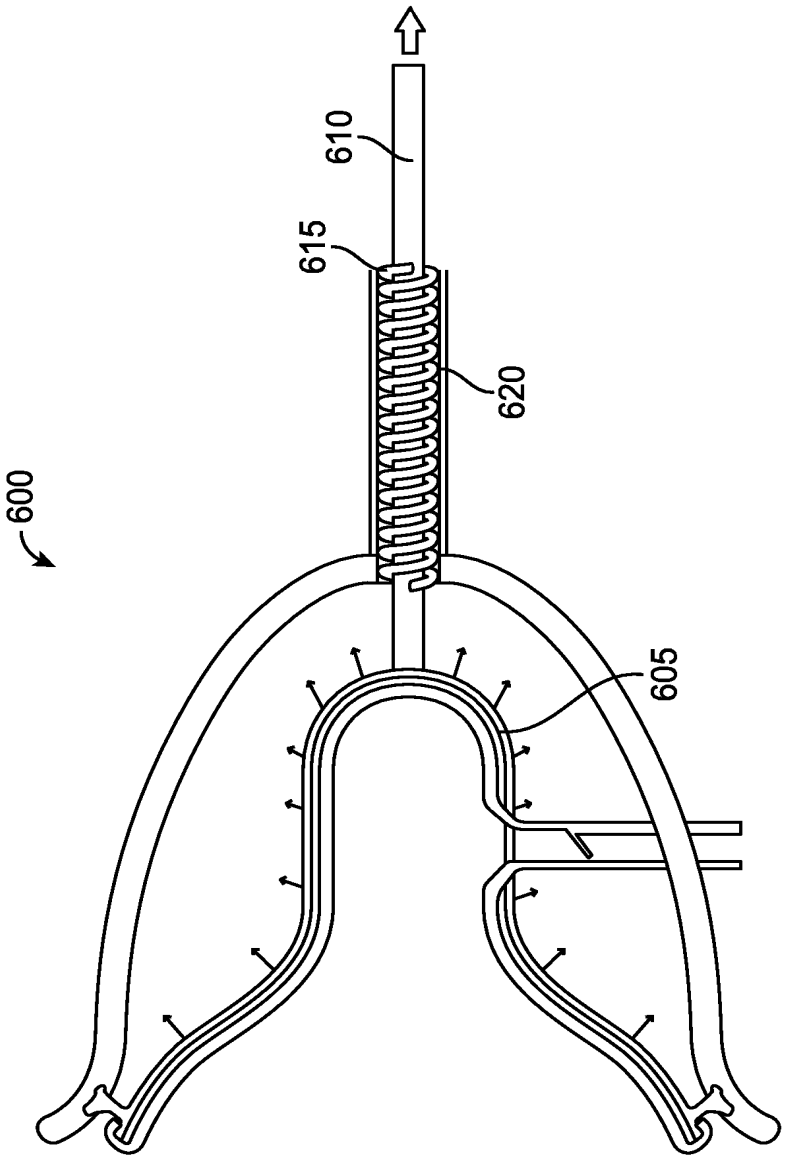


FIG. 9

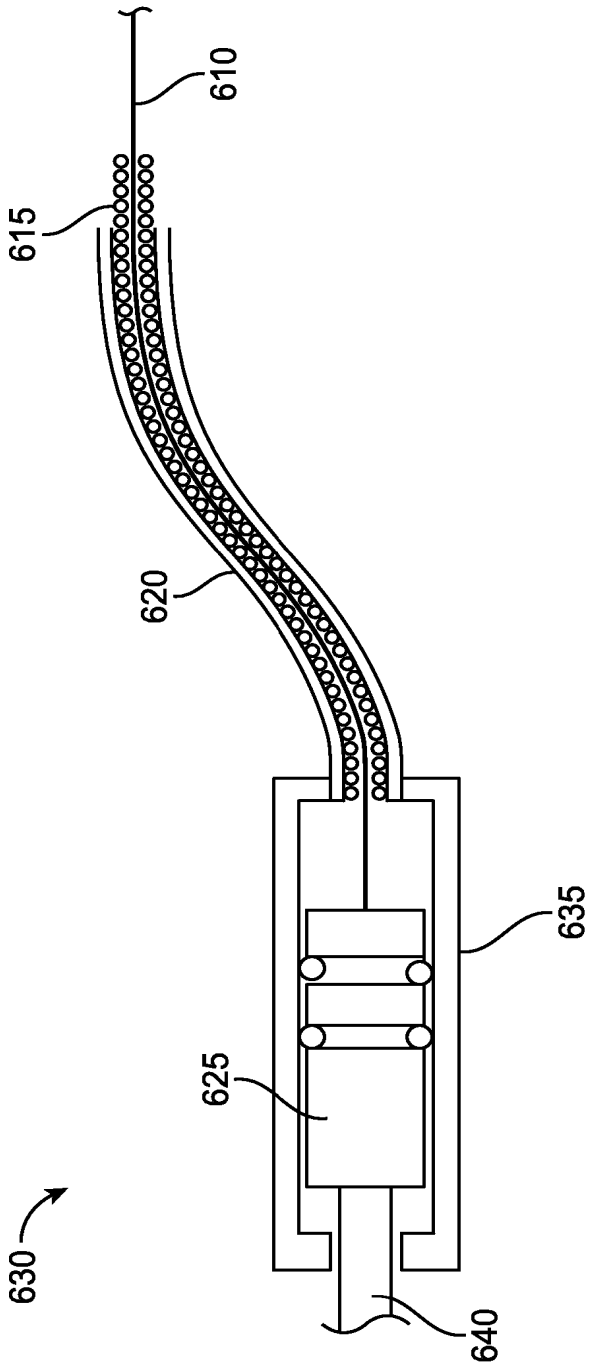


FIG. 10

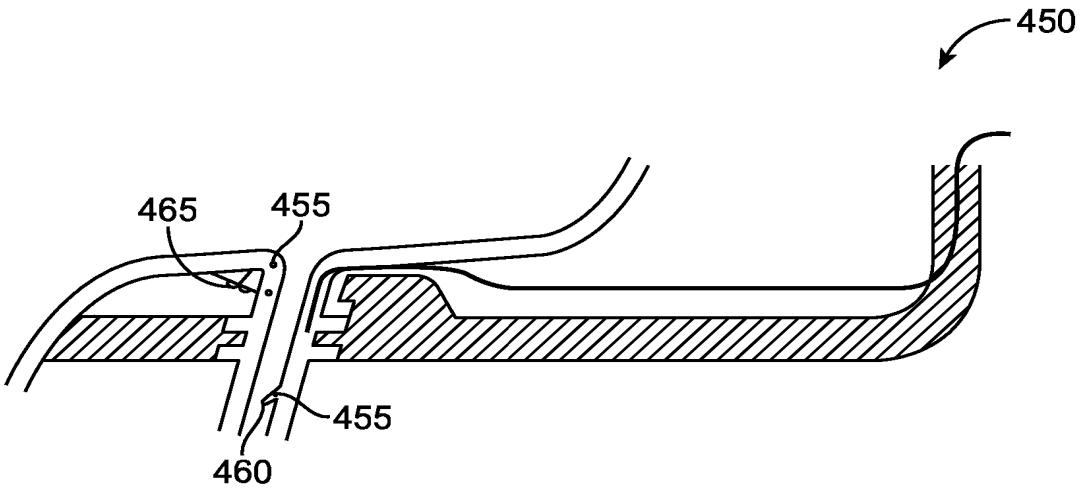


FIG. 11A

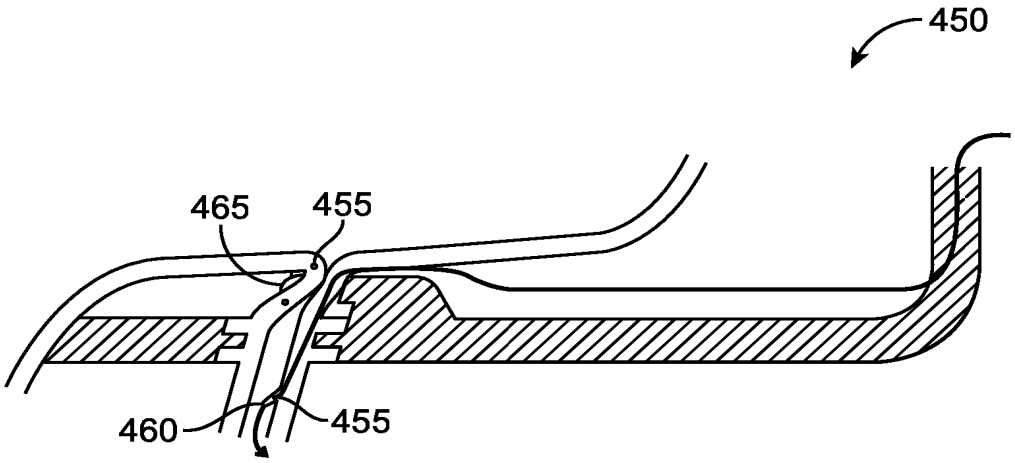


FIG. 11B

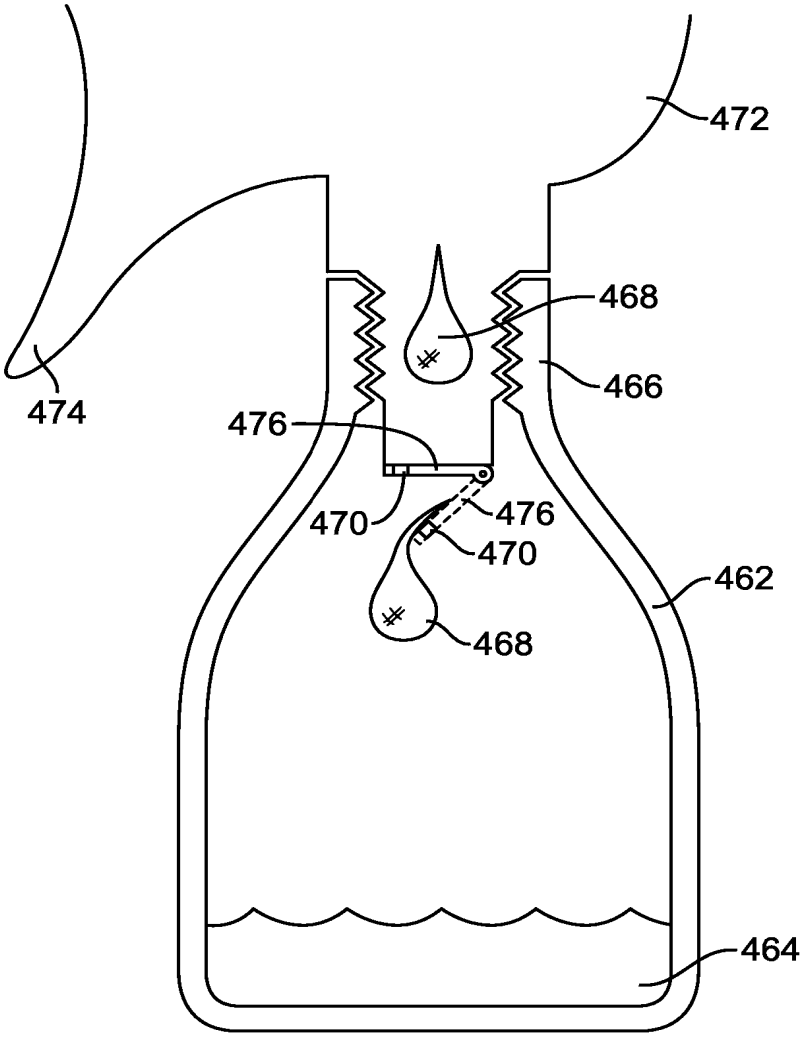


FIG. 11C

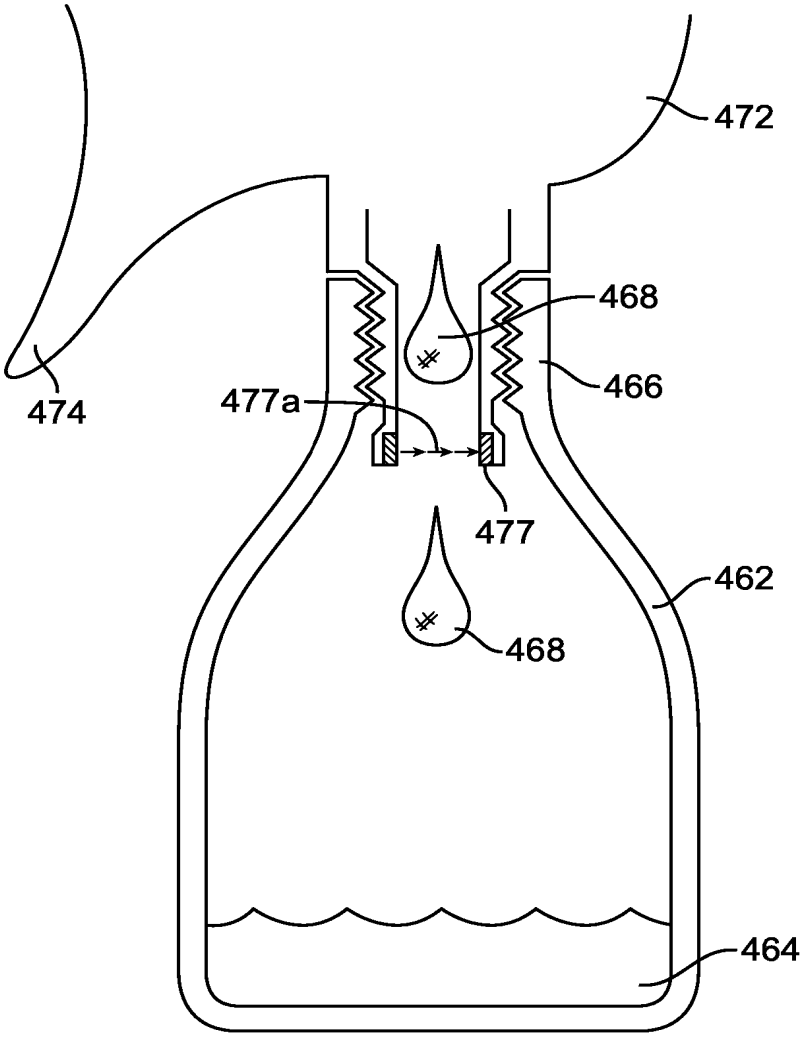


FIG. 11D

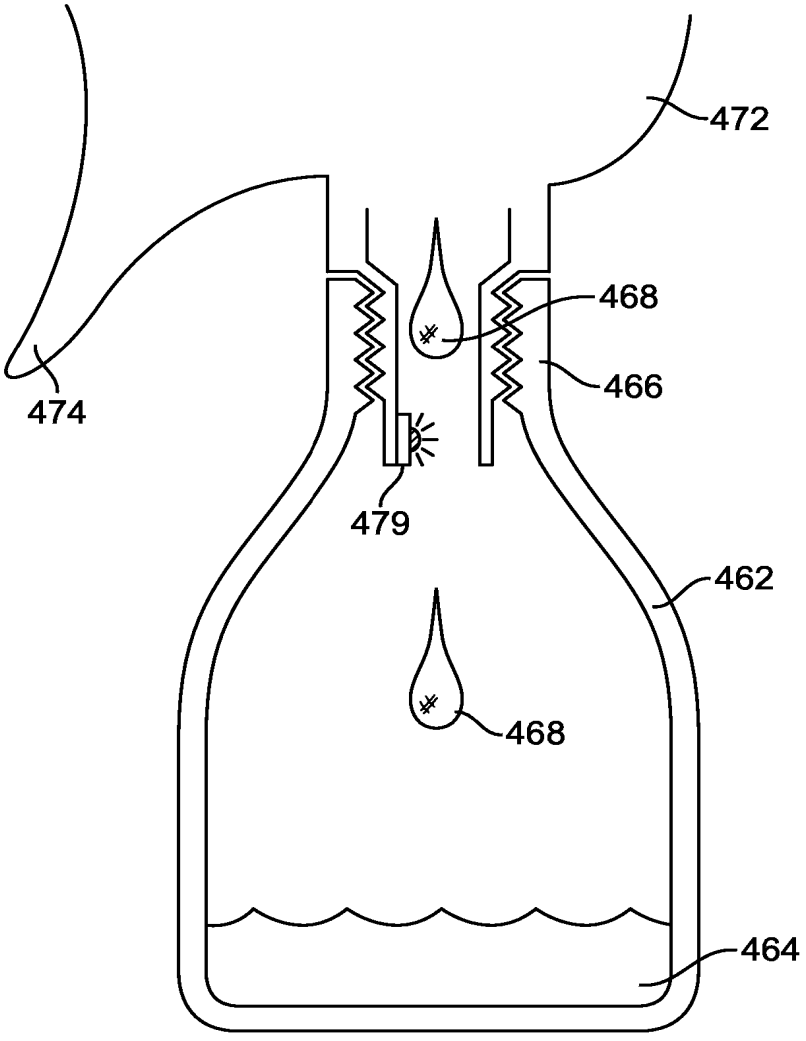


FIG. 11E

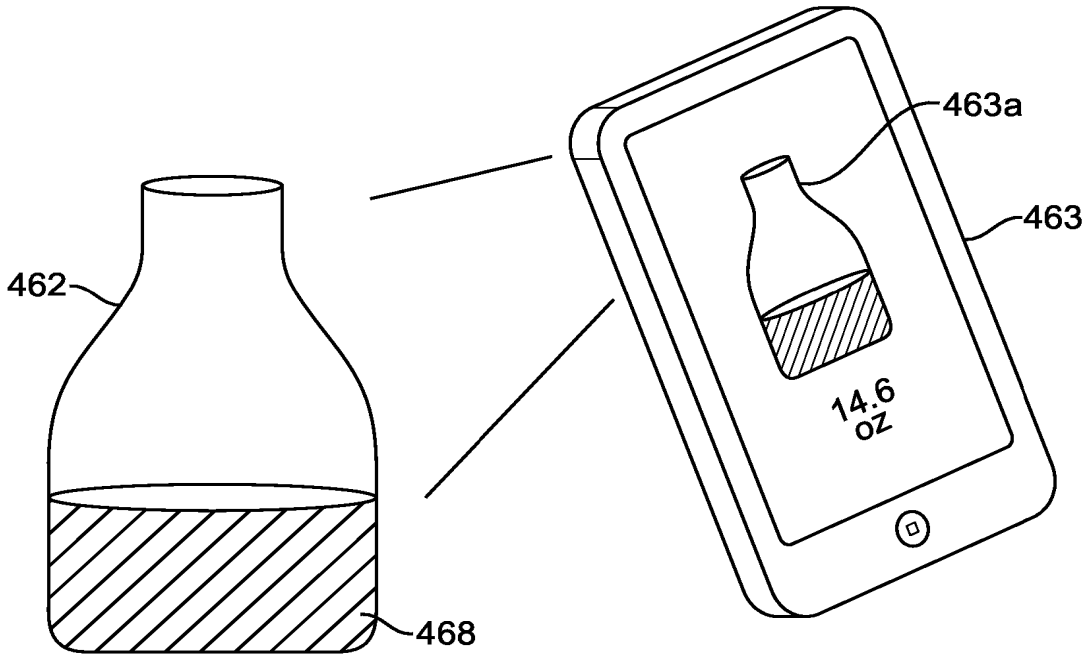


FIG. 11F

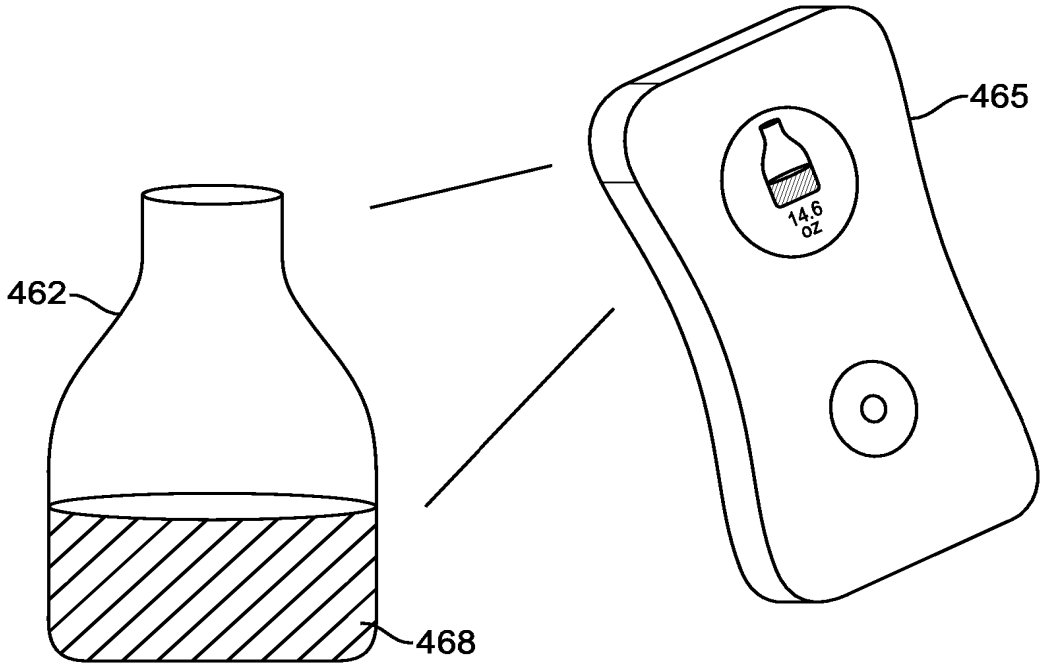


FIG. 11G

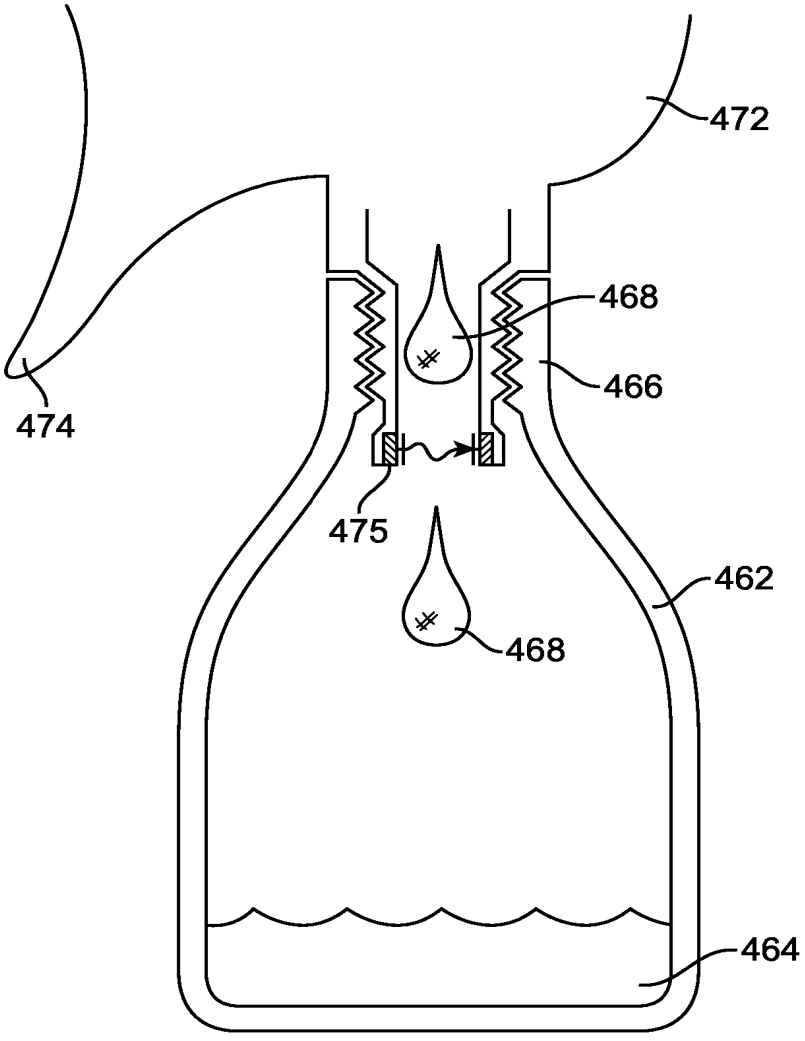


FIG. 11H

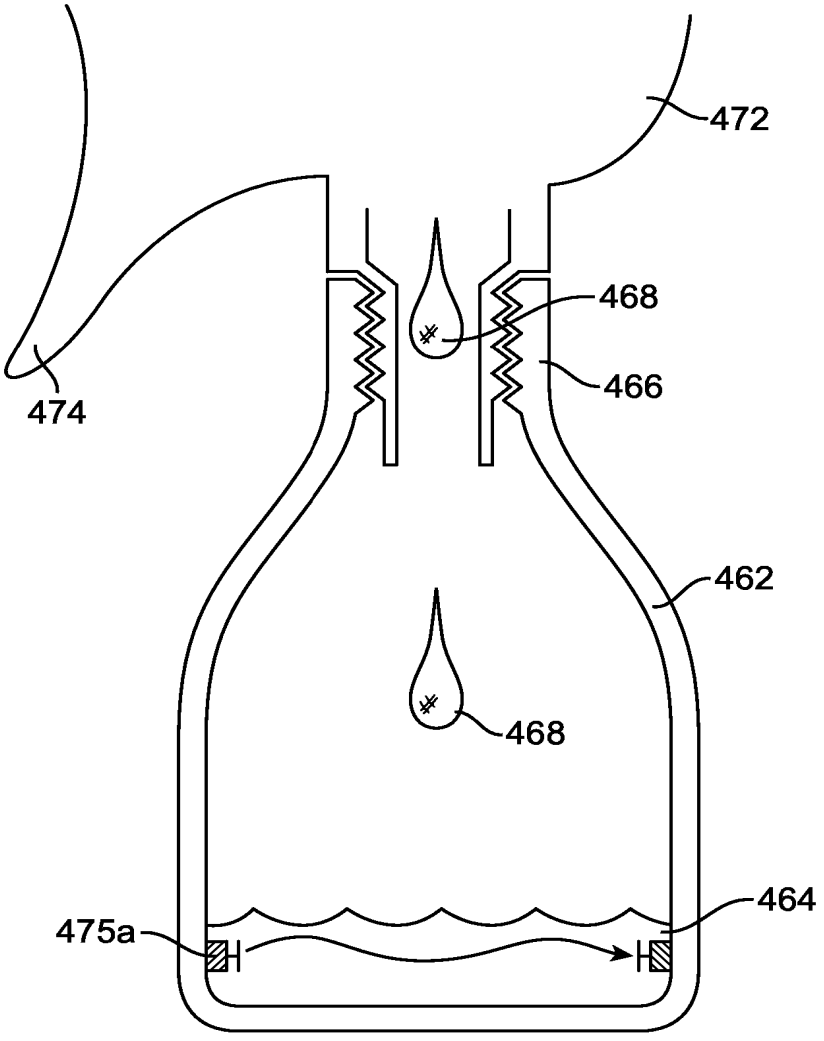


FIG. 11I

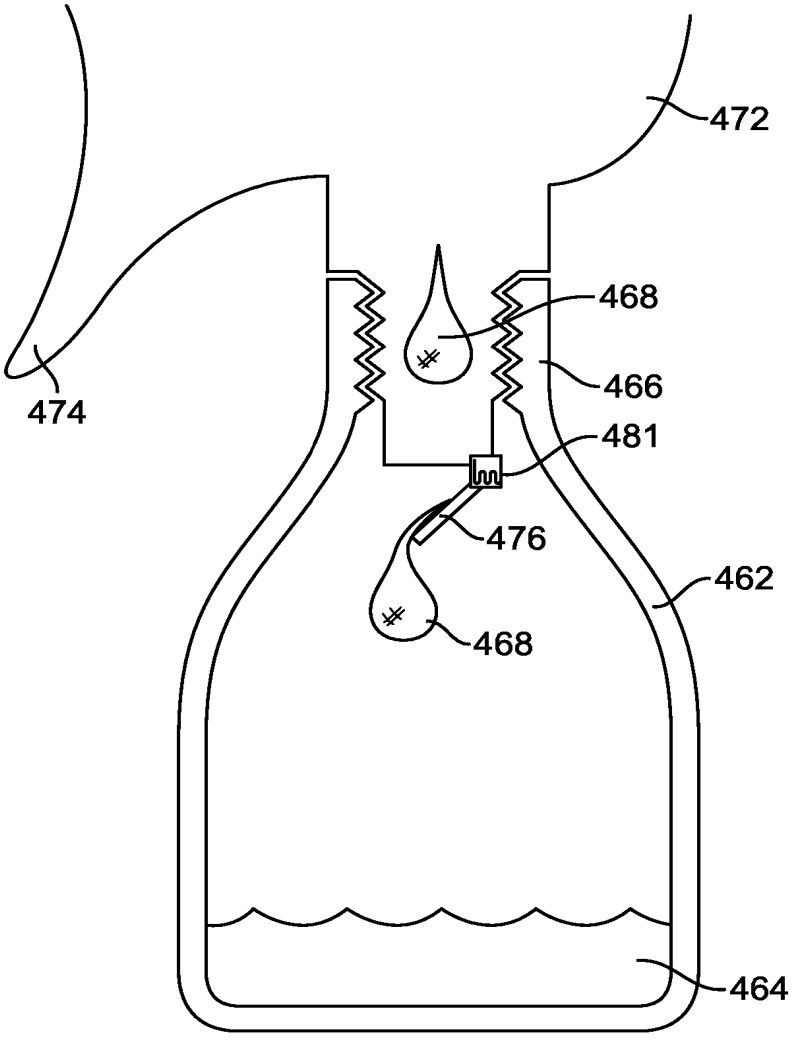


FIG. 11J

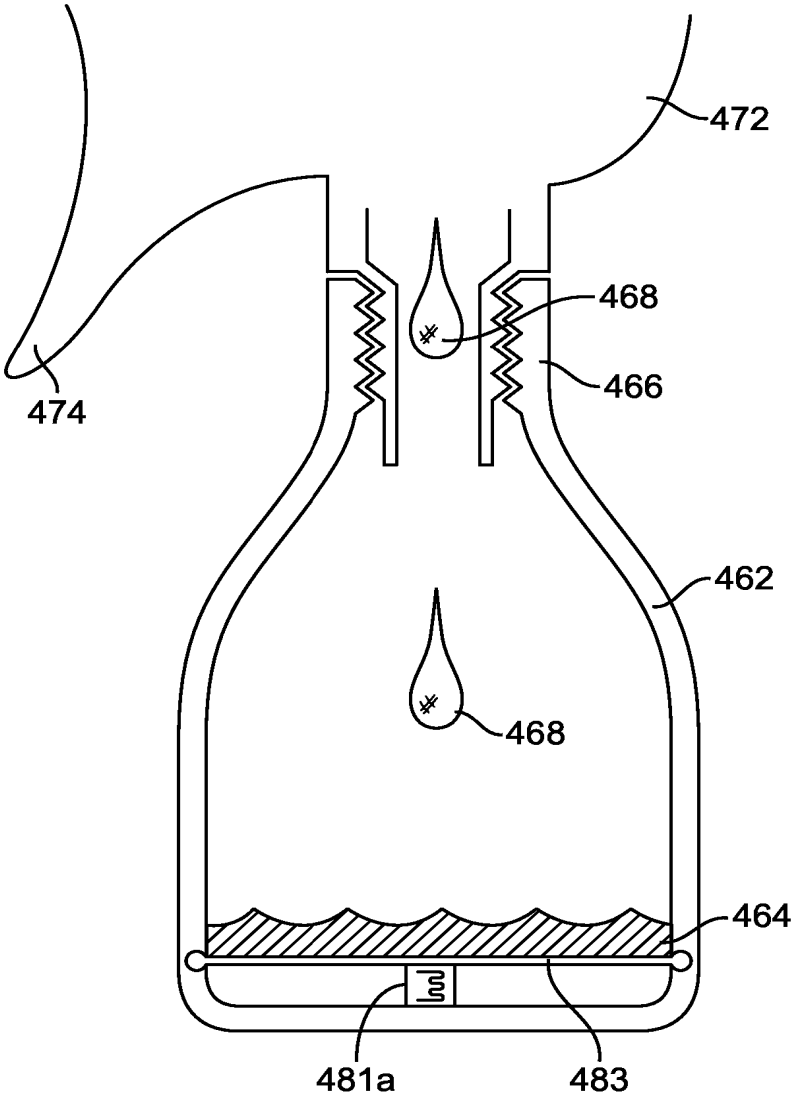


FIG. 11K

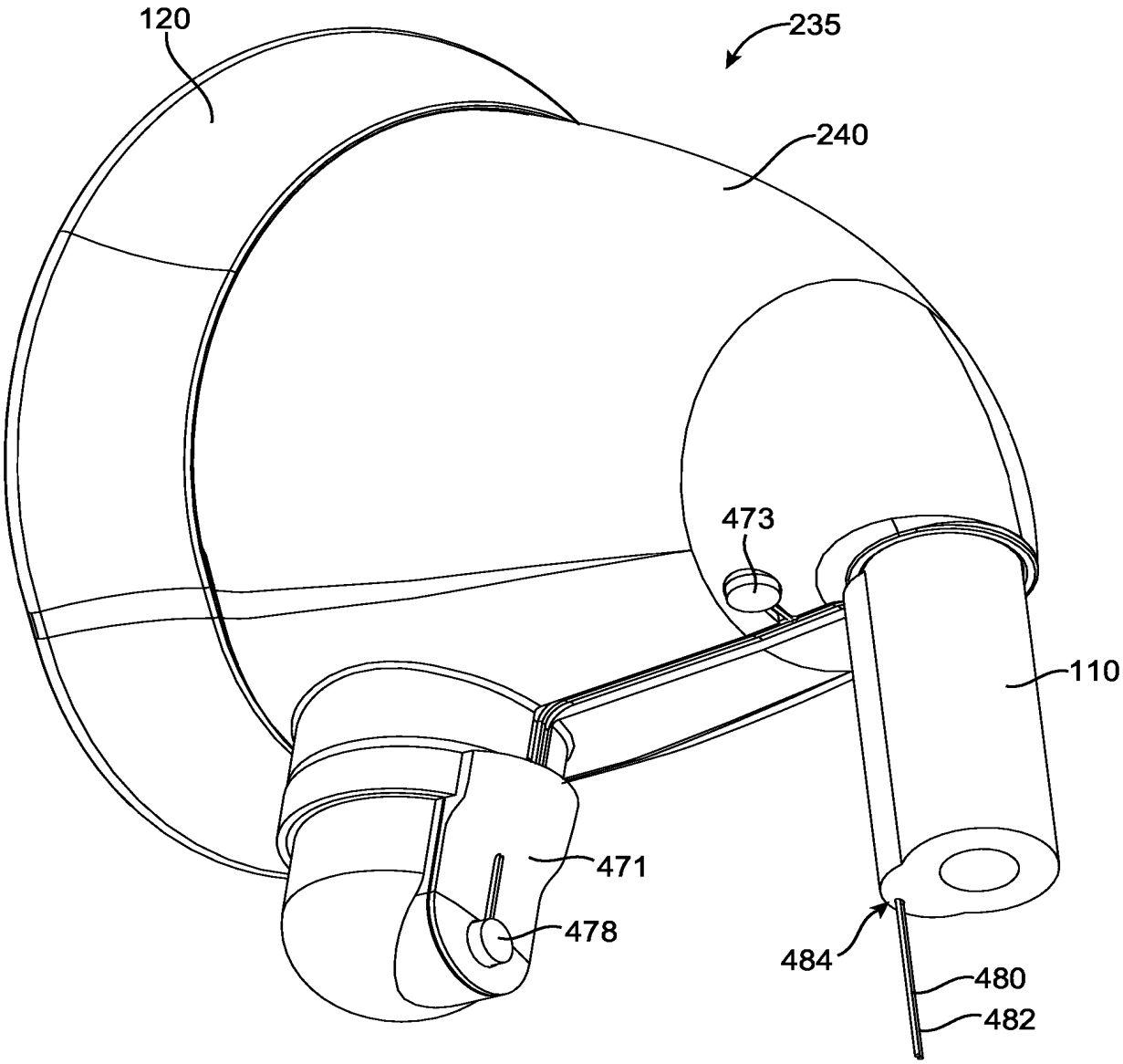


FIG. 11L

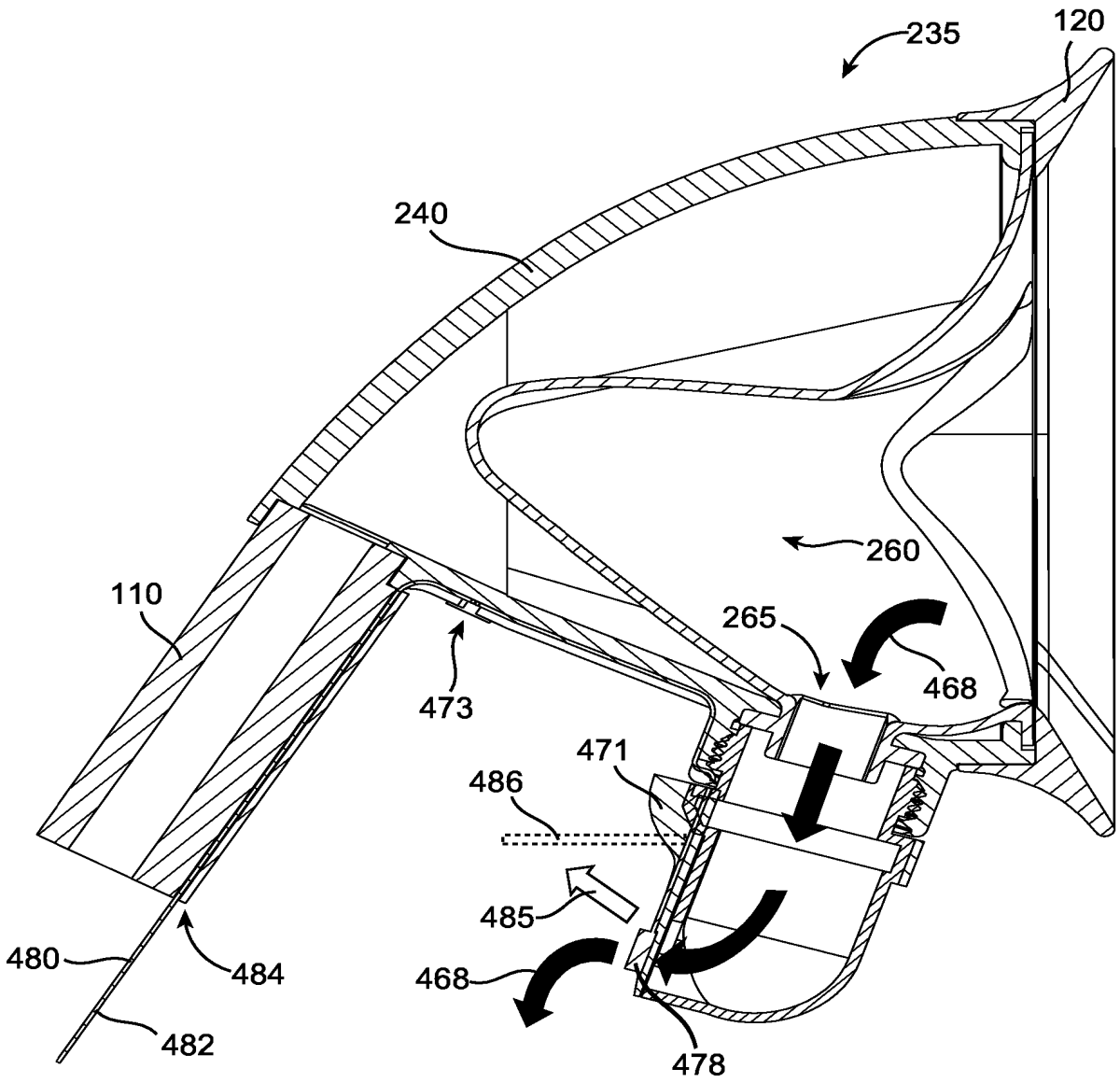


FIG. 11M

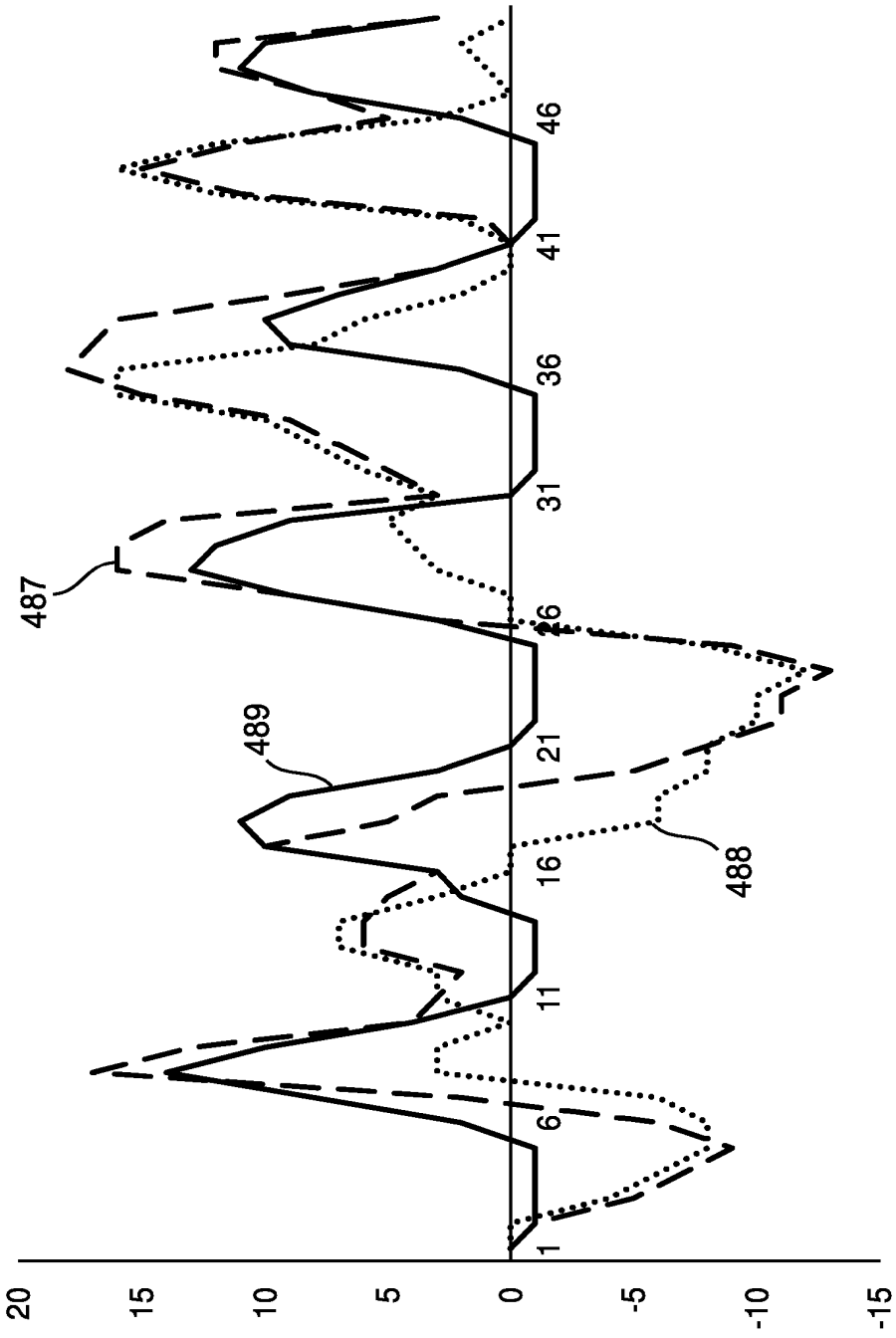


FIG. 11N

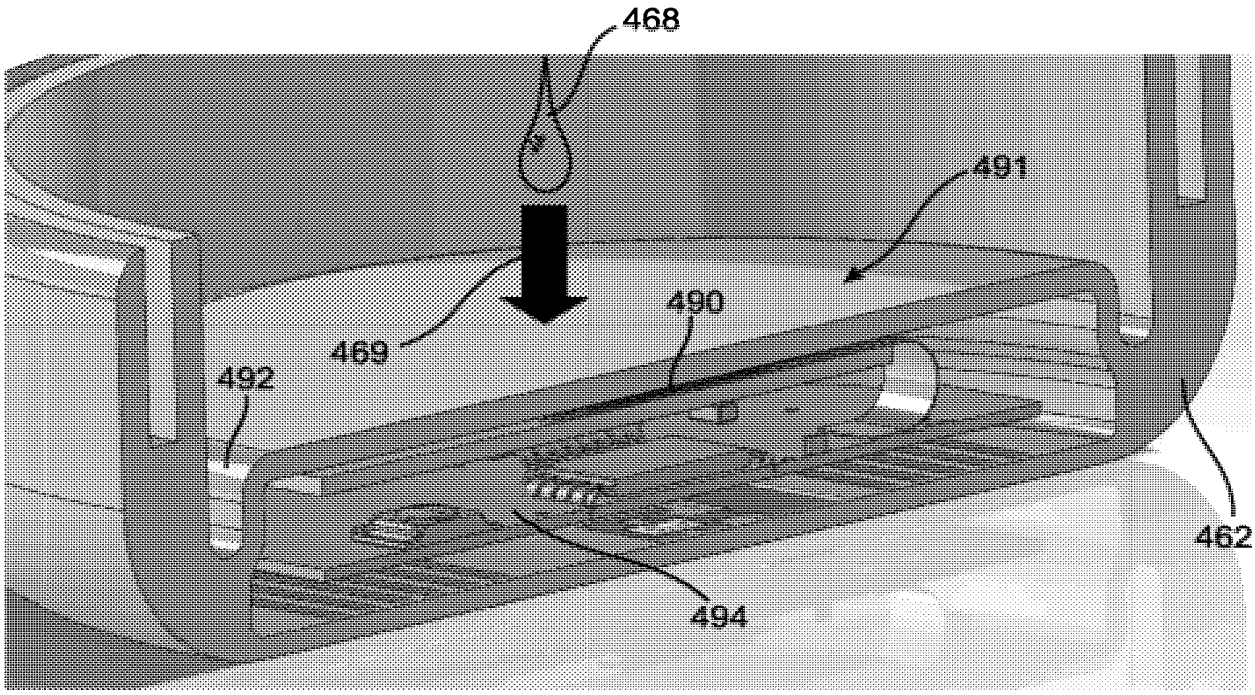


FIG. 11O

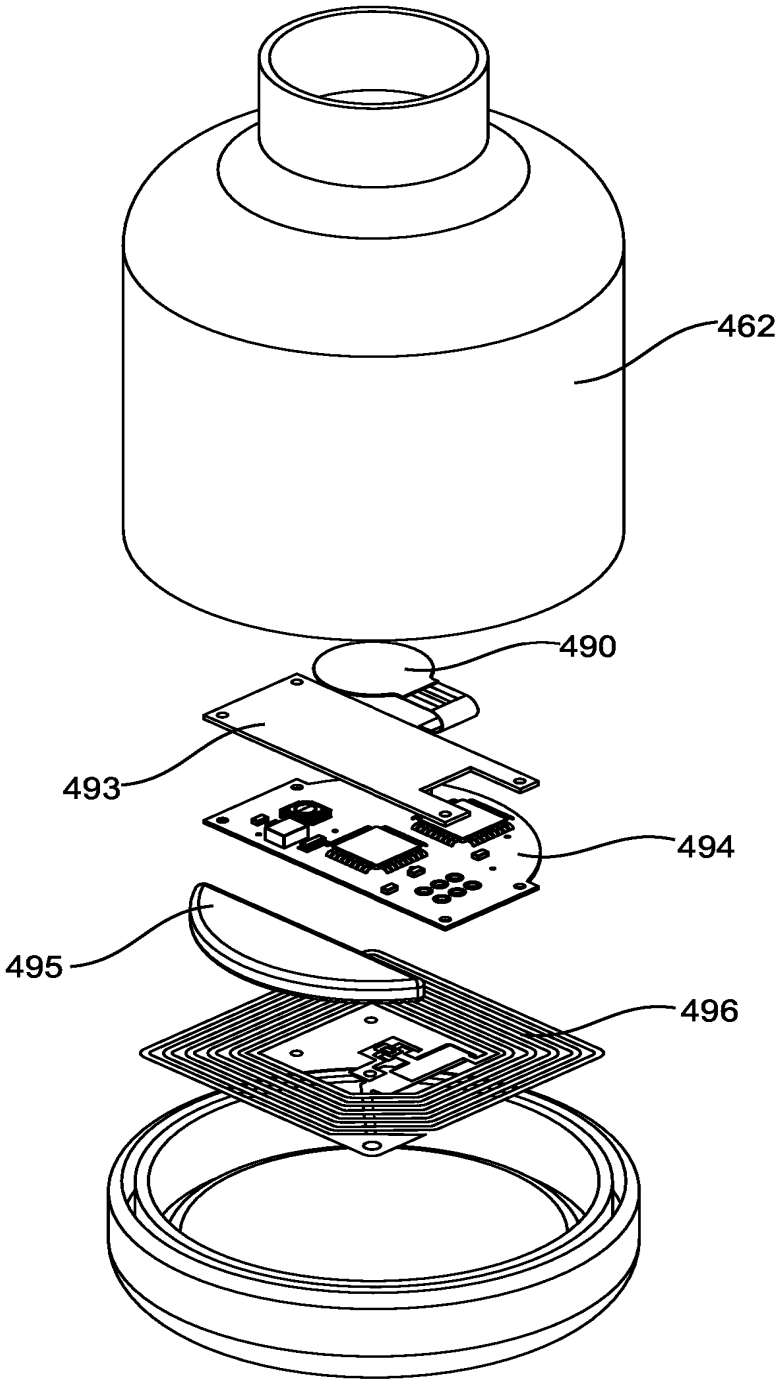


FIG. 11P

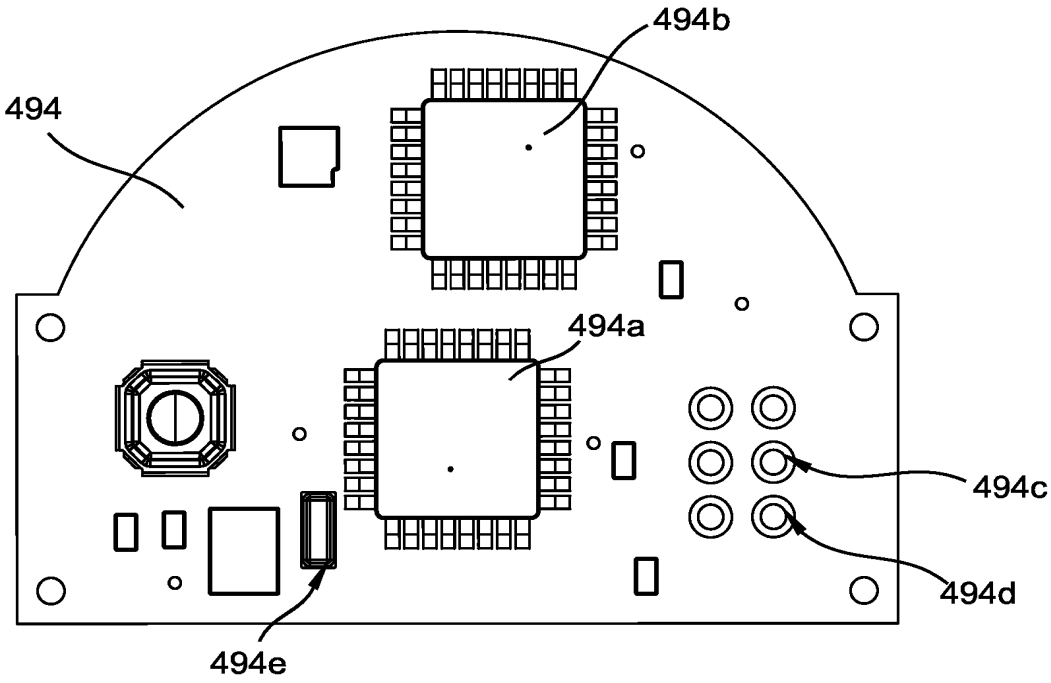


FIG. 11Q

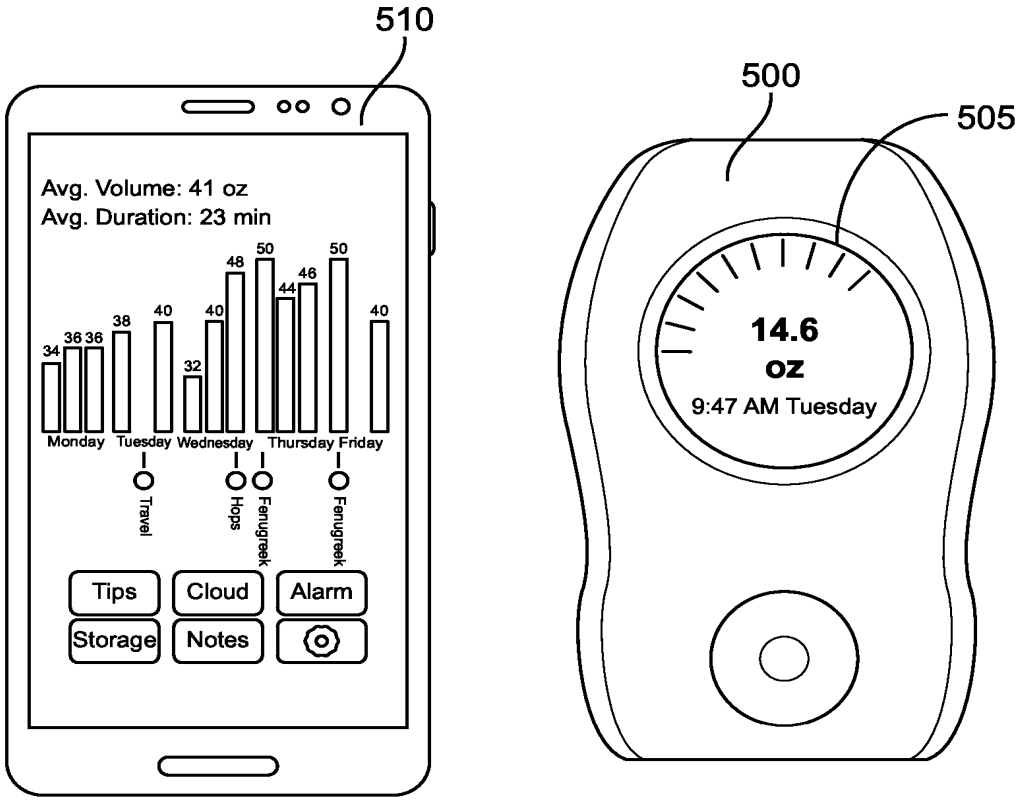

510
500
505
Avg. Volume: 41 oz
Avg. Duration: 23 min
34 36 36 38 40 32 40 48 50 44 46 50 40
Monday Tuesday Wednesday Thursday Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 12

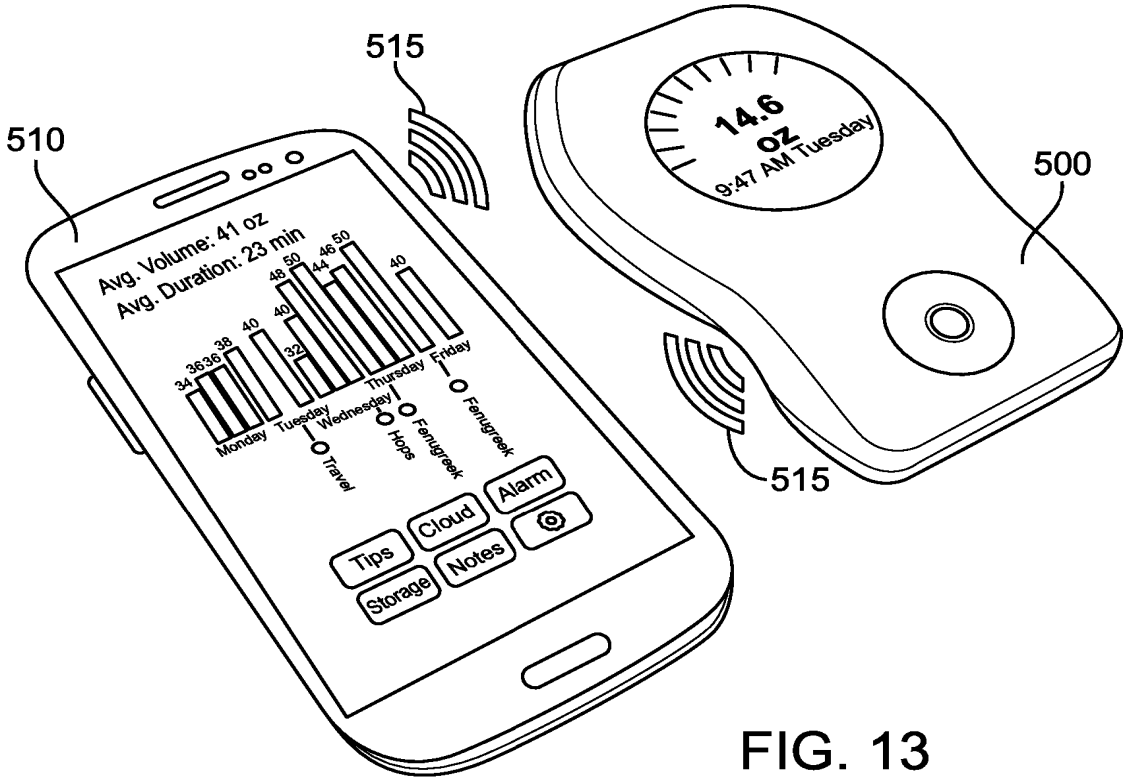

515
510
500
Avg. Volume: 41 oz
Avg. Duration: 23 min
34 36 36 38 40 32 40 48 50 44 46 50 40
Monday Tuesday Wednesday Thursday Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday
515

FIG. 13

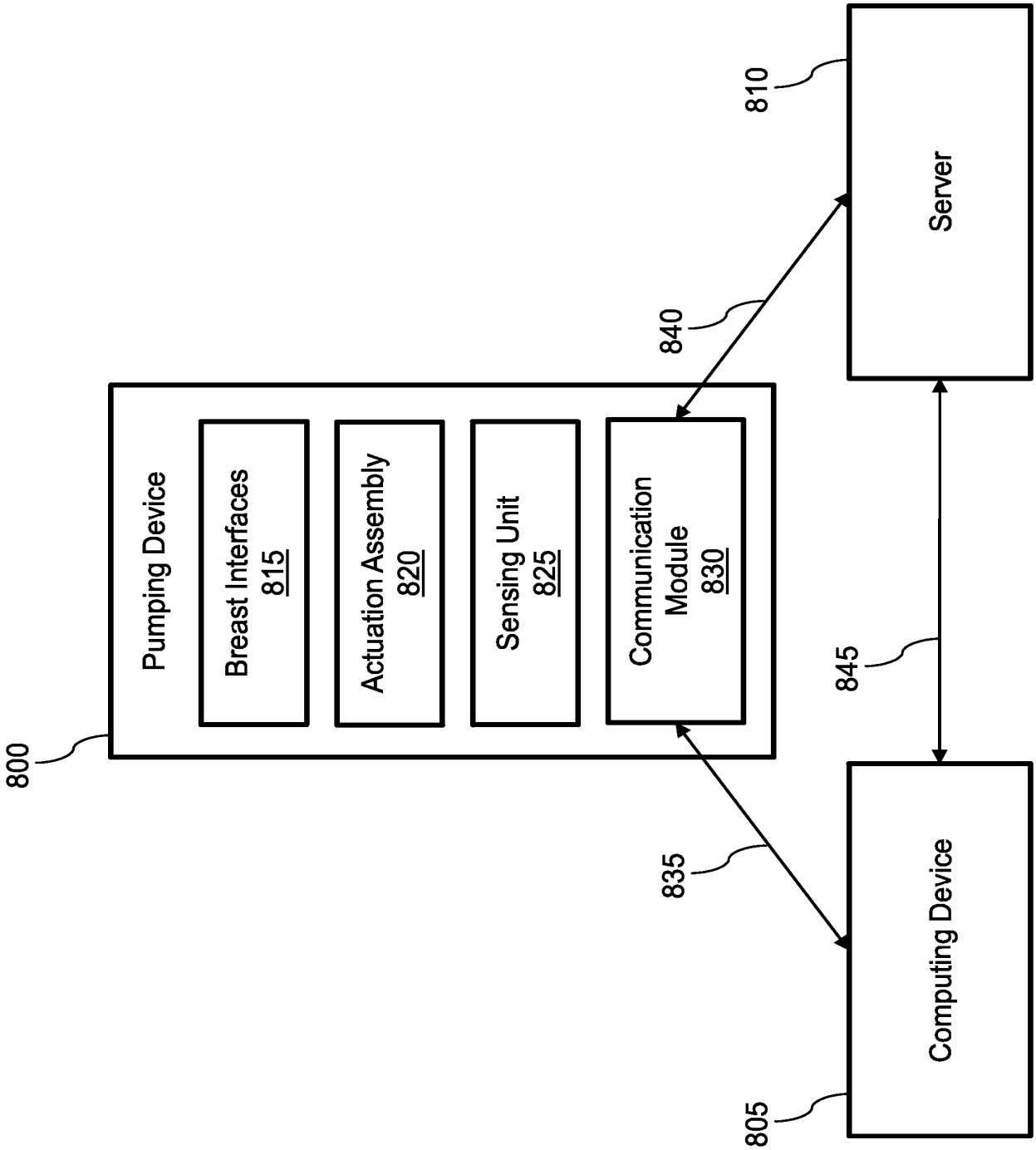

Server
810
840
Pumping Device
Breast Interfaces
815
Actuation Assembly
820
Sensing Unit
825
Communication
Module
830
800
845
835
Computing Device
805

FIG. 14

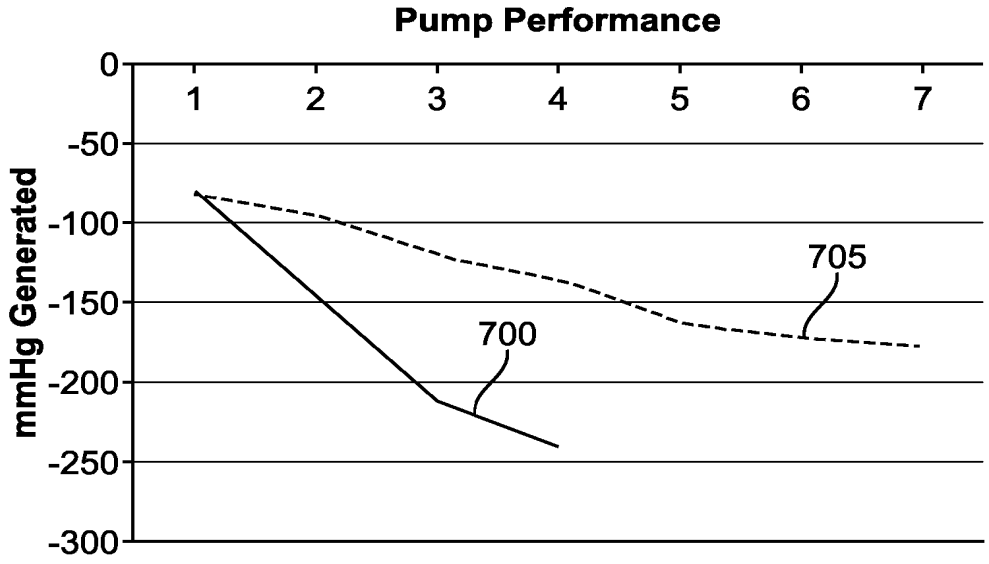

Pump Performance
0
-50
-100
-150
-200
-250
-300
mmHg Generated
1
2
3
4
5
6
7
705
700

FIG. 15

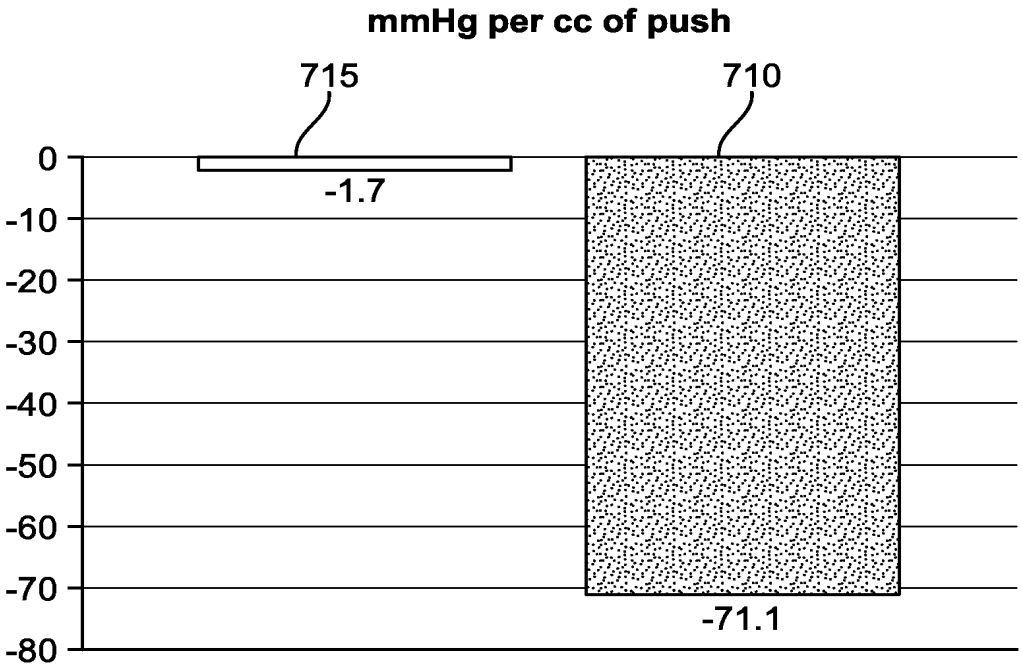


FIG. 16

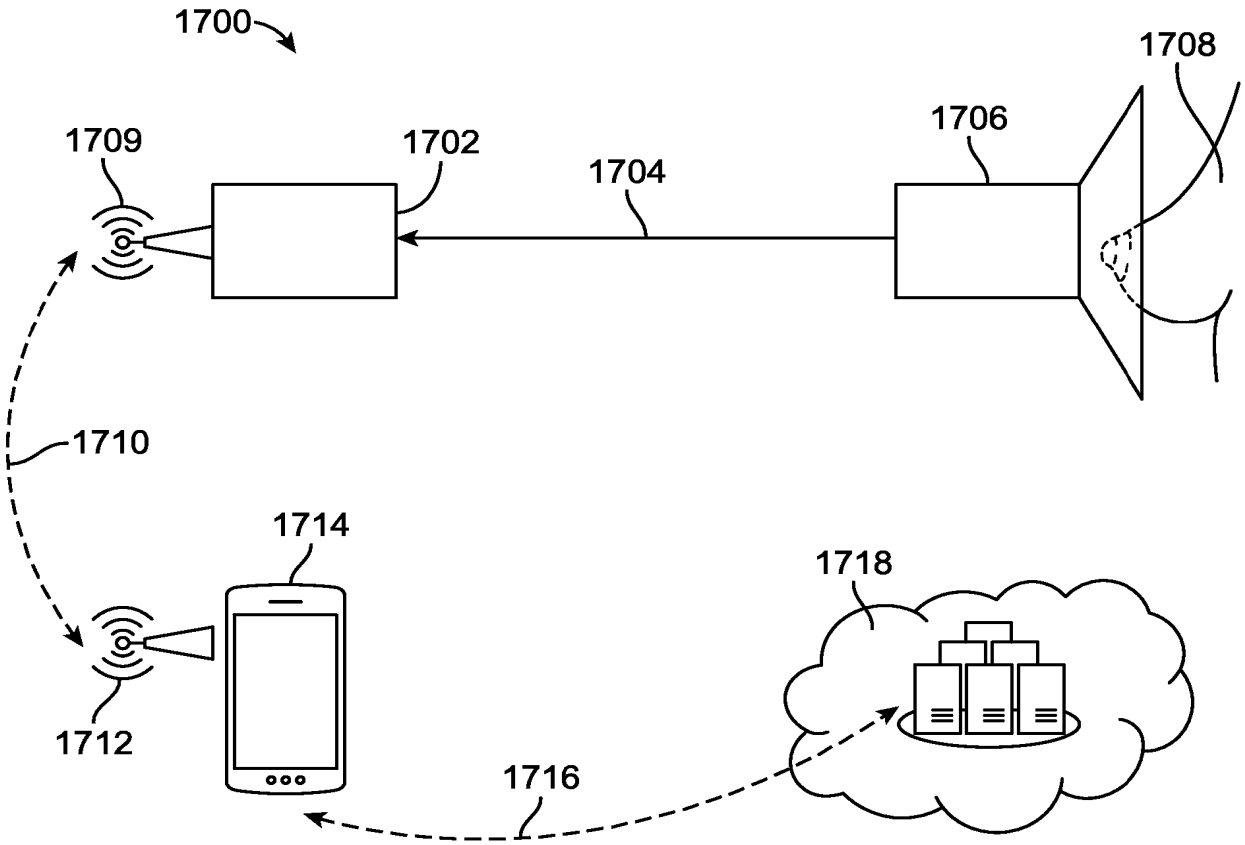


FIG. 17

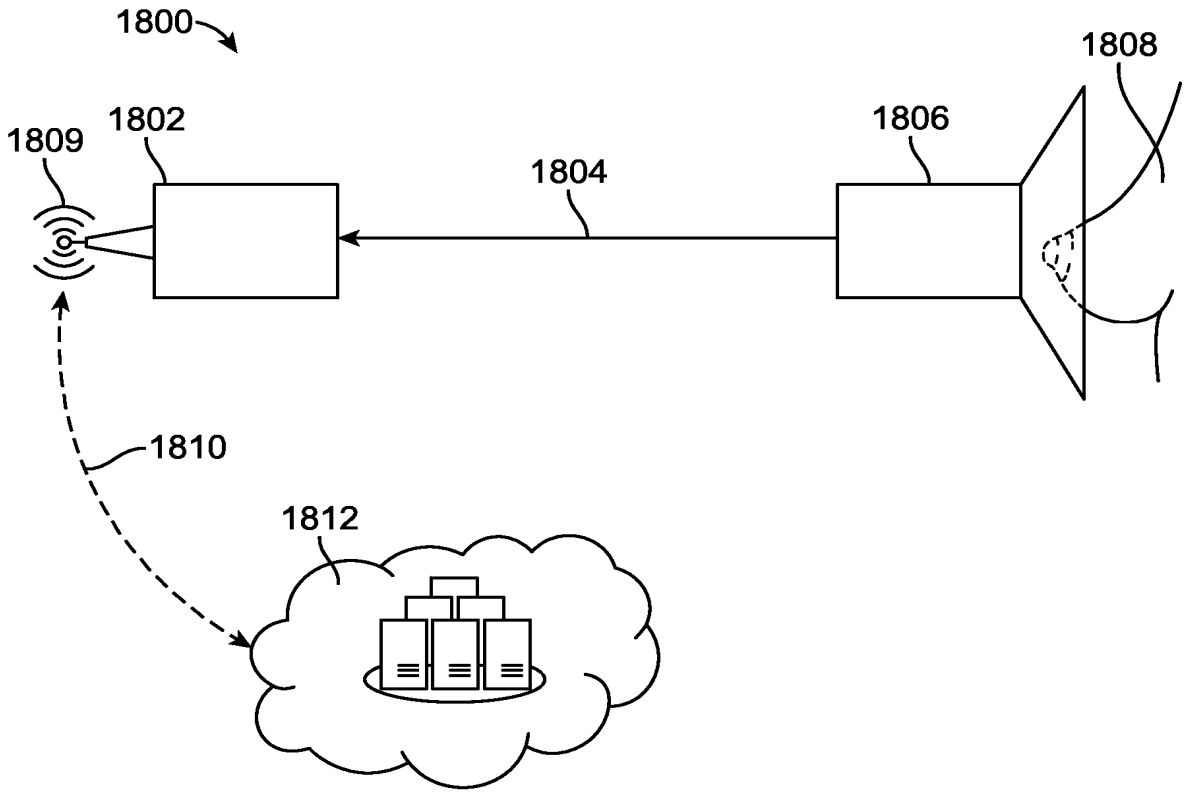


FIG. 18

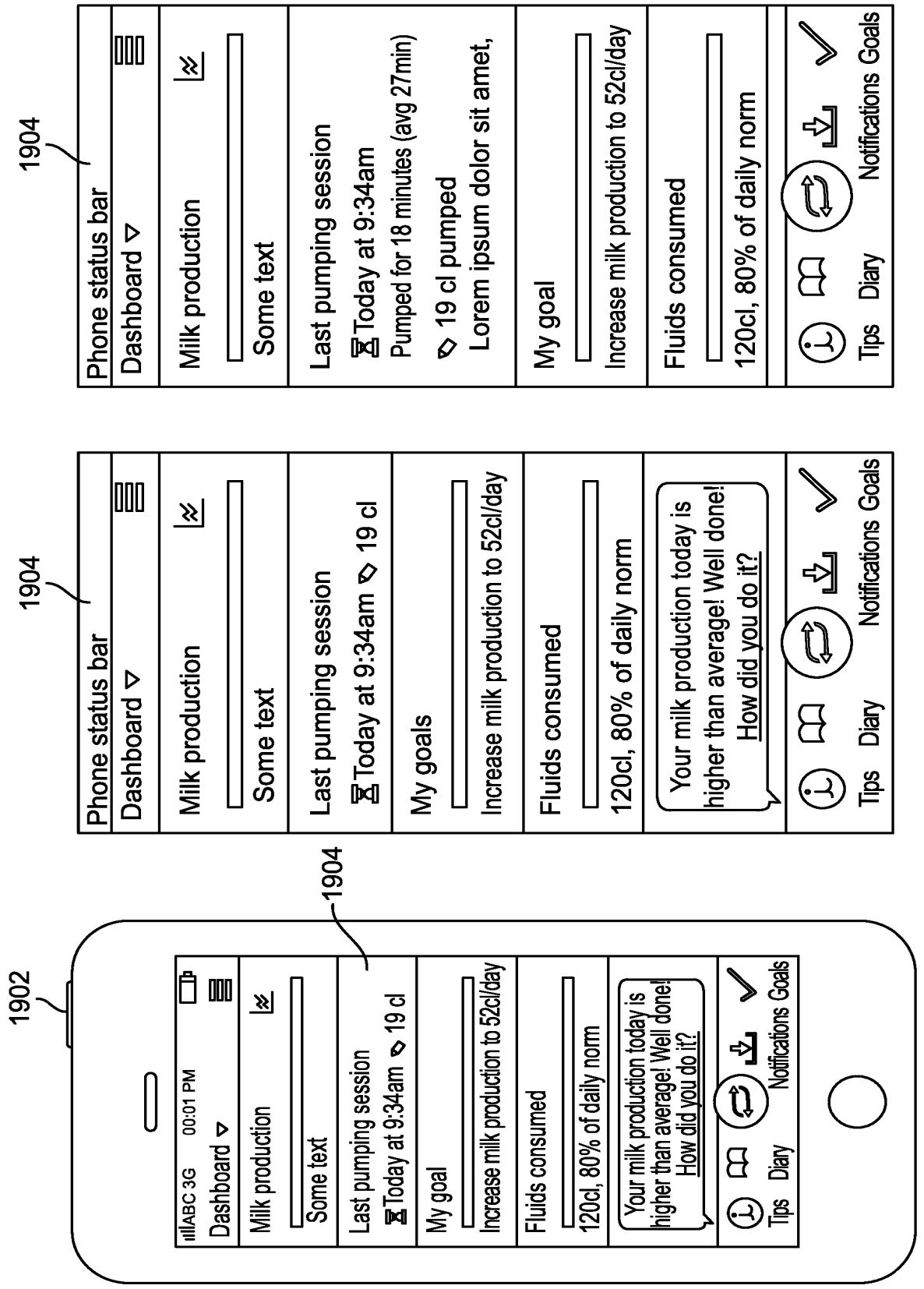


FIG. 19A

FIG. 19B

FIG. 19C

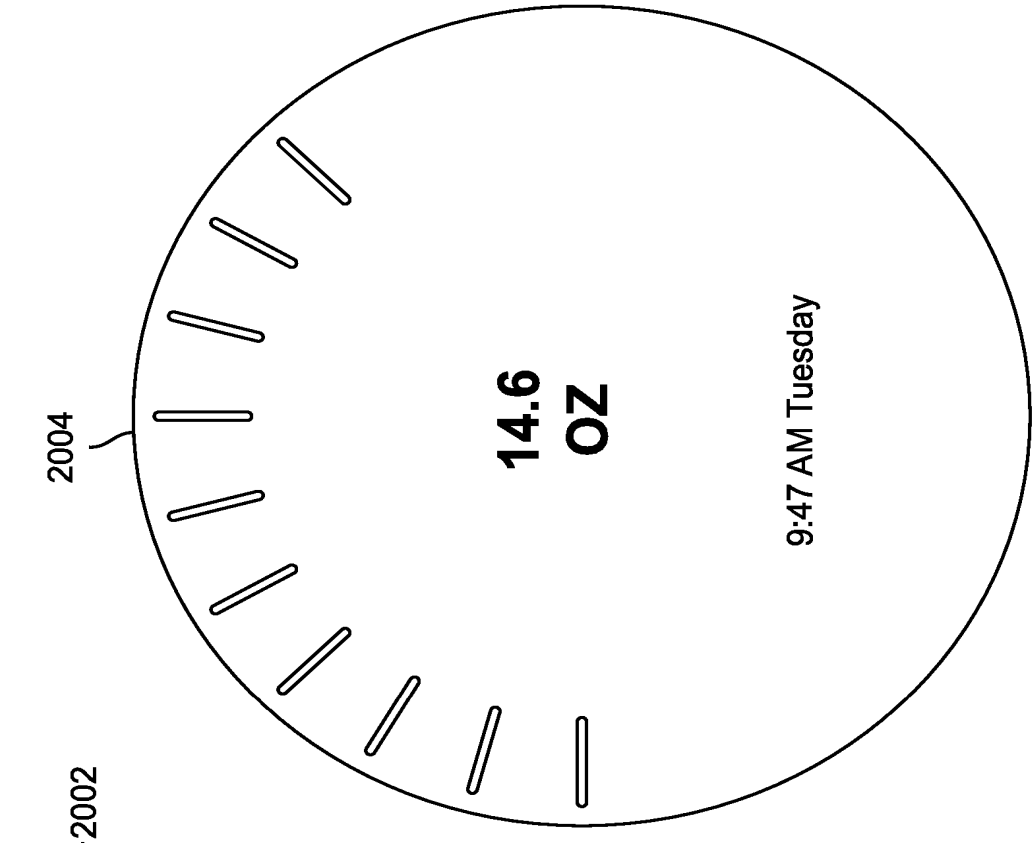


FIG. 20B

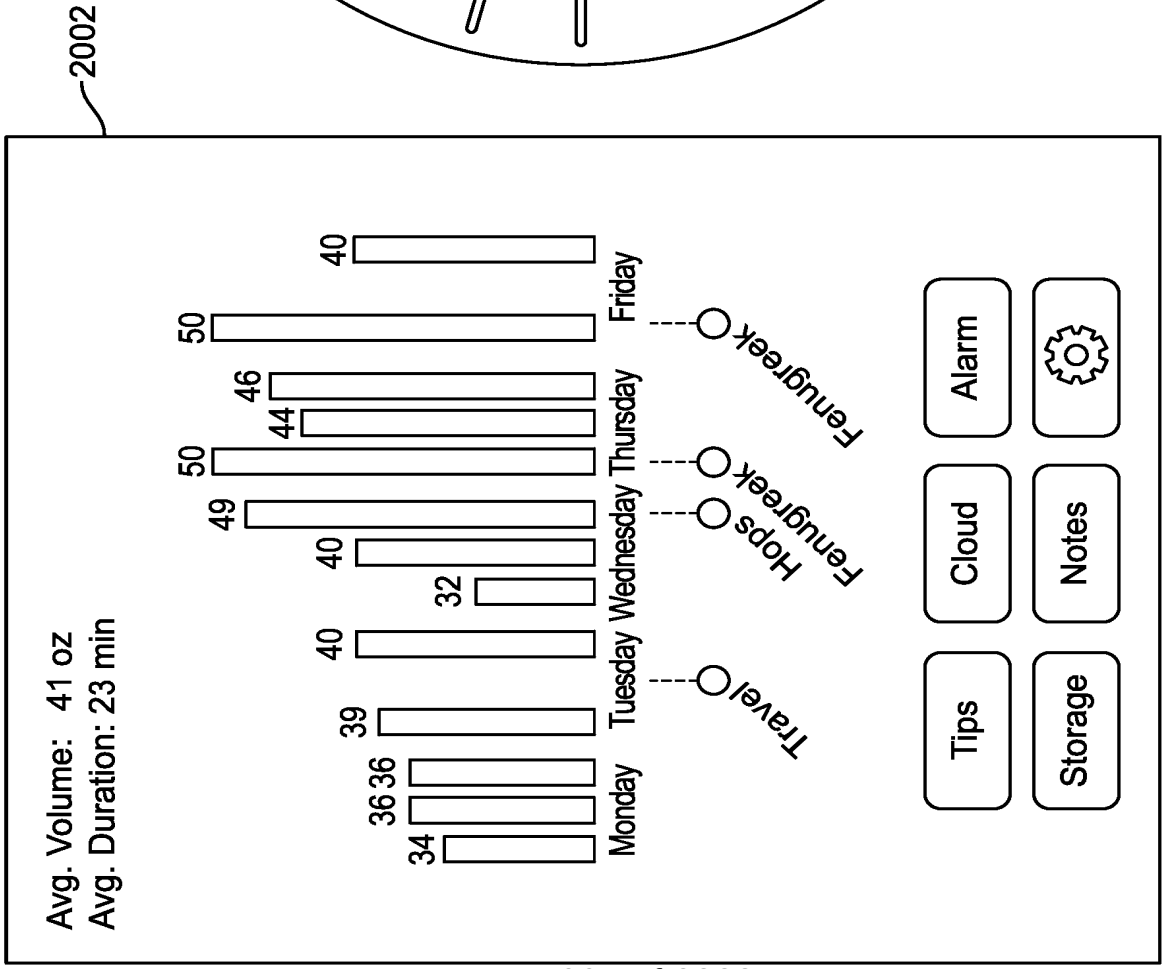


FIG. 20A

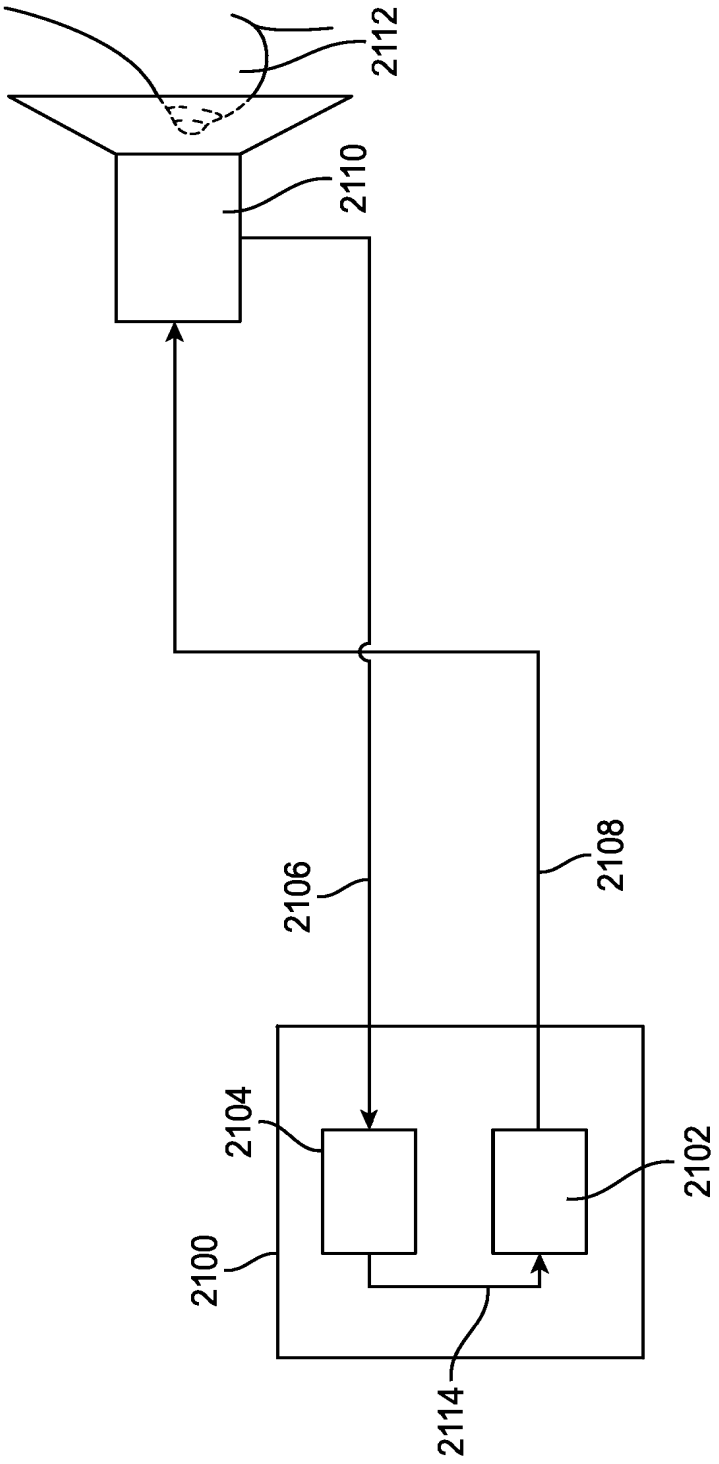


FIG. 21

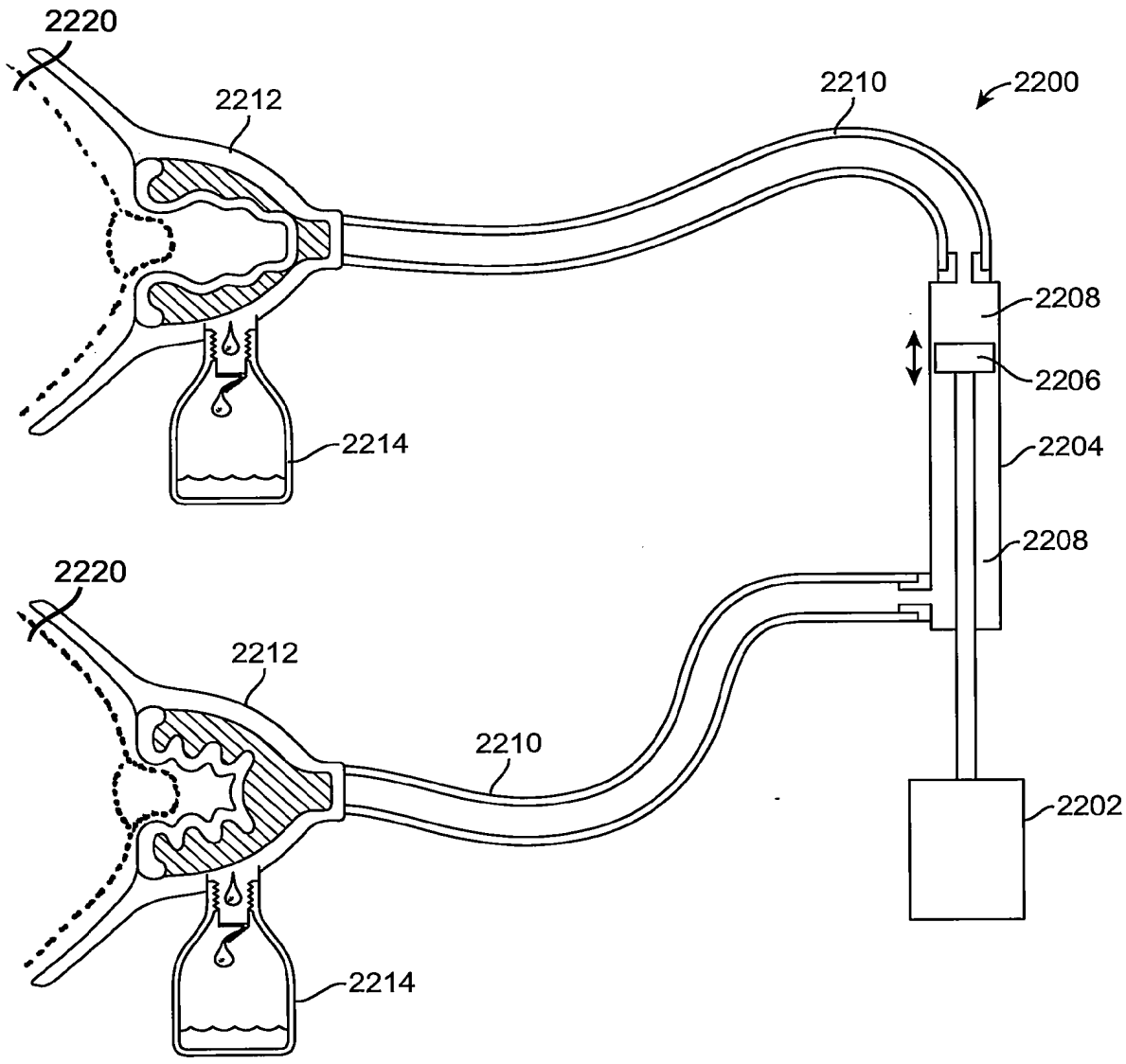

2220
2212
2210
2200
2208
2206
2214
2204
2208
2220
2212
2210
2202
2214

FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A01J 5/00, 5/007; A61M 1/06 (2015.01)
CPC - A01J 5/047; A61M 1/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A01J 5/00, 5/007; A61M 1/06 (2015.01)
CPC: A01J 5/047; A61M 1/06; USPC: 119/14.02; 604/74, 346

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google; Google Scholar; Google Patent; ProQuest; Medline/PubMed. Search terms: Breast*, Milk*, Mammar* W5 Pump*, Express*, Vacuum*, Draw*, Computer*, Processor*, CPU, Microprocess*, Data*, Internet*, Server*, Informat*, Network*, Wireless*, Near, Field, USB, Connect*, Communicat*, Transfer*, SMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6547756 B1 (GRETER, A, et al.) April 15, 2003; abstract; figure 1; column 2, lines 24-37; column 5, lines 46-57; column 7, lines 53-56; column 8, lines 8-11; column 9, lines 39-55; claims 8,20, 25, 29-31	1, 3-8, 14, 15, 19, 22-24, 28, 30-33, 38, 39, 45, 48, 49
Y		2, 9-13, 16-18, 20, 21, 25, 26, 29, 34-37, 40-44, 46, 47, 50
Y	US 2010/0121266 A1 (BRYAN, RG et al.) May 13, 2010; figure 2; paragraph [0070]	2, 29
Y	US 2007/0209595 A1 (UMEGARD, A, et al.) September. 13, 2007; paragraphs [0016], [0023]-[0024]; claim 10	9-13, 25, 26, 34-37, 46, 47, 50
Y	WO 00/41744 A1 (TAGGART MEDO) July 20, 2000; page 2, lines 10-21; page 11, lines 28-31; page 12, lines 1-2; claims 1, 7	16, 17, 20, 43
Y	WO 2013/070063 A1 (LELY PATENT N.V.) May 16, 2013; page 6, fourth paragraph	18, 44
Y	US 2013/0125821 A1 (GIBBS, RN et al.) May 23, 2013; paragraphs [0053], [0054]	20, 21, 40-42
A	US 2010/0284251 A1 (CHANG, S) November 11, 2010; abstract; paragraph [0004]	1-26, 28-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 April 2015 (30.04.2015)	08 JUL 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-26 and 28-50 are directed toward a method, system and apparatus for measuring milk expression from a breast.

Group II: Claims 27 and 51 are directed toward a method for controlling and remotely controlling expression of milk from a breast comprising receiving a control signal from a server via a network.

Group III: Claims 52-91 are directed toward an apparatus and method for measuring the volume of fluid expressed from a breast, comprising: a sensing unit configured to generate measurement data indicative of volume of expressed fluid from the breast.

-***-Continued Within the Extra Sheet-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26, 28-50

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Continuation of Box No. III - Observations where unity of invention is lacking:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include transmitting the measurement data from the sensing unit to a computing device via a data connection, which are not present in Groups II-III; the special technical features of Group II include receiving a control signal from a computing device via a data connection, which are not present in Groups I and III; the special technical features of Group III include generating, via the sensing unit, measurement data indicative of volume of the expressed fluid, which are not present in Groups I-II.

The common technical features of Groups I, II and III are an apparatus, system and method relating to expression of fluid/milk from a breast, comprising: providing a breast fluid expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit; engaging the interface with a breast; actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast; expressing fluid from the breast.

These common technical features are disclosed by US 6,547,756 B1 to Greter et al. (hereinafter 'Greter'). Greter discloses an apparatus, system and method relating to expression of fluid/milk from a breast (breastpump which can be programmed to generate a plurality of differing milk expression sequences; abstract), comprising: providing a breast fluid expression apparatus comprising an interface (breastpump with breastshield; claim 1), an actuation assembly operably coupled to the interface (programmable controller having an interface for the inputting of programs; figures 9-10; claim 1), and a sensing unit (sensing mechanism 78 uses a toothed wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b; signals generated by the counter 78b are processed by the cpu of the breastpump; column 7, lines 1-4); engaging the interface with a breast (a breastshield having a portion within which a woman's breast is received for the expression of milk; claim 1); actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast (a source of vacuum in communication with said breastshield; claim 11); expressing fluid from the breast (claim 1).

Since the common technical features are previously disclosed by the Greter reference, the common features are not special and so Groups I, II and III lack unity.

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(54) **Title**: BREAST PUMP AND EXPRESSION KIT FOR A BREAST PUMP

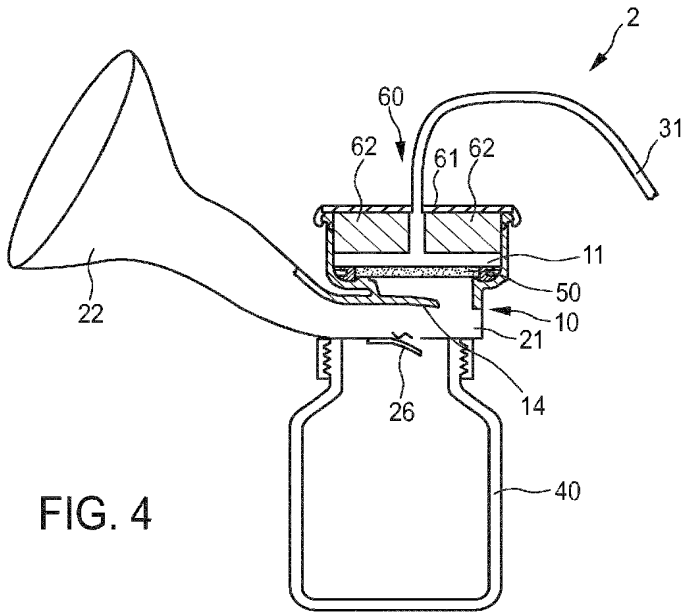


FIG. 4

(57) **Abstract**: The present invention relates to an expression kit (2) for a breast pump (1) for extracting breast milk (101) from a human teat (102). The expression kit (2) comprises: a breast pump body (10) comprising a first pressure chamber (11) and a second pressure chamber (21); wherein the first pressure chamber (11) is configured for connection to a pressure unit (30) for generating a in the pressure chamber (11); wherein the second pressure chamber (21) comprises a breast-receiving funnel (22), a milk outlet (23) and a milk path (24) from the breast- receiving funnel (22) to the milk outlet (23); and wherein the first and the second pressure (11, 21) chamber are separated by a breathable membrane (50), which is gas-permeable and liquid-impermeable, for separating the first pressure chamber (11) from liquid in the milk path (24), wherein the breathable membrane (50) is a hydrophobic membrane. Further, the present invention relates to a breast pump (1).

WO 2015/150225 A1

Breast pump and expression kit for a breast pump

FIELD OF THE INVENTION

The present invention relates to a breast pump for extracting breast milk from a human teat, and more specifically to an expression kit for a breast pump.

BACKGROUND OF THE INVENTION

A breast pump is a device used by mothers for expressing their breast milk into a baby-feeding bottle. The milk is typically expressed by generating a negative pressure in a vacuum chamber of the breast pump in which the teat is positioned. The part of the breast pump which is applied to the breast can be referred to as an expression kit.

For hygienic reasons, most breast pumps use a diaphragm. A non-permeable resilient silicone diaphragm acts as a hygienic shield between the breast and the vacuum pump. For creating a vacuum at the breast, the diaphragm has to make a stroke. The vacuum pump causes the diaphragm to flex thereby expanding the air in the vacuum chamber. This expansion creates the required vacuum at the breast. When the vacuum at the pump side is released, the resilient diaphragm will move to its rest position again. Since the vacuum at the vacuum pump is indirectly causing the vacuum at the breast, the hygienic function is implemented. This concept is well-established and has been used in the industry for many years.

US 2012/0116299 A1 discloses a breast pump, wherein a deformation of a non-permeable resilient silicone membrane as the diaphragm creates a negative pressure in the vacuum chamber.

WO 2014/045159 A1 discloses a further breast pump with a non-permeable deformable membrane as the diaphragm. The breast pump comprises a limiter to limit a deformation of the membrane. A stroke volume of the membrane can thus be limited.

WO 2008/057218 A2 discloses a further conventional breast pump with a non-permeable resilient diaphragm as a barrier which prevents contamination from entering a vacuum pump air line.

Since the diaphragm has to make a stroke for creating the vacuum at the breast, a large air volume is required. The stroke can only be made when there is a

sufficiently large air volume available in the breast pump for the displacement of the diaphragm. Thus, the required air volume limits the minimum size of the breast pump.

US 5,071,403 relates to protecting the pump of a breast pump from fouling by milk. Air being drawn toward the vacuum pump passes through a porous body disposed in an air passage interconnecting the vacuum pump and a breast-contacting hood. When milk reaches the porous body and wets it, air may no longer pass through the porous body at least where the porous body is wet. Depending upon the extent of contact of milk with the porous body, the amount of vacuum that reaches an interior of the breast-receiving hood is reduced or eliminated, thereby reducing or eliminating further expression of milk. The continued flow of air to the vacuum pump is reduced or halted in order to protect the pump. Hence, the hydrophilic porous body serves as a barrier across a vacuum line that protects the pump.

US 2003/004459 A1 discloses a breast pump with an optional hydrophilic filter for added isolation of the vacuum pump and vacuum lines.

US 2007/135761 A1 discloses a breast pump with a liquid crystal display which can display information about the usage of the breast pump such as volume of milk pumped.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a more compact expression kit, while keeping the vacuum pressure at the breast unchanged compared to conventional breast pumps. It is a further object to provide hygienic function of the expression kit and breast pump, in particular in rental and/or hospital use.

In a first aspect of the present invention an expression kit for a breast pump for extracting breast milk from a human teat is presented, the expression kit comprising:

- a breast pump body comprising a first pressure chamber and a second pressure chamber,
- wherein the first pressure chamber is configured for connection to a pressure unit for generating a pressure in the first pressure chamber,
- wherein the second pressure chamber comprises a breast-receiving funnel, a milk outlet and a milk path from the breast-receiving funnel to the milk outlet, and
- wherein the first and the second pressure chamber are separated by a breathable membrane, which is gas-permeable and liquid-impermeable, for separating the first pressure chamber from liquid in the milk path, wherein the breathable membrane is a hydrophobic membrane.

In a further aspect of the invention a breast pump for extracting breast milk from a human teat is presented, the breast pump comprising:

- an expression kit as described above, and
- a pressure unit for generating a pressure.

Preferred embodiments of the invention are defined in the dependent claims. It shall be understood that the claimed breast pump has similar and/or identical preferred embodiments as the claimed expression kit and as defined in the dependent claims.

Instead of using a non-permeable silicone diaphragm according to the prior art, it is suggested to use a breathable membrane, which is gas-permeable and liquid-impermeable for separating the first pressure chamber from the milk path. The inventors thereby break with the well-established concept of strictly separating breast and pressure unit with a diaphragm which is impermeable for gas and liquid.

When a woman's breast is placed in the breast-receiving funnel, that opening of the second pressure chamber is sealed closed. Accordingly, when a milk receptacle such as a baby-feeding bottle is connected to the milk outlet, that opening of the second pressure chamber is sealed closed. The skilled person will appreciate that the term sealed in this context is not limited to hermetically sealed but also allows a minor leakage as long as the breast milk can be extracted. The breast-receiving funnel is in fluid communication with the milk outlet via the milk path.

In operation, the pressure unit may generate a pressure, for example a negative pressure or vacuum, in the first pressure chamber. Due to the breathable membrane between the first pressure chamber and the second pressure chamber, this causes a corresponding vacuum in the second pressure chamber for extracting breast milk from the teat. If the negative pressure at the first pressure chamber is released, this causes a corresponding pressure in the second pressure chamber. For example, a sequence of vacuum and ambient pressure can mimic the sucking motion of a baby and stimulate lactation. Since the breathable membrane is permeable to air, a negative pressure can be generated in the second vacuum chamber without having to move a diaphragm. Hence, the space requirement reduces significantly.

In other words, there is no need for providing an air volume in the breast pump body for a movement of the resilient diaphragm. The volume for the movement of the resilient diaphragm is also referred to as ‘dead volume’. Hence, the dead volume for displacing the flexible silicone membrane can be omitted. As a first advantage, this increases the design freedom and enables a breast pump with reduced size and improved handling. As a

second advantage, the air volume which has to be displaced by the pressure unit reduces and thus a smaller and less expensive pressure unit can be used.

Furthermore, in contrast to conventional breast pumps, wherein a resilient silicone diaphragm has to be flexed, i.e., a significant amount of pump power is required for overcoming a spring force of the silicone diaphragm, the breathable membrane can provide a lower resistance for the pressure unit. This further supports the use of a smaller and less expensive pressure unit.

It should be noted that a silicone diaphragm for conventional breast pumps can be made in different hardnesses and shapes. All will have different elastic behaviors but all designs will require an optimization of the design to allow for a small pressure drop. A large area membrane allows for relatively small pressure drop across the diaphragm but will require a large diameter somewhere in the product, thereby limiting the design of the product. A smaller area will lead to more design freedom but to a larger pressure drop. This pressure drop will demand a more powerful vacuum pump. A more powerful vacuum pump, however, will be larger and/or more expensive. In contrast to the prior art, the solution according an aspect of to the present invention allows for a very small pressure drop and allows both a more compact and less expensive expression kit and breast pump.

Furthermore, the breathable membrane according an aspect of the present invention can be mounted in all kinds of shapes, such as single or double curved surfaces, while a moving diaphragm according to the prior art needs specific shapes in order to work efficiently.

As a further advantage, since the flexible, bending diaphragm is omitted, a cleanability of the breast pump body can be improved. This is particularly advantageous for small sized expression kits, where conventionally a corrugated or folded diaphragm is employed. In other words, the resilient silicone diaphragm in conventional breast pumps may include a bellows section which is deformed when the resilient diaphragm is moved up and down in the pumping process. A bellows section can be necessary to provide sufficient flexing capability of the diaphragm. An advantage of the breathable membrane according to an aspect of the present invention is that the breathable membrane does not have to be deformed. This avoids the bellows section or corrugated section and thereby simplifies a cleaning process of the membrane. In other words, the breathable membrane can be a planar, partially planar or substantially planar membrane and thus simplify the cleaning process.

Further advantageously, the expression kit comprises the breast pump body, with the first pressure chamber and the second pressure chamber, and the breathable

membrane in-between the pressure chambers as one entity. Thereby, the number of entities can be reduced and a handling of the breast pump can be simplified.

As used herein, the term 'breathable membrane', refers to a membrane which is breathable in that gases pass whereas liquids do not. The breathable membrane can also be referred to as a semipermeable membrane. For example, it can breathe air but does not pass milk and/or water. Main parameters for choosing a breathable membrane comprise, for example, required flow, required pressure drop over the membrane (membrane air-restriction), bio-compatibility, sterilization/cleaning properties, mounting to a carrier material such as lasering, gluing, ultrasonic welding and the like.

The breathable membrane according to an aspect of the present invention is a hydrophobic membrane. An advantage of a hydrophobic membrane is that it repels water and breast milk. Droplets of water and/or breast milk can clear off the membrane automatically. This ensures that a sufficient area of the breathable membrane is available for gas exchange between the first and the second pressure chamber. Hence, the size of the breathable membrane can be reduced compared with a non-hydrophobic or hydrophilic breathable membrane. In contrast to a membrane that can be wetted, there is no need to provide a large surface area with some added safety margin. In order to provide a sufficient gas volume flow, a safety margin would be required in case some of the surface area would be blocked by droplets. A low pressure drop across a membrane of a given surface area can thus be provided also when droplets of water and/or milk reach the breathable membrane. Advantageously, the breathable membrane is a hydrophobic porous membrane for allowing air to pass but which does not allow water or milk to pass. Hence, no droplets reach the first pressure chamber.

Further, the inventors have found that being hydrophobic positively influences bacteria-retention and can prevent that bacteria are transferred to the vacuum tube and pump. Hence, the hygienic function can be improved, in particular for rental or hospital use. Due to the hydrophobic property and thus the milk repellent behavior of the hydrophobic breathable membrane, the time of contact between the milk and the breathable membrane can be reduced. Thereby, the likelihood of transferring germs and bacteria, which are carried by the milk towards the breathable membrane and further on to pump and vacuum line can be further reduced.

As a further advantage, a hydrophobic breathable membrane positively influences the liquid-impermeable behavior. Due to the hydrophobic property and liquid repellent behavior, the requirements regarding liquid impermeability are reduced. Hence, for

example, a thinner membrane or a membrane with larger pore diameter can be used while still maintaining an overall liquid-impermeable behavior at typical pressures of a breast pump. Thereby, a lower pressure drop across the membrane can be realized such that a smaller area and thus more compact membrane can be used and/or a lower pump power is required.

Advantageously, the hydrophobic behavior is tuned to the application.

Advantageously, the breathable membrane is a bacteria-retentive hydrophobic breathable membrane. Methods used to determine bacterial retention are described in the ASTM standards. Bacterial retention in a filter used for liquid filtration can be determined as described in the standard ASTM F838 - 05(2013) "Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration".

In a further refinement, the hydrophobic breathable membrane is bacteria-retentive in an aerosol environment. An aerosol can be considered as a mixture, in particular a colloid, of fine solid particles or liquid droplets, in air or another gas. While the prior art focuses on preventing milk as a liquid from reaching the vacuum pump, the inventors have realized that aerosol components should also be taken into account. Due to the vacuum pressure, the transfer from liquid phase into gaseous phase is fostered such that undesired components could pass a breathable membrane in this state even though the membrane is liquid-impermeable. In particular, germs such as bacteria could potentially be transferred past a liquid-impermeable but gas-permeable membrane. It is therefore suggested to use a hydrophobic breathable membrane, wherein the breathable membrane is a bacteria-retentive membrane, which is bacteria-retentive in an aerosol environment. Bacteria retention in an aerosol environment can be determined by BFE (bacterial filtration efficiency) testing as described in the standard ASTM F2101 - 14 "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus".

In an embodiment, the breathable membrane (50) comprises a hybrid membrane structure comprising both a woven and non-woven membrane structure. An advantage of this embodiment is that the advantages of woven and non-woven materials can be combined. For example, a woven layer can be arranged on top of a non-woven layer. The woven layer can face the second pressure chamber. The non-woven layer can face the first pressure chamber. The woven layer can be liquid-impermeable and thereby prevents milk from passing the breathable membrane as a first membrane stage. An advantage of a woven layer can be its tribo-electrical properties. As a second membrane stage, the non-woven layer

can be bacteria retentive in an aerosol environment. An advantage of the non-woven layer is that a non-woven layer can provide a low resistance with high efficiency.

In an embodiment, the breathable membrane comprises a hydrophobic backing. A backing refers to a support layer, in particular a stiff support layer, of the breathable membrane. Advantageously, the hydrophobic backing faces the second pressure chamber. The use of a hydrophobic backing can prevent liquids to come into contact with an additional layer of the breathable membrane. Hence, a hydrophobic backing can advantageously be combined with one or more further in particular high efficiency membrane layers, wherein the additional layers can also be non-hydrophobic.

In an embodiment, the breathable membrane is gas-permeable and liquid-impermeable in both directions. In other words, gases can pass from the first pressure chamber to the second pressure chamber and from the second pressure chamber to the first pressure chamber, whereas liquids are blocked in both directions. In contrast to a one-way permeable membrane, such a two-way breathable membrane avoids a continuous build-up of vacuum pressure at the breast and teat which may cause discomfort to the user.

In an embodiment, at least a portion of the breathable membrane is arranged at an angle with respect to the milk outlet. Advantageously, the breathable membrane is thereby arranged at an angle with respect to a horizontal plane when the expression kit is applied to the human teat. In other words, the breathable membrane is in a non-horizontal orientation during typical use of the expression kit. The angle can be determined with respect to a plane of the milk outlet, wherein the plane of the milk outlet can correspond to a plane in which a rim of a milk receptacle is located when the milk receptacle is connected to the breast pump body. An advantage of this embodiment is that droplets of milk and/or water can clear off the membrane automatically since they are drawn away by gravity. In a further refinement, the breathable membrane comprises sub-sections wherein the sub-sections of the breathable membrane are arranged at an angle with respect to each other. This ensures that at least a sub-section of the breathable membrane is arranged in a non-horizontal orientation when the breast pump is used. For example, a pyramid shape or free form that is partially non-horizontal can be used.

In an embodiment, the breathable membrane comprises one or more of polyethylene, polypropylene, polybutylene terephthalate (PBT), polytetrafluoroethylene or expanded polytetrafluoroethylene. In a further embodiment, the breathable membrane consists of polyethylene, polypropylene, polybutylene terephthalate (PBT) polytetrafluoroethylene and/or expanded polytetrafluoroethylene. An advantage of a

breathable membrane made of such material is that it can be manufactured at reasonable cost. Furthermore, the material can be designed to withstand the expected cleaning procedures including manual washing, dishwasher, hot water and the like with or without detergents, but it can also be capable of the withstanding hospital kind of cleaning techniques such as Gamma, ETO, Autoclave Sterilization and disinfection methods.

In an embodiment the breathable membrane is configured as a hygienic shield. Advantageously, the properties of the breathable membrane go beyond merely being gas-permeable and liquid-impermeable, but further accomplish a hygienic shielding function. For example, this can be implemented by choosing a porous material wherein the structure and/or size of the porous openings prevents undesired components, for example germs, to pass. Alternatively or in addition, a thickness of the membrane is chosen accordingly.

In an embodiment the expression kit further comprises a support structure for supporting the breathable membrane. The support structure can be implemented as an integral part of the membrane, as a separate dedicated element or as a part of the breast pump body. In other words, the support structure serves as a carrier for the breathable membrane. The support structure can be configured to provide mechanical stability, in particular for preventing the membrane from unduly flexing due to the applied pressure. For example, the support structure can be a rigid structure such as a mesh structure. Advantageously, the support structure is implemented at a side of the breathable membrane which faces the first pressure chamber such that the support structure does not come into contact with the milk path. Thereby, the support structure is easier to clean. Further advantageously, the support structure provides better handling of the breathable membrane. Further advantageously, the support structure also protects the membrane from damage by the user.

In an embodiment, the expression kit further comprises a seal arranged between the breathable membrane and the breast pump body. For example, the seal is a seal ring around the breathable membrane which is configured to prevent leakage, in particular liquid leakage, between the first vacuum chamber and the second vacuum chamber. In an embodiment, the breathable membrane comprises a seal ring with a silicone seal for sealing, a hard plastic ring as a support structure. An advantage of this embodiment is that the breathable membrane including seal and support structure can be separated from the breast pump body for easy cleaning. In an alternative embodiment, the breathable membrane is directly fixed to the pump body and thereby prevents leakage. An advantage of this embodiment is the very low amount of materials used and thus a reduced manufacturing cost.

In an embodiment, the expression kit further comprises a wear indicator for indicating a wear of the expression kit, in particular of the breathable membrane. An advantage is that the wear indicator indicates how often the device has been used. Thus, the wear indicator can indicate when it is time, for example, to replace the breathable membrane or a seal. The wear indicator can be implemented as a counter, a counter which is manually operated or, for example, as a color that fades over time such as a blue color indicator.

In an embodiment, the expression kit further comprises a restrictor for reducing a surface area of the breathable membrane. In other words, a resistance provided by the breathable membrane can be tuned for example by reducing the surface area of the breathable membrane. The restrictor can thus be used to tune an effective surface area of the breathable membrane. A small surface area of the breathable membrane can lead to a slower build-up of the pressure in the second pressure chamber. Hence, as an alternative to controlling the pressure unit, a mechanical restrictor can be used. Thereby, a simpler and less expensive pressure unit can be used. The use of a restrictor is also advantageous for manual breast pumps, wherein one and the same pumping mechanism can be used for providing different pressure situations at the breast, as desired by the woman, by simply choosing an appropriate restrictor. Alternatively, the restrictor is an integral part of the membrane which defines a resistance the membrane exerts to the gas volume flow from the first pressure chamber to the second pressure chamber or from the second pressure chamber to the first pressure chamber.

In an embodiment, the expression kit further comprises a splash guard arranged between the milk path and the breathable membrane. An advantage of this embodiment is that the splash guard acts as an additional shield for preventing breast milk to reach the breathable membrane. Hence, the splash guard avoids that a substantial part of the breathable membrane is covered with liquid and thus not capable of passing a sufficient amount of air anymore.

In an embodiment at least one of the first pressure chamber and the second pressure chamber is configured to enable access to the breathable membrane. An advantage of this embodiment is that it provides easy access for cleaning purposes. For example, the second pressure chamber of the breast pump body may comprises a lid that can be opened and provide access to the breathable membrane for cleaning and/or for removing the breathable membrane. Alternatively or in addition, access can be provided from the second pressure chamber. An optional splash guard can be implemented as a flexible element which can be removed or pushed aside for cleaning.

In an embodiment the expression kit further comprises a milk receptacle for connection to the milk outlet. The expression kit may comprise a fitting to enable a receptacle such as a milk-collection bottle having a co-operating fitting to be coupled to the breast pump body. Alternatively, the milk receptacle forms part of the breast pump body. Advantageously, the milk flows into the receptacle or storage container by gravity. The second vacuum chamber can be sealed by the milk receptacle. Alternatively, or in addition, the milk outlet further comprises a one-way valve to allow expressed milk to exit the second pressure chamber but to prevent air from entering the second pressure chamber through the milk outlet.

The pressure unit can be a manual or electric pump which is arranged directly at the expression kit or at a remote location. The pressure unit is configured for connection to the first pressure chamber. A remote pressure unit can be connected to the first pressure chamber by a tube system. Hence, the expression kit can optionally comprise a tube system for connection to a remote vacuum unit.

As used herein, the term 'negative pressure' or 'vacuum' refers to a negative pressure with respect to ambient pressure.

The expression kit as described above enables the design of a more compact expression kit, because a large volume for the diaphragm to make a stroke for creating the vacuum at the breast is no longer required. A more compact expression kit and a smaller volume to be pressurized allow the appliance of a smaller pressure unit having reduced power. A smaller pressure unit is generally less expensive. Furthermore, with the appliance of a membrane the hygienic function is maintained since the breathable membrane is impermeable to breast milk, such that the pressure unit is separated from the milk path between the breast-receiving funnel and the milk outlet.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter. In the following drawings

Fig. 1 shows a perspective view of a first embodiment of a breast pump;

Fig. 2 shows the breast pump during application;

Fig. 3 shows an exploded view of a second embodiment of a breast pump;

Fig. 4 shows an expression kit according to a third embodiment;

Fig. 5 shows an expression kit according to a fourth embodiment;

Fig. 6 shows an embodiment of a breathable membrane;

Figs. 7A and 7B show further embodiments of a breathable membrane;

Fig. 8 shows a perspective view of an embodiment of an interface assembly;

Fig. 9 shows relations between membrane parameters;

Fig. 10A to 10D show different retention mechanisms;

Fig. 11 shows an exemplary relation of retention mechanisms versus particle size;

Figs. 12A and 12B show the impact of membrane parameters on a particle.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows an embodiment of a breast pump 1 comprising an expression kit 2 and a pressure unit 30 for generating a pressure, for example a negative pressure or vacuum. The expression kit 2 comprises a breast pump body 10 and a milk receptacle 40 in form of a baby-feeding bottle. The breast pump body 10 is a body, which is part of expression kit 2 of the breast pump 1. In this embodiment, the pressure unit 30 is an electric vacuum unit. Alternatively, a manual pressure unit or pump can be used. The electric vacuum unit 30 is connected to the breast pump body 10 via a tube 31. The electric vacuum unit 30 can thus be arranged at a remote location for reducing the size of that part of the breast pump 1 which is to be applied to a woman's breast. Alternatively, the vacuum unit can be directly arranged at the breast pump body 10 of the expression kit 2, as for example shown in US 2012/0116299 A1.

The expression kit 2 comprises a breast pump body 10 having a first pressure chamber 11 and a second pressure chamber 21. In this embodiment, the pressure chambers can also be referred to as vacuum chambers. The first pressure chamber 11 is configured for connection to the vacuum unit 30 via a connector 12 for connection to the tube 31 to the electric vacuum unit 30.

It should be noted that a plurality of expression kits 2 can share a common pressure unit 30, for example for expressing milk from both teats at the same time.

The second pressure chamber 21 comprises a breast-receiving funnel 22, a milk outlet 23 and a milk path 24 from the breast-receiving funnel 22 to the milk outlet 23. The breast-receiving funnel 22 is thus in fluid communication with the milk outlet 23 via the milk path 24. The breast-receiving funnel 22 can further comprise a massage cushion 25 being designed to feel soft and warm and imitating a baby's sucking action to provide fast milk flow quietly, comfortably and gently.

The first pressure chamber 11 and the second pressure chamber 21 are separated by a breathable membrane 50. The breathable membrane 50 is gas-permeable and liquid-impermeable and separates the first pressure chamber 11 from the milk path 24 in the second pressure chamber 21. The breathable membrane 50 is a hydrophobic breathable membrane.

Fig. 2 shows the application of the breast pump 1 extracting breast milk 101 from the breast 102 of a woman 100 during typical use of the expression kit 2. When a woman's breast 102 is placed in the breast-receiving funnel 22 of the expression kit 2, that opening of the second pressure chamber 21 is sealed closed. Correspondingly, the milk outlet 23 of the second pressure chamber 21 is sealed closed by the milk receptacle 40.

Fig. 3 shows a further embodiment of a breast pump 1 according to an aspect of the present invention. The breast pump 1 is configured for manual operation. The breast pump 1 comprises an expression kit 2 comprising a breast pump body 10 comprising a first pressure chamber 11 and a second pressure chamber 21. The first pressure chamber 11 is configured for connection to a pressure unit 30 for generating a pressure in the first pressure chamber 11.

Instead of using an electric pressure unit as shown in Fig. 1, in this embodiment the pressure unit 30 is a manual pressure unit comprising a handle 32 and a piston 33. The handle 32 engages with the joint 13 arranged at the breast pump body 10. Operation of the handle 32 of the pressure unit 30 thereby causes an up and down movement of the piston 33 in the first pressure chamber 11 and thereby displaces the air volume in the first pressure chamber 11. It should be noted that a piston pump requires less space than a conventional diaphragm pump and thus enables a more compact design. Alternative means for generating a pressure in the first pressure chamber 11 can also be used.

The second pressure chamber 21 comprises a breast-receiving funnel 22 which can optionally be equipped with a massage cushion 25 for improved user comfort. The second pressure chamber 21 further comprises an aperture acting as the milk outlet 23. Optionally, a one-way valve 26 is arranged at the milk outlet 23. The one-way valve is configured to let milk pass from the second pressure chamber 21 to the milk receptacle 40. The milk receptacle 40 is connectable to the bottom of the pump body 10, e.g. by screwing, and thereby closes the lower end of the second pressure chamber 21.

The first and the second pressure chamber 11, 21 are separated by a hydrophobic breathable membrane 50, which is gas-permeable and liquid-impermeable, for separating the first pressure chamber 11 from the milk path 24 from the breast-receiving

funnel 22 to the aperture of the milk outlet 23. Optionally, the breathable membrane 50 is fixed to the breast pump body 10. This reduces the number of parts to be handled and thereby reduces handling errors.

Exemplary embodiments of the breathable membrane 50 will be described in more detail with reference to Figs. 6, 7a and 7b further below.

Fig. 4 shows a third embodiment of an expression kit 2 comprising a breast pump body 10 having a first pressure chamber 11 and a second pressure chamber 21. The first pressure chamber is configured for connection to a remote pressure unit via a tube 31.

In an advantageous refinement, the elements are configured for retrofitting a conventional diaphragm-based breast pump body as for example known from the breast pump model Philips Avent SCF334/02.

The first and the second pressure chamber 11, 21 are separated by a breathable membrane 50, which is gas-permeable and liquid-impermeable, for separating the first pressure chamber 11 and the second pressure chamber 21. The breathable membrane 50 is a hydrophobic breathable membrane. For example, a vacuum applied to the first pressure chamber 11 also causes vacuum in the second pressure chamber 21 since air can pass, whereas water and/or milk in the second pressure chamber are blocked. Thereby, the breathable membrane 50 acts as a hygienic shield. Being hydrophobic further positively influences the bacteria-retention and prevents that bacteria are transferred to the vacuum tube 31 and pump.

The second pressure chamber 21 again comprises a breast-receiving funnel 22, a milk outlet 23 and a milk path 24 from the breast-receiving funnel 22 to the milk outlet 23. In the shown embodiment, the milk outlet 23 is equipped with an optional alternative embodiment of a one-way valve 26 in form of a flap.

The breast pump body 10 comprises an optional splash guard 14 arranged in the second pressure chamber 21 for shielding the breathable membrane 50 from droplets of breast milk. Thereby, the splash guard 14 can act as a first barrier which avoids that too much breast milk reaches the breathable membrane 50. Droplets of milk can clear off the hydrophobic breathable membrane 50 automatically.

An interface assembly 60 is arranged in the first pressure chamber 11 and configured for providing connection to the vacuum unit via the tube 31. The interface assembly 60 comprises a lid 61 for sealing the first pressure chamber 11. Advantageously, the interface assembly 60 of the expression kit further comprises one or more volume-reduction elements 62, which reduce the dead air volume in the first pressure chamber 11.

Thereby, the air volume which has to be evacuated is significantly reduced. Thus, a smaller and/or less expensive vacuum unit can be used.

In an alternative embodiment, when there is no need for compatibility with existing breast pump bodies, the volume of the first pressure chamber 11 can be reduced by design. This is possible since there is no need for a diaphragm to perform a stroke.

In the embodiment shown in Fig. 4, a diameter of an upper portion of the first pressure chamber 11 is larger or equal to a diameter of the breathable membrane 50. The first pressure chamber 11 is thus configured to enable access to the breathable membrane 50 when the interface assembly 60 is removed. An advantage of this embodiment is easy access to the breathable membrane 50 for cleaning or replacement.

Fig. 6 shows an embodiment of a breathable membrane 50 in more detail. The breathable membrane 50 comprises a breathable central membrane portion 51 which is gas-permeable and liquid-impermeable. A support structure in form of a rigid ring 52 can be arranged at a perimeter of the central membrane portion 51 for providing mechanical stability. Optionally, the rigid ring 52 is configured as a restrictor for limiting the surface area of the breathable central membrane portion 51 to a desired area.

Furthermore, a seal 53 such as a silicone seal can be provided as a seal to a wall of the breast pump body 10, for example to avoid leakage. It should be noted that the seal does not necessarily have to be air tight as long as it prevents breast milk from flowing from the second pressure chamber to the first pressure chamber. An optional wear indicator 58 indicates a wear of the breathable membrane 50, including the seal 53, and thereby indicates when it is time to replace the breathable membrane 50.

Figs. 7A and 7B show alternative structures for providing mechanical stability to the breathable membrane 50.

In the embodiment shown in Fig. 7A, a mesh structure 54, for example made from a hard plastic or metal, is provided at one or both surfaces of the breathable membrane 50. Advantageously, the support structure is arranged at the side of the breathable membrane 50 which faces the first vacuum chamber for easier cleaning.

In the alternative embodiment shown in Fig. 7B, the breathable membrane 50 can comprise a carrier layer 55 that is much stronger and/or stiffer than the sub layers 56 and 57 which ensure that the membrane is breathable. The permeability of the sub layers 56 and 57 is adjusted to be gas-permeable and liquid-impermeable by selecting an appropriate mesh structure and/or layer thickness. At least one of the layers is hydrophobic. For example, layer 55 and/or sub-layer 56 are hydrophobic and face the second pressure chamber wherein sub-

layer 57 does not have to be hydrophobic. Instead of a mesh structure an alternative porous structure can be used such as a non-woven structure. A hybrid membrane structure comprising both a woven and a non-woven structure can be used. For example sub-layer 56 is a woven, hydrophobic structure, wherein sub-layer 57 is a non-woven structure.

In an embodiment, the pore size together with the thickness of the membrane achieves the desired hygienic function. In an embodiment, the pore size is less than 1 µm, in particular less than 500 nm, in particular less than 100 nm. An advantage of this embodiment is that germs such as bacteria can be blocked. Advantageously, the pore size is not only an average value but all pores are smaller than the specified pore size in order to prevent germs to pass somewhere in the membrane.

In an embodiment two sub layers 56, 57, having a first pore size, for example 1 µm, are stacked to achieve a membrane with an apparent or effective pore size being smaller than the first pore size. The pore sizes of the sub-layers 56, 57 can be the same or different.

Optionally, a further support layer is arranged on top of layer 57 for protection of the breathable membrane in Fig. 7B. Advantageously, the support structure also protects the membrane from damage by the user, for example during the cleaning process.

Fig. 5 shows an embodiment of an expression kit which is based on Fig. 4. Fig. 5 illustrates an alternative interface assembly 60. In this embodiment, the interface assembly 60 of the expression kit 2 comprises the first pressure chamber 11 and the breathable membrane 50. For example, the interface assembly 60 can be fabricated as a silicone interface assembly which optionally also seals a top portion of the breast pump body 10. Optionally the breathable membrane 50 can be removed, for example for cleaning. A cross-section of the interface assembly 60 is shown in Fig. 5. A perspective view of the interface assembly 60 is shown in Fig. 8.

The interface assembly 60 is optionally configured for retrofitting a conventional breast pump body 10 and comprises an optional volume-reduction element 62 for reducing the dead volume of the breast pump body 10. In this case, a volume of the second pressure chamber 21 can be reduced.

Advantageously, as shown with reference to Fig. 5, the breathable membrane 50 is arranged non-horizontally and thereby enables milk droplets 63 to roll down due to gravity, as indicated by arrow 64. In other words, the breathable membrane 50 is arranged at an angle with respect to a horizontal plane when the expression kit 2 is applied to the human teat. Thus, if a droplet 63 of breast milk manages to reach the breathable membrane 50, the

droplet 63 will clear automatically. Advantageously, the breathable membrane 50 is made from a hydrophobic material which further supports the rolling off of any droplets 63.

Even though the membrane is breathable, the membrane provides a pneumatic restriction to the gas volume flow. The pneumatic restriction, the surface area of the membrane and the power of the pressure unit are aligned in order to enable a desired gas volume flow. In particular, the breathable membrane has a pneumatic restriction that is low enough to enable breast pump function. For example, the pneumatic restriction is selected such that, using a vacuum pump that can deliver a free flow of e.g. 0.3 liters per minute and that has an end vacuum of e.g. -1000 mbar, a small volume of 15 ml can be evacuated to -333 mbar in approximately 1.2 seconds. When the first pressure chamber has a minimal volume, a delta pressure of 1000 mbar will be put across the breathable membrane almost immediately. The exemplary volume of the second pressure chamber of 15 ml is small, however, in general the skilled person will reduce the volume of the first and/or second pressure chamber further in order to enable the use of a small, cheap and/or energy efficient pressure unit. The values are to be understood as exemplary values for a breast pump. The skilled person will appreciate that generally other values can be selected which enable the extraction of breast milk.

In view of the foregoing, the breathable membrane with its pneumatic restriction can be specified in that the membrane provides a flow of e.g. at least 0.3 liters per minute when a pressure difference over the membrane of e.g. -1000 mbar is applied and the membrane has a predetermined surface area. These parameters enable the skilled person to determine the required flow parameter Q of the breathable membrane and select the membrane accordingly. The flow parameter Q can be defined as Q = flow through the membrane / (surface area of the membrane × pressure difference over the membrane). For a breast pump, the surface area is preferably as small as possible. A further advantage of a small membrane can be low material costs. In an advantageous embodiment, the surface area is less than 2827 mm^2, corresponding to a disk-shaped area having a radius of 30 mm, in particular less than 707 mm^2, corresponding to a disk-shaped area having a radius of 15 mm. In view of the pneumatic restriction and a maximum membrane surface area a suitable membrane can be determined.

A desired pressure profile, i.e. a time-variant pressure, can be applied to the woman's breast using a suitable pressure unit and taking into account the pneumatic restriction of the breathable membrane.

A pneumatic restriction or resistance requirement of the hydrophobic breathable membrane can be determined via calculation. An air speed $v[m/s]$ through the membrane can be determined via a required vacuum profile, i.e., dP/dt in a certain volume. A pressure drop over the membrane (dP) is advantageously kept as low as possible, e.g. less than 100 mbar, in particular less than 50 mbar, in particular less than 20 mbar, to enable the use of a low power and compact pump (as well as low stresses in the membrane). Advantageously, a surface area is also kept as low as possible to ensure e.g. design freedom, reduce a risk of damage, improve cost efficiency and the like. For example, the membrane is a substantially circular membrane having a diameter of about 20 mm and a surface area of about 350 mm^2. Based thereon, a maximum resistance that is allowed for the membrane can be calculated by:

$$dP[Pa] = R[Pas/kg] \cdot q[kg/s]$$
$$q[kg/s] = v[m/s] \cdot A[m^2] \cdot rho[kg/m^3]$$
$$R[Pas] = \left(dP[Pa]/A[m^2]\right) \cdot \left(1/v[m/s]\right) \cdot \left(1/rho[kg/m^3]\right)$$

The determination of the membrane characteristics can thus be based on this maximum resistance R as well as the retention requirements of the membrane such as bacteria retention (ASTM F2101 – 14). The membrane efficiency will determine if the membrane can meet the required retention and the required R.

Parameters influencing the membrane efficiency 900 are illustrated exemplarily with reference to Fig. 9. There are multiple aspects that influence the membrane efficiency. Several parameters have in turn interdependencies between each other which are indicated by arrows in Fig. 9. For example, the membrane efficiency is influenced by pore size 901, pore shape 902, pore structure 903, membrane and/or composite thickness 904, particle travel distance 905, fiber coating 906, fiber orientation 907, fiber mix 908, fiber shape 909, membrane backing and/or facing layer 910, fiber diameter 911, tribo-electrical parameters 912 as well as the material type 913.

Optionally, the particle speed can be reduced to increase the chance of capturing particles.

Regarding interdependencies, for example the particle travel distance 905 depends on the composite thickness 904, the pore structure 903 as well as fiber mix 908 and fiber orientation 907. As shown in Fig. 12A, a particle 1004 which enters a straight fiber 1201 at 1202 and travels along a straight path 1203 has a shorter travel distance 905 compared to a particle 1004 which enters a curved fiber 1204 at 1205 and travels along a winding path 1206. The longer travel distance along the curved fiber 1204 provides better

retention properties compared to the straight fiber 1201. However, there can be a tradeoff between retention and flow resistance.

Figs. 10A to 10D illustrate different retention mechanisms. Fig. 10A illustrates the sieve effect. A particle 1004 travelling along a particle path 1003 cannot pass between fibers 1001 of the membrane and is thus retained whereas an airflow 1002 passes the membrane. Fig. 10B illustrates the inertial mass effect. A particle 1004 travelling along a particle path 1003 is incepted by a fiber 1001 of the membrane. Due to its inertial mass, the particle does not follow the airflow 1002 around the fiber but collides with the fiber 1001. Fig. 10C illustrates the interception effect wherein a particle 1004 travelling along a particle path 1003 is drawn towards the fiber 1001 of the membrane and thereby prevented from passing the membrane. This effect is also exemplarily shown with reference to Fig. 12B. For example, active carbon 1210 is capable of intercepting particles 1004 including gaseous particles and thus prevents them from passing on. Fig. 10D illustrates the diffusion effect. A particle 1004 travels along a corrugated diffuse path 1003, collides with a fiber 1001 of the membrane and does not pass the breathable membrane.

Depending on the particle size, one or more of the aforementioned retention mechanisms can be combined. Fig. 11 shows an exemplary relation of particle size in [µm] versus the retention mechanisms described with reference to Figs. 10A to 10D. For example for a range 1101 of coarse membranes the sieve effect 1104A of Fig. 10A can be used. For a range 1102 of fine membranes, the inertial mass effect 1104B of Fig. 10B can be used, whereas for micro filtering 1103 the use of the interception effect 1104A of Fig. 10C as well as the diffusion effect 1104D of Fig. 1104D have shown good results.

The membrane can be applied as a composite of one or more membranes and optionally one or more supporting layers. A membrane can be provided with a backing and/or facing, in particular a hydrophobic backing and/or facing or as the membrane only. In such a composite, filtration properties can be generated by the one or more same or different membranes and can optionally be further supported by the backing and/or facing.

In conclusion, a breast pump and an expression kit for a breast pump for extracting breast milk from a human teat have been presented. Advantageously, the proposed solution with a hydrophobic breathable membrane for separating the first pressure chamber from the milk path provides a more compact and less expensive expression kit and breast pump, wherein the hygienic function is improved or at least maintained compared with an expression kit using a non-permeable resilient diaphragm.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments. Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims.

In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single element or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

Any reference signs in the claims should not be construed as limiting the scope.

CLAIMS:

1. An expression kit (2) for a breast pump (1) for extracting breast milk (101) from a human teat (102), the expression kit (2) comprising:

- a breast pump body (10) comprising a first pressure chamber (11) and a second pressure chamber (21),
- wherein the first pressure chamber (11) is configured for connection to a pressure unit (30) for generating a pressure in the first pressure chamber (11),
- wherein the second pressure chamber (21) comprises a breast-receiving funnel (22), a milk outlet (23) and a milk path (24) from the breast-receiving funnel (22) to the milk outlet (23), and
- wherein the first and the second pressure chamber (11, 21) are separated by a breathable membrane (50), which is gas-permeable and liquid-impermeable, for separating the first pressure chamber (11) from liquid in the milk path (24), wherein the breathable membrane (50) is a hydrophobic membrane.

2. The expression kit for a breast pump according to claims 1, wherein the breathable membrane is a bacteria-retentive hydrophobic breathable membrane.

3. The expression kit for a breast pump according to claim 2, wherein the breathable membrane (50) is bacteria-retentive in an aerosol environment.

4. The expression kit for a breast pump according to any of the preceding claims, wherein the breathable membrane (50) comprises a hybrid membrane structure comprising both a woven and non-woven membrane structure.

5. The expression kit for a breast pump according to any of the preceding claims, wherein the breathable membrane (50) comprises a hydrophobic backing.

6. The expression kit for a breast pump according to any of the preceding claims, wherein the breathable membrane (50) is gas-permeable and liquid-impermeable in both directions.

7. The expression kit for a breast pump according to any of the preceding claims, wherein at least a portion of the breathable membrane (50) is arranged at an angle with respect to the milk outlet (23).

8. The expression kit for a breast pump according to any of the preceding claims, wherein the breathable membrane (50) comprises one or more of polyethylene, polypropylene, polybutylene terephthalate, polytetrafluoroethylene or expanded polytetrafluoroethylene.

9. The expression kit for a breast pump according to any of the preceding claims, further comprising a support structure (52, 53, 54, 55) for supporting the breathable membrane (50, 56, 57).

10. The expression kit for a breast pump according to any of the preceding claims, further comprising a seal (53) arranged between the breathable membrane (50) and the breast pump body (10).

11. The expression kit for a breast pump according to any of the preceding claims, further comprising a wear indicator (58) for indicating a wear of the expression kit (2), in particular of the breathable membrane (50).

12. The expression kit for a breast pump according to any of the preceding claims, further comprising a restrictor (52) for reducing a surface area of the breathable membrane.

13. The expression kit for a breast pump according to any of the preceding claims, further comprising a splash guard (14) arranged between the milk path (24) and the breathable membrane (50).

14. The expression kit for a breast pump according to any of the preceding claims, wherein at least one of the first pressure chamber (11) and the second pressure chamber (21) is configured to enable access to the breathable membrane (50).

15. A breast pump for extracting breast milk (101) from a human teat (102), the breast pump comprising:

- an expression kit (2) according to any of the preceding claims, and
- a pressure unit (30) for generating a pressure.

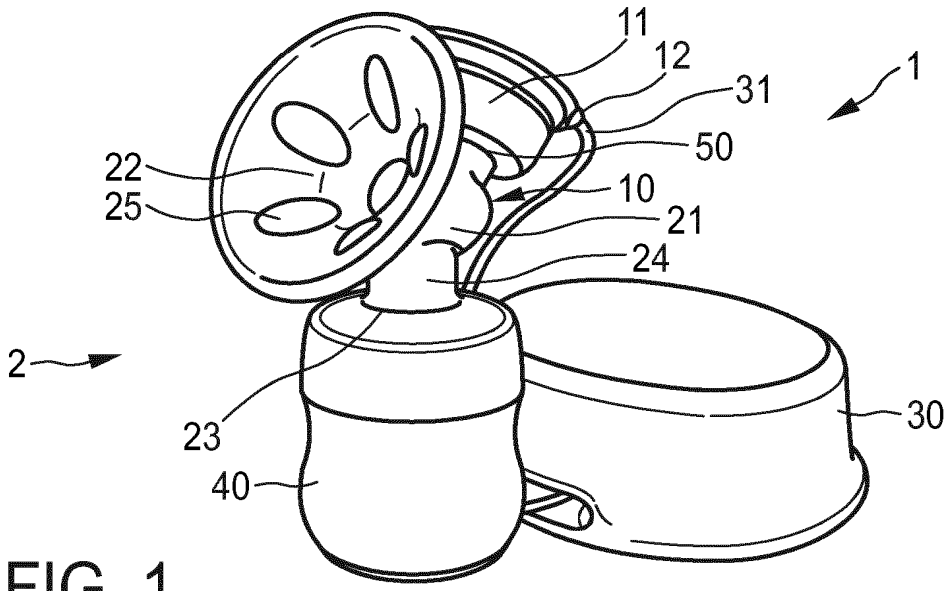


FIG. 1

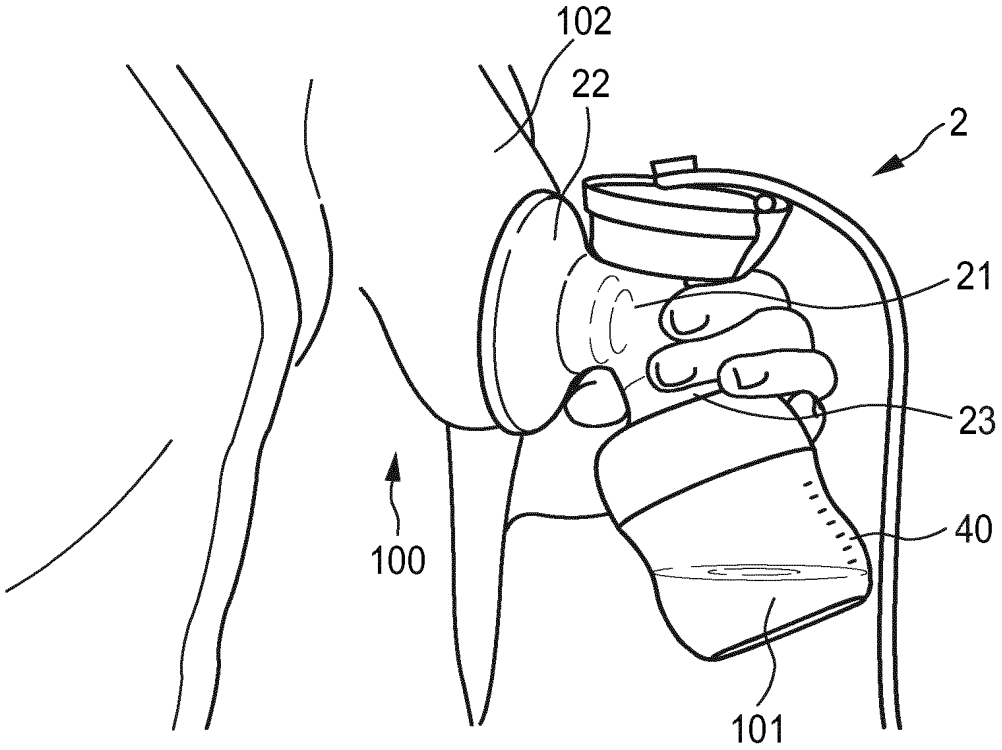


FIG. 2

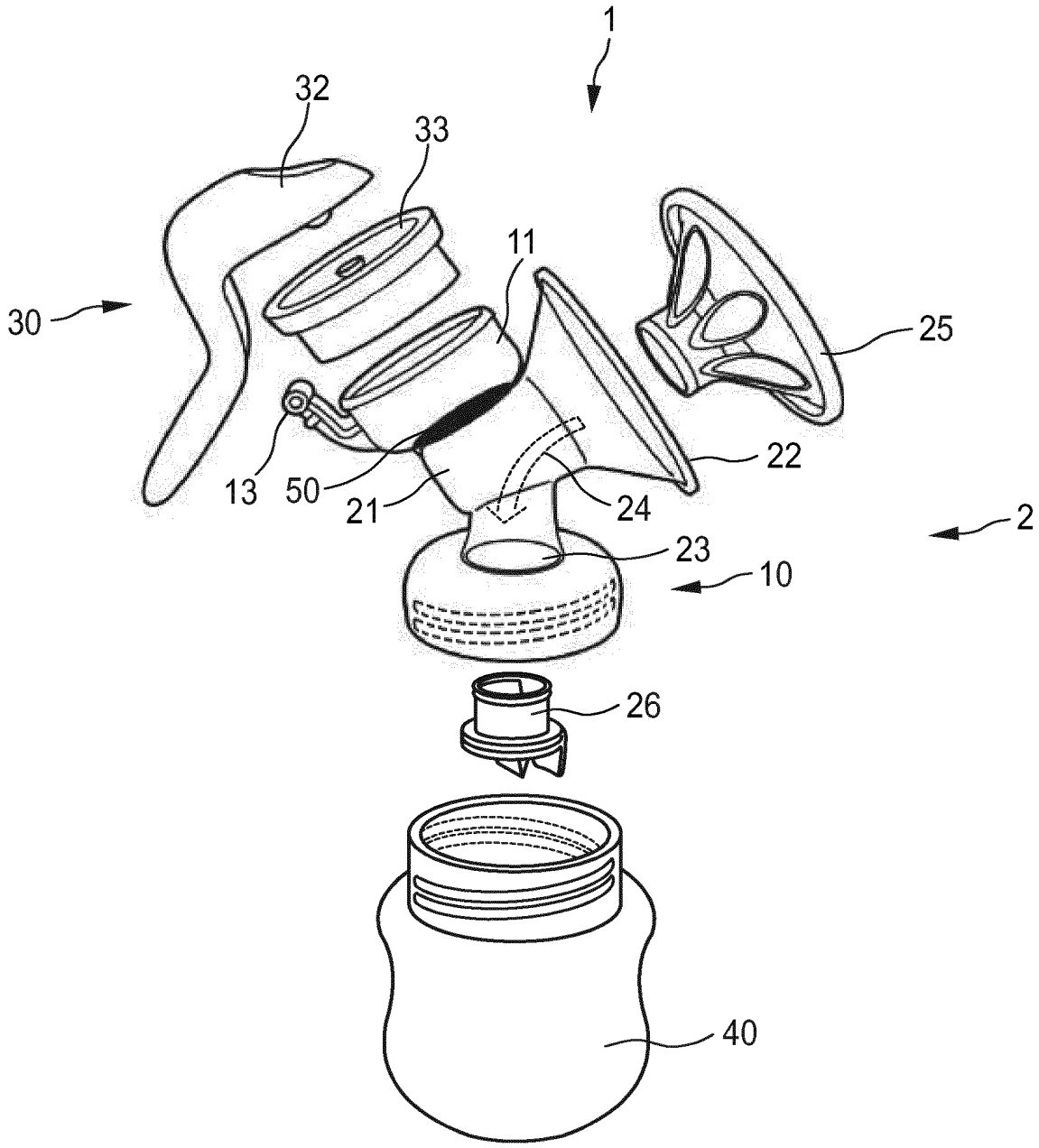


FIG. 3

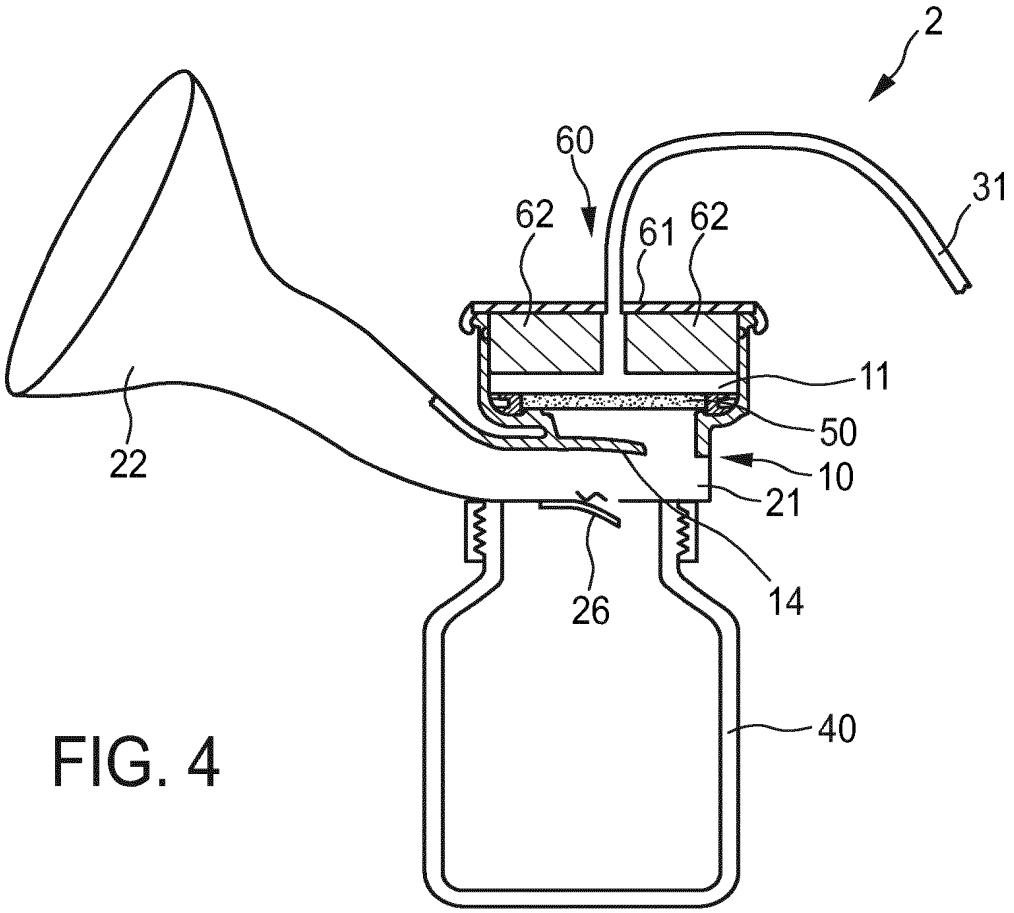

2
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31
62
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62
11
50
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21
22
14
26
40

FIG. 4

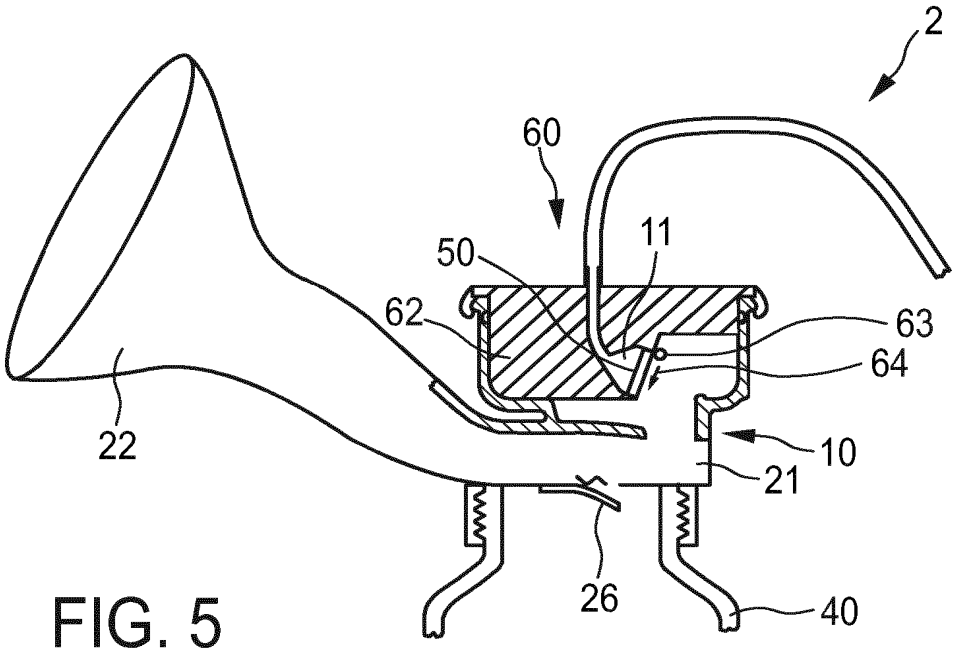
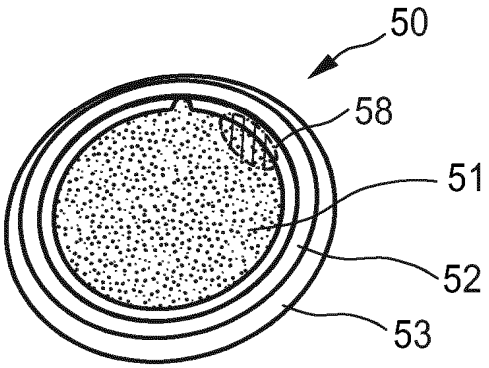

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FIG. 5

FIG. 6



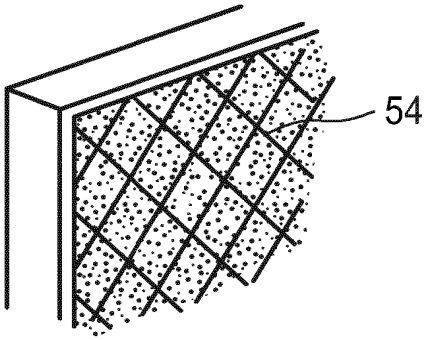


FIG. 7A

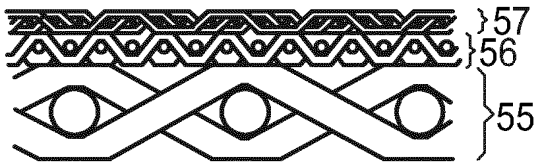


FIG. 7B

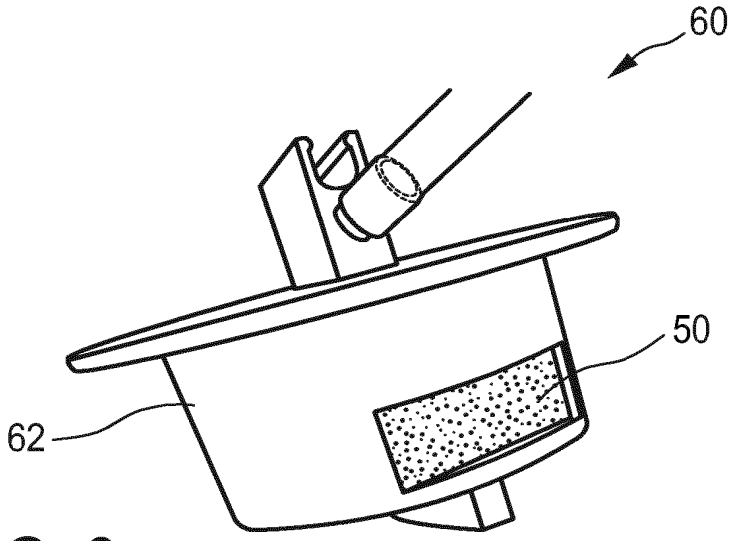


FIG. 8

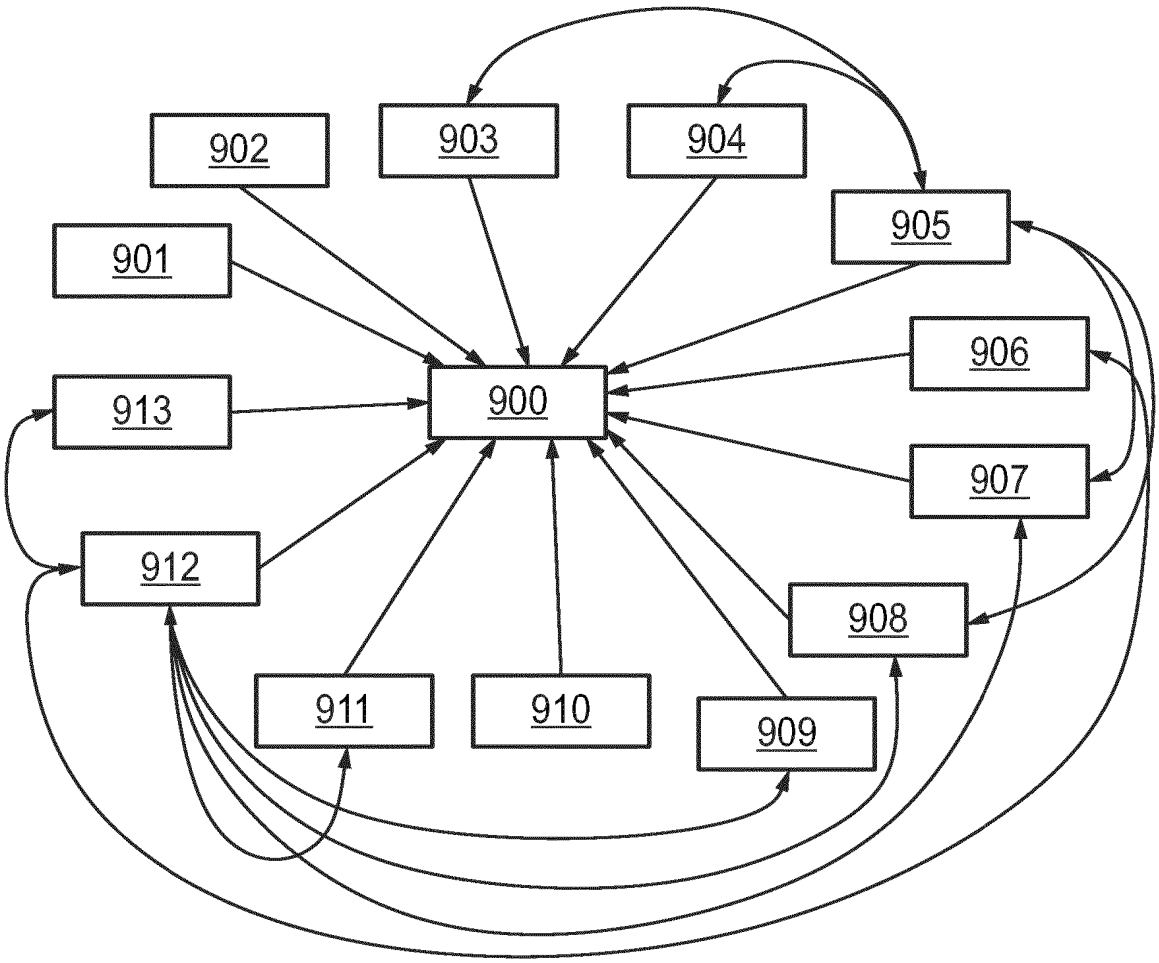


FIG. 9

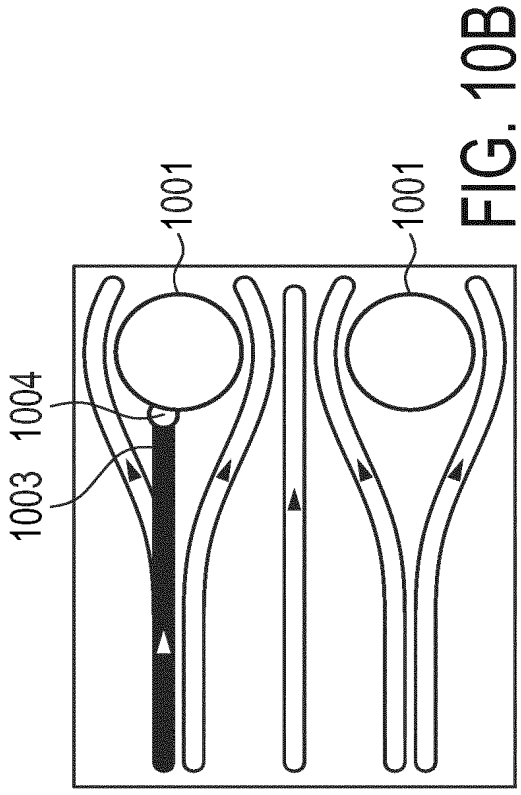


FIG. 10B

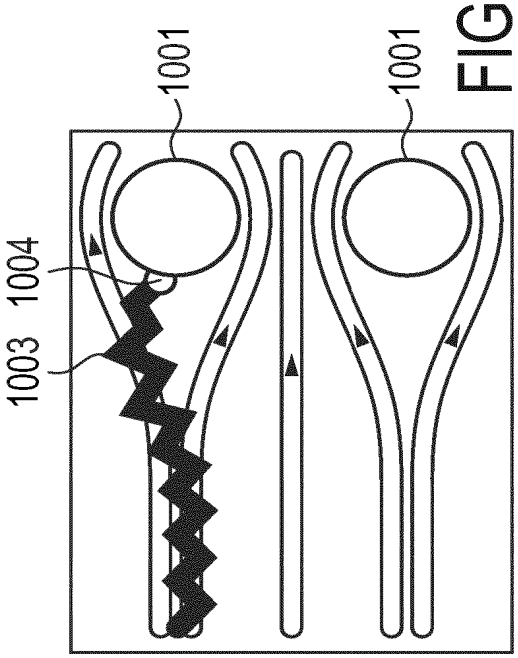


FIG. 10D

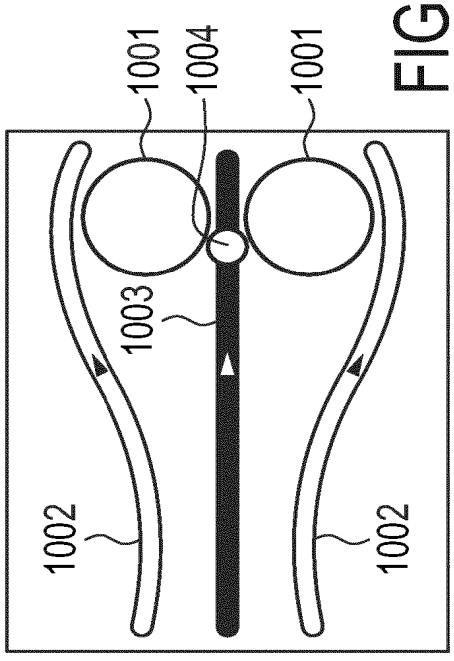


FIG. 10A

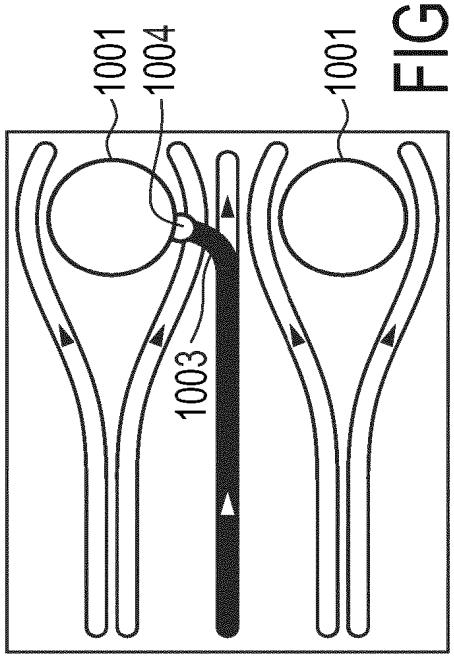


FIG. 10C

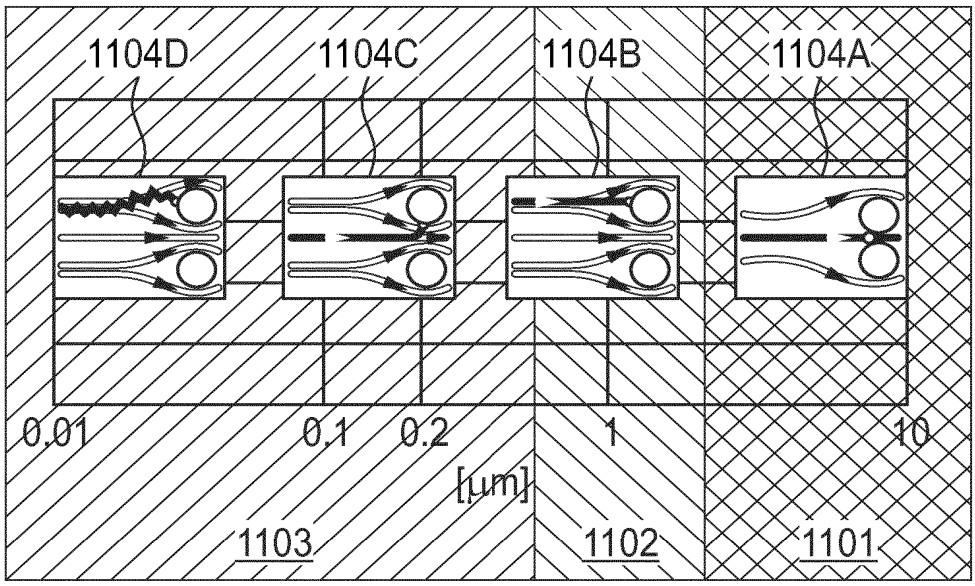


FIG. 11

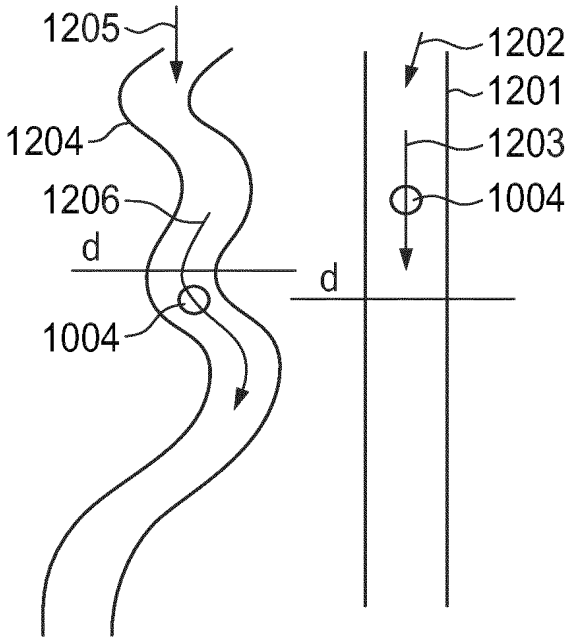


FIG. 12A

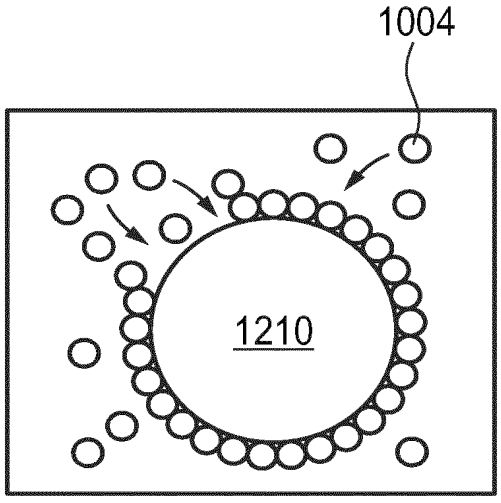


FIG. 12B

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/056575

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00 A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 071 403 A (LARSSON KARL O A H [CH]) 10 December 1991 (1991-12-10) column 2, lines 35-43; column 2, lines 62-68; column 3, line 23 - column 4, line 4; column 4, lines 30-62; column 5, lines 60-66; claim 1; figures 1, 2	1-15
A	US 2003/004459 A1 (MCKENDRY BRUCE [US] ET AL) 2 January 2003 (2003-01-02) paragraphs 0033, 0034, 0036, 0038, 0039, 0046; figures 1, 2, 5	1-15
A	WO 2008/057218 A2 (MEDELA HOLDING AG [CH]; LUZBETAK MARK A [US]; SUTRINA THOMAS A [US]; P) 15 May 2008 (2008-05-15) page 2, lines 15-21; page 12, lines 7-9; figures 1, 2, 4	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 June 2015	17/07/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Martin Amezaga, J

3

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/056575

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5071403 A	10-12-1991	NONE	
US 2003004459 A1	02-01-2003	AU 5186601 A	13-12-2001
		US 2003004459 A1	02-01-2003
WO 2008057218 A2	15-05-2008	AU 2007318174 A1	15-05-2008
		CA 2667089 A1	15-05-2008
		CN 101553264 A	07-10-2009
		EP 2077868 A2	15-07-2009
		JP 5121840 B2	16-01-2013
		JP 2010508117 A	18-03-2010
		JP 2013013793 A	24-01-2013
		KR 20090089850 A	24-08-2009
		US 2008171970 A1	17-07-2008
		US 2012071820 A1	22-03-2012
		WO 2008057218 A2	15-05-2008

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A61M 1/06 (2006.01) *G01F 23/26* (2006.01)

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8 April 2016 (08.04.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/144,857 8 April 2015 (08.04.2015) US

(71) Applicant: **NAYA HEALTH, INC.** [US/US]; 390 Bridge Parkway, Suite C, Redwood City, CA 94065 (US).

(72) Inventors: **GASKIN, Nathaniel**; 701 East Charleston Road, Palo Alto, CA 94303 (US). **ALVAREZ, Jeffery, B.**; 412 Lanyard Drive, Redwood City, CA 94065 (US). **ALVAREZ, Janica, B.**; 412 Lanyard Drive, Redwood City, CA 94065 (US).

(74) Agents: **PARK, Kyung** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title**: FLUID MEASURING RESERVOIR FOR BREAST PUMPS

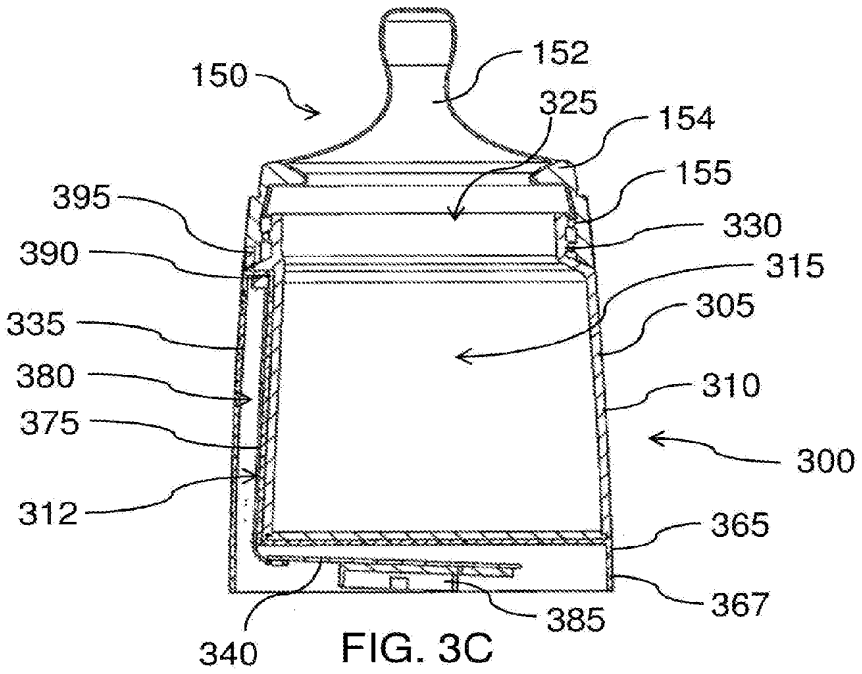


FIG. 3C

(57) **Abstract**: Systems, methods, and apparatus are provided for containing and measuring a fluid in a reservoir. A sensing reservoir comprises a reservoir comprising an opening and a wall, the opening configured to allow passage of the fluid in and out of the reservoir, and the wall defining a chamber configured to contain the fluid. The sensing reservoir further comprises a fluid sensing unit coupled to the sensing reservoir, the fluid sensing unit configured to generate measurement data indicative of a volume of the fluid contained in the reservoir.

WO 2016/164853 A1

FLUID MEASURING RESERVOIR FOR BREAST PUMPS

CROSS-REFERENCE

[0001] The present application is a non-provisional of, and claims the benefit of U.S. Provisional Patent Application No. 62/144,857, filed on April 8, 2015 [attorney docket no. 44936-711.101], the entire content of which is incorporated herein by reference.

[0002] This application is related to the following co-pending provisional and non-provisional patent applications: U.S. Patent Application No. 14/221,113, filed on March 20, 2014 [attorney docket no. 44936-703.201], U.S. Patent Application No. 14/616,557, filed on February 6, 2015 [attorney docket no. 44936-704.201], U.S. Patent Application No. 14/793,606, filed on July 7, 2015 [attorney docket no. 44936-705.201], U.S. Patent Application No. 14/793,613, filed on July 7, 2015 [attorney docket no. 44936-706.201], U.S. Patent Application No. 14/793,617, filed on July 7, 2015 [attorney docket no. 44936-707.201], U.S. Patent Application No. 14/858,924, filed on September 18, 2015 [attorney docket no. 44936-709.201], and U.S. Provisional Patent Application No. 62/144,854, filed on April 8, 2015, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention. The present invention generally relates to medical and pediatric nutrition devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. In order to understand their milk production and ensure that the production is maintained at a sufficient level, mothers often keep records of their pumping sessions manually, for example in journals or spreadsheets. Manual record keeping can be cumbersome and prone to inaccuracies or lapses in record-keeping.

[0005] It would be desirable to provide a way for mothers to automatically keep track of their milk production and the consumption of milk by their infants. It would be further desirable for the means to quantify breast milk production to be adaptable for use with various types of breast pumps. Automatic milk production quantification and inventory tracking via communication with mobile devices are further desirable for enhanced user convenience.

[0006] At least some of these objectives will be satisfied by the devices and methods disclosed below.

[0007] 2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0008] The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0009] Systems, methods, and apparatus are provided for containing and measuring a fluid in a reservoir. A sensing reservoir comprises a reservoir comprising an opening and a wall, the opening configured to allow passage of the fluid in and out of the reservoir, and the wall defining a chamber configured to contain the fluid. The sensing reservoir further comprises a fluid sensing unit coupled to the sensing reservoir, the fluid sensing unit configured to generate measurement data indicative of a volume of the fluid contained in the reservoir.

[0010] In one aspect, an apparatus for containing and measuring a fluid is provided. The apparatus comprises a reservoir and a fluid sensing unit coupled to the reservoir. The reservoir comprises an opening configured to allow passage of the fluid in and out of the reservoir, and a wall defining a chamber configured to contain the fluid. The fluid sensing unit may be configured to generate measurement data indicative of a volume of the fluid contained in the reservoir.

[0011] In some embodiments, the fluid sensing unit is coupled to the wall of the reservoir. The fluid sensing unit may be coupled to an exterior surface of the wall of the reservoir. The exterior surface of the wall of the reservoir may comprise a recessed region, wherein the fluid sensing unit may be received within the recessed region and coupled directly or indirectly to the exterior surface of the wall. The fluid sensing unit may be embedded in the wall of the reservoir adjacent an interior surface of the wall of the reservoir.

[0012] The apparatus may further comprise an insulating unit coupled to the reservoir. The insulating unit may be configured to cover the fluid sensing to provide one or more of electrical isolation or protection from physical damage of the fluid sensing unit. The insulating unit may comprise a material with high electrical resistance, such as one or more plastics or rubbers configured to provide electrical isolation of the fluid sensing unit. The insulating unit may be configured to provide an air gap between the insulating unit and fluid sensing unit. For example, the insulating unit may comprise an internal surface defining a

cavity configured to receive a fluid sensor of the fluid sensing unit therein. The cavity may have a thickness greater than a thickness of the fluid sensor, thereby establishing an air gap between the insulting unit and the fluid sensor when the fluid sensor is disposed within the cavity.

[0013] The apparatus may further comprise a processing unit in communication with the fluid sensing unit, the processing unit configured to receive the measurement data from the fluid sensing unit. The processing unit may comprise a communication module configured to communicate with one or more of a computing device or a server. The processing unit may further comprise a memory configured to store the measurement data. The apparatus may further comprise a power source operatively coupled to one or more of the fluid sensing unit or the processing unit. The apparatus may further comprise a housing coupled to the wall of the reservoir, the housing configured to encase one or more of the fluid sensing unit, the processing unit, or the power source. The housing may be removably coupled to the reservoir.

[0014] In some embodiments, the fluid sensing unit comprises one or more capacitive sensors, wherein the one or more capacitive sensors may be in communication with a processing unit. The one or more capacitive sensors may be configured to measure a change in capacitance of the one or more capacitive sensors. The change in capacitance can be affected by the fluid in proximity to the one or more capacitive sensors, such that the measurement data generated by the one or more capacitive sensors can produce an indication of the volume of the fluid contained in the reservoir. The change in capacitance may comprise one or more of a change in self-capacitance between a capacitive sensor and a surrounding environment, or a change in a mutual capacitance between a first capacitive sensor of the one or more capacitive sensors and a second capacitive sensor of the one or more capacitive sensors.

[0015] Each of the one or more capacitive sensors may comprise one or more continuous sensing regions, each continuous sensing region extending continuously along a length of the reservoir. Alternatively or in combination, each of the one or more capacitive sensors may comprise an array of discrete sensing regions, the array of discrete sensing regions extending along a length of the reservoir. Each of the one or more capacitive sensors may comprise one or more sensing regions configured to increase in area from one end of the sensing region to the other end of the sensing region. For example, each discrete sensing region of the array of discrete sensing regions may comprise an area, wherein the area of a first discrete sensing

region disposed adjacent a first end of the array is greater than the area of a second discrete region disposed adjacent a second end of the array opposite the first end.

[0016] In some embodiments, the fluid sensing unit comprises one or more base sensors coupled to one or more fluid sensors of the fluid sensing unit. The one or more base sensors may be configured to electrically isolate the one or more fluid sensors from sources of interference outside the reservoir.

[0017] The fluid sensing unit may comprise a plurality of fluid sensors distributed about the reservoir in a predetermined distribution. For example, the predetermined distribution may comprise an equal distribution about the periphery of the reservoir.

[0018] The apparatus may further comprise one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the apparatus. The one or more reservoir sensors may comprise one or more of an accelerometer and a gyroscope. The one or more reservoir sensors may be coupled to a processing unit of the apparatus, the processing unit in communication with the fluid sensing unit.

[0019] The apparatus may further comprise one or more proximity sensors. The one or more proximity sensors may be configured to detect presence of one or more proximity triggers disposed within a predetermined distance from the one or more proximity sensors. The one or more proximity triggers may be coupled to a component comprising a coupling mechanism to couple the component to the reservoir, such that the one or more proximity triggers can be placed within the predetermined distance when the component is coupled to the reservoir.

[0020] The component may comprise a pumping device, a feeding attachment, or a storage cap.

[0021] The one or more proximity sensors may comprise one or more assemblies of a light source and a light detector, and the one or more proximity triggers may comprise one or more reflective markers. The light source may be configured to emit light towards the one or more proximity triggers, the one or more reflective markers may be configured to reflect the light, and the light detector may be configured to detect the reflected light.

[0022] The one or more proximity sensors may comprise one or more Hall effect sensors, and the one or more proximity triggers may comprise one or more magnets. The one or more Hall effect sensors may be configured to detect an intensity of a magnetic field generated by the one or more magnets.

[0023] The one or more proximity sensors may comprise one or more reed switches, and the one or more proximity triggers may comprise one or more magnets. The one or more

reed switches may be configured to electrically switch on or off in response to detection of a magnetic field generated by the one or more magnets.

[0024] The apparatus may further comprise a processing unit in communication with the fluid sensing unit and the one or more proximity sensors, wherein the processing unit is configured to identify a type of the component in response to measurement data generated by the one or more proximity sensors. The one or more proximity sensors may be configured to produce different readout values when components of different types are coupled to the reservoir. The processing unit may be configured to associate each component of a specific type with a specific readout value to identify the type of the component coupled to the reservoir. The components of different types may comprise proximity triggers configured to have different properties. The components of different types may comprise different numbers of proximity triggers. The one or more proximity sensors may comprise a plurality of proximity sensors disposed at different locations of the reservoir, and the processing unit may be configured to associate each component of a specific type with one or more of the plurality of proximity sensors disposed at one or more specific locations to identify the type of the component coupled to the reservoir.

[0025] The processing unit may be configured to switch between a standby state and a measurement state in response to measurement data generated by the one or more proximity sensors. The fluid sensing unit may operate in a low-power standby mode during the standby state. The fluid sensing unit may obtain the measurement data during the measurement state.

[0026] The processing unit may be configured to determine, in response to measurement data generated by the one or more proximity sensors, an analysis mode for analyzing the measurement data generated by the fluid sensing unit. The analysis mode may correspond to a filling state or a draining state of the reservoir.

[0027] The fluid sensing unit may be encased within an insulating unit coupled to the wall of the reservoir, and the one or more proximity sensors may be disposed within the insulating unit adjacent the fluid sensing unit and near the opening of the reservoir.

[0028] In another aspect, a system for containing and measuring a fluid is provided. The system comprises a sensing reservoir for containing and measuring a fluid, wherein the sensing reservoir may comprise a fluid sensing unit coupled to a reservoir. The fluid sensing unit may be configured to generate measurement data indicative of a volume of the fluid contained in the reservoir. The system further comprises a computing device in communication with the reservoir, the computing device configured to receive the measurement data.

[0029] In some embodiments, the sensing reservoir further comprises a communication module, and the computing device communicates with the sensing reservoir via the communication module. In some embodiments, the sensing reservoir further comprises one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the sensing reservoir.

[0030] The computing device may comprise a processing unit having instructions stored thereon for performing an analysis of the measurement data. The computing device may further comprise a user interface configured to display the measurement data to a user.

[0031] The system may further comprise a remote server in communication with the reservoir or the computing device. The remote server may be configured to perform one or more of analysis and storage of the measurement data.

[0032] In another aspect, a method of measuring a fluid contained in a reservoir is provided. The method comprises providing a sensing reservoir for containing and measuring a fluid, wherein the sensing reservoir comprises a fluid sensing unit coupled to a reservoir. The method further comprises performing a system check to ensure that the sensing reservoir is functioning properly. The method further comprises generating measurement data using the fluid sensing unit, wherein the measurement data is indicative of a volume of the fluid contained in the reservoir. The method further comprises analyzing the measurement data to determine the volume of the fluid contained in the reservoir.

[0033] Performing the system check may comprise taking one or more baseline measurements using the fluid sensing unit. Performing the system check may further comprise confirming that the fluid sensing unit is in communication with a processing unit of the sensing reservoir. The sensing reservoir may further comprise one or more reservoir sensors, and performing the system check may comprise measuring one or more of a position, orientation, or motion of the sensing reservoir using the one or more reservoir sensors. The method may further comprise determining whether the sensing reservoir is in an inactive state based on the one or more of a position, orientation or motion of the sensing reservoir. The method may further comprise determining whether the sensing reservoir is undergoing excessive motion based on the one or more of a position, orientation or motion of the sensing reservoir.

[0034] The sensing reservoir may comprise one or more reservoir sensors, and generating the measurement data may further comprise measuring one or more of a position, orientation, or motion of the sensing reservoir with the one or more reservoir sensors, thereby determining an operating state of the sensing reservoir. The operating state of the sensing

reservoir may comprise a filling state or a draining state. The one or more of a position, orientation, or motion of the sensing reservoir may comprise one or more of a vertical offset or a rotational offset of the sensing reservoir. The method may further comprise determining whether the sensing reservoir is in an acceptable orientation for generating the measurement data using the fluid sensing unit, based on the one or more of the vertical offset or the rotational offset of the sensing reservoir.

[0035] The fluid sensing unit may comprise one or more capacitive sensors, and generating measurement data may comprise measuring a capacitance of each of the one or more capacitive sensors. The measured capacitance may indicate of a level of fluid at each of the one or more capacitive sensors.

[0036] The fluid sensing unit may comprise a plurality of fluid sensors, and analyzing the measurement data may comprise determining a level of fluid at each of the plurality of fluid sensors, thereby determining a tilt of the sensing reservoir. Analyzing the measurement data may comprise calculating a volume of fluid contained in the sensing reservoir based on the measurement data generated by the fluid sensing unit, and measurement data generated by one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the sensing reservoir.

[0037] The sensing reservoir may further comprise one or more proximity sensors configured to detect one or more proximity triggers disposed within a predetermined distance from the one or more proximity sensors. The method may further comprise generating measurement data using the one or more proximity sensors to determine whether the sensing reservoir is coupled to a component comprising the one or more proximity triggers.

[0038] The method may further comprise setting the sensing reservoir in a standby state in response to a determination that the sensing reservoir is not coupled to the component, and setting the sensing reservoir in a measurement state in response to a determination that the sensing reservoir is coupled to the component. Steps of performing the system check, generating the measurement data using the fluid sensing unit, and analyzing the measurement data may be performed when the sensing reservoir is set in the measurement state.

[0039] The method may further comprise transmitting the measurement data generated using the fluid sensing unit or the volume of the fluid contained in the reservoir to another computing device in communication with the sensing reservoir.

[0040] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0041] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0042] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0043] FIG. 1 is a perspective view of a pumping device suitable for use with present embodiments;

[0044] FIG. 2A is a perspective view of an exemplary embodiment of a sensing reservoir coupled to a pumping device;

[0045] FIG. 2B shows an exploded view of a sensing reservoir, in accordance with embodiments;

[0046] FIG. 2C shows an exemplary embodiment of a fluid sensing unit coupled to an insulating unit;

[0047] FIG. 2D is a cross-sectional view of the fluid sensing unit coupled to an insulating unit as shown in FIG. 2C;

[0048] FIG. 3A is a side view of a sensing reservoir coupled to a feeding attachment;

[0049] FIG. 3B is an exploded view of the sensing reservoir of FIG. 3A;

[0050] FIG. 3C is a vertical cross-section of the sensing reservoir of FIG. 3A along line 3C-3C;

[0051] FIG. 3D is a horizontal cross-section of the sensing reservoir of FIG. 3A along line 3D-3D;

[0052] FIG. 4A is a side view of the sensing reservoir of FIGS. 3A-3D coupled to a pumping device;

[0053] FIG. 4B is an exploded view of the sensing reservoir of FIG. 4A;

[0054] FIG. 4C is a horizontal cross-section of the sensing reservoir of FIG. 4A along line 4C-4C;

[0055] FIG. 5 is a top view of an exemplary embodiment of a processing unit suitable for incorporation with a sensing reservoir in accordance with embodiments;

[0056] FIGS. 6A-6D illustrate capacitive sensors having one or more continuous sensing regions configured to extend continuously along a length of the reservoir;

[0057] FIGS. 6E and 6F illustrate capacitive sensors having a plurality of discrete sensing regions configured to be placed along the length of the reservoir;

[0058] FIGS. 6G and 6H illustrate an exemplary embodiment of a base sensor that may be coupled to a capacitive sensor in accordance with embodiments;

[0059] FIG. 7A is a graph showing an exemplary response of a continuous sensing region of a capacitive sensor;

[0060] FIG. 7B is a graph showing an exemplary response of a continuous, multi-fingered sensing region of a capacitive sensor;

[0061] FIG. 7C is a graph showing an exemplary response of a discrete sensing region of a capacitive sensor;

[0062] FIG. 8A illustrates an exemplary embodiment of a sensing reservoir in the filling state, in a tilted orientation;

[0063] FIGS. 8B and 8C show exemplary graphs of fluid sensor response measured during operation of the sensing reservoir of FIG. 8A, in the filling state;

[0064] FIG. 9A illustrates an exemplary embodiment of a sensing reservoir in the draining state, at a tilted orientation;

[0065] FIGS. 9B and 9C show exemplary graphs of fluid sensor response measured during operation of the sensing reservoir of FIG. 9A, in the draining state;

[0066] FIG. 10 illustrates an exemplary method for determining the volume of fluid contained in a sensing reservoir in accordance with embodiments;

[0067] FIGS. 11A and 11B show a side perspective view and a top view, respectively, of a sensing reservoir comprising a single fluid sensor, oriented at a maximum rotational offset;

[0068] FIGS. 11C and 11D show a side perspective view and a top view, respectively, of a sensing reservoir comprising a single fluid sensor, oriented at an intermediate rotational offset;

[0069] FIGS. 11E and 11F show a side perspective view and a top view, respectively, of a sensing reservoir comprising a single fluid sensor, oriented at zero rotational offset;

[0070] FIG. 12 illustrates the effect of vertical and rotational offset of a sensing reservoir on the confidence of measurement data generated by a fluid sensing unit of the reservoir;

[0071] FIG. 13 illustrates a method for determining the volume of fluid contained in a sensing reservoir in accordance with embodiments;

[0072] FIG. 14 illustrates a method for transmitting data from a sensing reservoir in accordance with embodiments;

[0073] FIGS. 15A-15C illustrate exemplary computing device displays; and

[0074] FIGS. 16A-16B illustrate other exemplary displays suitable for incorporation with embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[0075] Specific embodiments of the disclosed systems, devices, and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. Although the present invention primarily relates to breast milk, any description herein of expression and collection of breast milk can also be applied to other types of fluids expressed from the breast, such as colostrum, or from other glands, organs, or anatomical regions of the body. Furthermore, the disclosed embodiments may be used in other applications, particularly applications involving the measurement of any fluids collected in a collection vessel.

[0076] FIG. 1 illustrates an exemplary embodiment of a breast pump suitable for use with present embodiments. Pumping device 100 (also known as an "expression apparatus") includes breast interfaces 105, a tube 110, and a controller 115 (sometimes also referred to as a "pendant unit") operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels or reservoirs 125. Controller 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices, as described in further detail herein. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from controller 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into reservoirs 125. The device 100 may further comprise one or more sensors configured to track various characteristics of the collected fluid, as described in further detail herein. Power may be provided to the one or more sensors via a connection to the controller 115, or to another source of power.

[0077] In many instances, it can be desirable to measure and track various characteristics of the collected fluid such as expressed breast milk, such as the amount of milk production

(e.g., volume, weight), expression frequency (e.g., time, date), and/or expression duration. In existing approaches, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Sensors integrated for use with a pumping device can provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy. For example, sensors can be used to measure the volume of expressed milk as volume per unit time, or total volume per pumping session.

[0078] Sensors for quantifying the composition of the expressed milk may also be provided with a pumping device. The composition of breast milk can be valuable information for understanding whether an infant is obtaining the appropriate amount of nutrition via the milk. This information can help mothers or clinicians identify whether additional nutrition should be supplied to the infant. Components of breast milk considered to be nutritionally important include carbohydrates such as glucose and lactose, fats such as triglycerides, proteins such as lactoferrin, organic acids such as taurine, vitamins such as vitamin D, and minerals such as zinc, copper, and iron. Sensors may be provided for measuring the relative amounts of one or more of such components in the expressed milk. Sensors may also be configured to determine the estimated caloric value of the expressed milk and/or the percentage of alcohol, drugs, or other contaminants present in the milk. Such sensors may include devices that can spectroscopically measure the presence of certain compounds in a volume of breast milk, or devices that can measure the enzymatic activity produced by certain compounds of breast milk that act as substrates for specific enzymes.

[0079] The one or more sensors may be coupled to a pumping device, such as to one or more portions of a breast interface. In embodiments in which the one or more sensors are coupled to one or more portions of the breast interface, the sensors may be further coupled to the pump controller via one or more communication lines configured to transmit signals between the sensors and the controller. Alternatively, the sensors may be coupled wirelessly to the controller or to a mobile device configured to control the pumping device, for example via a communication module coupled to the sensors. Embodiments of pumping devices having one or more sensors coupled thereto are disclosed in greater detail in U.S. Patent Application No. 14/616,557 (Attorney Docket No. 44936-704.201), the entire content of which is incorporated herein by reference.

[0080] The one or more sensors may also be provided in a separate accessory adaptable for use with various pumping devices, such as a sensing adaptor that can couple to a pumping device on one end, and to a reservoir on the other end. Such an adaptor may comprise

sensors configured to measure one or more characteristics of the fluid as the fluid passes through the adaptor into a collection reservoir.

[0081] The one or more sensors may also be coupled to the fluid collection reservoir. For example, a reservoir may comprise an integrated fluid sensing unit configured to measure one or more characteristics of the fluid contained in the reservoir. Some embodiments of a sensing reservoir are disclosed in U.S. Patent Application No. 14/616,557 (Attorney Docket No. 44936-704.201), the entire content of which is incorporated herein by reference.

[0082] A sensing reservoir may be supplied with its own processing unit and power source, such that the sensing capability of the reservoir may function independently of the pumping device. Providing a sensing capability in an accessory, such as a reservoir, completely separate from the pumping device can have many benefits for users. The sensing reservoir may be adaptable for use with various pumping devices, including many commercially available systems, providing a great range of flexibility for users. For example, a user may choose to add the sensing reservoir to a pumping system she already owns, in order to gain the benefits provided by an automatic fluid sensing function. In addition, in case of failure of one or more of its components, a stand-alone sensing reservoir may be easier to repair or replace than a sensor integrated into a pumping system.

[0083] The sensing reservoirs described herein may comprise collection vessels configured to couple to a pumping device for collecting expressed breast milk. Alternatively or in combination, the reservoirs may comprise bottles configured to couple to an outlet mechanism, for example a baby bottle coupled to a feeding nipple for feeding an infant. The sensing reservoirs can include one or more sensors for generating measurement data indicative of one or more characteristics of milk expression as described herein (*e.g.*, volume of expressed milk, composition of the expressed milk, etc.). The sensors may be configured to generate the measurement data at set intervals over time, and/or at the occurrence of specific events as detected automatically or as directed by a user. Any description herein pertaining to measurement of volume can also be applied to measurements of any other characteristics, and vice-versa. Any suitable type of sensor can be used, such as accelerometers, Hall effect sensors, photodiode/LED sensors, CCD sensors, cameras and other imaging devices, capacitive sensors, strain gauges, etc., and such sensors can be used in any number and combination. The sensors can be positioned at any location on the reservoir suitable for measuring the fluid contained in the reservoir.

[0084] A processing unit may be suitably combined with any sensing reservoir described herein, wherein the processing unit may be configured to receive data from the sensor and

store the data, analyze the data, and/or transmit the data to another device. A sensing reservoir having an integrated sensor and processing unit can help automate the management and monitoring of milk production, thus reducing the need for manually maintaining records related to milk production. For example, a sensing reservoir can monitor the quantity of milk produced, and automatically process and send the data to a computing device, from which the user may easily access the information. A sensing reservoir as described herein may also be used to monitor the quantity of milk consumed by an infant. Such a system can greatly improve convenience for the users, and also help reduce human errors related to manual record maintenance. System and methods for managing an inventory of expressed breast milk, suitable for incorporation with the fluid measurement devices and methods disclosed in the present application, are disclosed in further detail in co-pending U.S. Patent Application No. 14/858,924, incorporated herein by reference in its entirety.

[0085] FIG. 2A shows an exemplary embodiment of a sensing reservoir 200 coupled to a pumping device 100. The sensing reservoir 200 comprises a reservoir 205, the reservoir having a wall 210 that defines a chamber 215. The chamber is configured to contain a fluid, such as breast milk. The chamber can have a controlled or known geometry, such that the relationship between fluid level and the volume of fluid contained is known. Such a relationship may be known for the reservoir in a substantially upright position, as shown in FIG. 2A, as well as for the reservoir in a substantially inverted position. The sensing reservoir 200 further comprises a fluid sensing unit 270, configured to generate measurement data indicative of a characteristic of the fluid contained in the reservoir. In many embodiments, the fluid sensing unit comprises one or more sensors configured to generate measurement data indicative of a volume of the fluid contained in the reservoir. Alternatively or in combination, the fluid sensing unit may comprise one or more sensors configured to generate measurement data indicative of one or more properties of the fluid, such as a composition or nutritional content of breast milk. The fluid sensing unit may be coupled to the wall of the reservoir 205, or may be disposed at any other location suitable for measuring the contained fluid.

[0086] The fluid sensing unit may comprise one or more sensors of many types and configurations. In preferred embodiments, the fluid sensing unit comprises a capacitive sensor coupled to the wall of the reservoir, configured to measure a change in capacitance affected by the fluid in proximity to the capacitive sensor, as described in further detail herein. Alternatively or in combination, the fluid sensing unit may comprise one or more of other types of sensors. For example, the fluid sensing unit may comprise a strain gauge to measure a strain placed on the gauge by the fluid contained in the reservoir, wherein the

strain gauge may be coupled to a bottom of the reservoir or to a valve disposed adjacent the opening of the reservoir. The fluid sensing unit may comprise an accelerometer disposed on a valve adjacent the reservoir opening, the accelerometer configured to measure the motion of the valve to determine the quantity of fluid passing through. The fluid sensing unit may comprise a beam-break sensor disposed adjacent the opening of the reservoir, configured to generate a signal when a fluid breaks a beam by passing between a beam emitter and a beam detector. The fluid sensing unit may comprise an image sensor coupled to the opening of the reservoir or to a portion of the wall, the image sensor configured to capture images of the fluid to quantify fluid volume.

[0087] The sensing reservoir 200 can measure the contained fluid while the sensing reservoir is in a filling state as shown in FIG. 2A, wherein the reservoir is in a generally upright position and fluid is being collected in the reservoir. For example, the sensing reservoir can operate in the filling state while the reservoir is coupled to a pumping device and collecting expressed breast milk, to measure the volume of breast milk expressed and collected in the reservoir. The sensing reservoir can further measure the fluid while the reservoir is in a draining state, wherein the reservoir is in a generally inverted position and fluid is being drained from the reservoir. For example, the sensing reservoir can operate in the draining state while the reservoir is coupled to a feeding attachment such as a feeding nipple and the contained breast milk is fed to an infant, thereby generating an indication of the volume of milk consumed by the infant. The sensing reservoir may be configured to determine the appropriate operating state, for example by sensing an orientation or tilt of the sensing reservoir, or by sensing the coupling of the reservoir to a pumping device or a feeding attachment, as described in further detail herein. Based on the determined operating state and the known geometry of the reservoir 205 and the chamber 215, appropriate algorithms may be applied in analyzing the measurement data generated by the fluid sensing unit, so as to compensate for the orientation of the reservoir and determine the correct volume of fluid contained in the reservoir.

[0088] FIG. 2B shows an exploded view of a sensing reservoir 200, in accordance with embodiments. The sensing reservoir comprises the reservoir 205 and the fluid sensing unit 270 coupled to a portion of the reservoir, such as the wall 210 of the reservoir. The sensing reservoir may further comprise an insulating unit 235, configured to encase the fluid sensing unit. The sensing reservoir may further comprise a processing unit 240, in communication with the fluid sensing unit 270 and configured to receive the measurement data generated by the fluid sensing unit. The processing unit and/or the fluid sensing unit may be powered by a

power source (not shown) integrated with or coupled to the sensing reservoir. The sensing reservoir may further comprise a housing 265, configured to encase the electrical components of the sensing reservoir such as the processing unit and/or the power source. For example, the housing 265 may comprise a bottom cap 267 configured to couple to the bottom of the reservoir 205, as shown in FIG. 2B. Optionally, the housing 265 may be further configured to encase at least a portion of the fluid sensing unit 270 and/or the insulating unit 235. The housing may be fixedly coupled to the fluid sensing unit, insulating unit, the processing unit, and/or the power source, and removably couplable to the reservoir 205, such that the reservoir 205 may be an interchangeable component of the sensing reservoir 200.

[0089] The reservoir 205 comprises an opening 225 configured to allow passage of the fluid in and out of the reservoir. The opening 225 comprises a coupling mechanism 230, configured to removably couple to another device such as the pumping device 100 or feeding nipple. The coupling mechanism may comprise any coupling mechanism known in the art, such as screw threads, quarter turn couplings, bayonet couplings, interference fits, and the like. In preferred embodiments, the coupling mechanism comprises male screw threads, so as to make the sensing reservoir widely adaptable for use with many off-the-shelf pumping devices utilizing screw threads to attach a collection vessel to the pumping device. The reservoir 205 may further comprise one or more additional openings, such as vent openings to allow passage of air and thereby facilitate passage of the fluid through the opening 225.

[0090] The fluid sensing unit 270 may comprise one or more fluid sensors 275, distributed about the reservoir 205 in a known manner. For example, the fluid sensors 275 may be distributed about the periphery of the reservoir at a known rotational offset, as shown in FIG. 2B. For example, the fluid sensing unit may comprise three fluid sensors, the first fluid sensor offset at a 90° angle from the second sensor, and the third sensor offset at a 180° angle from the second sensor. In some embodiments, the fluid sensing unit comprises a plurality of fluid sensors distributed about the periphery of the reservoir at a substantially equal rotational offset from one another, such that the position of the fluid in the reservoir can be accurately determined. For example, the fluid sensing unit may comprise three fluid sensors rotationally offset at 120° angles from one another. In embodiments comprising three fluid sensors, the fluid position and reservoir orientation can be determined via triangulation of the fluid level sensed by each fluid sensor, as described in further detail herein. In some embodiments, the fluid sensing unit comprises a single fluid sensor.

[0091] The fluid sensing unit 270 may be coupled to the reservoir 205 in a manner that enables accurate measurement of the interior surface of the reservoir. For example, the one or

more fluid sensors 275 may be placed on the interior surface of the reservoir for direct exposure to the fluid, or the fluid sensors placed on the interior reservoir surface may be covered with a thin film coating. In preferred embodiments, the fluid sensing unit is embedded in the wall of the reservoir, such that the fluid sensors are closer to the interior surface than to the external surface of the reservoir. While embodiments described herein are directed to a fluid sensing unit coupled to the wall of the reservoir, a fluid sensing unit may be coupled to any suitable location on the sensing reservoir.

[0092] The fluid sensing unit 270 may be fixedly coupled to the reservoir, in a manner that protects the component sensors from signal interference or damage. Alternatively, the fluid sensing unit may be removably couplable to the reservoir 205, such that the sensing unit may, for example, be removed from the reservoir while the reservoir is washed and/or sterilized. Optionally, the fluid sensing unit may be fixedly coupled to a housing that is removably couplable to the reservoir 205, wherein the housing is also coupled to electrical components of the sensing reservoir. For example, the fluid sensing unit and the processing unit and power source operably coupled thereto may be at least partially encased within a housing, which may be removably attached to a reservoir 205.

[0093] The sensing reservoir 200 may comprise a processing unit 240 in communication with the fluid sensing unit 270. The processing unit may be configured to receive measurement data from the fluid sensing unit and store the data, analyze the data, and/or transmit the data to another computing device, such as a smartphone, tablet, desktop computer, laptop computer, etc. The processing unit may perform analysis of the collected data and transmit the analyzed data to another device; alternatively, the processing unit may transmit raw measurement data to another computing device configured to perform the data analysis. The processing unit and/or the fluid sensing unit may be powered by a power source (not shown) such as a battery, operatively coupled to the processing unit. A housing 265 may be configured to surround the processing unit and/or the power source, in order to protect the electrical components. Optionally, the housing may also couple to or at least partially surround the fluid sensing unit 270. The housing may comprise a material with properties such that the housing can protect the encased structures from mechanical stresses and/or water damage. In some embodiments, the housing completely encases the housed components in a leak-proof manner to protect the components from water damage. The processing unit and/or power source may be fixedly coupled to the reservoir in a manner that can withstand mechanical stresses, extreme temperatures, and/or exposure to fluids (*e.g.*, during milk expression or feeding or during washing of the sensing reservoir). For example,

the electrical components can be encased in a housing having appropriate material properties, fixedly coupled to the reservoir via appropriate means (*e.g.*, epoxy or cyanoacrylate adhesive bonding, ultrasonic welding, etc.). Alternatively, the processing unit and/or power source may be removably couplable to the sensing reservoir, such that the processing unit and/or power source may, for example, be removed from the reservoir while the reservoir is washed and/or sterilized. For example, the electrical components can be encased in a housing as described, wherein the housing may comprise a coupling mechanism that can be releasably coupled to the sensing reservoir.

[0094] FIG. 2C shows an exemplary embodiment of a fluid sensing unit 270 coupled to an insulating unit 235. The insulating unit 235 can be configured to cover or encase the one or more fluid sensors 275 of the fluid sensing unit, thereby insulating the fluid sensing unit from external factors. For example, the insulating unit can provide electrical isolation of the sensors and protect the sensors from physical damage. The insulating unit can, for example, isolate the fluid sensors from the effects of physical contact with one or more human fingers holding the sensing reservoir during use. The insulating unit may comprise a material having a high electrical resistance, such as one or more plastics or rubbers or combinations thereof, or an air gap as described in further detail herein. The insulating unit can further provide protection against physical damage. For example, the insulating unit can comprise a material having properties to protect the encased sensors from mechanical stress, extreme temperatures, and/or water damage. The insulating unit may, for example, comprise one or more plastics or rubbers or combinations thereof, such as silicone. The insulating unit can be coupled to the reservoir so as to form a fluid tight seal around the fluid sensing unit, such that the sensing reservoir may be exposed to fluids (*e.g.*, during milk expression or feeding or during washing of the sensing reservoir) without adversely affecting the function of the encased fluid sensors. Further, the insulating unit can provide improved aesthetics and/or user ergonomics, such as a comfortable grip feature.

[0095] FIG. 2D is a cross-sectional view of the fluid sensing unit 270 coupled to an insulating unit 235 as shown in FIG. 2C, along line 2D-2D. In preferred embodiments, the insulating unit 235 is coupled to the wall 210 of the reservoir in a manner that establishes an air gap 280 between the fluid sensor 275 and the insulating unit. For example, the insulating unit may comprise an internal surface 236 and an external surface 237 opposite the internal surface, the internal surface configured to face the reservoir wall 210 when coupled to the reservoir 205 and the external surface configured to face away from the reservoir wall when coupled to the reservoir. When the insulating unit is coupled to the reservoir, the reservoir

wall 210 and the internal surface 236 of the insulating unit may collectively define a cavity 238 therebetween, the cavity configured to receive a fluid sensor 275 therein. The insulating unit may be shaped and sized to define the cavity 238 having a thickness 239 that is greater than a thickness 279 of a fluid sensor 275 disposed within the cavity. Thus, when the fluid sensor 275 is placed within the cavity and flush against the external surface of the reservoir wall 210, as shown in FIG. 2D, the air gap 280 may be established between the fluid sensor 275 and the internal surface 236 of the fluid sensing unit. The air gap can provide an area of constant dielectric strength, separating the fluid sensor from any interfering signals that may contact the insulating unit (*e.g.*, human fingers, water or milk). The electrical isolation provided by the air gap can help improve the accuracy of the measurements made by the fluid sensors.

[0096] In many embodiments, the sensing reservoir 200 further comprises one or more reservoir sensors, configured to measure a position, orientation, and/or motion of the reservoir. For example, reservoir sensors may comprise one or more accelerometers configured to detect motion of the sensing reservoir. Alternatively or in combination, the reservoir sensors may comprise one or more gyroscopes configured to detect an orientation of the sensing reservoir. The one or more reservoir sensors can improve the accuracy of fluid measurement by the fluid sensing unit. As described in further detail herein, reservoir sensors that provide the orientation of the sensing reservoir can enable an algorithmic compensation for the reservoir orientation, thereby increasing the accuracy of fluid volume calculation based on the fluid levels detected by the fluid sensors. Often, the top portion of a reservoir chamber can have a different geometry than the bottom portion of the reservoir chamber, such that the translation between fluid level and contained fluid volume depends on whether the reservoir is substantially upright or inverted. Reservoir sensors configured to determine whether the reservoir is in an upright or inverted configuration can thus facilitate the selection of the correct translation algorithm in performing analysis of the fluid sensor data. Further, reservoir sensors can enable the sensing reservoir to switch from one operating state to another. For example, reservoir sensors configured to measure a position or motion of the sensing reservoir can determine when the reservoir is in an inactive/standby or "sleep" state, filling state, draining state, or in transition between one operating state to another. The fluid sensing unit can be configured to pause data collection during times the reservoir is determined to be in a standby or sleep state, so as to reduce power consumption and the collection of redundant data points. Further, the fluid sensing unit may be configured to collect data only during times the reservoir is determined to be in a stable filling state or

draining state without excessive detected motion, so as to reduce the collection of unusable (*e.g.,* excessively noisy) data points.

[0097] The reservoir sensors may be disposed on any portion of the sensing reservoir. For example, the reservoir sensors may be integrated with the fluid sensing unit 270. In preferred embodiments, the reservoir sensors are disposed on the processing unit 240, and in communication with a microcontroller or microprocessor of the processing unit.

[0098] Optionally, the sensing reservoir 200 may further comprise a means for detecting the coupling of the sensing reservoir to another component, such as a pumping device, a feeding attachment, or a storage cap. The detection of the coupling may be used as a cue for the fluid sensing unit and/or the reservoir sensors to initialize the system, determine the appropriate operating state, and begin sensor interrogation, enabling the sensing reservoir to switch quickly and accurately between different operating states (*e.g.*, standby/sleep, filling, draining) and thereby optimize the efficiency of power consumption by the sensing reservoir. In some embodiments, the means for detecting the coupling may comprise one or more proximity sensors coupled to the sensing reservoir, and one or more corresponding proximity triggers coupled to a component to be coupled to the reservoir. The proximity sensors may be located near the portion of the reservoir configured to couple to the component, and the proximity triggers may be located near the portion of the portion of the component configured to couple to the sensing reservoir, such that the sensors and the triggers are brought into proximity when the sensing reservoir is coupled to the component. The proximity sensor may be configured to detect the proximity trigger when the proximity trigger is placed within a predetermined distance from the proximity sensor. When the component comprising the proximity trigger is coupled to the sensing reservoir, the proximity trigger is brought within the predetermined distance from the proximity sensor, thus enabling the proximity sensor to detect the coupling of the component to the sensing reservoir.

[0099] The proximity sensors and proximity triggers may be provided in various configurations in order to enable identification of the component that is coupled to the sensing reservoir. Thus, the sensing reservoir may be able to distinguish between the coupling of the reservoir to a feeding attachment or to a pumping device, enabling the system to determine the operating state of the sensing reservoir (*e.g.*, whether the reservoir is about to begin filling (when attached to pumping device) or draining (when attached to feeding attachment)). In this case, the detection of a coupling event can not only direct the system to begin interrogation of the fluid sensing unit, but also help the processing unit select the appropriate analysis algorithm for the calculation of fluid levels based on the measurement

data produced by the fluid sensing unit. The proximity sensor-derived operating state information can be cross-checked against the operating state information derived from the reservoir sensors and/or the fluid sensing unit to verify the current operating state (*e.g.*, standby, filling, draining) of the sensing reservoir.

[00100] In some embodiments, a proximity sensor may comprise a combination of one or more light emitting diodes (LEDs) or other suitable light sources and one or more photodiodes. In such a system, a proximity trigger may comprise one or more highly reflective markers, disposed at predetermined locations with respect to the LED/photodiode sensor assembly when the component comprising the proximity trigger is coupled to the sensing reservoir. To detect the coupling of the sensing reservoir to the component, the LEDs may emit light directed towards the predetermined location of the component. When the sensing reservoir is not coupled or is coupled improperly or incompletely to the component, light emitted from the LEDs misses the reflective markers, hits only a relatively small portion of the reflective markers, and/or hits the reflective markers at a distance that is too far for reflected light to reach the photodiode. In this case, the photodiode detects no or little reflected light, below a pre-designated threshold intensity that indicates light reflection from the reflective markers. Accordingly, the measurement by the proximity sensor indicates that the sensing reservoir is not properly connected to the component. When the sensing reservoir is properly coupled to the component, light emitted from the LEDS hits at least a substantial portion of the reflective markers at an appropriate distance, such that at least a substantial portion of the emitted light is reflected back towards the LED/photodiode assembly. In this case, the photodiode detects reflected light at a high intensity, above the pre-designated threshold value, indicating the light has been reflected from the reflective markers. Accordingly, the measurement by the proximity sensor indicates that the sensing reservoir is properly connected to the component.

[00101] In some embodiments, a proximity sensor may comprise one or more Hall effect sensors configured to measure the intensity of a magnetic field. In such a system, a proximity trigger may comprise one or more magnets of predetermined magnetic strengths. The one or more magnets may be embedded in the component such that when the sensing reservoir is properly coupled to the component, the Hall effect sensors can sense the magnetic field generated by the one or more magnets. When the Hall effect sensors output voltage above a predetermined threshold corresponding to the predetermined magnetic strength of the magnet, the system may indicate that the sensing reservoir is properly connected to the component.

[00102] In some embodiments, a proximity sensor may comprise one or more reed switches configured to electrically on or off, or between a "connected" or "not connected" state, in response to detection of a magnetic field of a predetermined strength. In such a system, a proximity trigger may comprise one or more magnets of the predetermined magnet strengths. The one or more magnets may be embedded in the component such that when the sensing reservoir is properly coupled to the component, the reed switch can sense the magnetic field generated by the one or more magnets. When the reed switch "switches" in response to the detection of a magnetic field above the threshold strength, the system may indicate that the sensing reservoir is properly connected to the component.

[00103] The identity of the component that is coupled to the sensing reservoir may be determined in many ways. In some embodiments, different types of components may be associated with different predetermined threshold values of sensor output. For example, in embodiments comprising LED/photodiode assemblies as the proximity sensors and reflective markers as the proximity triggers, different predetermined threshold values of reflected light intensity may be set for different types of components. A pump device may comprise one or more first reflective markers having a first reflective index, while a feeding attachment may comprise one or more second reflective markers having a second reflective index different from the first reflective index. The processing unit may be pre-programmed with a first threshold value corresponding to the intensity of light reflected from the first reflective markers, and a second threshold value corresponding to the intensity of light reflected from the second reflective markers. Thus, when the intensity of light detected by the photodiode is substantially similar to the first threshold value, the processing unit may determine that the reservoir is connected to a pump device, and when the intensity of light detected by the photodiode is substantially similar to the second threshold value, the processing unit may determine that the reservoir is connected to a feeding attachment. Similarly, in embodiments comprising Hall effect sensors as the proximity sensors and magnets as the proximity triggers, different predetermined threshold values of magnetic field strength may be set for different types of components. To produce different sensor outputs between different types of components, proximity triggers with varying signal levels may be used (*e.g.*, reflective markers with different reflective indexes, magnets with different magnetic strengths), and/or different numbers or areas/sizes of proximity triggers may be used.

[00104] In some embodiments, different types of components may be associated with proximity triggers disposed at different, known locations. The sensing reservoir may comprise a plurality of proximity sensors disposed at various locations of the reservoir

corresponding to the different locations of proximity triggers on different components. For example, the sensing reservoir may comprise a first proximity sensor disposed at a first location of the reservoir, and a second proximity sensor disposed at a second location different from the first location. A pumping device may comprise a proximity trigger disposed at a location corresponding to the first location of the reservoir, and a feeding attachment may comprise a proximity trigger disposed at a location corresponding to the second location of the reservoir. Thus, when the pumping device is coupled to the sensing reservoir, the first proximity sensor detects a connection, whereas when the feeding attachment is coupled to the sensing reservoir, the second proximity sensor detects a connection. The processing unit may be pre-programmed with the associations between sensor locations and component types, such that the sensing reservoir can identify the type of component coupled to the reservoir based on the location of the proximity sensor that detects a connection.

[00105] FIGS. 3A-3D illustrate an exemplary embodiment of a sensing reservoir 300 comprising a proximity sensor 390 and coupled to a feeding attachment 150. FIG. 3A is a side view of the sensing reservoir 300 coupled to the feeding attachment 150. FIG. 3B is an exploded view of the sensing reservoir 300 of FIG. 3A. FIG. 3C is a vertical cross-section of the sensing reservoir 300 of FIG. 3A along line 3C-3C. FIG. 3D is a horizontal cross-section of the sensing reservoir 300 of FIG. 3A along line 3D-3D. The sensing reservoir 300 can be similar in many aspects to the sensing reservoir 200 described with reference to FIGS. 2A-2D. For example, the sensing reservoir 300 may comprise a reservoir 305, a fluid sensing unit 370, an insulating unit 335, a housing 365, a processing unit 340, and one or more reservoir sensors (not shown), each of which may be similar in many aspects to the correspondingly-named component described with reference to sensing reservoir 200 of FIGS. 2A-2D. The sensing reservoir further comprises a power source 385 coupled to the processing unit 340. The sensing reservoir 300 further comprises one or more proximity sensors 390, and the feeding attachment 150 comprises one or more proximity triggers 395 configured to be detected by the one or more proximity sensors 390 when the feeding attachment is coupled to the sensing reservoir.

[00106] The feeding attachment 150 may comprise a feeding nipple 152 and a coupling adaptor 154 coupled together fixedly or removably. The feeding attachment may further comprise one or more proximity triggers 395, which may be embedded within the coupling adaptor as best shown in FIG. 3C. The coupling adaptor 154 may comprise a coupling

mechanism 155, such as a threaded interior surface, configured to couple the adaptor to the reservoir 305.

[00107] The reservoir 305 may be coupled to the feeding attachment 150 via a coupling mechanism 330 disposed adjacent the opening 325 of the reservoir, the coupling mechanism 330 configured to couple to the coupling mechanism 155 of the coupling adapter 154. For example, the coupling mechanism 330 may comprises a threaded external surface configured to mate with a threaded interior surface of the coupling adaptor 154. The reservoir 305 may comprise two or more portions that can be fixedly coupled together to collectively define the chamber 315 of the reservoir. For example, the reservoir may comprise a body portion 306 and a bottom portion 307, wherein the bottom portion is configured to couple to the body portion, for example via a snap fit or a press fit. The reservoir wall 310 may define one or more recessed regions 312 on the external surface of the wall. The recessed region may be shaped to receive a fluid sensor therein, so that the fluid sensor can be embedded within the reservoir wall in close proximity to the interior surface of the reservoir wall. The recessed region may be shaped to receive the fluid sensor such that the sensor lays flush against the external surface of the reservoir wall. Optionally, the fluid sensor may be encased within an insulating unit as described herein, and the recessed region may be shaped to receive a portion of the insulating unit and the fluid sensor disposed therein such that an external surface of the insulating unit lays flush against the external surface of the reservoir wall. In embodiments of the fluid sensing unit comprising a plurality of fluid sensors, the reservoir may comprise a plurality of recessed regions, each of which may be shaped to receive each of the plurality of fluid sensors.

[00108] The fluid sensing unit 370 may comprise one or more fluid sensors 375 configured to measure information relating to the level of fluid contained inside the reservoir 305. For example, the fluid sensing unit may comprise one or more capacitive sensors as described in further detail herein. FIGS. 3A-3D show the fluid sensing unit 370 comprising a single fluid sensor 375 configured to be embedded in a wall of the reservoir 305. The fluid sensor 375 may be disposed within an insulating unit 335 configured to provide electrical isolation of the fluid sensor and protect the sensor from physical damage, as described herein. For example, as best shown in FIG. 3D, the insulating unit may be configured to establish an air gap 380 between the fluid sensor and the insulting unit when the fluid sensor is encased within the insulting unit. The insulating unit may comprise an internal surface 336 defining an internal cavity 338 configured to receive the fluid sensor 375 therein. The internal cavity 338 may have a minimum thickness 339 greater than the thickness 379 of the fluid sensor

375, such that when the fluid sensor is disposed within the cavity flush against a first internal surface 336a of the insulating unit, an air gap 380 is established between the fluid sensor and a second internal surface 336b opposite the first internal surface. In embodiments further comprising a proximity sensor 390 disposed within the insulating unit, as described in further detail herein, the thickness of the cavity 338 may also be greater than a thickness of the proximity sensor, such that an air gap is also established between the proximity sensor and an internal surface of the insulating unit. The insulating unit may be configured to couple to the reservoir 305 fixedly or removably, for example by fitting within one or more recessed regions 312 of the reservoir.

[00109] The sensing reservoir may further comprise one or more proximity sensors 390 configured to detect one or more corresponding proximity triggers. The one or more proximity sensors 390 may be disposed within the insulating unit 335 and/or coupled to the fluid sensing unit 370. For example, the proximity sensors may be coupled to a top end of the fluid sensor 375 and enclosed within the insulating unit 335, as shown in FIGS. 3B and 3C. In embodiments comprising capacitive fluid sensors having a conductive material printed onto a flexible circuit board, the proximity sensors may also be printed onto the same circuit board above the capacitive sensor.

[00110] As shown in the FIG. 3C, when the feeding attachment 150 is coupled to the sensing reservoir 300, the proximity sensor 390 is brought adjacent to the proximity trigger 395, such that the proximity sensor can detect the trigger and thereby determine that a connection to a component has been made. Further, as described herein, the proximity sensor can determine the type of component (*e.g.*, feeding attachment) that has been coupled to the reservoir, thereby helping to identify the operating state of the reservoir (*e.g.*, draining). The proximity sensor 390 and proximity trigger 395 may comprise any combination of proximity sensors and triggers as described herein, such as an LED/photodiode assembly and one or more reflective markers, a Hall effect sensor and one or more magnets, a reed switch and one or more magnets, or any other suitable combination of a sensor and an element capable to triggering a sensor output when the element is brought into proximity of the sensor.

[00111] The processing unit 340 may be operably coupled to the fluid sensing unit 370, proximity sensors 390, and/or reservoir sensors (not shown), and to a power source 385. As described herein, the processing unit may be configured to receive measurement data from the fluid sensing unit, reservoir sensors, and/or proximity sensors, store the data, analyze the data, and/or transmit the data to another computing device. The power source may be configured to provide power to the processing unit, fluid sensing unit, and the one or more

proximity sensors. A housing 365 may be provided to surround and protect the processing unit and/or the power source, as described herein. The processing unit and power source may be enclosed within a bottom portion 367 of the housing, which may be sized and shaped to align with the bottom of the reservoir 305. Optionally, the insulating unit 335 and the housing 365 may comprise a single integrated component, configured to house the proximity sensors, fluid sensing unit, processing unit, and the power source. The single, integrated housing, containing all of the components of the sensing reservoir except the reservoir 305, may be removably couplable from the reservoir 305, so as to enable quick and easy exchange of the reservoir 305 (*e.g.*, for washing/sterilization or replacement of the reservoir).

[00112] FIGS. 4A-4C illustrate the sensing reservoir 300 of FIGS. 3A-3D coupled to a pumping device 100. FIG. 4A is a side view of the sensing reservoir 300 coupled to the pumping device 100. FIG. 4B is an exploded view of the sensing reservoir 300 of FIG. 4A. FIG. 4C is a horizontal cross-section of the sensing reservoir 300 of FIG. 4A along line 4C-4C. The sensing reservoir 300 is substantially similar to the sensing reservoir 300 described with reference to FIGS. 3A-3D, but is coupled to a pumping device 100 instead of a feeding attachment.

[00113] The pumping device 100 may comprise a breast interface 105 configured to seal against a breast to express breast milk therefrom, and configured to couple to a collection vessel, such as the sensing reservoir 300, where expressed breast milk may be collected. The breast interface 105 may comprise a coupling mechanism 130 configured to mate with a coupling mechanism 330 of the reservoir 305, to couple the breast interface to the sensing reservoir. For example, the coupling mechanism 130 may comprise a threaded internal surface, and the coupling mechanism 330 of the reservoir 305 may comprise a threated external surface.

[00114] The pumping device 100 further comprises one or more proximity triggers 395 embedded within the breast interface 105 near the portion of the breast interface configured to couple to the sensing reservoir 300. In the embodiment shown in FIG. 4B, the breast interface comprises two proximity triggers 395, compared to the single proximity trigger 395 embedded in the feeding attachment 150 as shown in FIG. 3B. The different number of proximity triggers in the pumping device compared to the feeding attachment can help the proximity sensor 390 of the sensing reservoir 300 distinguish between the different components, as described in further detail herein. For example, in embodiments comprising a Hall effect sensor as the proximity sensor and one or more magnets as the proximity trigger, the feeding attachment may comprise one magnet while the pumping device may comprise

two magnets, such that the proximity sensor produces output of different intensities when the different components are coupled to the sensing reservoir. Alternatively to using different numbers of proximity triggers, different locations of proximity triggers may also be used to distinguish between different components, as described herein.

[00115] FIG. 5 illustrates an exemplary embodiment of a processing unit suitable for incorporation with a sensing reservoir in accordance with embodiments. For example, the processing unit may comprise the processing unit 240 shown and described with reference to FIGS. 2A-2D, or the processing unit 340 shown and described with reference to FIGS. 3A-3D or 4A-4C. The processing unit may comprise one or more of a printed circuit board (PCB) 242 housing one or more of a microcontroller or microprocessor 244, a communication module 246, a fluid sensor connection 248, a power connection 250, a proximity sensor connection 256, and a timer 252. The processing unit may further comprise a memory (not shown). Power may be supplied to the processing unit via a power source comprising a battery or a direct contact connection such as a cable or pad connectors. Alternatively or in combination, power may be supplied via an inductive charging system comprising a battery and a wireless charger, which may be charged using an inductive charging method as known in the art.

[00116] The processing unit may receive signals from the fluid sensing unit through the fluid sensor connection 248, and the signals may be transmitted to the microprocessor 244. One or more reservoir sensors 260, configured to measure a position, orientation, and/or motion of the sensing reservoir, may also be disposed on the processing unit, and may transmit measured signals directly to the microprocessor 244. Optionally, the processing unit may also receive signals from one or more proximity sensors through the proximity sensor connection 256, and the signals may be transmitted to the microprocessor 244. The microprocessor may comprise a non-transitory computer readable medium comprising instructions to collect and process the signals received from the fluid sensing unit, the reservoir sensors, and/or the proximity sensors. The microprocessor may further comprise instructions to transmit the collected and/or processed signals to a memory for storage, or to the communication module 246 for transmission to another computing device. The communication module may comprise a wireless transmitter/receiver such as a Blue Tooth or a WiFi module, for example. The communication module may be configured to transmit the measurement data to another computing device, such as a mobile phone, tablet, or personal computer, for data analysis and/or display of the analyzed data to a user. Alternatively or in combination, the communication module may be configured to transmit the measurement

data to a server for data analysis, and the server may transmit the analyzed data to a personal computing device for display to the user. The user may view and track the analyzed measurement data from the computing device, for example via a mobile application on a mobile phone.

[00117] Referring again to FIGS. 2A-2D, 3A-3D, and 4A-4C, in preferred embodiments, the one or more fluid sensors 275 or 375 of the fluid sensing unit 270 or 370 comprise one or more capacitive sensors. A capacitive sensor can measure the level of fluid in the reservoir, by detecting a change in capacitance affected by the dielectric permittivity of the fluid in proximity to the sensor. The capacitive sensor may be configured to measure self-capacitance, or parasitic capacitance, between the sensor and its surrounding environment. Alternatively or in combination, the capacitive sensor may be configured to measure mutual capacitance between one capacitive sensor and another capacitive sensor disposed nearby.

[00118] A liquid brought in close proximity to a capacitive sensor can change the self-capacitance of the sensor, based on the electrical properties of the liquid. Table 1 summarizes the dielectric constants of some common materials. Liquids such as water or milk generally have a dielectric permittivity greater than the dielectric permittivity of plastics commonly used in making collection reservoirs. Accordingly, the self-capacitance of a capacitive sensor embedded in the wall or

Table 1. Dielectric constants of common materials.

Material	Dielectric constant (ε)
Air	1
Glass	5 – 10
Polyethylene	2.25
Polypropylene	2.2
Silicone	3.6
Polycarbonate, molded	2.8 – 3.4
Polystyrene	2.5 – 2.6
Water, room temp.	80.4

otherwise coupled to the interior surface of a plastic reservoir can increase when a fluid such as breast milk is brought in proximity to the capacitive sensor.

[00119] The change in the capacitance of a capacitive sensor may be observed by a microprocessor in communication with the sensor. A program or functional unit of the microprocessor can apply a signal to a pin that is coupled to the capacitive sensor. An analog

circuit, such as an analog-to-digital converter (ADC), can sample and measure the voltage on the pin. The capacitance and resistance of the pin, the connection to the capacitive sensor, and the capacitive sensor itself can affect the speed with which the pin reaches the signal level. The microprocessor can record the time or count value required for the pin to reach the signal level. As the environment of the electrode changes, the amount of time required for the pin to reach the voltage level generally changes. For example, as fluid collects inside a reservoir, the self-capacitance of the capacitive sensor can increase, consequently increasing the time delay required for the pin to reach the voltage level. This increase in time delay, recorded by the microprocessor, can thereby indicate the increase in fluid level inside the reservoir.

[00120] FIGS. 6A-6H illustrates some exemplary configurations of a capacitive sensor 400 suitable for incorporation with a sensing reservoir. The capacitive sensor may comprise a conductive material, such as copper, aluminum, silver, indium tin oxide (ITO), or a combination thereof. The material may comprise solid sheet of material or a mesh, such as an optically clear silver mesh. The material may comprise a flexible polyimide.

[00121] FIGS. 6A-6D illustrate capacitive sensors having one or more continuous sensing regions configured to extend continuously along a length, such as the height, of the reservoir. Capacitive sensors with continuous sensing regions may be configured to measure self-capacitance, mutual capacitance between two adjacent sensing regions, or a combination of self-capacitance and mutual capacitance. For self-capacitance measurements, each continuous sensing region may be connected to the processing unit for read-out. For mutual capacitance measurements, one sensing region may be connected to the processing unit, while the adjacent sensing region may be charged to a known voltage. As the reservoir is filled with fluid and the level of fluid along the sensing region rises, the total capacitance of a sensor can change, and the change may be detected and recorded as described herein. In embodiments comprising two or more sensing regions, the spacing between two adjacent sensing regions may be configured to provide maximal mutual capacitance between the two sensing regions. The spacing may be constant or varying through the length of the sensing regions.

[00122] FIG. 6A illustrates a capacitive sensor having continuous sensing regions 405 with a shape that is uniform through the length of a sensing region. A sensing region 405 may have a width configured to provide an area of the sensor sufficient for detecting changes in capacitance affected by the fluid contained in the reservoir. In embodiments of the capacitive sensor comprising two or more sensing regions 405, the two or more sensing regions may have the same width, or each sensing region may have a different width.

[00123] FIG. 6B illustrates a capacitive sensor having continuous sensing regions 410 with a shape that varies directionally along the length of a sensing region. For example, as shown in FIG. 6B, each of the sensing regions 410a and 410b may be shaped to increase in width from one end to the other end, such that the capacitive area of each sensing region increases from one end to the other end. The directionally varying shape of sensing regions 410 may help compensate for the saturation effect of the capacitive sensors, wherein the changes in capacitance can become more difficult to detect as the fluid level inside the reservoir reaches the maximal level, due to saturation of capacitance of the sensors. The capacitive sensor may comprise two or more directionally varying sensing regions 410a and 410b having complementary shapes, such that the sensor may provide compensation for the saturation effect whether the reservoir is in an upright or inverted orientation. In the embodiment shown in FIG. 6B, sensing region 410a can provide a larger capacitive area at high fluid levels while the reservoir is in a substantially upright orientation. Similarly, sensing region 410b can provide a larger capacitive area at high fluid levels while the reservoir is in a substantially inverted orientation.

[00124] FIGS. 6C and 6D illustrate capacitive sensors comprising multi-fingered sensing regions. FIG. 6C shows a multi-fingered sensing region 415 comprising a plurality of fingers 416 connected to a stem 417, the stem configured to extend through the middle of the fingers 416. FIG. 6D shows a multi-fingered sensing region 420 comprising a plurality of fingers 421 connected to a stem 422, the stem configured to extend through one side of the fingers 421. Each finger may be configured to have a greater width than the stem, such that each finger provides a larger capacitive area than the portion of the stem preceding the finger. As fluid fills the reservoir and the fluid level passes between the fingers of a single sensing region through a stem portion, small capacitance changes may be observed. As the fluid covers the region of a finger, a larger and more perceptible change may be observed. This discrete change can facilitate the detection of fluid level changes. While FIGS. 6C and 6D depict fingers of a sensing region having a uniform size and shape, the size and/or shape of the fingers may vary within a single sensing region. For example, the fingers may be configured to increase in area from one end of the sensing region to the other, in order to compensate for the saturation effects of the capacitive sensor as described in relation to the embodiments of FIGS. 6A and 6B. In addition, single capacitive sensor may comprise two or more multi-fingered sensing regions having complementary patterns, configured to interlock with constant or varying spacing between the sensing regions. The multi-fingered shape of the

sensing regions can help increase the mutual capacitance between the two sensing regions, by providing a greater total capacitive area between the sensing regions.

[00125] FIGS. 6E and 6F illustrate capacitive sensors having a plurality of discrete sensing regions configured to be placed along a length, such as the height, of the reservoir. A capacitive sensor may comprise an array 425 of uniformly-sized sensing regions 426, as shown in FIG. 6E, or the sensor may comprise an array 430 of discrete sensing regions 431-435, each having a different size, as shown in FIG. 6F. When fluid in the reservoir comes in proximity to or in contact with a discrete sensing region, a change in capacitance of the sensing region can be detected and recorded by the microprocessor. When the fluid level of the reservoir falls between two discrete regions, the sensors may detect very little or no changes in capacitance. Hence, the spacing between two adjacent discrete sensing regions can determine the resolution or detectable increment in the measurement of fluid volume, wherein smaller spacing can provide a finer resolution. The spacing may be adjusted so as to provide any desired resolution, for example 1 oz, 1/2 oz, 1/4 oz, 1/8 oz, or 40ml, 30 ml, 20 ml, 10 ml, or 5 ml. An array of discrete sensing regions may be configured to have constant or varying spacing between two adjacent sensing regions. While the embodiments of FIGS. 6E and 6F show rectangularly-shaped discrete sensing regions, a discrete sensing region may have any shape or size suitable for detecting changes in capacitance affected by the fluid inside the reservoir. Further, a capacitive sensor may comprise any number of discrete sensing regions, in any combination of shapes and sizes. In the embodiment of FIG. 6F, the discrete sensing regions are shown to increase in area from one end of the array 430 to the other, such that sensing region 431 has the smallest area, and sensing region 435 has the largest area. Such a configuration may help compensate for the saturation effects of the capacitive sensor as described in relation to the embodiments of FIGS. 6A and 6B.

[00126] Each sensing region may be connected to its own read-out channel in the microprocessor, via a separate, dedicated line, as shown in FIG. 6E. Alternatively or in combination, two or more sensing regions may be connected to a single read-out channel via the same line. For example, as shown in FIG. 6F, sensing regions 431 and 433 may be connected to line 436, regions 432 and 434 may be connected to line 437, and region 435 may be connected to line 438. In such a configuration, a read-out channel connected to two or more sensing regions may detect only half of the total capacitance change when only half of the connected sensing regions are in proximity to the fluid. Such a configuration can help simplify system configuration and reduce power requirements of the system, by reducing the number of required read-out channels.

[00127] Each discrete sensing region may be disposed on a known position along the height of the reservoir, such that the measurement data generated by the sensing regions can be used to determine the fluid level. For example, in the embodiment shown in FIG. 6F, the system may be programmed to know that sensing region 431 has a vertical position that is offset from the bottom of the reservoir by 1/5 of the total height of the reservoir. The system may further be programmed with a translation between fluid height and fluid volume for a specific operating state of the reservoir, such that the volume of the fluid in the reservoir may be calculated from the fluid levels as indicated by the sensors. Capacitive sensors comprising an array of discrete sensing regions can provide the advantage of reduced power consumption by the system, since the system can be configured to supply power to only a portion of the array of sensing regions. For example, in the embodiment of FIG. 6F, if sensing region 431 does not detect any fluid, the system may be configured to pause interrogation of sensing regions 432, 433, 434, and 435, thus conserving power.

[00128] The various shapes of the sensing regions shown in FIGS. 6A-6H may be combined in any way. For example, a capacitive sensor may comprise a plurality of continuous sensing regions having different shapes (*e.g.*, multi-fingered and uniform), or a capacitive sensor may comprise a combination of a continuous sensing region and an array of discrete sensing regions. Further, one or more capacitive sensors having different configurations of sensing regions may be combined in a single fluid sensing unit.

[00129] FIGS. 6G and 6H illustrate an exemplary embodiment of a base sensor 440 that may be coupled to a capacitive sensor in accordance with embodiments. The base sensor 440 may be optionally coupled to any capacitive sensor as described herein, such as the embodiments illustrated in FIGS. 6A-6F, in order to isolate the sensor from electrical interference. FIG. 6G shows the base sensor 440 coupled to a multi-fingered sensing region 415, while FIG. 6H shows the base sensor 440 coupled to an array 425 of discrete sensing regions 426. The base sensor can be disposed on the exterior side of the capacitive sensor, wherein the interior side of the sensor is oriented towards the interior surface of the reservoir, and can be held at a known voltage. In such a configuration, the base sensor may isolate the sensing regions of the capacitive sensors from interference from electrical and capacitive sources outside the reservoir (*e.g.*, human fingers, water, milk, etc.).

[00130] FIG. 7A is a graph showing an exemplary response of a continuous sensing region of a capacitive sensor. In an ideal response 412, the increase in the fluid level (x-axis) is linearly related to an increase in the read-out value (measured time delay, y-axis). In such an ideal response, the continuous sensing region detects constantly increasing capacitance as the

fluid level rises. A response 407 of a uniformly-shaped, continuous sensing region may differ from the ideal response 412. As the fluid level in the reservoir nears the maximal level, the concomitant increase in detected capacitance can begin to plateau (as shown by portion 408 of the response 407), as the capacitance of the sensing region reaches its saturation level. Accordingly, changes in fluid level near the capacity of the reservoir may become relatively more difficult to detect, when using continuous sensing regions having a uniform shape. A capacitive sensor having a continuous sensing region with a directionally varying shape, such as in the embodiment illustrated in FIG. 6B, may help to compensate for the saturation effect of the sensors, by increasing the capacitive area of the sensing region as the fluid level rises.

[00131] FIG. 7B is a graph showing an exemplary response 417 of a continuous, multi-fingered sensing region, such as in the embodiment illustrated in FIG. 6D. In the response 417 shown, as the fluid level rises, the read-out value (time delay) indicating the change in capacitance generally rises. Due to the non-uniform shape of the sensing regions, wherein a series of fingers having large capacitive areas are connected by stem portions having relatively smaller areas, the response 417 may not be completely linear. For example, small "bumps" 418 in the response may be detected, caused by large increases in the measured response as the fluid level rises to submerge a large capacitive area. The relatively smaller connecting areas between the large areas may contribute a relatively smaller amount of change in capacitance, shown by the relatively flatter portions 419 of the response 417. The "bumps" or relatively steeper portions 418 of the response may facilitate the determination of the correct fluid level from the measurement data, by providing clearly-identifiable points in the response that can be correlated to known positions of specific areas of a sensing region along the length of the reservoir.

[00132] FIG. 7C is a graph showing an exemplary response 422 of a discrete sensing region, such as in the embodiments illustrated in FIGS. 6E and 6F. A single discrete sensing region will generally remain substantially unresponsive until the fluid level rises sufficiently to come in proximity to or in contact with the sensing region. Once fluid is in proximity to or in contact with the sensing region, the sensing region may detect a large increase in capacitance that continues to increase as the fluid level rises over the height of the sensing region, as shown by portion 423 of the response 422. When the fluid level rises above the sensing region to fully cover the entire sensing region, the capacitance of the sensing region can reach its saturation level, resulting in a plateau 424 in the measured response of the sensing region. In this manner, a capacitive sensor comprising a plurality of discrete sensing regions can clearly identify the points at which the fluid level rises to the position of each

discrete sensing region along the length of the reservoir, thereby facilitating the determination of fluid level as well as enabling the determination of the orientation or tilt of the reservoir.

[00133] The measurement data generated by the one or more capacitive sensors may be transmitted to a processing unit, as described herein. The processing unit may further receive measurement data generated by one or more reservoir sensors, configured to measure a position, orientation, or motion of the reservoir, and/or by one or more proximity sensors, configured to detect the connection of the reservoir to another component such as a pumping device or a feeding attachment. The collective measurement data, including data generated by the fluid sensing unit as well as data generated by the reservoir sensors, may subsequently be analyzed in order to determine the volume of fluid contained in the reservoir. The analysis may be performed by the microprocessor of the processing unit integrated with the sensing reservoir, or by another computing device in communication with the processing unit. For example, the analysis may be performed by a personal computing device (*e.g.*, smartphone, tablet, laptop), or by a remote server in communication with the personal computing device and/or the sensing reservoir. Alternatively, the analysis may be performed partially by the processing unit of the sensing reservoir, and partially by another computing device.

[00134] The measurement data generated by one or more capacitive sensors as described herein may be analyzed using an algorithm appropriately selected for the specific configuration of the capacitive sensor's sensing regions. In many embodiments, the algorithms include a calibration step, wherein a translation may be established between the read-out values of a particular sensor and the corresponding fluid level. The translation may be stored in a memory of the processing unit performing the analysis.

[00135] For sensors comprising continuous sensing regions, the algorithm may comprise an initial calibration to determine 1) a reference or baseline value, corresponding to the sensor response when there is no fluid in the reservoir, and 2) a maximum fill value, corresponding to the sensor response when the reservoir is filled to the maximal level. The sensor response value for a specific measurement may then be compared to the reference value and the maximum fill value, to determine the proportion of the maximum fill value represented by the measured value.

[00136] For sensors comprising continuous sensing regions with non-uniform shapes, such as the multi-fingered configurations illustrated in FIGS. 6C and 6D, the periodic jumps in detected capacitance, corresponding to the fluid level reaching the relatively large capacitive areas of a sensing region, can enable the determination of fluid level for a specific sensor measurement. For example, the measured sensor response can be divided by a constant value

representing the sensor response for a single large capacitive area, and a marginal response value can be added to account for the sensor response for the relatively smaller, connective area. Fluid levels corresponding to the sensor response values may be determined using known positions of the sensing region's capacitive areas along the length of the reservoir.

[00137] For sensors comprising a plurality of discrete sensing regions, the measured response of each sensing region may be compared against a baseline value determined during an initial calibration. When the measured response of a specific sensing region is close to or exceeds its baseline value, the fluid level can be determined to have reached the location of the specific sensing region. To determine the fluid level of a sensor comprising an array of discrete sensing regions, the read-out values of the sensing regions may be processed starting from the sensing region at the lowest position in the array; information generated by the reservoir sensors may be used to determine which sensing region is at the lowest position, based on the orientation or operating state (upright/filling or inverted/draining) of the sensing reservoir. When multiple sensing regions are connected to a single read-out channel, a combination of processing techniques can be used to determine the fluid level.

[00138] FIG. 8A illustrates an exemplary embodiment of a sensing reservoir 200 in the filling state, at a tilted orientation. The reservoir comprises a plurality of fluid sensors 275a, 275b, and 275c, dispersed about the periphery of the reservoir. While FIG. 8A shows the fluid sensors 275a and 275b, and sensors 275b and 275c rotationally offset from each other at 90° angles, and sensors 275a and 275c rotationally offset from each other at a 180° angle, the sensors may be distributed in any predetermined distribution that enables the determination of the reservoir's orientation. Generally, an equal distribution of the plurality of fluid sensors about the periphery of the reservoir can yield the most accurate estimation of the reservoir's orientation. As described herein, the read-out value of each fluid sensor can be processed to indicate the fluid level at the specific sensor. The fluid level at the three locations of the fluid sensors can be triangulated to determine the angle θ, corresponding to the tilt or vertical offset of the reservoir with respect to a vertical position. The known tilt or orientation of the reservoir can then allow the calculation of fluid volume based on the fluid levels at the three fluid sensors.

[00139] FIGS. 8B and 8C show exemplary graphs of fluid sensor response measured during operation of a sensing reservoir of FIG. 8A, in the filling state. FIG. 8B represents exemplary measurement data generated by fluid sensors having continuous sensing regions, and FIG. 8C represents exemplary measurement data generated by fluid sensors having a plurality of discrete sensing regions. The graphs of FIGS. 8A and 8B indicate sensor response

measured at an initial time point, t_0, and at a subsequent time point, t_1, wherein the fluid level at t_1 is higher than the fluid level at t_0 for a reservoir in the filling state. Depending on the tilt or orientation of the reservoir, the plurality of fluid sensors may report different read-out values. For example, in the reservoir shown in FIG. 8A, sensor 275a reports the highest read-out value of the three sensors, due to the tilt or vertical offset angle θ of the reservoir. For a sensing reservoir in a perfectly vertical position (*e.g.*, angle θ equals 0), the plurality of fluid sensors can report the same read-out values. Thus, the fluid levels measured at different sensor locations can help determine the orientation of the reservoir.

[00140] FIG. 9A illustrates an exemplary embodiment of a sensing reservoir 200 in the draining state, at a tilted orientation. In the draining state, the reservoir may be coupled to a feeding nipple as shown, so as to feed the milk contained in the reservoir to an infant. The reservoir comprises a plurality of fluid sensors 275a, 275b, and 275c, dispersed about the periphery of the reservoir. As described herein, the read-out value of each fluid sensor can be processed to indicate the fluid level at the specific sensor. The fluid level at the three locations of the fluid sensors can be triangulated to determine the angle θ, corresponding to the tilt or vertical offset of the reservoir with respect to a vertical position. The known tilt or orientation of the reservoir can then allow the calculation of fluid volume based on the fluid levels at the three fluid sensors.

[00141] FIGS. 9B and 9C show exemplary graphs of fluid sensor response measured during operation of a sensing reservoir of FIG. 9A, in the draining state. FIG. 9B represents exemplary measurement data generated by fluid sensors having continuous sensing regions, and FIG. 9C represents exemplary measurement data generated by fluid sensors having a plurality of discrete sensing regions. The graphs of FIGS. 9A and 9B indicate sensor response measured at an initial time point, t_0, and at a subsequent time point, t_1, wherein the fluid level at t_1 is lower than the fluid level at t_0 for a reservoir in the draining state. Depending on the tilt or orientation of the reservoir, the plurality of fluid sensors may report different read-out values. For example, in the reservoir shown in FIG. 9A, sensor 275a reports the highest read-out value of the three sensors, due to the tilt angle 315 of the reservoir. For a sensing reservoir in a perfectly vertical position (*e.g.*, angle θ equals 0), the plurality of fluid sensors can report the same read-out values. Thus, the fluid levels measured at different sensor locations can help determine the orientation of the reservoir.

[00142] While the vertical tilt of the reservoir may be determined from the fluid sensor data, the operating state of the reservoir (filling or draining) may be difficult to establish based only on the fluid sensor data. Whether the fluid sensors comprise continuous sensing

regions or a plurality of discrete sensing regions, the generated measurement signals may be similar for reservoirs in an upright position (filling state) or in an inverted position (draining state). The translation between sensor response and fluid levels, and hence fluid volume, can differ depending on the operating state of the reservoir, since the geometry of the top of the reservoir may differ from the geometry of the bottom of the reservoir. In order to accurately determine fluid levels from measured sensor response, one or more reservoir sensors configured to determine an orientation or motion of the reservoir may be provided with the sensing reservoir. For example, one or more gyroscopes and/or accelerometers may be provided to sense the motion and orientation of the reservoir, thereby enabling the sensing reservoir to toggle the operating state of the system between filling and draining. The reservoir sensors can also help to eliminate noisy readings, by detecting excessive motion and thereby giving the system an indication to pause data collection until the reservoir reaches a more stable state.

[00143] In embodiments of the sensing reservoir further comprising one or more proximity sensors, measurement data from the proximity sensors may also be used to determine the orientation and corresponding operating state of the sensing reservoir. For example, as described herein, a proximity sensor may detect the coupling of the reservoir to a pumping device, which may indicate that the reservoir is in a generally upright orientation and about to begin filling with fluid. A proximity sensor may detect the coupling of the reservoir to a feeding attachment, which may indicate that the reservoir is in a generally inverted orientation and about to begin draining. The information provided by the proximity sensors can not only be used to efficiently manage the data measurement by the fluid sensing unit, as described further herein, but can also provide validation of the tilt or orientation of the reservoir as determined by measurement data from the reservoir sensors and/or the fluid sensing unit.

[00144] FIG. 10 illustrates a method 500 for determining the volume of fluid contained in a sensing reservoir in accordance with embodiments. The method 500 may comprise three stages: 1) system setup; 2) measurement data generation; and 3) data analysis.

[00145] System setup may comprise steps 505-515. At step 505, fluid sensor readings are taken to check that the fluid sensors are working properly. For example, a baseline read-out value of the fluid sensors may be compared to a known baseline value, to ensure that the readings fall within an appropriate range. At step 510, reservoir sensor readings are taken to check that the motion or tilt readings fall within an appropriate range. For example, accelerometer readings may be taken to ensure that the reservoir is not undergoing excessive

motion. At step 515, the communication between the sensors and the processing unit may be verified.

[00146] Measurement data generation may comprise steps 520-540. At step 520, the reservoir sensors may be read to determine the operating state of the sensing reservoir (*e.g.*, filling state or draining state). At step 525, the fluid sensors may be read to generate read-out values indicative of the level of fluid at each fluid sensor. At step 530, the read-out values generated by the fluid sensors and/or the reservoir sensors may be stored into a memory of the processing unit, for storage and/or transmission to another computing device. At step 535, the system may wait a set delay, or wait until an indication to continue is received from the sensing unit or the processing unit. At step 540, the sensor reading steps 520 and 525 are repeated. Steps 520-540 of measurement data generation may be repeated continuously as long as motion of the sensing reservoir is detected, or a change over time in the read-out values of the fluid sensors is detected. When neither motion of the reservoir nor changes in the fluid sensor readings are detected, the sensing reservoir may enter an inactive or "sleep" state, during which the generation of measurement data may be paused.

[00147] Data analysis may comprise steps 545-550. At step 545, the fluid sensor readings may be processed in order to determine fluid level values. If the fluid sensors comprise continuous sensing regions, the sensor read-out at each measurement may be used to determine the fluid level. If the fluid sensors comprise a plurality of discrete sensing regions, the orientation of the reservoir (upright or inverted) as determined by the reservoir sensor readings may be used to determine which sensing region is at the lowest position, and the fluid sensor data from the plurality of regions may be processed sequentially from the sensing region at the lowest position through to the sensing region at the highest position. At step 550, the processed fluid sensor data may be compared with the reservoir sensor readings in order to ensure that the two sets of data generally match.

[00148] The steps of method 500 are provided as an example of a method to determine a fluid volume using a sensing reservoir, in accordance with embodiments. A person of ordinary skill in the art will recognize many variations and modifications based on the disclosure provided herein. For example, some steps may be added or removed. Some of the steps may comprise sub-steps, and many of the steps may be repeated. The processor as described herein can be programmed with one or more instructions to perform one or more of the steps of method 500.

[00149] Referring again to FIGS. 3A-4C, in some embodiments, a sensing reservoir 300 may comprise a fluid sensing unit 370 having only a single fluid sensor 375. In such a

configuration, the triangulation of the fluid levels to determine the orientation of the reservoir, as shown and described with reference to FIGS. 8A-9C, may not be possible. To determine the orientation and the corresponding operating state of the sensing reservoir (*e.g.*, upright/filling, inverted/draining), measurement data from the one or more reservoir sensors, such as accelerometers and/or gyroscopes, may be analyzed. Alternatively or in combination, data from the proximity sensors may also be used to confirm the orientation and corresponding operating state of the sensing reservoir as determined by the reservoir sensors.

[00150] In embodiments of the sensing reservoir comprising a single fluid sensor, the tilt or vertical offset of the reservoir as well as the rotational offset of the reservoir can affect the accuracy of fluid level measurement by the fluid sensor. FIGS. 11A and 11B show a side perspective view and a top view, respectively, of a sensing reservoir 300 comprising a single fluid sensor 375, oriented at a maximum rotational offset. The sensing reservoir is shown tilted, or vertically offset by an angle θ with respect to the vertical axis of the reservoir in a fully upright position. At this vertical offset, the fluid level is highest at point P_{max} along the periphery of the reservoir, positioned at the base of the tilt. Conversely, the fluid level is lowest at point P_{min} directly opposite point P_{max}. As shown in FIG. 11B, the fluid sensor 375 is rotationally offset from point P_{max} by an angle φ of 180°. At this maximum rotational offset, the fluid sensor is positioned over point P_{min}, at which the fluid level is lowest. Therefore, at this maximum rotational offset of the fluid sensor with respect to the base of the tilt, the measurement generated by the fluid sensor is generally less reliable. FIGS. 11C and 11D show a side perspective view and a top view, respectively, of a sensing reservoir 300 comprising a single fluid sensor 375, oriented at an intermediate rotational offset. As in FIGS. 11A and 11B, the sensing reservoir is shown tilted, or vertically offset by an angle θ with respect to the vertical axis of the reservoir in a fully upright position. As shown in FIG. 11D, however, the fluid sensor 375 is now rotationally offset from point P_{max} by an angle φ of 90° rather than 180°. In this orientation, the fluid sensor can generate a measurement with higher confidence than in the orientation shown in FIGS. 11A and 11B. FIGS. 11E and 11F show a side perspective view and a top view, respectively, of a sensing reservoir 300 comprising a single fluid sensor 375, oriented at zero rotational offset. As in FIGS. 11A-11D, the sensing reservoir is shown tilted, or vertically offset by an angle θ with respect to the vertical axis of the reservoir in a fully upright position. As shown in FIG. 11F, however, the fluid sensor 375 is now positioned over point P_{max}, or at a rotational offset angle φ of 0°. In this orientation, the fluid sensor can generate a measurement with maximum confidence for the given vertical offset.

[00151] FIG. 12 illustrates the effect of vertical and rotational offset of a sensing reservoir on the confidence of measurement data generated by a fluid sensing unit of the reservoir. The x-axis represents the tilt or vertical offset of the reservoir with respect to the upright position, in terms of angle θ. The y-axis represents the rotational offset of the fluid sensor with respect to the position along the periphery of the reservoir at the base of the tilt, in terms of angle φ. As described with reference to FIGS. 11A-11F, the rotational offset φ can range from a minimum of 0° (bottom horizontal line/x-axis) to a maximum of 180° (top horizontal line). For vertical and rotational offsets falling within the shaded area 600, the fluid sensing unit provides relatively high-confidence measurements, whereas for vertical and rotational offsets falling outside of the shaded area 605, the fluid sensing unit provides relatively low confidence measurements. As shown in this graph, the greater the rotational offset, the smaller the allowable vertical offset that could still yield relatively high-confidence measurements by the fluid sensing unit. Conversely, the greater the vertical offset, the smaller the allowable rotation offset that could still yield relatively high-confidence measurements by the fluid sensing unit.

[00152] In order to improve the efficiency and accuracy of fluid level measurements by the sensing reservoir, the processing unit may be configured to determine whether the reservoir is in an acceptable orientation for fluid measurement, prior to interrogating the fluid sensors for measurement data. Acceptable ranges of vertical and rotational offsets may be calculated based on the specific dimensions and/or characteristics of the sensing reservoir and its components. When the sensing reservoir is determined to be oriented outside of the predetermined acceptable ranges of vertical and rotational offsets, the processing unit may forgo interrogation of the fluid sensors for fluid level measurement, in view of the high probability that the measurement may yield unusable data. Data collection by the fluid sensing unit may be paused until the reservoir is determined to be oriented within the acceptable ranges of vertical and rotational offsets. Such a system configuration can help reduce or eliminate noisy fluid sensor readings, as well as improve the efficiency of power consumption by the system.

[00153] FIG. 13 illustrates a method 700 for determining the volume of fluid contained in a sensing reservoir in accordance with embodiments. Method 700 comprises switching between a low-power, standby state and a measurement state based on information provided by one or more proximity sensors (*e.g.*, LED/photodiode assemblies, Hall effect sensors, reed switches) of the sensing reservoir. Steps 705-710 may be performed while the sensing reservoir is operating in a low-power, standby state, wherein the reservoir is not measuring

fluid levels. Steps 715-755 may be performed while the sensing reservoir is operation in a measurement state, wherein the reservoir is actively measuring fluid levels.

[00154] At step 705, a user of the sensing reservoir may prompt the system to begin fluid measurement. For example, the user may indicate through a user interface of the sensing reservoir (*e.g.*, mobile application) or using a physical switch or button on the reservoir that the user is about to begin pumping or feeding, thereby that the reservoir is about to begin filling or draining. At step 710, the processing unit may interrogate the proximity sensor to determine whether a connection to another component (*e.g.*, pumping device, feeding attachment) is detected. The processing unit may be configured to perform step 705 at regular, pre-set intervals, for example every 1 second. At step 715, the processing unit may determine whether a connection is detected, based on data from the proximity sensor. If a connection is not detected, step 705 may be repeated.

[00155] If a connection is detected, at step 715, the processing unit may set the analysis mode to "filling" or "draining" based on the detected component type. For example, if the proximity sensor detects a connection to a pumping device, the analysis mode may be set to "filling". If the proximity sensor detects a connection to a feeding attachment, the analysis mode may be set to "draining".

[00156] At step 720, the processing unit may interrogate one or more reservoir sensors (*e.g.*, accelerometers and/or gyroscopes) for reservoir orientation information. For example, the reservoir sensors can provide the vertical offset and rotational offset of the reservoir as described herein. At step 725, the processing unit may determine whether the orientation of the sensing reservoir is acceptable for fluid measurement. As described herein, the processing unit may be pre-programmed with acceptable ranges or threshold values for vertical and rotational offset of the reservoir, against which the measured values may be compared. If the orientation is found to be unacceptable for fluid measurement (*e.g.*, confidence of fluid measurement data would be low at given orientation), step 720 may be repeated at regular, pre-set intervals (*e.g.*, every 1 second) until an acceptable orientation is detected.

[00157] If the orientation is found to be acceptable, at step 730, the processing unit may interrogate the fluid sensing unit to obtain fluid measurement data. At step 735, the measurement data may be stored in a memory of the processing unit. At step 740, the processing unit may analyze the fluid measurement data to determine fluid level of the milk contained within the reservoir. At step 745, the determined fluid level data may be stored in the memory.

[00158] At step 750, the processing unit may interrogate the proximity sensor again to determine whether the connection to the component is still detected. At step 755, the processing unit may determine whether or not the connection is still detected, based on data from the proximity sensor. If the connection is still connected, steps 720-755 may be repeated. If the connection is no longer detected, the sensing reservoir may return to the low-power, standby state, and step 705 may be repeated.

[00159] The steps of method 700 are provided as an example of a method to determine a fluid volume using a sensing reservoir, in accordance with embodiments. A person of ordinary skill in the art will recognize many variations and modifications based on the disclosure provided herein. For example, some steps may be added or removed. Some of the steps may comprise sub-steps, and many of the steps may be repeated. The processor as described herein can be programmed with one or more instructions to perform one or more of the steps of method 700.

[00160] FIG. 14 illustrates a method 800 for transmitting data from a sensing reservoir in accordance with embodiments. The steps of the method 800 may be repeated at regular, pre-set intervals (*e.g.*, every 24 hours, every hour, every minute, etc.), or may be performed upon prompting by a user of the sensing reservoir.

[00161] At step 805, the processing unit of the sensing reservoir may check to see whether any new, not yet transmitted data is stored on the memory. At step 810, the processing unit determines whether there is new data to be transmitted. If not, step 805 may be repeated, for example at regular, pre-set intervals (*e.g.*, every 24 hours, every hour, every minute, etc.).

[00162] If there is new data stored on the memory, at step 815, the processing unit may check for a connection to the computing device to which the user desires to transfer the data. The computing device may comprise a personal computer, laptop, tablet, or smartphone, which may be configured to provide a software or application to manage breast milk inventory. Alternatively or in combination, the computing device may comprise a remote server configured to store the user's data. Step 815 may be performed by a communication module coupled to or integrated with the processing unit, wherein the connection may comprise a wired connection, a wireless short range connection, or a wireless long range connection. At step 820, the processing unit determines whether connection is detected. If not, step 815 may be repeated, for example at regular, pre-set intervals.

[00163] If a connection to the computing device is detected, at step 825, the processing unit may generate a data packet containing all of the new data that has not yet been

transmitted from the sensing reservoir. At step 830, the processing unit may transmit the data packet to the target computing device, for example via the communication module.

[00164] The steps of method 800 are provided as an example of a method to transmit measurement data from a sensing reservoir, in accordance with embodiments. A person of ordinary skill in the art will recognize many variations and modifications based on the disclosure provided herein. For example, some steps may be added or removed. Some of the steps may comprise sub-steps, and many of the steps may be repeated. The processor as described herein can be programmed with one or more instructions to perform one or more of the steps of method 800.

[00165] In any of the embodiments disclosed herein, the sensing reservoirs described herein can be configured to communicate with another entity, such as one or more computing devices and/or servers. Exemplary computing devices include personal computers, laptops, tablets, and mobile devices (e.g., smartphones, cellular phones). The servers can be implemented across physical hardware, virtualized computing resources (e.g., virtual machines), or any suitable combination thereof. For example, the servers may comprise distributed computing servers (also known as cloud servers) utilizing any suitable combination of public and/or private distributed computing resources. The computing devices and/or servers may be in close proximity to the sensing adaptor and the pumping device (short range communication), or may be situated remotely from the sensing adaptor and the pumping device (long range communication). Any description herein relating to communication between a computing device and a sensing reservoir can also be applied to communication between a server and a sensing reservoir, and vice-versa.

[00166] The sensing reservoir can communicate with another computing device via a communication module, as described herein. The communication module can utilize any communication method suitable for transmitting data, such as a wired communication (e.g., wires, cables such as USB cables, fiber optics) and/or wireless communication (Bluetooth®, WiFi, near field communication). In many embodiments, data can be transmitted over one or more networks, such as local area networks (LANs), wide area networks (WANs), telecommunications networks, the Internet, or suitable combinations thereof.

[00167] The computing device may be associated with data stores for storage of the measurement data and/or analysis results. Applications of the computing device can also collect and aggregate the measurement data and/or analysis results and display them in a suitable format to a user (e.g., charts, tables, graphs, images, etc.). Preferably, the application includes additional features that allow the user to overlay information such as lifestyle

choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. The analysis and display functionalities described herein may be performed by a single entity, or by any suitable combination of entities. For example, in many embodiments, data analysis can be carried out by a server, and the analysis results may be transmitted to another computing device for display to the user.

[00168] Other types of data can also be transmitted between the sensing adaptor and other computing devices. For example, in many embodiments, firmware updates for one or more components of the sensing adaptor can be transmitted to the adaptor from the computing device.

[00169] FIGS. 15A-15C illustrate exemplary computing device displays 1904. For example, FIG. 15A illustrates an exemplary display on a mobile phone 1902 and graphically illustrates milk production, the time of the last pumping session, a graphic of goal attainment, and a graphic illustrating the fluid consumption of the user. Additionally, the display 1904 may also provide user encouragement or user feedback based on the amount of milk production. FIG. 15B is an enlarged view of the display 1904 in FIG. 15A. FIG. 15C illustrates additional information that the display 1904 may show when a touch screen is actuated (e.g. by swiping or touching the screen). For example, the volume of the milk expressed is indicated after the "Last Pumping Session" section of the display is selected. Some or all items may be expanded, as also indicated in FIG. 15C. Additional information, or in some situations, less information may be displayed as desired.

[00170] FIGS. 16A-16B illustrate other exemplary displays which may be used in a milk expression system. For example, FIG. 16A is an exemplary display 2002 on any of the computing devices disclosed herein and operably coupled with any of the pump units described herein. The display may indicate an average volume of milk expressed over any time period, along with an average duration of the expression session during that same time period. Graphics may be used (e.g. bar chart, pie chart, x-y plot, etc.) to show volume expressed during individual sessions over the course of several days, here Monday through Friday. The display may allow a user to annotate the display so that missed sessions may be accounted for, for example if a session is omitted due to traveling, the display may show travel during that time period. Other annotations may also be made, such as when certain foods or nutritional supplements are taken, here hops or fenugreek. This allows the user to recall when expressed milk samples were obtained relative to the consumption of the food or nutritional supplements. The display may have other functional buttons such as for obtaining

tips, accessing the cloud, setting an alarm, making notes, storing data, or establishing system preferences. FIG. 16B illustrates another exemplary display 2004 of the computing device. The display 2004 is similar to a dashboard style gauge and indicates the volume of fluid expressed and collected and the time. Other information may also be displayed.

[00171] The various techniques described herein may be partially or fully implemented using code that is storable upon storage media and computer readable media, and executable by one or more processors of a computer system. Storage media and computer readable media for containing code, or portions of code, can include any appropriate media known or used in the art, including storage media and communication media, such as but not limited to volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage and/or transmission of information such as computer readable instructions, data structures, program modules, or other data, including RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disk (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, solid state drives (SSD) or other solid state storage devices, or any other medium which can be used to store the desired information and which can be accessed by the a system device. Based on the disclosure and teachings provided herein, a person of ordinary skill in the art will appreciate other ways and/or methods to implement the various embodiments.

[00172] It shall be understood that different aspects of the invention can be appreciated individually, collectively, or in combination with each other. Suitable elements or features of any of the embodiments described herein can be combined or substituted with elements or features of any other embodiment.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. An apparatus for containing and measuring a fluid, the apparatus comprising:

a reservoir comprising an opening and a wall, the opening configured to allow passage of the fluid in and out of the reservoir, and the wall defining a chamber configured to contain the fluid; and

a fluid sensing unit coupled to the reservoir, the fluid sensing unit configured to generate measurement data indicative of a volume of the fluid contained in the reservoir.

2. The apparatus of claim 1, wherein the fluid sensing unit is coupled to the wall of the reservoir.

3. The apparatus of claim 2, wherein the fluid sensing unit is coupled to an exterior surface of the wall of the reservoir.

4. The apparatus of claim 3, wherein the exterior surface of the wall of the reservoir comprises a recessed region, and wherein the fluid sensing unit is received within the recessed region and coupled directly or indirectly to the exterior surface of the wall.

5. The apparatus of claim 2, wherein the fluid sensing unit is embedded in the wall of the reservoir adjacent an interior surface of the wall of the reservoir.

6. The apparatus of claim 1, further comprising an insulating unit coupled to the reservoir, the insulating unit configured to cover the fluid sensing unit to provide one or more of electrical isolation or protection from physical damage of the fluid sensing unit.

7. The apparatus of claim 6, wherein the insulating unit comprises one or more plastics or rubbers configured to provide the electrical isolation of the fluid sensing unit.

8. The apparatus of claim 6, wherein the insulating unit comprises an internal surface defining a cavity configured to receive a fluid sensor of the fluid sensing unit therein, the cavity having a thickness greater than a thickness of the fluid sensor, thereby establishing an air gap between the insulating unit and the fluid sensor when the fluid sensor is disposed within the cavity.

9. The apparatus of claim 1, further comprising a processing unit in communication with the fluid sensing unit, the processing unit configured to receive the measurement data from the fluid sensing unit.

10. The apparatus of claim 9, wherein the processing unit comprises a communication module configured to communicate with one or more of a computing device or a server.

11. The apparatus of claim 9, wherein the processing unit comprises a memory configured to store the measurement data.

12. The apparatus of claim 9, further comprising a power source operatively coupled to one or more of the fluid sensing unit and the processing unit.

13. The apparatus of claim 9, further comprising a housing coupled to the wall of the reservoir, the housing configured to encase one or more of the fluid sensing unit, the processing unit, or the power source.

14. The apparatus of claim 13, wherein the housing is removably coupled to the reservoir.

15. The apparatus of claim 1, wherein the fluid sensing unit comprises one or more capacitive sensors, the one or more capacitive sensors in communication with a processing unit.

16. The apparatus of claim 15, wherein the one or more capacitive sensors are configured to measure a change in capacitance of the one or more capacitive sensors, the change in capacitance affected by the fluid in proximity to the one or more capacitive sensors, such that the measurement data generated by the one or more capacitive sensors produces an indication of the volume of the fluid contained in the reservoir.

17. The apparatus of claim 16, wherein the change in capacitance comprises one or more of a change in self-capacitance between a capacitive sensor and a surrounding environment, or a change in a mutual capacitance between a first capacitive sensor of the one or more capacitive sensors and a second capacitive sensor of the one or more capacitive sensors.

18. The apparatus of claim 15, wherein each of the one or more capacitive sensors comprises one or more continuous sensing regions, each continuous sensing region extending continuously along a length of the reservoir.

19. The apparatus of claim 15, wherein each of the one or more capacitive sensors comprises an array of discrete sensing regions, the array of discrete sensing regions extending along a length of the reservoir.

20. The apparatus of claim 19, wherein each discrete sensing region of the array of discrete sensing regions comprises an area, and the area of a first discrete sensing region disposed adjacent a first end of the array is greater than the area of a second discrete sensing region disposed adjacent a second end of the array opposite the first end.

21. The apparatus of claim 1, wherein the fluid sensing unit comprises one or more base sensors coupled to one or more fluid sensors of the fluid sensing unit, the one or more base sensors configured to electrically isolate the one or more fluid sensors from sources of interference outside the reservoir.

22. The apparatus of claim 1, wherein the fluid sensing unit comprises a plurality of fluid sensors distributed about the reservoir in a predetermined distribution.

23. The apparatus of claim 22, wherein the predetermined distribution comprises an equal distribution about the periphery of the reservoir.

24. The apparatus of claim 1, further comprising one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the apparatus.

25. The apparatus of claim 24, wherein the one or more reservoir sensors comprise one or more of an accelerometer or a gyroscope.

26. The apparatus of claim 24, wherein the one or more reservoir sensors are coupled to a processing unit of the apparatus, the processing unit in communication with the fluid sensing unit.

27. The apparatus of claim 1, further comprising one or more proximity sensors configured to detect presence of one or more proximity triggers disposed within a predetermined distance from the one or more proximity sensors, wherein the one or more proximity triggers are coupled to a component comprising a coupling mechanism to couple the component to the reservoir, such that the one or more proximity triggers are placed within the predetermined distance when the component is coupled to the reservoir.

28. The apparatus of claim 27, wherein the component comprises a pumping device, a feeding attachment, or a storage cap.

29. The apparatus of claim 27, wherein the one or more proximity sensors comprise one or more assemblies of a light source and a light detector, and wherein the one or more proximity triggers comprise one or more reflective markers, the light source configured to emit light towards the one or more proximity triggers, the one or more reflective markers configured to reflect the light, and the light detector configured to detect the reflected light.

30. The apparatus of claim 27, wherein the one or more proximity sensors comprise one or more Hall effect sensors, and wherein the one or more proximity triggers comprise one or more magnets, the one or more Hall effect sensors configured to detect an intensity of a magnetic field generated by the one or more magnets.

31. The apparatus of claim 27, wherein the one or more proximity sensors comprise one or more reed switches, and wherein the one or more proximity triggers comprise one or more magnets, the one or more reed switches configured to electrically switch on or off in response to detection of a magnetic field generated by the one or more magnets.

32. The apparatus of claim 27, further comprising a processing unit in communication with the fluid sensing unit and the one or more proximity sensors, wherein the processing unit is configured to identify a type of the component in response to measurement data generated by the one or more proximity sensors.

33. The apparatus of claim 32, wherein the one or more proximity sensors are configured to produce different readout values when components of different types are coupled to the reservoir, and wherein the processing unit is configured to associate each component of a specific type with a specific readout value to identify the type of the component coupled to the reservoir.

34. The apparatus of claim 33, wherein the components of different types comprise proximity triggers configured to have different properties.

35. The apparatus of claim 33, wherein the components of different types comprise different numbers of proximity triggers.

36. The apparatus of claim 32, wherein the one or more proximity sensors comprise a plurality of proximity sensors disposed at different locations of the reservoir, and wherein the processing unit is configured to associate each component of a specific type with one or more of the plurality of proximity sensors disposed at one or more specific locations to identify the type of the component coupled to the reservoir.

37. The apparatus of claim 27, wherein the processing unit is configured to switch between a standby state and a measurement state in response to measurement data generated by the one or more proximity sensors, wherein the fluid sensing unit operates in a low-power standby mode during the standby state, and wherein the fluid sensing unit obtains the measurement data during the measurement state.

38. The apparatus of claim 27, wherein the processing unit is configured to determine, in response to measurement data generated by the one or more proximity sensors, an analysis mode for analyzing the measurement data generated by the fluid sensing unit, wherein the analysis mode corresponds to a filling state or a draining state of the reservoir.

39. The apparatus of claim 27, wherein the fluid sensing unit is encased within an insulating unit coupled to the wall of the reservoir, and wherein the one or more proximity sensors are disposed within the insulating unit adjacent the fluid sensing unit and near the opening of the reservoir.

40. A system for containing and measuring a fluid, the system comprising:

a sensing reservoir for containing and measuring a fluid, wherein the sensing reservoir comprises a fluid sensing unit coupled to a reservoir, the fluid sensing unit configured to generate measurement data indicative of a volume of the fluid contained in the reservoir; and

a computing device in communication with the reservoir, the computing device configured to receive the measurement data.

41. The system of claim 40, wherein the sensing reservoir further comprises a communication module, and the computing device communicates with the sensing reservoir via the communication module.

42. The system of claim 40, wherein the sensing reservoir further comprises one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the sensing reservoir.

43. The system of claim 40, wherein the computing device comprises a processing unit having instructions stored thereon for performing an analysis of the measurement data.

44. The system of claim 40, wherein the computing device comprises a user interface configured to display the measurement data to a user.

45. The system of claim 40, further comprising a remote server in communication with the reservoir or the computing device, the remote server configured to perform one or more of analysis of the measurement data and storage of the measurement data.

46. A method of measuring a fluid contained in a reservoir, the method comprising:

providing a sensing reservoir for containing and measuring a fluid, the sensing reservoir comprising a fluid sensing unit coupled to a reservoir;

performing a system check to ensure that the sensing reservoir is functioning properly;

generating measurement data using the fluid sensing unit, the measurement data indicative of a volume of the fluid contained in the reservoir; and

analyzing the measurement data to determine the volume of the fluid contained in the reservoir.

47. The method of claim 46, wherein performing the system check comprises taking one or more baseline measurements using the fluid sensing unit.

48. The method of claim 46, wherein performing the system check comprises confirming that the fluid sensing unit is in communication with a processing unit of the sensing reservoir.

49. The method of claim 46, wherein the sensing reservoir comprises one or more reservoir sensors, and wherein performing the system check comprises measuring one or more of a position, orientation, or motion of the sensing reservoir with the one or more reservoir sensors.

50. The method of claim 49, further comprising determining whether the sensing reservoir is in an inactive state based on the one or more of a position, orientation or motion of the sensing reservoir.

51. The method of claim 49, further comprising determining whether the sensing reservoir is undergoing excessive motion based on the one or more of a position, orientation or motion of the sensing reservoir.

52. The method of claim 46, wherein the sensing reservoir comprises one or more reservoir sensors, and wherein generating measurement data further comprises measuring one or more of a position, orientation, or motion of the sensing reservoir with the one or more reservoir sensors, thereby determining an operating state of the sensing reservoir.

53. The method of claim 52, wherein the operating state of the sensing reservoir comprises a filling state or a draining state.

54. The method of claim 52, wherein the one or more of a position, orientation, or motion of the sensing reservoir comprises one or more of a vertical offset or a rotational offset of the sensing reservoir, and wherein the method further comprises determining whether the sensing reservoir is in an acceptable orientation for generating the measurement data using the fluid sensing unit, based on the one or more of the vertical offset or the rotational offset of the sensing reservoir.

55. The method of claim 46, wherein the fluid sensing unit comprises one or more capacitive sensors, and generating measurement data comprises measuring a capacitance of each of the one or more capacitive sensors, the measured capacitance indicative of a level of fluid at each of the one or more capacitive sensors.

56. The method of claim 46, wherein the fluid sensing unit comprises a plurality of fluid sensors, and analyzing the measurement data comprises determining a level of fluid at each of the plurality of fluid sensors, thereby determining a tilt of the sensing reservoir.

57. The method of claim 46, wherein analyzing the measurement data comprises calculating a volume of fluid contained in the sensing reservoir based on the measurement data generated by the fluid sensing unit and measurement data generated by one or more reservoir sensors configured to measure one or more of a position, orientation, or motion of the sensing reservoir.

58. The method of claim 46, wherein the sensing reservoir further comprises one or more proximity sensors configured to detect one or more proximity triggers disposed within a predetermined distance from the one or more proximity sensors, and wherein the method further comprises generating measurement data using the one or more proximity sensors to determine whether the sensing reservoir is coupled to a component comprising the one or more proximity triggers.

59. The method of claim 58, further comprising setting the sensing reservoir in a standby state in response to a determination that the sensing reservoir is not coupled to the component, and setting the sensing reservoir in a measurement state in response to a determination that the sensing reservoir is coupled to the component, wherein steps of performing the system check, generating the measurement data using the fluid sensing unit, and analyzing the measurement data are performed when the sensing reservoir is set in the measurement state.

60. The method of claim 46, further comprising transmitting the measurement data generated using the fluid sensing unit or the volume of the fluid contained in the reservoir to another computing device in communication with the sensing reservoir.

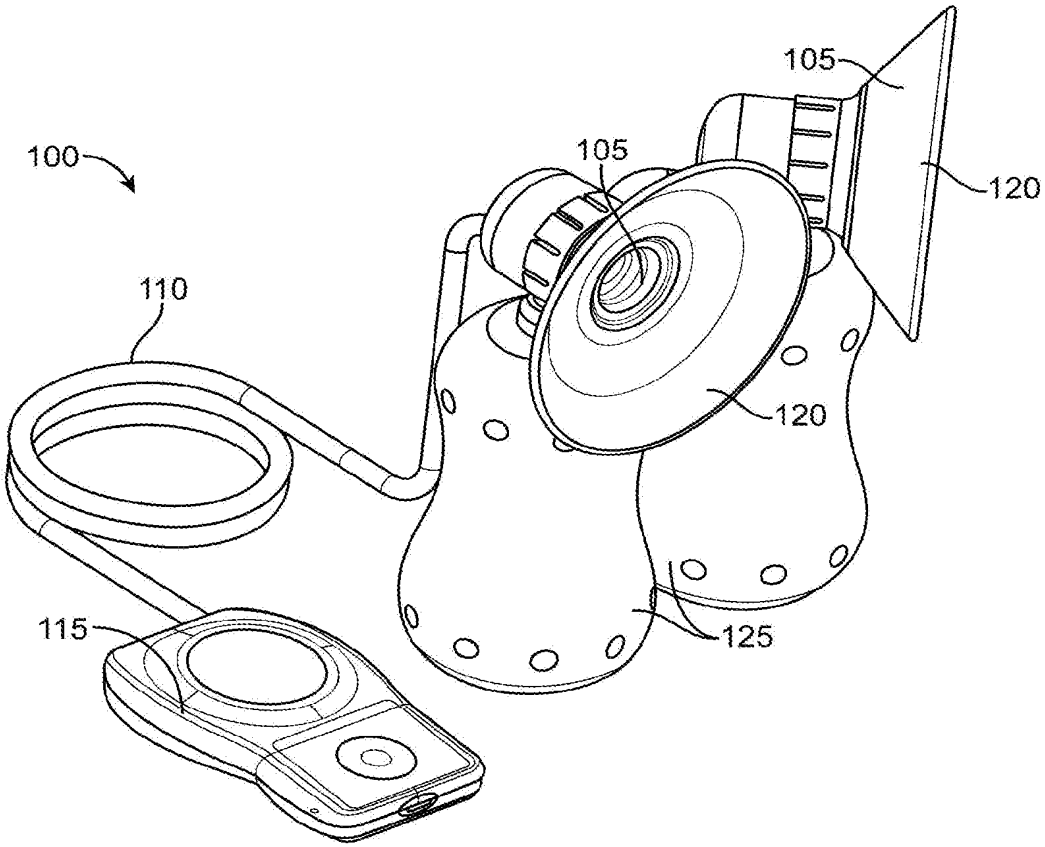


FIG. 1

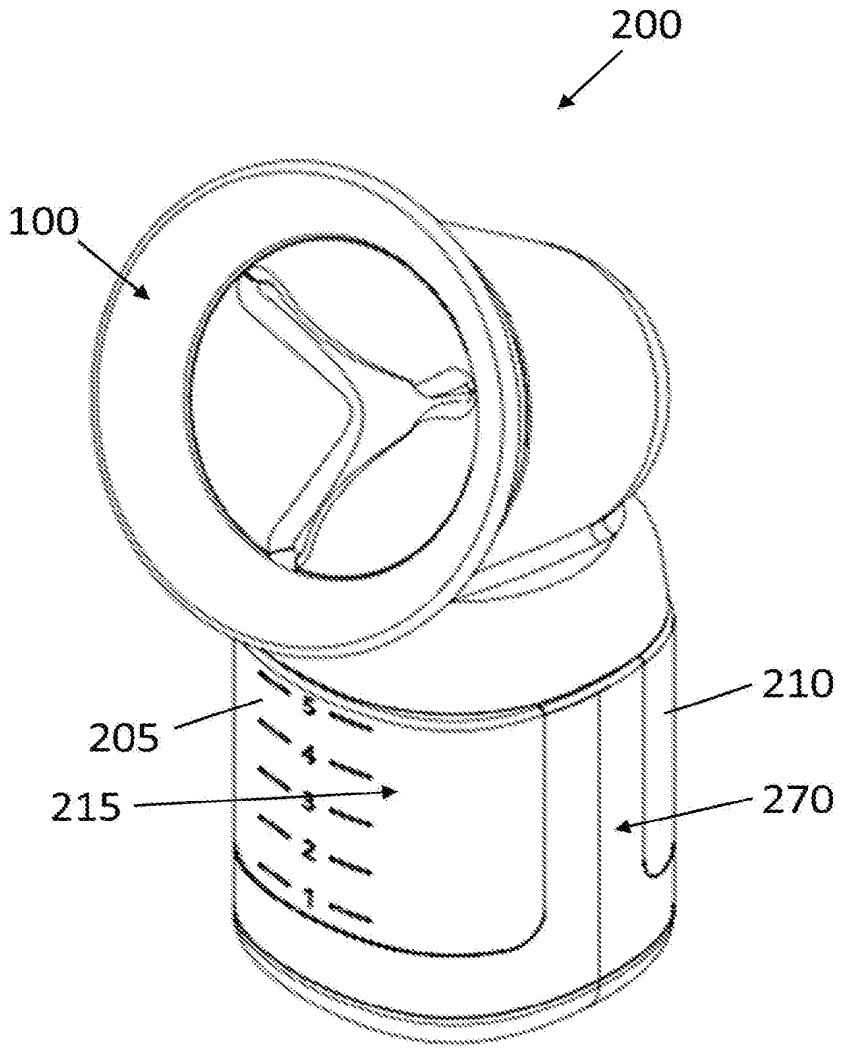


FIG. 2A

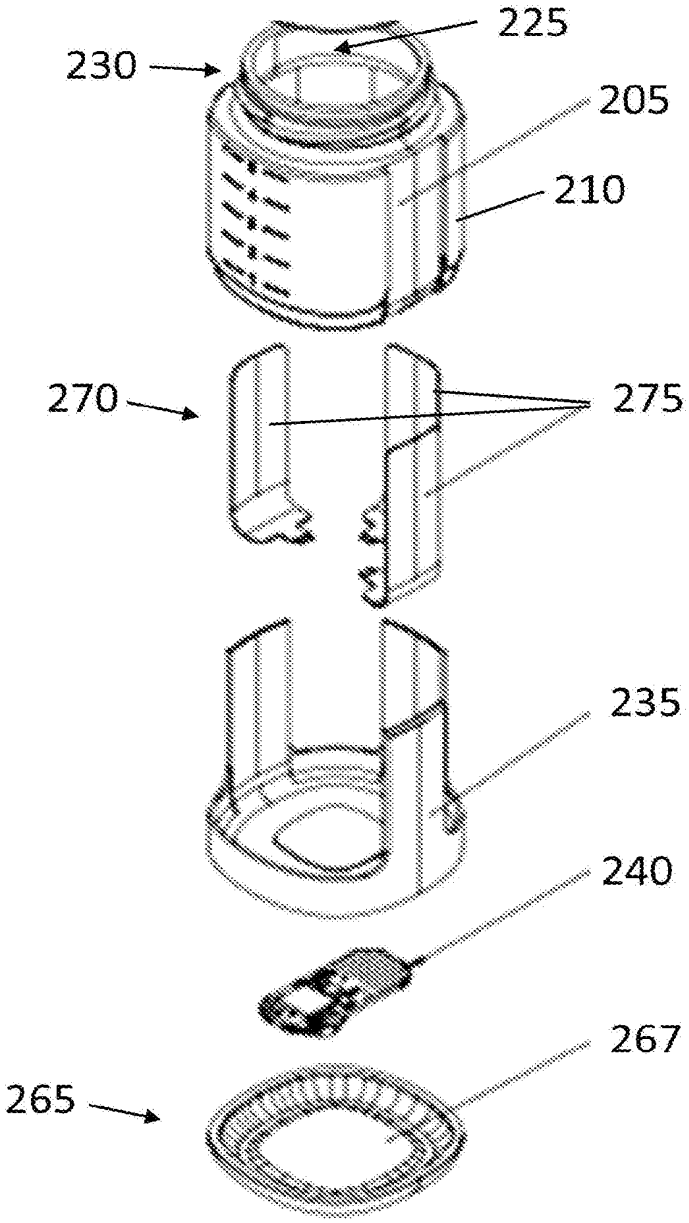


FIG. 2B

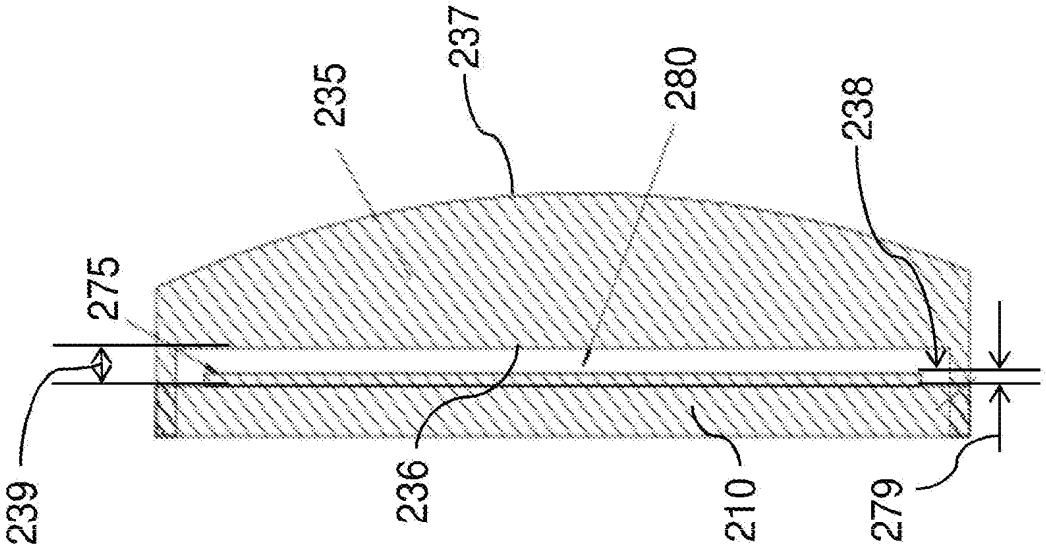


FIG. 2D

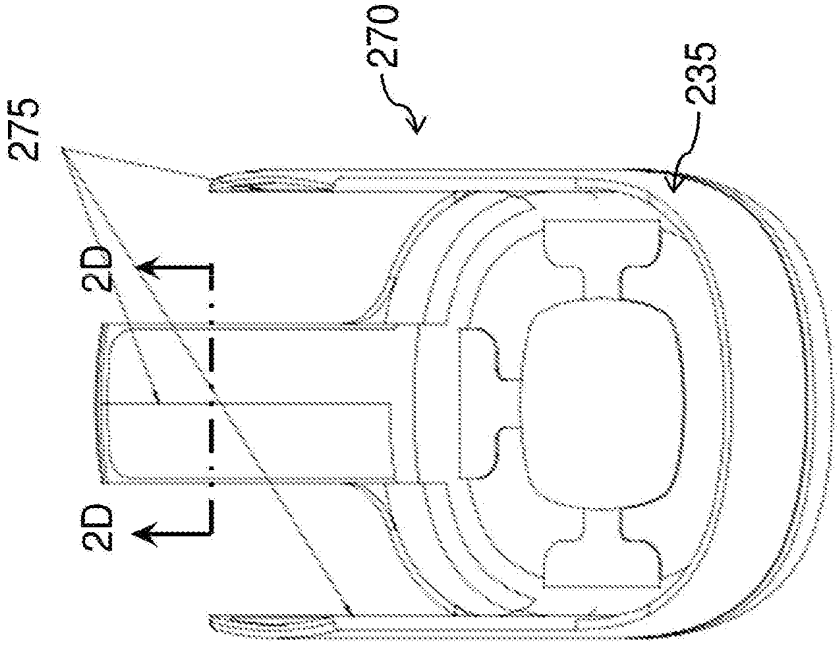


FIG. 2C

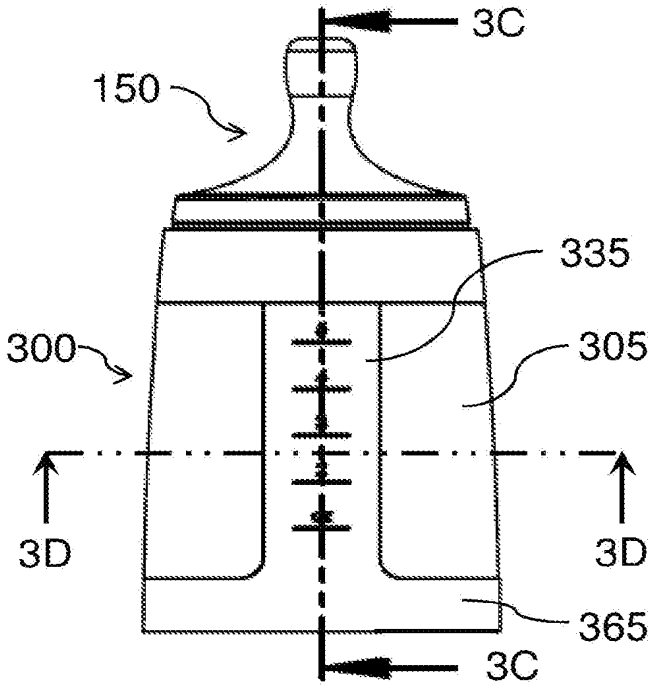

3C
150
335
300
305
3D
3D
365
3C

FIG. 3A

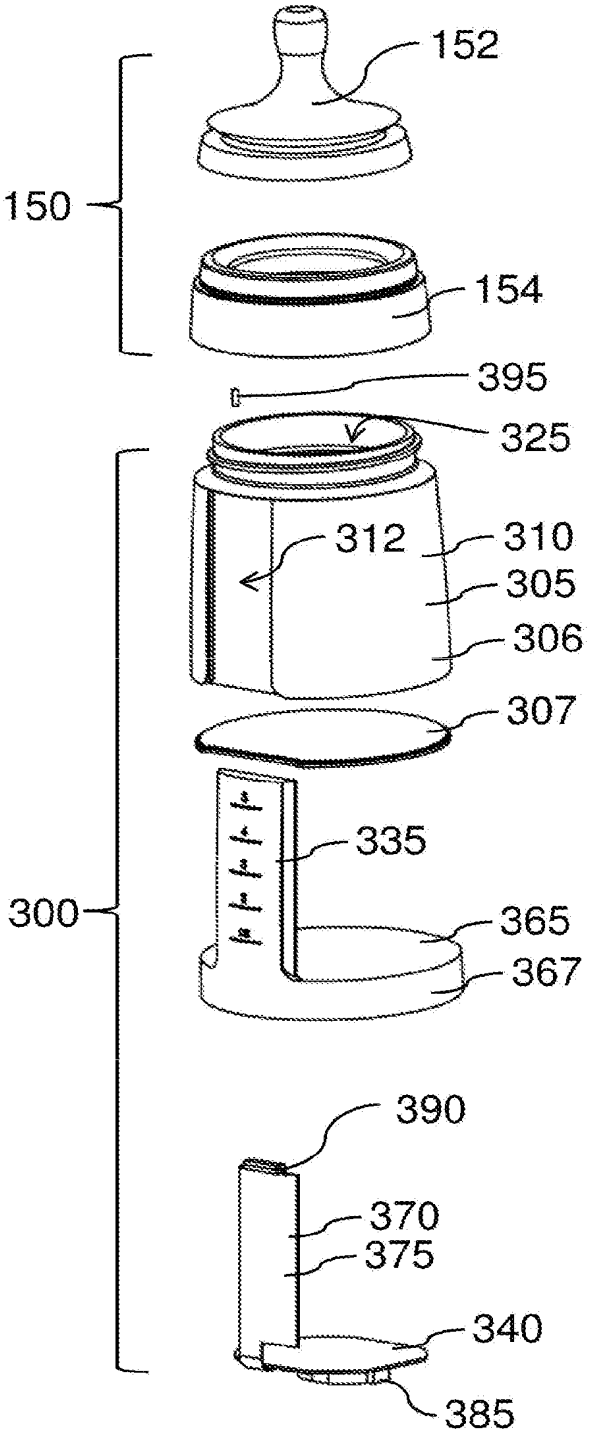

152
150
154
395
325
312
310
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307
335
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365
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390
370
375
340
385

FIG. 3B

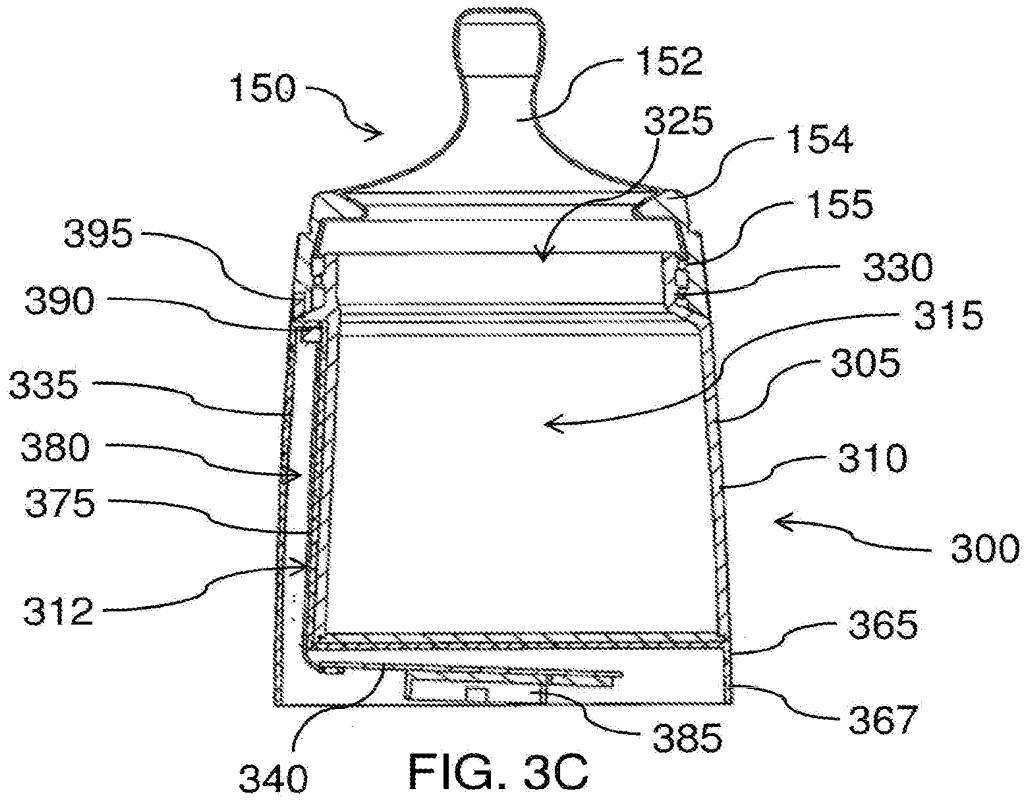

150
152
325
154
155
395
330
390
315
335
305
380
310
375
300
312
365
367
385
340

FIG. 3C

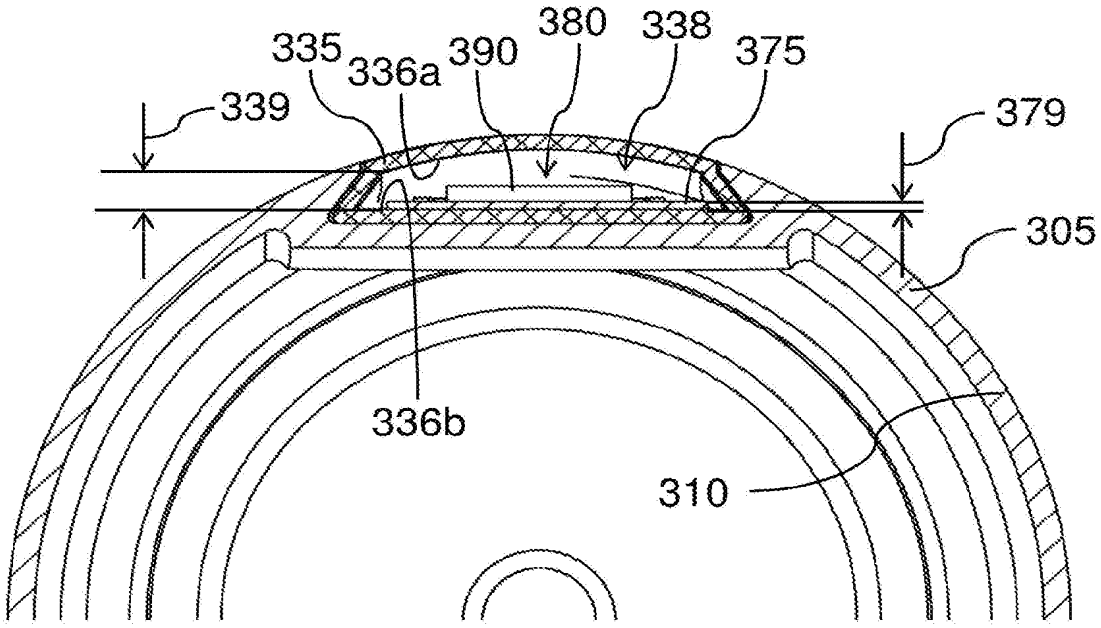

335
336a
390
380
338
375
339
379
305
336b
310

FIG. 3D

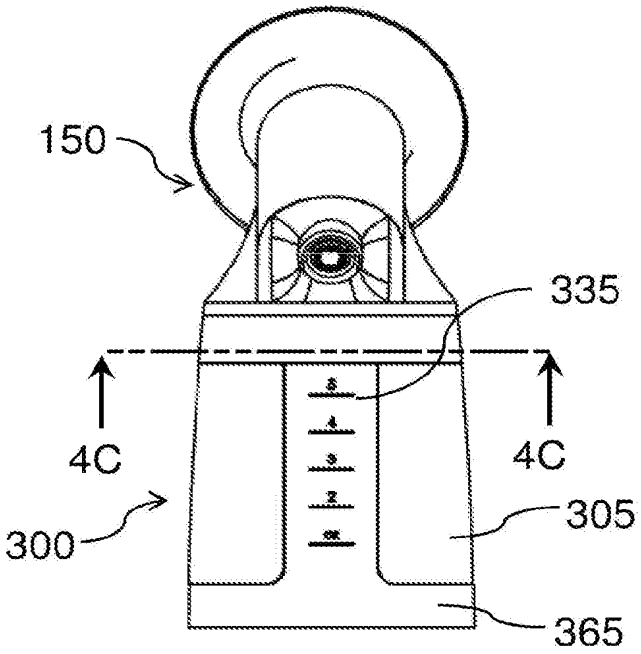


FIG. 4A

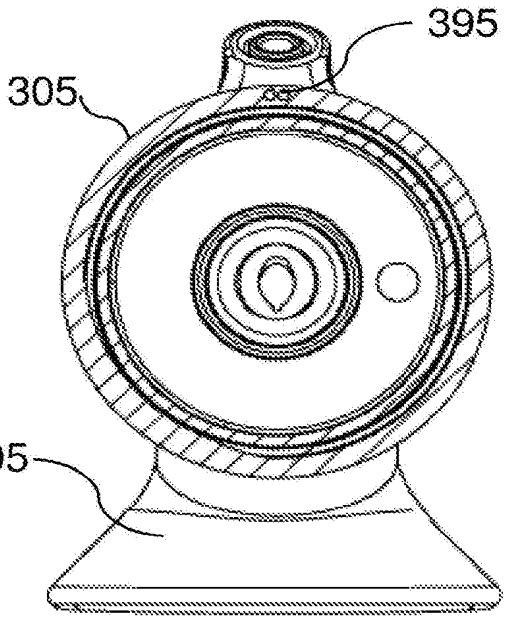


FIG. 4C

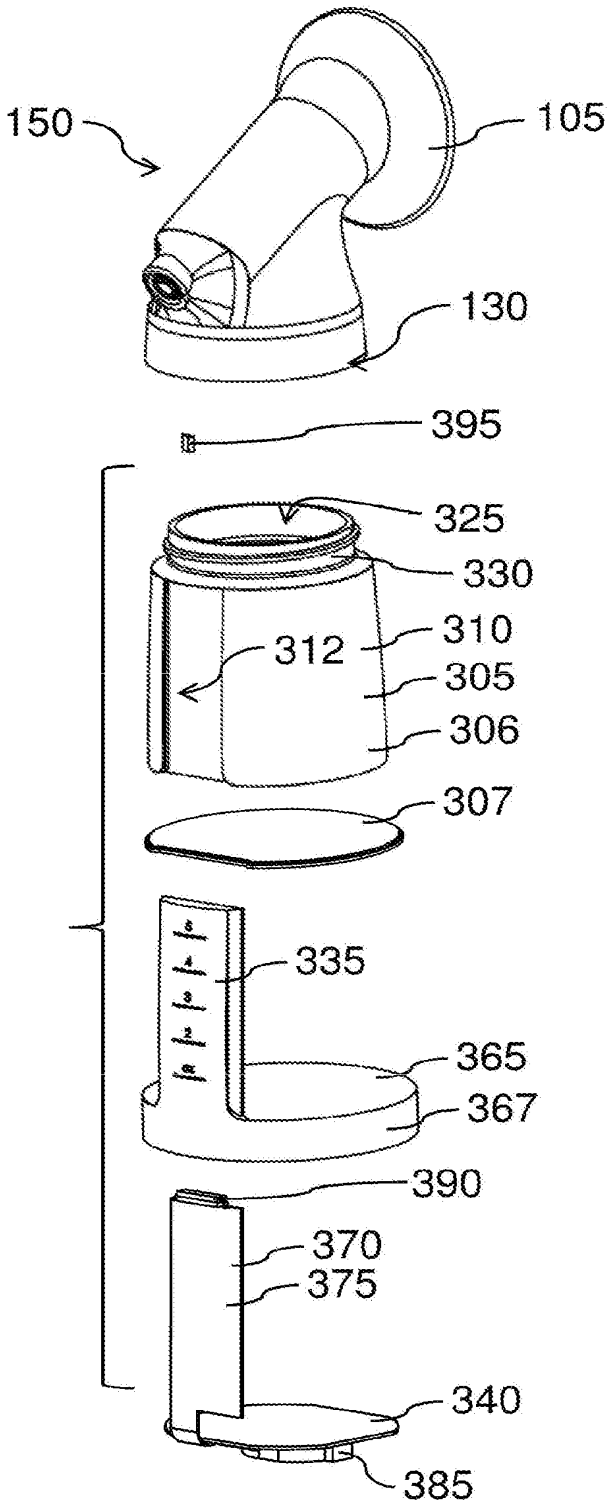


FIG. 4B

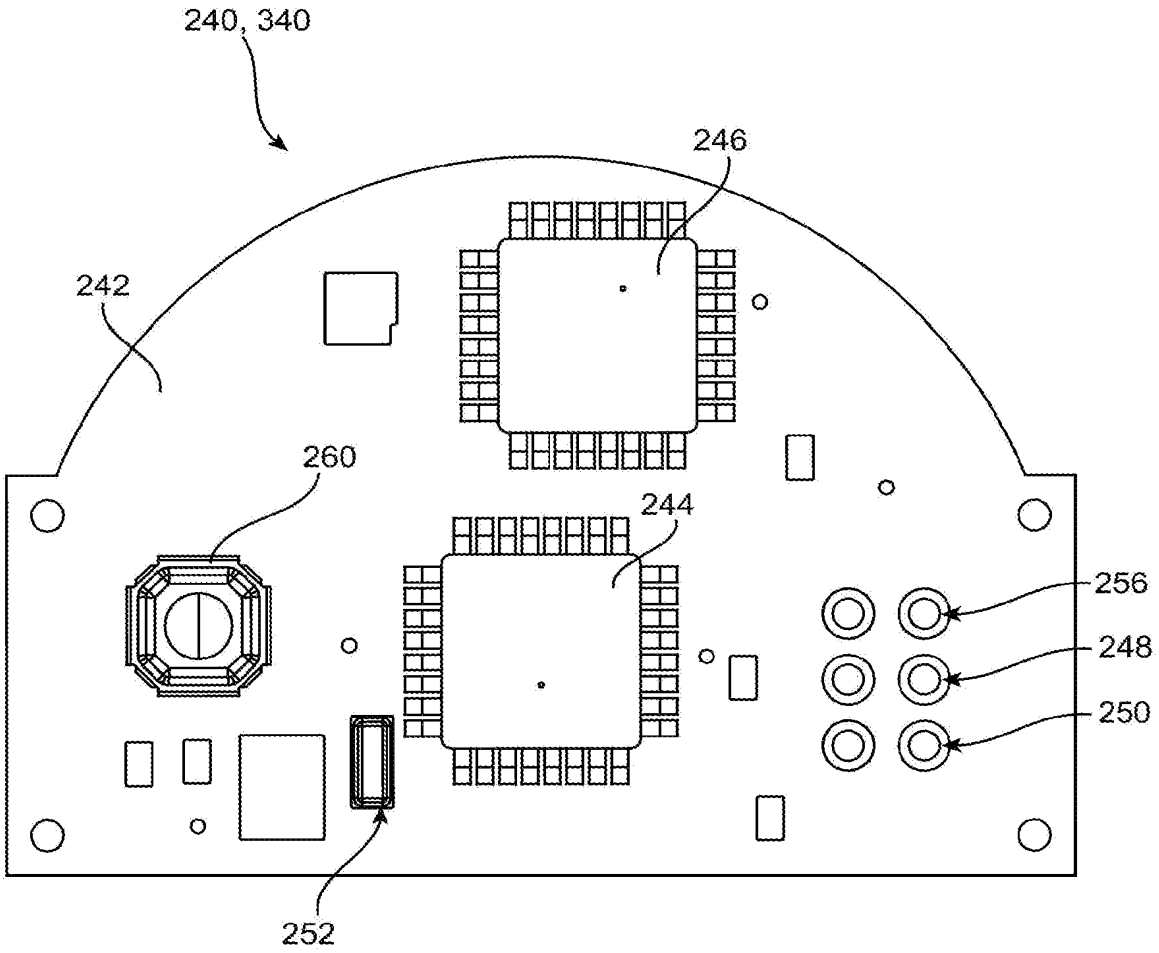


FIG. 5

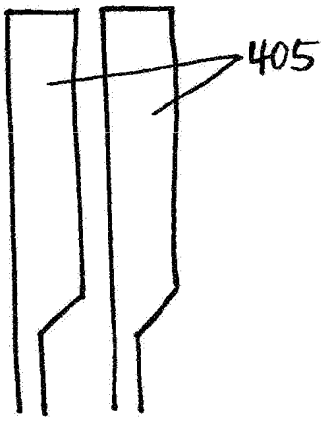


FIG. 6A

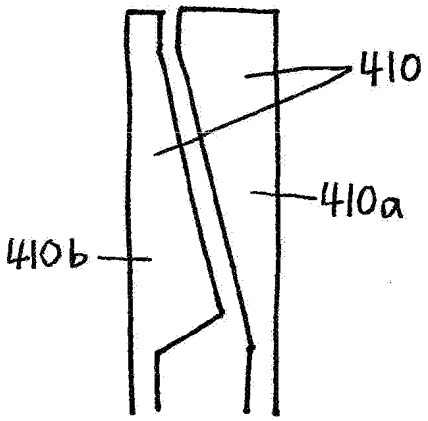


FIG. 6B

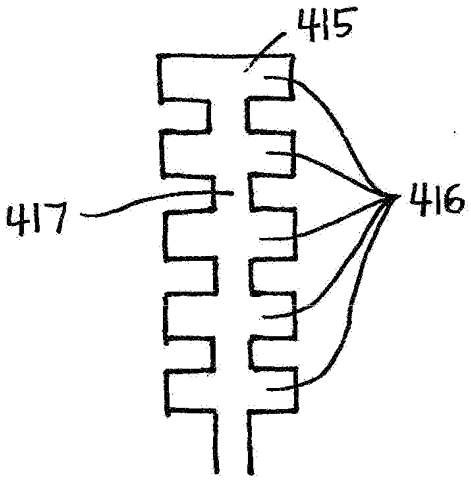


FIG. 6C

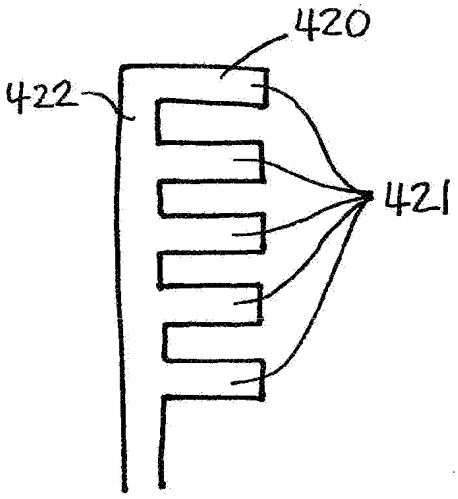


FIG. 6D

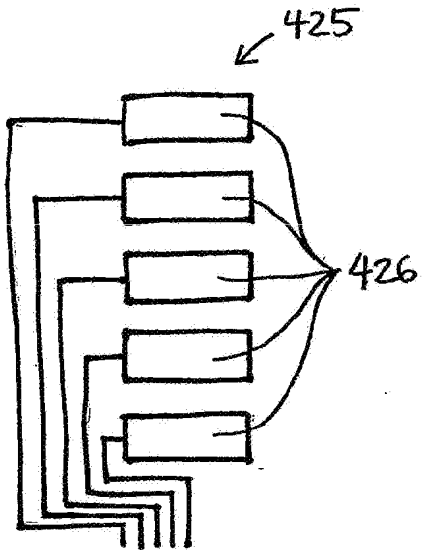


FIG. 6E

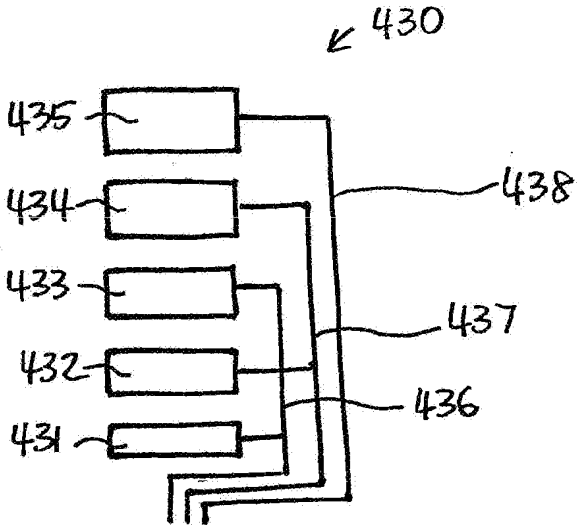


FIG. 6F

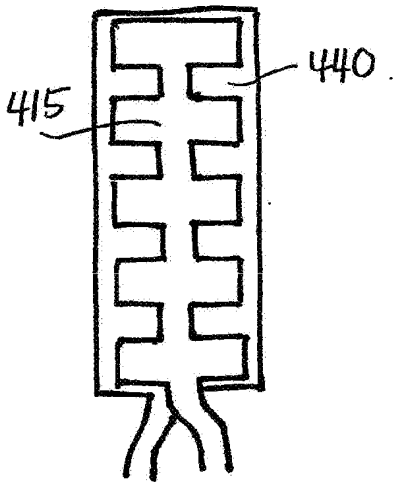


FIG. 6G

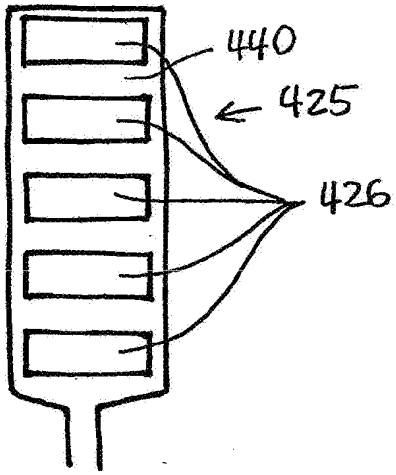


FIG. 6H

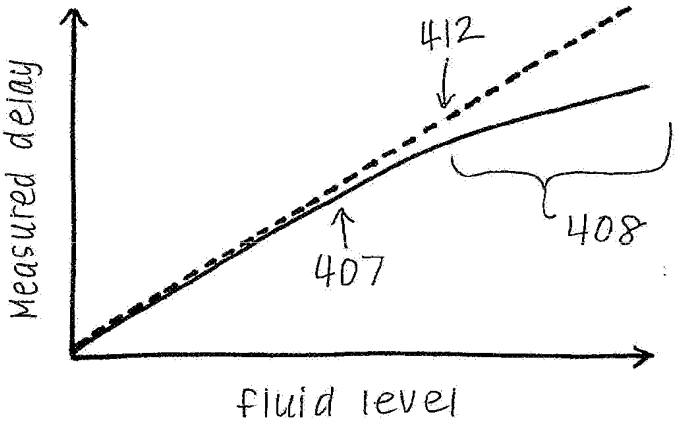


FIG. 7A

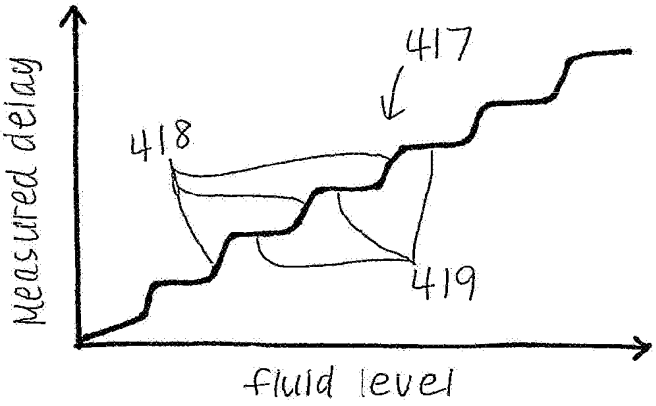


FIG. 7B

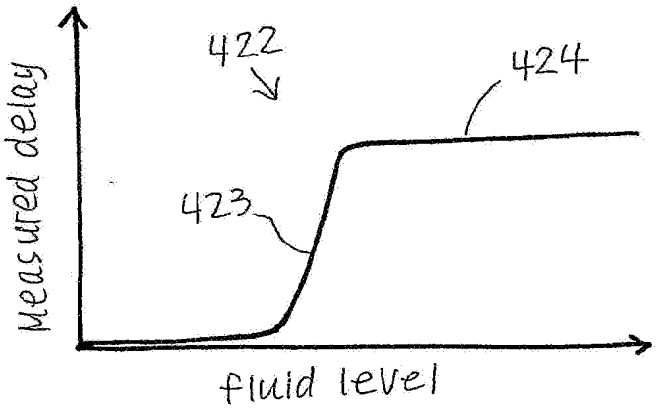


FIG. 7C

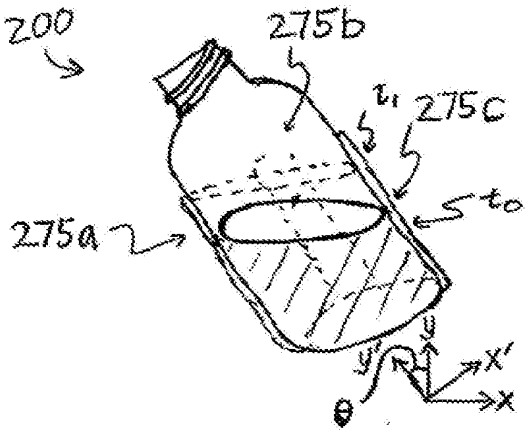


FIG. 8A

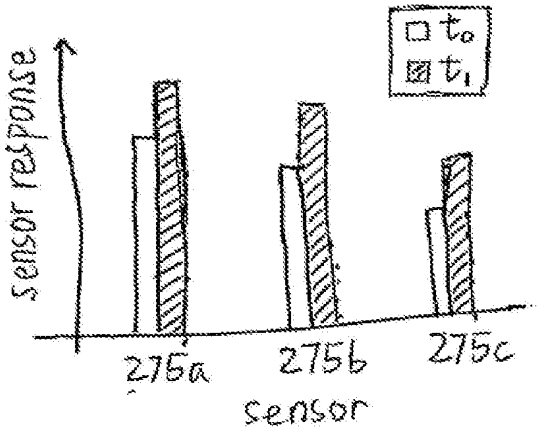


FIG. 8B

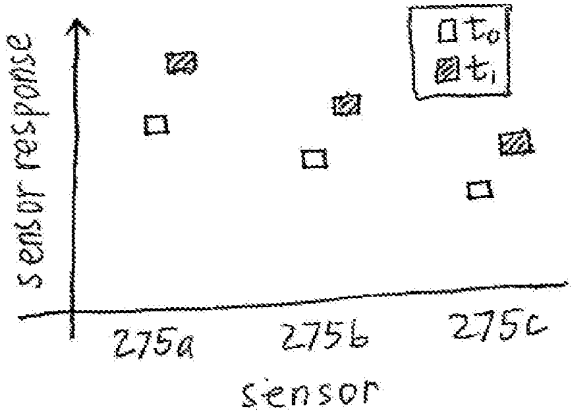


FIG. 8C

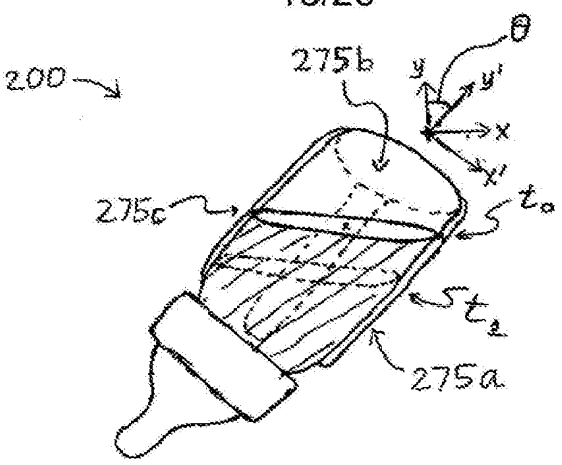


FIG. 9A

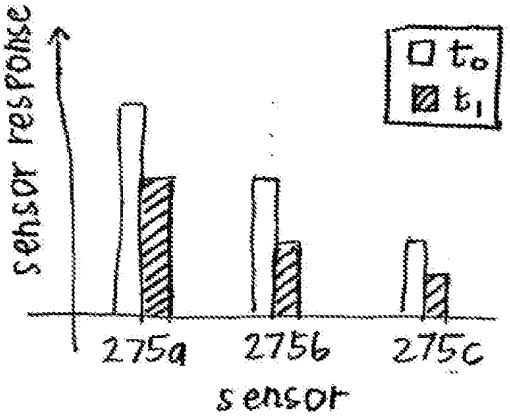


FIG. 9B

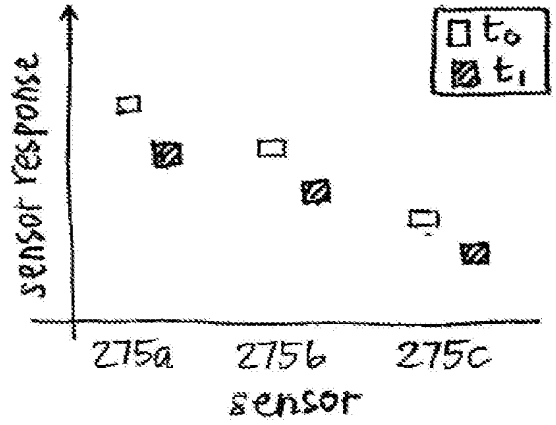


FIG. 9C

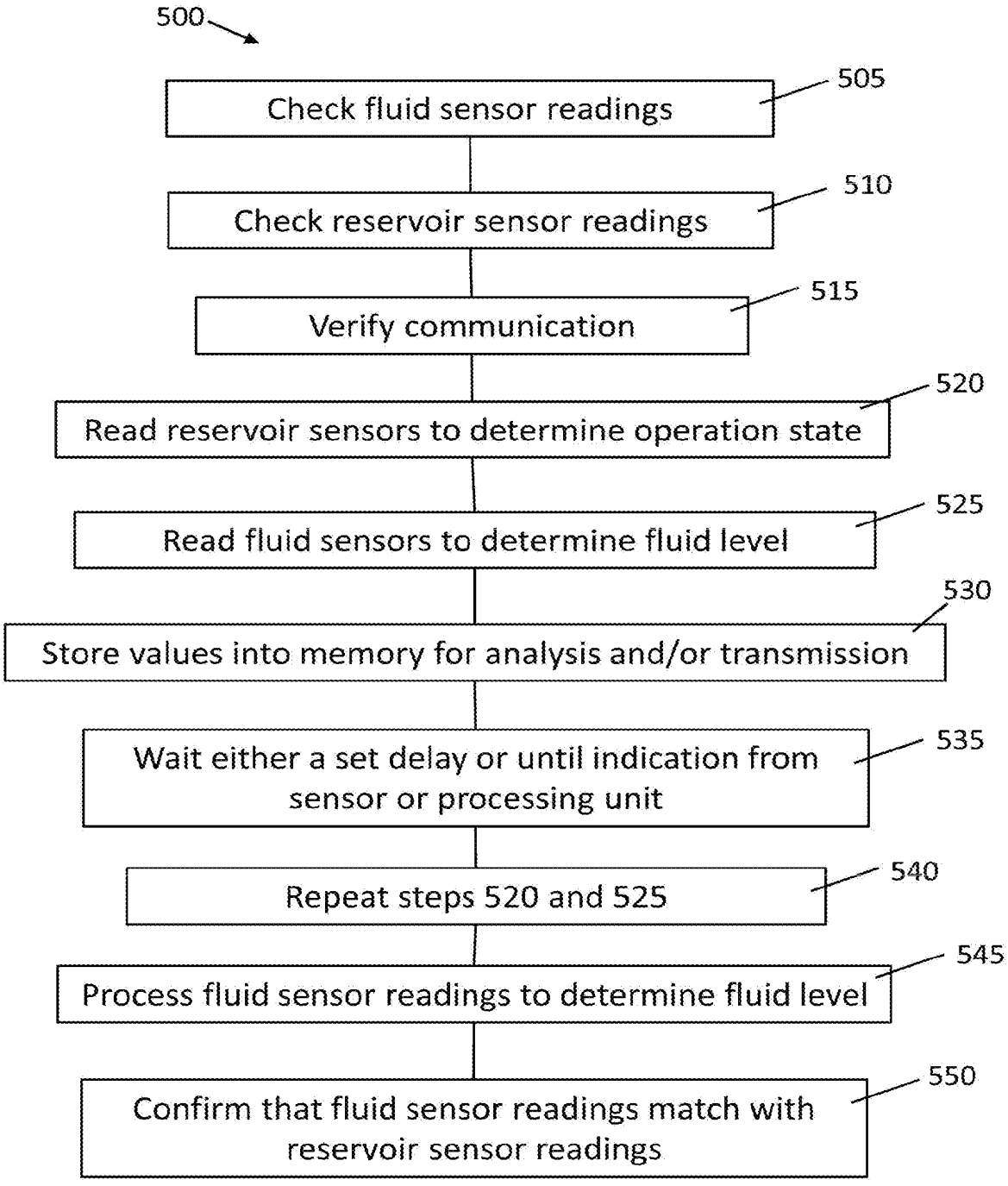

500
Check fluid sensor readings
505
Check reservoir sensor readings
510
Verify communication
515
Read reservoir sensors to determine operation state
520
Read fluid sensors to determine fluid level
525
Store values into memory for analysis and/or transmission
530
Wait either a set delay or until indication from sensor or processing unit
535
Repeat steps 520 and 525
540
Process fluid sensor readings to determine fluid level
545
Confirm that fluid sensor readings match with reservoir sensor readings
550

FIG. 10

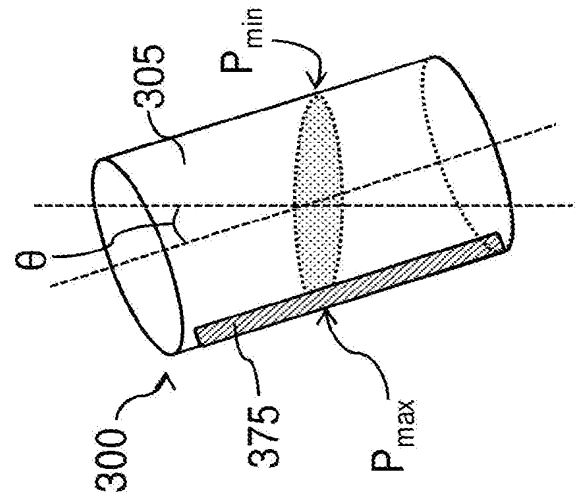


FIG. 11E

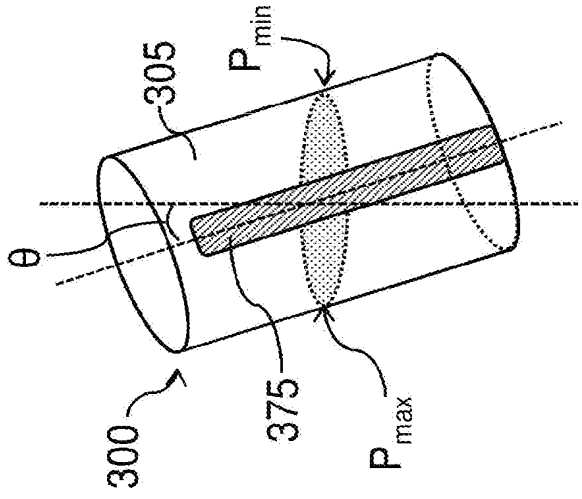


FIG. 11C

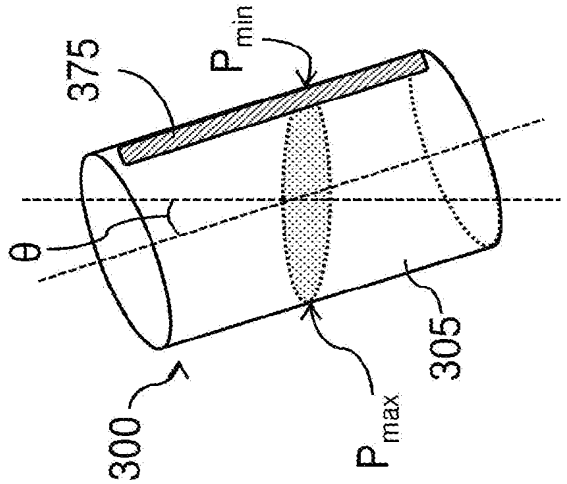


FIG. 11A

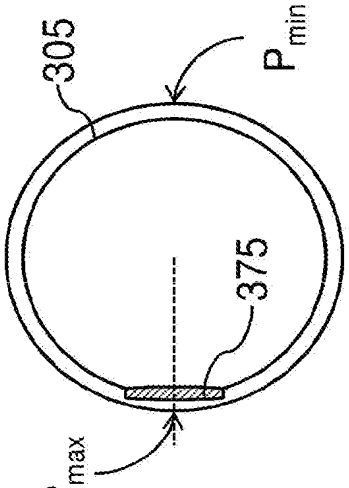


FIG. 11F

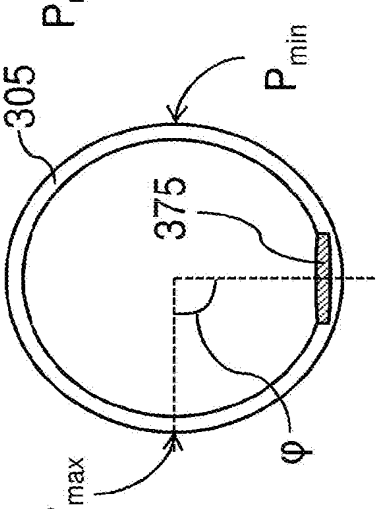


FIG. 11D

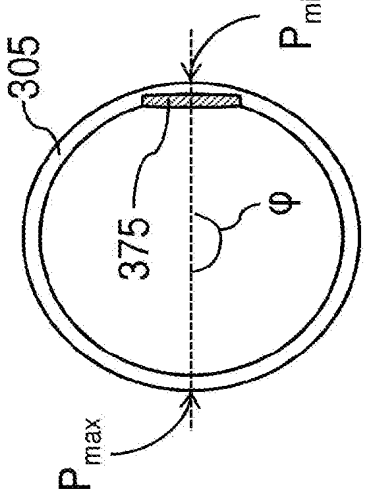


FIG. 11B

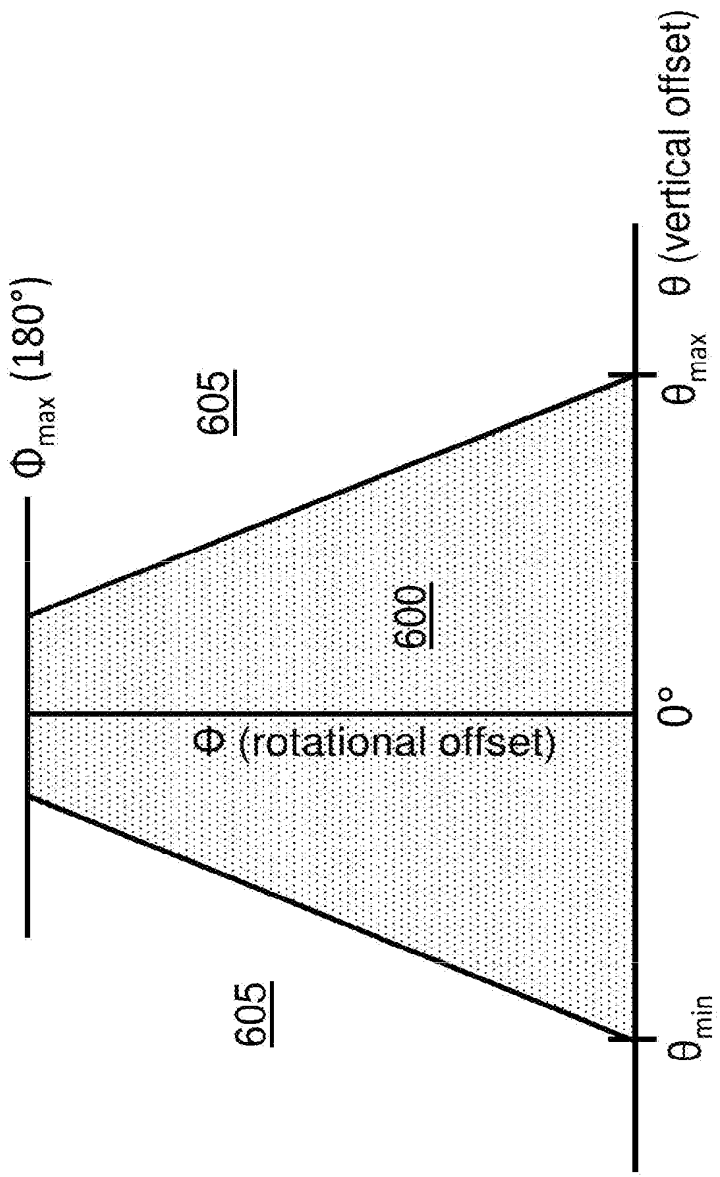

Φmax (180°)
605
600
Φ (rotational offset)
605
θmax θ (vertical offset)
0°
θmin

FIG. 12

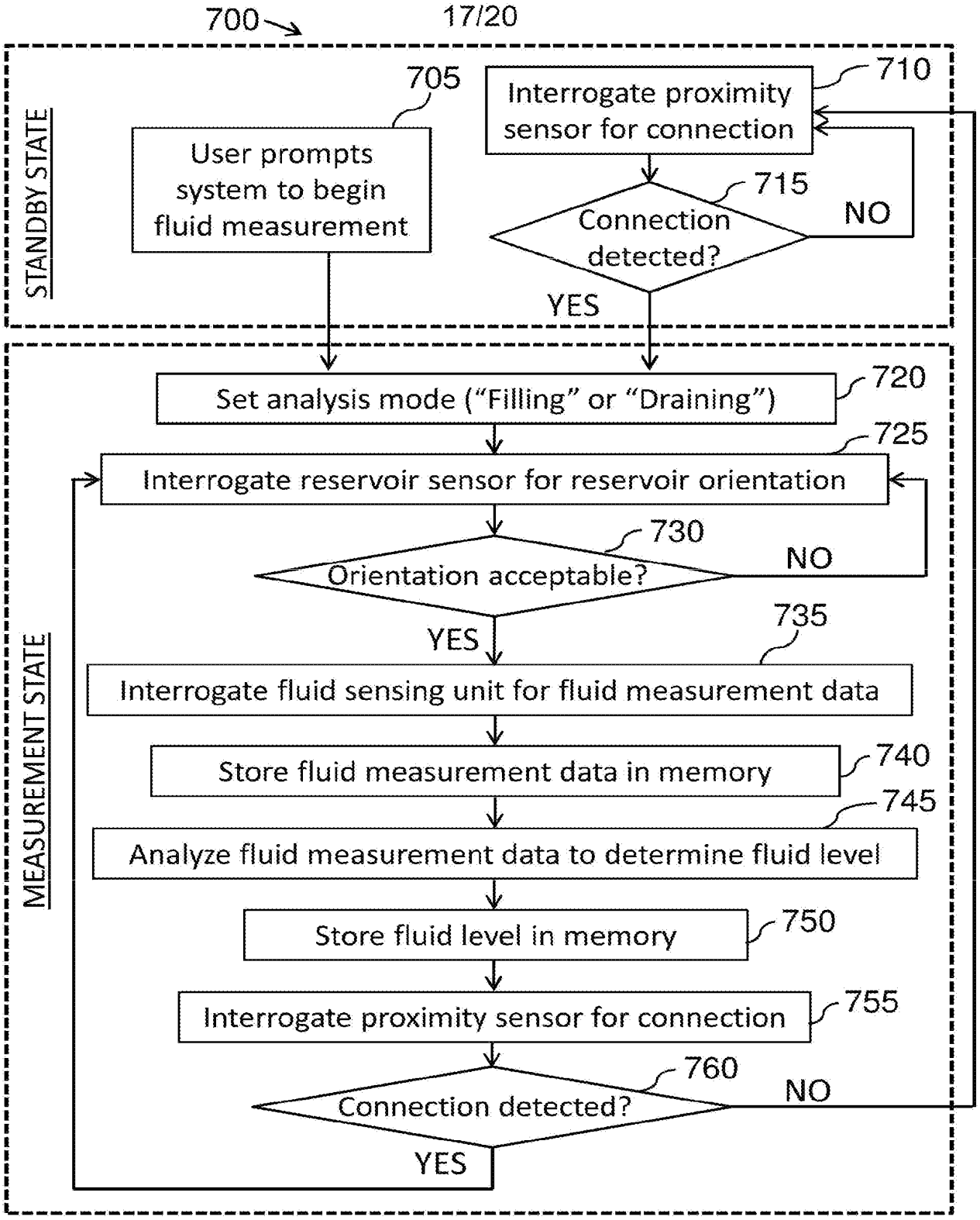

700
17/20
STANDBY STATE
705
User prompts system to begin fluid measurement
710
Interrogate proximity sensor for connection
715
Connection detected?
NO
YES
MEASUREMENT STATE
720
Set analysis mode ("Filling" or "Draining")
725
Interrogate reservoir sensor for reservoir orientation
730
Orientation acceptable?
NO
YES
735
Interrogate fluid sensing unit for fluid measurement data
740
Store fluid measurement data in memory
745
Analyze fluid measurement data to determine fluid level
750
Store fluid level in memory
755
Interrogate proximity sensor for connection
760
Connection detected?
NO
YES

FIG. 13

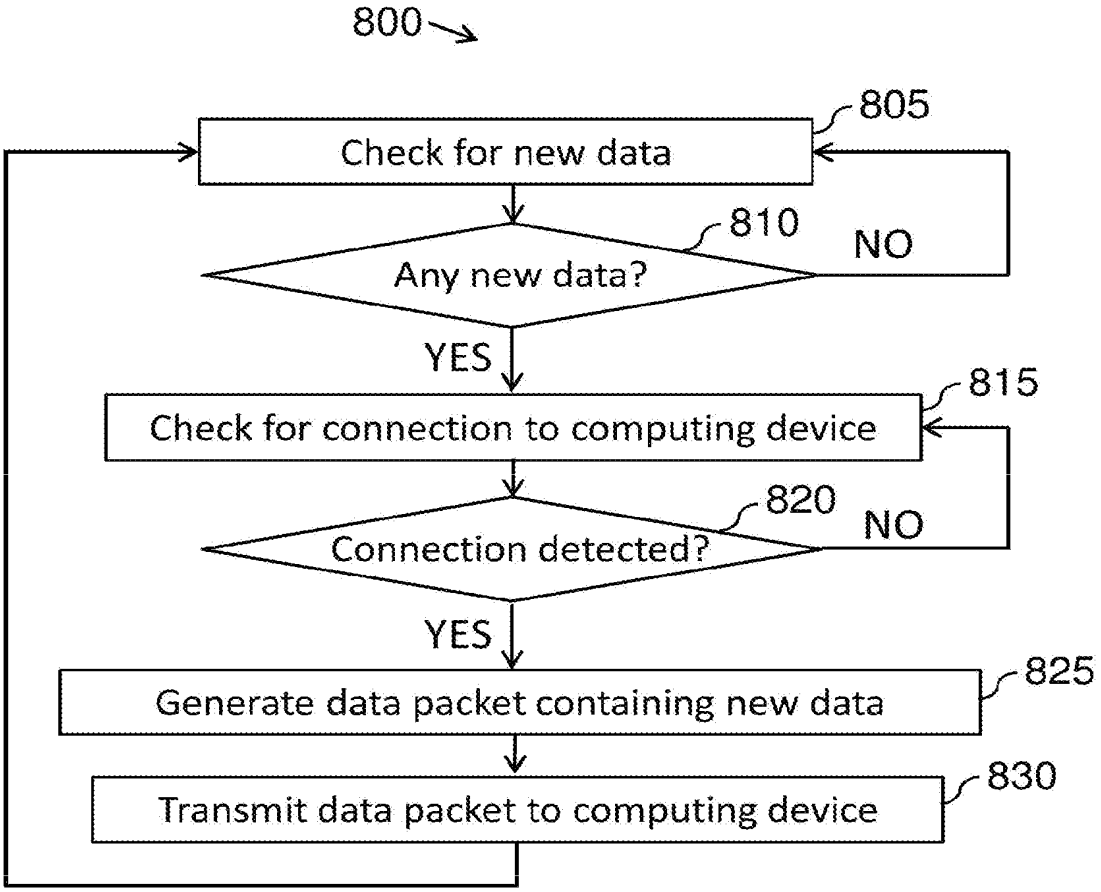

800
805
Check for new data
810
Any new data?
NO
YES
815
Check for connection to computing device
820
Connection detected?
NO
YES
825
Generate data packet containing new data
830
Transmit data packet to computing device

FIG. 14

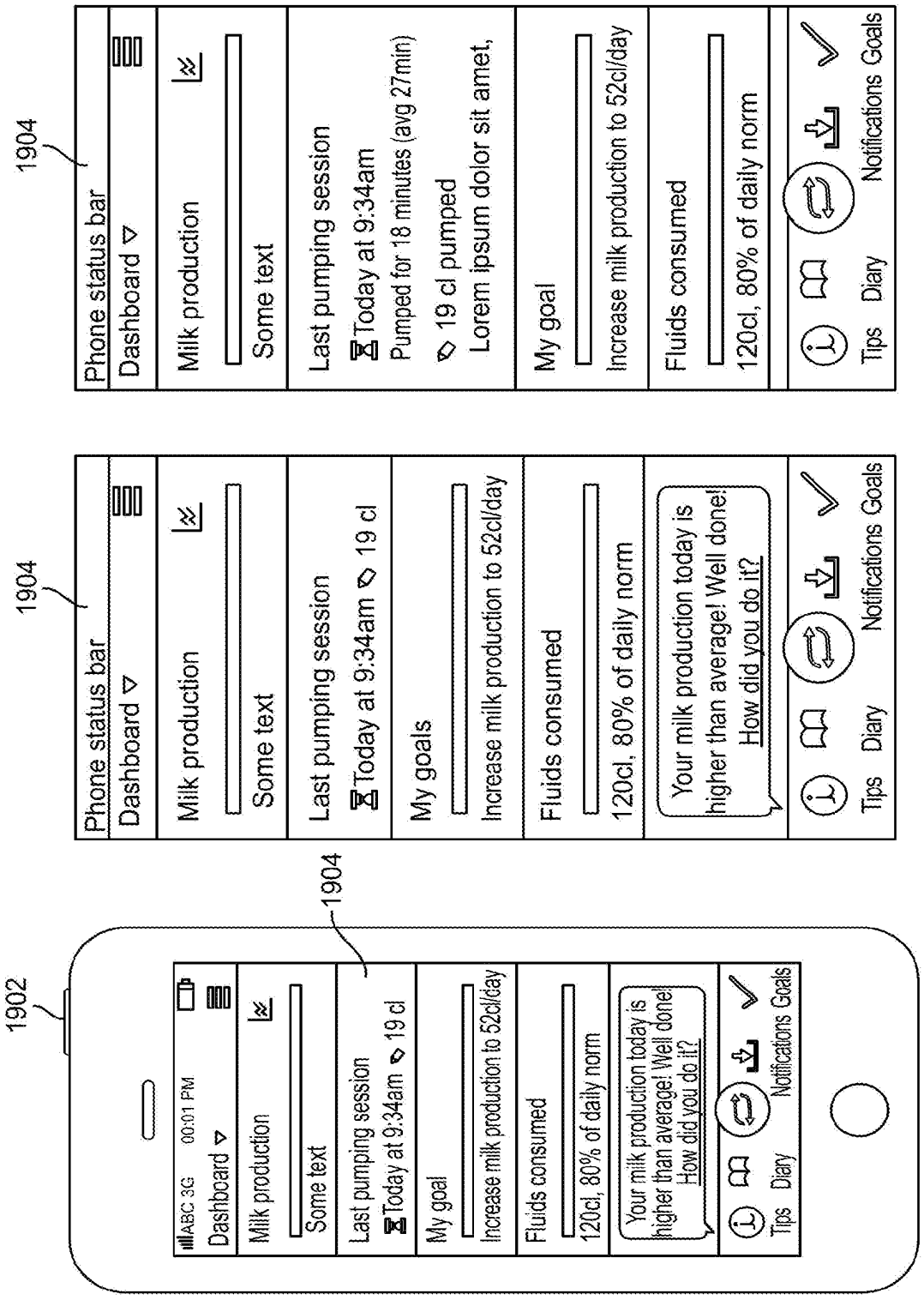


FIG. 15A FIG. 15B FIG. 15C

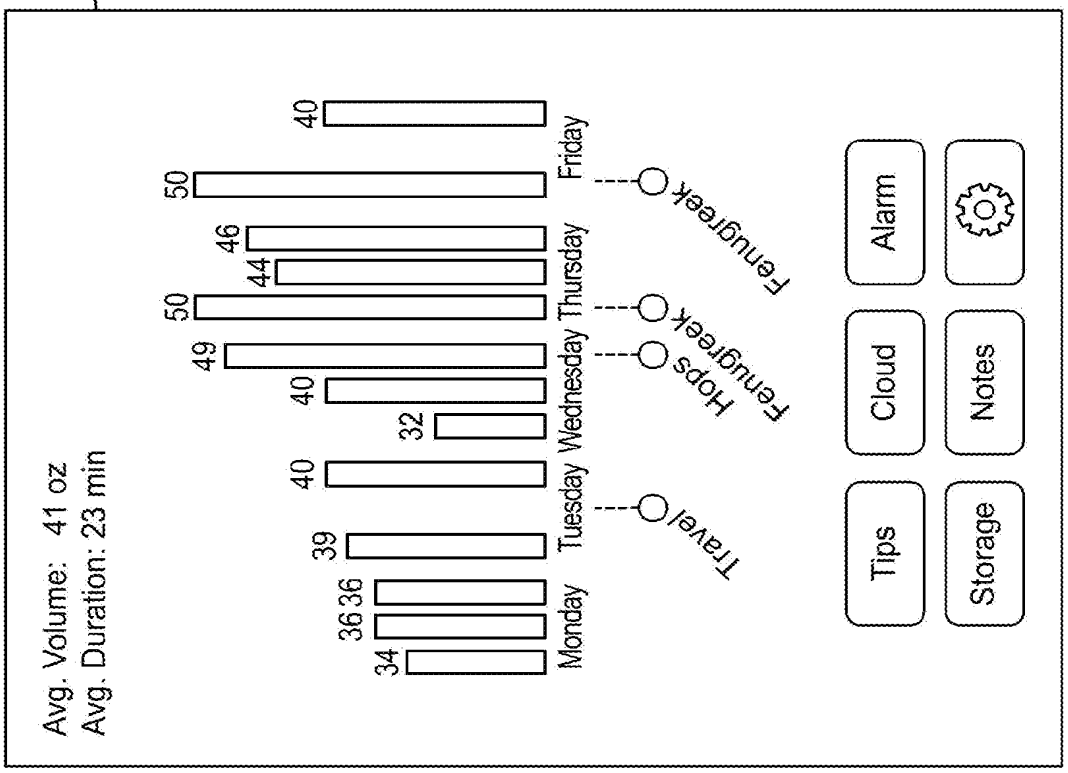


FIG. 16A

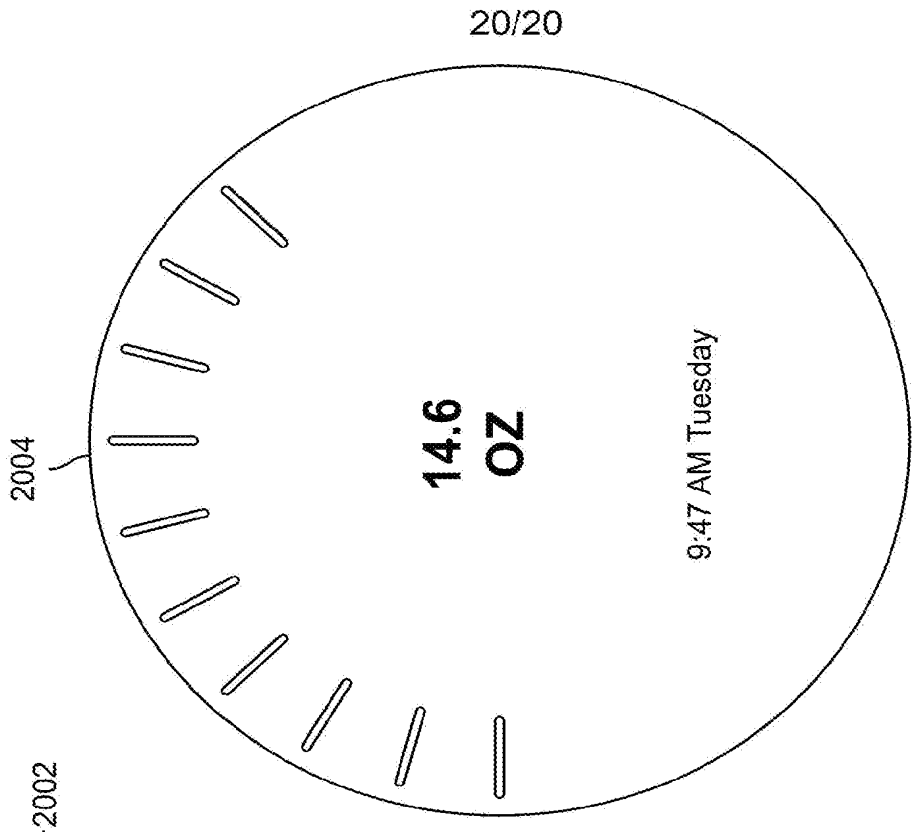


FIG. 16B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/26827

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06; G01F 23/26 (2016.01)
CPC - A61M 1/007; G01F 23/26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61M 1/00, 1/06; G01F 23/00, 23/26 (2016.01)
CPC: A61M 1/00, 1/06, 1/007; G01F 23/00, 23/26

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, Other Countries (INPADOC), RU, AT, CH, TH, BR, PH); EBSCO; IEEE/IEEEXplore; Google/Google Scholar; Keywords: reservoir, vessel, container, tank, receptacle, sensor, fluid, liquid sensor, proximity, location, baseline, reference, accelerometer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0261539 A1 (ABBOTT MEDICAL OPTICS INC.) 03 October 2013; figure 3D; paragraphs [0051], [0062], [0069], [0070].	1-3, 6, 9-11, 15-17, 19, 22-23, 40-41, 43, 45
---		---
Y		4-5, 7-8, 12-14, 18, 20-21, 24-26, 42, 44, 46-52, 53-57, 60
Y	US 2012/0277737 A1 (CURLEY, M.) 01 November 2012; figure 8; paragraphs [0083], [0086].	4
Y	US 6,125,696 A (HANNAN, A. et al.) 03 October 2000; figures 11a, 11b; column 16, lines 21-26; claims 9-10.	5
Y	US 2005/0172712 A1 (NYCE, D.) 11 August 2005; figure 12; paragraph [0037].	8
Y	US 6,164,132 A (MATULEK, M.) 26 December 2000; figure 3; column 6, lines 59-67.	18, 20
Y	US 6,490,920 B1 (NETZER, Y.) 10 December 2002; column 5, lines 44-48.	21
Y	US 2014/0095103 A1 (CAPTON, INC.) 03 April 2014; figure 14B; paragraphs [0057], [0087], [0088], [0090], [0154].	7, 12-14, 24-26, 42, 46-60
Y	US 7,600,423 B1 (FLUHLER, H. et al.) 13 October 2009; column 9, lines 29-32.	44

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2016 (13.06.2016)	07 JUL 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/26827

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 2011/0240136 A1 (TROTTIER, R.) 06 October 2011; figure 4B; paragraphs [0033], [0055].	58 -------- 27-39
Y	US 2002/0032403 A1 (SAVAGLE, G. et al.) 14 March 2002; figure 8; paragraphs [0033], [0045], [0047], [0051].	59
A	US 2006/0072928 A1 (YOUNG, J.) 06 April 2006; entire document.	1-60
A	US 2015/0047825 A1 (STRONG, G.) 19 February 2015; entire document.	1-60

Form PCT/ISA/210 (continuation of second sheet) (January 2015)

(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2017 年 4 月 13 日(13.04.2017)

WIPO | PCT

(10) 国際公開番号
WO 2017/061349 A1

(51) 国際特許分類:
F04B 45/047 (2006.01) *F04B 45/04* (2006.01)

(21) 国際出願番号: PCT/JP2016/079212

(22) 国際出願日: 2016 年 10 月 3 日(03.10.2016)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願 2015-197801 2015 年 10 月 5 日(05.10.2015) JP
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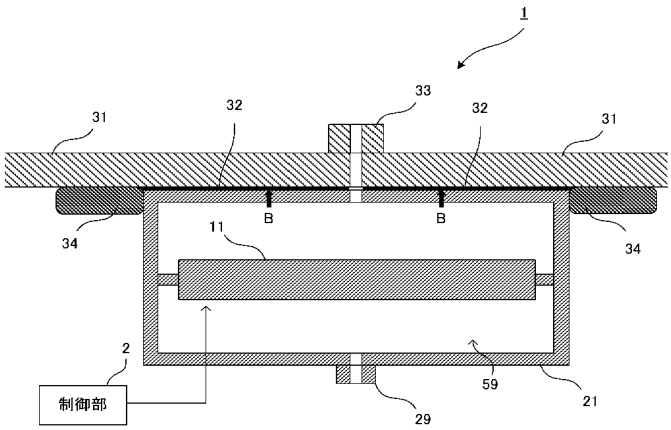
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(54) **Title**: FLUID CONTROL DEVICE, PRESSURE REDUCTION DEVICE, AND PRESSURE DEVICE

(54) 発明の名称 : 流体制御装置、減圧装置、および、加圧装置

図1



2 Controller

(57) **Abstract**: A fluid control device (1) is equipped with: a case (21) provided with a case top panel, case side panels, and a case bottom panel, and having an interior space (59) and an opening; a pump (11) that is disposed at a location such that the interior space (59) is divided into a bottom panel-side area and a top panel-side area, and that creates a flow of a fluid between the bottom panel-side area and the top panel-side area and regulates the direction of the flow of the fluid; and fasteners (31) for fastening the case (21). The case (21) is mounted to the fasteners (31) by using either the case top panel or the case bottom panel as a mounting surface (B).

(57) 要約: 流体制御装置（１）は、ケース天板、ケース側板、およびケース底板を備え、内部空間（５９）および開口が設けられているケース（２１）と、内部空間（５９）を底板側領域と天板側領域とに分割する位置に設けられ、底板側領域と天板側領域との間に流体の流れを生じさせるとともに流体の流れの方向を規制するポンプ（１１）と、ケース（２１）を固定する固定部材（３１）と、を備える。そして、ケース（２１）は、ケース天板またはケース底板を取付面（Ｂ）として固定部材（３１）に取り付けられている。

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明　細　書

発明の名称 ： 流体制御装置、減圧装置、および、加圧装置

技術分野

[0001] 本発明は、流体を輸送する流体制御装置と、流体を吸引する減圧装置と、流体を吐出する加圧装置と、に関するものである。

背景技術

[0002] 従来、流体の輸送を伴って動作する各種の装置（この発明では流体制御装置と言う。）では、圧電アクチュエータと弁部とを備える圧電マイクロポンプが広く使用されている（例えば特許文献１参照）。圧電マイクロポンプは、流入口および流出口が設けられたケースに圧電素子等を収納した状態で提供され、流体制御装置の内部に、ケースに格納されたまま取り付けられることがあった。

[0003] 図１７（Ａ）は、流体制御装置におけるポンプの従来の取り付け構造の一例を示す模式図である。

[0004] 流体制御装置１０１は、ポンプ１１１と、ポンプ１１１を格納するケース１２１と、フレームや外装板などの固定部材１３１と、を備える。固定部材１３１には、パッキン１３３が取り付けられ、ケース１２１の側面はパッキン１３３により保持されている。ケース１２１の内部は、ポンプ１１１によって底面側の空間１２４と天面側の空間１２５に区画されている。ポンプ１１１は、アクチュエータ（不図示）を備え、アクチュエータの駆動により底面側の空間１２４と天面側の空間１２５との間に流体の流れを生じさせる。また、ポンプ１１１は、弁部（不図示）を備え、弁部の動作により流体の流れの方向を規制し、２つの空間１２４，１２５に大きな圧力差を生じさせて、高い流体圧を得る。

[0005] ここで、ケース１２１の底面側の空間１２４から天面側の空間１２５への流体の流れが生じる場合、底面側の空間１２４が外部空間に常時開放され、天面側の空間１２５が圧力容器に接続されていると、天面側の空間１２５と

圧力容器が外部空間よりも高い流体圧に加圧されることになる。したがって、この場合の流体制御装置１０１は、加圧装置を構成することになる。また、天面側の空間１２５が外部空間に常時開放され、底面側の空間１２４が圧力容器に接続されていると、底面側の空間１２４と圧力容器が外部空間よりも低い流体圧に減圧されることになる。したがって、この場合の流体制御装置１０１は減圧装置を構成することになる。

先行技術文献

特許文献

[0006] 特許文献1：特表２０１２－５２８９８１号公報

発明の概要

発明が解決しようとする課題

[0007] 加圧装置や減圧装置では、圧力状態を切り替える際などに、以下の理由により、部材の変形音や部材間の摩擦音が生じることがあった。図１７（Ｂ）は、流体制御装置１０１を加圧装置として構成する場合に生じる変形を模式的に示す図である。

[0008] １．２つの空間１２４，１２５の一方（図１７（Ｂ）では天面側の空間１２５）は外部空間との圧力差が大きいので、その空間に面するケース１２１の天面または底面（図１７（Ｂ）では天面）には、圧力状態の切り替えに伴って、膨らむ、または、へこむ状態と平坦な状態との間で変形が生じる。また、この変形が、固定部材１３１等の他部材に伝わることで、他部材にも変形が生じることがある。

[0009] 特に圧力容器の変形または温度変化による圧力容器内の圧力変化がポンプに伝播した場合、ポンプで発生しうる以上の圧力差が生じる可能性がある。

[0010] ２．圧力状態の切り替えに伴って、ケース１２１の天面または底面に変形が生じ、その反力でマイクロポンプ１１１を収納するケース１２１が天面方向または底面方向に移動する。

[0011] 上記の変形や移動は、圧力状態の切り替えに伴う不要音の発生要因となる

だけでなく、その際の衝撃によってケース１２１の固定が次第に緩んだり、部材の剥がれや割れなどの不具合を招いたりするおそれもあった。

[0012] 不具合については上記に加えて、ケース１２１が変形してポンプ１１１に接触した場合、ポンプ１１１に応力がかかって特性が変化する恐れも含まれる。

[0013] そこで、本発明の目的は、圧力状態の切り替えに伴って発生する不要音や不具合を低減できる、静音性および耐久性に優れた流体制御装置、減圧装置、および、加圧装置を提供することにある。

課題を解決するための手段

[0014] 本発明の流体制御装置は、内部空間を囲う天板、側板、および底板を備え、前記内部空間を外部空間に通じさせる開口が設けられているケースと、前記内部空間を天板側領域と底板側領域とに分割する位置に設けられていて、前記天板側領域と前記底板側領域との間に流体の流れを生じさせるアクチュエータおよび前記流体の流れの方向を規制する弁部を備えるポンプと、前記ケースを固定する固定部材と、を備える。そして、前記ケースは、前記天板または前記底板を取付面として前記固定部材に取り付けられている。

[0015] この構成では、アクチュエータを駆動すると、ケースの天板側領域と底板側領域とのうちの一方は、開口を介して通じる外部空間と同程度の流体圧となり、他方は、弁部により外部空間との圧力差が大きくなる。したがって、圧力差が大きい領域に面するケースの天板または底板に変形が生じることになる。この変形は、不要音や不具合の発生要因となりうるが、上記のようにケースが天板または底板を取付面として固定部材に取り付けられていれば、ケースの天板または底板の変形の反力で生じる移動が抑制されるために、不要音や不具合の発生を抑制できる。

[0016] 更に、上記変形が抑制されるために、ケースの天板側領域と底板側領域とのうち、外部空間との圧力差が大きくなる領域はポンプとの距離を近接できるため、流体制御装置を低背化できる。

[0017] この発明の流体制御装置において、前記天板側領域と前記底板側領域との

うち、前記取付面に近い側に位置する一方は、他方よりも、前記ポンプの動作中の前記外部空間との圧力差が小さくてもよい。この場合には、外部空間との圧力差による撓みが殆ど生じない天板または底板が固定部材への取付面となるので、ケースと固定部材との取り付け部分に割れや剥がれといった不具合が生じたり、固定部材に変形が伝わって他部材で不要音や不具合が生じたりすることを特に抑制できる。

[0018] この発明の流体制御装置において、前記天板側領域と前記底板側領域とのうち、前記取付面に近い側に位置する一方は、他方よりも、前記ポンプの動作中の外部空間との圧力差が大きくてもよい。この場合には、外部空間との圧力差が大きい領域に面する天板または底板の変形が固定部材により抑制され、ケースやポンプで不要音や不具合が生じることを特に抑制できる。

[0019] 前記天板側領域と前記底板側領域とのうち、前記ポンプの動作中の外部空間との圧力差が大きい方の領域は、ポンプと天板との距離またはポンプと底板との距離が、天板または底板の変形量より充分大きいことが好ましい。天板または底板とポンプとの接触を防止することで、ポンプの特性変化という不具合を防止できるためである。

[0020] この発明の流体制御装置において、前記内部空間を圧力容器に通じさせるノズルを備え、該ノズルは、前記取付面から前記固定部材を通るように突出していてもよい。ケースの取付面から圧力容器との接続を行う場合、仮に固定部材にノズルが設けられていると、ケースと固定部材との間をパッキン等で気密する必要が生じる。そこで、ケースに、取付面から固定部材を通るように突出するノズルを設けることで、ケースと固定部材との間を気密する必要を無くし、パッキン等を設けずにより簡便にケースを固定することができる。

[0021] この発明の流体制御装置において、前記内部空間を圧力容器に通じさせるノズルを備え、該ノズルは、前記側板に設けられていてもよい。この場合にも、ケースと固定部材との間をパッキン等でシールする必要がなく、パッキン等を設けずにより簡便にケースを固定することができる。また、ケースと

固定部材との取付面の面積が増すので、取付面の強度が増し、より変形しにくくすることができる。

[0022] この発明の流体制御装置において、前記アクチュエータを間欠的に駆動させる制御部を更に備えてもよい。間欠動作時は、アクチュエータの駆動の度に各部の変形が生じ、不要音・不具合発生の度合いが大きいので、本発明による改善の効果が大きい。

[0023] この発明の減圧装置は、上述した流体制御装置と、前記天板側領域と前記底板側領域とのうち、外部空間よりも減圧される領域に接続した圧力容器と、を備えるものである。また、この発明の加圧装置は、上述した流体制御装置と、前記天板側領域と前記底板側領域とのうち、外部空間よりも加圧される領域に接続した圧力容器と、を備えるものである。減圧装置は、例えば鼻水吸引器や、搾乳器、局所陰圧閉鎖療法（ＮＰＷＴ）の分泌物吸引器などである。加圧装置は、例えばエアマット、血圧計のカフなどである。

発明の効果

[0024] 本発明によれば、圧力状態の切り替えに伴って生じる不要音や不具合の発生を抑制できる。したがって、部材間の固定の緩み、部材の割れ、剥がれといった不具合が生じにくくでき、耐久性および静音性に優れた流体制御装置、減圧装置、および、加圧装置を提供できる。

図面の簡単な説明

[0025] [図1]図１は第１実施形態に係る流体制御装置を模式的に示す断面図である。

[図2]図２は第１実施形態に係るケースおよびポンプの構成例を示す分解斜視図である。

[図3]図３は第１実施形態に係るケースおよびポンプの第１の動作状態を示す断面図である。

[図4]図４は第１実施形態に係るケースおよびポンプの第２の動作状態を示す断面図である。

[図5]図５は第１実施形態に係る流体制御装置の第１の変形例を示す断面図である。

[図6]図６は第１実施形態に係る流体制御装置の固定部材の具体的な構成例を示す図である。

[図7]図７は第１実施形態に係る流体制御装置の第２の変形例を示す断面図である。

[図8]図８は第１実施形態に係る流体制御装置の第３の変形例を示す断面図である。

[図9]図９は第１実施形態に係る流体制御装置の第４の変形例を示す断面図である。

[図10]図１０は第１実施形態に係る流体制御装置の第５の変形例を示す断面図である。

[図11]図１１は第１実施形態に係る流体制御装置の第６の変形例を示す断面図である。

[図12]図１２は第２実施形態に係る流体制御装置の構成例を示す断面図である。

[図13]図１３は第３実施形態に係る流体制御装置の構成例を示す断面図である。

[図14]図１４は第４実施形態に係る流体制御装置の構成例を示す断面図である。

[図15]図１５は第５実施形態に係る減圧装置を模式的に示す断面図である。

[図16]図１６は第６実施形態に係る加圧装置を模式的に示す断面図である。

[図17]図１７（Ａ）は、流体制御装置におけるポンプの従来の取り付け構造の一例を示す模式図である。図１７（Ｂ）は、流体制御装置１０１を加圧装置として構成する場合に生じる変形を模式的に示す図である。

発明を実施するための形態

[0026] 《第１実施形態》

以下、第１実施形態に係る流体制御装置１について説明する。

[0027] 図１は、第１実施形態に係る流体制御装置１を模式的に示す断面図である。

[0028] ここで示す流体制御装置１は、空気等の気体の輸送を伴って動作するものであり、例えば、鼻水吸引器、搾乳器、局所陰圧閉鎖療法（ＮＰＷＴ）の分泌物吸引器、エアマット、血圧計のカフなどである。

[0029] 流体制御装置１は、固定部材３１と、粘着シート３２と、パッキン３４と、ケース２１と、ポンプ１１と、制御部２と、ノズル２９，３３を備えている。固定部材３１は、特許請求の範囲に記載の「固定部材」に相当するものである。この固定部材３１は、後に示すように、例えば流体制御装置１の筐体、流体制御装置１の内にある制御ユニットの筐体、回路基板、バッテリー、ヒートシンク、ヒートパイプ等である。固定部材３１は、ケース２１の取付面よりも剛性が高い材料で構成されていることが好ましい。また、固定部材３１の材質には金属のように弾性率の高いものが好ましい。樹脂のように弾性率が低い材料である場合には、固定部材３１の厚みがケース２１より厚いことが好ましい。

[0030] ケース２１は、後述する天面または底面を取付面Ｂとして固定部材３１に取り付けられている。ノズル２９はケース２１に付設されている。ノズル３３は固定部材３１に付設されている。ノズル２９とノズル３３とのうちの一方は、圧力容器（不図示）に接続されるものであり、特許請求の範囲に記載の「ノズル」に相当している。ノズル２９とノズル３３とのうちの他方は、外部空間に開放されるものであり、特許請求の範囲に記載の「開口」に相当している。ポンプ１１は、ケース２１の内部空間５９に収納されている。制御部２は、交流の駆動電圧をポンプ１１に出力する。ポンプ１１は、交流の駆動電圧が印加されることで駆動し、ケース２１内の気体に所定の流れを生じさせる。このため、ポンプ１１を駆動すると、ノズル２９，３３を介して気体が流れ、圧力容器（不図示）と外部空間との圧力差を大きくすることができる。粘着シート３２は、ケース２１の取付面Ｂと固定部材３１とに接着することにより、両者を固定している。パッキン３４は、ケース２１または固定部材３１と粘着シート３２との間に接着不良があっても気密を保つために、取付面Ｂの外側を囲んでケース２１と固定部材３１とに密着するように

設けている。

[0031] また、後に示すように、外部空間との圧力差が大きい面を、圧力容器に固定する構成でもよい。その場合には、固定部両面の圧力差が減少するため、さらにケースの変形が抑制され、不要音や不具合の低減効果が大きい。

[0032] 圧力容器は、マットやカフ、ガーゼのように、ナイロンなどの樹脂材料でできた薄い袋状容器でもよいし、厚い材料でできた箱状容器でもよい。

[0033] なお、ケース２１と固定部材３１とは、粘着シート３２によらず、接着剤による接着、直接接合、ねじ止め、嵌合など、その他の方法で固定されていてもよい。また、パッキン３４は、ケース２１と固定部材３１との接着面を気密する必要が無いような場合には設けなくてもよい。

[0034] 図２は、ケース２１およびポンプ１１の構成例に係る分解斜視図である。図３は、該構成例に係る第１の動作状態を示す断面図である。図４は、該構成例に係る第２の動作状態を示す断面図である。以下、ケース２１およびポンプ１１において、図２における上方向を天面方向または天面側と言い、図２における下方向を底面方向または底面側と言う。

[0035] ここで示すケース２１およびポンプ１１は、薄板状部材の積層構造を有する積層モジュール３を構成している。積層モジュール３は、ケース天板４１、バルブ天板４２、バルブ側板４３、バルブフィルム４４、バルブ底板４５、ポンプ側板４６、振動板４７、圧電素子４８、ケース側板４９、および、ケース底板５０を備えている。

[0036] ケース天板４１、ケース側板４９、および、ケース底板５０は、それぞれ天面側から底面側にかけて順に積層した状態で接合されてケース２１を構成している。

[0037] ケース天板４１は、例えば樹脂からなる円板状の部材であり、円形の開口５１が天面方向（底面方向）に貫通して設けられている。この開口５１は、ケース２１の内部から気体を排出する排出口として機能する。

[0038] ケース底板５０は、例えば樹脂からなる円板状の部材であり、円形の開口６０が天面方向（底面方向）に貫通して設けられている。この開口６０は、

ケース２１の内部に気体が流入する流入口として機能する。

[0039] ケース側板４９は、ケース天板４１とケース底板５０との間に設けられた円筒状の部材であり、ケース天板４１の開口５１およびケース底板５０の開口６０と通じる内部空間５９が設けられている。ケース側板４９には、内周面から内部空間５９に突出するとともに内周に沿って延在するように、隔壁２６が設けられている。隔壁２６は、ケース側板４９における天面方向（底面方向）の中央付近に位置している。

[0040] バルブ天板４２、バルブ側板４３、バルブフィルム４４、バルブ底板４５、ポンプ側板４６、振動板４７、および、圧電素子４８は、ポンプ１１を構成している。ポンプ１１は、ケース側板４９における隔壁２６の天面側の面にバルブ底板４５の底面側の外縁部分を接合させることで、ケース天板４１とケース底板５０との間で中空に支持される。以下、内部空間５９における、ポンプ１１および隔壁２６よりも天面側の領域を天板側領域２５（図３および図４参照。）と言う。また、内部空間５９における、ポンプ１１および隔壁２６よりも底面側の領域を底板側領域２４（図３および図４参照。）と言う。すなわち、ポンプ１１は、ケース２１の内部空間５９が天板側領域２５と底板側領域２４とに分割される位置に設けていて、隔壁２６とともに天板側領域２５と底板側領域２４とを区画している。流入口としての開口６０に連通する底板側領域２４は本発明に係る「第１気室」に相当し、排出口としての開口５１に連通する天板側領域２５は本発明に係る「第２気室」に相当する。

[0041] また、ポンプ１１は、バルブ１２とアクチュエータ１３とを備えている。アクチュエータ１３は、ポンプ１１における底面側に設けられていて、駆動されることで振動し、底板側領域２４から天板側領域２５への気体の流れを生じさせる。バルブ１２は、特許請求の範囲に記載の「弁部」に相当するものであり、ポンプ１１における天面側に設けられていて、天板側領域２５から底板側領域２４への気体の流れを規制し、気体の流れの方向を天面方向（底板側領域２４から天板側領域２５に向かう方向）に限定する。

[0042] アクチュエータ１３は、振動板４７の底面側に圧電素子４８が積層して接合されることで構成されている。圧電素子４８は、例えばチタン酸ジルコン酸鉛系セラミックスなどからなる面内方向に伸縮する圧電性を有する円板状の部材に、天面側電極および底面側電極を形成して構成している。振動板４７は、例えば金属材料からなる円板状の部材である。この振動板４７は、圧電素子４８に生じる面内方向の伸縮を拘束することにより、圧電素子４８とともに同心円状に撓むように変形する（図３および図４参照）。したがって、アクチュエータ１３は、圧電素子４８に交流の駆動電圧が印加されることで駆動し、同心円状に繰り返し撓むように振動する。

[0043] 振動板４７には、円形の開口５７が天面方向（底面方向）に貫通して設けられている。また、圧電素子４８には、円形の開口５８が天面方向（底面方向）に貫通して設けられている。これらの開口５７，５８は、底板側領域２４からポンプ１１に気体が流入する流入口として機能する。なお、ここでは、開口５７，５８を振動板４７および圧電素子４８の中央付近に配しているが、圧電素子４８には開口５８を設けず、振動板４７の開口５７を圧電素子４８に重ならない位置に設けるようにしてもよい。それにより、圧電素子４８に穴あけ加工が不要なため、圧電素子の製造が容易かつ安価となる。また、圧電素子４８の穴あけに伴う欠陥が生じないため、長期使用に伴う圧電素子の故障も生じにくい。

[0044] アクチュエータ１３の天面側には、ポンプ側板４６が積層して接合されている。ポンプ側板４６は、例えば金属からなる円環状の部材であり、円形の開口５６が天面方向（底面方向）に貫通して設けられている。この開口５６は、気体に圧力変化を生じさせるポンプ室として機能する。

[0045] ポンプ側板４６の天面側には、バルブ底板４５が積層して接合されている。バルブ底板４５は、例えば金属からなる円板状の部材であり、複数の円形の開口５５が天面方向（底面方向）に貫通して設けられている。複数の開口５５は、バルブ底板４５の中央付近に集中して配置されている。これらの開口５５は、ポンプ室（開口５６）からバルブ１２に気体が流入する流入口と

して機能する。

[0046] バルブ１２は、バルブフィルム４４を内部に収容した状態で、バルブ天板４２、バルブ側板４３、および、バルブ底板４５が、それぞれ天面側から底面側にかけて順に積層して接合されることにより構成されている。バルブ側板４３は、例えば金属からなる円環状の部材であり、円形の開口５３が天面方向（底面方向）に貫通して設けられている。この開口５３は、バルブフィルム４４を収納するバルブ室として機能する。バルブ天板４２は、例えば金属からなる円板状の部材であり、複数の円形の開口５２が天面方向（底面方向）に貫通して設けられている。複数の開口５２は、バルブ天板４２の中央付近に集中して配置されている。これらの開口５２は、バルブ室（開口５３）から天板側領域２５に気体を排出する排出口として機能する。開口５２は、複数である方がポンプとして高い特性が得られるが、複数でなくてもよい。また、開口５２はそれぞれ円形でなくてもよい。

[0047] バルブフィルム４４は、円板状のフィルム部材であり、複数の円形の開口５４が天面方向（底面方向）に貫通して設けられている。複数の開口５４は、バルブフィルム４４の中央付近に集中して配置されている。バルブフィルム４４は、バルブ側板４３の厚みよりも薄い厚みに設定されるとともに、バルブ室（開口５３）の開口径よりも微小に小さい外周径を有するように設定されている（図３および図４参照。）。そして、バルブフィルム４４は、極めて軽い質量となるように、ポリイミドなどの軽量な樹脂で構成されている。これにより、バルブフィルム４４は、バルブ室（開口５３）内で天面方向（底面方向）に沿って移動自在である。

[0048] なお、バルブフィルム４４の外周の一部には、突起２７を設けている。そして、バルブ側板４３の内周面には、突起２７が係止される溝２８を天面方向（底面方向）に延びるように設けている。この溝２８に突起２７が係止されることにより、バルブフィルム４４は、バルブ室（開口５３）内で天面方向（底面方向）に沿って移動する際、回転しないように構成されている。

[0049] また、バルブ天板４２の開口５２とバルブフィルム４４の開口５４とは、

互いに対向する位置に配置されている。一方、バルブ底板４５の開口５５とバルブフィルム４４の開口５４とは、互いに対向しない位置に配置されている。このため、バルブフィルム４４が天面側に移動してバルブ天板４２に接する状態では、バルブ天板４２の開口５２とバルブフィルム４４の開口５４とが通じる。一方、バルブフィルム４４が底面側に移動してバルブ底板４５に接する状態では、バルブ底板４５の開口５５とバルブフィルム４４の開口５４とが通じなくなる。このことによって、バルブ１２では、バルブフィルム４４が移動することによって、バルブ天板４２の開口５２とバルブ底板４５の開口５５との間の流路開閉状態が変わることになる。

[0050] ここで、図３および図４に基づいて、積層モジュール３における気体の流れをより詳細に説明する。図３および図４中では、黒矢印で気体の流れを例示している。

[0051] 図３では、圧電素子４８が面内方向に拡大し、アクチュエータ１３が底面側に凸に撓む第１の動作状態を示している。このとき、ポンプ室（開口５６）の容積は増し、ポンプ室（開口５６）内の流体圧は減じる。これにより、バルブ室（開口５３）および底板側領域２４に対してポンプ室（開口５６）が陰圧になる。すると、バルブ室（開口５３）において、バルブフィルム４４が底面側に引き寄せられてバルブ底板４５に接する。これにより、バルブ底板４５の開口５５が、バルブフィルム４４に塞がれる。よって、ポンプ室（開口５６）は、底板側領域２４から気体を吸引する。

[0052] 図４では、圧電素子４８が面内方向に縮小し、アクチュエータ１３が天面側に凸に撓む状態を示している。このとき、ポンプ室（開口５６）の容積は減じ、ポンプ室（開口５６）の流体圧は増す。これにより、バルブ室（開口５３）および底板側領域２４に対してポンプ室（開口５６）が陽圧になる。すると、バルブ室（開口５３）において、バルブフィルム４４が天面側に押し離されてバルブ天板４２に接する。これにより、バルブ天板４２の開口５２がバルブフィルム４４の開口５４と重なる。よって、ポンプ室（開口５６）は、バルブ室（開口５３）を介して天板側領域２５に気体を吐出する。ま

た、このときポンプ室（開口５６）の気体の一部は、底板側領域２４にも吐出される。

[0053] したがって、気体の流れは、バルブ１２の内部を底面側から天面側に通過するように限定される。そして、これらの動作状態は、ポンプ１１が駆動する間に交互に繰り返されるので、ケース２１の内部には、底板側領域２４から天板側領域２５へ向かう気体の流れが定常的に生じることになる。

[0054] 次に、図２乃至図４に示した積層モジュール３を備える流体制御装置１において、ポンプ１１を駆動している状態でケース２１に生じる変形について、より詳細に説明する。

[0055] 図５は、流体制御装置１を減圧装置として構成する場合において、ケース２１の天面側を取付面Ｂとして固定部材３１に取り付けたときに、ケース２１に生じる第１の変形例を説明する図である。図６は流体制御装置１の固定部材３１の具体的な構成例を示す図である。

[0056] ケース２１の内部では、底板側領域２４から天板側領域２５に流体の流れが生じるため、流体制御装置１を減圧装置として構成する場合には、ケース２１の底板側領域２４側に圧力容器２２を接続し、ケース２１の天板側領域２５側を外部空間に開放する必要がある。したがって、ケース２１の天面側を取付面Ｂとして固定部材３１に取り付ける際には、ケース２１の底面にノズル２９を付設して該ノズル２９を圧力容器２２に接続し、固定部材３１に付設されるノズル３３を外部空間に開放するとよい。図６に示す例では、固定部材３１は、流体制御装置が組み込まれる装置の筐体である。

[0057] このような状態で、ポンプ１１を駆動すると、ケース２１の底板側領域２４は、外部空間に対して陰圧になり、外部空間との圧力差ΔＰがマイナスになる。また、ケース２１の天板側領域２５は、外部空間と殆んど同じ流体圧になり、外部空間との圧力差ΔＰが略ゼロになる。これにより、ケース２１は、外部空間との圧力差によって底面のみがへこむように変形する。ここで、ケース２１の高さは低いので、ケース２１の側面は圧力による変形が少ない。

[0058] このような変形の反力により、ケース２１およびポンプ１１は底面側に移動しようとする。しかしながら、ケース２１の天面は取付面Ｂとして固定部材３１に取り付けられているために、ケース２１およびポンプ１１は底面側に殆ど移動することができない。

[0059] したがって、この第１の変形例では、変形に伴ってケース２１およびポンプ１１が底面側に加振されることが無く、加振による不要音や不具合の発生を抑制することができる。特に、この第１の変形例では、固定部材３１に対して、変形が殆ど生じないケース２１の天面が取り付けられるので、固定部材３１にケース２１の変形が伝わることもなく、固定部材３１の変形が防がれる。したがって、この場合の流体制御装置１では、固定部材３１での変形音の発生や、固定部材３１による他部材との摩擦音の発生、固定部材３１と他部材との固定の緩み、固定部材３１や他部材の割れや剥がれ、などを抑制することができる。

[0060] ここで底板側領域２４は、ケース２１が変形によりポンプ１１に接触しないよう、ケース２１とポンプ１１との距離は大きいほうが好ましい。ケース２１とポンプ１１との接触によるポンプの特性変化という不具合を防止できるためである。

[0061] 図７は、流体制御装置１を加圧装置として構成する場合において、ケース２１の底面側を取付面Ｂとして固定部材３１に取り付けたときに、ケース２１に生じる第２の変形例を説明する図である。

[0062] ケース２１の内部では、底板側領域２４から天板側領域２５に流体の流れが生じるため、流体制御装置１を加圧装置として構成する場合には、ケース２１の天板側領域２５側に圧力容器２２を接続し、ケース２１の底板側領域２４側を外部空間に開放する必要がある。したがって、ケース２１の底面側を取付面Ｂとして固定部材３１に取り付ける際には、ケース２１の天面にノズル２９を付設して該ノズル２９を圧力容器２２に接続し、固定部材３１に付設されるノズル３３を外部空間に開放するとよい。

[0063] このような状態で、ポンプ１１を駆動すると、ケース２１の天板側領域２

５は、外部空間に対して陽圧になり、外部空間との圧力差ΔＰがプラスになる。また、ケース２１の底板側領域２４は、外部空間と殆んど同じ流体圧になり、外部空間との圧力差ΔＰが略ゼロになる。これにより、ケース２１は、外部空間との圧力差によって天面のみが膨らむように変形する。

[0064] このような変形の反力により、ケース２１およびポンプ１１は底面側に移動しようとする。しかしながら、ケース２１の底面は取付面Ｂとして固定部材３１に取り付けられているために、ケース２１およびポンプ１１は底面側に殆ど移動することができない。

[0065] したがって、この第２の変形例でも、変形に伴ってケース２１およびポンプ１１が底面側に加振されることが無く、加振による不要音や不具合の発生を抑制することができる。そして、やはり、この場合の流体制御装置１でも、固定部材３１に対して、変形が殆ど生じないケース２１の底面が取り付けられるので、固定部材３１にケース２１の変形が伝わることもなく、固定部材３１の変形を防ぐことができる。

[0066] 図８は、流体制御装置１を減圧装置として構成する場合において、ケース２１の底面側を取付面Ｂとして固定部材３１に取り付けたときに、ケース２１に生じる第３の変形例を説明する図である。

[0067] この場合には、ケース２１の底面側を取付面Ｂとして固定部材３１に取り付けるので、ケース２１の天面にノズル２９を付設して該ノズル２９を外部空間に開放し、固定部材３１に付設されるノズル３３を圧力容器２２に接続するとよい。

[0068] このような状態で、ポンプ１１を駆動すると、ケース２１の底板側領域２４は、外部空間との圧力差ΔＰがマイナスになり、ケース２１の底面をへこむように変形させる力が生じる。しかしながら、ケース２１の底面が取付面Ｂとして固定部材３１に取り付けられているために、ケース２１の底面は殆ど変形しない。特に、固定部材３１の弾性率がケース２１の底面の弾性率より高い場合や、固定部材３１の厚みがケース２１の底面の厚みより大きい場合、変形抑制効果は大きい。

[0069] したがって、この第３の変形例では、取付面Ｂが加振されることが無く、加振による不要音や不具合の発生を抑制することができる。そして、特にこの第３の変形例では、変形が生じるケース２１の底面が固定部材３１に取り付けられるので、ケース２１の底面の変形量が低減される。したがって、この場合の流体制御装置１では、積層モジュール３における部材の割れや剥がれ、積層モジュール３からの不要音の発生などを抑制することができる。

[0070] 加えて、ケース２１の底面の変形量が抑制されるため、ポンプ１１とケース２１の底面とを近接でき、流体制御装置１を低背化できる。

[0071] 図９は、流体制御装置１を加圧装置として構成する場合において、ケース２１の天面側を取付面Ｂとして固定部材３１に取り付けたときに、ケース２１に生じる第４の変形例を説明する図である。

[0072] この場合には、ケース２１の天面側を取付面Ｂとして固定部材３１に取り付けるので、ケース２１の底面にノズル２９を付設して該ノズル２９を外部空間に開放し、固定部材３１に付設されるノズル３３を圧力容器２２に接続するとよい。

[0073] このような状態で、ポンプ１１を駆動すると、ケース２１の天板側領域２５は、外部空間との圧力差ΔＰがプラスになり、ケース２１の天面を膨らむように変形させる力が生じる。しかしながら、ケース２１の天面が取付面Ｂとして固定部材３１に取り付けられているために、ケース２１の天面は殆ど変形することができない。

[0074] したがって、この第４の変形例でも、取付面Ｂが加振されることが無く、加振による不要音や不具合の発生を抑制することができる。そして、この第４の変形例では、変形が生じるケース２１の天面が固定部材３１に取り付けられるので、ケース２１の天面の変形量が低減される。したがって、この場合の流体制御装置１でも、積層モジュール３における部材の割れや剥がれ、積層モジュール３からの不要音の発生などを抑制することができる。

[0075] 以上に説明したように、本実施形態に係る流体制御装置１では、ケース２１の天面または底面を取付面Ｂとして固定部材３１にケース２１を取り付け

ているので、圧力状態の切り替えに伴ってどのような変形が生じても不要音や不具合の発生を抑制できる。したがって、部材間の固定の緩み、部材の割れ、剥がれといった不具合が生じにくく、耐久性および静音性に優れた流体制御装置１を構成することができる。

[0076] 図１０は、流体制御装置１が組み込まれる装置の筐体以外の部材を固定部材として利用する例を説明する図である。この例では、ヒートシンク等の放熱体３６およびバッテリー３７の面に粘着シート３２を介してケース２１を接着している。このように、ヒートシンク等の放熱体３６やバッテリー３７を固定部材として利用してもよい。

[0077] 図１１は、流体制御装置１が組み込まれる装置の筐体以外の部材を固定部材として利用する別の例を説明する図である。この例では、圧力容器２２の外面にケース２１を接着している。このように、圧力容器２２を固定部材として利用してもよい。

[0078] 《第２実施形態》

次に、第２実施形態に係る流体制御装置１Ａについて説明する。

[0079] 図１２は、第２実施形態に係る流体制御装置１Ａを模式的に示す断面図である。

[0080] ここで示す流体制御装置１Ａにおける第１実施形態との相違点は、固定部材３１Ａとノズル３３Ａを備え、パッキン３４を省いた点にある。ノズル３３Ａは、圧力容器に接続されるものであり、固定部材３１Ａではなくケース２１に付設され、取付面Ｂから固定部材３１Ａを通るように突出している。固定部材３１Ａは、ノズル３３Ａが挿入される開口３５Ａが設けられている。

[0081] このような構成の流体制御装置１Ａでは、粘着シート３２に接着不良があったとしても、ノズル３３Ａがケース２１から直接、突出しているので、固定部材３１Ａとケース２１との間の気密が問題にならない。したがって、パッキン等の気密性を高める部材を設ける必要が無く、固定部材３１Ａとケース２１との固定に、より簡易な構成を採用することができる。

[0082] 《第３実施形態》

次に、第３実施形態に係る流体制御装置１Ｅについて説明する。

[0083] 図１３は、第３実施形態に係る流体制御装置１Ｅを模式的に示す断面図である。

[0084] ここで示す流体制御装置１Ｅにおける第１実施形態との相違点は、固定部材３１Ｅとノズル３３Ｅを備え、パッキン３４を省いた点にある。ノズル３３Ｅは、ケース２１における側面から突出するように設けられている。固定部材３１Ｅは、開口が設けられていない。

[0085] このような構成の流体制御装置１Ｅでも、粘着シート３２に接着不良があったとしても、固定部材３１Ｅとケース２１との間の気密が問題にならないので、パッキン等を省いた簡易な構成で、固定部材３１Ｅとケース２１とを固定することができる。また、固定部材３１Ｅとケース２１の取り付け部分の面積が増すので、取り付け部分の剛性を高めて、より変形しにくくすることができる。

[0086] 加えて、第２実施形態との相違点として、ノズル３３Ｅの向きが粘着シート３２に対し略平行に配されている。従って、圧力容器とノズル３３Ｅとを挿抜する際、粘着シート３２にかかる応力がせん断方向となり、強度をより高めることができる。

[0087] 《第４実施形態》

次に、第４実施形態に係る流体制御装置１Ｂについて説明する。

[0088] 図１４は、第４実施形態に係る流体制御装置１Ｂを模式的に示す断面図である。

[0089] ここで示す流体制御装置１Ｂにおける第１実施形態との相違点は、固定部材３１Ｂとノズル２９Ｂ，３３Ｂを備え、パッキン３４を省いた点にある。ノズル２９Ｂ，３３Ｂは、いずれもケース２１における側面から突出するように設けられている。固定部材３１Ｂは、開口が設けられていない。

[0090] このような構成の流体制御装置１Ｂでも、第３実施形態と同様、簡易な構成で固定部材３１Ｂとケース２１とを固定することができ、また、固定部材

３１Ｅとケース２１の取り付け部分の剛性を高めることができる。その上、この流体制御装置１Ｂでは、ノズル２９Ｂ，３３Ｂがいずれもケース２１の側面に設けられているので、ケース２１およびノズル２９Ｂ，３３Ｂを全体として薄く構成することができる。

[0091] 《第５実施形態》

次に、第５実施形態に係る減圧装置１Ｃについて説明する。

[0092] 図１５は、第５実施形態に係る減圧装置１Ｃを模式的に示す図である。

[0093] 減圧装置１Ｃは、ポンプ１１、ケース２１、固定部材３１、および、圧力容器９Ｃを備えている。圧力容器９Ｃは、例えば鼻水吸引用や、搾乳用、局所陰圧閉鎖療法（ＮＰＷＴ）の分泌物吸引用のアダプタに取り付けられるものであり、ケース２１の外部空間に対して陰圧となる底板側領域２４に、接続チューブ等を介して接続されている。この減圧装置１Ｃは、ポンプ１１を駆動することで圧力容器９Ｃを外部空間に対して陰圧にすることができ、圧力容器９Ｃを介して外部の流体を吸引することができる。

[0094] なお、吸引物の除去や駆動中に圧力容器９Ｃの吸引口を大気に開放した場合、急激な圧力変化が底板側領域２４に伝播し、ケース内で不要音や不具合が発生する恐れがあるが、固定部材３１に対して、変形が殆ど生じないケース２１の天面が取り付けられるので、固定部材３１にケース２１の変形が伝わることもなく、固定部材３１の変形を防ぐことができ、減圧装置としての不具合発生を低減し、減圧装置外への不要音の伝搬を抑制できる。

[0095] 《第６実施形態》

次に、第６実施形態に係る加圧装置１Ｄについて説明する。

[0096] 図１６は、第６実施形態に係る加圧装置１Ｄを模式的に示す図である。

[0097] 加圧装置１Ｄは、ポンプ１１、ケース２１、固定部材３１、および、圧力容器９Ｄを備えている。圧力容器９Ｄは、例えば横臥用のエアマットや、血圧計のカフなどであり、外部空間に対して陽圧となるケース２１の天板側領域２５に接続チューブ等を介して接続されている。この加圧装置１Ｄは、ポンプ１１を駆動することで圧力容器９Ｄを外部空間に対して陽圧にすること

ができる。

[0098] なお、例えば、加圧装置１Ｄが、圧力容器９Ｄとして横臥用のエアマットを備える場合には、横臥用のエアマットに排気のための電磁弁１０Ｄを付設し、制御部２で、ポンプ１１による圧力容器９Ｄ（エアマット）の吸気だけでなく、電磁弁１０Ｄによる圧力容器９Ｄ（エアマット）の排気を制御するようにしてもよい。この場合、制御部２で、圧力容器９Ｄ（エアマット）に対する吸気と排気とを定期的に変更するよう制御し、体圧分散や床ずれ対策等の機能を実現することも可能である。

[0099] このように制御部２でポンプ１１を間欠動作させるような用途の場合には、ケース２１内の圧力状態が頻繁に変更されることになるので、ケース２１を天面または底面で固定部材３１に取り付けて不要音や不具合の発生を抑制することが特に有効である。なお、流体制御装置を加圧装置でなく減圧装置として構成する場合にも、例えば、局所陰圧閉鎖療法の分泌物吸引用とする場合には、制御部２でポンプ１１を時間経過に伴い間欠動作させる必要があるので、やはり、ケース２１を天面または底面で固定部材３１に取り付けて不要音や不具合の発生を抑制することによる効用が特に大きい。

[0100] なお、横臥用のエアマットにおいて、使用者が乗った場合、もしくは寝返りなどで急激な圧力変化が圧力容器９Ｄに発生し、天板側領域２５に伝播し、不要音や不具合が発生する恐れがあるが、ケース２１の天板板側領域２５の天板を固定部材３１に固定することにより、前記不要音や不具合の発生を低減できる。

[0101] 《その他の実施形態》

前述した実施形態では、流体として気体を用いたが、気体の他の流体、例えば液体、粉体（気固混合流体）、固液混合流体、気液混合流体、ゲル等を流体として用いて、流体制御装置を実施することもできる。

[0102] また、前述した実施形態では、弁部として、バルブフィルムを有する積層構造のバルブを用いたが、これとは異なる弁構造を用いて、流体制御装置を実施することもできる。弁部は、ポンプの動作状態にかかわらず常に流体の

流れる方向を規制する逆止弁構造であってもよく、ポンプが駆動を停止すると弁機能も停止するような弁構造であってもよい。例えば、ポンプ室に通じる流路の一部で、アクチュエータの振動に伴って流路面積が増減するような弁構造を用いることもできる。

[0103] また、前述した実施形態ではアクチュエータを圧電駆動したが、他の駆動方法、例えば、電磁駆動等によってアクチュエータを動作させて、流体制御装置を実施することもできる。また、ポンプ室の形状やポンプ室に通じる流路の形状などを変更して、流体制御装置を実施することもできる。

[0104] また、前述した実施形態では、圧電材料にチタン酸ジルコン酸鉛系セラミックスを用いたが、他の圧電材料、例えば、ニオブ酸カリウムナトリウム系やアルカリニオブ酸系セラミックス等の非鉛系圧電体セラミックスを圧電材料に用いて、流体制御装置を実施することもできる。

[0105] また、前述した実施形態では、振動板の片面に圧電素子を設けたユニモルフ型のアクチュエータを使用したが、他のアクチュエータ、例えば振動板の両面に圧電素子を設けたバイモルフ型のアクチュエータを用いて、流体制御装置を実施することもできる。

[0106] また、前述した実施形態では、積層モジュールを構成する各部材として外形および内形が円状のものを使用したが、他の形状、例えば楕円形や多角形などの外形や内形を有する部材を用いて、流体制御装置を実施することもできる。

[0107] 最後に、前述した実施形態の説明は、すべての点で例示であって、制限的なものではないと考えられるべきである。本発明の範囲は、前述した実施形態ではなく、特許請求の範囲によって示される。さらに、本発明の範囲には、特許請求の範囲と均等の意味および範囲内でのすべての変更が含まれることが意図される。

符号の説明

[0108] Ｂ…取付面

１，１Ａ，１Ｂ…流体制御装置

１Ｃ…減圧装置

１Ｄ…加圧装置

２…制御部

３…積層モジュール

９Ｃ，９Ｄ…圧力容器

１０Ｄ…電磁弁

１１…ポンプ

１２…バルブ

１３…アクチュエータ

２１…ケース

２２…圧力容器

２４…底板側領域

２５…天板側領域

２６…隔壁

２７…突起

２８…溝

２９，３３…ノズル

３１…固定部材

３２…粘着シート

３３…ノズル

３４…パッキン

３６…放熱体

３７…バッテリー

４１…ケース天板

４２…バルブ天板

４３…バルブ側板

４４…バルブフィルム

４５…バルブ底板

４６…ポンプ側板

４７…振動板

４８…圧電素子

４９…ケース側板

５０…ケース底板

５１，５２，５３，５４，５５，５６，５７，５８，６０…開口

５９…内部空間

請求の範囲

[請求項1] 内部空間を囲う天板、側板、および、底板を備え、前記内部空間を外部空間に通じさせる流入口および排出口が設けられた、平板状構造のケースと、

前記内部空間を、前記流入口に連通する第１気室と前記排出口に連通する第２気室とに仕切る弁部と、

前記ケースを固定する固定部材と、を備え、

前記第１気室または前記第２気室の一方が前記ケースの底板側に位置し、他方が天板側に位置し、

前記ケースは、前記天板または前記底板を取付面として前記固定部材に取り付けられている、流体制御装置。

[請求項2] 前記第１気室と前記第２気室とのうち、前記取付面に近い側に位置する一方は、他方よりも、前記弁部の動作中の前記外部空間との圧力差が大きい、請求項１に記載の流体制御装置。

[請求項3] 前記第１気室と前記第２気室とのうち、前記取付面に近い側に位置する一方は、他方よりも、前記弁部の動作中の前記外部空間との圧力差が小さい、請求項１に記載の流体制御装置。

[請求項4] 前記内部空間を圧力容器に通じさせるノズルを備え、該ノズルは、前記取付面から前記固定部材を通るように突出している、請求項１乃至３のいずれかに記載の流体制御装置。

[請求項5] 前記内部空間を圧力容器に通じさせるノズルを備え、該ノズルは、前記側板に設けられている、請求項１乃至３のいずれかに記載の流体制御装置。

[請求項6] 前記弁部を間欠的に動作させる制御部を更に備える、

請求項１乃至５のいずれかに記載の流体制御装置。

[請求項7] 請求項１乃至６のいずれかに記載の流体制御装置と、

前記第１気室と前記第２気室とのうち、前記外部空間よりも減圧される領域に接続した圧力容器と、を備える、

減圧装置。

[請求項8] 請求項１乃至６のいずれかに記載の流体制御装置と、

前記第１気室と前記第２気室とのうち、前記外部空間よりも加圧される領域に接続した圧力容器と、を備える、

加圧装置。

[請求項9] 請求項２に記載の流体制御装置と、

前記第１気室と前記第２気室とのうち、前記外部空間よりも減圧される領域に接続した圧力容器と、を備え、

前記固定部材は前記圧力容器であり、

前記取付面は、前記第１気室と前記第２気室とのうち、前記外部空間との圧力差が大きい側の面である、

減圧装置。

[請求項10] 請求項２に記載の流体制御装置と、

前記第１気室と前記第２気室とのうち、前記外部空間よりも加圧される領域に接続した圧力容器と、を備え、

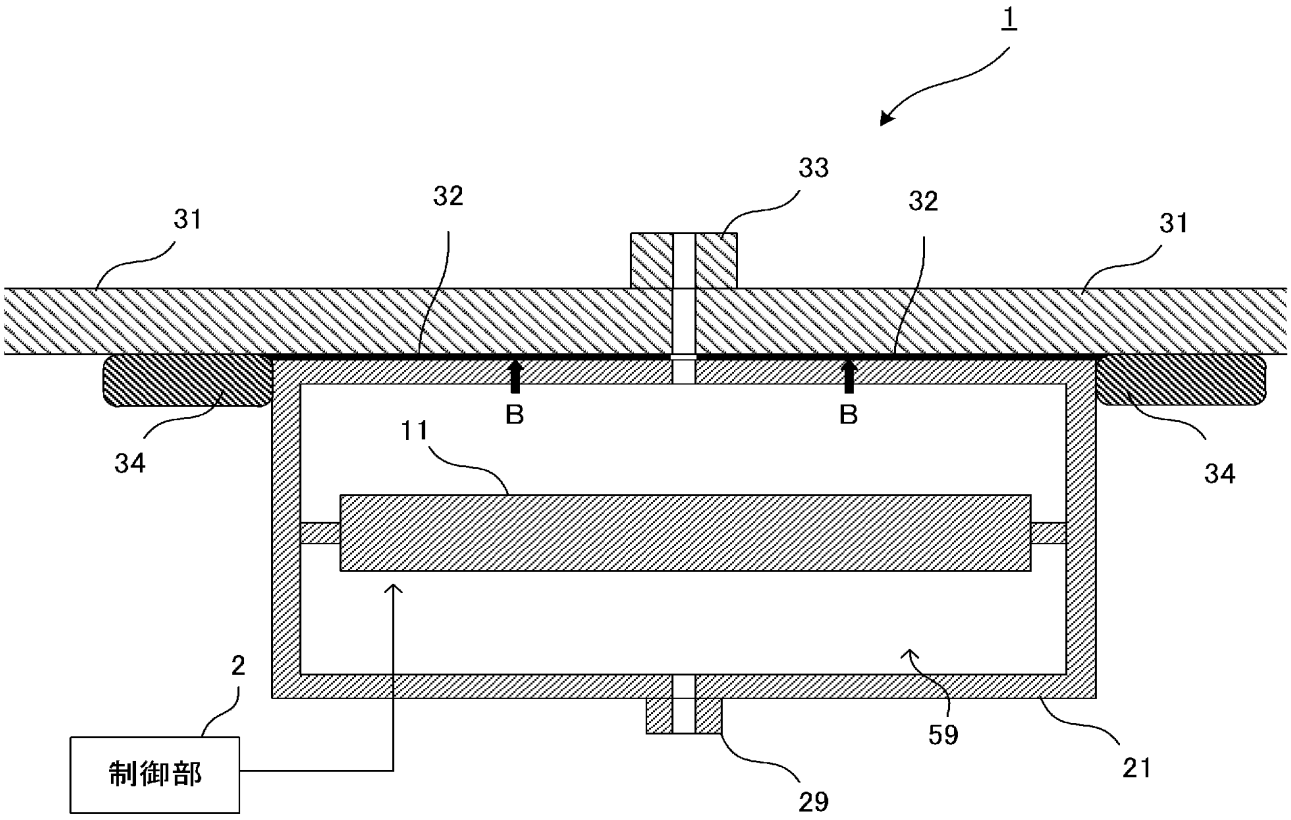
前記固定部材は前記圧力容器であり、

前記取付面は、前記第１気室と前記第２気室とのうち、前記外部空間との圧力差が大きい側の面である、

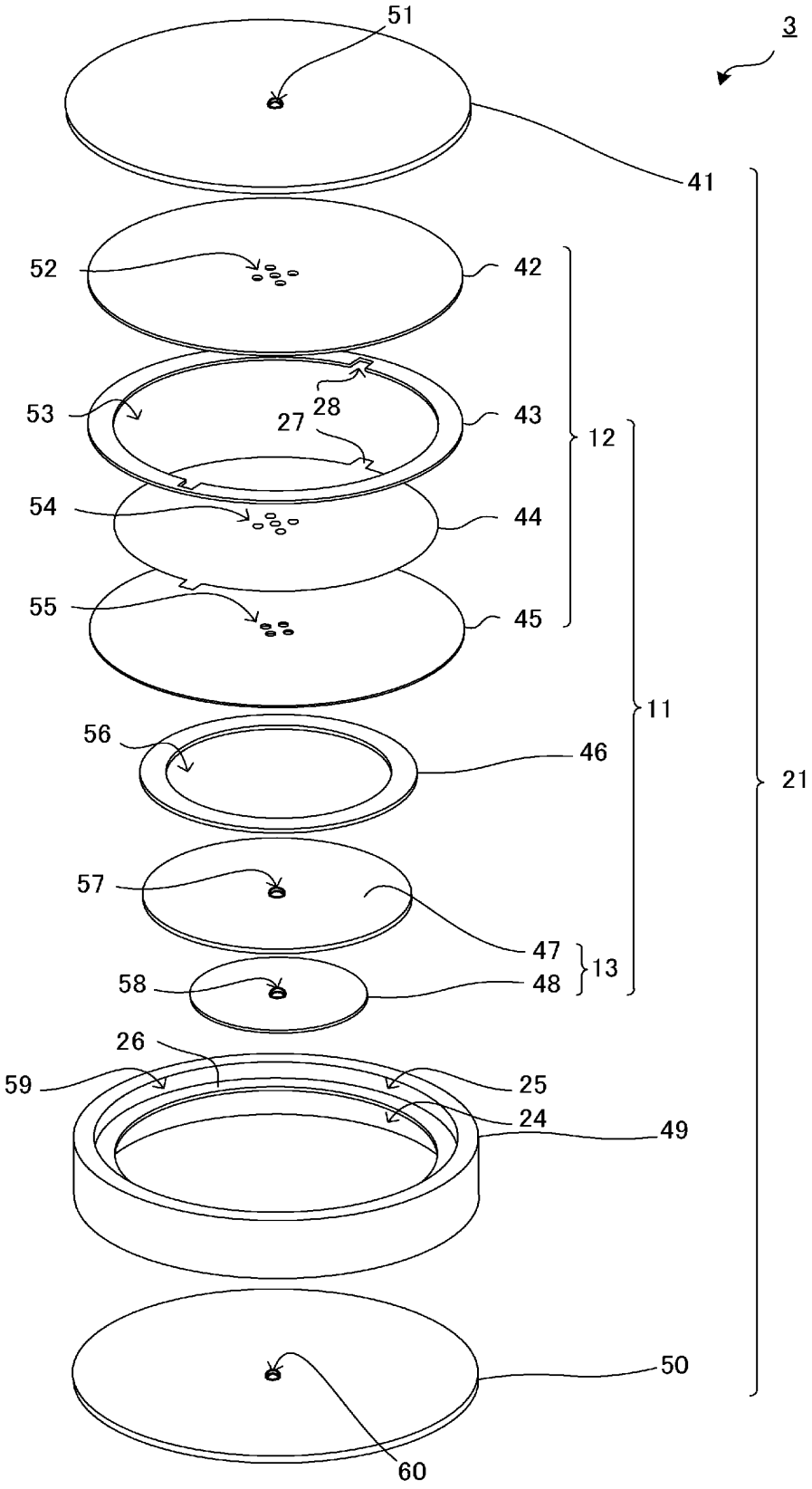
加圧装置。

[図1]

図1

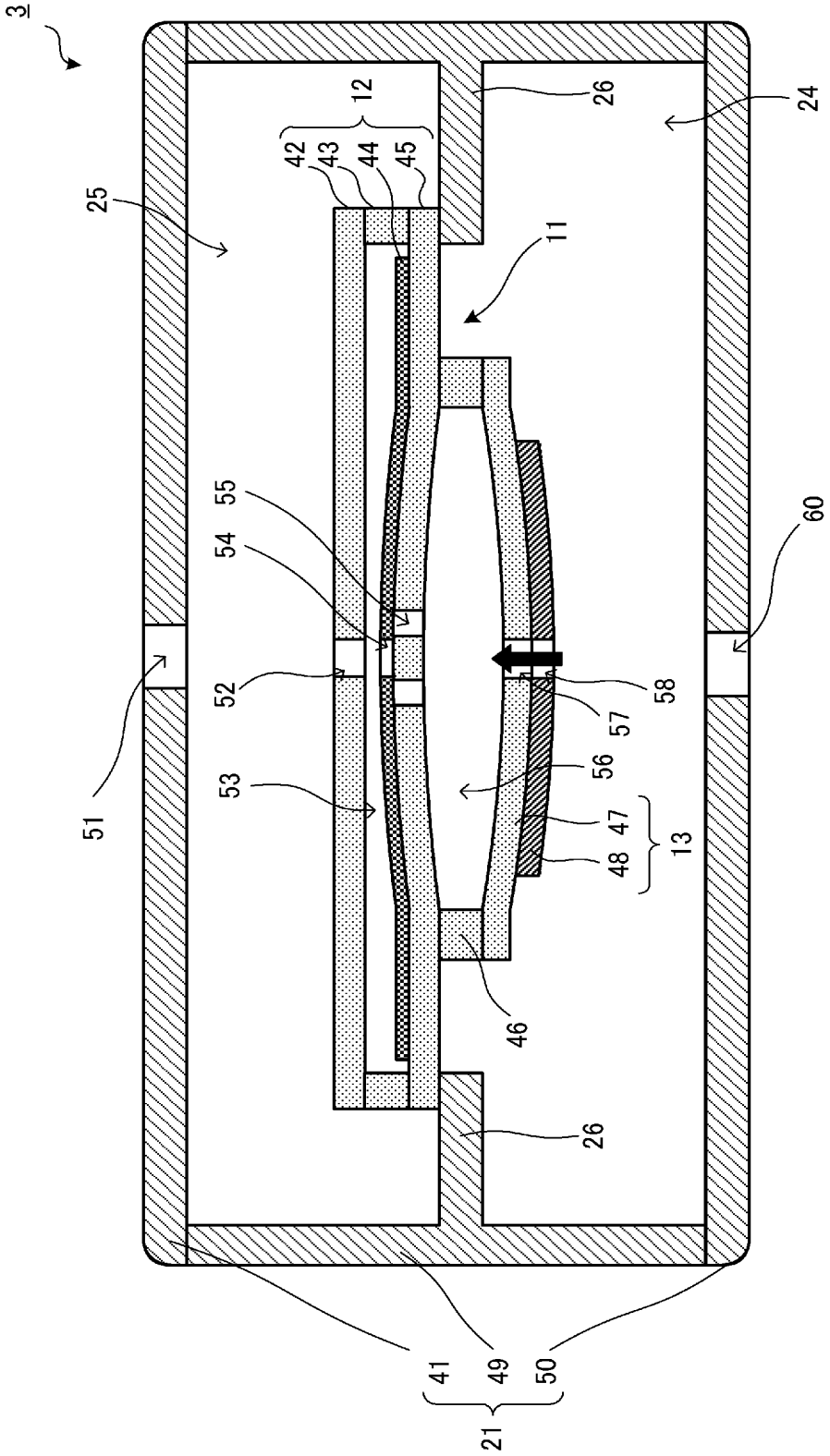


[図2]
図２


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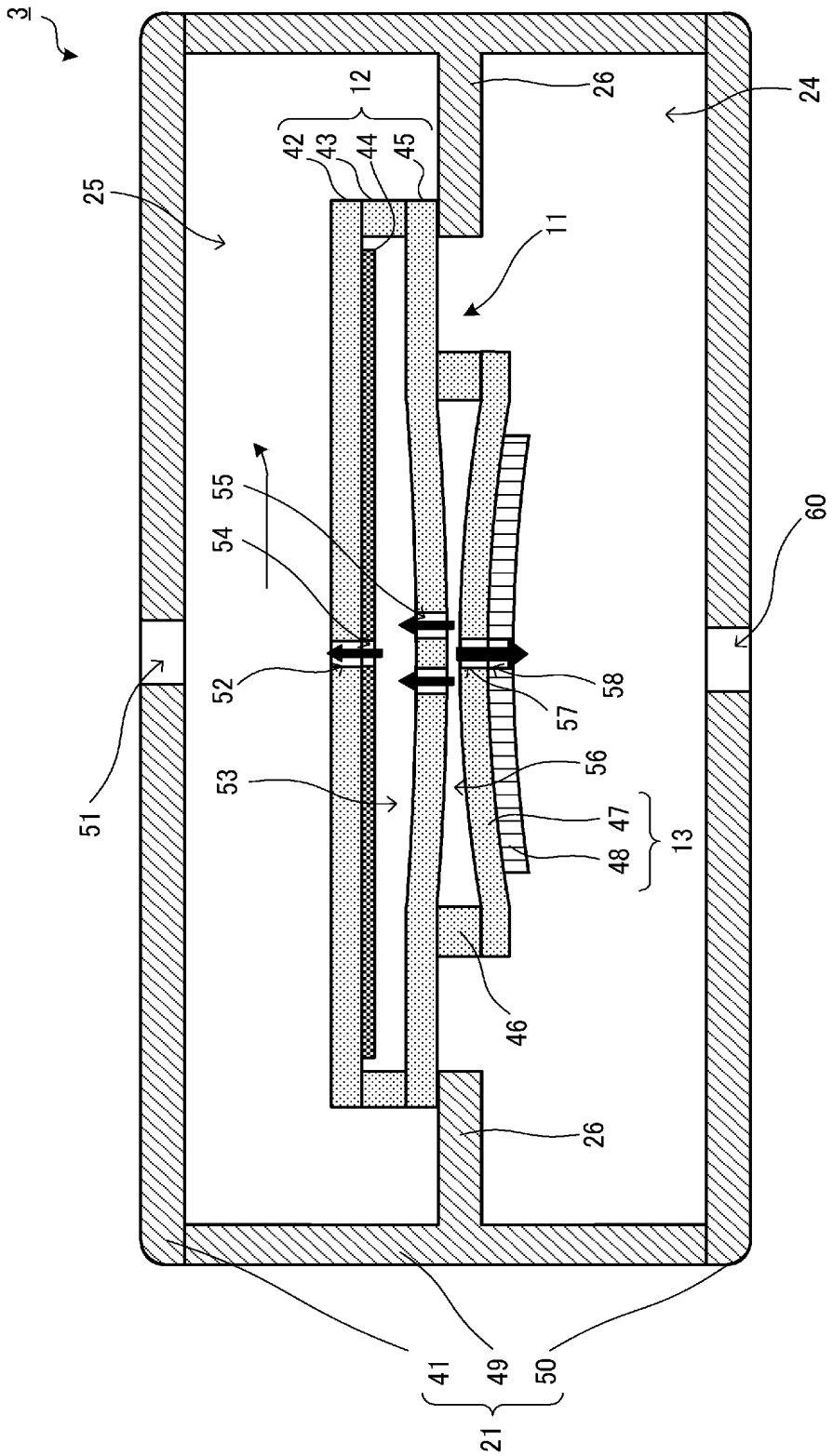
[図3]

図3

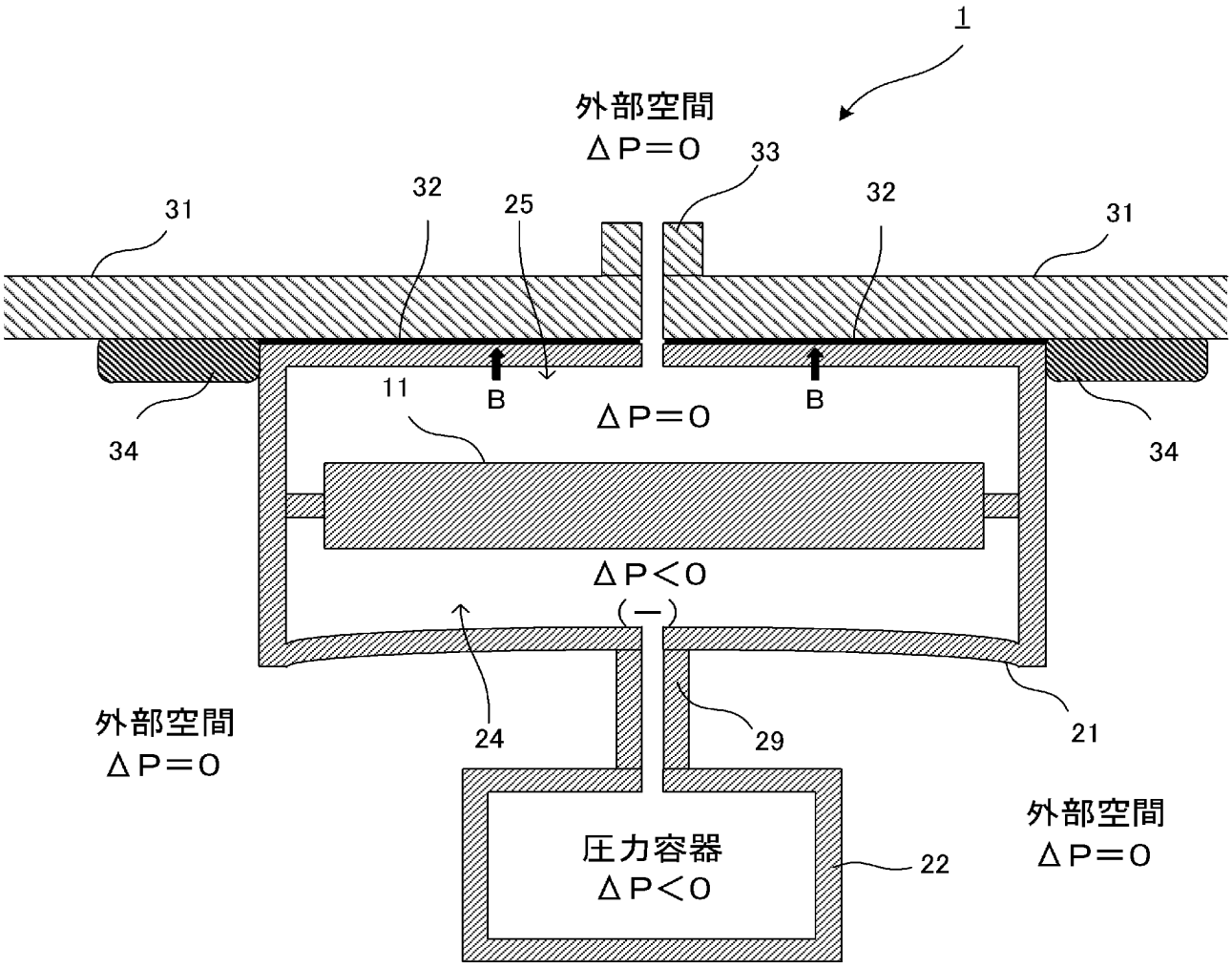

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[図4]

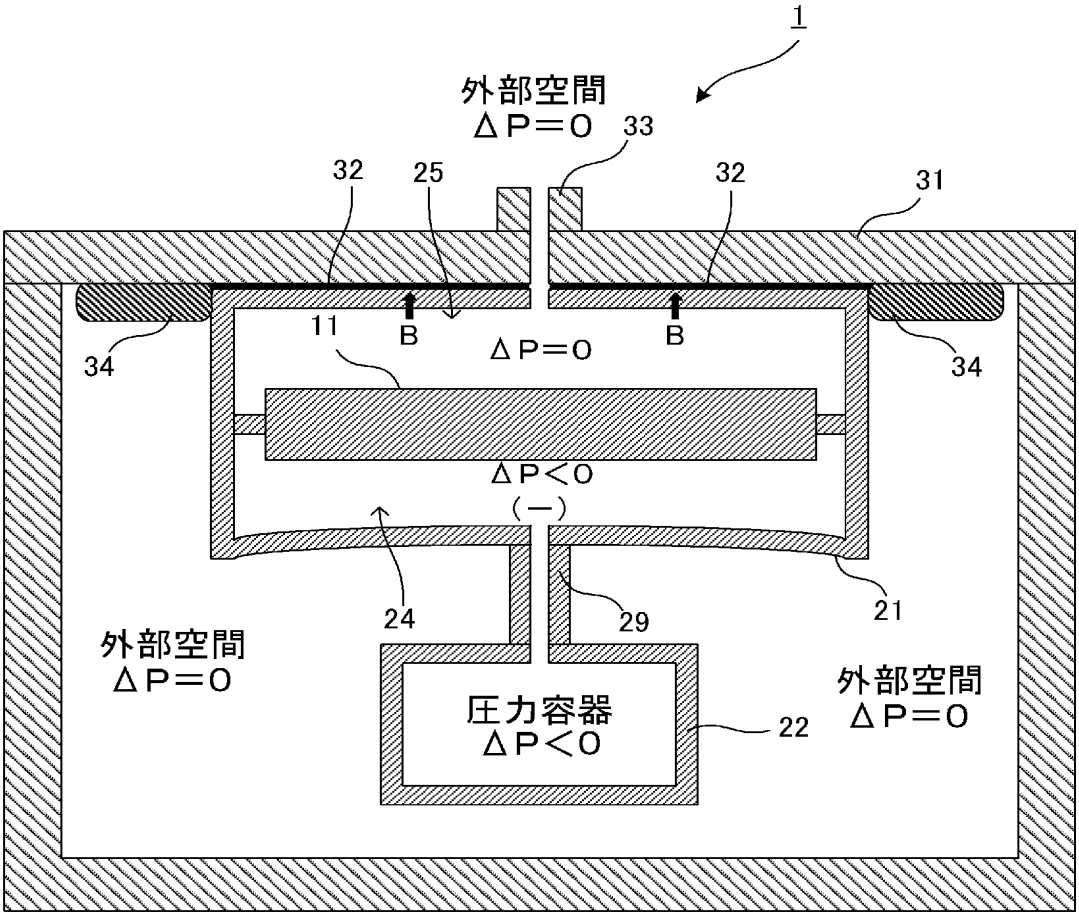
図4


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[図5]
図５

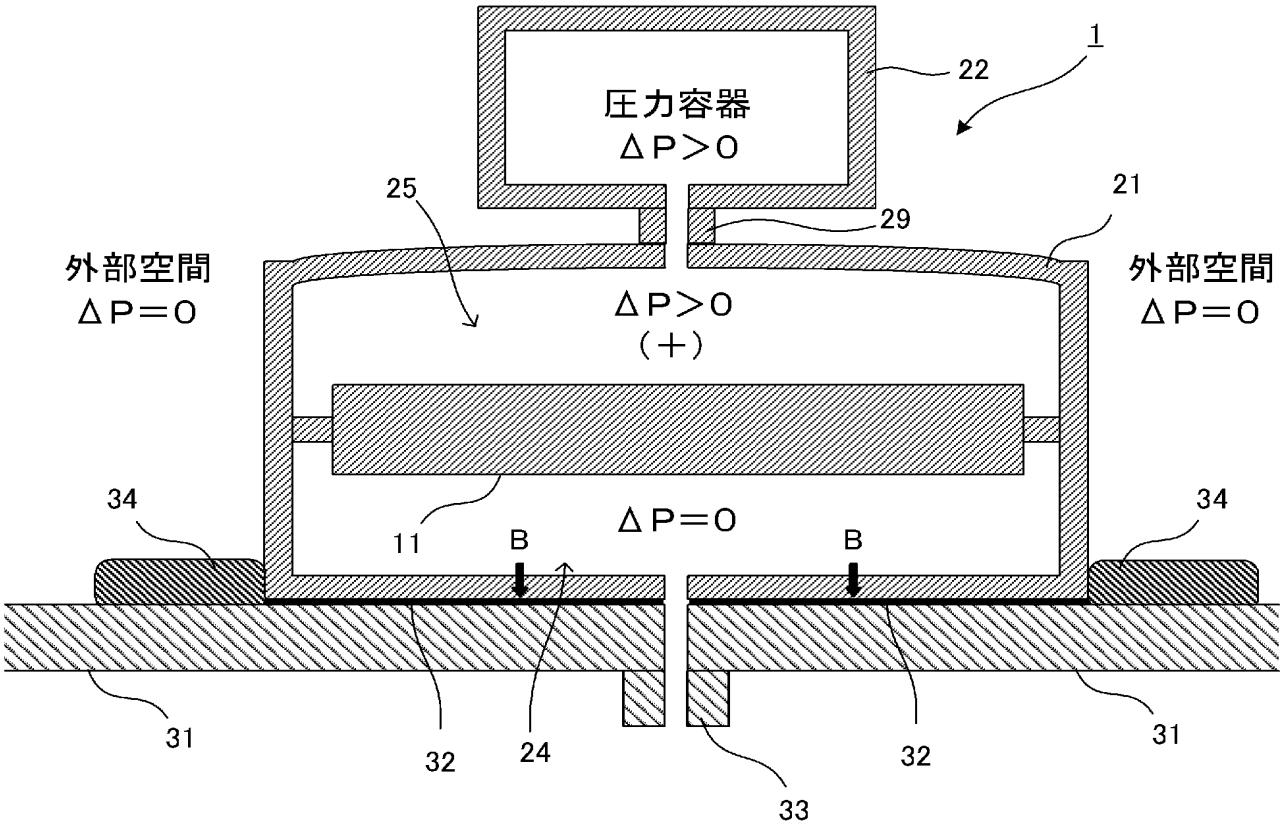

1
外部空間
ΔP＝0
33
32
25
32
31
31
11
B
B
ΔP＝0
34
34
ΔP＜0
(－)
外部空間
ΔP＝0
24
29
21
外部空間
ΔP＝0
圧力容器
ΔP＜0
22

[図6]
図6


1
外部空間
ΔP＝0
33
32
25
32
31
11
B
ΔP＝0
B
34
34
ΔP＜0
(－)
24
29
21
外部空間
ΔP＝0
圧力容器
ΔP＜0
22
外部空間
ΔP＝0

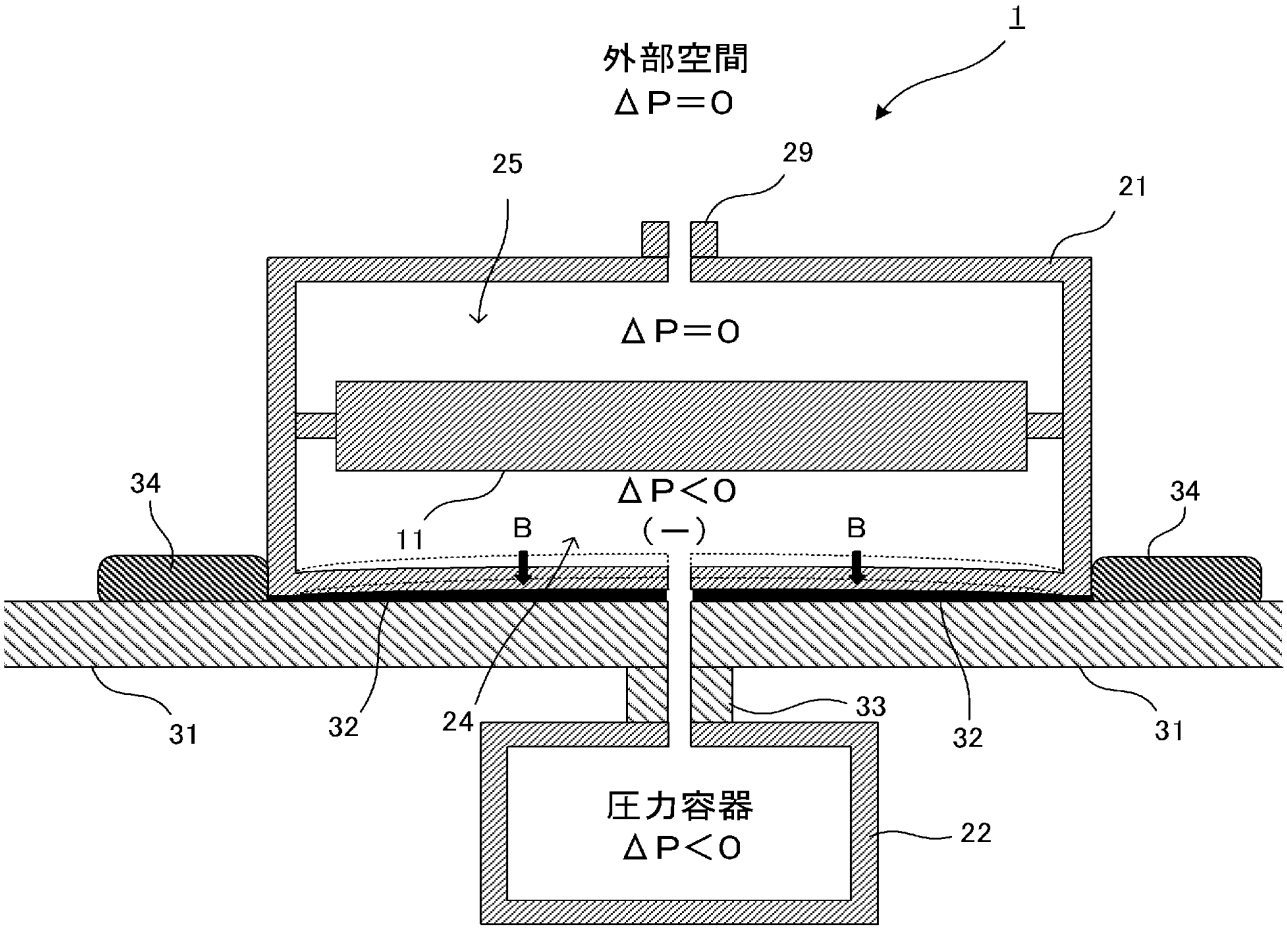
[図7]

図7


1
22
圧力容器
ΔP＞0
25
29
21
外部空間
ΔP＝0
ΔP＞0
（＋）
外部空間
ΔP＝0
34
11
B
ΔP＝0
B
34
31
32
24
33
32
31
外部空間
ΔP＝0

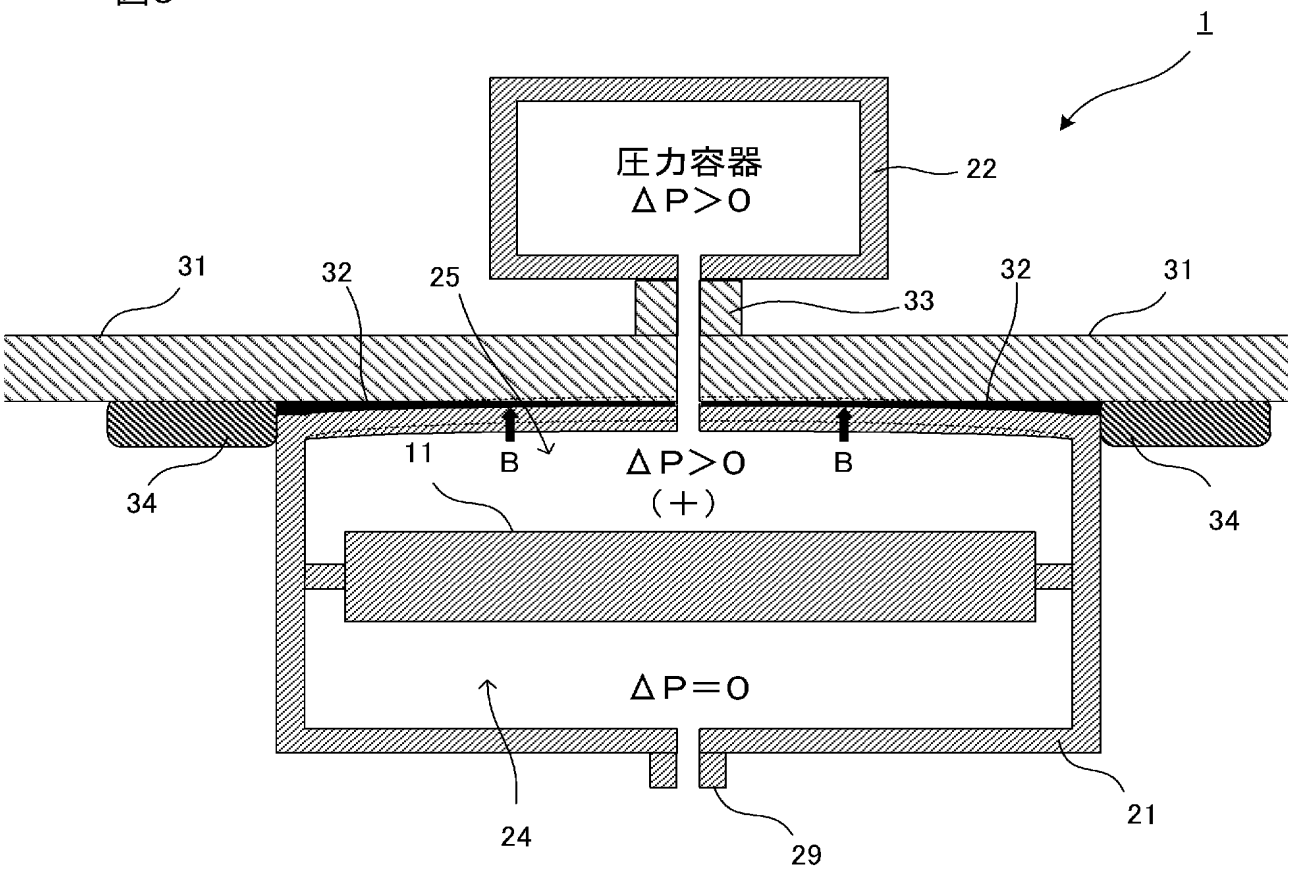
[図8]

図8

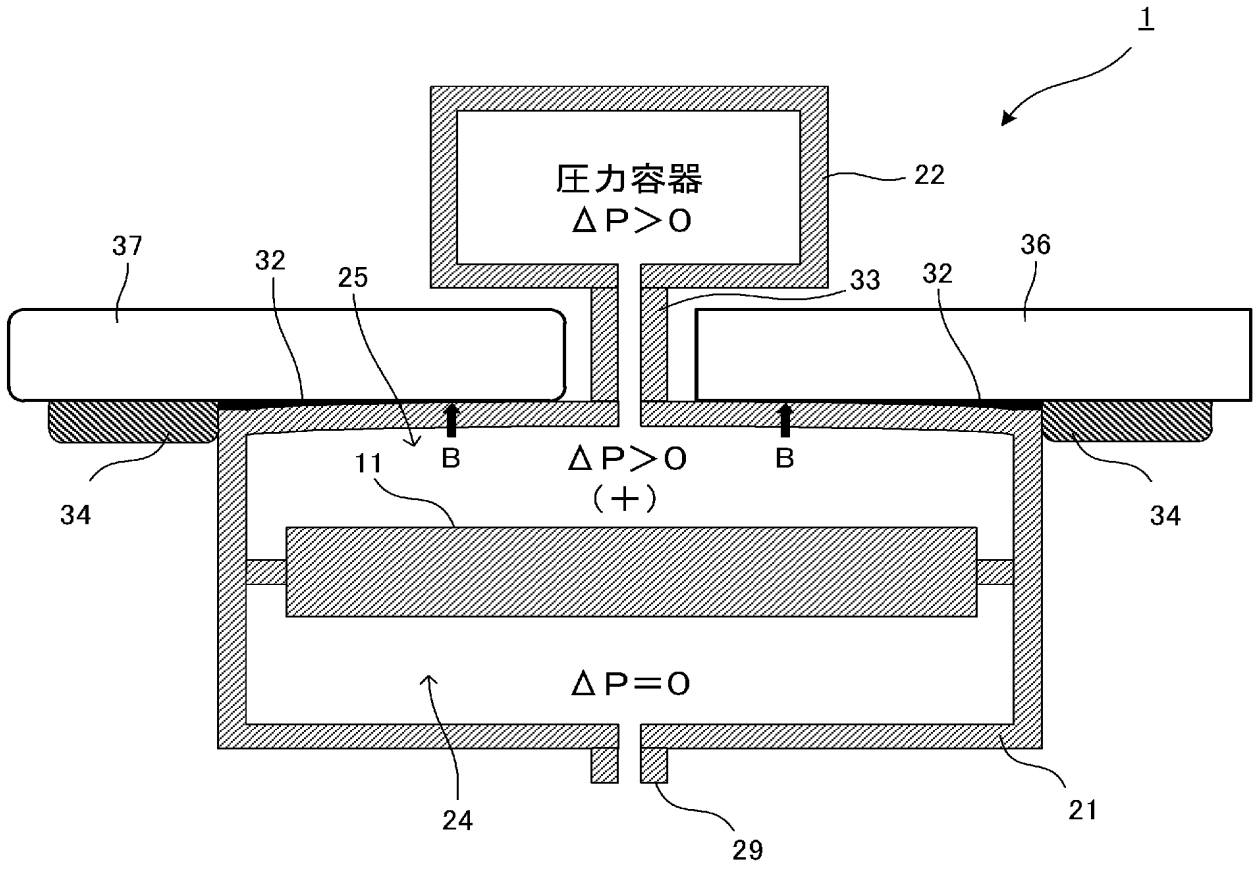


[図9]

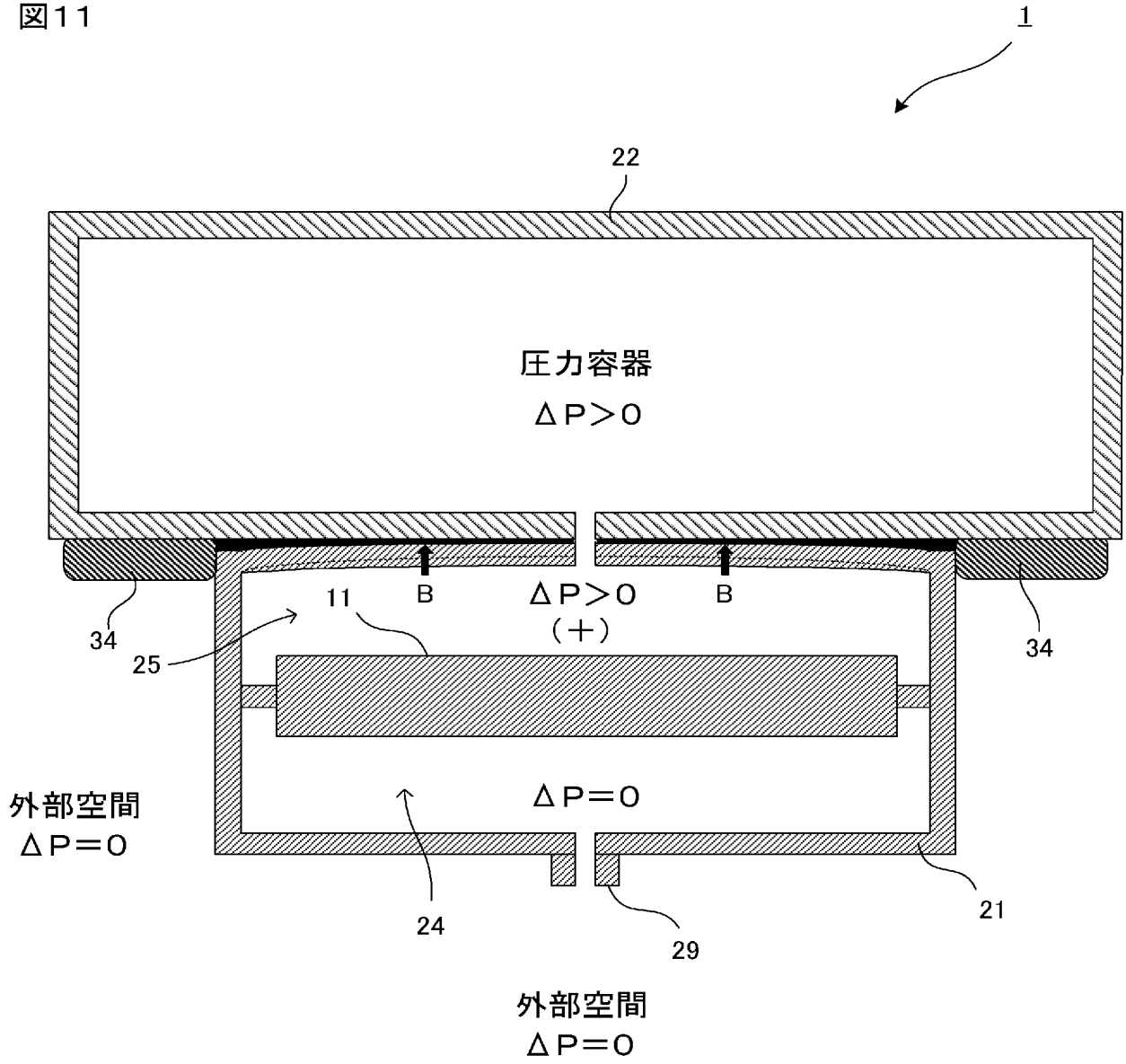
図９



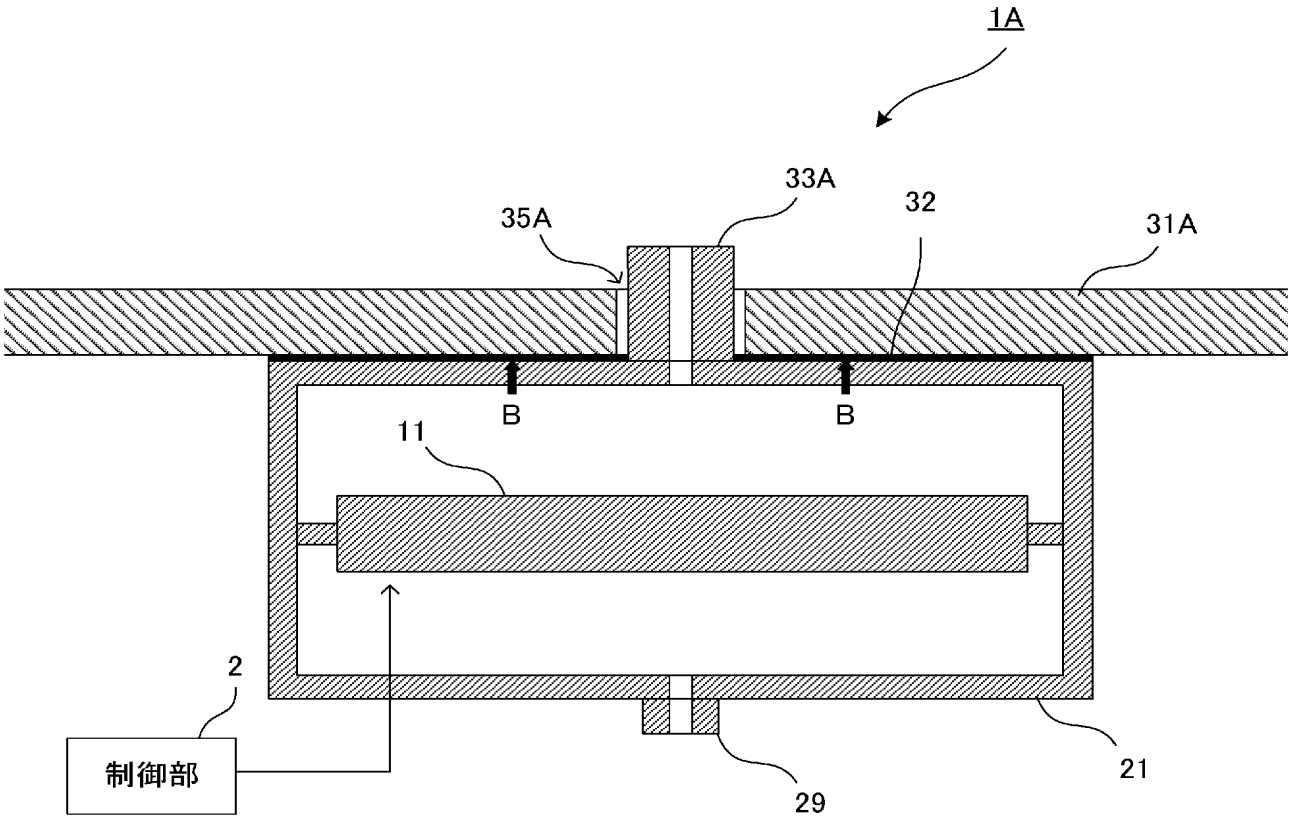
[図10]
図１０



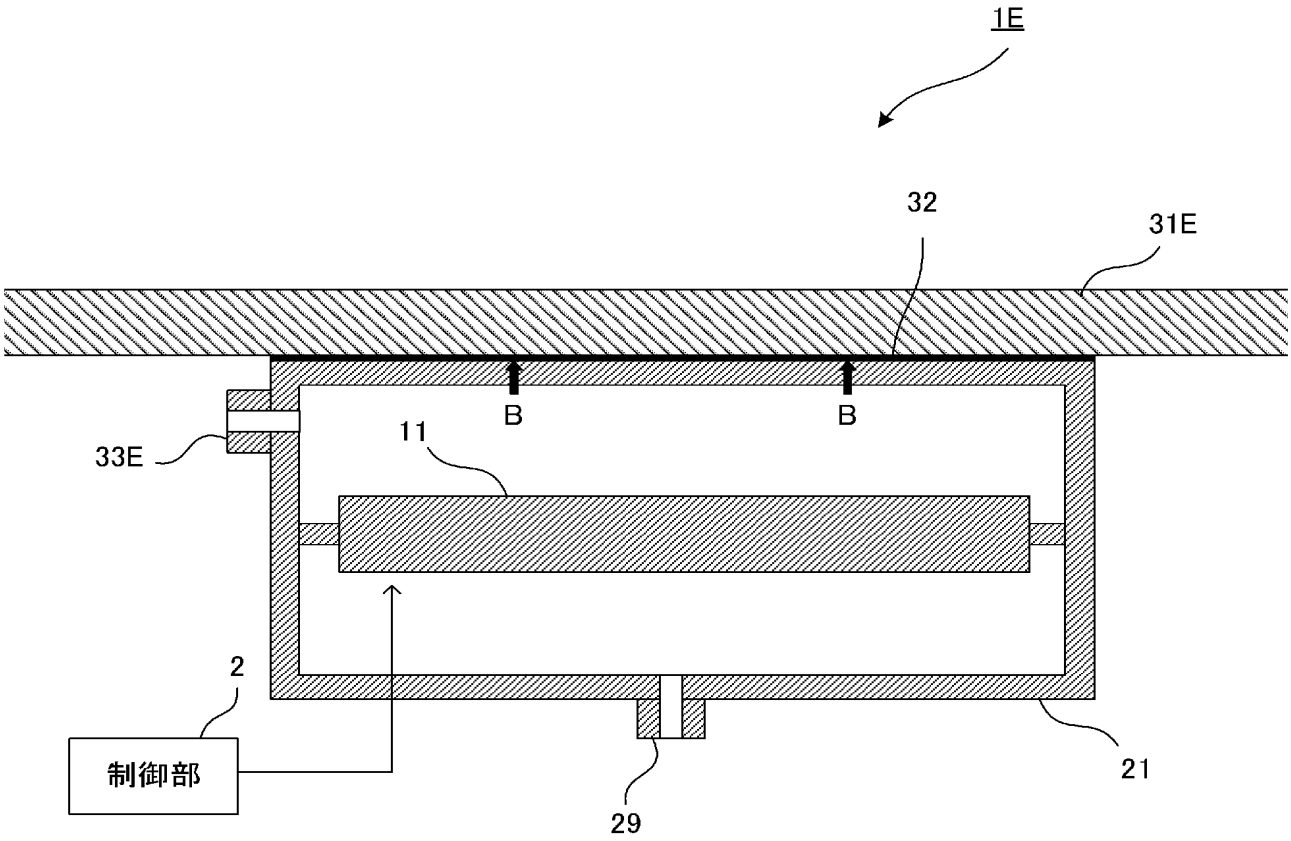
[図11]
図１１



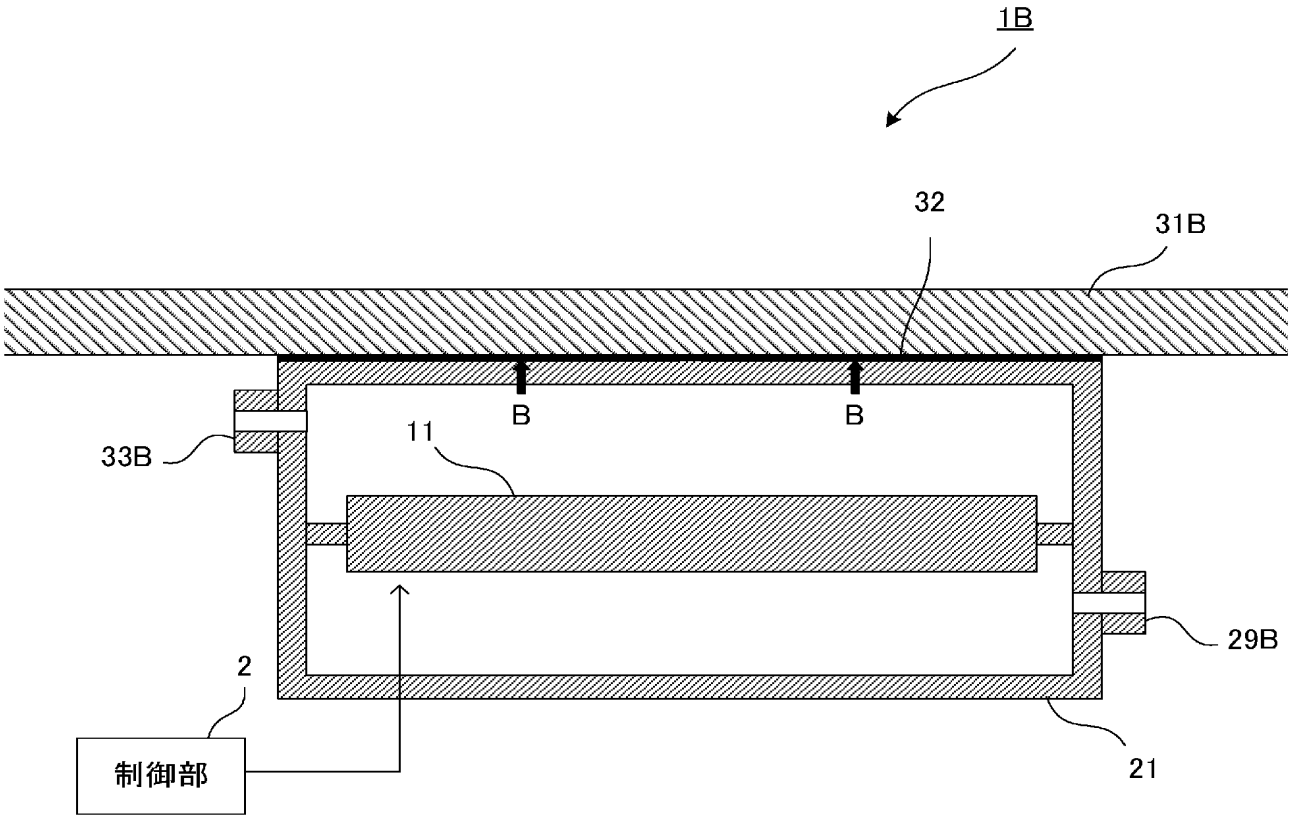
[図12]
図１２



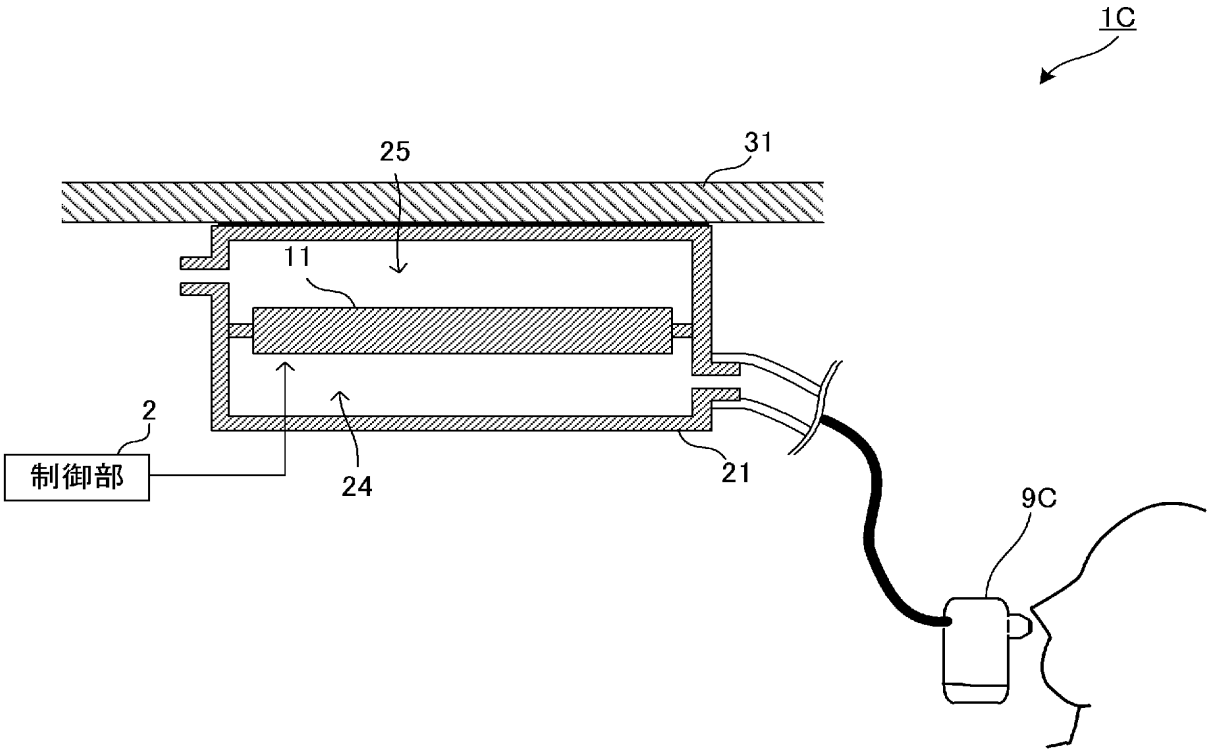
[図13]
図１３



[図14]
図14

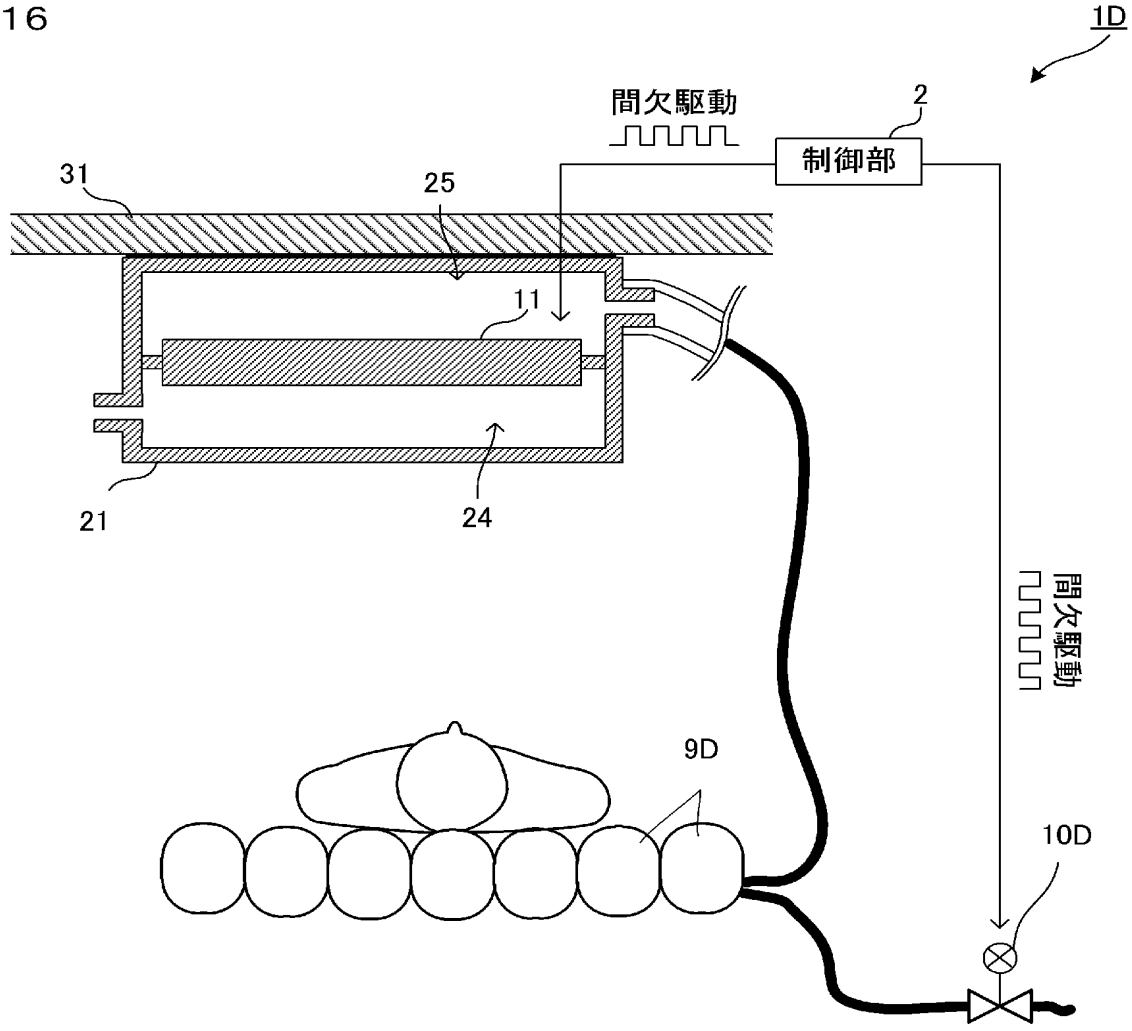


[図15]
図１５



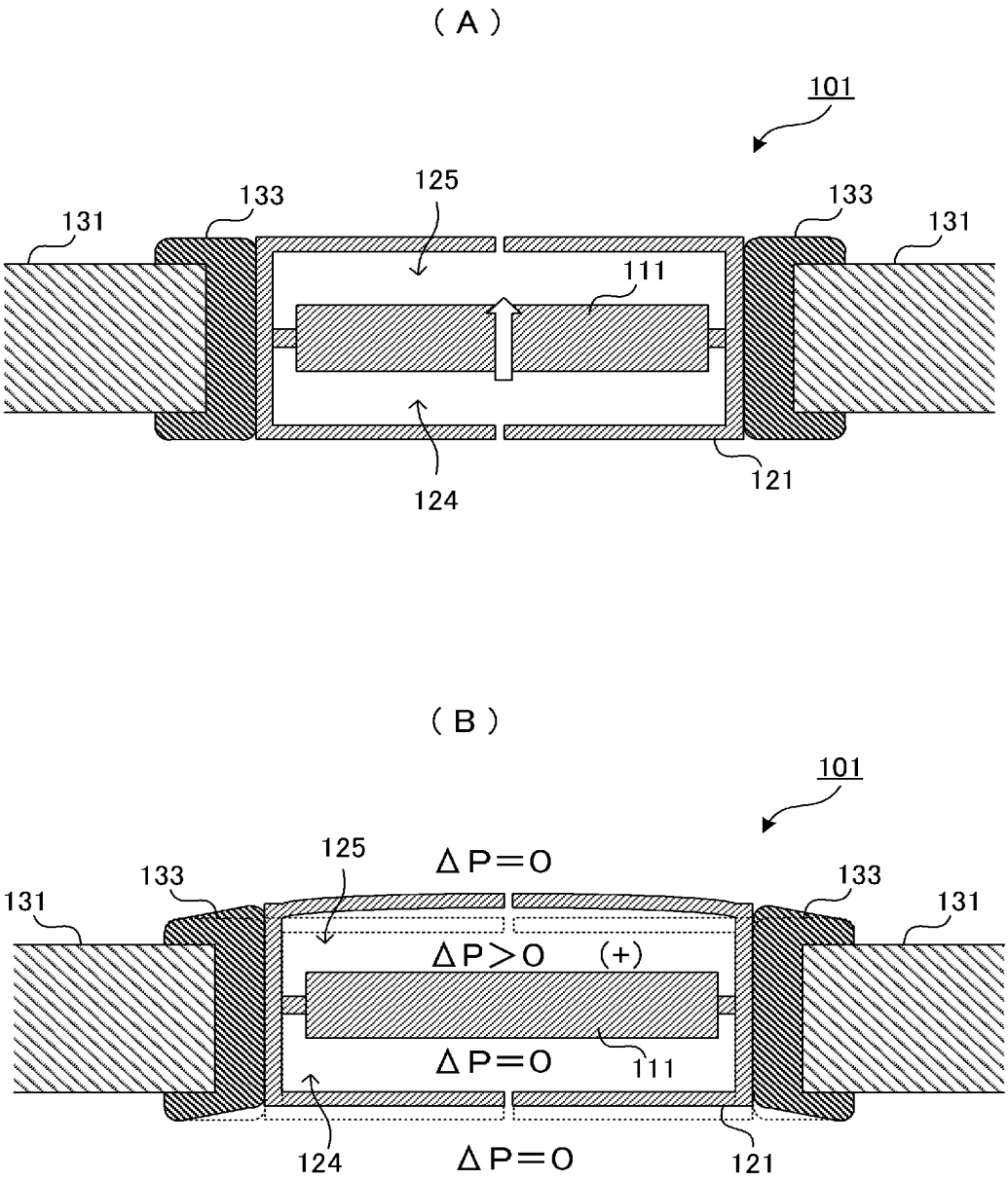
[図16]

図１６



[図17]

図17


（A）
101
125
133
133
131
131
111
124
121
（B）
101
125
ΔP＝0
133
133
131
131
ΔP＞0 (+)
ΔP＝0
111
124
ΔP＝0
121

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2016/079212

A. CLASSIFICATION OF SUBJECT MATTER
F04B45/047(2006.01)i, *F04B45/04*(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
F04B45/047, F04B45/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2016
Kokai Jitsuyo Shinan Koho 1971-2016 Toroku Jitsuyo Shinan Koho 1994-2016

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 2013-245649 A (Omron Healthcare Co., Ltd.), 09 December 2013 (09.12.2013), paragraphs [0025] to [0038], [0082] to [0089]; fig. 1 to 3, 9 to 12 & US 2015/0150470 A1 0039 to 0052, 0096 to 0103; fig. 1 to 3, 9 to 12 & WO 2013/179789 A1 & CN 104302913 A	1-10
Y	JP 2013-151908 A (Murata Mfg. Co., Ltd.), 08 August 2013 (08.08.2013), paragraphs [0021] to [0040]; fig. 1 to 6(B) (Family: none)	1-10

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 December 2016 (07.12.16)	20 December 2016 (20.12.16)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/187271 A1 (Murata Mfg. Co., Ltd.), 19 December 2013 (19.12.2013), paragraphs [0089] to [0113]; fig. 9 to 11(B) & US 2015/0071797 A1 0102 to 0126; fig. 9 to 11(B) & JP 5692465 B & CN 104364526 A	4,6-10
Y	WO 2011/145544 A1 (Murata Mfg. Co., Ltd.), 24 November 2011 (24.11.2011), paragraphs [0061] to [0062], [0067]; fig. 13, 16 & US 2012/0171062 A1 0087 to 0088, 0093; fig. 13, 16 & JP 2014-98396 A & EP 2557312 A1 & KR 10-2012-0032566 A & CN 102597520 A	5-10
Y	WO 2012/140931 A1 (Murata Mfg. Co., Ltd.), 18 October 2012 (18.10.2012), paragraphs [0044] to [0075]; fig. 1 to 10 & JP 2015-92082 A & JP 5776767 B	7-10
Y	JP 2014-137032 A (Murata Mfg. Co., Ltd.), 28 July 2014 (28.07.2014), paragraphs [0023] to [0037]; fig. 1 to 3 (Family: none)	7-10
A	US 2006/0232167 A1 (JORDAN,Tony), 19 October 2006 (19.10.2006), paragraphs [0027] to [0047]; fig. 1A to 5D & WO 2006/113341 A2	1-10
A	JP 2014-526654 A (KCI Licensing, Inc.), 06 October 2014 (06.10.2014), paragraphs [0018] to [0030]; fig. 1A to 3 & WO 2013/043300 A1 0044 to 0056; fig. 1A to 3 & US 2013/0071273 A1 & EP 2758666 A1 & AU 2012312898 A & CA 2845880 A1 & CN 103814217 A	1-10

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１６／０７９２１２

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　F04B45/047(2006.01)i, F04B45/04(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　F04B45/047, F04B45/04

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１６年
日本国実用新案登録公報	１９９６－２０１６年
日本国登録実用新案公報	１９９４－２０１６年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	JP 2013-245649 A (オムロンヘルスケア株式会社) 2013.12.09, 段落 0025-0038, 0082-0089, 図 1-3, 9-12 & US 2015/0150470 A1, 0039-0052, 0096-0103, FIG. 1-3, 9-12 & WO 2013/179789 A1 & CN 104302913 A	1-10
Y	JP 2013-151908 A (株式会社村田製作所) 2013.08.08, 段落 0021-0040, 図 1-6(B) (ファミリーなし)	1-10

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

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「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
０７．１２．２０１６	２０．１２．２０１６

国際調査機関の名称及びあて先
日本国特許庁（ＩＳＡ／ＪＰ）
郵便番号１００－８９１５
東京都千代田区霞が関三丁目４番３号

特許庁審査官（権限のある職員）　３Ｏ　９５２３
鈴木　貴雄
電話番号　０３－３５８１－１１０１　内線　３３５８

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	WO 2013/187271 A1 (株式会社村田製作所) 2013.12.19, 段落 0089-0113, 図 9-11(B) & US 2015/0071797 A1, 0102-0126, FIG. 9-11(B) & JP 5692465 B & CN 104364526 A	4, 6-10
Y	WO 2011/145544 A1 (株式会社村田製作所) 2011.11.24, 段落 0061-0062, 0067, 図 13, 16 & US 2012/0171062 A1, 0087-0088, 0093, FIG. 13, 16 & JP 2014-98396 A & EP 2557312 A1 & KR 10-2012-0032566 A & CN 102597520 A	5-10
Y	WO 2012/140931 A1 (株式会社村田製作所) 2012.10.18, 段落 0044-0075, 図 1-10 & JP 2015-92082 A & JP 5776767 B	7-10
Y	JP 2014-137032 A (株式会社村田製作所) 2014.07.28, 段落 0023-0037, 図 1-3 (ファミリーなし)	7-10
A	US 2006/0232167 A1 (JORDAN, Tony) 2006.10.19, 段落 0027-0047, FIG. 1A-5D & WO 2006/113341 A2	1-10
A	JP 2014-526654 A (ケーシーアイ　ライセンシング　インコーポレイテッド) 2014.10.06, 段落 0018-0030, 図 1A-3 & WO 2013/043300 A1, 0044-0056, FIG. 1A-3 & US 2013/0071273 A1 & EP 2758666 A1 & AU 2012312898 A & CA 2845880 A1 & CN 103814217 A	1-10

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(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 November 2009 (05.11.2009)

PCT

(10) International Publication Number
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(51) International Patent Classification:
A61M 1/06 (2006.01)

(21) International Application Number:
PCT/US2008/063362

(22) International Filing Date:
12 May 2008 (12.05.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/113,563 1 May 2008 (01.05.2008) US

(71) Applicants and
(72) Inventors: **DAO, Stella** [US/US]; 2526 Capitol Avenue, Sacramento, CA 95816 (US). **GARBEZ, Dan** [US/US]; 2526 Capitol Avenue, Sacramento, CA 95816 (US).

(74) Agent: **ROCKMAN, Howard, B.**; Reed Smith, LLP, 10 S. Wacker Drive, Chicago, IL 60606-7507 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

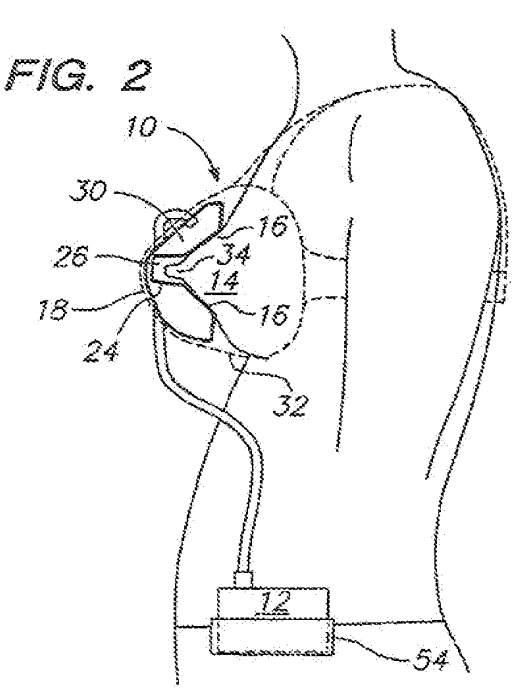
Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: BREAST PUMP DEVICE WITH SELF-CONTAINED BREAST MILK RESERVOIR



(57) **Abstract**: The present invention is a compact and hands-free human breast milk collection device that fits into a mother's existing nursing or standard brassiere The invention can be attached to a conventional electric or manual pump for active milk collection and also can be used without a pump for passive milk collection Additionally, the invention can be used for collection of handexpressed milk The invention compnses a breast adaptor which, in an embodiment, has at one end a funnel-shaped inlet coupled to a reservoir, wherein when the breast is inserted into the breast adaptor, the breast milk is expressed into the reservoir through a unique valve assembly and the milk is stored in the reservoir until the device is removed and the collected milk emptied into a container In an embodiment, the valve assembly is mounted concentπcally on a second end of the breast adaptor.

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Continuation- in- Part Patent Application

for

BREAST PUMP DEVICE WITH SELF-CONTAINED BREAST MILK RESERVOIR

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BREAST PUMP DEVICE WITH SELF-CONTAINED BREAST MILK RESERVOIR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This utility patent application is a continuation-in-part of United States Nonprovisional Application Serial No. 12/113,563, filed on May 1, 2008, which is incorporated herein by reference to the extent allowed by law.

TECHNICAL FIELD

[0002] This invention relates to the field of human breast milk collection devices and more specifically, to breast milk collection devices which can fit discreetly and ergonomically within a woman's brassiere to provide hands-free breast milk collection, and can furnish breast milk to the collection device without causing milk to enter the associated vacuum pumping system, thus preventing backflow of milk into the vacuum pumping system.

BACKGROUND

[0003] Breastfeeding is recommended by the American Academy of Pediatrics, the World Health Organization and medical professionals worldwide as the preferred method for feeding infants during the first year of life. Human breast milk has significant health benefits that cannot be replicated by infant formula. Specifically, breast milk has been shown to reduce the incidence of infectious diarrhea, respiratory infections, otitis media and childhood obesity. Breastfeeding also has been shown to have health benefits for mothers, by reducing the risk of postpartum bleeding and anemia. Risks are also lowered for ovarian and premenopausal breast cancer. Further, postpartum weight loss is enhanced in breastfeeding mothers. Other benefits of breastfeeding include its comforting effect upon both mother and infant. For these reasons, many

health professionals have determined that breastfeeding produces healthier, happier, infants and mothers, which is why breastfeeding is being promoted worldwide as a public health measure.

[0004] No infant formula can completely replicate the composition and benefits of human breast milk. Therefore, any proportion of breast milk in an infant's diet is preferable to no breast milk at all. Health professionals strive to encourage new mothers to provide their infants with the highest proportion of breast milk possible during the first year of life.

[0005] Unfortunately, there are many challenges to implementing breastfeeding. Breastfeeding requires constant attendance by the nursing mother every 1-2 hours, around the clock, for the baby's first 1-2 months of life, and approximately every 3-4 hours for the next 9 months of life. Furthermore, newborns may require up to 45 minutes per feeding. Nursing mothers must get adequate sleep, nutrition and hydration to maximize their milk production. For mothers with twins, triplets, or greater multiple births, the demand on the nursing mother's time is even greater. Some mothers have physical limitations which inhibit breastfeeding, such as inverted or sore nipples. Other mothers simply cannot make enough milk for their infants, and find that they must supplement their milk production with formula. In other cases, the physical limitations lie with the infant, namely premature or low birth weight infants who have weak suckling abilities, "floppy" infants with poor muscle tone, "tongue tied", cleft lip or cleft palate infants who cannot create a seal between their mouth and the nipple. In addition to physical limitations, societal norms create obstacles to breastfeeding. Breastfeeding in public is often prohibited, which limits mothers to breastfeeding at home.

[0006] Consequently, despite many government programs and initiatives to promote breastfeeding, most American women abandon breastfeeding long before the recommended first

year of life. Studies have shown that only two-thirds of mothers breastfeed their infants when they leave the hospital, and at six months, that number shrinks to one third.

[0007] The alternatives to fulltime breastfeeding are either formula feeding, or feeding expressed human breast milk by bottle. Breast milk can be expressed, or released from the mother's lactating breasts, by massaging the breast by hand, or by the application of manual or electromechanical pumping equipment acting upon the breasts, both of which are commonly available in the domestic U.S. market.

[0008] For a woman to continue lactating a sufficient volume of milk, she must empty her breasts according to the feeding schedules and milk quantities demanded by an infant. Therefore, mothers who work outside of the home must stop working approximately every two and a half hours to pump breast milk in order to maintain an adequate milk supply. When pumping equipment is employed, it takes approximately 30 minutes for a mother to set up the pumping equipment, undress, pump, and perform cleanup. Because most current breast milk pumping and collection systems require a mother to frontally undress, a private setting is usually deemed necessary. This process, which must be continually repeated every two and a half hours is isolating, cumbersome, and extremely disruptive during work. Additionally, many breast pumping devices require the mother to use both of her hands to keep the equipment in position for efficient pumping, which prevents the mother from being able to perform other tasks as may be required in the workplace. The initial and recurring costs involved with using pumping equipment is a further factor which may limit the attractiveness of continuing to breastfeed.

[0009] Presently, few breast pumping devices allow for true hands-free operation. Most breast pump devices have hand-held funnel-shaped nipple adaptors, which allow suction to be applied to the nipples for milk expression. The nipple adaptors are then attached to baby bottles for milk

collection. Examples of these types of devices are shown in U.S. Patent Nos. 6,575,202 (Laford), 5,295,957 (Aida et al.), 5,071,403 (Larsson) and 5,358,476 (Wilson). Typically, suction is provided to these devices by a table-top electric pump. The pump can be situated nearby on the floor or on a tabletop, and the suction connection is made with small diameter (as little as .125" I.D.) flexible plastic tubing to facilitate the relatively low pressure, high volume, suction that is required to pull the woman's breast into the adaptor. A typical pump that is cylinder-actuated operates as a closed system, trapping a volume of air in the adaptor. When the woman's breast is pressed into the adaptor, it seals itself against the sides of the adaptor and forms the enclosed space in front of the nipple. When suction is applied, the malleable breast is pulled into the adaptor and toward the opening at the end of the funnel-shaped adaptor. A typical pump's cylinder, with an interior volume of several cubic inches, cycles back and forth repetitiously, completing an in-out "throw" over the course of a second or two, to create a massaging pulling rhythm upon the woman's breasts by alternating positive and negative pressure. This rhythm stimulates the mother's milk to be released, or "letdown," whereupon it flows, and is eventually collected in the manner already described.

[0010] Many of the vacuum source pumps are very durably constructed, provide significant suction, and since they are commonly used in hospital maternity wards to help new mothers stimulate milk production for their newborns, the pumps are constructed so that the major components can be disassembled and thoroughly cleaned between patients, for re-use. There are also a variety of other powered and manual pump types available on the market and well known in the pumping arts, ranging from very simple compact hand pumps, to innovative electromechanical concepts. The predominant and preferred pumps known to those skilled in the art for long term use are consumer versions of the very effective hospital grade pumps. For cost

considerations, these pumps are not constructed to allow such thorough cleaning as the true hospital grade pumps, and so are intended for single users. However, since their performance characteristics are considered by professionals in the art of breastfeeding to be on a par with the pumps utilized in hospitals, these more substantial consumer pumps are commonly referred to as "hospital grade."

[0011] Certain pumps utilize an electromechanical construction with an impeller or other means that creates a constant suction with a pressure relief mechanism or valve, wherein the pump builds up negative pressure to some predefined, preset or adjustable maximum, and then a relief valve or other means releases the negative pressure, so that during the cycle the vacuum pressure peaks, then is relieved and suction drops and approaches a more close-to-neutral negative pressure measurement. In these constant suction pumps, the negative pressure builds up, is relieved, and then the cycle repeats itself as the relief mechanism shuts itself off again and negative pressure begins to build up again.

[0012] In these constant suction systems, the tendency for milk to migrate through the vacuum lines is great, and a key element often utilized to protect the pump's works from contamination is an inline porous filter in the vacuum feed line, which is well known in the art. These filters allow air to pass through, but collect most or all of the milk that reaches them. These filters can then be regularly cleaned or replaced when they have collected too much milk, allowing adequate air passage to achieve the desired suction. These pumps can be cost effective and efficient pumps for users who must pump frequently.

[0013] Many pumps during a typical cycle create negative pressure, and then alternately return toward a neutral pressure, which may give the user the sense of an alternating negative and positive pressure, even though no positive pressure may actually be measured during the

majority of cycles from the pump. The benefit of these systems is that the adaptor, once placed against the breast, has a tendency to hold onto the breast, especially if the pump's cycle, once engaged and some air is purged from the trapped enclosure, alternates between strong negative pressure and weak negative pressure, but never alternates to all the way back to a neutral or positive pressure. If substantial positive pressure was actually introduced into this cycle, there would be a tendency to "blow" the adaptor off the breast, resulting in a disruption of the pumping rhythm, and possibly causing small amounts of milk in the adaptor to leak from the device and onto the user, rather than migrate into the collection container. For these reasons, during the initial engagement of the pumping cycle and the purging of excess air from the enclosure, and for the duration of the pumping session, a secure seating of the adaptors to the breasts is preferred, to establish a consistent and relaxing rhythm which most mothers find essential to letting down their milk, which does not usually come for a minute or more after the pumping has begun. Thus, even though a pump, once engaged for a pumping session may never reach into the positive pressure range on an atmospheric scale, the valving means adapted for such pumps are usually weak enough so that simply the weight of expressed milk which builds up within the enclosure can force itself through.

[0014] For alternating cycle pumps, some combination of valving and relief features are especially important to allow the volume of air trapped in the enclosure to constantly adjust itself, as the propensity for a malfunction to cause the adaptor to "blow" off the breast is more common with these pump types. What is common to all pumps, however, is that they of necessity, to stimulate the mother to release milk somewhat replicate the suckling of an infant, and so the sensation that must be created by the pump alternates between a somewhat strong negative pressure, and a weak or non-existent negative pressure, with a complete alternating

cycle usually lasting only a second or two. These various pump systems, during a single cycle, alternate between generating a stronger negative pressure until a peak, and then the mechanism begins to cycle in the other, or "positive," direction, by whatever mechanical means, thereby relieving negative pressure within the subject enclosure. In this context, "positive pressure" does not necessarily refer to an objective measure of pressure within the device, relative to the surrounding atmospheric pressure.

[0015] Different pumps have different cycling characteristics, and differ from one another in achievable pressures. Different users may differ in their preferences for the specific rhythmic characteristics of various pumps on the market, but those skilled in the art generally agree that the more substantial "hospital grade" pumping equipment that provides more negative pressure and a more reliable and consistent suction and rhythm provides the most benefit for mothers whose circumstances require that they must for an extended period frequently utilize a breast pump. While many of these devices provide good suction and milk collection characteristics, hands-free operation is not possible because of the need to use the hands to hold the device against the breast during milk collection. Furthermore, because of the size and shape of these devices, the user must be frontally undressed to pump milk.

[0016] Some manufacturers have attempted to make pumping more discreet and hands-free by securing the assembly of adaptors, bottles and hoses with specialized straps, brassieres and harnesses. These types of devices are represented in U.S. Patent Nos. 6,004,186 (Penny) and 6,379,327 (Lundy). However, since the entire assembly of adaptors, bottles and hoses is relatively large and cumbersome, in practice these devices still require a woman to undress to put on and to remove these devices with each use. Furthermore, as the bottles fill with milk, they may require some support of the bottle assembly system by hand.

[0017] U.S. Patent No. 6,440,100 (Prentiss) presents a hands-free option which uses a low profile nipple cap held in place by a nursing brassiere. The nipple cap is placed over the nipple and a tube, for both vacuum supply and milk collection, extends from below the nipple cap to a collection container. A vacuum source, such as an electric pump, draws the milk from both breasts into the collection container which hangs below the brassiere. While this solution goes a long way towards providing a hands-free design, the placement of the collection container outside of the brassiere is cumbersome and unwieldy when placing and removing this device.

[0018] Also, while Prentiss attempts to provide an unobservable and virtually unnoticeable low profile application beneath normal clothing, the Prentiss design raises other issues. Namely, Prentiss attempts to minimize the profile of the nipple cap by placing the vacuum source directly below the nipple. With this design, when suction is applied, the nipple is drawn downward, which tends to inhibit the flow and expression of milk by drawing the nipple onto the vacuum source or by pinching the milk ducts. Ideally, the nipple should be drawn forward to create the smooth and unobstructed action necessary to trigger the expression of milk. Elongation of the nipple and forward suction is the same as that applied by a suckling infant. Therefore, while Prentiss is likely to be effective for passive milk collection or for women with an abundant milk supply who require little suction to release their milk, its design may result in the failure to trigger the milk expression reflex in many women.

[0019] A hands-free pump is manufactured by Whisper Wear, Inc., of Marietta Georgia. This device is comprised of a dome-shaped body having a self-contained AA battery powered pump. The rear of the body has a funnel adaptor for placement of the nipple. This device is only several inches in diameter and can be placed easily and discreetly within a regular brassiere. A collection bag attaches to the device and visibly hangs below the brassiere. If two devices are used at once,

two bags are necessary for milk collection. While less cumbersome and completely portable when compared to the other solutions discussed herein, the use of the hanging plastic milk bags employed by the Whisper Wear device is unwieldy. Additionally, the system is expensive when the up front costs of the device are considered along with the ongoing costs of disposable batteries and single-use collection bags. This renders the system uneconomical for many mothers. But perhaps the greatest shortcoming of the Whisper Wear device when compared to the larger tabletop electric pumps is the strength of the suction it applies to the breast. The problem is one of scale. Once the Whisper Wear pump is placed over the nipple, the total volume of air trapped inside the mechanism is quite small, usually less than one cubic inch on average. Furthermore, the housing of the device limits the "throw" within this cavity to less than an inch, resulting in a much lower displacement, and therefore, a much less vigorous pumping action for milk expression. Also, being an integrated mechanical pump and battery, coupled with the weight of a suspended milk reservoir, the Whisper Wear devices are much heavier when worn hands-free within a brassiere than the adaptor and bottle assemblies discussed previously, which use tabletop electric pumps. During use, the weight and placement of the Whisper Wear devices within the bra can pinch some milk ducts, while simultaneously emptying others. These characteristics make the Whisper Wear pump inadequate for many women as a full time pumping solution. A stronger pump is necessary for some women to relieve obstructed milk ducts and empty their breasts completely.

[0020] U.S. Patent No. 4,857,051 to Larsson ("Larsson") discloses a breast pump device having a hood member with a first funnel end and a second end which communicates with a collection chamber and a vacuum line. Larsson further discloses a breast pump device having a valve mechanism which closes a collection chamber when a vacuum is applied to a hood

member and which opens the collection chamber when the vacuum is removed. Larsson further discloses a baffle in the hood member where the baffle is formed by a separation wall located between the second end of the hood member and the vacuum line. The baffle is located directly in front of a user's nipple when her breast is placed against the hood member in use of the pump device and prevents milk from reaching the vacuum line. Larsson does not disclose a breast pump collection device having a breast adaptor with a valve assembly wherein the valve assembly comprises a baffle structure configured to prevent the back flow of milk into the vacuum line when large amounts of aerated milk flow up into an overflow chamber before the suction of a negative pumping cycle is released, without milk entering the vacuum line.

[0021] U.S. Patent Number 4,929,229 to Larsson ("Larsson") discloses another breast pump device having a hood member with a first funnel end and a second end which communicates with a collection chamber and a vacuum line. A downwardly extending separation wall forms a baffle located between the second end of the hood member and the vacuum line. Milk that is expressed into the hood member is then blocked by the separation wall or baffle from reaching the vacuum passage. Again, this baffle is located directly in front of a user's nipple when her breast is placed against the breast shield assembly and prevents milk from reaching the vacuum passage. Larsson here does not disclose a breast pump collection device having a breast adaptor with a valve assembly wherein the valve assembly comprises a baffle structure configured to prevent the back flow of milk into the vacuum line when large amounts of aerated milk flow up into an overflow chamber before the suction of a negative pumping cycle is released.

[0022] U.S. Patent No. 6,652,484 to Hunckler, et al. ("Hunckler") discloses a breast pump device having a downwardly extending separation wall forming a baffle located between a second end of a breast hood or breast shield assembly and a vacuum passage. Milk that is

expressed into the breast shield assembly is then blocked by the separation wall or baffle structure from reaching the vacuum passage. Again, this baffle is located directly in front of a user's nipple when her breast is placed against the breast shield assembly and prevents milk from reaching the vacuum passage. Hunckler does not disclose a breast pump collection device having a breast adaptor with a valve assembly wherein the valve assembly comprises a baffle structure configured to prevent the back flow of milk into the vacuum line when large amounts of aerated milk flow up into an overflow chamber before the suction of a negative pumping cycle is released.

[0023] Therefore, it would be desirable to have a pumping system that is hands free, but that is also easy to assemble, disassemble and clean, and reassemble, and to position under normal clothing without the need to undress or to don complicated and overtly visible harness systems, which pumping system can be adapted to function with a wide variety of the more substantial "hospital grade" pump technologies available.

[0024] Passive milk collection is also an area of breastfeeding worth addressing. Passive milk collection extends from the natural "letdown" reflex a woman experiences when an infant "latches" onto a woman's breast and begins nursing. When a breast is stimulated to release milk by a nursing infant, or through pumping a single breast, the second breast also naturally begins to release milk. If the milk being expressed from the second, unattended breast is not collected, the amount of milk that is wasted can range from a negligible percentage to as much as a third of a mother's milk supply. Therefore, due to this "letdown phenomenon," a great deal of milk that could be collected and fed to the infant via bottle is currently being wasted by most breastfeeding mothers. Presently, the predominant practice among nursing mothers to address this phenomenon

is the use of absorbent, disposable or reusable pads placed inside the bra cup of the unattended breast.

[0025] Therefore, it would be desirable to have a device that can collect passively released milk from the unattended breast for subsequent feeding.

[0026] Breastfeeding physically challenged infants presents its own special problems. A significant number of infants with physical challenges, such as floppy infants, premature infants, or infants with cleft lip/palate have difficulty initiating the letdown reflex on their own. These challenges may be due to a lack of adequate strength to latch onto the breast, difficulty creating sufficient suction, or a lack of focused attention. As a result, many physically challenged infants cannot derive sufficient caloric intake for their sustenance from natural breast feeding. It would therefore be desirable to have a compact, hands-free device which can be used to pump one breast, thereby initiating the letdown reflex from both breasts, for the purpose of allowing a mother to hold and nurse a physically challenged infant from the opposite breast.

[0027] Consequently, a need exists for a breast milk collection device which can fit completely within a woman's standard brassiere. Such a device would be less likely to interfere with breastfeeding from the opposite breast and avoid the isolating, disruptive, and sometimes embarrassing need to disrobe to pump breast milk, which device can be adapted to function with a wide variety of the more substantial "hospital grade" and other pump technologies available.

[0028] A need also exists for a breast milk collection device that is both sufficiently powerful and hands-free.

[0029] A further need exists for a breast milk collection device that provides a viable solution for passive milk collection while simultaneously breastfeeding.

[0030] A need also exists for a breast milk pumping and collection device which can help compromised infants breastfeed.

[0031] Furthermore, a need exists for a breast milk collection device having reduced maintenance requirements provided by inhibiting the back flow of breast milk into the pump or suction lines.

[0032] A further need exists for a breast milk collection device having a vacuum pressure hose inlet port that is located apart from the path of milk expressed from the breast during the pumping operation, whereby the inlet port is not in direct contact with the expressed milk.

[0033] An additional need exists for a breast milk collection device having an overflow chamber and baffle combination that when the flow of breast milk is large in a single cycle, milk flows into the overflow chamber from a drip tube at an end of the breast adaptor before suction is released. When the overflow chamber is used, the mixture of milk and air in the drip tube can cause turbulence in the liquid, causing the milk to bubble and become airborne due to the suction force. The baffle in the overflow chamber deflects or redirects any airborne mist of milk that is pulled in the direction of the vacuum hose inlet port. In this way, bacteria-forming milk is kept from entering the pump's inner works and suction hoses.

[0034] A need also exists for a hands free, concealable and ergonomically shaped breast milk collection device that can be adapted for use with an internal or inline filter system for use with a constant suction pump, so that air is allowed to pass through the filter, while milk is trapped, protecting the pump's inner works.

[0035] A further need exists for a hands free, concealable and ergonomically shaped breast milk collection device that can be supported by an ordinary bra, which also integrates a vacuum barrier, to allow use of the device with pumps that require separation of the air in the vacuum

lines and pump works from the air in direct communication with the breast and milk collection means.

[0036] Yet another need exists for a breast milk collection device whose several parts are easily manually disassembled for cleaning and decontamination, and are subsequently easy to manually reassemble in only a single, correct configuration for proper use of the collection device.

[0037] A further need exists for a hands free, concealable and ergonomically shaped breast milk collection device wherein a tortuous path is provided between the application of suction pressure and the breast for the purpose of preventing the backflow of expressed milk into the suction pressure hose or related suction pump mechanism.

[0038] Still another need exists for a breast milk collection device having an adaptor connected between the collection device vacuum hose and the outlet hose of a vacuum pump system that allows the vacuum hose and the outlet hoses to be properly connected even where the two hoses have different inner or outer diameters.

[0039] Yet another need exists for a breast milk collection device having a source of vacuum pressure applied to the breast to produce the expressions of breast milk, wherein the source of vacuum pressure is totally isolated from the flow path of the milk from the breast into the collection device reservoir.

[0040] The foregoing reflects the state of the art of which the inventors are aware, and is tendered with a view toward discharging in part the inventors' acknowledged duty of candor, which may be pertinent to the patentability of the present invention. It is respectfully stipulated, however, that the foregoing discussion does not teach or render obvious, singly or when considered in combination, the inventors' claimed invention.

SUMMARY OF THE INVENTION

[0041] The present invention is a compact, ergonomic and hands-free human breast milk collection device that fits into a mother's existing nursing or standard brassiere. The invention can be attached to a regular electric pump or manual pump utilizing suction hoses for active milk collection, and also can be used without a pump for passive milk collection and to collect manually expressed breast milk.

[0042] The invention comprises a breast adaptor which is preferably a funnel-shaped inlet coupled to a reservoir, wherein when the breast is inserted into the breast adaptor, the expressed breast milk flows, or drips into the reservoir. In an embodiment, a flap valve may be inserted between the drip tube and the reservoir. The milk is held in the reservoir until the device is removed and emptied. In the illustrated embodiment, the reservoir takes the form of a cup, and the breast adaptor takes the form of a funnel within a lid, which adaptor detachably couples upon the open end of the reservoir cup. The reservoir can also be formed into the shape of a woman's breast, thereby providing a more natural appearance when the device is placed into a woman's brassiere. In another embodiment, the invention further comprises a valve assembly mounted concentrically on a second end of the breast adaptor. The valve assembly alternately opens and closes communication between the breast adaptor and the reservoir. The valve assembly comprises a valve body, a valve cap mounted concentrically on the valve body, and a valve flap attached to the valve cap. The valve assembly further includes a baffle structure integrally formed with an interior wall of the valve cap and extending substantially into an overflow chamber, to prevent the overflow of milk into the pump and associated vacuum lines before suction is released from a negative pressure cycle of the pump.

[0043] Another embodiment of the invention eliminates the baffle structure and fills much of the overflow assembly with a barrier comprising collapsible bladder whose internal volume is in direct communication with the assembly's vacuum hose port, and which barrier largely conforms to the interior surface of the overflow chamber when not subjected to negative pressure. When vacuum pressure is exerted into the collapsible bladder within the relatively more rigid overflow chamber, the bladder collapses in the direction of the vacuum inlet, and the negative pressure is communicated to the rest of the enclosure of the overflow chamber and the adaptor, directly applying the negative force on the breast, and ultimately inducing milk letdown, as has been described.

[0044] Yet another embodiment of the invention may provide a filtration material, as commonly known in the art, between the overflow chamber and the vacuum passage for use with a constant suction pump, allowing the collection device to be utilized with these economical devices while protecting their mechanical works.

BRIEF DESCRIPTION OF THE DRAWINGS

[0045] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0046] FIG. 1 is a front perspective view of a woman's torso showing an embodiment of the inventive device attached to each breast for completing a breast pumping cycle.

[0047] FIG. 2 is a side view of a woman's torso showing the inventive device of FIG. 1 being positioned in a brassiere for hands-free breast milk collection.

[0048] FIG. 3A is a side view of the embodiment of the inventive device of FIG. 1 which has the shape of a human breast.

[0049] FIG. 3B is a perspective view of the embodiment of the inventive device shown in FIG.3A.

[0050] FIG. 4 is an exploded perspective view of the inventive device of FIG. 1 showing the reservoir being detachable from the adaptor.

[0051] FIG. 5A is a side cutaway view of the inventive device of FIG. 1.

[0052] FIG. 5B is a perspective cutaway view of the inventive device of FIG. 1.

[0053] FIG. 5C is a perspective view of a screw cap embodiment of the device shown in FIGS. 5A and 5B, showing the screw cap adaptor detached from the reservoir.

[0054] FIG. 6 is a close up cutaway side view of the inventive device of FIG. 1 shown attached to a woman's breast and coupled to an electric pump device.

[0055] FIG. 7 is a close up cutaway side view of the inventive device of FIG. 1 shown attached to a breast and coupled to an electric pump device. This view also includes a milk barrier located in the breast adaptor to prevent the back flow of milk.

[0056] FIG. 8 is a close up cutaway side view of the inventive device of FIG. 1 which employs an air or fluid filled bladder for enhanced comfort and sealing characteristics.

[0057] FIG. 9 is a close up cutaway side view of the inventive device of FIG. 1, this view eliminating the drip tube to enhance the device's usefulness for passive breast milk collection.

[0058] FIG. 10A is a front perspective view of a woman's torso showing the inventive device being worn in a nursing brassiere.

[0059] FIG. 10B is a front perspective view of a woman's torso showing the inventive device of FIG. 1 placed on the woman's left breast for milk collection while allowing her hands to remain free to nurse her infant on her opposite breast.

[0060] FIG. 11A is an elevated perspective cutaway view of an alternative embodiment of the inventive device which employs a valve to produce increased suction.

[0061] FIG. 11B is an elevated perspective view of the adaptor and valve of the embodiment of FIG. 11A shown attached to a vacuum hose.

[0062] FIG. 11C is a close up side cutaway view of the drip tube, valve and distal end of the vacuum hose of the embodiment of FIG. 11A shown functioning during a negative pressure cycle.

[0063] FIG. 11D is a close up side cutaway view of the drip tube, valve and distal end of the vacuum hose of the embodiment of FIG. 11A shown functioning during a positive pressure cycle.

[0064] FIG. 11E is an exploded elevated perspective view of the adaptor and valve of the embodiment of FIG. 11A.

[0065] FIG. 11F is a rear view of the adaptor and valve of the embodiment of FIG. 11A.

[0066] FIG. 11 G is an elevated perspective view of the embodiment of FIG. 11A.

[0067] FIG. 12A is a front elevated perspective view of the flap valve component of the embodiment of FIGS. 11A-G.

[0068] FIG. 12B is a rear perspective view of the flap valve component of the embodiment of FIGS. 11A-G.

[0069] FIG. 13A is side perspective view of an alternative embodiment of the inventive device which employs baffles (shown in phantom) attached to the interior volume of the reservoir to reduce pumping volume.

[0070] FIG. 13B is an exploded side perspective view of the embodiment shown in FIG. 13A.

[0071] FIG. 14 is a perspective view of an alternative embodiment of the inventive device which is coupled to a suspension system, this embodiment not being dependent upon a brassiere for support upon a woman's breasts.

[0072] FIG. 15 is a rear perspective assembly view of another alternative embodiment of the inventive device.

[0073] FIG. 16 is a side sectional assembly view of the embodiment of the inventive device shown in Fig. 15 taken along line 16-16 in Fig. 15.

[0074] FIG. 17 is an exploded side sectional view of the illustrated embodiment of the inventive device of Figs. 15 and 16.

[0075] FIG. 18 is a detail cross-sectional view of the breast adaptor, valve assembly, and reservoir of the embodiment of the present invention shown in Figs. 15 and 16.

[0076] FIG. 19 is a detail sectional view of the connection between the breast adaptor and the reservoir of the embodiment shown in Fig. 15.

[0077] FIG. 20 is a cross-sectional perspective view of the valve assembly for the embodiment of Figs. 15 to 18.

[0078] FIG. 21 is a front perspective detail view of the valve body of the valve assembly for the embodiment shown in Fig. 15.

[0079] FIG. 21A is a rear perspective view of the valve cap and baffle of the embodiment shown in FIG. 15.

[0080] FIG. 21B is a detail perspective view of the valve flap of the apparatus shown in FIG. 15.

[0081] FIG. 22 is a side view of the embodiment of the present invention shown in Fig. 15, illustrating the combined vacuum tube access slot and pour spout on each of the reservoir and the adaptor.

[0082] FIG. 23 is a front perspective partially cut-away assembly view of the tubing fitting for the vacuum hose connection apparatus for the embodiment shown in Fig. 15.

[0083] FIG. 24 is a front view of a woman's torso showing the present invention of Fig. 15 manually held under a woman's breast for use during hand expression of milk.

[0084] FIG. 25 is a perspective cross-sectional assembled view of the valve and valve cap of the present invention, showing an embodiment comprising a collapsible bladder isolating the path of breast milk flow from the source of vacuum pressure.

[0085] FIG. 26 is a cross sectional assembled view of a portion of the breast adaptor, the valve and the valve cap, showing an embodiment with a filter located between the overflow chamber and the source of vacuum pressure.

[0086] FIG. 27 is a front perspective partially cut-away embodiment of the tubing fitting for the vacuum hose connection apparatus for the embodiment of the invention shown in FIGS. 15 and 23, including the placement of a filter in the connection apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0087] The inventive device dramatically improves the feasibility of pumping breast milk for women by allowing for the use of a breast pump at a stationary place in the workplace, in a vehicle with a power adaptor, or other public places with a minimum of interference or immodesty, and relatively minor disruption in these settings compared with the current state of the art for mothers who pump breast milk. Also, by eliminating the pump, the present invention can function as a passive breast milk collection device.

[0088] Referring to FIGS. 1 and 2, the inventive device 10 is shown attached to a woman's breast with a pump 12 attached in a typical breast milk collection mode. As shown, the device 10 includes an adaptor 16 within which the breast 14 is inserted, the adaptor 16 opening into a reservoir 18 which collects breast milk being expressed from the breast 14. The adaptor 16 includes a funnel, which is a shape that has been found to accommodate a wide variety of breast shapes and sizes. Additionally, the adaptor 16 and reservoir 18 can be made in various larger or smaller dimensions to accommodate larger or smaller breasts.

[0089] Referring also to the additional figures, the wide end of the funnel-shaped adaptor 16 opens to the rear 20 of the device 10. Proceeding forward from the rear 20 to the front 22 of the device 10, the adaptor 16 narrows and terminates at a drip tube 24 having an aperture 26 at its distal end 28, through which flows expressed breast milk to fill the reservoir 18. The funnel adaptor 16 protrudes a distance into the confines of the reservoir's interior volume 30 to give the device 10 a compact configuration. Also, the protrusion of the adaptor 16 into the reservoir 18, which can be an inch or more, gives the nipple room to elongate in a forwardly driven motion during pumping, which provides an optimal nipple orientation for milk expression. This orientation avoids pinching off of milk ducts which can lead to reduced milk expression. As shown in FIG. 2, a large portion of the breast 14 fits into the adaptor 16 and the compact configuration of the device 10 further aids in its ability to fit discreetly within a woman's standard or nursing brassiere 32. The fact that the reservoir 18 fits into a brassiere cup 32 obviates the need to have external collection bags or bottles located outside of the brassiere cup. In this way, the adaptor 16 and reservoir 18 comprise a single self-contained unit that is not dependent on external collection containers. The device 10 is shown placed within a woman's brassiere 32, in position for either pumping milk or passive milk collection. The profile of the

device 10 is such that it does not protrude extensively beyond that of a normal woman's breast profile and may give the user the appearance of wearing a figure enhancing brassiere.

[0090] The adaptor 16 is preferably formed from a variety of materials including polypropylene, silicone or materials which may be developed in the future capable of making a superior seal around the breast 14 (to reduce leakage of expressed breast milk) or by making the adaptor 16 more breathable or more comfortable to wear. The materials or combination thereof can be made to be firm or soft, slick or sticky. For example, a sticky silicone might be used to form the adaptor 16 so that a tight fitting seal is made with the breast 14 while the reservoir 18 might be comprised of a rigid plastic. The rigid reservoir 18 could be formed in a shape to match that of a natural breast profile. Alternatively, the adaptor 16 and reservoir 18 might be made of a more flexible material to assume a natural breast profile as it conforms to a brassiere cup, while the drip tube 24 remains rigid to provide a closed chamber around the nipple 34 that will not collapse under the force of negative suction.

[0091] In FIGS. 3A and 3B are shown two views of an embodiment of the device 10 which is intended to approximate the profile of a normal breast. This embodiment is shown with a flattened area 36 formed on the exterior front of the reservoir to allow the device to be set down on a flat surface, without tipping or wobbling, while containing milk. However, alternative embodiments could be made without this flattened area.

[0092] FIG. 4 illustrates the reservoir 18 being detachable from the adaptor 16. In this fashion when the interior volume 30 of the reservoir 18 is full, the adaptor 16 can be removed and the breast milk poured into a baby bottle, or other container, for storage. In this detachable embodiment, the reservoir 18 is cup-like and the adaptor 16 functions as a lid which detachably engages with the cup-like reservoir.

[0093] Referring now to FIGS. 5A and 5B, the adaptor 16 includes a lid portion 38 which is continuous with the adaptor 16 and extends circumferentially around the cup-like reservoir 18. An overlapping lip 40 extends outward and downward from the lid portion 38 and includes a means for engaging the upper edge 42 of the reservoir 18. The engaging means can be of an overlapping snap-fit variety of a type well known in the lid fastening arts or a screw cap variety employing engaging threads 44 as shown in FIG. 5C. When attached, the adaptor 16 and reservoir 18 achieve a seal at the junction of lid portion 38 and edge 42 which cannot be compromised by the suction forces supplied by pump 12. Alternatively, the device may be one solid component, wherein the adaptor 16 does not detach from the reservoir 18 and wherein both suction and milk transfer/retrieval is accomplished through a single port hole or stem 48. Also as seen in FIG. 5B the lid portion 38 can be provided with graduations 46 denoting the number of ounces of milk contained within the reservoir 18.

[0094] FIG. 6 illustrates the inventive device 10 being used in a typical pumping cycle. A stem 48 located on the top exterior surface of reservoir 18 attaches to the pump 12 by way of a vacuum hose 50. The vacuum hose 50 attaches to the stem 48 at the top so that the pump 12 will not suction breast milk 52 into the workings of the pump 12. The pump 12 shown is a hospital grade tabletop electric pump. Additionally, although not shown, a manual pump can be employed. To further aid in the portability of the system, a belt holder 54 (See also FIGS. 1 and 2) or possibly backpack, operates to receive the electric pump 12 and allows it to be carried around while the inventive device 10 is being used. The pump 12 provides suction to the interior volume 30 of the reservoir 18 and stimulates the mother's milk to be released, or "letdown," for collection.

[0095] Examples of tabletop electric pumps presently in existence which could be used with the inventive apparatus 10 include those made by Medela, Inc., or Ameda/Hollister. These pumps can be carried in a portable manner by employing a belt holder 54 as shown in the Figures. Manual pumps which could be used include the Medela foot pump or the Versa Ped™ foot pump.

[0096] During the pumping cycle, the device 10 is located within, and supported by the brassiere (See FIGS 1 and 2), thereby allowing the woman using the device to engage in normal workday tasks in a completely hands-free manner. A woman may use the device 10 to pump both breasts 14 at once, or else a single breast. If a woman pumps one breast 14, it is recommended that she wear the device 10 on the second breast 14 too, so that any milk 52 expressed passively, as a result of the letdown reflex, can be collected and stored.

[0097] FIG. 7 shows an alternative embodiment of the invention which is designed to further prevent leakage of expressed breast milk 52. A circular barrier 56 formed into the transition area 58 separating the narrow end of the funnel adaptor 16 and the proximal end of drip tube 24 helps prevent the backflow of expressed breast milk 52.

[0098] FIG. 8 illustrates an embodiment having the interior 60 of the funnel adaptor 16 lined with a pliable gas or liquid-filled bladder 62 for achieving enhanced sealing contact with the breast 14. The bladder 62 flexes with the shape of the breast 14 and molds the adaptor 16 thereto for enhanced sealing and comfort.

[0099] FIG. 9 shows an embodiment wherein the drip tube 24 is eliminated and, instead, the adaptor 16 narrows to an aperture 64, only, through which is placed the nipple portion 34 of the breast 14. In this version, breast milk 52 would drip directly off of the nipple 34 into the reservoir 18, without traveling down a drip tube 24. The adaptor 16 and lid portion 38 are

preferably constructed from a highly flexible (possibly silicone) material which forms closely to the breast 14 to better accommodate passive breast milk collection. In addition to being used as a passive milk collector, this embodiment could also double as a false breast insert for purposes of enhancing a woman's bust line, especially if the reservoir 18 is shaped to conform to a natural breast outline.

[00100] FIGS 10A and 10B show the device 10 being placed within a woman's nursing brassiere 32. Figure 10A demonstrates how such a compact device 10 may be concealed under normal clothing and used hands-free, thereby allowing a woman to carryon workplace tasks without significant interruption. FIG. 10B illustrates the hands-free advantage of the invention by showing a woman using both hands 68 to hold her nursing infant 66 on one breast 14, while either passively or actively collecting milk from the opposite breast with the device 10. Also, this illustrates how the invention can significantly simplify the nursing task for compromised infants who may nurse when the device is used with a pump on the opposite breast.

[00101] FIGS 11A-G illustrate an alternative embodiment of the invention which introduces negative pumping pressure directly to the smaller inner sub-volume 70 of the drip tube 24 rather than to the entire reservoir volume 30 as described in the embodiments up to this point. If a similarly sized pump is used with this embodiment the negative pressure made by the same pump is enhanced in the smaller drip tube volume 70 when compared with the previous embodiments which pump the entire reservoir volume 30. This introduction of enhanced pressure may result in faster pumping of breast milk 52 particularly in women who have difficulty with initiating the letdown reflex. Furthermore, it reduces the chances of leaking from the milk reservoir.

[00102] FIG. 11A illustrates the components of the alternative embodiment 10. As shown, a vacuum hose 50 extends down through a notch 41 imparted into the lip 40 of the lid portion 38 and further extends into the drip tube volume 70 at its distal end 72. The vacuum hose 50 seats in a valve 74 which is attached to the distal end 28 of the drip tube 24. The valve 74 seals off the drip tube volume 70 when suction is applied, while alternately allowing milk to drip through into the reservoir volume 30 when suction is released. FIG. 11B shows the adaptor 16, valve 74 and vacuum hose 50 detached from the reservoir 18. The notch 41 in the lip 40 of the adaptor 16 allows the vacuum hose 50 to be snugly seated therein. A matching notch (not shown) is placed in the edge 42 of the reservoir 18 to similarly accommodate the vacuum hose 50. When the adaptor 16 is coupled to the reservoir 18, the two notches align to form a port. At the end of the pumping cycle, the vacuum hose 50 can be removed and milk 52 poured out from the reservoir 18 through the vacuum hose port.

[00103] FIG. 11C is a close up view of the drip tube 24, valve 74 and the distal end 72 of the suction hose 50 during a negative pressure cycle of the pump. With a breast 14 being inserted into the adaptor 16, the drip tube volume 70 which would be pumped would be the volume extending from the front of the nipple 34 to the distal end 28 of the drip tube 24 that is closed off by valve 74. The valve 74 is preferably a flap valve having a flap 80 which seals off the distal end 28 of the drip tube 24. A barrier 76 (See FIG. 11E), which spans across the drip tube aperture 26, prevents the flap 80 from becoming suctioned inwardly into the drip tube volume 70 during the negative pressure cycle and consequently breaking suction. However, the flap valve and aperture assembly can be modified in a number of ways so that no barrier 76 is needed. Furthermore, it is conceivable to those skilled in the art, that other types of valves such as a duckbill, or a ball valve could be used in alternative embodiments.

[00104] FIG. 11D shows a positive pressure cycle of the pump with the flap 80 in a relaxed state to allow the expressed milk 52 to flow into the reservoir volume 30. The barrier 76 is molded into the drip tube 24 as shown in FIG. 11E. This view illustrates the flap valve 74 disengaged from the end of the drip tube 24 to which it is attached. FIG. 11F illustrates another view of the adaptor 16 and barrier 76 showing a tab 78 molded to the lip 40 of the adaptor to allow for easy detachment of the adaptor 16 from the reservoir 18. FIG. 11G illustrates this alternative embodiment of the invention 10 fully assembled, as it might appear from the exterior.

[00105] FIGS. 12A and 12B illustrate front and rear perspective views of the preferred flap valve 74 used in the embodiment described above and shown in FIGS. 11A-G. The flap valve 74 shown is comprised of a semi-circular front face 82 from which downwardly extends the movable flap 80 shown previously in FIGS. 11C and 11D. Two stacked, semi-circular preforms 84 and 86 protrude rearward at right angles from the front face 82. The lower preform 86 has an outside circumference sized to fit snugly within the inside circumference of the drip tube 24, while the upper preform 84 has an inside circumference sized to fit snugly around the outside circumference of the drip tube 24. The space 88 located between the upper and lower preforms 84, 86 is sized to receive the distal end 28 of the drip tube 24 in the "sandwiching" manner shown in FIGS. 11C and 11D. A notch 90 is placed into each preform. The notches 90 are sized to receive the vacuum tube 50, the vacuum tube being connected to a vacuum pump as already described herein. The lower preform notch 90 is offset slightly forward of (closer to the front face 82) of upper preform notch 90, for reasons further described below. The drip tube 24 likewise has a notch 92 (See FIG. 11E) imparted inwardly from its distal end 28 for receiving the vacuum tube 50. When the flap valve 74 is installed on the distal end 28 of drip tube 24, the notches 90 of the upper and lower preforms 84, 86 of the flap valve align with the drip tube

notch 92 to create a port for inserting the end of the vacuum hose 50 as shown in FIGS. 11C and 11D. As shown, the offset upper and lower notches 90 cause the vacuum hose 50 to be received into valve 74 at an angle. This angular position of the vacuum tube 50 helps prevent it from becoming disengaged from the valve 74 during pumping. The interplay of the vacuum tube 50 supplying vacuum to the inner sub-volume 70 of drip tube 24 along with flap valve 74 functioning in the manner herein described supplies an efficient and reliable mechanism for expressing milk from a woman's breast.

[00106] FIG. 13A illustrates yet another alternative embodiment of the invention 10. This embodiment increases pumping efficiency by introducing baffles 94, 95 into the interior volume 30 of the reservoir 18. Baffles 94, 95 are attached to the interior sides of reservoir 18 and seal off a sub volume 30 between the baffles. Upper and lower baffles 94, 95 are spaced to accommodate the funnel portion of adaptor 16, there between, when the adaptor 16 is coupled to the reservoir 18 as shown in FIG. 13A. Vacuum hose 50 is introduced to the sub-volume 30 between baffles 94, 95 via notch 96 located in the upper baffle 94. The lip 40 and reservoir 18 have mating cutouts as described previously which form a port to allow entry of vacuum hose 50. The lower baffle 95 has a valve 98 (check # on drawing) to allow milk to drip into the lower portion 100 of the reservoir 18. When suction is introduced, the baffles 94, 95 reduce the interior volume 30 required to be pumped within the reservoir and a high negative pressure zone is created. If the same pump is used, the amount of suction is greater with baffles 94, 95, compared to when baffles are eliminated from the reservoir 18 (in which case the pump would be working against the entire reservoir volume 30). The advantage of this design is that fewer parts are required for assembly and cleaning.

[00107] FIG. 14 illustrates yet another embodiment of the invention 10 which employs a system of brassiere-like adjustable straps 102 coupled to the invention 10. This allows the device to be worn like a brassiere by the wearer.

[00108] FIGS. 15-27 illustrate additional embodiments of the breast milk collection device 200 which includes a valve assembly and baffle structure configured to prevent overflow of milk into the pump and associated vacuum line. The tapered fits and smooth surfaces of the various parts of this embodiment allow the device to reliably seal on multiple surfaces and allow use of a vacuum pump without expressed milk backing up into the vacuum pump and hose system, as will be described below. The structural features and function of the illustrated embodiments also help reduce build up and bacterial growth in the collection device, thereby reducing contamination risk in the expressed breast milk. In addition, the individual parts comprising the valve assembly of these embodiments can be readily disassembled for cleaning, and due to the unique use of keyways, keys, slots and mating angled portions, the individual parts can be re-assembled in only one, correct way by the user after cleaning.

[00109] Referring to Fig. 15-17, the illustrated embodiment of the inventive device 200 includes an adaptor 216 within which a woman's breast is inserted. The adaptor 216 opens into a reservoir 218 that collects and stores breast milk being expressed from the breast. In the illustrated embodiment, the adaptor 216 is cone or funnel shaped to form a seal with the breast during the milk expression process. As shown in Figs. 15-17, the funnel-shaped adaptor 216 has a first end 217 which opens to the rear 201 of the collection device 200, and a second end 219 forming a drip tube that, in the assembled device, is adjacent the front end 222 of the device 200. As described for previous embodiments, the adaptor 216 protrudes a distance into the confines of the reservoir's interior volume 230 to provide the device 200 with a compact configuration. The

adaptor 216 may be formed from a variety of materials including polypropylene, silicone, or other materials which may be capable of forming a superior seal around the breast or making the adaptor 216 more comfortable for a user.

[00110] The illustrated embodiment shows a flattened area 236 formed on the front end 222 of the reservoir 218, which allows the device to be set down on a flat surface without tipping or wobbling and prevents spillage when the device 200 contains milk. The general structure and function of the breast adaptor 216 and the reservoir 218 is otherwise similar to that described for the previous embodiments. As previously discussed, various electromechanical or manual pumps known in the art may be used with the illustrated embodiment to provide alternating vacuum pressure to the user's breast.

[00111] FIGS. 16 and 19 illustrate an embodiment of the device where the adaptor 216 is readily manually detachable from the reservoir 218. As described for the previous embodiments, when the interior volume 230 of reservoir 218 is full, the adaptor 216 can be removed from reservoir 218 and the breast milk emptied into a baby bottle or other container for storage. Further, the adaptor 216 must be removed from reservoir 218 to access the interior parts of the collection device 200, as will be explained. Referring to Fig. 19, the adaptor 216 further includes a lid portion 238 which is continuous with the adaptor 216 and extends circumferentially around the reservoir 218. An overlapping flange 240 extends outward from the lid portion 238 and engages the upper lip 242 of the reservoir 218. In the illustrated embodiment of Fig. 19, a molded snap bump 243 integrally formed in the reservoir 218 engages a corresponding cradle 248 in the adaptor 216 to maintain the adaptor 216 in a fitted and sealed position connected to the reservoir 218. Other overlapping fasteners known in the art may also be employed as described for previous embodiments. Due to the inherent flexibility of the materials from which

adaptor 216 is constructed, flange 240 flexes outward when adaptor 216 is manually removed from, or assembled with reservoir 218 as cradle 248 slides over snap bump 243.

[00112] Referring to FIGS. 16-18 and 20-21B, a three-part valve assembly 250 is removably mounted concentrically on the drip tube at the second end 219 of the breast adaptor 216. The valve assembly 250 comprises a valve body 252, a valve cap 254 mounted concentrically on the valve body 252, and a valve flap 256 flexibly attached to the valve cap 254. The valve assembly 250 in its operative position is mounted over the second end 219 of the breast adaptor 216, and alternately opens and closes communication between the breast adaptor 216 and the reservoir 218 as the vacuum pump (not shown) alternates between a negative or vacuum pressure and approaches a neutral or positive pressure, as will be explained. In the illustrated embodiment shown in FIGS. 16, 20 and 21, the second end 219 of the breast adaptor 216 has an enlarged opening 251 on the top side to allow the flow of positive, neutral or negative air pressure from the vacuum line 265 leading to the vacuum pump, and through an overflow chamber 258 formed by the valve assembly 250. A baffle structure 260 is attached to the valve cap 254 to provide a torturous path for the air pressure to flow between vacuum hose 265 and the user's breast, and to assist in substantially preventing an overflow of milk from entering the vacuum line 265 or pump assembly, as will be explained.

[00113] As seen in Figs. 16-18, the valve body 252 further includes a port 262 communicating with a channel 263 for a direct and removable connection of an external suction source to the valve assembly 250. Suction or vacuum hose 265 in this embodiment is removably inserted directly into inlet port 262 at the rear top of the valve body 252. The opposite end (not shown) of vacuum line 265 is connected to a vacuum pump of the type known to those skilled in the art to alternately apply positive, ornamental and negative pressure to the user's breast to facilitate

the expression of milk. In the illustrated embodiment of FIGS. 16-18, the inlet port 262 is adapted to receive suction or vacuum hose 265 by providing a tapered female fitting formed integrally by channel 263 in the valve body 252. The valve assembly 250 creates an indirect path between adaptor 216 and vacuum line 265 to prevent expressed milk under heavy flow conditions from flowing back through the suction path to vacuum hose 265 and to an external pump (not shown) as will be explained.

[00114] The valve cap 254 as seen in FIGS. 16 and 18 is slidably and sealingly positioned concentrically over the valve body 252 and further includes baffle structure 260 integrally formed with an interior wall 259 of the valve cap 254. Baffle 260 extends substantially perpendicular to the lower portion of interior wall 259. When the valve cap 254 is in the assembled concentric position around the valve body 252 (FIG. 18), the baffle structure 260 extends axially into the central portion of overflow chamber 258, and terminates prior to reaching end wall 261 or either side wall of overflow chamber 258, thus creating a space between baffle structure 260 and side walls and end wall 261 of the overflow chamber that provides a torturous and diffuse path through chamber 258 for the flow of positive and negative air pressure from vacuum line 265 to breast adaptor 216. The baffle structure 260 also combines with overflow chamber 258 to prevent the back flow of milk through valve body 252 and to the vacuum line 265 and associated pump.

[00115] In the assembled concentric position shown in FIGS. 15, 16 and 18, flap valve 256 releasably closes off aperture 264b formed in valve cap 254. Aperture 264b is in communication with larger aperture 264a in valve body 252, and with aperture 264 at second end 219 of adaptor 216. The flap valve 256 may be molded from a soft, flexible rubber-like plastic or other material and includes a flexible pin 266 extending perpendicular to the surface of the flap valve 256. The

pin 266 is press fit into an aperture 257 in the valve cap 254 to hold the flap valve 256 in place flush against aperture 264b of the valve cap 254 to cover the aperture 264, 264a and 264b during the negative or vacuum pressure portion of the pumping cycle. Flexible pin 266 has a predetermined polygoval cross sectional shape, such as triangular as shown in FIG 21B. Valve cap 254 includes corresponding aperture 257 having the same polygoval peripheral shape as pin 266, with aperture 257 located above aperture 264b (FIG 21A). Upon assembly of flap valve 256 is flush against the portion of valve cap 254 surrounding aperture 264a. Pin 266 may also include a slightly longer protruding portion (not shown) extending in the radial direction on pin 266 at a distance substantially equal to the thickness of valve cap 254. This protruding portion will prevent pin 266 from sliding out of aperture 257 during heavy milk flows, or during the application of positive pressure through valve assembly 250. The polygoval shape of aperture 257 and pin 266 enable the flap valve 256 to be correctly assembled in only one way by the user. With the flap valve covering aperture 264a, the flap valve 256 cannot be moved angularly away with respect to aperture 264a, since the polygoval, or triangular, shape of pin 266 and aperture 257 prevent the flap valve from being incorrectly connected to valve cap 254, or rotated to an incorrect position once properly installed.

The valve flap 256 thus encloses the space within the drip tube at the second end 219 of the breast adaptor 216, overflow chamber 258 of valve assembly 250, and suction line 265 during a negative pressure cycle of the pump. Conversely, the valve flap 256 opens during the positive pressure cycle of the pump allowing the expressed milk to flow through apertures 264, 264a and 264b and into the collection volume 230 of reservoir 218. When the flap valve 256 closes off the apertures 264, 264a and 264b, a reduced volume is created within the second end 219 of the breast adaptor 216 compared with the size of reservoir collection volume 230. When suction is

introduced to this reduced volume, the reduced volume becomes an efficient negative pressure zone, drawing the breast and nipple forward, sealing the breasts to adaptor 216, and encouraging the expression of breast milk from a woman's breast.

[00116] In the illustrated embodiment of Fig. 21B, the flap valve 256 is generally triangular in shape with rounded corners. One advantage of this shape is to alert the user if the flap valve 256 is not oriented properly during reassembly after cleaning. Also, the aperture 264b that flap valve 256 covers is as large as possible to allow the escape of milk to reservoir 218 when large amounts of milk are expressed in a short period of time. The size of aperture 264b compliments the overflow chamber 258, so that milk that backs up into the overflow chamber during the negative or suction portion of the pump cycle escapes through aperture 264b as soon as negative pressure is released and flap valve 256 opens aperture 264b. In the illustrated embodiment, flap valve 256 is made of advanced polymer materials that provide flexibility and memory to the flap valve, while also achieving the necessary surface tension between the flap valve and valve cap to hold a suction inside valve assembly 250 and adapter 216. The curved edges of the triangular configuration of the illustrated flap valve 256 keep the flap valve from bending and creasing during suction, thereby maintaining the integrity of the vacuum

[00117] The overflow chamber 258 and baffle structure 260 combine to create an overflow capacity for the second end 219 of the breast adaptor 216 that prevents breast milk from entering and contaminating the vacuum line 265 and the associated vacuum pump mechanism during a suction portion of the pumping cycle. The various elements comprising breast milk collection device 200 described above are adapted to be easily drained and cleaned after each use, eliminating the possibility that milk can remain on the various parts long enough to spawn the growth of bacteria. Likewise, the configuration of valve body 252 with overflow chamber 258,

and of valve cap 254 with baffle 260 extending into overflow chamber 258, specifically prevents breast milk from entering vacuum line 265 and the associated vacuum pump which may not be as easy to clean as are adaptor 216, valve body 252, valve cap 254 and flap valve 256. The space created between overflow chamber 258 and the baffle structure 260, and the second end 219 of the breast adaptor 216, including opening 251 leading from second end 219 and overflow chamber 258, allows the breast milk collection device 200 to deal effectively with sudden, intermittent large letdowns of milk. The baffle structure 260 and overflow chamber 258 may be employed infrequently during operation, as the majority of the expressed milk may trickle out of the nipple in small quantities and proceed directly through apertures 264, 264a and 264b and through flap valve 256 into the interior volume 230 of reservoir 218. As described above, in certain circumstances when the letdown of milk in a single cycle is large enough that milk reaches the flap valve 256 before the suction of the pump's negative pressure cycle is released, expressed milk can back up into the overflow chamber 258 under the force of the vacuum pressure. The pump pressure cycling between negative and positive pressures in the enclosed area formed by the closing of flap valve 256 can create significant turbulence in a volume of milk which is trapped in the second end 219 of the breast adaptor 216 before traveling through the valve flap 256 and into the reservoir 218. The milk may bubble, and become airborne due to the suction force. If milk is flowing from the nipple, aerating inside the adaptor 216, and attempting to follow the suction path, the baffle structure 260 will diffuse the aerated milk by interrupting its path toward the vacuum line 265. Milk sprayed up into the overflow chamber 258 will be deflected or redirected off of the baffle structure 260 and toward the interior surfaces of the valve assembly 250 and of overflow chamber 258. The surrounding walls of the overflow chamber 258 in the valve assembly 250 are configured to allow milk to drain back down into the

adaptor 216 and through the flap valve 256 into the reservoir 218 during portions of the pumping cycle when the negative pressure is released.

[00118] Referring to FIG. 22, a slot 275 is integrally formed in the upper lip 242 of the reservoir 218. The slot 275 is also aligned with a corresponding notch 277 integrally formed in the flange or lip 240 of the adaptor 216. The vacuum hose 265, which is ultimately connected to a vacuum hose 272 (FIG. 23) extending from the external suction source extends down through slot 275 (FIGS. 19, 22) where the hose 265 connects to channel 263 of the valve assembly 250 (FIG. 16). The slot 275 also provides a vent to accommodate the necessary fluctuations of air volume in the reservoir 218 due to alternating positive and negative pressures created as a result of the pump cycling, and due to the changing volume of milk in reservoir 218. The shape of the slot 275 further provides a pour spout allowing the user to easily and simply pull the vacuum hose directly out of the channel 263 of the valve body through the slot 275, and transfer milk to a baby bottle or other storage device without having to remove the lid adaptor 216 from the reservoir 218 and risk spillage. When the device 200 is inverted to pour the milk into another container, the flap valve 256 moves to its open position, and acts as a pressure relief mechanism for the reservoir's interior volume, allowing air to mix with the exiting milk stream, with air replacing the milk in the reservoir's interior volume, resulting in a smooth steady flow of milk without air bubbles or "gurgling," while pouring. This is important since most storage devices are baby bottles with relatively small diameter openings to pour into.

[00119] Referring to FIG. 23, the collection device 200 may further include a detachable external connection apparatus 270 which connects the vacuum line 265 that is attached to the collection device 200 to a vacuum line 272 extending from the external suction source or pump (not shown). The connection apparatus 270 provides a user with flexibility and convenience

during the process of pumping breast milk. In the illustrated embodiment, the connection apparatus 270 is a partially tapered tubular fitting having outer male and female ends, and a hollow channel 273 extending the length of the connector apparatus. Connection apparatus 270 includes a first portion 274 having an outer diameter that may be cylindrical or slightly tapered. A second portion 276 of connection apparatus 270 is tapered from end 278 of first portion 274 to the male end 280 of second portion 276. The end 282 of first portion 274 provides the female end of the connection apparatus 270, as will be explained. The interior and exterior dimensions of connection apparatus 270 are calculated to accommodate various sizes of vacuum hoses 272 for a wide variety of pumps on the market. Other embodiments may also include tubular fittings having male/male connections or female/female connections. One of ordinary skill in the art will appreciate that the connection apparatus 270 should create a sufficient seal between the vacuum hoses 265, 272 to operate the device 200 at the appropriate vacuum pressure while facilitating the easy, frequent and reliable assembly and disassembly of the vacuum pump connection, so as to facilitate optimal user flexibility before, during and after pumping has been initiated, interrupted, resumed and completed.

[00120] In the illustrated embodiment of FIG. 23, the tapered second portion 276 of connection apparatus 270 allows easy insertion of hose 272 over end 280 to create the necessary seal and to also provide for easy assembly and disassembly. Also, channel 273 at end 282 of connection device 270 is dimensioned to receive vacuum line 265 and to accommodate some variations in the outer diameter, and to tightly fit around the outer diameter of vacuum line 265, by means of a slightly tapering internal channel, thus forming a seal between the vacuum line and the connector apparatus. The external connection apparatus 270 allows a mobile user to assemble the device under her clothing and into a brassiere privately, and then move to another location, if necessary,

to connect the collection device 200 to a pump which may be left in a stationary location such as a workstation via the connection apparatus 270. In this scenario, the vacuum line 265 could protrude slightly from under a user's clothing, or be hidden, and remain easily accessible to provide a simple and secure connection to an external pump. With the external connection apparatus 270, a user may easily interrupt the milk pumping process to tend to ongoing or unexpected tasks at work or at home without disassembling all the equipment, undressing, and/or cleaning up leaking milk. A user may also continue pumping breast milk discretely into one or two collection devices 200 located in the user's bra in the presence of others without the need to relocate to another area because of the need for social modesty, or to partially undress, as required by most other hands free systems. When pumping is complete, a user may then proceed to a private place, remove the collection devices 200, transfer the milk to storage containers, and clean the devices prior to the next pumping session. Or, because of the device's innate hands free, ergonomic, secure and concealed nature, the user may engage in some other more pressing tasks not related to the task of pumping and engage those tasks after disconnecting from the pump, but in advance of finishing up the pumping process, and then later remove the devices, transfer milk and clean and prepare for the pumping next session.

[00121] The human breast milk collection device 200 of the present invention includes features that render the device easy to disassemble, clean and re-assemble by the nursing user. Each of the parts comprising the collection device 200 are specifically configured to fit together when assembled through tapered surfaces to form the seals necessary to prevent the milk from leaking from the device 200, or as explained previously, from entering the vacuum line 265, 272 or the mechanical parts of the vacuum pump (not shown). The several parts of the collection device are also configured for ready disassembly for cleaning and decontamination, such as in a normal

household dishwasher, sterile cleanser hand cleaning or the like by the user after the milk expression and collection process has been completed and the reservoir 218 has been emptied of milk. In addition, as explained below in greater detail, the components of the breast milk collection device 200 can only be reassembled in their correct orientation by the user after cleaning.

[00122] The second end or drip tube 219 of the adaptor 216 comprises a circular and smooth outer surface 300 that tapers in the axial direction towards second end 219, as seen in FIGS. and 18. A corresponding circular and smooth inner surface 294, that tapers in the same axial direction as outer surface 300, is formed on the wall portion 302 of valve body 252 that forms passageway 296 (FIG. 20.).

[00123] Referring to FIGS. 16-18 and 21, a pair of projections 290, 292, extend downward and inward from the interior tapered circular surface 294 forming passageway 296 of the valve body 252. When the second end 219 of adapter 216 is inserted into chamber 296 in an improper circular orientation, the edge or end 219 of valve body 252 will abut the ends 298 of projections 290, 292, preventing tapered surface 294 of valve body 252 from properly seating on, and forming a seal with, corresponding tapered outer surface 300 of adaptor 216 (FIG. 18). Upon rotating valve body 252 into its proper orientation with respect to second end 219 of adaptor 216, the sidewalls 306 (FIG. 18) of large opening 251 will slide to a position adjacent to, and not abutting, projections 290, 292, as best seen in FIG. 18. In this orientation, tapered circular surface 294 of valve body 252 tightly engages tapered circular surface 300 of adapter 216, thus forming a seal between valve body 252 and second end 219 of adaptor 216. In use, after the user has washed the disassembled adaptor 216 and valve body 252 (FIG. 17) the valve body 252 is rotated while being slid over surface 300 of the second end 219 of adaptor 216. Not until

sidewalls 306 (FIG. 18) of opening 251 in valve body 252 are in proper alignment with projections 290, 292, as explained above, will the user be able to make the proper tight sealing fit between surface 300 of the adaptor 216 and surface 294 of the valve body 252.

[00124] In similar manner, the re-assembly of valve cap 254 over the valve body 252 can only be accomplished when the valve cap and the valve body are properly concentrically rotatably oriented. To this end and referring to FIGS. 16-18, 21 and 21A, a key 308 is mounted on the upper surface of valve body 252. A corresponding keyway slot 310 is located on an upper portion of valve cap 254. When the user assembles valve cap 254 and the valve body 252 by inserting valve cap inner surface 312 over valve body outer surface 314 with baffle 260 inserted into overflow chamber 258, the valve cap 254 is rotated so that keyway slot 310 is aligned with key 308. The valve cap and valve body are then moved together, as shown in FIGS. 18 and 20, until a seal is formed between valve cap inner surface 312 and valve body outer surface 314, and key 308 is lodged in keyway slot 310, ensuring the proper rotational orientation between valve body 252 and valve cap 254, and the proper location of baffle 260 in overflow chamber 258.

[00125] A second structural relationship between valve body 252 and valve cap 254 ensures that the valve body and valve cap are properly oriented when re-assembled after cleaning. Referring to FIG. 21, valve body 252 includes a pair of contoured outer surfaces 316, 318 that are slightly curved over their respective extents. Valve cap 254 includes a contoured inner surface 320 having a pair of downward extending curved portions 322 (FIG 21A). Contoured surfaces 316, 318 of valve body 252 are adapted to contact or closely abut contoured portions 322 of valve cap 254 in a mating relationship when valve cap 254 is slid over valve body 252 during re-assembly. If the valve body 252 and valve cap 254 are not properly circumferentially oriented, the

contoured surfaces 316, 318 and 322 will not coincide, and the valve body 252 and valve cap 254 cannot be forced into a misaligned fitting juxtaposition.

[00126] The assembly and disassembly of adaptor 216 and reservoir 218 in the illustrated embodiment is also facilitated by the use of finger tabs that are adapted to be gripped by the user. As seen in FIGS. 19 and 22, a finger tab 324 is disposed on the outer surface of flange 240 of the adaptor 216. Also, referring to FIG. 22 a pair of finger indentations 326 are located on the outer surface of reservoir 218. When the user desires to separate adaptor 216 from reservoir 218, two fingers of one hand are each placed in indentations 326 and a slight gripping pressure is applied to reservoir 218. A finger or thumb of the other hand is placed on finger tab 324, and upon moving the hands apart, the adaptor 216 is separated from reservoir 218 as snap bump 243 emerges from cradle 248 (FIG 19).

[00127] In like manner, a pair of finger tabs 328 (FIGS. 20, 21) are located on opposite sides of the outer circumference of valve body 252. The finger tabs 328 extend radially outward and are adapted to be grasped by the user's fingers when disassembling valve body 252 from adaptor 216 by sliding valve body 252 in an axial direction away from second end 219 of adaptor 216. In similar fashion, finger tabs 328 are grasped by the user when separating valve cap 254 from valve body 252.

[00128] In the illustrated embodiment, finger tab 324 is located on the adaptor 216, and finger tabs 328 are disposed on the valve body 252. It is within the scope of the present invention to include finger tabs on the valve cap 254 and reservoir 218 if desired to assist the user in the assembly and disassembly of the breast milk collection device 200 of the present invention.

[00129] In an embodiment of the present invention, at least a portion of the components required in assembling the device 200 may be manufactured from an antibacterial material to

reduce the chance of bacterial growth and reduce risk of contamination in the expressed breast milk. The antibacterial material can be in the form of a special coating, or parts may be fabricated from a material which integrally possesses antibacterial properties. One of ordinary skill in the art will appreciate that other methods employing materials having antibacterial properties may be used.

[00130] In use of the invention embodiment of FIGS. 15-24, a woman assembles the valve body 252 and valve cap 254 as described above and as shown in FIGS. 16 and 18, with flap valve 256 attached to valve cap 254 and covering opening 264b. One end of the suction hose 265 is firmly inserted into channel 263 of the valve body 252 through port 262. Next, the valve body, valve cap, valve flap and suction hose are assembled as described above, and the valve assembly 250 is placed axially over second end 219 of the adaptor 216 to form a seal between valve body 252 and second end 219 of the adaptor. As set forth above, the valve body, valve cap, flap valve and adaptor are all correctly rotationally aligned when assembled. Reservoir 218 is then positioned adjacent the adaptor 216 with second end 219 of adaptor 216, valve body 252, valve cap 254 and flap valve 256 all assembled and located in the interior volume 230 of reservoir 218 (FIG. 16). Reservoir 218 is rotated relative to adaptor 216 until slot 275 in upper lip 242 of the reservoir is aligned with notch 277 formed in lip 240 of adaptor 216 (FIG. 22). Suction hose 265 is laterally inserted into slot 275, and the reservoir 218 is then brought into contact with adaptor 216. Using hand pressure, snap fitting bump 243 of reservoir 218 is inserted into corresponding cradle 248 in adaptor 216 to maintain the adaptor in releasable contact with the reservoir 218. Except for the juxtaposition of slot 275 and notch 277 (FIG. 22), the engagement of snap fitting bump 243 with cradle 248 creates a seal between the adaptor 216 and reservoir 218 that prevents expressed milk from leaking from the reservoir. In use, the slot 275, notch 277 and suction hose 265 are

located at the uppermost position of the device 200 to prevent the escape of expressed milk. The slot 275 also provides a vent to prevent the buildup of pressure in the reservoir 218, and provides a pouring opening when transferring milk from the reservoir to another container.

[00131] The other end of suction hose 265 is connected to an alternating suction pump (not shown), or to a connection device 270 (FIG. 23) that is connected to a hose 272 extending from an alternating suction pump. The woman then places her breast inside the breast adaptor 216, and places the device 200 within her brassiere to hold the device 200 in place so that she can utilize the device in a hands free manner. The user then activates the external pump, or other suction source, thus creating an alternating suction/positive pressure in hose 265. The flap valve 256 in the valve assembly 250, during the negative pressure cycle of the pump, encloses the space within the second end 219 of the breast adaptor 216, the valve assembly 250, and the suction line 265. During the negative or suction pressure cycle, the flap valve 256 is pulled tightly over the opening 264 in the valve cap 254 of the valve assembly 250 to create the reduced enclosed space which causes the breast to be drawn into the second end 219 of the breast adaptor 216 and release milk. After a period of time, if the expression of milk is rapid and voluminous, the expressed milk may fill up the second end 219 of the breast adaptor 216 and then flow through opening 251 and into the overflow chamber 258 during a single cycle. During the positive pressure cycle of the pump, the flap valve 256 opens and allows expressed milk to flow through the opening 264b in the end of the valve cap 254 and into the interior volume 230 of reservoir 218. During the ensuing negative or suction cycle of the pump, the flap valve 256 is again forced into contact with the valve cap and then tightly held against opening 264b to create the same reduced enclosure volume that applies suction directly to the breast, irrespective of the changing volume of air within the collection volume 230, which has been separated from the

negative pressure volume. This cycle of operation is repeated until the woman decides that the expression of milk for that time period has concluded. Milk may then be transferred from the reservoir 218 into a suitable container for use at a later time. After use of the breast milk collection device 200, the various parts of the device are disassembled, thoroughly cleaned and decontaminated by hand washing, use of a dishwasher, steam sterilizer or the like, and then re-assembled as described above. It is contemplated that the various parts of the collection device 200 will be made from dishwasher safe materials and alternative materials can be adapted for specialized hospital applications.

[00132] The illustrated embodiment as shown in FIGS. 15-24 further allows a woman to pump one or both breasts in a variety of positions such as lying down, sitting upright, standing, or the like. Pumping while lying down, for example, will allow a woman to safely rest, or hold her infant while she is pumping, and possibly provide a woman the flexibility and convenience to easily breast feed her baby for a longer period of time in the child's life, by pumping whenever necessary to maintain her milk supply, which will diminish or cease altogether if pumping and/or breastfeeding are not performed on a several times daily and regular basis. In the illustrated embodiment, the circular ergonomic shape of the breast adaptor 216 and the milk reservoir 218 make pumping in a variety of positions feasible.

[00133] In an additional embodiment of the present invention disclosed in FIG. 25, the vacuum source is physically isolated from the flow path of the expressed milk, totally preventing milk from entering and possibly contaminating the vacuum pump mechanism or the vacuum source line 265 (FIG. 16). FIG. 25 discloses the valve body 252 and valve cap 254 of the embodiment of FIGS. 15 to 24, with pertinent modifications, and like numerals identify like parts. In this embodiment, baffle 260 (FIGS. 16, 20) is removed from valve cap 254. A barrier comprising a

collapsible hollow bladder 350 is located in overflow chamber 258, and in the illustrated embodiment of FIG. 25, occupies a substantial portion of the volume of overflow chamber 258 when expanded. Bladder 350 includes a tubular neck 352 having a hollow portion 354 at one end that communicates directly with the interior 356 of bladder 350. Neck 352 at another end is tightly inserted into one end of channel 263, while vacuum source tube 265 is inserted in the other end of channel 263. The exterior surfaces of neck 352 and vacuum tube 265 tightly fit into their respective ends of channel 263, forming an air and fluid tight seal with channel 263 and port 262, and pneumatically connecting hollow portion 356 of bladder 350 to the source of vacuum pressure. In this manner, the vacuum pressure source conveyed through tube 265 is isolated from contact with overflow chamber 258, preventing milk that may enter chamber 258 from contacting or entering vacuum tube 265 or the pump supplying the vacuum source.

[00134] The collapsible bladder 350 may be formed in one piece, or more than one piece, from materials such as silicone, latex, or other such flexible materials, as are known to those of ordinary skill in the art. The volume of the interior 356 of collapsible bladder 350 is dimensioned sufficiently to transmit vacuum, or negative, pressure to the breast from the vacuum source, while applying sufficient oscillations on the breast to result in milk expression.

[00135] In use of the embodiment of FIG. 25, the vacuum source first creates a negative pressure through tube 265 and in hollow portion 356, causing bladder 350 to collapse. This creates a negative pressure in the interior of overflow chamber 258, with flap valve 256 in the closed portion over aperture 264. This negative pressure is conveyed through aperture 251 into passageway 296, and is applied to the breast and nipple, thereby drawing the breast and nipple into passageway 296. Milk is then expressed into passageway 296. Upon the release of negative pressure from the interior 356 of bladder 350, by the application of a pressure in excess of

vacuum pressure, such as a positive pressure through tube 265 or by the application of a lesser negative pressure or a neutral pressure in tube 265 by releasing the vacuum pressure through a relief valve, bladder 350 expands to its full volume position, applying a positive pressure in overflow chamber 258, opening flap valve 256 and the milk is released through aperture 264b into reservoir 218 as previously described. As seen in FIG. 25, if there is an expression of a large volume of milk and a portion of the milk enters overflow chamber 258 through large aperture 251, the milk will be prevented by bladder 350, and the seal between tubular neck 352 and channel 263, from entering port 262, vacuum tube 265, or the pump mechanism providing the source of vacuum pressure. Thus, the possibility of contamination of vacuum tube 265 or of the source of vacuum pressure is eliminated.

[00136] For cleaning purposes, after the reservoir 218 has been removed from adaptor 216, valve cap 254 is removed from valve body 252, providing access to overflow chamber 258 and bladder 350. Neck 352 is manually removed from channel 263 and bladder 350 is removed from overflow chamber 258. Bladder 350 can then be washed manually or mechanically along with the other disassembled components of device 200.

[00137] In a further embodiment of the present invention as disclosed in FIG. 26, a filter 360 is disposed adjacent opening 362 of channel 263. A resident single cage-like prong, or multiple spring prongs 364 are attached to one side of filter 360. Prongs 364 are adapted to extend into channel 263 through opening 362 and hold filter 360 in sealing engagement with opening 362.

[00138] Filter 360 is configured to allow air to pass from vacuum tube 265 and channel 263 through the filter 360 and into overflow chamber 258 and into passageway 296 during a negative pressure portion of the vacuum pressure cycle described previously. However, filter 360 is also configured to prevent the flow of expressed milk in the direction from overflow chamber 258 to

vacuum source tube 265, thus preventing the flow of milk into tube 265 or to the pump providing the source of vacuum pressure.

[00139] Prongs 364 comprise outwardly extending tension springs that tightly engage the inner surface of channel 263, as seen in FIG. 26. The tension force applied by prongs 364 is sufficient to prevent filter 360 from becoming dislodged from channel 263 during repeated cycles of negative and positive pressure being applied through channel 263. Yet, the tension force applied by prongs 364 allows a user to manually remove the filter 360 from opening 362 for cleaning or for replacement.

[00140] In a further embodiment illustrated in FIG. 27, connection apparatus 270 (FIG. 23) may be constructed with a filter 370, similar to the filter 360 described in conjunction with FIG. 26, inserted in channel 273. The filter 370 in channel 273 will be configured to allow positive, negative or neutral pressure air to pass between the source of vacuum pressure and channel 263 (FIG. 18), but the filter 370 will not allow milk to pass through the filter in the opposite direction through connection apparatus 270. Since connection apparatus 270 is a relatively inexpensive part of the invention described herein, if the filter 370 becomes clogged with milk, connection apparatus 270 may be discarded and replaced with a new connection apparatus and filter apparatus.

[00141] The collection device 200 of the illustrated embodiment in Figs. 15-27 is multi-faceted. In addition to use with manual and electromechanical pumps and use for passive collection of breast milk, the device 200 can also be used as a collection device for hand expression of milk before, during, or after pumping. The collection device 200 can be used for collection of breast milk via hand expression while the device is held by hand as illustrated in FIG. 24, or placed on a table top with flat end 222 of reservoir 218 facing down, for example. By providing a wide

opening to easily collect milk, either the first end 217 of the adaptor 216 when assembled on the collection device 200, or the reservoir 218 used alone allows a woman to lean over the device 200 while she is hand-expressing milk. Gravity will allow milk from a user's breast 14 to fall into the device 200 with a minimum of spillage and loss. The flap valve 256 is soft enough to allow expressed milk to flow from valve body passageway 296, through openings 264a and 264b, past valve 256 and into reservoir 218. The collection device 200 further allows a woman to follow up the pumping process with the recommended hand expression and massage techniques with a minimum of additional machines, hardware, and utensils to manage and clean. In an example, a woman may use the collection device 200 to pump breast milk hands-free, and after pumping, remove the device and place it flat on a nearby table or other flat surface, and continue expressing the remainder of milk by hand into the collection device 200.

[00142] A user may choose to remove the lid or adaptor 216 and use the reservoir 218 alone to collect hand-expressed milk. Additionally, a woman may choose to leave the device 200 fully assembled, and the funnel shape of the adaptor 216 will provide a large diameter area to collect milk and induce the milk via gravity to flow down through the adaptor 216 into the collection area or reservoir 218. This latter method reduces the risk of spillage or loss for expressed milk in the reservoir 218. After hand-expression is complete, a user may transfer the milk to a baby bottle or other storage device as previously described.

[00143] Finally, although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently illustrated embodiments of this invention. This invention may be altered and rearranged in numerous ways by one skilled in the art without departing from the coverage of any patent claims which are supported by this specification.

CLAIMS

What is claimed is:

1. A breast milk collection device to be secured within and supported by an ordinary brassiere worn by a lactating woman, the collection device comprising;

an adaptor adapted to fittingly and sealingly receive the woman's breast;

a reservoir having an internal volume, said internal volume adapted to collect and store said milk expressed from said woman's breast;

said adaptor being received within said internal volume of said reservoir.

2. The device of claim 1, wherein said reservoir and said adaptor are detachably coupled.

3. The device of claim 1, wherein said reservoir comprises an approximately cup shaped exterior.

4. The device of claim 2 wherein said adaptor and said reservoir each have detachably mating circumferential edges.

5. The device of claims 1 or 10, further including a source of vacuum pressure detachably coupled to said internal volume of said reservoir, said vacuum pressure adapted to encourage the flow of said milk from said breast.

6. The device of claim 5 wherein said source of vacuum pressure is in communication with said internal volume of said reservoir through a vacuum hose detachably coupled to said internal volume of said reservoir.

7. The device of claim 1 wherein said adaptor comprises a funnel having a receiving end adapted to secure the woman's breast;

said funnel having a narrow end opposite said receiving end, said narrow end including an aperture adapted to secure a nipple portion of said breast;

said funnel protruding into said internal volume of said reservoir, said aperture adapted to deliver said breast milk to said internal volume of said reservoir.

8. The device of claim 7, further comprising a valve attached to said narrow end of said funnel, said valve closing said aperture in a first position and opening said aperture in a second position;

a source of vacuum pressure detachably coupled to said narrow end of said funnel, said source of vacuum pressure applying a vacuum pressure to said narrow end of said funnel;

said valve creating a reduced volume in said narrow end of said funnel when said valve is in said closed position, said reduced volume providing a high negative pressure zone upon the introduction of said suction pressure to said reduced volume, said high negative pressure zone adapted to encourage the expression of said milk from said breast.

said reduced volume being less than said internal volume of said reservoir.

9. The device of claim 1 wherein

said brassiere includes at least one support structure of a predetermined internal shape;

said reservoir having an external contour approximately the same as said predetermined internal shape of said at least one support structure of said brassiere;

said at least one support structure adapted to support said reservoir and said adaptor when said adaptor is placed over said woman's breast and said reservoir and said adaptor are located in said at least one support structure of said brassiere.

10. A breast milk collection device comprising:

a breast adaptor having a first receiving end adapted to fittingly and sealingly receive at least a portion of a woman's breast, the adaptor having a second end opposite the first end, the second end including a first aperture adapted to receive a nipple portion of the breast;

a reservoir coupled with the adaptor to form a single unit with the adaptor, the adaptor received within an interior volume of the reservoir, the interior volume of the reservoir adapted to receive breast milk produced from the woman's breast through the first aperture of the second end of the adaptor, the interior volume of the reservoir adapted to collect and store the milk within a brassiere worn by a woman, the reservoir adapted to be supported by the brassiere; and

a valve assembly disposed between the adaptor and the reservoir, the valve assembly alternately opening and closing fluid communication between the adaptor and the reservoir.

11. The device of claim 10, wherein said valve assembly comprises a valve body removably mounted on said second end of said adaptor, a valve cap removably mounted on the valve body, and a flap valve removably attached to the valve cap, the flap valve alternately opening and closing a passage formed through a combination of the first aperture at the second end of the breast adaptor and a second aperture extending through the valve assembly.

12. The device of claim 10 wherein said valve assembly includes a valve body mounted on said second end of said adaptor; and

an overflow chamber formed in said valve body, said overflow chamber in fluid communication with a fluid passage formed in said second end of said adaptor;

said overflow chamber adapted to receive breast milk from said second end of said adaptor upon the release of a volume of breast milk in excess of the capacity of the fluid passage formed in the second end of said adaptor.

13. The device of claim 12 wherein said valve body includes a first opening in communication with said overflow chamber, said first opening also communicating with a source of vacuum pressure, said vacuum pressure applied to said overflow chamber and to said fluid passage formed in said second end of said adaptor, said vacuum pressure being isolated from being applied to said interior volume of said reservoir.

14. The device of claim 13, including a channel formed in said valve body, said first opening formed at a first end of said channel, a second end of said channel having a second

opening communicating with said overflow chamber, said first opening releasably receiving a vacuum hose, said vacuum hose connected to said source of vacuum pressure.

15. The device of claim 12, including a valve cap sealingly mounted on said valve body, said valve cap including a baffle structure extending partially into said overflow chamber when said valve cap is mounted on said valve body.

16. The device of claim 15, said overflow chamber being operatively connected to a source of vacuum pressure, said baffle providing a torturous path for the vacuum pressure applied through the overflow chamber to the fluid passage formed in the second end of said adaptor.

17. The device of claim 10, wherein:

said adaptor includes a fluid passageway formed in said second end of said adaptor, said fluid passageway in fluid communication with a second aperture extending through said valve assembly, said second aperture in fluid communication with the interior volume of said reservoir;

a flap valve attached to said valve assembly, said flap valve alternately opening and closing fluid communication between the fluid passageway formed in the second end of the adaptor and the interior volume of said reservoir.

18. The device of claim 17 wherein:

said valve assembly includes an overflow chamber formed therein, said overflow chamber in constant fluid communication with said fluid passageway formed in the second end of the adaptor;

said second aperture adapted to permit milk to flow from said overflow chamber and said fluid passageway formed in the second end of the adaptor through said second

aperture and into said volume of said reservoir upon release of a vacuum pressure applied to said valve assembly and said flap valve moving to an open position.

19. The device of claim 10, wherein:

said reservoir includes a lip portion defining a rim of said reservoir, a slot formed in said lip portion, said slot extending from the exterior of said reservoir to said interior volume of said reservoir;

said adaptor having a flange portion adapted to removably engage said lip portion of said reservoir, a notch in said flange portion, said notch aligned with said slot in said reservoir when said reservoir and said adaptor are engaged;

said aligned notch and slot forming an access aperture in said adaptor and said reservoir, said access aperture extending between the interior volume of said reservoir and the exterior of said reservoir;

said access aperture adapted to receive a vacuum pressure hose, said vacuum pressure hose removably connected at one end to said valve assembly and at a second end to a source of vacuum pressure.

20. The device of claim 10, further including:

a source of vacuum pressure;

a first flexible tubular vacuum hose connected to said source of vacuum pressure, said first vacuum hose having an inner diameter of a first dimension;

a second flexible tubular vacuum hose removably connected to said valve assembly, said second vacuum hose having an outer diameter of a second dimension;

a connection apparatus adapted to removably and replaceably connect said second vacuum hose to said first vacuum hose forming a vacuum pressure passageway between said source of vacuum pressure and said valve assembly;

said connector apparatus having a bore extending axially through said connector apparatus, said bore having an inner diameter adapted to sealingly receive one of said first and second flexible vacuum hoses.

21. The device of claim 10, wherein said valve assembly includes a second volume less than the interior volume of the reservoir;

a hollow flexible bladder located in said second volume, the interior of said hollow flexible bladder in communication with a source of alternating vacuum pressure and pressure in excess of vacuum pressure, said hollow flexible bladder contracting in said second volume upon application of said vacuum pressure to said interior of said hollow flexible bladder, the contraction of said hollow flexible bladder creating a vacuum pressure in said second volume;

said second volume being isolated from said interior volume of said reservoir when said vacuum pressure is created in said second volume;

said second volume in fluid communication with said interior volume of said reservoir when said pressure in excess of vacuum is introduced into said second volume;

the hollow interior of said flexible bladder being sealed against fluid communication with said second volume.

22. The device of claim 14 further including a filter removably located adjacent said second opening, said filter allowing the passage of air through said second opening, said filter adapted to prevent the flow of breast milk through said second opening.

23. The device of claim 20 wherein said filter is located in said bore, said filter allowing the passage of air through said filter, said filter adapted to prevent the flow of breast milk through said bore.

24. The device of claim 10, wherein said valve assembly includes a valve body removably and concentrically mounted on said second end of said adaptor;

a passageway extending through said second end of said adaptor, said passageway including an opening portion adjacent an edge of said second end of said adaptor;

said valve body including a chamber sealingly receiving the second end of said adaptor upon mounting said valve body on said second end of the adaptor, said chamber including at least one projection extending partially into said chamber of said valve body, said at least one projection advancing into said opening portion of said adaptor only when said valve body is correctly circumferentially oriented with said adaptor.

25. The device of claim 10, wherein said second end of said adaptor has a tapered outer surface, and said chamber in said valve body has a tapered inner surface, said tapered inner and outer surfaces forming a fluid tight seal between said second end of said adaptor and said chamber when said valve body chamber is mounted on said tapered surface of said second end of said adaptor and said at least one projection advances into said opening.

26. The device of claim 10 wherein said valve assembly includes a valve body having an outer circumferential surface;

said valve assembly further including a valve cap having a circumferential inner surface portion, said circumferential inner surface portion removably and sealingly mounted on the outer circumferential surface of said valve body;

said outer circumferential surface of said valve body comprising a key located at a predetermined location on said outer surface;

said circumferential inner surface of said valve cap comprising a keyway slot, said keyway slot receiving said key when said valve body and said valve cap are correctly concentrically oriented.

27. The device of claim 10 wherein said valve assembly includes a valve body having at least one contoured outer surface;

said valve assembly also including a valve cap removably mounted on said valve body, said valve cap having a contoured inner surface, said contoured inner surface of said valve cap contacting said at least one contoured outer surface of said valve body when said valve cap is correctly concentrically mounted on said valve body.

28. The device of claim 5 wherein said valve assembly includes a first linear flow path adapted to substantially linearly advance said breast milk to said reservoir, said first flow path defining a first axis;

said source of vacuum pressure providing said vacuum pressure to said valve assembly along a second axis;

said first and second axes being spaced apart in said valve assembly.

FIG. 1

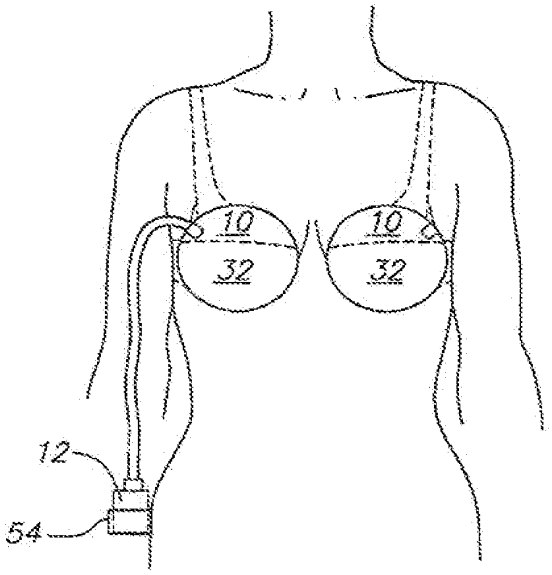


FIG. 2

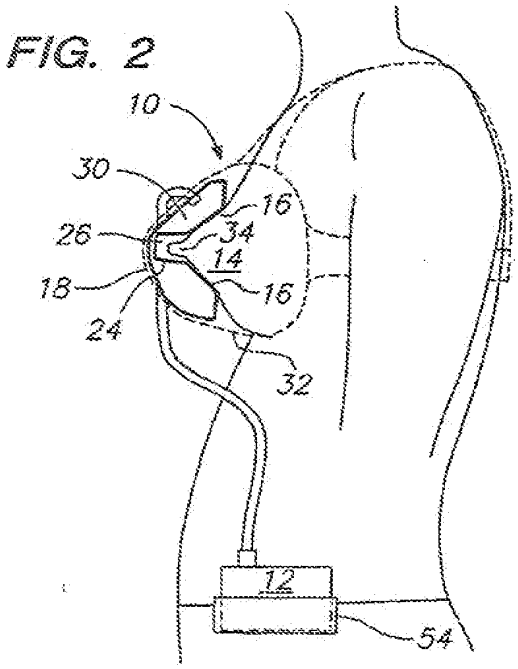


FIG. 3A

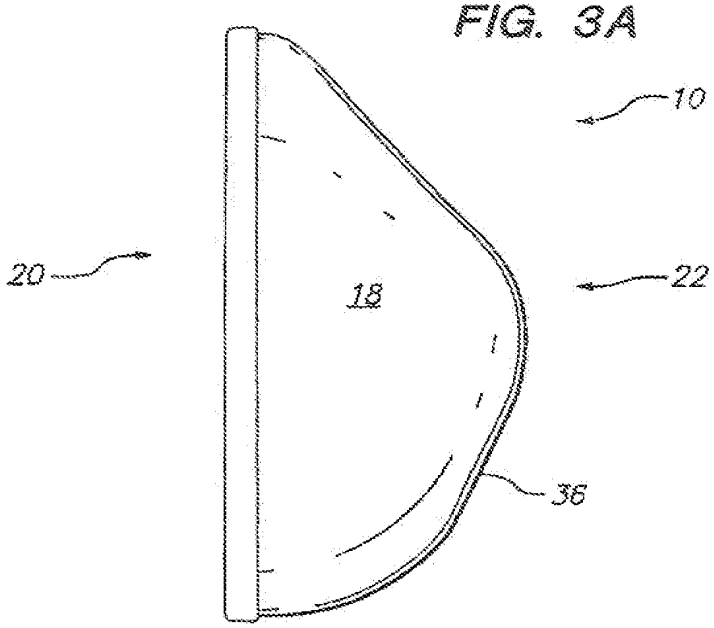


FIG. 3B

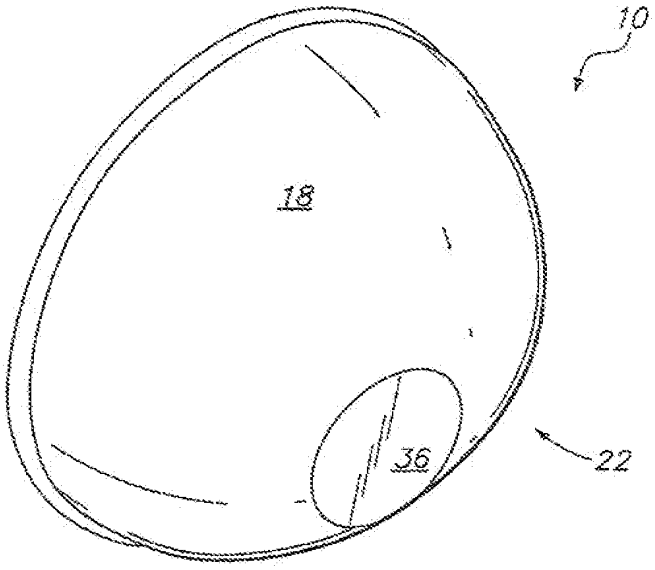


FIG. 4

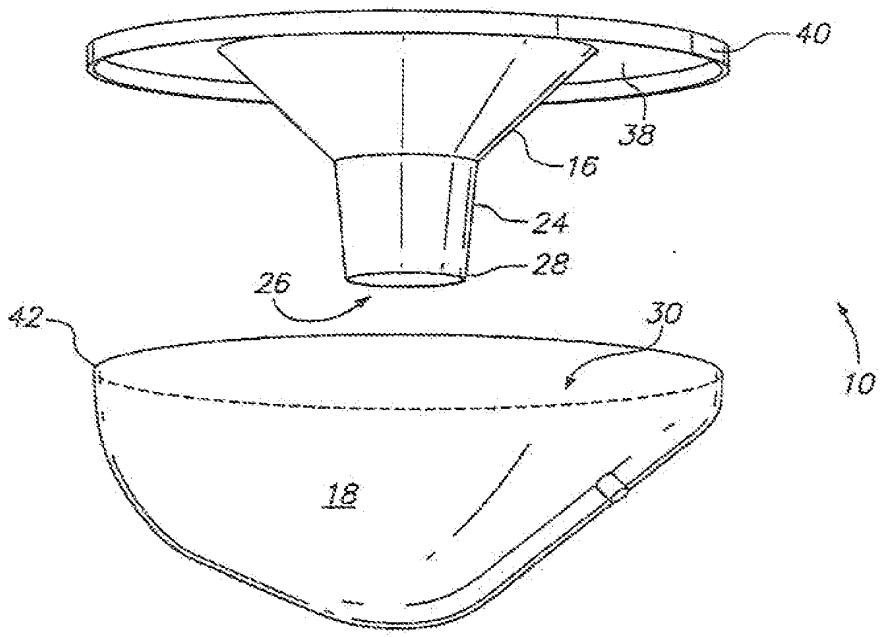


FIG. 5A

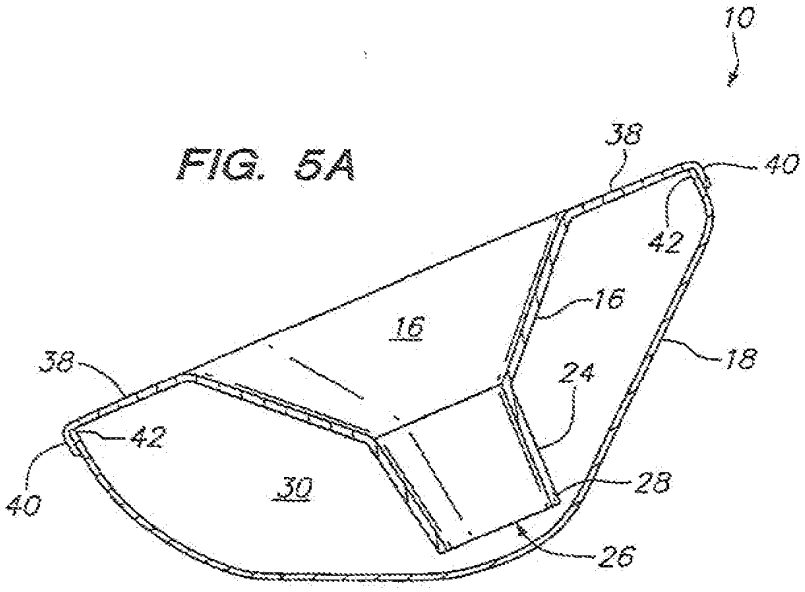


FIG. 5B

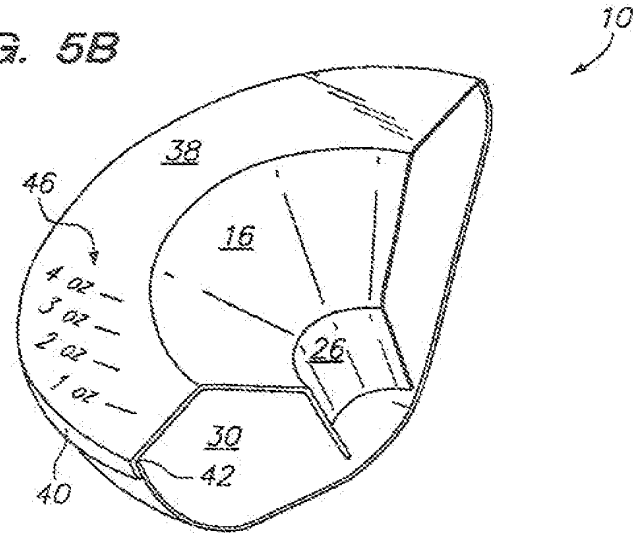


FIG. 5C

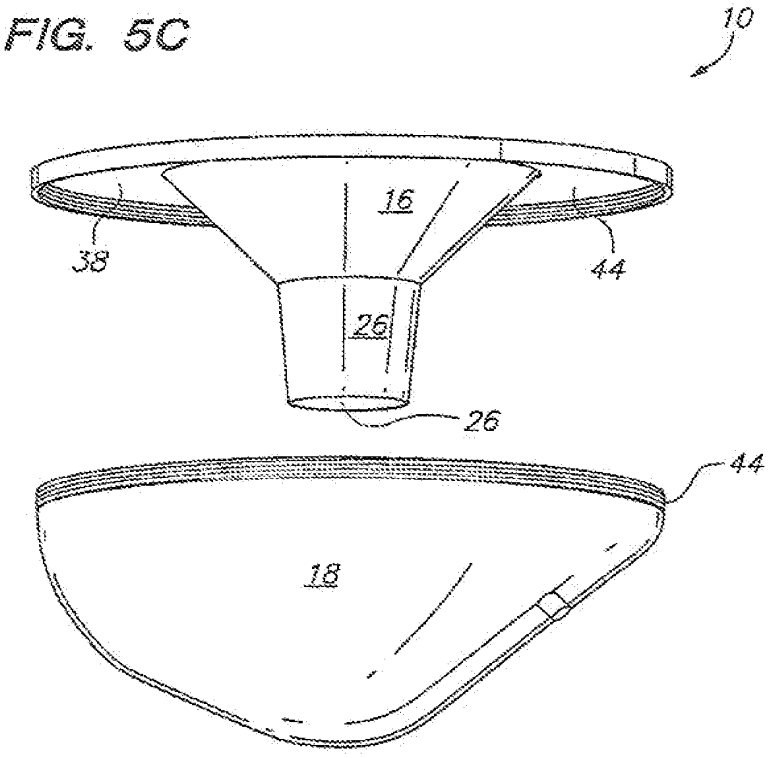


FIG. 6

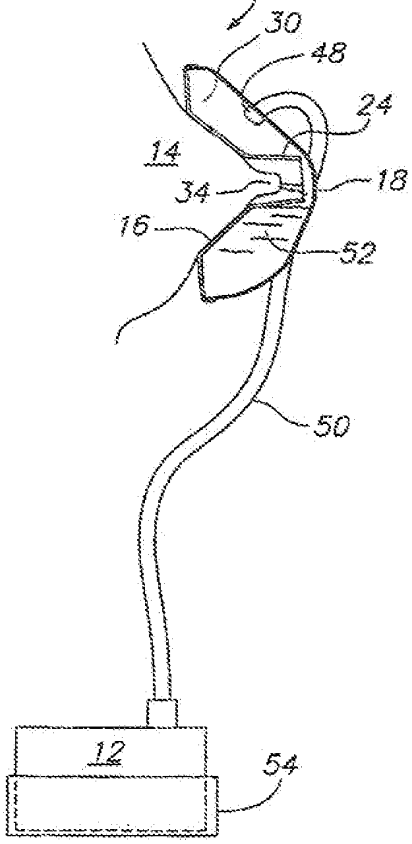


FIG. 7

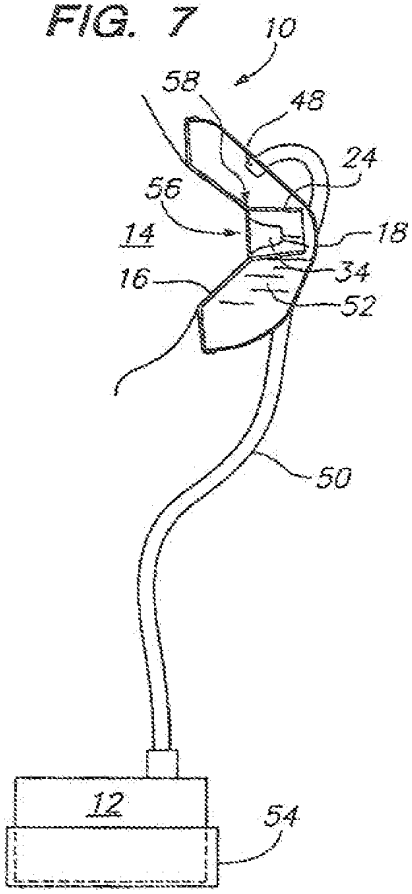


FIG. 8

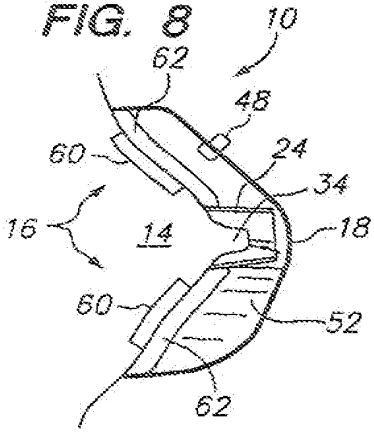


FIG. 9

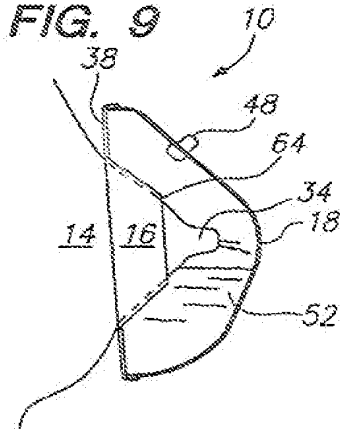


FIG. 10A

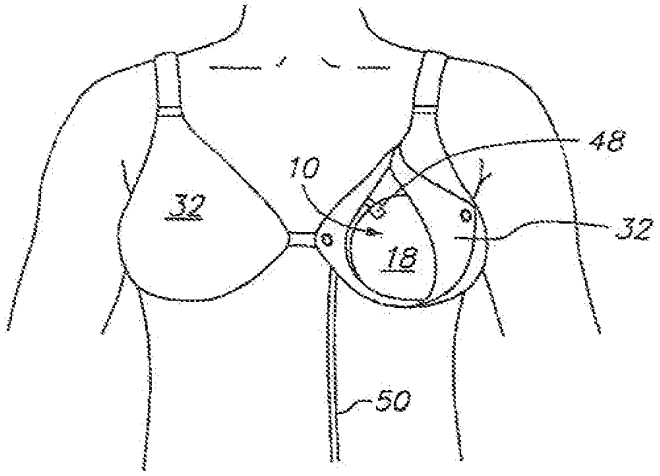


FIG. 10B

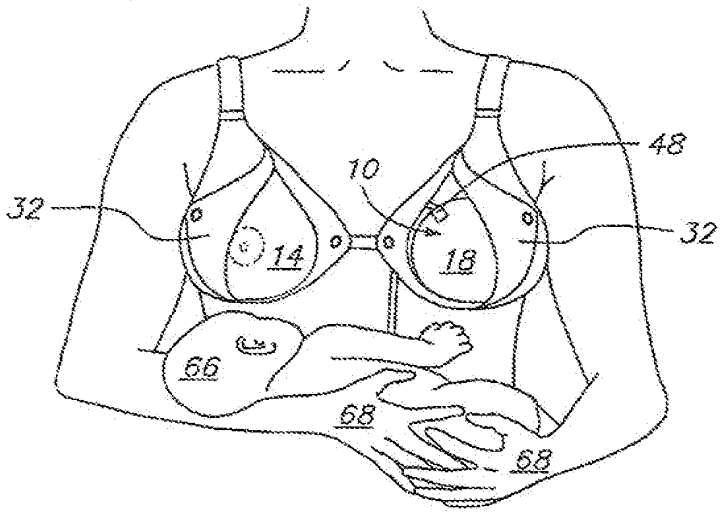


FIG. 11A

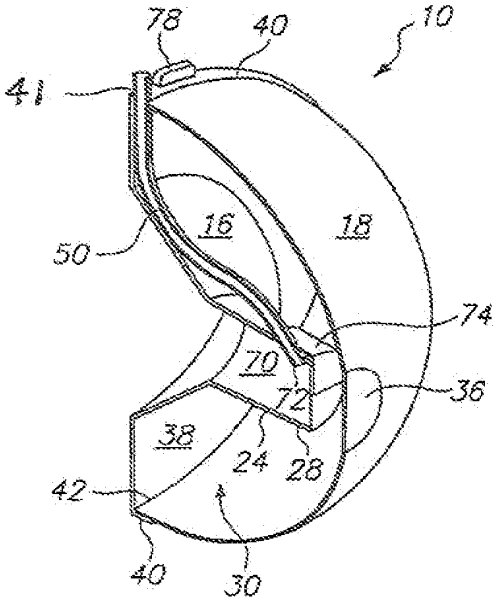


FIG. 11B

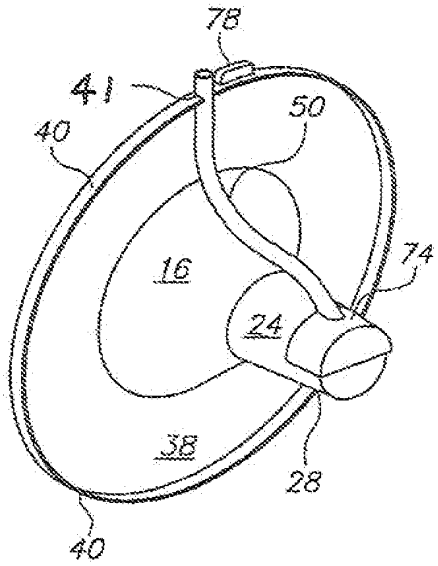


FIG. 11C

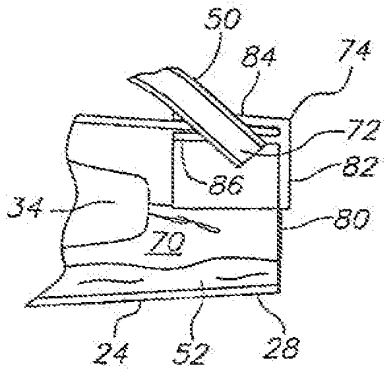


FIG. 11D

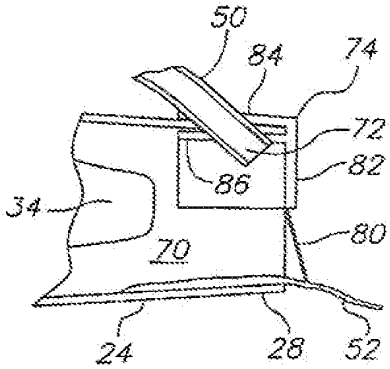


FIG. 11E

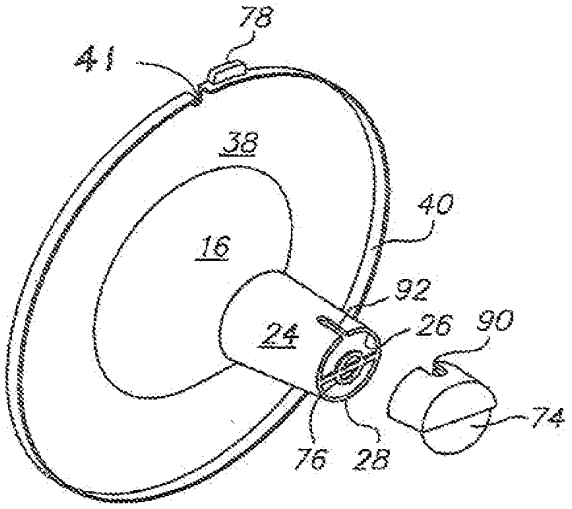


FIG. 11F

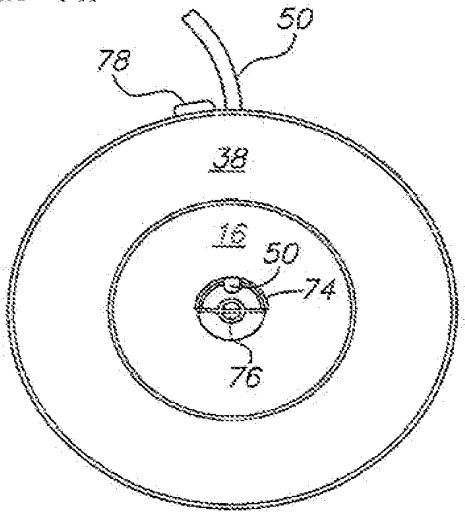


FIG. 11G

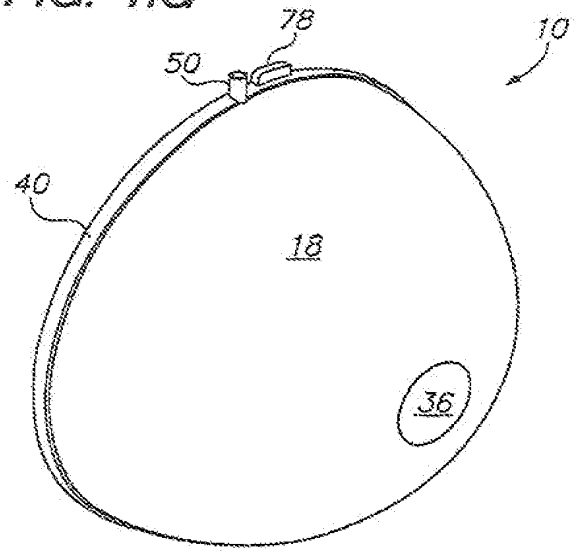


FIG. 12A

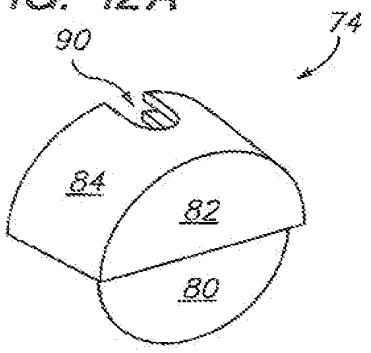


FIG. 12B

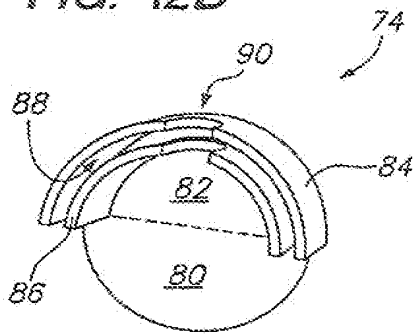


FIG. 13A

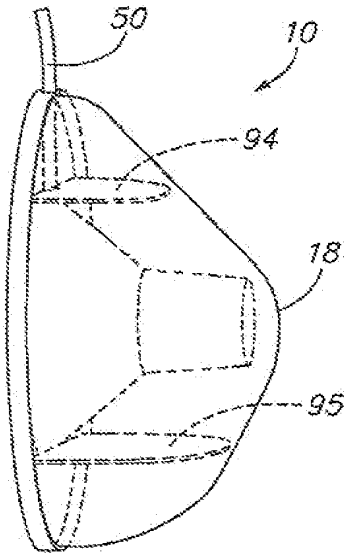


FIG. 13B

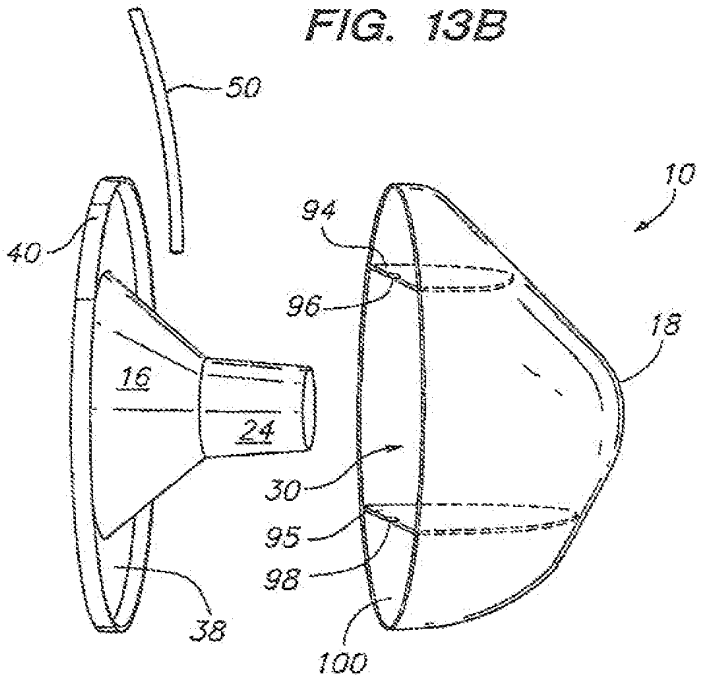


FIG. 14

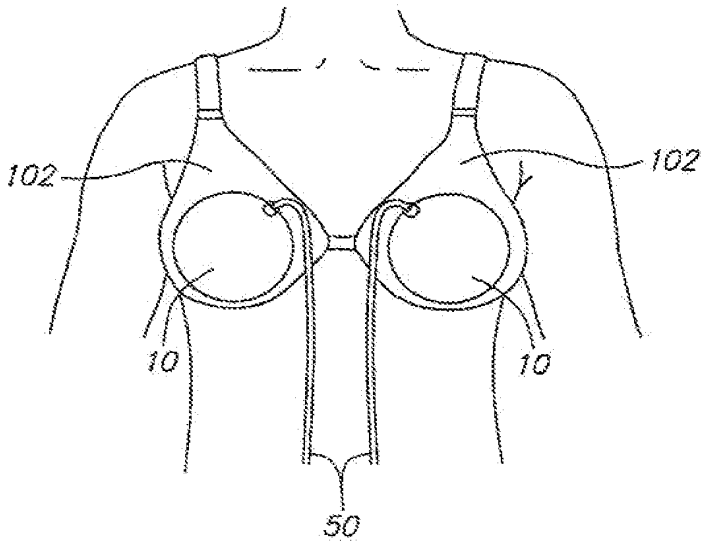


Fig. 15

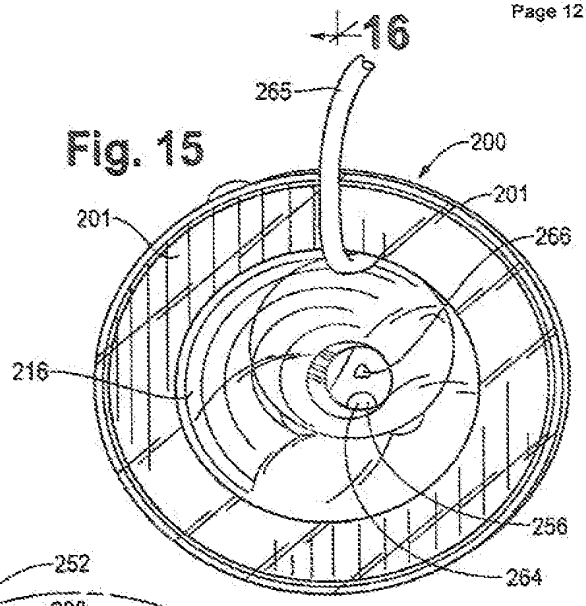
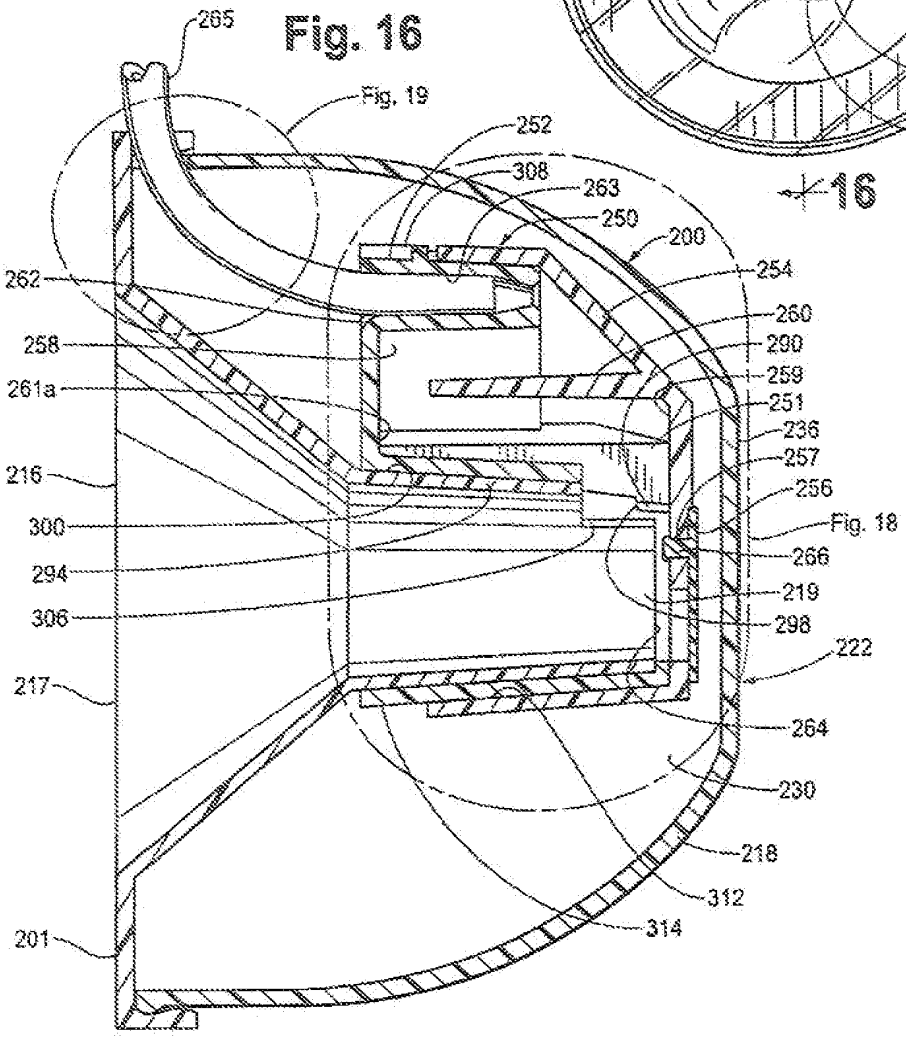

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Fig. 16


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Fig. 19
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Fig. 18
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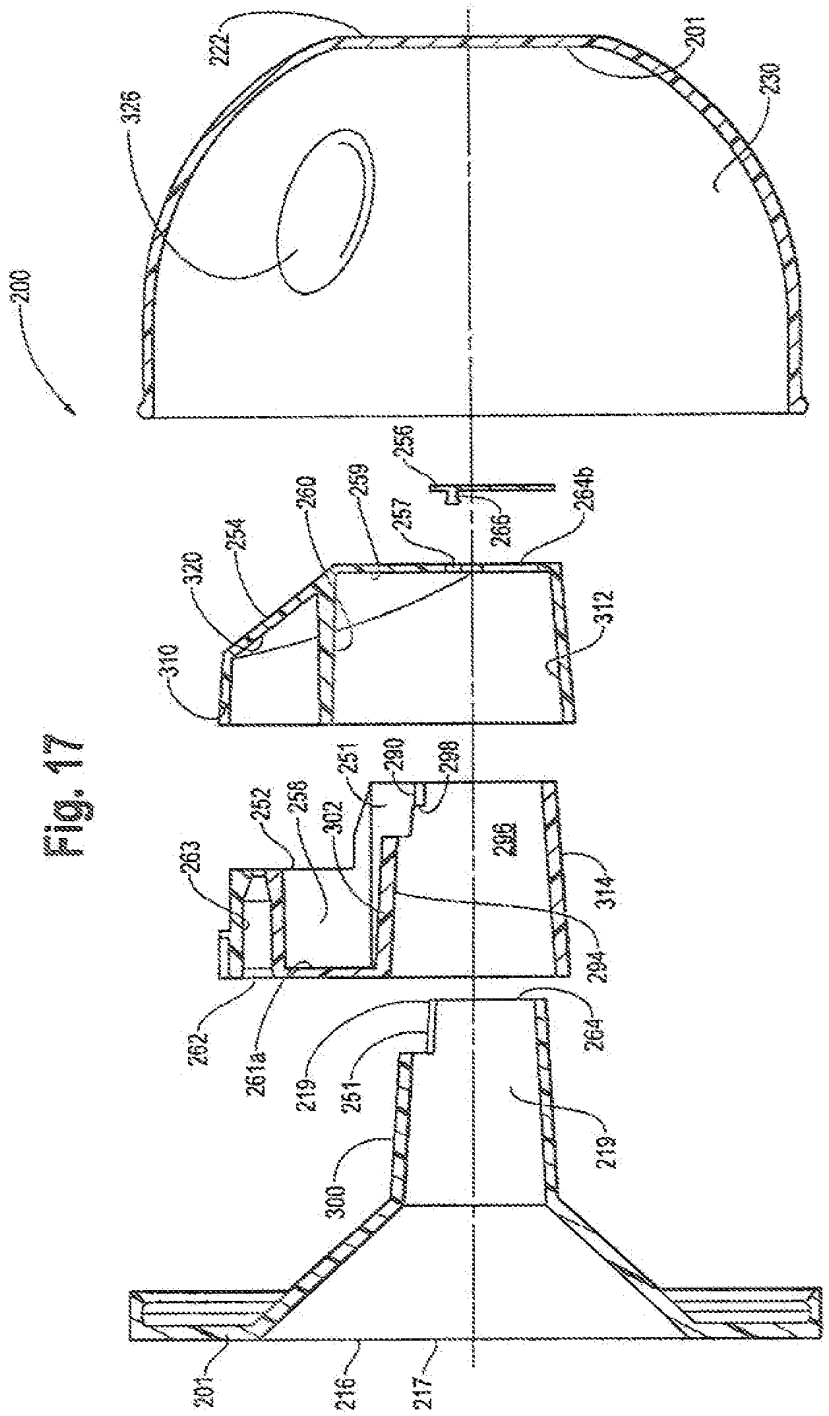

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Fig. 17

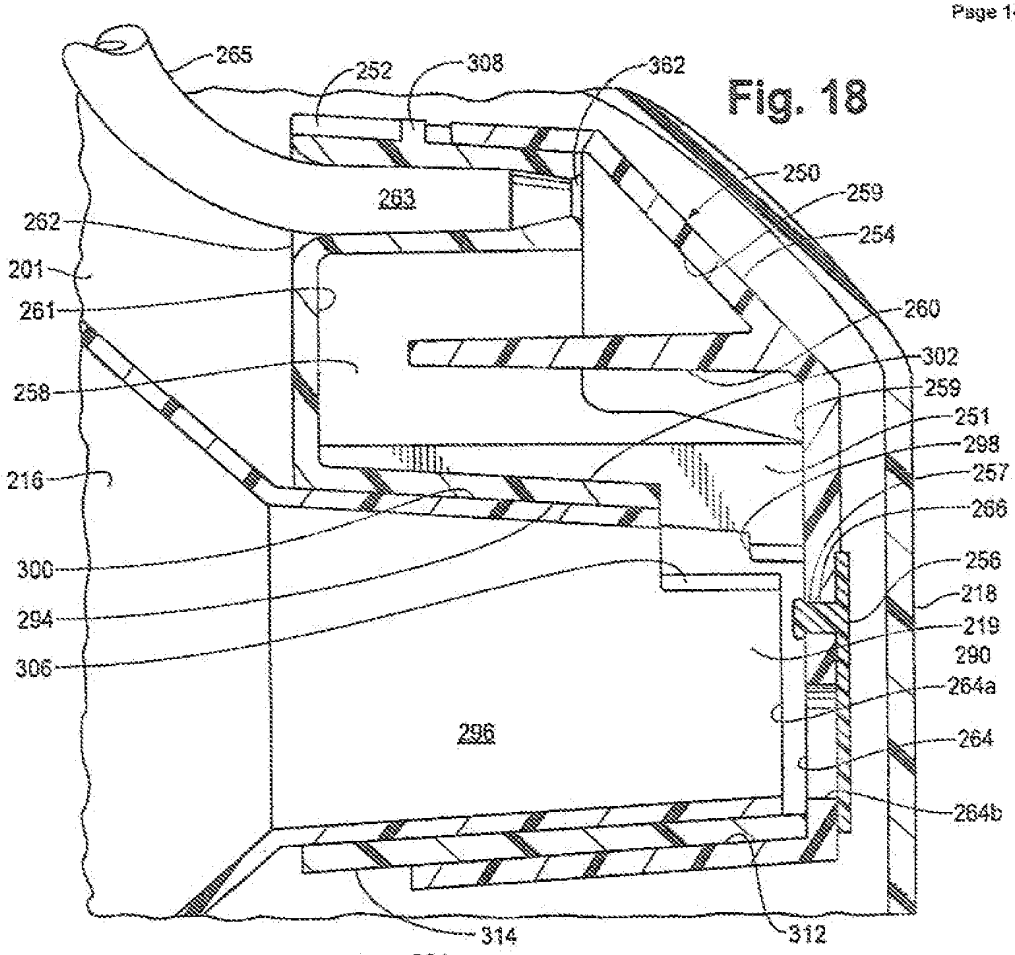

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Fig. 18

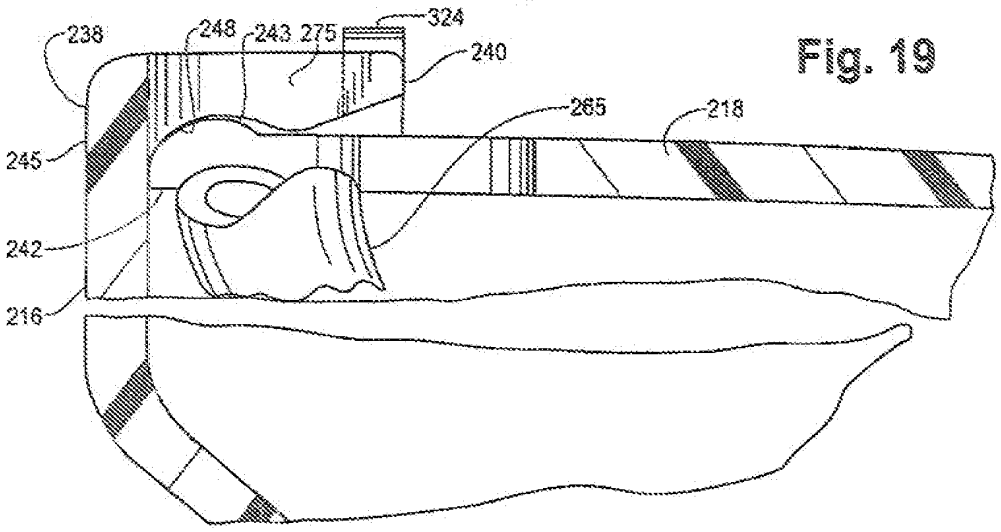

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Fig. 19

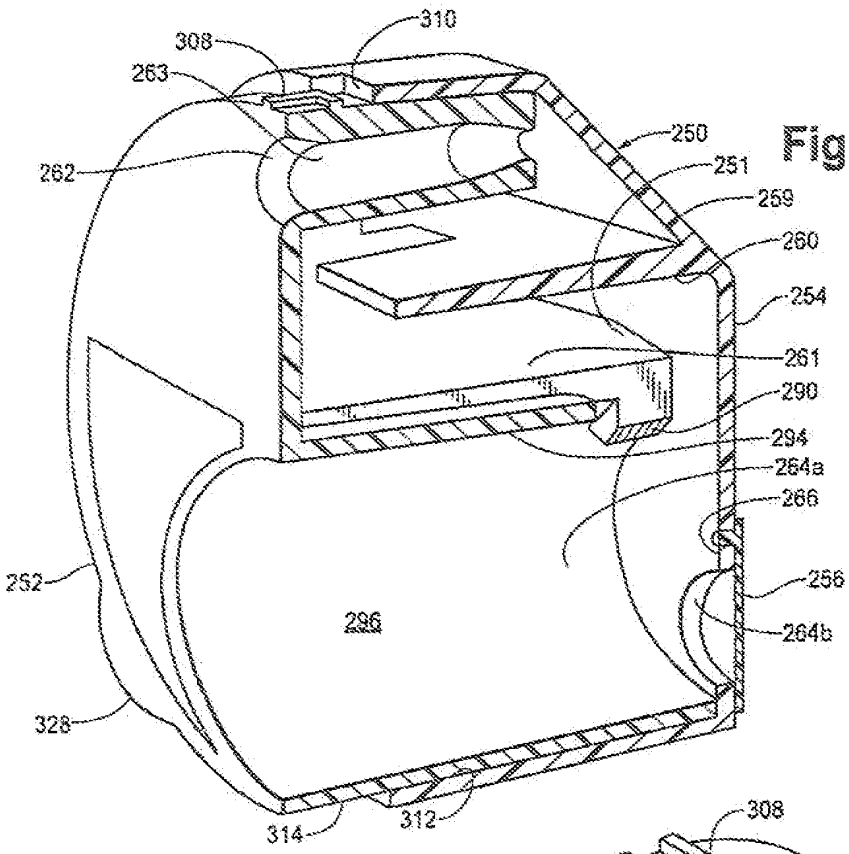

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Fig. 20

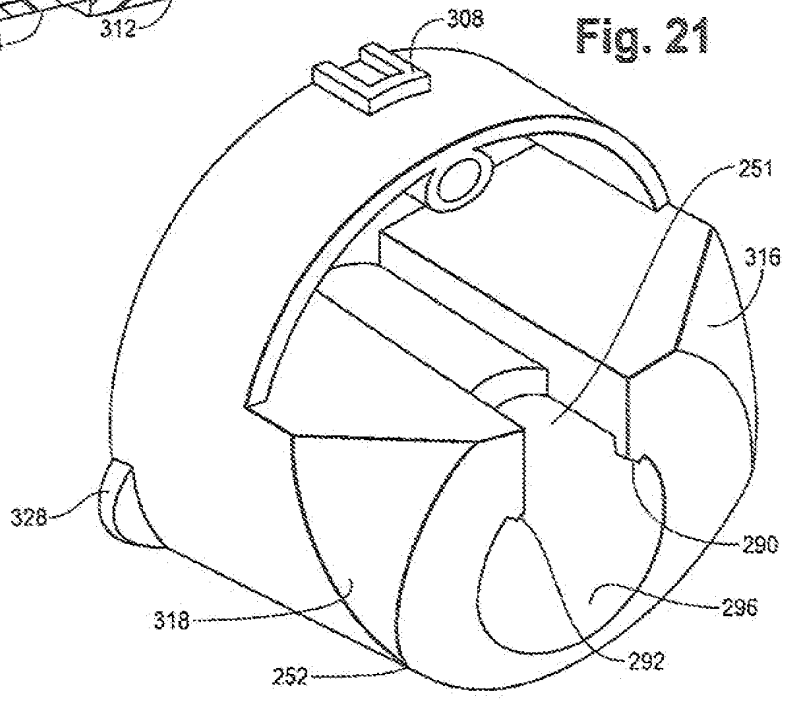

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Fig. 21

Fig. 21A

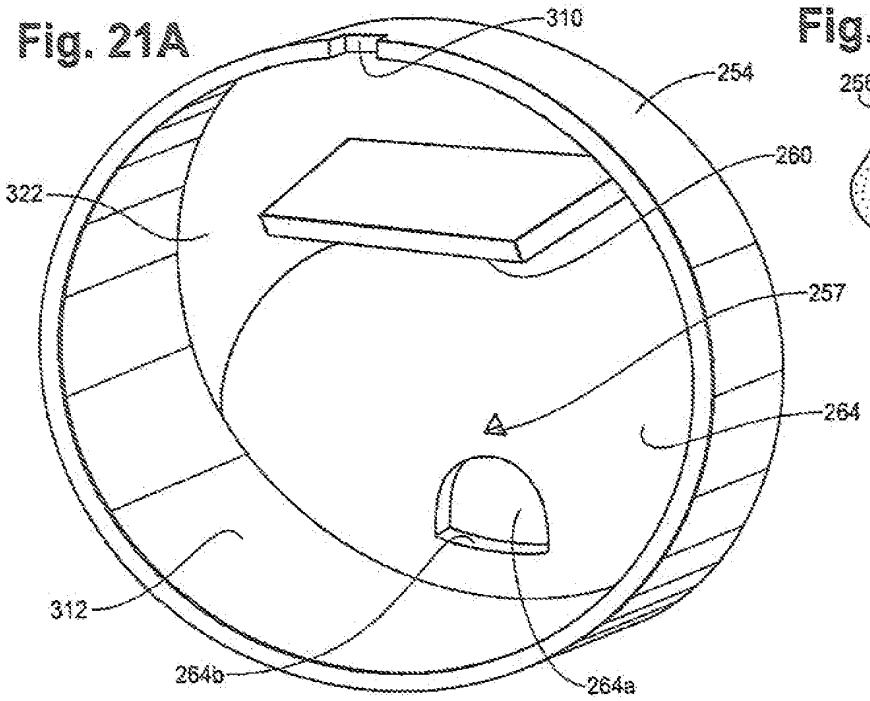


Fig. 21B

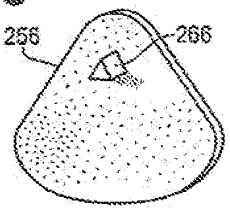


Fig. 22

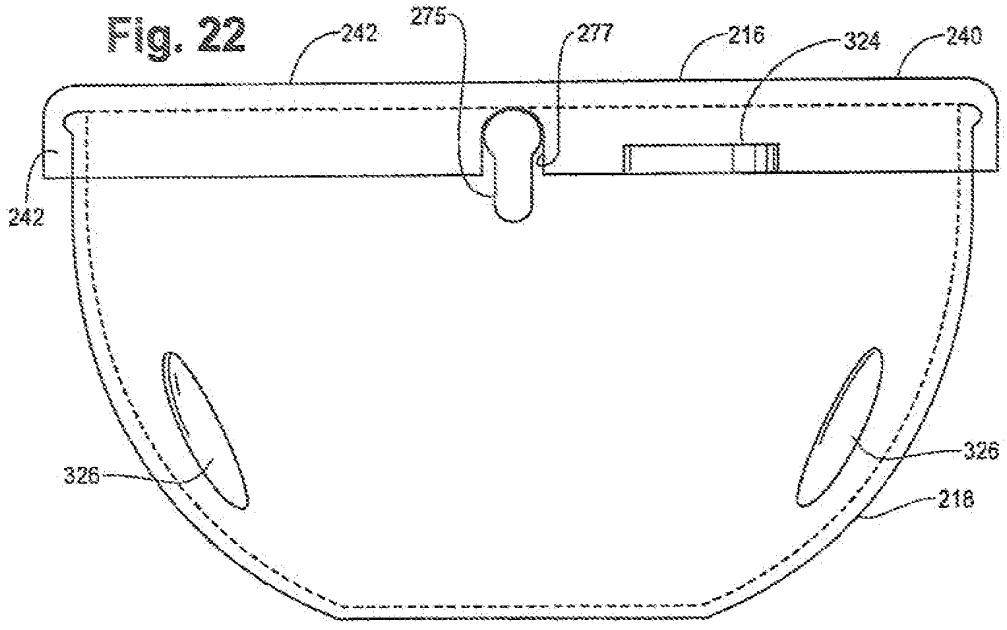


Fig. 23

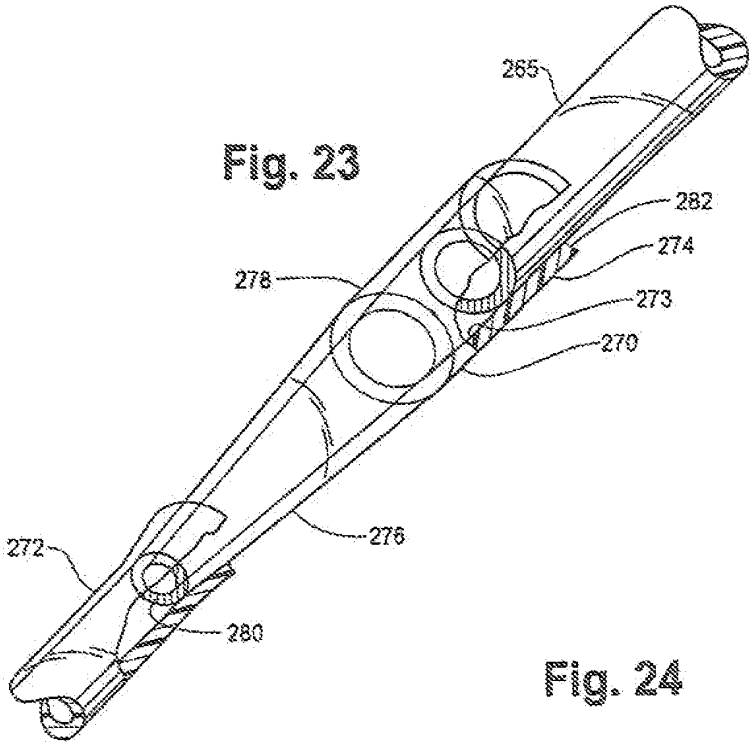
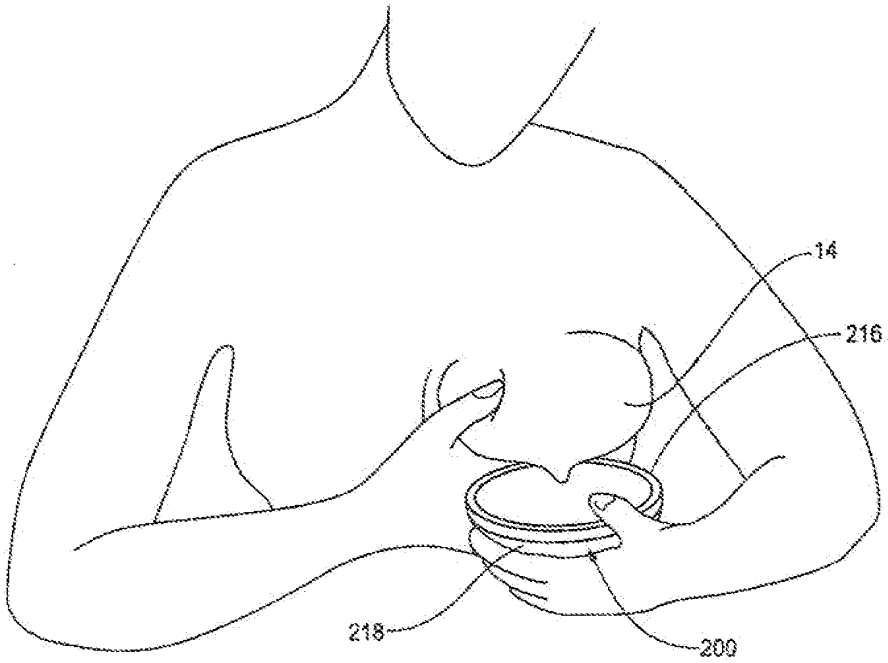


Fig. 24



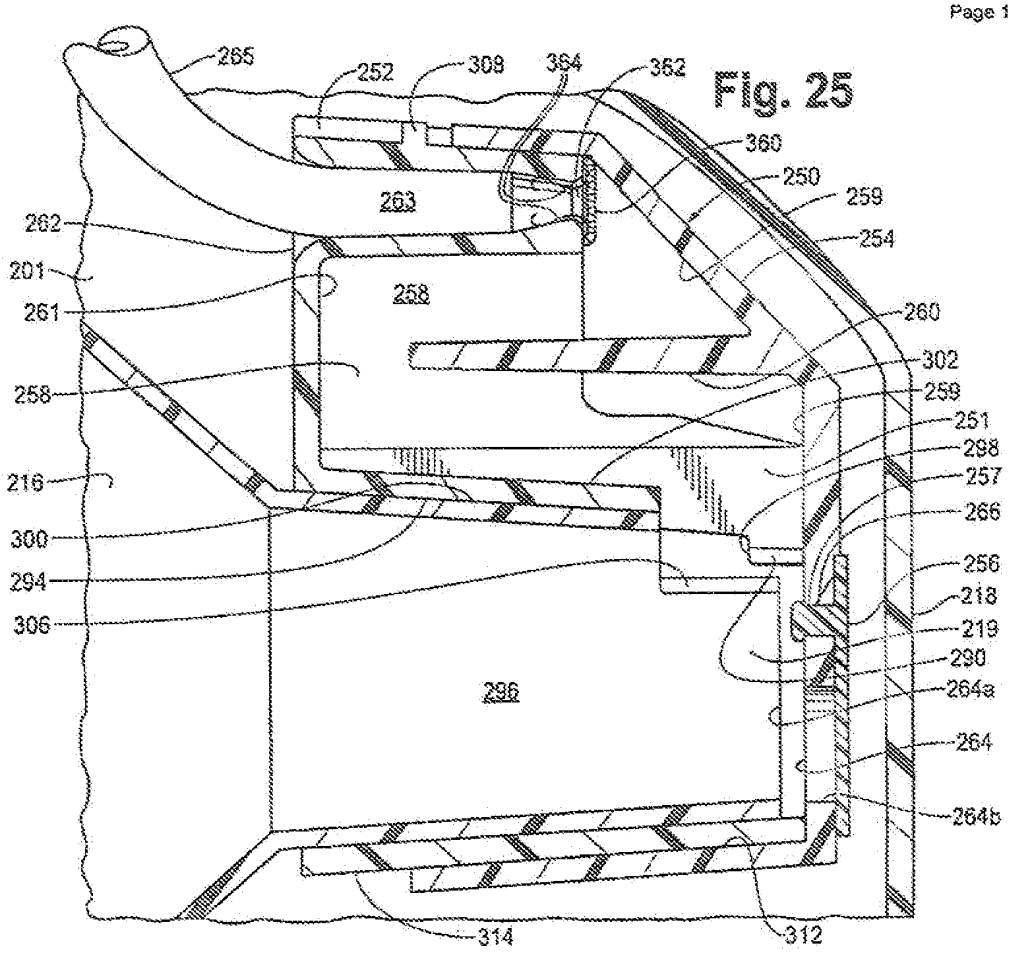

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Fig. 25

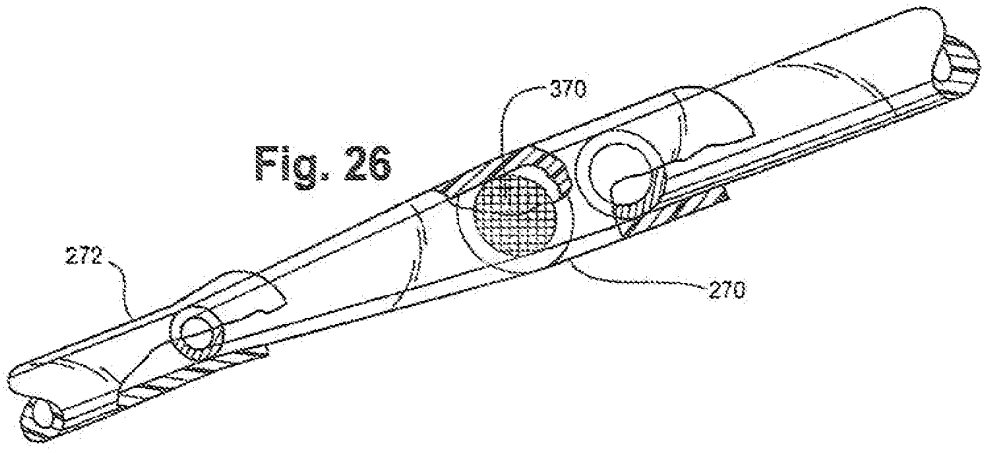
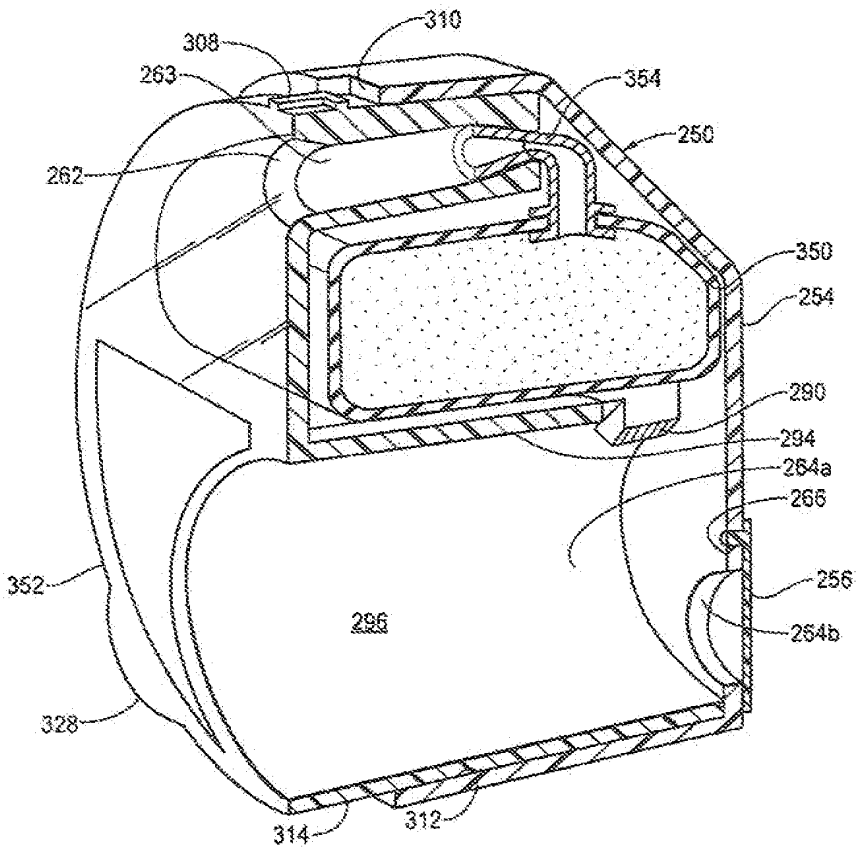

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Fig. 26

Fig. 27


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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/063362

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2008.04)
USPC - 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 1/06 (2008.04)
USPC - 604/74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2,138,686 A (GANNON et al) 31 October 1984 (31.10.1984) entire document	1-4, 7-9
Y	US 2003/0167037 A1 (FIALKOFF) 04 September 2003 (04.09.2003) entire document	1-4, 7-9, 10-18, 20-27
Y	US 5,071,403 A (LARSSON) 10 December 1991 (10.12.1991) entire document	10-18, 20-27
Y	US 5,571,084 A (PALMER) 05 November 1996 (05.11.1996) entire document	10-18, 20-27
Y	US 5,954,690 A (LARSSON) 21 September 1999 (21.09.1999) entire document	11, 17, 18
Y	US 2003/0191433 A1 (PRENTISS) 09 October 2003 (09.10.2003) entire document	20, 23
Y	US 6,379,327 B2 (LUNDY) 30 April 2002 (30.04.2002) entire document	20, 23
Y	US 4,582,073 A (SIMKANICH) 15 April 1986 (15.04.1986) entire document	21
Y	US 4,425,935 A (GONZALEZ) 17 January 1984 (17.01.1984) entire document	25, 26

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2008	06 OCT 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/063362

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5, 6, 28
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 436 277 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
04.04.2012 Bulletin 2012/14

(51) Int Cl.:
A41C 3/04 *(2006.01)*

(21) Application number: **10251682.0**

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Designated Extension States:
BA ME RS

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Alban Patent Agency
The Old Pump House
1a Stonecross
St. Albans
Hertfordshire AL1 4AA (GB)

(54) Maternity brassieres

(57) The present invention provides a brassiere comprising one or a pair of breast supporting cups and of the type where at least one of the breast-supporting cups has a frontal opening (5) to expose the breast, the breast-supporting cup comprising a panel/flap (2A) that covers the opening and a part of which is releasably attachable to the shoulder strap (3) of the brassiere when closing the opening and so that on release the opening may be uncovered, wherein the means by which the panel/flap (2A) is releasably attachable to the shoulder strap comprises a clasp (8) on the shoulder strap (3) that is movable up and down the shoulder strap (3) to a selected position and having a clamping part (8B) so that it may be clamped at the selected position, thereby providing adjustment of the breast-supporting cup, the clasp (8) incorporating co-operative engagement means (6,7) thereon for the releasable attachment of the panell flap (2A).

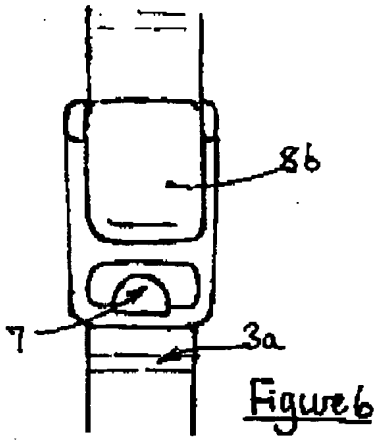
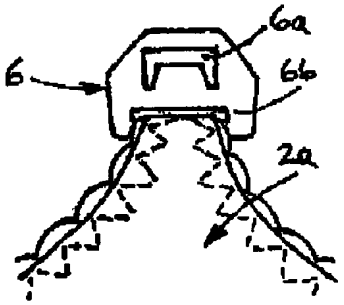


Figure 6



EP 2 436 277 A1

Description

Field of the-Invention

[0001] The present invention concerns improvements in and relating to brassieres of the type where the cups are openable such as in maternity and nursing brassieres or medical brassieres.

Background to the Invention

[0002] Maternity, nursing and some pre/post-operative surgical! medical brassieres generally share the feature of having a central panel in one or both of the brassiere cups that is in the form of a flap that may be peeled back at an edge to expose the wearer's corresponding breast. For maternity and nursing brassieres this facilitates suckling of the infant and for surgical/ medical brassieres this facilitates treatment of the breast whether preceding or following biopsy, partial mastectomy or other procedure.

[0003] In maternity brassieres simple clips have been used for many years to detachably secure the apex/ leading edge of the panel closed. These clips are generally of hook and eye type with a hook at the apex of the panel to engage in an eye on the bra's shoulder strap. A problem common to the majority of such brassieres is that they do not have flexibility to accommodate for the substantial changes in breast size and shape that occur in lactating mothers or as a result of surgery or other breast tissue damage/ trauma. In mothers who breastfeed their babies the breast expands substantially when full with milk, swelling to even go up a whole cup size, and then shrinking again once the mother has fed her baby. In essence half of the time these mothers are wearing the wrong cup size of bra - either the bra is too big or too small, since there is no way to adjust the size of the cups.

[0004] Proposals have been made in the past to try to address this problem, including multi-point fastening arrangements as set out in US patents numbers US 2,317,664 and US 4,390,024. Each of these patents proposes use of several eyes arranged in a line up the shoulder strap of the brassiere to be electively engaged by a hook at the apex of the central panel/ flap. The choice of eye gives the user the ability to raise or lower the point at which the apex of the flap is secured to the strap and hence adjusts for enlargement or diminution of the breast. The perimeter of the cups in US 4,390,024 is defined by wide stretchable bands to give greater elastic accommodation for the flux in breast size.

[0005] It is an objective of the present invention to provide an improved brassiere of the type where the cups are openable/ adjustable and which substantially alleviates the problems of fluctuating breast size. It is a further object to provide a brassiere which gives the user control over adjustment for fluctuating breast size independently of attaching the opening flap/ panel of the brassiere cup to the brassiere shoulder strap. It is a further object to provide a brassiere which gives the user a relatively fine control over adjustment. The improved brassiere is to have an adjust-to-fit component to raise the bra cup up and down the bra strap and which may provide a better quality, continually supportive, and more comfortable maternity bra to the market.

Summary of the Invention

[0006] According to a first aspect of the present invention there is provided a brassiere comprising one or a pair of breast supporting cups and of the type where at least one of the breast-supporting cups has a frontal opening to expose the breast, the breast-supporting cup comprising a panel/flap that covers the opening and a part of which is releasably attachable to the shoulder strap of the brassiere to support the breast-supporting cup and so that on release the opening may be uncovered, characterized in that the means by which the panei/ fiap is releasable attachable to the shoulder strap comprises a clasp on the shoulder strap that is movable up and down the shoulder strap to a selected position and having a clamping part so that it may be clamped at the selected position, thereby providing adjustment of the breast-supporting cup, the clasp incorporating co-operative engagement means thereon for the releasable attachment of the panel/ flap.

[0007] Preferably the shoulder strap has a plurality of transverse ribs thereon each serving as an abutment on the shoulder strap for the clamping part of the clasp to stop against

[0008] Suitably the co-operative engagement means on the clasp comprises a hook and the cup panel/flap has a tab with an aperture to engage with the hook.

[0009] The brassieres allows the user to raise the bra cup up and down the bra strap and provides a better quality, continually supportive, and more comfortable maternity bra. Moreover it gives the user control over adjustment for fluctuating breast size independently of attaching the opening flap/ panel of the brassiere cup to the brassiere shoulder strap and the user can have a much finer control over adjustment than is afforded by the prior art.

[0010] The brassieres may riot only be used by nursing mothers. For medical brassieres the adjustment of the present invention is useful since after any breast surgery the straps can be adjusted to allow for any post surgery swelling and the cups can be adjusted individually. Therefore, if only one breast is operated on both breasts can be perfectly supported even if they are of different sizes due to removal of tissue or due to swelling.

Brief Description of the Drawing

[0011] A preferred embodiment of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a front elevation view of a brassiere embodying the invention and **Figure 2** is a corresponding view showing the panel/ flap of the left cup of the brassiere hanging down for exposure of the breast;

Figure 3 is a front elevation view of the clasp showing the clasp in the closed state and, below the clasp, the co-operating eye tab that fits on the apex of the flap/panel;

Figure 4 is a side elevation view of the clasp in part-opened state, the clasp being shown installed upon the lower front end of the bra's shoulder strap and Figure 5 is a corresponding view of the clasp in fully opened state and shifted one 'rung' down the shoulder strap;

Figure 6 is a front elevation view of the shut state of the clasp installed on the shoulder strap and, below the clasp, the co-operating eye tab is shown installed on the apex of the flap/panel being brought up to the hook on the clasp to be hooked in place;

Figure 7 is a side elevation view of the Figure 6 arrangement;

Figure 8 is a front elevation view of the clasp installed on the shoulder strap and with the co-operating eye tab hooked onto the hook of the clasp, the clasp being open for upward or downward adjustment of the clasp's position on the shoulder strap; and

Figure 9 is a side elevation view of the Figure 8 arrangement but with the clasp shut to lock it at its selected position on the strap.

Description of the Preferred Embodiment

[0012] Referring to Figures 1 and 2, these show a maternity brassiere 1 with its characteristic fold-down central panels/ flaps 2a at the front of the cups 2.

[0013] The panels 2a have an approximately triangular form and when they are in the closed state the apex of each triangle is uppermost and detachably fastens to the lower end of the front length of a respective one of the shoulder straps 3 of the brassiere 1. The perimeter of each cup 2 is defined by bands 4 of a material that suitably is an elasticated fabric that can adjust somewhat to breast size fluctuation and the bands 4 of each cup form an aperture/opening 5 at the centre that exposes the underlying wearer's breast for breast-fieeding. The central cup openings 5 are covered over by the central panel flap 2a until access is needed for breast-feeding at which point the panel 2a apex is detached from the shoulder strap 3 and the flap is folded down as shown on the right of Figure 2.

[0014] The releasable attachment of the central panel/ flap 2a to the shoulder strap 3 has a unique arrangement. The apex of each central panel/ flap 2a carries a tab 6, suitably of moulded plastics or of metal, which incorporates an eyehole 6a. A second aperture 6b in the tab 6 receives a length of the fabric of the panel/flap 2a passing through it and looped and stitched to secure the tab 6 on the panel/flap 2a. The eyehole 6a of the tab 6 is designed to oo-operatively engage in use with a corresponding hook formation 7 that is formed on the lower front end of a clasp structure 8 that is mounted on the brassiere strap 3.

[0015] The clasp structure 8 is adapted to have one of the brassiere's shoulder straps 3 passing through it and to be moved up and down the shoulder strap 3 with the clasp in its opened state and secured to the strap 3 at a selected location by closing of the clasp 8. The clasp structure 8 is suitably of moulded plastics or of metal and has a body part Be that fits on and is movable up and down the shoulder strap 3 and a clamp part 8b with teeth 8d, the damp part 8b being pivotally mounted 8c to the body part 8a to pivot between open and closed states to bite into and lock on the strap 3 when the chosen position on the strap 3 has been selected.

[0016] The teeth 8d of the clasp structure 8 effectively close down on the strap 3 behind one of a number of ribs 3a that are provided on the strap 3. The ribs 3a are in the region of the strap 3 where the apex of the flap is to attach and the ribs 3a extend transversely of the longitudinal axis of the strap 3 and can be many and at very close-spaced intervals down the strap 3 to allow for a fine and extensive degree of control over the position of attachment and hence over cup-size adjustment.

[0017] The ribs 3a of the bra shoulder strap 3 may be formed by insertion of short lengths of wire in the strap or may be formed by stitching, folding or addition of other material to that area of the strap 3a. Although illustrated in the side elevation views as bulging to both front and rear of the strap 3, each rib 3a might suitably be provided bulging only forwardly/ in the direction facing the clamping part 8b of the clasp 3 so that the rear of the strap 3 is smooth, aiding upward and downward adjustment. Notably, the ribs 3a are generally of such small scale that they do not affect the wearer's comfort.

[0018] Referring to Figures 4 to 9, the clasp structure 8 may be adjusted to the desired position by the wearer independently of the step of hooking attachment of the central panel 2a and thus may be done before, during or after the central panel 2a is hooked to it. The clasp 8 installed on the bra shoulder strap 3 with the clamping part 8b raised, as in Figures 4 and 5, is able to be moved up and down to then be clamped at any chosen position. The step of hooking the eyelet 6a of the tab 6 at the apex of central panel 2a to the hook 7 on the clasp 8 is shown in Figures 7 to 9. For this the state of the clasp clamping part 8a does not matter and it may be in its raised/ opened state as in Figure 8 or lowered/ closed state as in Figure 9 while hooking to suit the wearer's preference in how they fit and adjust the brassiere cup.

Claims

1. A brassiere comprising one or a pair of breast supporting cups and of the type where at least one of the breast-supporting cups has a frontal opening to expose the breast, the breast-supporting cup comprising a panel/flap that covers the opening and a part of which is releasably attachable to the shoulder strap of the brassiere when closing the opening and so that on release the opening may be uncovered, **characterized in that** the means by which the panel/flap is releasably attachable to the shoulder strap comprises a clasp mounted on the shoulder strap with the strap extending through it and which is movable up and down the shoulder strap to any of a number of selected positions and having a clamping part so that it may be clamped at the selected position, thereby providing adjustment of the breast-supporting cup, the clasp incorporating co-operative engagement means thereon for the releasable attachment of the panel/ flap.

2. A brassiere as claimed in claim 1, wherein the shoulder strap has a plurality of transverse ribs thereon each serving as an abutment on the shoulder strap for the clamping part of the clasp to stop against.

3. A brassiere as claimed in claim 1 or 2. wherein the co-operative engagement means on the clasp comprises a hook and the panel/flap of the cup has a tab with an aperture to engage with the hook.

4. A brassiere as claimed in claim 3, wherein the tab has an aperture that receives material of the panel/flap therethrough to secure the tab to the panel/flap.

5. A brassiere as claimed in claim 2, wherein the ribs incorporate plastic or metal wire.

6. A brassiere as claimed in claim 2 or 5, wherein the ribs are provided on the front length of the strap at the lower end thereof.

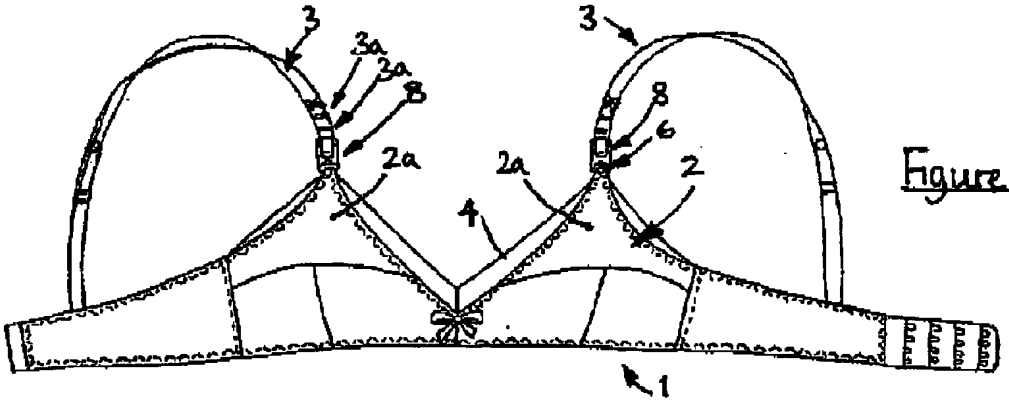


Figure 1

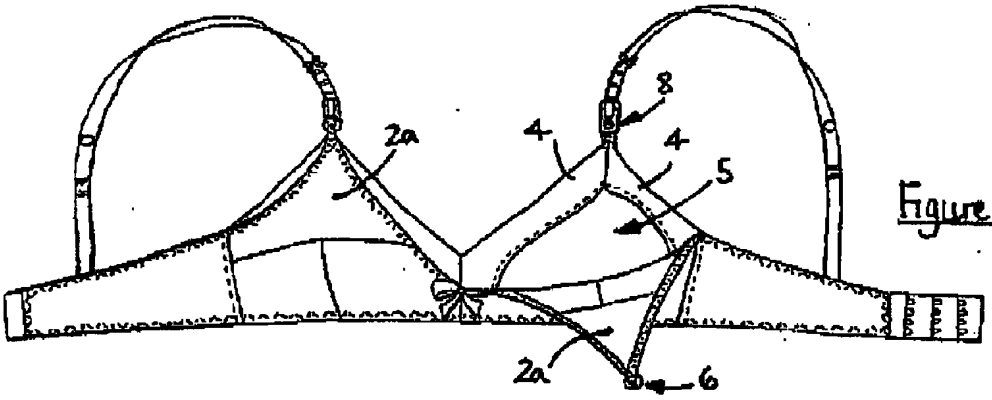


Figure 2

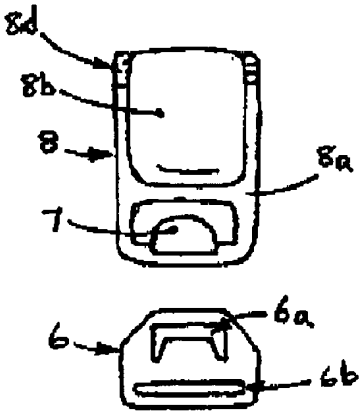


Figure 3

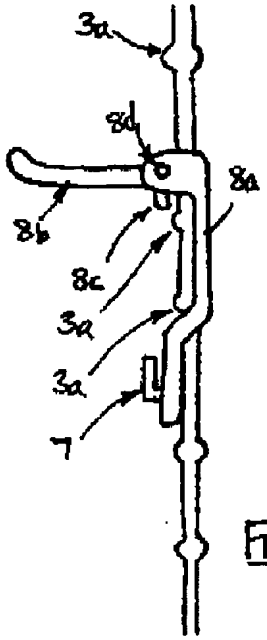


Figure 4

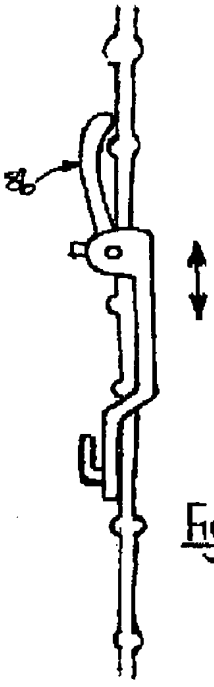


Figure 5

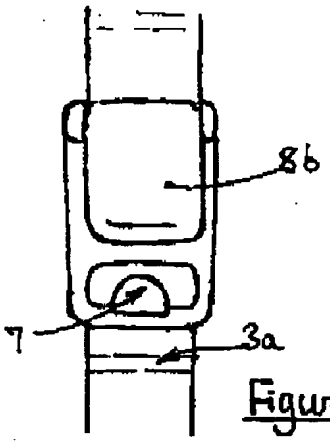
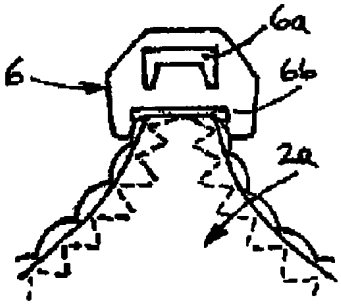


Figure 6



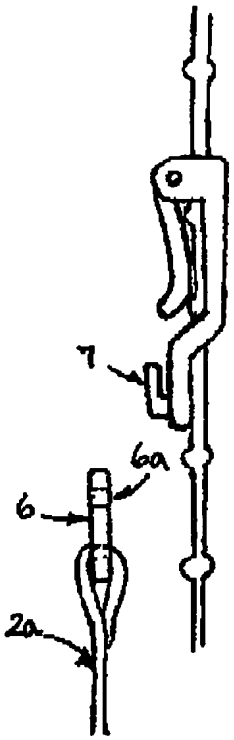


Figure 7

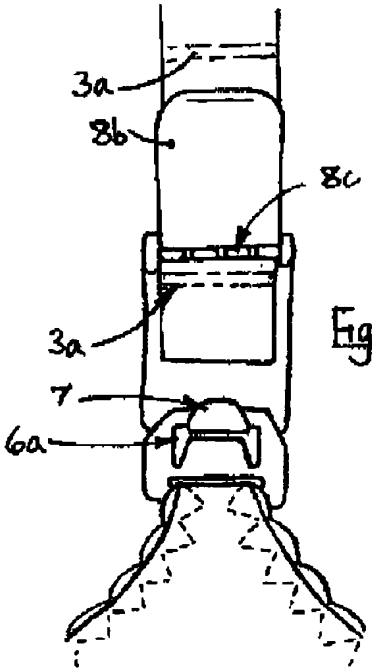


Figure 8

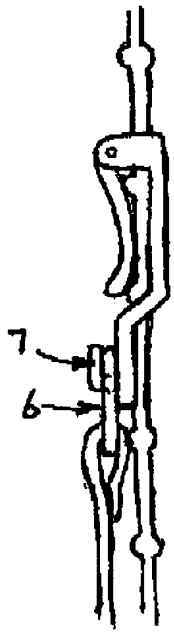


Figure 9

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European Patent Office
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EUROPEAN SEARCH REPORT

Application Number
EP 10 25 1682

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	WO 2008/051484 A2 (MEDELA HOLDING AG [CH]; SOLBERG JILL M [US]; LUZBETAK MARK A [US]; PFE) 2 May 2008 (2008-05-02) * page 4, lines 7-12 * * page 6, line 31 - page 8, line 23 * * page 11, lines 8-32; figures 2,3,5 *	1-6	INV. A41C3/04
A	DE 44 16 799 A1 (ANITA INTERNATIONAL DR HELBIG [DE] F & E GES FUER BEKLEIDUNGSINNO [DE]) 9 November 1995 (1995-11-09) * abstract; figures 1,2 *	1	
A	US 4 390 024 A (WILLIAMS MARGUERITE R [US]) 28 June 1983 (1983-06-28) * the whole document *	1	

TECHNICAL FIELDS SEARCHED (IPC)

A41C

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	16 February 2011	Monné, Eric

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 10 25 1682

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16-02-2011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008051484 A2	02-05-2008	AU 2007309553 A1	02-05-2008
		CA 2667220 A1	02-05-2008
		CN 101605473 A	16-12-2009
		EP 2076145 A2	08-07-2009
		JP 2010506668 T	04-03-2010
		KR 20090074773 A	07-07-2009
		US 2008146118 A1	19-06-2008
DE 4416799 A1	09-11-1995	AT 177913 T	15-04-1999
		EP 0681790 A1	15-11-1995
		US 5624296 A	29-04-1997
US 4390024 A	28-06-1983	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2317664 A **[0004]**
- US 4390024 A **[0004]**

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[Continued on next page]

(54) Title: BREAST PUMP CONTAINER ASSEMBLIES AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container assembly.

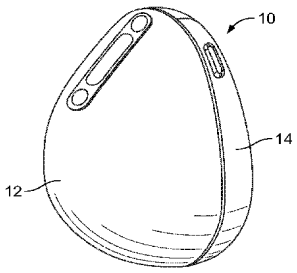


FIG. 1A

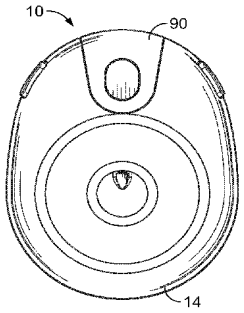


FIG. 1B

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

BREAST PUMP CONTAINER ASSEMBLIES AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to container assemblies for portable breast pump systems and methods for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, a number are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be inconvenient to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. Certain other of the breast pumps available are lacking in convenient storage containers. The storage containers can be difficult to package, install, remove and store thereby creating a barrier to effective use.

[0004] There is thus a continuing need for conveniently usable and effective container assemblies for portable wearable breast pump. The present disclosure addresses these and other needs.

SUMMARY OF THE DISCLOSURE

[0005] Briefly and in general terms, the present disclosure is directed toward container assemblies for a breast pump system. The system includes breast contacting structure and a storage container, and structure that delivers milk or other liquid from a breast to the storage container. The method involves pumping milk from a breast and delivering the pumped milk into the container assembly.

[0006] According to one aspect of the present disclosure, a system for pumping milk from a breast includes a container assembly in combination with one or more of: a skin contact member or flange configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; an external shell; and a non-transitory computer readable medium having stored thereon instructions executable by a computing device to cause the computing devices to perform functions associated with and directed by the firmware; wherein the external shell comprises a compartment facing a distal end of the external shell, the external shell further comprising a proximal end surface facing away from the proximal end; wherein the skin contact member, the conduit and the driving mechanism are received in the compartment of the external shell; wherein the milk collection container is positionable within the shell; and wherein the system is shaped and configured to be contoured to the breast of a user.

[0007] In various embodiments, the storage container can be specifically configured to prevent kinking and for durability and handling. A flow feature can be incorporated into the storage container, valves and materials can be chosen to facilitate removing air or gases, tabs and wings can be provided for handling, and structure adapted for the removal of milk from a container assembly. The container can be pre-formed to optimize or maximize space within a pump system. Further, the container can be placed into a flattened configuration to facilitate effective packaging.

[0008] In at least one embodiment, the flange or skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere.

[0009] In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit.

[0010] In at least one embodiment, the system further includes a milk collection container, wherein the milk collection container is in fluid communication with the conduit.

[0011] According to another aspect of the present disclosure, a method of operating a system for pumping milk into a storage container includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, and a controller configured to control operation of the driving mechanism; sealing the skin contact member to the breast; operating the driving mechanism to generate predetermined pressure cycles within the conduit; monitoring by the controller of at least one of position and speed of movement of the compression member relative to the conduit; measuring or calculating pressure within the conduit; maintaining or modifying motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0012] These and other features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the systems and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Fig. 1A shows a perspective view of a breast pump system according to an embodiment of the present disclosure.

[0014] Fig. 1B shows a rear view of the system of Fig. 1.

[0015] Fig. 2 is an exploded view of the system of Fig. 1, depicting mechanical components of the system.

[0016] Fig. 3 is a perspective view, depicting an approach to sealing the flange assembly.

[0017] Fig. 4 is an enlarged view, depicting a plug of the sealing approach of Fig. 3.

[0018] Fig. 5 is an enlarged view, depicting another approach to a plug;

[0019] Fig. 6 is an enlarged view, depicting yet another approach to a plug.

[0020] Fig. 7 is an enlarged view, depicting still yet another approach to a plug.

[0021] Figs. 8-10 show one approach to a container assembly arrangement.

[0022] Figs. 11A-D show various steps involved in installing a container assembly.

[0023] Figs. 12-14 show an alternative approach to a container assembly arrangement.

[0024] Figs. 15-16 show another alternative approach to a valve assembly arrangement.

[0025] Figs. 17-18 show a container assembly with yet another approach to a valve arrangement.

[0026] Fig. 19 shows another approach to a valve.

[0027] Fig. 20 shows still yet another approach to a valve arrangement.

[0028] Figs. 21 is a cutaway view, showing a further approach to a container assembly.

[0029] Fig. 22 shows yet another further approach to a container assembly with pouring structure.

[0030] Fig. 23 shows one approach to storing and structure for dispensing a container assembly.

[0031] Fig. 24 shows another approach to storing and dispensing a container assembly.

[0032] Fig. 25 show yet another approach for storing a container assembly.

[0033] Fig. 26 shows a still further approach to storing and dispensing a container assembly.

[0034] Fig. 27 shows structure for packaging container assemblies.

[0035] Figs. 28A-B show alternative structure for packaging container assemblies.

[0036] Fig. 29 shows yet another alternative approach for packaging container assemblies.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0037] Before the present systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[0038] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[0039] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0040] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a sensor" includes a plurality of such sensors and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[0041] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. The dates of publication provided may be

different from the actual publication dates which may need to be independently confirmed.

[0042] Various details of the present system can be found in PCT Application Nos. PCT/US15/41257, PCT/US15/41271, PCT/US15/41277, and PCT/US15/41285 each filed 07/21/2015, and PCT/US15/50340 filed 09/16/2015, each of which are hereby incorporated herein, in their entireties, by reference thereto

[0043] Figs. 1A-B are perspective and back views of a breast pump system 10 according to an embodiment of the present disclosure. The breast pump system 10 can include one or more of the below introduced or described features or functions, or a combination thereof. The housing or outer shell 12 of system 10 can be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. An opposite side of the pump system 10 is configured with a flange 14 which is sized and shaped to engage a breast of a user. The flange 14 is contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue.

[0044] Figure 2 depicts an exploded view of structural and mechanical components of the system 10. A housing overmold 61 shaped and sized to overlay the housing 12 is provided and can include a pattern of swirling lines that define a pleasing ornamental appearance to the system 10. Configured between the housing 12 and flange 14 is the chassis 35. Notably, the chassis can be configured to snap into engagement with the housing 12. Moreover, in a preferred embodiment, the chassis 35 supports directly or indirectly all of the pump components. In particular, a PCB controller mount 63 is supported by the chassis 35 and is configured to be connected to and support a circuit

board (not shown). A battery bracket 64 is also supported by the chassis 35 and is sized and shaped to receive a rechargeable battery assembly that powers the system 10. A cover jack 65 is further included to provide access to the battery assembly and for accepting a power cord connector (not shown). Motor mounting 66 and motor receiver structure 67 is also supported by the chassis 35 and are configured to receive and support the system motor which is powered by the battery and which functions to move actuators operating on the flex conduit or tube 32. Also supported by the chassis 35 are an actuator bracket 69, and a load cell bracket 70 and load cell receiver 71. Moreover, user interface panel can include a button membrane 72 and a button membrane housing 73 each supported on the housing 12 that provides the user with system control.

[0045] In order to connect the flex conduit or tube assembly 32 to the system 10, there are provided a flex conduit or tube ring 80 and a flex conduit or tube collar 82. The flex conduit or tube collar 82 is sized and shaped to be received into a pair of spaced snap buttons 84. In one specific embodiment, a fluid container fitment 86 (shown in isolation from the container) can be sized and shaped to be received into the flex conduit or tube collar 82. A door assembly 90 is attached to the flange 14 and configured to swing open and closed to both provide access to an interior of the system 10 as well as to support a robust connection between the fitment 86 and flex conduit or tube collar 82 as described in more detail below.

[0046] As shown in Fig. 3 where the flange 14 is shown as transparent, the system 10 can include additional structure to prohibit residual milk from spilling out from the flange 14 after completion of a pumping session or during a break in pumping. The flex conduit or tube 32 and flange 14 can retain residual milk that might spill when removing the pump system 10 from the breast or when the pump system is placed in a purse or elsewhere for temporary storage. That is, residual milk can spill out of the nipple receiving portion 101 of the flange 14. A plug 102 (See also Fig. 4) can be sized and shaped to be sealingly retained within the nipple receiving portion 101 to prohibit residual milk from exiting the system 10 through the flange 14. The plug 102 can include a handle 104 assuming various shapes such as a ball tip for grasping, and a body that is tapered and defines a generally circular shape in cross-section. In this way, the plug 102 can both sealingly engage with the nipple receiving portion 101 as

well as be conveniently handled.

[0047] In alternative approaches to the plug 102, there can also be included one or more annular rings 106 configured about the body of the plug to facilitate sealing of the plug 102 with the nipple receiving portion 101 of the flange 14 (Fig. 5). The plug 102 can also lack the handle portion (Fig. 6) and have a body shaped like a cork, or include a tapering handle 108 with an asymmetric thumb receiving indent 110 for grasping (Fig. 7).

[0048] As described in connection with the embodiments presented below, the system 10 can be configured to pump into a sealed container assembly, or one that includes an integral valve or an otherwise airtight container assembly, or combinations thereof. In one or more approaches, the valve can be integrally formed with a bag assembly such that it is molded along with one or more sheets defining bag structure. Sealed and/or airtight containers can hold liquids and gases without permitting a leak. Gas or liquids can be removed from such containers through a valve that is configured to be opened or defeated temporarily or permanently. Alternatively, an opening separate from the valve can be provided in the container, or the container can be configured to be split open or include scoring to aid in opening the container. Moreover, there are contemplated a range of disposable and durable combinations of container and valve fitment arrangements such that one or both of the container bag and fitment are disposable or reusable. Further, the container assembly has features to avoid failures such as the fitment rubbing through container bag film during vibrations associated with transport or use. The assembly can also have features so that the container bag and fitment are not damaged during loading or unloading and while in storage. Moreover, in at least one embodiment, the milk collection container can comprise a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit. In one embodiment, the collection container or container assembly includes an extra part, valve or fitment that is attached thereto and facilitates creating a seal with the container to establish a closed system. In one embodiment, the milk container can include a one-way valve that cannot be removed without destroying milk container or valve function. The valve can assume a myriad of shapes and kinds including an umbrella valve, a duckbill valve, a

ball valve or other valve. Moreover, in one or more embodiments, the container can be flexible or rigid, or disposable or reusable.

[0049] Turning now to Figs. 8-10, one embodiment of a sealed or sealable container assembly 120 is shown. In one particular embodiment, the container assembly 120 can be formed from about two 2.5-3.0 mil sheets 121 of material that is joined (i.e., welded) together along a perimeter 122 of the assembly, and can be sized to retain up to 4.5 ounces, or alternatively 8 ounces of fluid. A body of the container assembly is shaped to fit within flange 14 and includes a generally asymmetrical central opening 124 created by an interior seal. Material 126 extends into the central opening 124 to define a pair of spaced curved flaps and are provided for handling and facilitating positioning of the container assembly 120 within a pump system 10. A narrow neck portion 128 is centrally positioned and extends longitudinally away from the central opening 124. The container assembly 120 can be re-sealable, re-usable, include larger or smaller openings, or include spout structure for pouring contents. Thus, in alternative embodiments, the container assembly 120 can be re-sealable, re-usable, include larger or smaller openings or include spout structure for pouring contents. The valve of the container assembly can also be re-usable with a second or subsequent container assembly, and therefore is removable from the container assembly.

[0050] Moreover, in one particular embodiment, the container assembly 120 can be made from polyethylene and can be bisphenol A free, as well as food grade material. It is freezable without tearing and withstand approximately 0-80 degree Celsius temperatures. Additionally, tensile strength can be from 2300-2900 psi and tear strength from 440-600 psi, with a water vapor transmission rate max of about 0.5g/100in2/24hrs and an oxygen transfer rate of about 150cc/100in2/24hrs. In alternate embodiments, the material of the container assembly can be Gore-tex or Tyvek, for example. Such alternative materials can permit out-gasing such that any air that is pumped into the container assembly will escape through the material while the container assembly retains the fluid. In this specific regard, other vents or approaches to venting the system can be incorporated into one or more embodiments. Thus, self-venting of the container assembly or active venting while using the pump system or after use can be accommodated. In one approach, a pressure valve can be incorporated

into the system and configured to activate after some system pressure is reached, and further the valve can be designed to act as a fluid barrier, only allowing air and not fluid to escape. The container assembly can also additionally or alternatively include a rigid or flexible sealing component, such as a ring or gasket into which the pump or container valve is pushed or twisted and sealed.

[0051] The container assembly 120 can further include a relatively stiff grommet 130 adhered to the material forming the container assembly. A hole 132 can be formed in one layer of the sheet material 121 of the container assembly 120, a central hole 134 formed in the grommet providing access to and supporting the hole 132 which is undersize with respect to the central hole 134. A pump outlet 138 having a through hole 140 and a barbed body 141 can be provided and can be formed from turned Delrin for example. Utilizing plastic deformation of the sheet material 121, a one-time seal can be created by stretching the sheet material 121 over the barbed body 141 creating the completed assembly depicted in cross-section in Fig. 10.

[0052] Various steps in loading a container assembly 120 into the system 10 is shown in Figs. 11A-D. In a first step (Fig. 11A), the flange 14 is removed from engagement with the remainder of the system 10. Attached to the flange is the flex conduit or tube 32. A central portion of the container assembly 120 is placed over a central projection 110 of the flange 14 and the flex conduit or tube 32. Next, the user can pinch the container assembly and configure it under the flex conduit or tube 32 (Fig. 11C) followed by tucking the container 120 into the flange 14. The opening 132 is fluidly connected to the flex conduit or tube 32 such as via the pump outlet 138 (See Fig 11D). Once connected the door assembly 90 can be rotated over the flex conduit or tube collar 82 and pump outlet connection (See Fig. 1A) to provide support and a robust engagement between the parts. In certain embodiments, the container assembly 120 can have useful labels, icons or notifications. For example, milk droplet icons 139 can be printed on the container 60 in increasing size to indicate the degree to which the container is filled such as when the milk collected is filled to the larger icons, the user will know that the container assembly is filling up. When the level of the milk corresponds to the smaller icons, then the user will know that the container is less fill. Moreover, a “this side up” message can be included to aid the user in properly

installing container 60.

[0053] It is contemplated that the door assembly 90 (See Figs. 1B, 11D) can be employed to both provide a continuous contour of the flange 14 for engaging a user's breast as well as to support the engagement of the container assembly 120 with the system 10. Thus, the door assembly 90 can be configured to pivot with respect to the flange 14, and employed to close the system 10 as it is snapped over and closes the pump. With this approach, the container assembly 120 is securely sandwiched within the door assembly 90. The collar 82 can also provide rigidity to the flex conduit or tube 32 so that it can be loaded into the flange 14 as well as to provide an annular back-up.

[0054] In at least one embodiment, the pressure at which a valve between the pump system and the container assembly opens to allow flow into the milk collection container is about 25mm Hg. The valve can be configured and designed such that it allows fluid to flow through it when the pressure in flex conduit or tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "opening pressure". The action of compression elements on the flex conduit or tube 32 cycles between increasing vacuum when the compression elements move in a direction away from flex conduit or tube 32 and decreasing when the compression elements compress the flex conduit or tube 32, but typically should not increase the vacuum to greater than the predetermined maximum vacuum. As the compression elements compress the flex conduit or tube 32, the pressure in the system 10 goes up and reaches the minimum suction level (e.g., latch suction level, such as -60mmHg, -30mm Hg, or some other predetermined latch suction level), at which time a compression member (pinch valve) seals off a portion of the flex conduit or tube 32 thereby maintaining the minimum suction (latch suction) against the breast. Continued compression of the flex conduit or tube 32 continues to increase the pressure downstream until the opening pressure is reached (e.g., 25mm Hg or some other predetermined, positive opening pressure), that opens the valve. The compression elements continue compressing flex conduit or tube 32, pumping fluid (milk) through the valve and into the collection container assembly.

[0055] In another approach (Figs. 12-14), the container assembly 120 can include an integrated valve that uses an opposite side of container material 121 as flapper valve

structure to thereby define a sealed or sealable container. Here, a port 140 can be sized and shaped to mate with an opening to the flex conduit or tube. The port 140 can be affixed such as by a glue joint 141 to an outside portion of the container sheet material 121. A movable support 144 including a foam assist member 146 can be provided on an opposite outside surface of the container sheet material 121. Under vacuum, the foam assist member 146 presses the sheet material 121 against the port 140 and a seal results. When there is positive pressure from the pump system which exceeds the forces provided by the foam assist member 146, then flow into the container can begin (Fig. 13). In one approach (Fig. 14), the support structure 144 can be attached to a hinge 148 and can further include a latch 150 for maintaining the support 144 in place against the container assembly. This approach lends itself to a very simple container assembly design. It is also contemplated that various parts of the valve can be disposable. The foam assist member 146 can be replaced as necessary when worn out, or should a seal be lost. Valve opening pressure can be adjusted by alternating foam density, increasing interference force provided by the movable support, or by changing the size of the foam assist member 146.

[0056] Installation of a container assembly with the port 140 is a simple process. The port 140 is pressed onto the pump outlet, and the support structure 144 is rotated into place. A latch 150 associated with the support 144 can be placed on securing structure to hold the support 144 in place.

[0057] Turning now to Figs. 15-18, there are shown yet other approaches to valves for a container assembly. In a first approach (Figs. 15-16), a standalone valve 160 with a silicone flapper 162 is contemplated. The valve 160 has a fill port 164 that can be attached to an outlet port of a pump system. In one particular embodiment, the flapper 162 can be cut from a .032 inch silicone sheet and have a long dimension on the order of .563 inches. Such dimensions and material can provide the flapper 162 with desired rigidity and flexibility to cooperate with the pump assembly to both allow milk flow into a container assembly and to prohibit milk escaping the container. A mounting surface 165 is provided on an underside of the valve, and the valve further includes a recess 166 against which the flapper 162 engages to seal the valve against egress and ingress.

[0058] In a related approach (Figs. 17-18), there is provided a container assembly 120 with an integrated flapper valve 170 that facilitates defining a sealed or sealable container. A fill port 172 is provided and includes a mating and mounting face 174. The mating and mounting face 174 can be affixed to container material 121. A flapper 176 can be cut into the container material 121, the flapper 176 being sized and shaped to engage the mating and mounting face 174. Notably, the fill port 172 is affixed to an outer surface of the container material 121 over an incomplete circular cut (i.e., 300 degree cut) that forms the flapper 176.

[0059] In one or more approaches (Fig. 19), the container assembly can further or alternatively include a pulltab 180 affixed to valve structure 182. Here, the valve structure configured within an inlet port 183 can be removed by pulling on the pull tab 180. Accordingly, once the container assembly is full or it is no longer being used to receive milk, the valve structure 182 can be removed from the container assembly and milk can be poured out from the container through the inlet port 183.

[0060] As shown in Fig. 20, the container assembly can additionally or alternatively include integrated structure for facilitating maintaining an engagement with a pump system. In one contemplated approach, a hook or other latching structure 186 can be attached to the container assembly 120. The latching structure 186 can be rotatable or articulated to engage the pump system or an outlet tube 187 thereof to maintain a sealing engagement.

[0061] Turning now to Fig. 21, there is shown a container assembly 120 with an integrated bicuspid valve assembly 190 which facilitates defining a sealed or sealable container. A pair of 1.5 mil leaflets define the valve assembly 190 and are formed by attaching the leaflet material at one end, and bending the leaflet material approximately 180 degrees to thereby provided desired biasing. A machined flange defines an opening 192 to the container assembly 120 and seals (such as band seals) are employed to attach the material sheets comprising the assembly.

[0062] In yet another approach (Fig. 22), the container assembly 120 can be provided with a dispensing port 198 that provides structure for quick and easy transfer of milk from a container assembly to a bottle or other storage container. A seal configured at the dispensing port can be a ziplock arrangement, a peelable adhesive strip or a bar-seal

that peels apart.

[0063] Referring to Figs. 23-29, there are shown various approaches to packaging and storing container assemblies prior to use. The container can be pre-formed to optimize or maximize space within a pump system. Further, the container can be placed into a flattened configuration by applying a vacuum to facilitate effective packaging. In one approach (Fig. 23), container assemblies 120 can be laid flat in a stack in a generally rectangular receptacle 200. The valves 202 or other fitments forming inlets/outlets of the container assemblies 120 can be aligned or staggered within the receptacle 200. The receptacle 200 can further include a lid (not shown) which can be removed to gain access to the container assemblies 120, and the container assemblies can be removed as needed. In a second approach (Fig. 24), a receptacle 210 can further include a central column 212 sized and shaped to be received within a central opening formed in the container assemblies. The column 212 can assist in retaining the container assemblies 120 in an organized manner within the receptacle 210. In a related approach (Fig. 25), a generally cylindrical receptacle 220 can be equipped with a central column configured to assist in retaining container assemblies in a staggered fashion. In this specific approach, the container assemblies are folded into a depth of the receptacle 220. It is also contemplated that a receptacle can be defined by a generally square column 230 as shown in Fig. 26. Here, the valves or fitments 202 forming part of the container assemblies 120 can be configured on opposite sides of the receptacle 230 so that a more compact packaging arrangement can be presented.

[0064] In yet a further approach (Fig. 27), container assemblies 120 can be wrapped about an external surface of a tubular retaining body 240. The valves/fitments 202 of the container assemblies 120 can be conveniently grasped and the container assemblies 120 removed from the packaging as needed. Alternatively (Fig. 28), the container assemblies 120 can be stored within a tubular receptacle body 250 with the valves/fitments 202 of the container assemblies 120 being folded against the outside of the body 250. Additionally, the container assemblies 120 can simply be aligned and rolled into a bundle and held in place with a securing means for shipment.

[0065] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various

changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure.

CLAIMS:

That which is claimed is:

1. A container assembly for a pump, comprising:

a body;

a neck portion; and

a valve;

wherein the valve assembly is configured to mate with the pump and the container assembly defines a sealed or sealable structure in combination with the pump.

2. The container assembly of claim 1, wherein the valve assembly is integrated into the container assembly.

3. The container assembly of claim 1, wherein the container assembly is sealed.

4. The container assembly of claim 1, wherein the container assembly is airtight.

5. The container assembly of claim 1, wherein the container assembly is formed from two sheets of material band welded together along a perimeter.

6. The container assembly of claim1, wherein the valve permits milk inflow into the container assembly but prevents backflow.

7. The container assembly of claim 1, further comprising an hole formed in the neck portion and a grommet attached to the neck, wherein the grommet provides support to the container assembly when the container assembly is attached to an outlet of the pump.

8. The container assembly of claim 1, wherein the valve opens to allow flow into the container assembly at about 25mm Hg.

9. The container assembly of claim 1, further comprising an integrated valve, the integrated valve including a port formed on a first outside surface of the container assembly

and a foam assist member configured on an opposite outside surface of the container assembly, the foam assist member maintaining the port closed until an opoening pressure is reached.

10. The container assembly of claim 9, further comprising a support attached to the foam assist member, a hinge attached to the support that permits the support to rotate, and a latch for retaining the support in a position for engaging the foam assist member with the container assembly.

11. The container assembly of claim 1, wherein the valve assembly includes a flapper.

12. The container assembly of claim 1, wherein a portion of the neck includes a punched out portion, the punched out portion cooperating with a port to define an integrated valve.

13. The container assembly of claim 1, further comprising a pull tab connected to the valve assembly, wherein pulling on a pull tab results in removing the valve from the container assembly.

14. The container assembly of claim 1, further comprising a latch which can be rotated into engagement with the pump.

15. The container assembly of claim 1, wherein the valve is a bicuspid valve formed by a pair of leaflets contained within an interior of the neck portion.

16. The container of claim 1, further comprising a outlet formed by the body of the container assembly, the outlet created by separating sheets forming the body of the container assembly.

17. A system, comprising:

a breast contacting structure configured and dimensioned to form a seal with the breast;

a container assembly for storing tmilk pumped from the breast; and

a tube in fluid communication with the container assembly;

wherein the container assembly includes a valve and the container assembly and system define a sealed or sealable arrangement.

18. The system of claim 17, wherein the valve is integral with the container assembly.

19. The system claim 17, wherein the container assembly defines a sealed structure.

20. The system of claim 17, wherein the container assembly is airtight.

21. The system of claim 17, wherein the breast contacting structure includes a nipple receiving portion, and further comprising a plug sized and shaped for sealing the nipple receiving portion closed.

22. The system of claim 21, wherein the plug includes a handle for grasping.

23. The system of claim 17, further comprising a storage container for receiving and carrying a plurality of container assemblies.

24. The system of claim 23, wherein the storage container stores container assemblies in a flat orientation.

25. The system of claim 23, wherein the storage container stores container assemblies so that the neck portions are staggered.

26 The system of claim 17, wherein the storage container can be pre-formed to optimize or maximize space within a pump system.

27. The system of claim 17, wherein storage container can be placed into a flattened configuration by applying a vacuum to facilitate effective packaging.

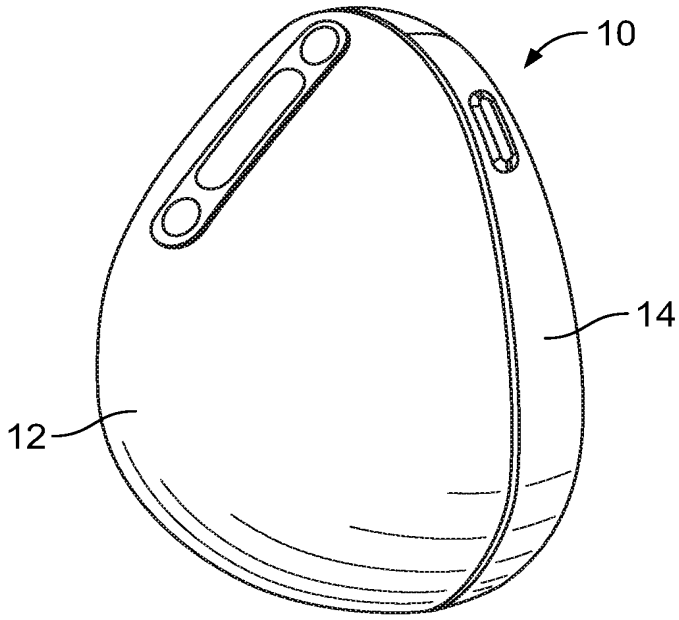


FIG. 1A

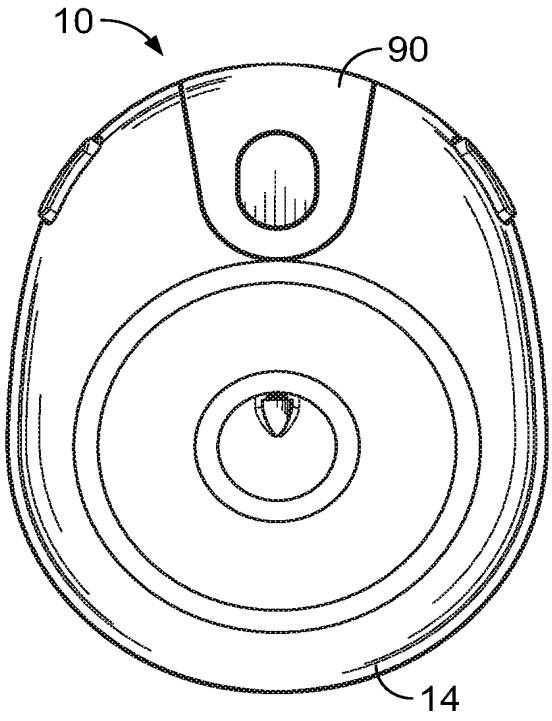


FIG. 1B

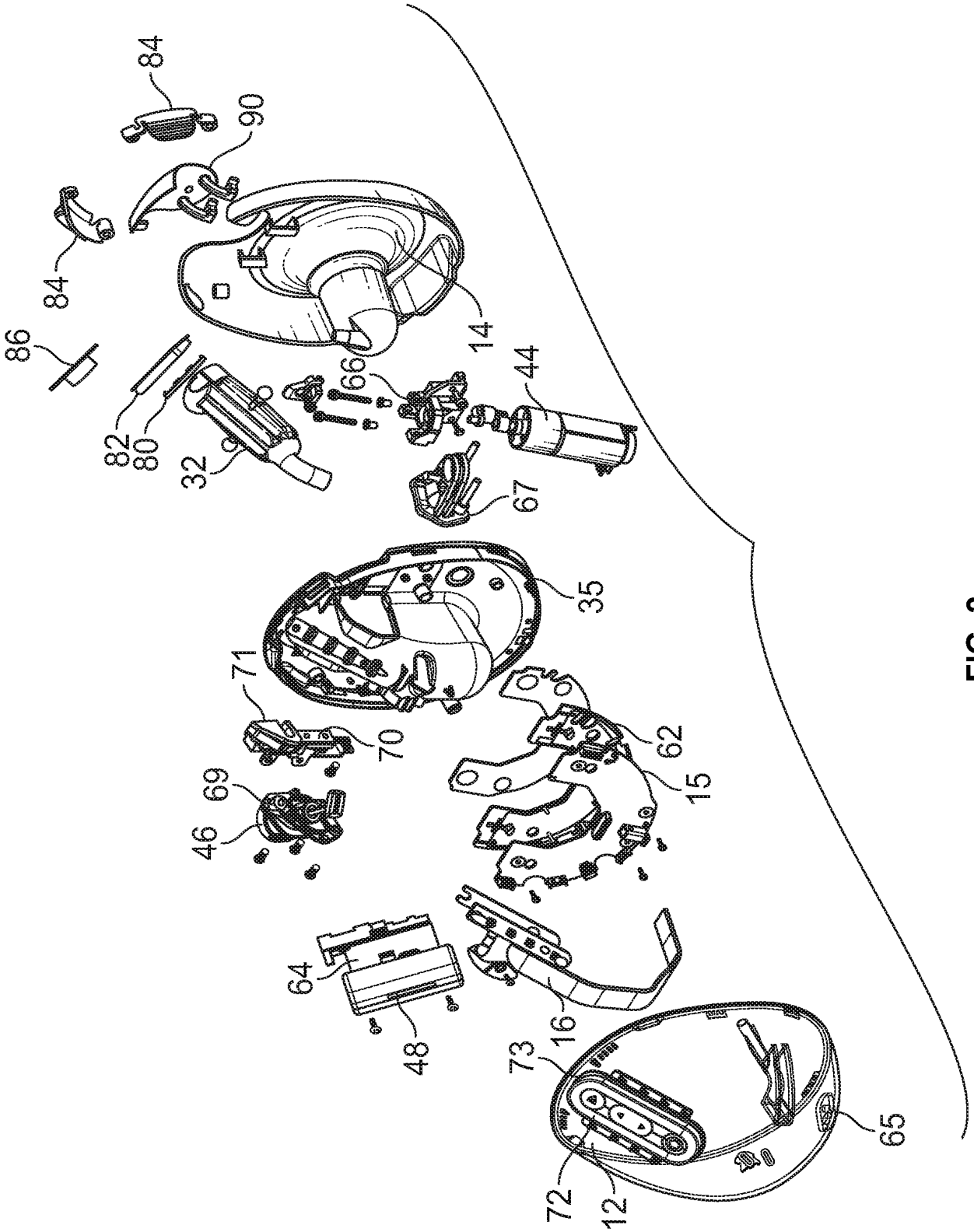

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FIG. 2

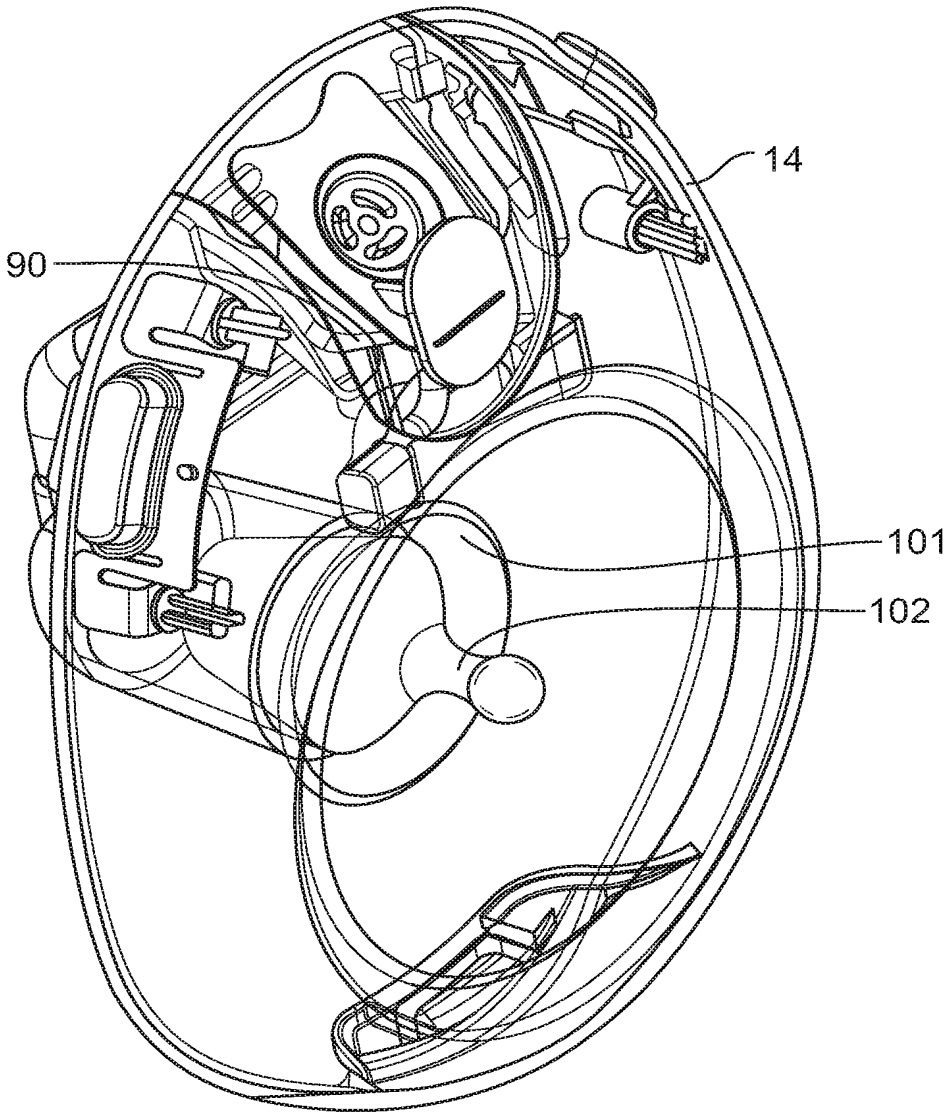


FIG. 3

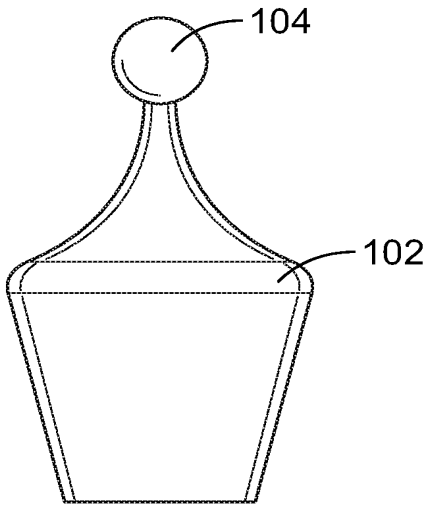


FIG. 4

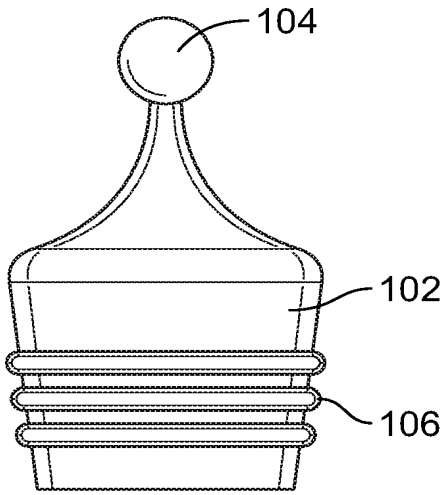


FIG. 5

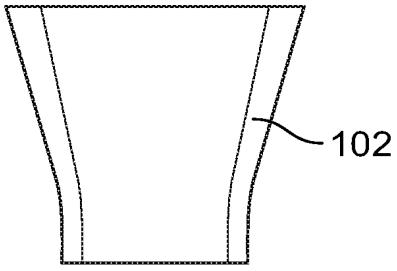


FIG. 6

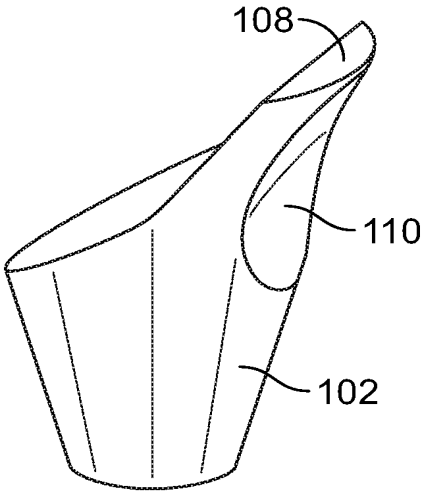


FIG. 7

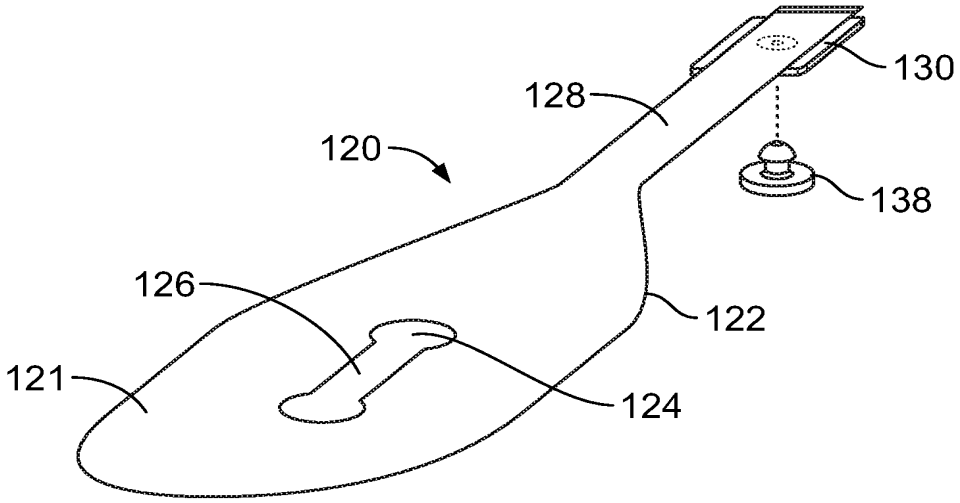


FIG. 8

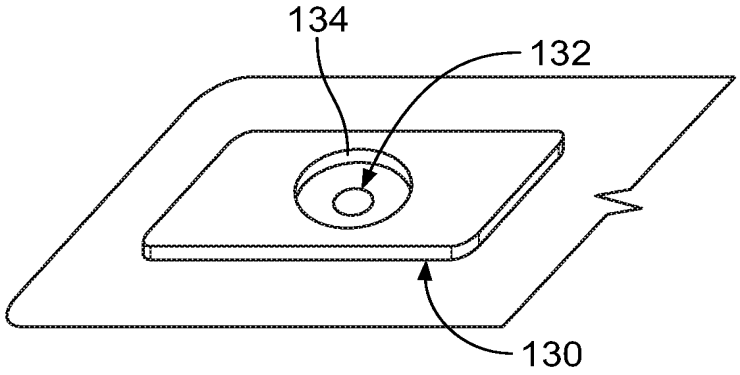


FIG. 9

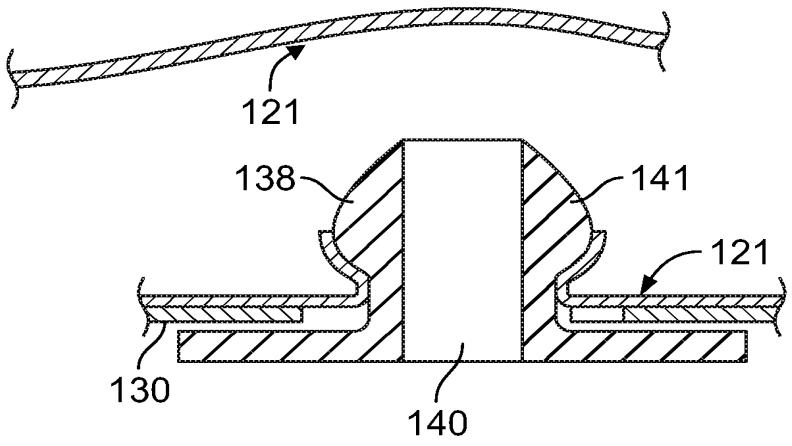


FIG. 10

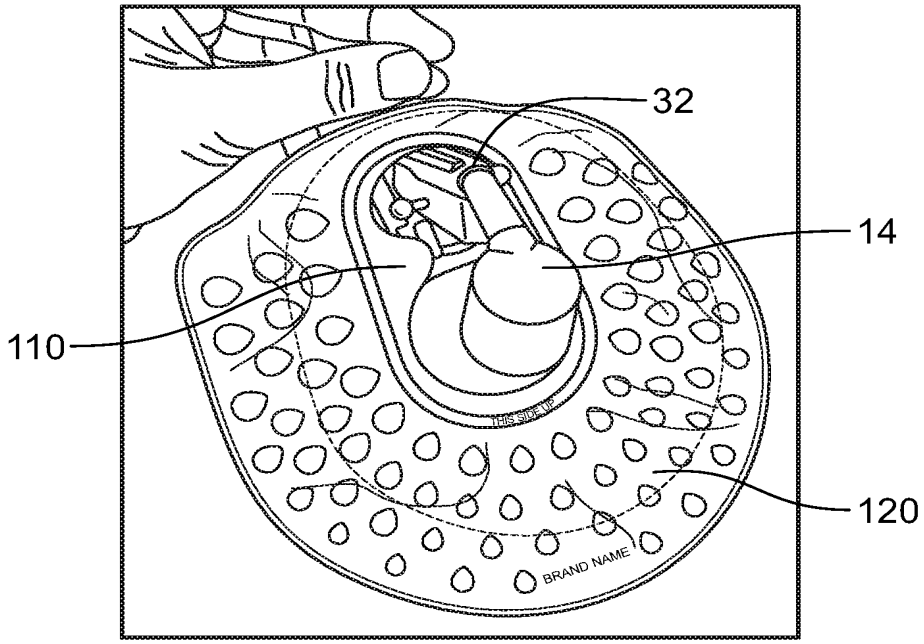


FIG. 11A

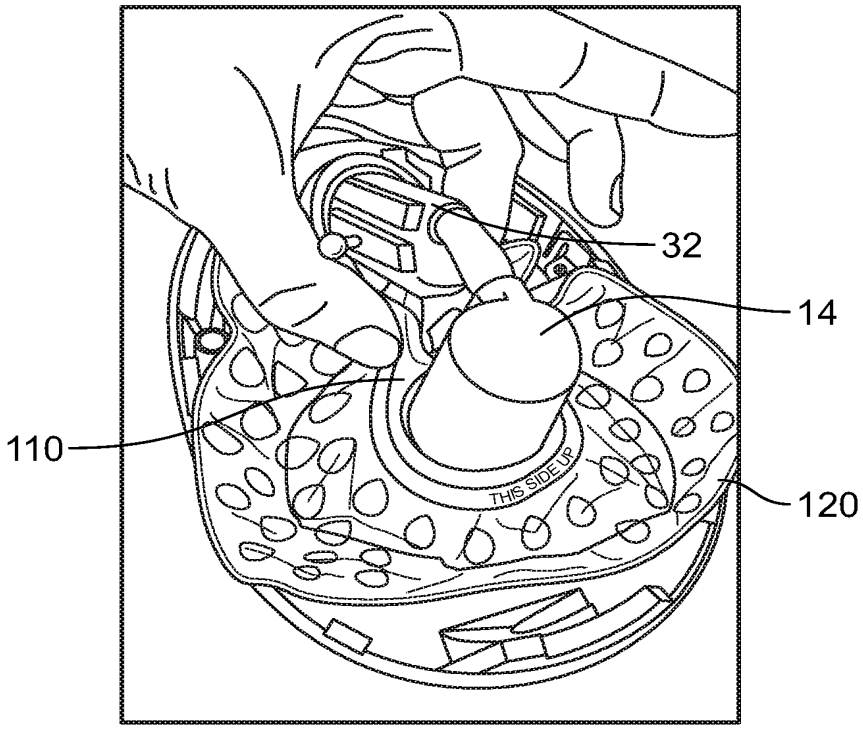


FIG. 11B

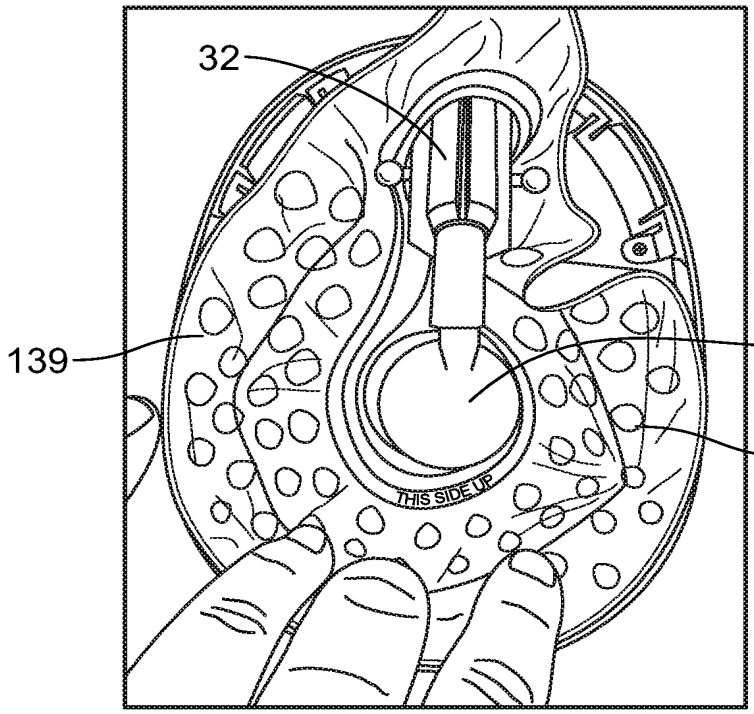


FIG. 11C

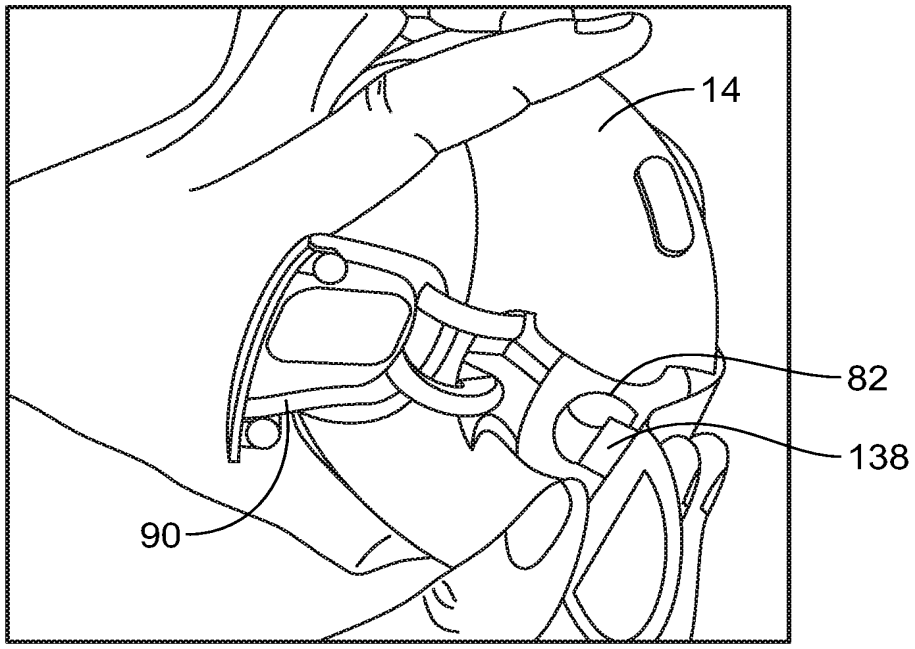


FIG. 11D

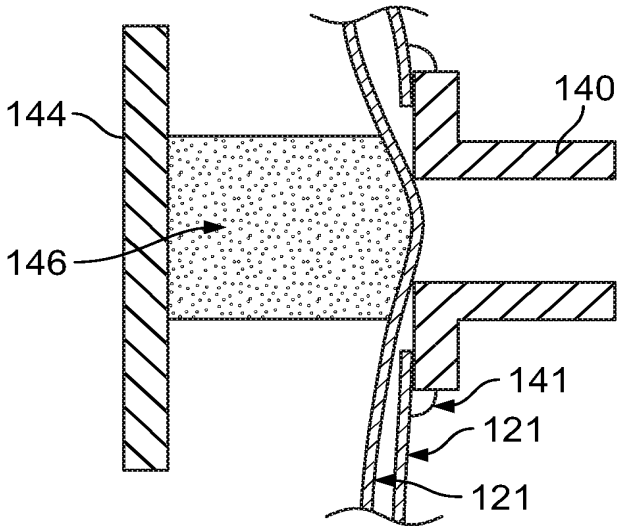


FIG. 12

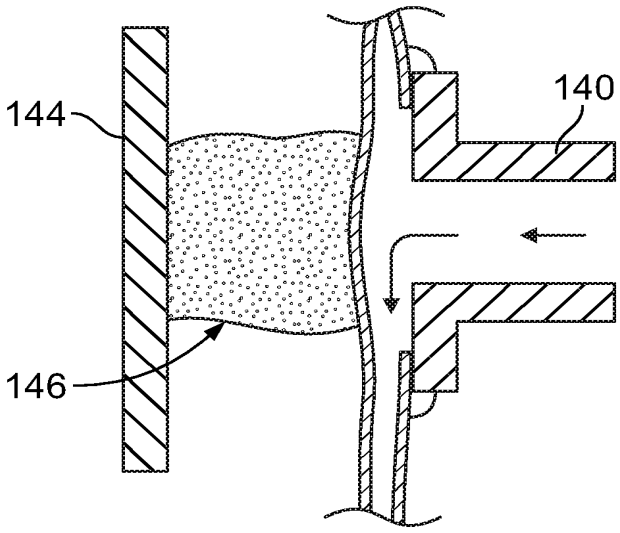


FIG. 13

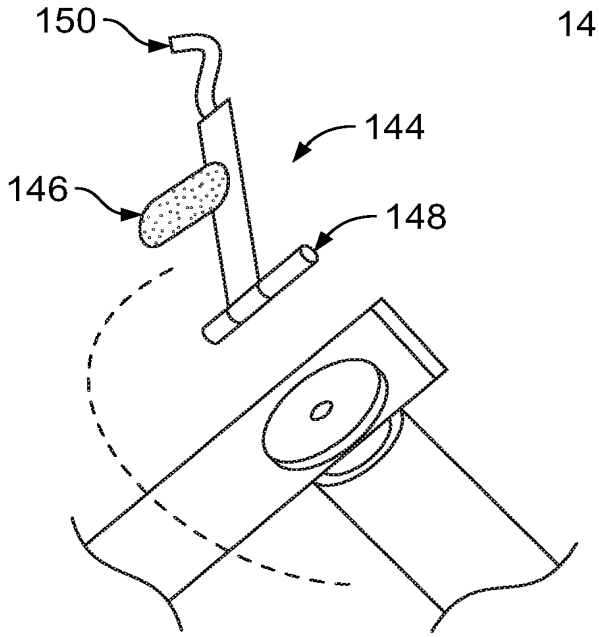


FIG. 14

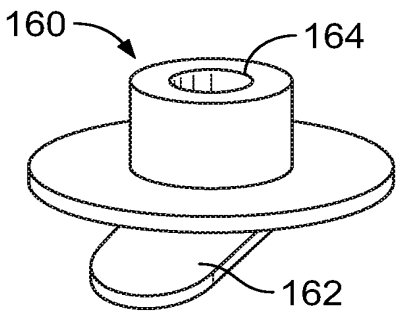


FIG. 15

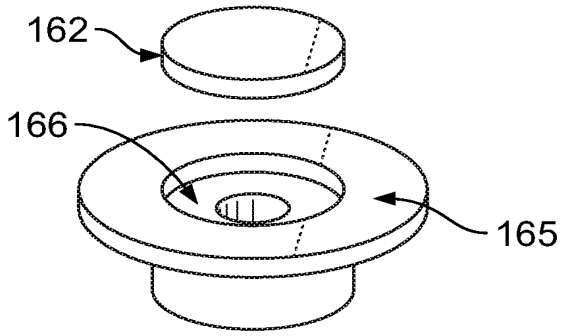


FIG. 16

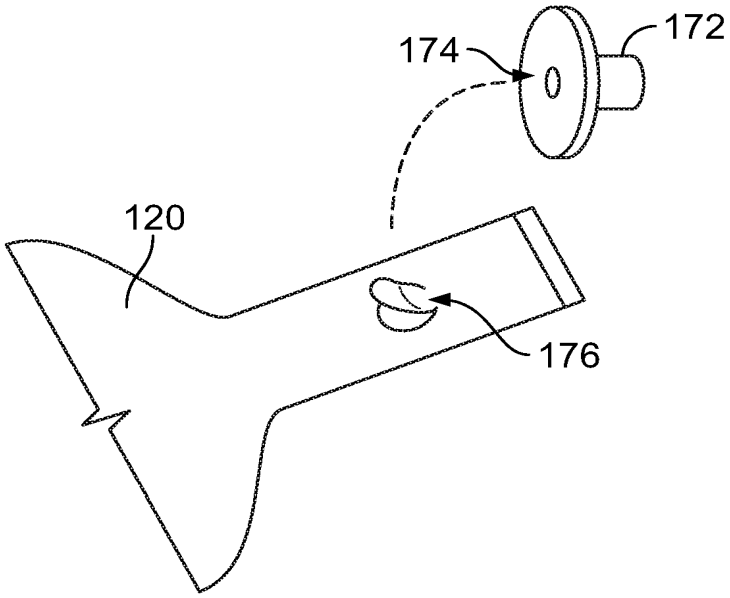


FIG. 17

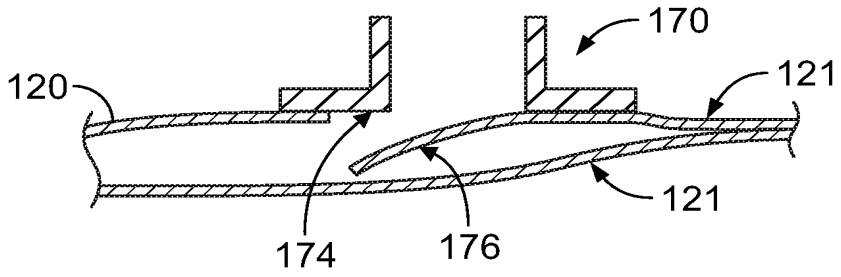


FIG. 18

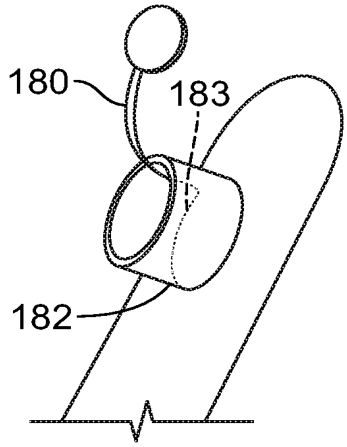


FIG. 19

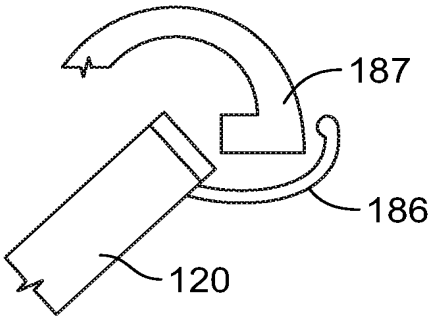


FIG. 20

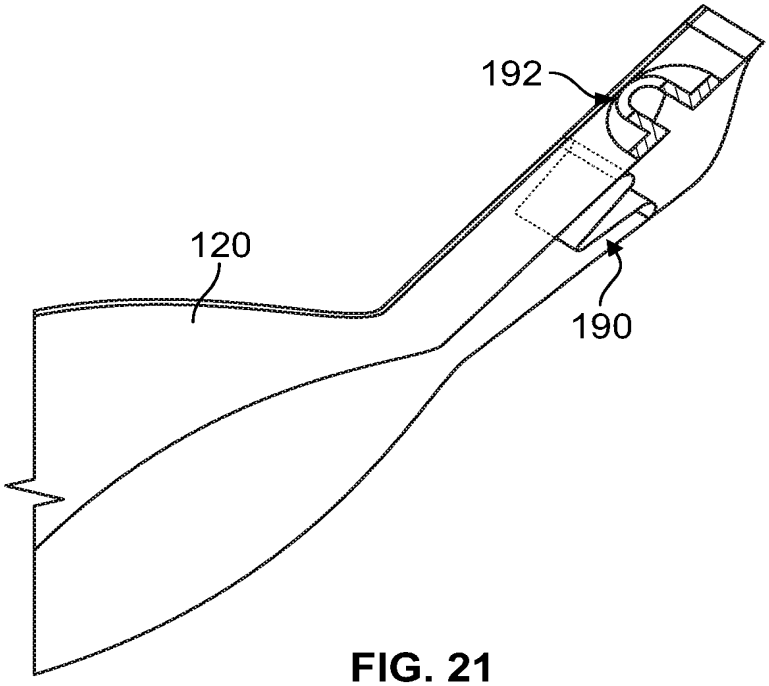


FIG. 21

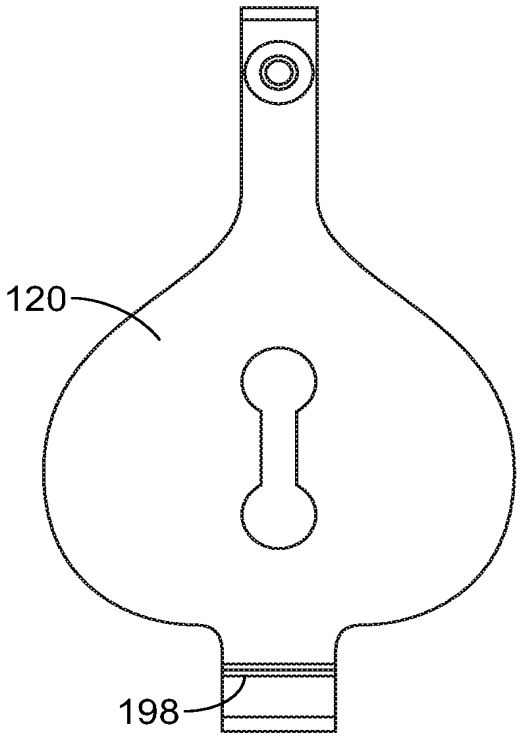


FIG. 22

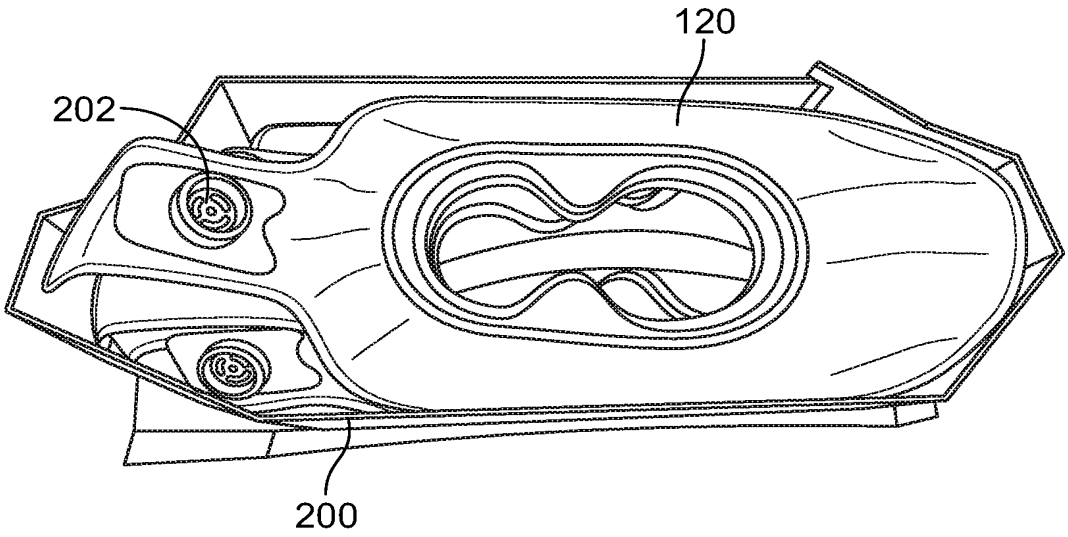


FIG. 23

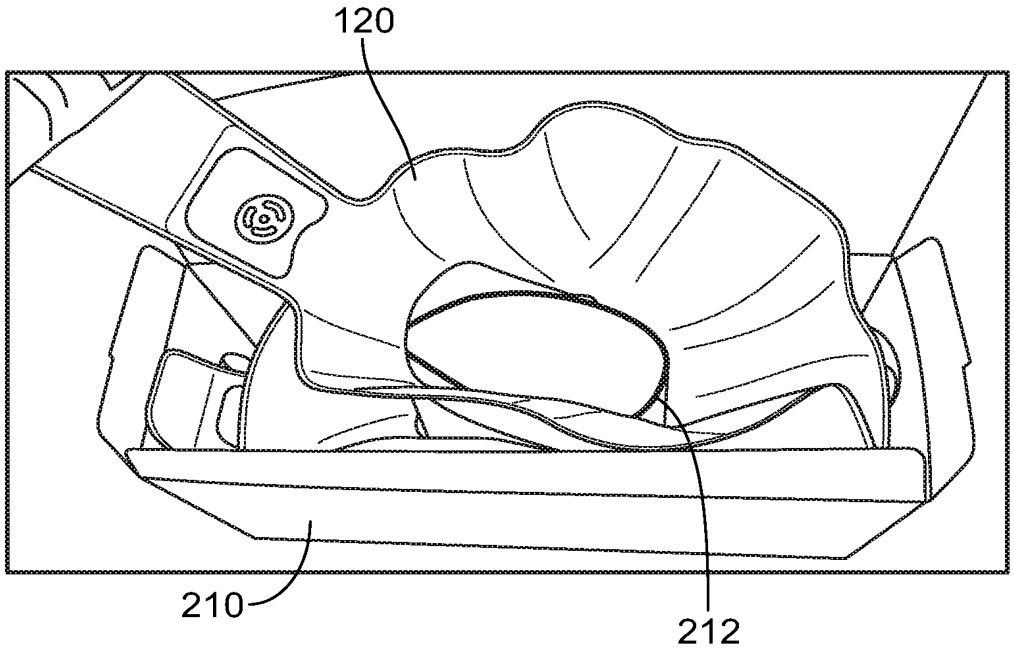


FIG. 24

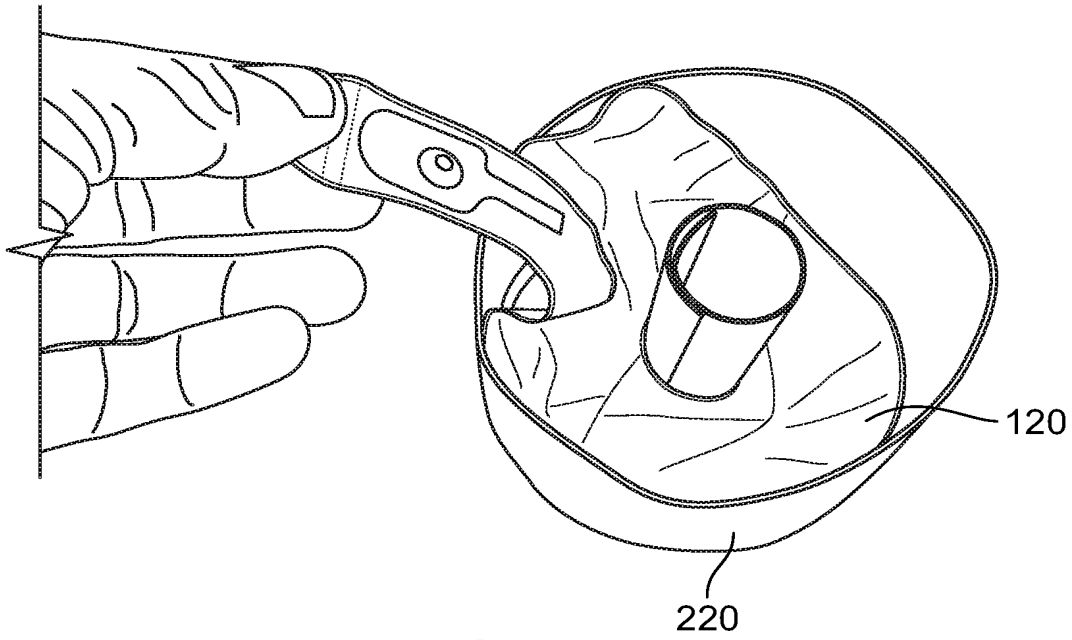


FIG. 25

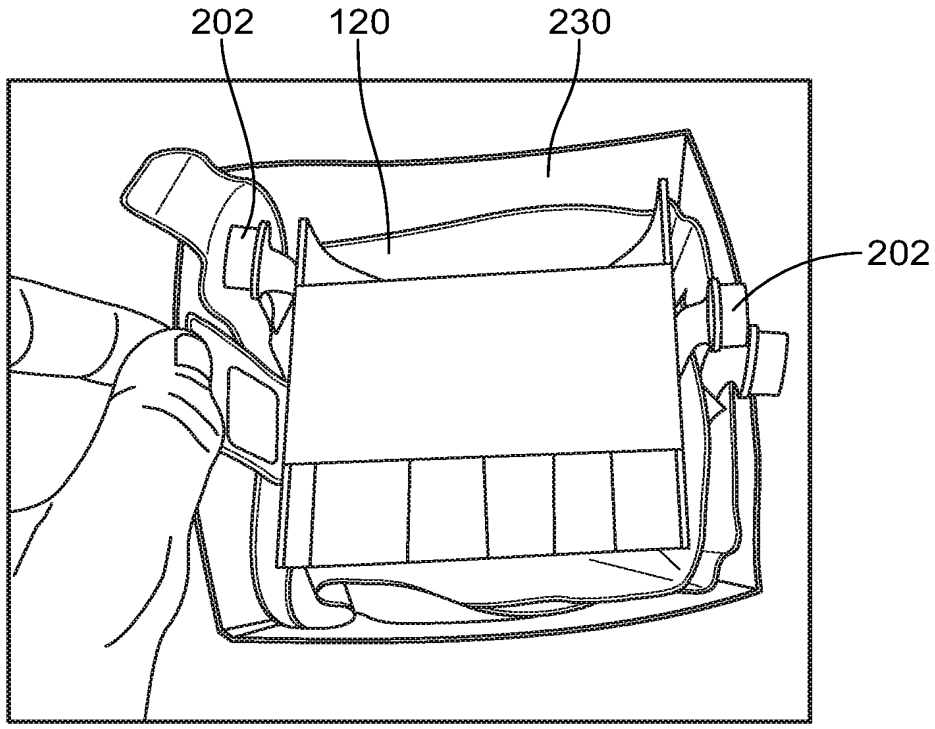


FIG. 26

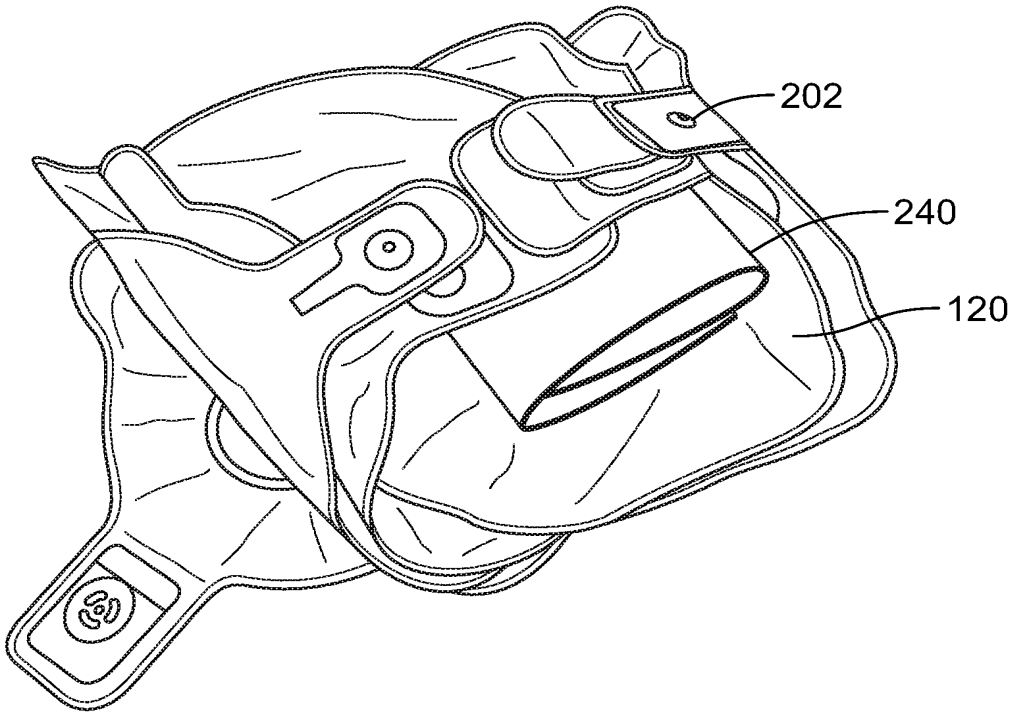


FIG. 27

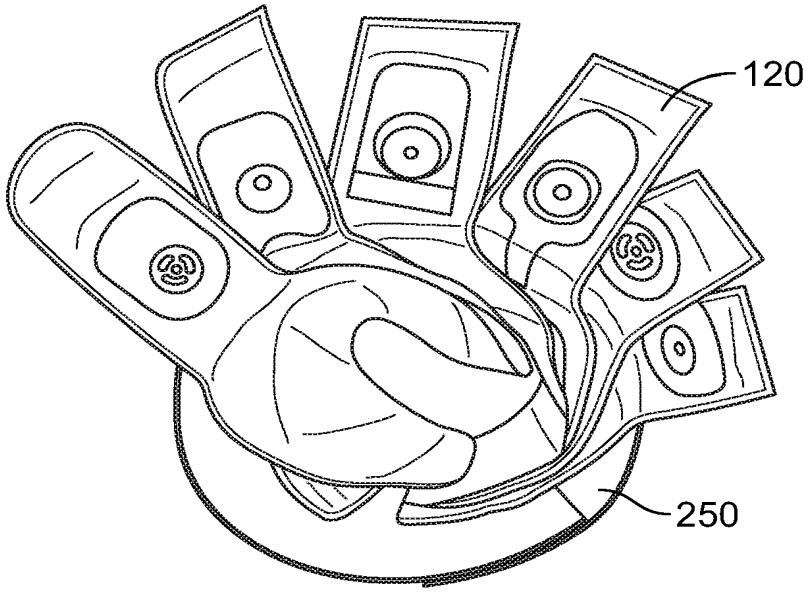


FIG. 28A

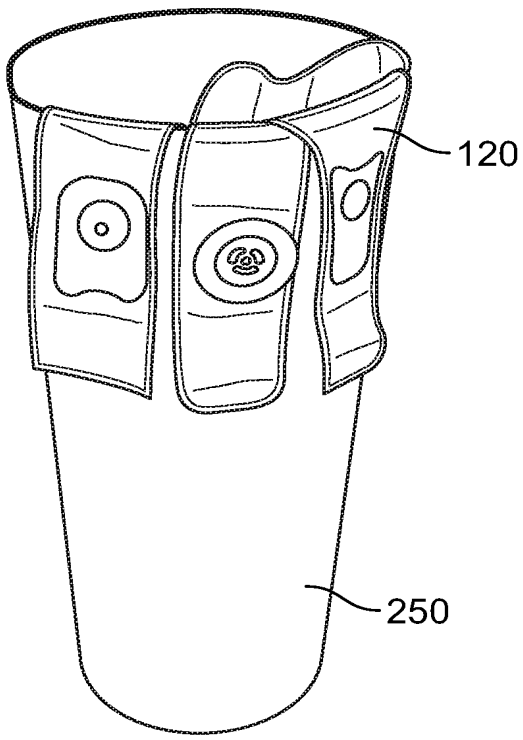


FIG. 28B

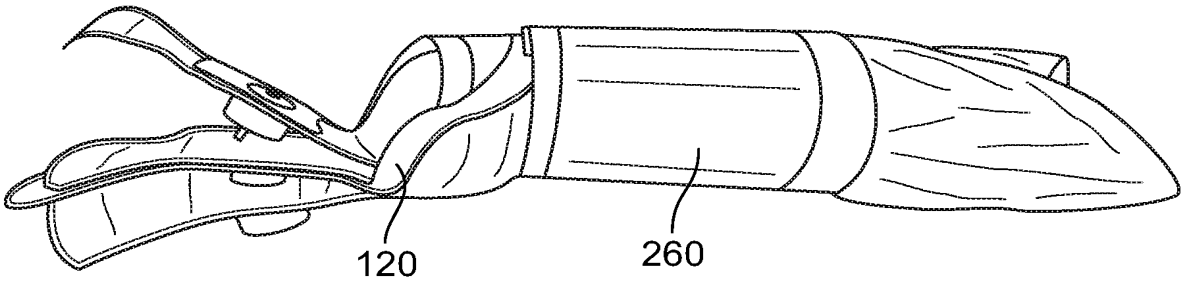


FIG. 29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2017/017212

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 *(2006.01)*
A61M 39/24 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/00, 1/06, 39/24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 8357116 B2 (MEDELA HOLDING AG) 22.01.2013, fig. 4-5, col. 1, lines 11-34, col. 4, lines 6-24, col. 2, line 64 - col. 3, line 25	1, 3, 4, 8, 11-15 2, 5, 6, 16, 20 7, 9, 10
Y	US 2014/0288466 A1 (NAIA HEALTH, INC.) 25.09.2014, paragraphs [0054], [0075]	2
Y	WO 2007/090222 A1 (MAM BABYARTIKEL GESELLSCHAFT M.B.H. et al.) 16.08.2007, p. 7, lines 9-14, p. 10, lines 12-16	5
Y	WO 1990/011097 A1 (MEDELA INC) 04.10.1990, p. 4, lines 27-35	16
Y	WO 2016/014494 A1 (EXPLORAMED NC7, LLC) 28.01.2016, paragraph [0051]	6

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 April 2017 (24.04.2017)	25 May 2017 (25.05.2017)

Name and mailing address of the ISA/RU:	Authorized officer
Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	M. Masalova Telephone No. (495)531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2013/0023821 A1 (MEDELA HOLDING AG) 24.01.2013, paragraphs [0003], [0006], [0009], [0010], [0058], [0069], fig. 9-11	17, 18, 19 20-27

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 586 340 A2

(12) EUROPEAN PATENT APPLICATION

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AL BA HR LV MK YU

(30) Priority: **12.04.2004 US 821924**

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(54) Breast pump

(57) An electric breast pump is disclosed as including a hood (12) to be fitted over a breast of a user, a chamber (37) in fluid communication with the hood member (12) via a one-way valve (48), a pump motor (42) operatively associated with a pump diaphragm (44) movable to draw air from the hood (12) into the chamber (37) via the valve (48), in which the chamber has an opening and a lid (66) which is operatively associated with the motor (42), in which the lid (66) is movable between a first position to close the opening and a second position in which the opening is open, and in which the lid (66) is at the first position when the motor (42) is in operation and is at the second position when the motor (42) is not in operation. The breast pump also includes sensors (38a,38b) for detecting the passing of milk, and a microcontroller (40) for calculating the rate of flow of milk on the basis of data received from the sensors (38a, 38b).

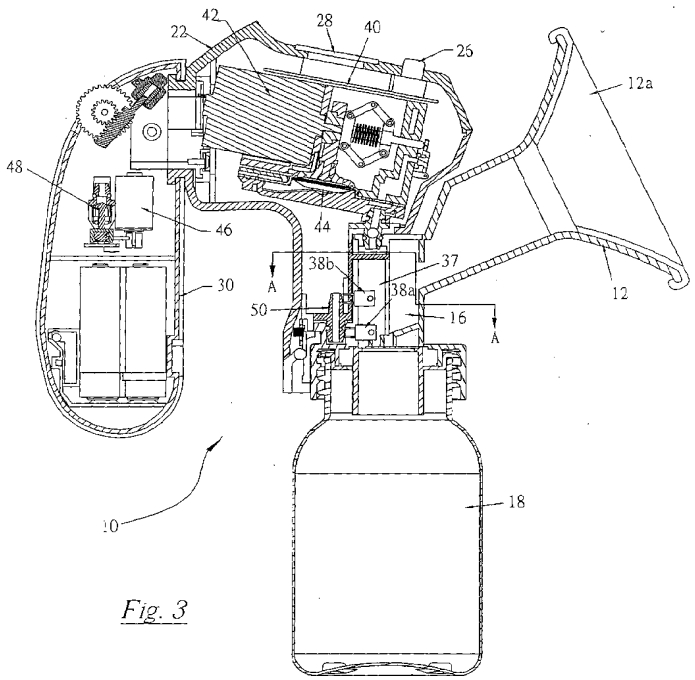


Fig. 3

EP 1 586 340 A2

Description

[0001] This invention relates to a breast pump and, in particular, an electrically operated breast pump for drawing milk from a user.

Background of the Invention

[0002] There are in existence a large number of electrically operated breast pumps, allowing a user, e.g. a mother, to pump milk from her breast. Various pumping mechanisms have been proposed for drawing milk from the mother's breast, including, for example, ones disclosed in US Patent Nos. 6,045,529 and 6,355,012 issued to Nüesch. Such mechanisms are generally speaking rather complicated, and thus costly to manufacture. In addition, most such mechanisms include gear trains which would generate much noise, especially when the motor is operating at a relatively high speed.

[0003] In addition, although a user may, with some existing breast pumps, be able to adjust the pumping cycles, e.g. by varying the number of suction cycles per minute, or adjusting the vacuum level for pumping milk from the user's breast, it is up to the user to decide whether to make such variation or adjustment, and the user may simply have no information on which to decide whether the current pumping rate is suitable or not In this connection, US Patent No. 6,547,756 issued to Greter et aL discloses a programmable breast pump which may be programmed to generate a number of different milk expression (extraction) sequences, or curves. In this arrangement, a motorized pump is provided with a microprocessor-based controller. Cards, with microprocessor "chips", containing instructions for different suction curves are also included, which may be inserted into the breast pump, so that the instructions in the cards may be read and acted upon by the breast pump. However, as in the case of other adjustable breast pumps discussed above, it is still up to a user to decide whether to change the mode of pumping operation of the breast pump, and a user may not know whether an alternative, and if so which, suction curve should be applied. A further shortcoming associated with conventional electric breast pumps is that the user is provided with no information as to the time required to fill up the milk receptacle, e.g. bottle.

[0004] Such and other shortcomings discussed above are also present in breast pumps disclosed in US Patent No. 6,673,036 issued to Britto and US Patent No. 6,090,065 issued to Giles.

[0005] It is thus an object of the present invention to provide an electric breast pump m which the aforesaid shortcomings are mitigated or at least to provide a useful alternative to the public.

Summary of the Invention

[0006] According to a first aspect of the present invention, there is provided an electric breast pump including at least one hood member adapted to be fitted over a breast of a user, a chamber adapted to be in fluid communication with said hood member *via* a first valve; a first motor operatively associated with a pumping member which is movable to draw air from said hood member into said chamber *via* said first valve; said chamber having at least a first opening and a closure member operatively associated with said first motor, wherein said closure member is movable between a first position to close said first opening and a second position in which said first opening is open; and wherein said closure member is at said first position when said first motor is in operation and is at said second position when said first motor is not in operation.

[0007] According to a second aspect of the present invention, there is provided an electric breast pump including at least one hood member adapted to be fitted over a breast of a user; and at least a first sensing unit adapted to detect the passing of milk.

Brief Description of the Drawings

[0008] A preferred embodiment of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of an electric breast pump according to the present invention;
Fig. 2 is an exploded view of the breast pump shown in Fig. 1;
Fig. 3 is a sectional view of the breast pump shown in Fig. 1;
Fig. 4 is a sectional view taken along the line A-A in Fig. 3;
Fig. 5 is a circuit diagram of the breast pump shown in Fig. 1;
Fig. 6 shows part of the circuitry in the breast pump shown in Fig. 1;
Fig. 7 shows a liquid crystal display (LCD) setting in the breast pump shown in Fig. 1;
Fig. 8 is a block diagram of an exemplary microcontroller which may be used in the circuit shown in Fig. 5;
Fig. 9 is an enlarged view showing the engagement between the pump motor and the diaphragm in the breast pump shown in Fig. 1;
Fig. 10 is an enlarged sectional view of part of the breast pump shown in Fig. 3;
Fig. 11 is an enlarged perspective view showing the mechanism for manual adjustment of the level of vacuum in the breast pump shown in Fig. 1;
Fig. 12 shows a first configuration of the manual vacuum adjustment mechanism shown in Fig. 11;
Fig. 13 shows a second configuration of the manual vacuum adjustment mechanism shown in Fig. 11;
Fig. 14 shows an enlarged sectional view of the milk flow sensing mechanism in the breast pump shown

in Fig. 1; and

Fig. 15 is a flow chart showing the steps of operation of the breast pump shown in Fig. 1.

Detailed Description of the Preferred Embodiment

[0009] Figs. 1 and 2 show an electrically operated breast pump according to a preferred embodiment of the present invention, generally designated as 10. The breast pump 10 has a hood 12 adapted to be fitted over a breast of a user in an essentially gas-tight manner, for pumping milk from the breast. An insert 12a for contacting the user's breast is received within the hood 12. The insert 12a is made of a soft plastic material, e.g. silicone, to provide comfort to the user during use. The hood 12 is in funnel shape and has a tunnel 14 leading to a connector 16, which fluidly communicates with the hood 12, and with a milk-receiving bottle 18 *via* a valve seat 20, the structure and function of which will be further discussed below.

[0010] The connector 16 is engaged with a head portion 22 which houses most of the operating components of the breast pump 10, as will be clear from the ensuing discussion. On a top surface 24 of the head portion 22 is provided with an ON/OFF button 26 for selectively activating/deactivating the breast pump 10. Also provided on the top surface 24 of the head portion 22 is a liquid crystal display (LCD) 28 for displaying various operation information and data relating to the operation of the breast pump 10. The head portion 22 is connected with a handle 30, which also acts as a battery compartment for housing a number of batteries 32 for powering the breast pump 10. The handle 30 is swivellable relative to the head portion 22 for easy handling. On each side of the handle 30 is provided a PAUSE button 34, allowing a user to temporarily suspend the operation of the breast pump 10 by pressing the button 34 once, and to resume its operation by pressing the button 34 once again. On a side of the head portion 22 is a power jack 36 which allows the breast pump 10 to be powered by an A/C source, possibly *via* a transformer (not shown).

[0011] Fig. 3 shows a sectional view of the breast pump 10. As shown in Fig. 3, provided in a chamber 37 of the connector 16 are two infrared (IR) units 38a, 38b, each including an IR transmitter and an IR receiver. Housed in the head portion 22 is a pump motor 42 for operating a pump diaphragm 44 for generating a low pressure (vacuum) in the breast pump 10. Within the handle 30 is a valve motor 46 for operating a needle valve 48. The valve 48 is pneumatically connected, e.g. *via* a hose (not shown), with a nozzle 50 which is in turn pneumatically connected with the milk-receiving bottle 18.

[0012] Housed in the head portion 22 is a microcontroller 40 for controlling the operation of various electronic and electrical components of the breast pump 10. As shown in Fig. 5, the microcontrolller 40 is electrically connected with and controls the operation of the pump motor 42, the valve motor 46, and the LCD display 28. The microcontroller 40 is also connected with and receives instructions and/or signals from the PAUSE buttons 34 and the IR units 38a, 38b. Fig. 6 shows in more detail a circuitry which controls the operation of the valve motor 46, the pump motor 42, and the IR units 38a, 38b, of which only one set 38a is shown here.

[0013] Fig. 7 shows the setting of the LCD display 28, and it can be seen that the LCD display 28 may display such information as the setting being used, the flow-rate (slow, medium, high), battery low, and the remaining time (in minutes) required for filling the bottle 18.

[0014] A microcontroller 40 suitable for use in the breast pump 10 may be one traded by Sino Wealth Microelectronics Corporation Limited, of Hong Kong, under serial number SH6622A, although other similar microcontrollers may also be used. SH6622A is a 4-bit microcontroller, which integrates a 4-bit CPU core with SRAM, 4K program ROM, timer and I/O Port Fig. 8 shows a block diagram of SH6622A. The CPU of SH6622A contains the following function blocks: Program Counter, Arithmetic Logic Unit (ALU), Carry Flag, Accumulator, Table Branch Register, Data Pointer (INX, DPH, DPM, and DPL), and Stack.

[0015] Fig. 9 shows an enlarged perspective view of the pump motor 42, having an output spindle 51 engaged with an eccentric cam 52 which in turn carries a yoke 54 fixed with the pump diaphragm 44. By way of such an arrangement, rotational movement of the output pin 51 is converted into linear reciprocal movement of the diaphragm 44 in the direction of the bi-directional arrow L-L.

[0016] As can be clearly seen in Fig. 10, fixed to the output spindle 51 of the pump motor 42 is a linkage mechanism 58 comprising six links 60 linked with one another in a hexagonal ring-shaped structure. Each link 60 is swivellable relative to two adjacent links 60 to which it is pivotally hinged. Over the output spindle 51 is also provided with a spring 62 which biases an end pin 64 outwardly, which in turn acts on and biases a lid 66 away from a vent hole 68. The diaphragm 44 is positioned in a chamber 71 which is closeable by the lid 66, a first one-way valve 70, and a second one-way valve 74. The first one-way valve 70 only allows air to enter the chamber 71 from a conduit 72, which is in turn in fluid communication with the hood 12. The second one-way valve 74 only allows air to exit the chamber 71.

[0017] When the motor 42 is not in operation, the linkage mechanism 58 will be biased by the spring 62 to assume the shape and configuration as shown in Figs. 3 and 10. During operation of the pump motor 42, rotation of the output spindle 51 will bring about simultaneous and corresponding rotation of the linkage mechanism 58, whereby the hexagonal ring-shaped structure 58 will "flatten" because of the centrifugal force generated by the rotation, thus retracting the end pin 64 against the outward biasing force of the spring 62. The lid 66 will thus close the vent hole 68. With the vent hole

68 closed by the lid 66, linear reciprocal movement of the diaphragm 44 in the direction of the bi-directional arrow L-L will draw air from the hood 12, through the conduit 72 and the first one-way valve 70, into the chamber 71, and push the air out through the second one-way valve 74, thus generating a lower pressure ("vacuum") in the hood 12 relative to the outside atmospheric pressure, and mimicking a sucking action of a baby on a mother's breast. The sucking/releasing cycle is completed by a releasing action when the motor 42 stops rotation. Upon stopping of the motor 42, the linkage mechanism 58 will, under the biasing force of the spring 62, resume the stable shape and configuration as shown in Figs. 3 and 10, whereupon the lid 66 will be pushed by the end pin 64 away from the vent hole 68, to thereby open the vent hole 68. When the vent hole 68 is opened, air will enter the vent hole 68, and then back into the hood 12, thus releasing the "vacuum" in the hood 12.

[0018] To allow further versatility of the breast pump 10, a manual pressure adjustment mechanism is provided, allowing the user to manually adjust the level of "vacuum" applied during operation of the breast pump 10, to suit individual need in different times. As shown in Fig. 11, the manual pressure adjustment mechanism includes a wheel 80 with a gear 82 in mesh with a pinion 84 on an end of a pin 86 and a valve seat 88. As can be seen in Figs. 10, 12 and 13, the wheel 80 is fixed to the handle 30 for rotational movement. The wheel 80 may be moved by a thumb of a user to rotate relative to the handle 30, about the longitudinal axis of the wheel 80. The valve seat 88 is also fixedly secured to the handle 30. Byway of such an arrangement, and because of the engagement between the gear 82 and the pinion 84, rotation of the wheel 80 will cause the pin 86 to move in or out of a recess 90 in the valve seat 88. In particular, rotation of the wheel 80 in the direction indicated by the arrow F in Fig. 12 will retrieve the pin 86 from the recess 90, whereas rotation of fhe wheel 80 in the direction indicated by the arrow R in Fig. 13 will insert the pin 86 further into the recess 90.

[0019] The valve seat 88 is made of a thermoplastic elastomer (TPE) or silicone, and when the pin 86 is fully received within the recess 90, the valve seat 88 is fully sealed, whereas air may enter the valve seat 88 if the pin 86 is retrieved from the valve seat 88, and the amount of air allowed to enter the valve seat 88 will depend on the extent to which the pin 86 is retrieved from the valve seat 88. The recess 90 is in fluid communication with a nozzle 92, which is in turn in fluid communication with the hood 12, e.g. *via* a hose (not shown) connected to the conduit 72, so that the pressure within the hood 12 when such is applied over a breast of a user may be fine-tuned by the user by manually operating the wheel 80.

[0020] When the breast pump 10 is fitted over a breast of a user and the pump motor 42 is activated, the pump diaphragm 44 will reciprocate to generate a lower pressure ("vacuum") in the hood 12, thus stimulating milk ejection reflex and subsequent expression of milk. Milk from the breast of the user will flow into the hood 12 and subsequently into the chamber 3 7 in the direction of the arrow M. The milk will accumulate in the chamber 37, first blocking the transmission of infrared signals between the transmitter and receiver of the lower IR unit 38a, and subsequently that between the transmitter and receiver of the upper IR unit 38b.

[0021] In the valve seat 20 is a one-way valve 96 which allows milk to enter the bottle 18, but not *vice versa*. Because the hood 12 is at a lower pressure than the bottle 18 during operation of the pumping action of the diaphragm 44, the higher pressure in the bottle 18 will prevent the milk in the chamber 37 from entering the bottle 18, thus allowing the milk level to rise in the chamber 37. It may take several sucking/releasing cycles before the milk level rises to, and blocks the transmission of infrared signals between the transmitter and receiver of, the upper IR unit 38b. When the milk level rises to the upper IR unit 38b, the motor 42 will stop, thus releasing the "vacuum" in the hood 12, in the manner discussed above. In addition, the needle valve 48 will be opened by the valve motor 46, whereby air will exit the bottle 18 *via* the nozzle 50, and subsequently out of the needle valve 48. The milk in the chamber 37 will thus fall, on its own weight, through the one-way valve 96 into the bottle 18, during the course of which the level of milk in the chamber 37 will fall. The transmission of IR signals between the transmitter and receiver of the upper IR unit 38b will thus resume, and then that between the transmitter and receiver of the lower IR unit 38a will resume.

[0022] As shown clearly in Figs. 4 and 14, above the upper IR unit 38b is a partition 98 which prevents milk from entering the interior of the head portion 22, e.g. when the breast pump 10 is accidentally knocked over. Milk entering the interior of the head portion 22 may damage the movement parts of the breast pump 10, thus shortening its useful life, or necessitating servicing.

[0023] Researches indicate that a baby's feeding is not a single continuous process, but rather a two-phased process in which the baby will initially suckle rapidly, called "stimulation". Once the breast has been sufficiently stimulated, milk begins flowing and the baby will settle into a slower, more relaxed sucking speed for the actual feeding phase, called "expression". The breast pump 10 can mimie the natural feeding pattern of a baby by first exhibiting rapid sucking/releasing actions to stimulate the milk ejection reflex (MER) or "let down". Once milk begins to flow, the breast pump 10 will then exhibit slower and longer sucking/releasing actions which help to maximize milk flow in less time.

[0024] The manner of operation of the breast pump 10 will be further discussed by reference to Fig. 15, which shows a flow chart of the steps of operation of the breast pump 10. Once the breast pump 10 is started (Step 100), the valve motor 46 will be triggered once to close the needle valve 48, which is called "retainer

valve" in Fig. 15 (Step 102). A "let down" sequence will be operated in which sucking/releasing actions will be carried out at a speed of 90 cycles per minute at a pressure of 5-7 inch mercury (in Hg) for 30 seconds (Step 104). If no milk flows (Step 106), an "expression" mode will be operated in which sucking/releasing actions will be carried out at a speed of 45 cycles per minute at a pressure of 7-9 in Hg for 30 seconds (Step 108). If there is still no milk flow (Step 110), the microcontroller 40 of the breast pump 10 (hereinafter simply referred to as the "breast pump 10" for simplicity) will determine if this is the first time such occurs since the breast pump 10 is started (Step 112). If not, the breast pump 10 will repeat the above process (Step 114) by carrying out the "let down" sequence again (Step 104). If, however, such a situation has already occurred once in this operation, a sign or symbol alerting the user to seek medical assistance, e.g. to undergo certain milk flow stimulation operation, will be displayed on the LCD display 28 (Step 115), and the breast pump 10 will also cease operation immediately (Step 116). For carrying out sucking/releasing actions at a frequency of 45 cycles per minute, the pump motor 42 may be activated for 0.8 second, then deactivated for 0.53 second, and then activated for 0.8 second, and so on.

[0025] If milk flows after the "let down" sequence (Step 104) or the "expression" sequence (Step 110), the breast pump 10 will then check whether transmission of IR signals in the lower IR unit 3 8a is interrupted (Step 118). If so, a timer in the microcontroller 40 will start timing (Step 120). The breast pump 10 will then check whether transmission of IR signals in the upper IR unit 38b is interrupted (Step 122). If so, the timer will stop (Step 124). Because the volume in the chamber 37 between the lower IR unit 38a and the upper IR unit 38b is known, it is possible to thus calculate the rate of flow of milk (in grams per second, g/s) and such is calculated. The valve motor 46 will be triggered once to open the needle valve 48, thus allowing milk in the chamber 37 to fall into the bottle 18. The breast pump 10 will also count the number of times of such triggers of the valve motor 46 as "X" (Step 126).

[0026] The breast pump 10 will then check whether transmission of IR signals in the lower IR unit 38a resumes ("released") within 2.5 seconds (Step 128). If so, the valve motor 46 will be triggered once to close the needle valve 48 (Step 130). If transmission of IR signals in the lower IR unit 38a does not resume ("released") within 2.5 seconds (Step 128), or after the closing of the needle valve 48 (Step 130), the breast pump 10 will then check if transmission of IR signals in the upper IR unit 38b is still blocked in 2.5 seconds (Step 132). If so, the pump motor 42 will stop operation, and the needle valve 48 will be opened once again (Step 134). If transmission of IR signals in the upper IR unit 38b is still blocked (Step 136), the pump motor 42 will stop operation again, and the needle valve 48 will be opened once again (Step 138). If transmission of IR signals in the upper IR unit 38b is still blocked (Step 140), the pump motor 42 will stop, a warning signal will be given on the LCD display 28, and the LCD display 28 will be turned off automatically in 5 minutes, (Step 142), and the operation of the breast pump 10 will also stop automatically (Step 116). Such will prevent the motor 42 from continuing operation when, e.g. the breast pump 10 accidentally topples over.

[0027] If transmission of IR signals in the upper IR unit 38b is not blocked after Step 132, Step 136 or Step 140, the breast pump 10 will operate according to the milk flow rate obtained in Step 126. If the flow rate is between 0.01 to 0.09 g/s (Step 144), the breast pump 10 will switch to "let down" sequence (Step 146) in which sucking/releasing action is carried out at a frequency of 90 cycles per minute at a pressure of 5-7 in Hg, and a sign or symbol indicating low flow rate will be displayed on the LCD display 28 (Step 148). If the flow rate is between 0.1 to 024 g/s (Step 150), the breast pump 10 will carry out sucking/releasing action at a frequency of 45 cycles per minute at a pressure of 7-9 in Hg (Step 152), and a sign or symbol indicating medium flow rate will be displayed on the LCD display 28 (Step 154). If the flow rate is 0.25 g/s or above (Step 156), the breast pump 10 will carry out sucking/releasing action at a frequency of 38 cycles per minute at a pressure of 6-8 in Hg (Step 158), and a sign or symbol indicating high flow rate will be displayed on the LCD display 28 (Step 160).

[0028] According to the present example, the bottle 18 is designed to hold 151.51g of milk, and in each cycle, the milk that enters, and is thus collected by, the bottle 18 is 1.5g. Based on such information, and the frequency at which sucking/releasing action is carried out, the breast pump 10 is able to calculate and display the remaining time required to fill the bottle 18. In this example, it normally requires 101 triggers of the valve motor 46, "X", to fill the bottle 18. Depending on the number of times, "X", the valve motor 46 has already been triggered to open the needle valve 48, the breast pump 10 can calculate the remaining time required for filling up the bottle 18 (Step 162). The remaining time required will be displayed on the LCD display 28 (Step 164).

[0029] If $1.5X > 151.51$ (Step 166), it means that the bottle 18 is filled up, the breast pump 10 will stop (Step 116). If not, the breast pump 10 will check again if transmission of IR signals in the lower IR unit 38a is interrupted (Step 118), and the pumping action will go on again.

[0030] It should be understood that the above only illustrates an example whereby the present invention may be carried out, and that various modifications and/or alterations may be made thereto without departing from the spirit of the invention. For example, although the present invention is here described in the context of a "one-pump" model, it is equally applicable to a "two-pump" model, in which a second breast pump is pneumatically connected with the first pump to share in the suction vacuum generated by the pump motor.

[0031] It should also be understood that certain features of the invention, which are, for clarity, described in

the context of separate embodiments, may be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any appropriate sub-combinations.

Claims

1. An electric breast pump **characterized in that** it comprises at least one hood member (12) adapted to be fitted over a breast of a user; a chamber (37) adapted to be in fluid communication with said hood member (12) via a first valve (48); a first motor (42) operatively associated with a pumping member (44) which is movable to draw air from said hood member (12) into said chamber (37) via said first valve (48); said chamber (37) having at least a first opening and a closure member (66) operatively associated with said first motor (42); wherein said closure member (66) is movable between a first position to close said first opening and a second position in which said first opening is open; and wherein said closure member is at said first position when said first motor (42) is in operation and is at said second position when said first motor (42) is not in operation.

2. A breast pump according to claim 1, **characterized in that** said closure member (66) is biased towards said second position.

3. A breast pump according to claim 2, **characterized in that** said closure member (66) is biased towards said second position by a spring member (62).

4. A breast pump according to any preceding claim, **characterized in that** said first valve is a one-way valve (70).

5. A breast pump according to any preceding claim, **characterized in that** said first motor (46) is engaged with said closure member (66) via at least one ring-shaped structure (60).

6. A breast pump according to claim 5, **characterized in that** said ring-shaped structure (60) is movable between a stable first configuration to which said ring-shaped structure is biased and a second configuration in which said closure member (66) is allowed to occupy said first position.

7. A breast pump according to claim 6, **characterized in that** said ring-shaped structure (60) is at said stable first configuration when said first motor (42) is not in operation and at said second configuration when said first motor (42) is in operation.

8. A breast pump according to claim 7, **characterized in that** said ring-shaped structure (60) rotates when said first motor (42) is in operation.

9. A breast pump according to claim 8, **characterized in that** said ring-shaped structure (60) moves from said first configuration to said second configuration by centrifugal force when said ring-shaped structure rotates.

10. A breast pump according to any preceding claim, **characterized in that** said chamber (37) includes at least a second opening closable by a second valve (74).

11. A breast pump according to claim 10, **characterized in that** said second valve (74) is a one-way valve.

12. A breast pump according to claim 10 or claim 11, **characterized in that** said second valve (74) only allows air to exit said chamber.

13. A breast pump according to any preceding claim, **characterized in that** it further includes an adjustment member manually operable to adjust the air pressure in said hood member (12).

14. A breast pump according to claim 13, **characterized in that** said adjustment member includes a third valve member (86) in fluid communication with said hood member (12).

15. A breast pump according to claim 14, **characterized in that** said adjustment member further includes a wheel member (80) manually operable to adjust the amount of air allowed to enter the third valve.

16. A breast pump according to any preceding claim, **characterized in that** it further includes a fourth valve (96) in fluid communication with the hood member (12).

17. A breast pump according to claim 16, **characterized in that** it further includes a second motor (46) for selectively opening or closing said fourth valve (96).

18. A breast pump according to claim 16 or claim 17, **characterized in that**, during operation of said breast pump, said fourth valve (96) is openable to release the vacuum in said hood member (12).

19. A breast pump according to any preceding claim, **characterized in that** it further includes at least one sensing unit (38b) adapted to detect the passing of milk.

20. An electric breast pump **characterized in that** it includes at least one hood member (12) adapted to be fitted over a breast of a user and at least a first sensing unit (38b) adapted to detect the passing of milk.

21. A breast pump according to claim 19 or claim 20, **characterized in that** it further includes a data processing unit (40) adapted to calculate the rate of flow of milk on the basis of data received from said sensing unit (38b).

22. A breast pump according to any one of claims 19 to 21, **characterized in that** said sensing unit (38b) includes at least one infrared (IR) transmitter and an IR receiver adapted to receive IR signals from said IR transmitter.

23. A breast pump according to any one of claims 19 to 22, **characterized in that** it further includes at least a second sensing unit (38a).

24. A breast pump according to claim 23, **characterized in that** said first and second sensing units (38b,38a) are arranged in series in the path of flow of milk in said breast pump.

25. A breast pump according to claim 24, **characterized in that** a timer is provided for determining the time duration between when passing of milk is detected by said first sensing unit (38b) and when passing of milk is detected by said second sensing unit (38a).

26. A breast pump according to any one of claims 23 to 25, **characterized in that** IR signals transmitted by said IR transmitter are prevented from being received by said IR receiver upon passing of milk therebetween.

27. A breast pump according to any one of claims 19 to 26, **characterized in that** further includes a display (28) for visually indicating the general rate of flow of milk into said breast pump.

28. A breast pump according to claim 22, **characterized in that** said data processing unit (40) is adapted to calculate the remaining time required for filling a receptacle of milk associated with said breast pump.

29. A breast pump according to claim 28, **characterized in that** it includes a motor operatively associated with a pumping member, wherein the frequency of movement of said pumping member is adapted to be varied on the basis of the rate of flow of milk calculated by said data processing unit.

30. A breast pump according to claim 29, **characterized in that** the motor is adapted to stop operation when IR signals transmitted by said IR transmitter are prevented from being received by said IR receiver for a predetermined period of time.

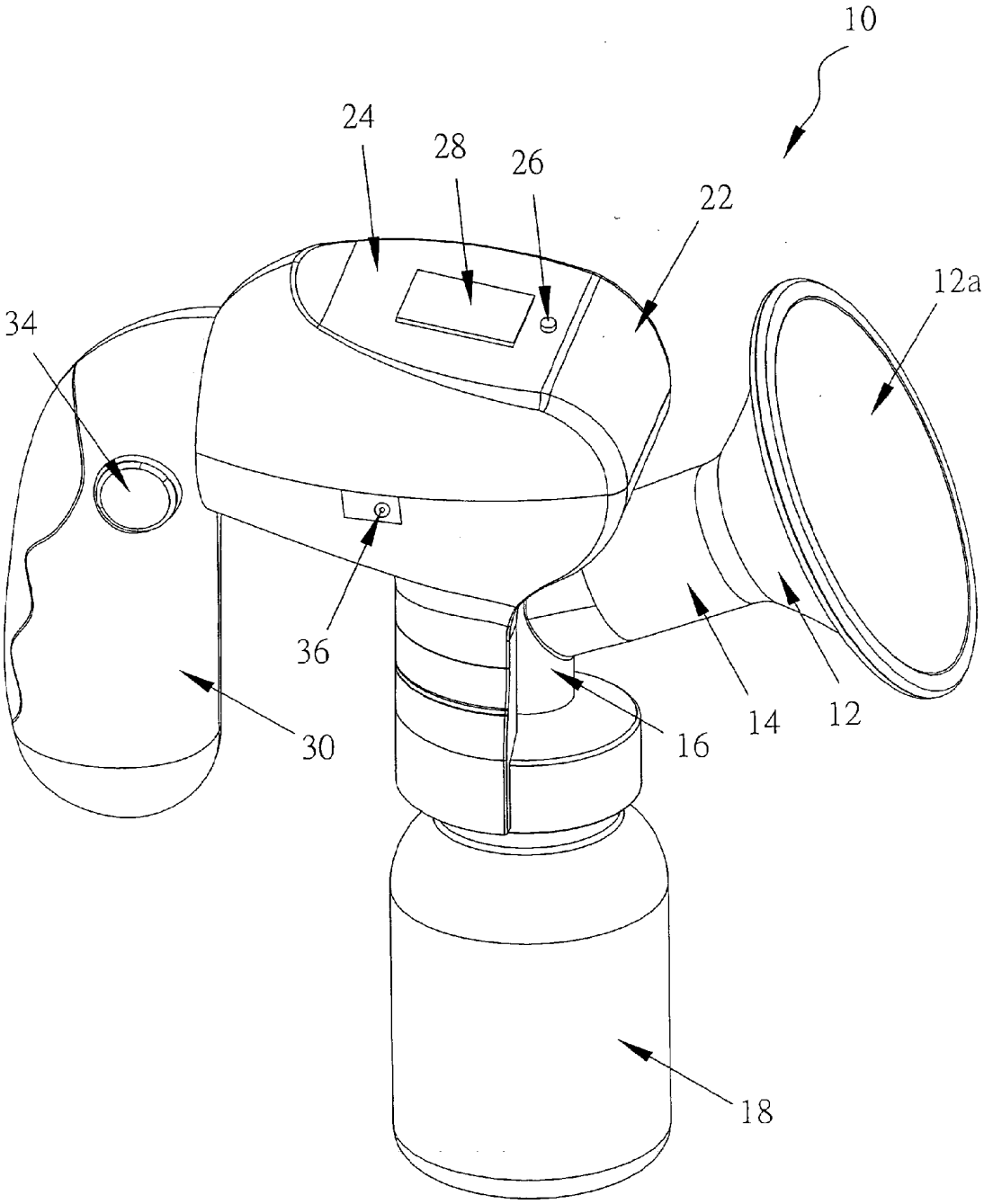


Fig. 1

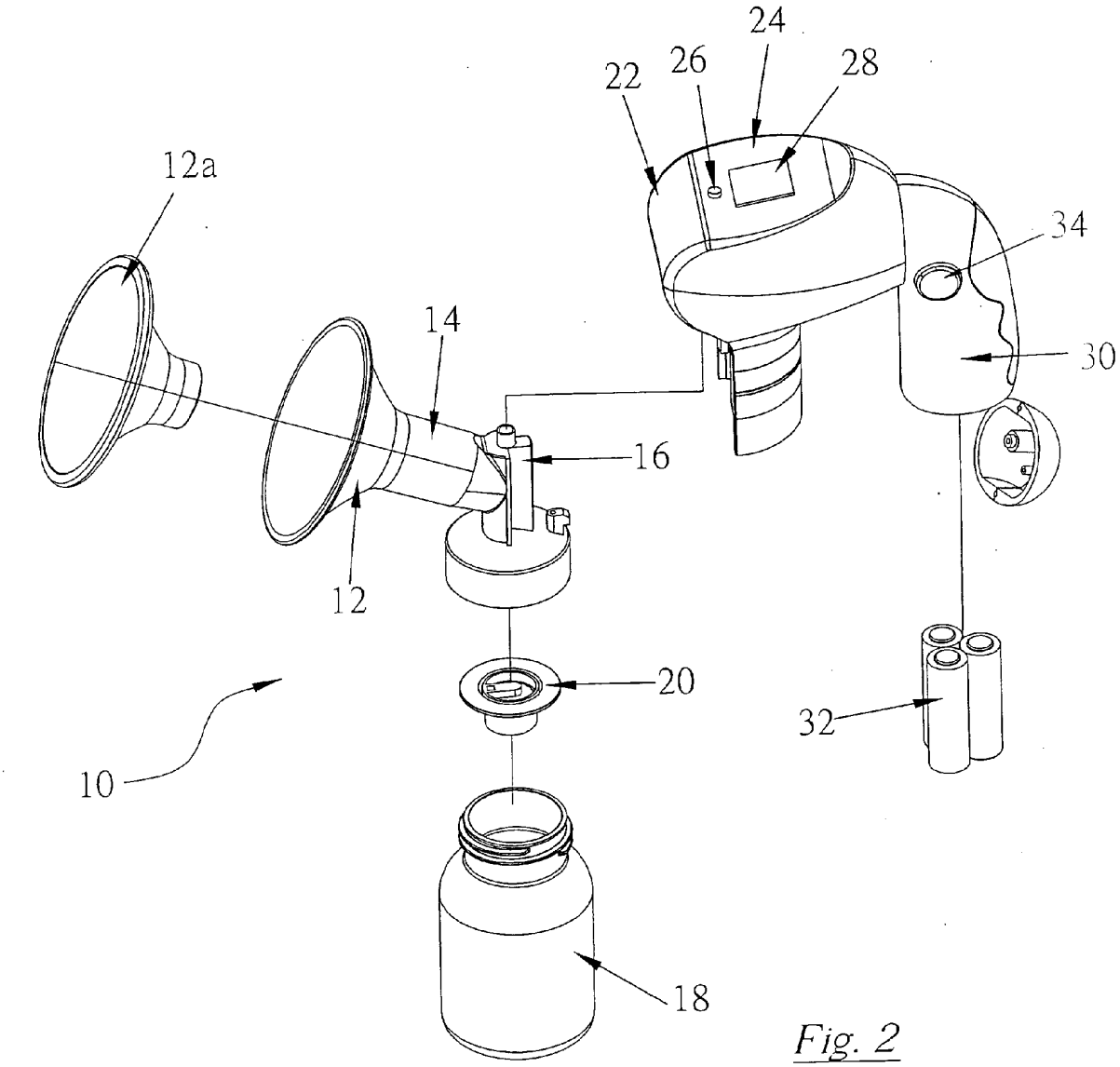


Fig. 2

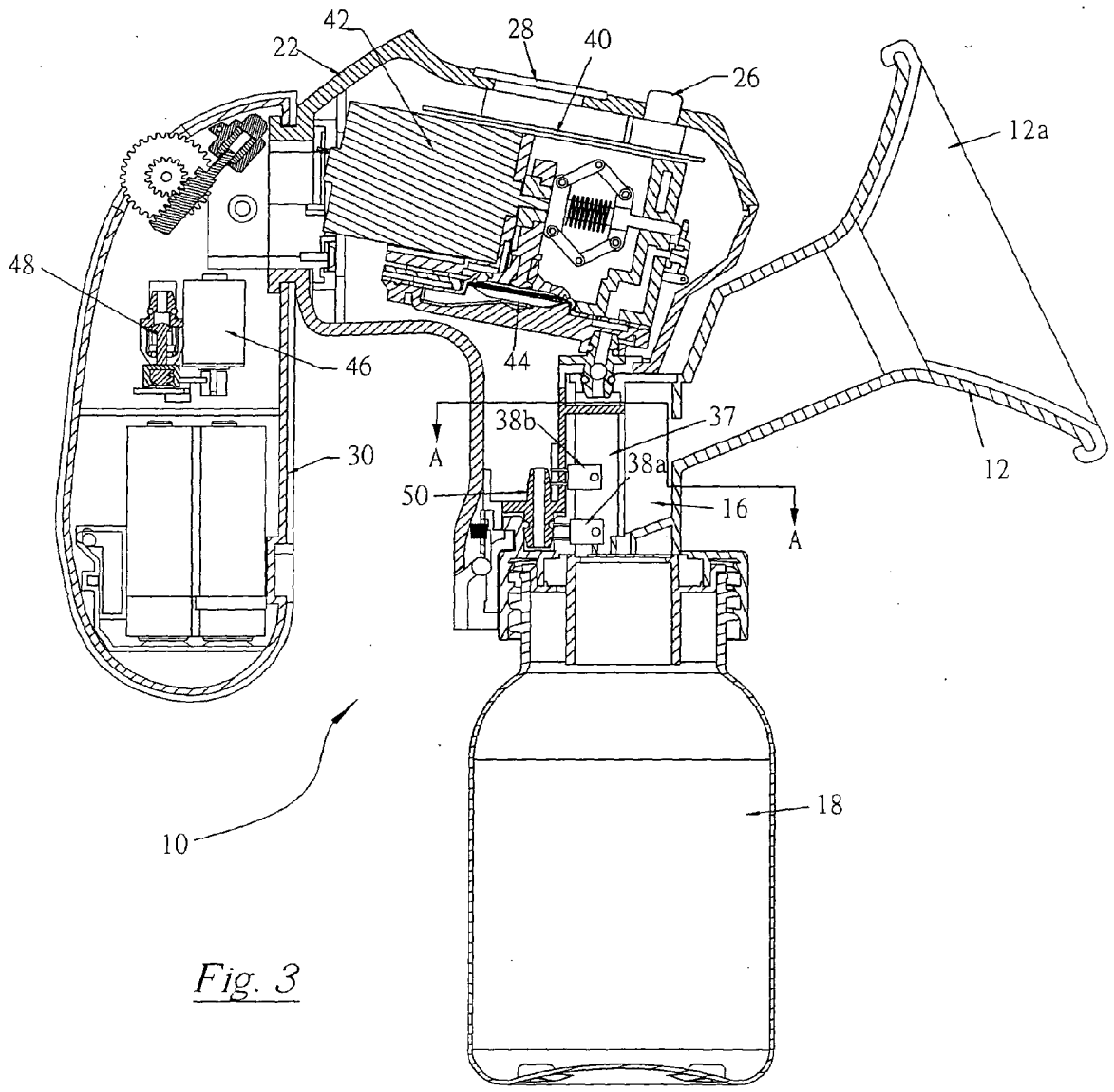


Fig. 3

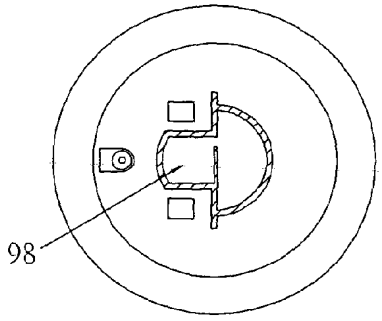


Fig. 4

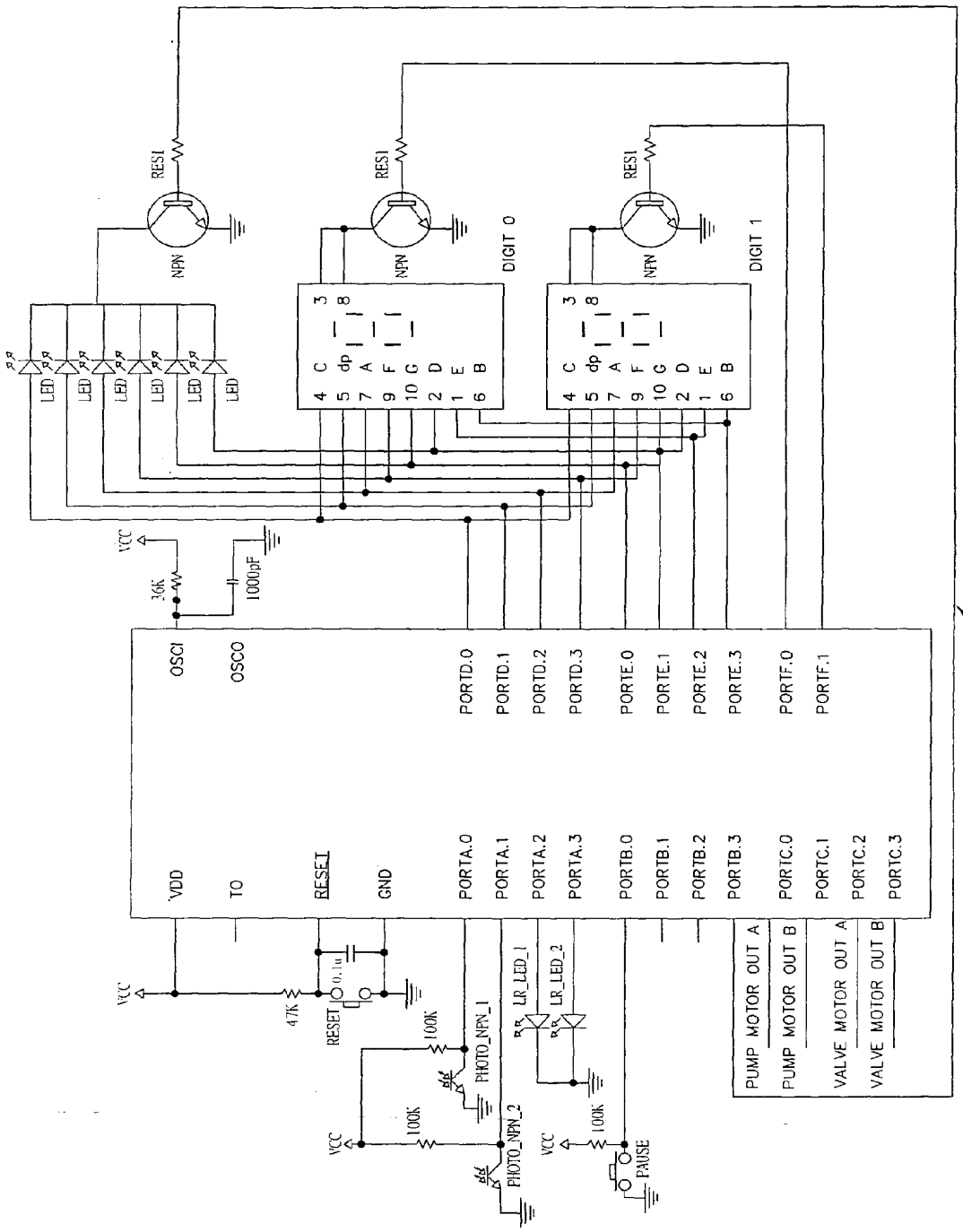

RES1
NPN
DIGIT 0
DIGIT 1
LED
VCC
36K
1000pF
OSCI
OSCO
VDD
TO
RESET
GND
PORTA.0
PORTA.1
PORTA.2
PORTA.3
PORTB.0
PORTB.1
PORTB.2
PORTB.3
PORTC.0
PORTC.1
PORTC.2
PORTC.3
PORTD.0
PORTD.1
PORTD.2
PORTD.3
PORTE.0
PORTE.1
PORTE.2
PORTE.3
PORTF.0
PORTF.1
47K
0.1u
100K
PHOTO_NPN_1
PHOTO_NPN_2
LR_LED_1
LR_LED_2
PAUSE
PUMP MOTOR OUT A
PUMP MOTOR OUT B
VALVE MOTOR OUT A
VALVE MOTOR OUT B
40

Fig. 5

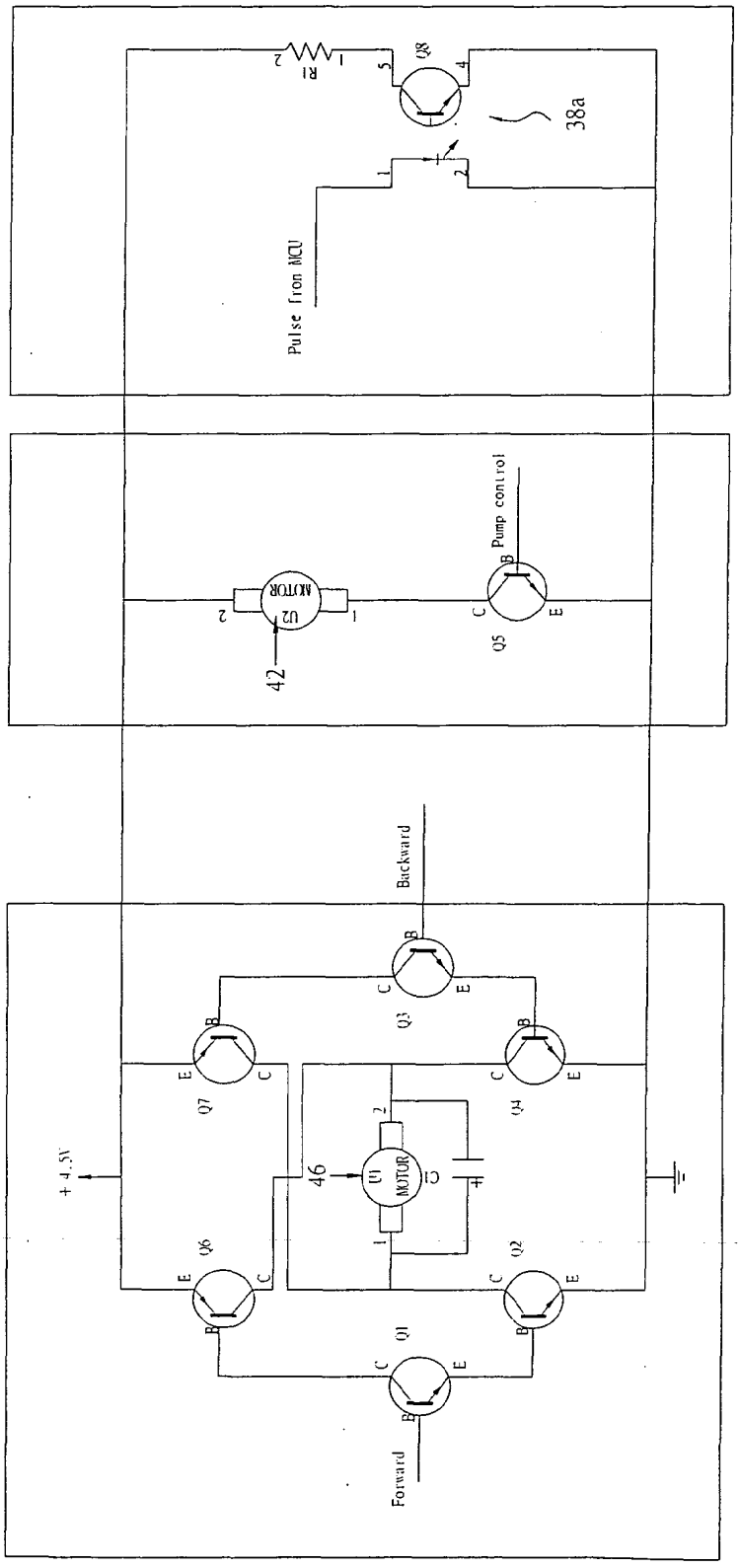

Pulse from MCU
38a
Q8
R
Pump control
Q5
MOTOR
U2
42
Backward
Q3
Q7
Q4
+4.5V
46
U1
MOTOR
C1
Q6
Q2
Q1
Forward

Fig. 6

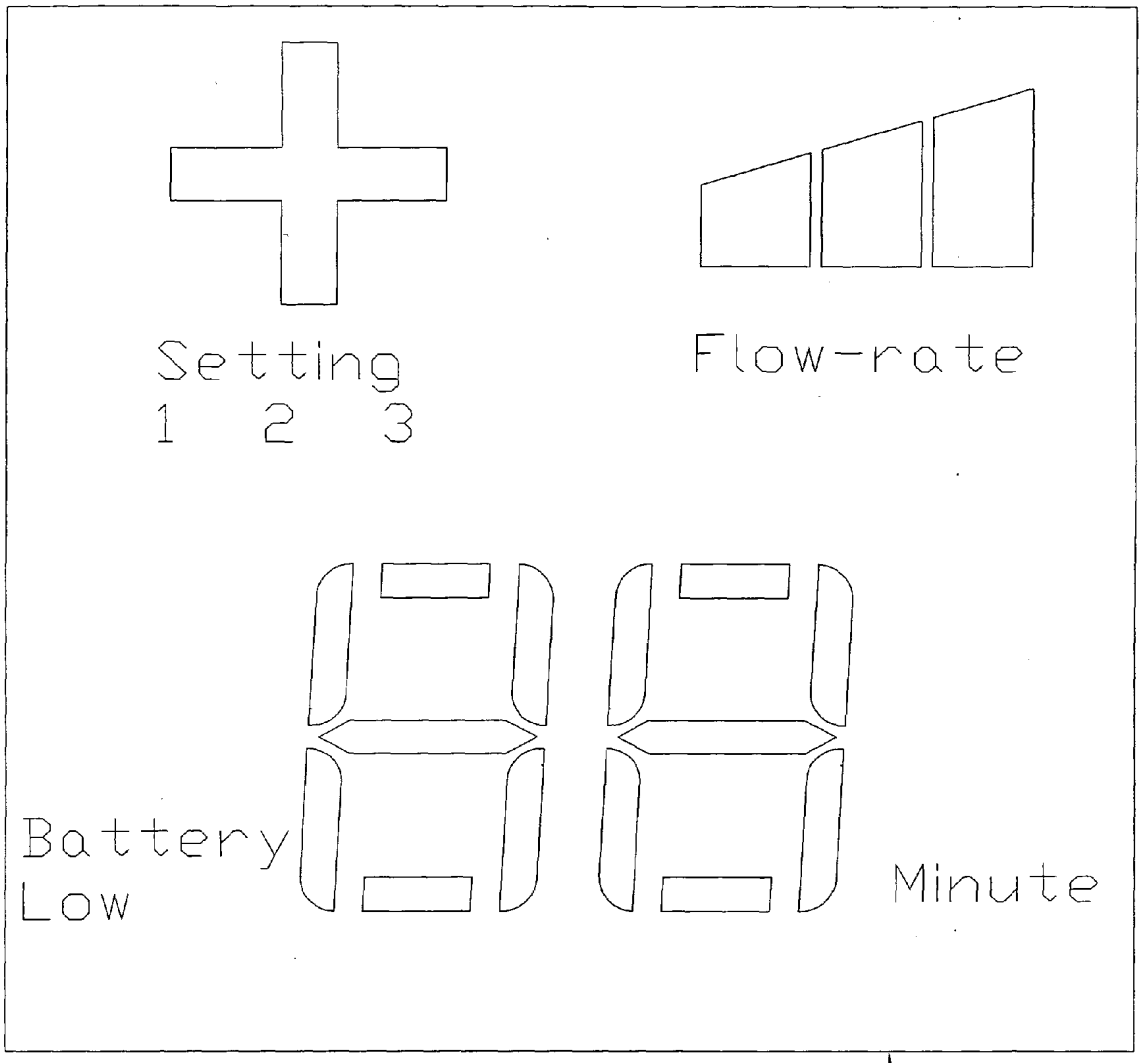


Fig. 7

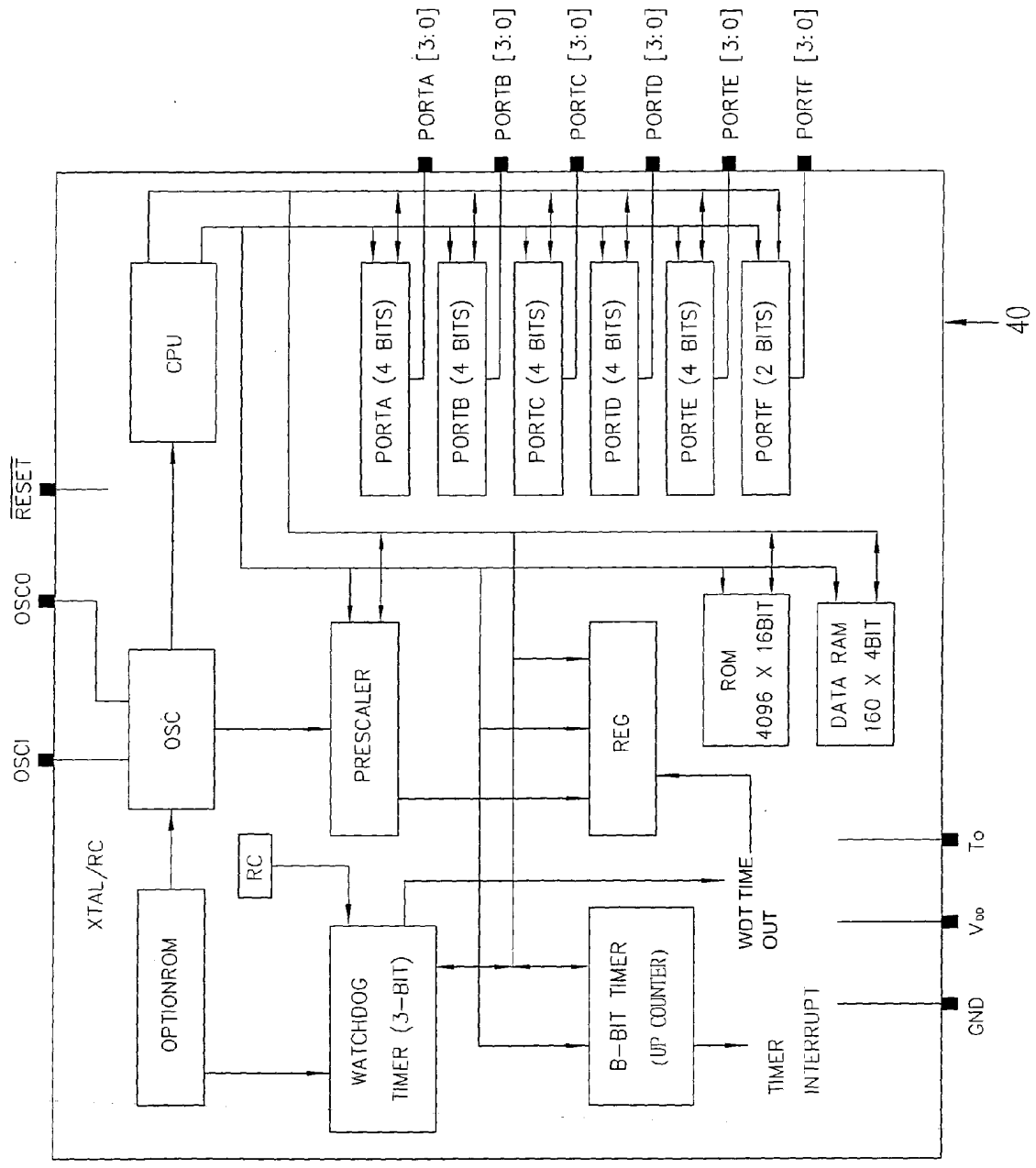

PORTA [3:0]
PORTB [3:0]
PORTC [3:0]
PORTD [3:0]
PORTE [3:0]
PORTF [3:0]
40
CPU
PORTA (4 BITS)
PORTB (4 BITS)
PORTC (4 BITS)
PORTD (4 BITS)
PORTE (4 BITS)
PORTF (2 BITS)
RESET
OSCO
OSCI
OSC
PRESCALER
REG
ROM
4096 X 16BIT
DATA RAM
160 X 4BIT
XTAL/RC
RC
OPTIONROM
WATCHDOG
TIMER (3-BIT)
B-BIT TIMER
(UP COUNTER)
WDT TIME
OUT
TIMER
INTERRUPT
To
Vdd
GND

Fig. 8

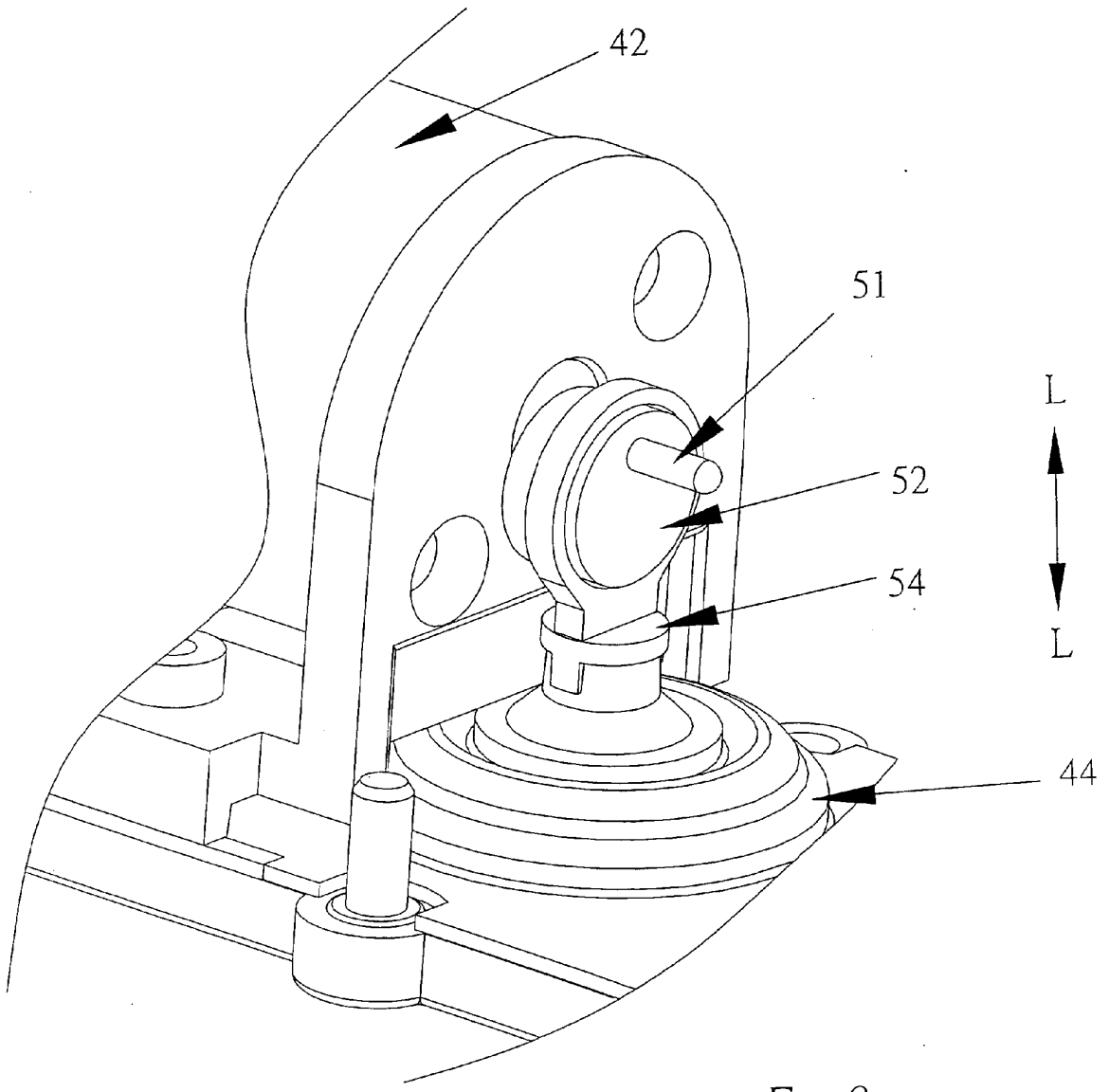


Fig. 9

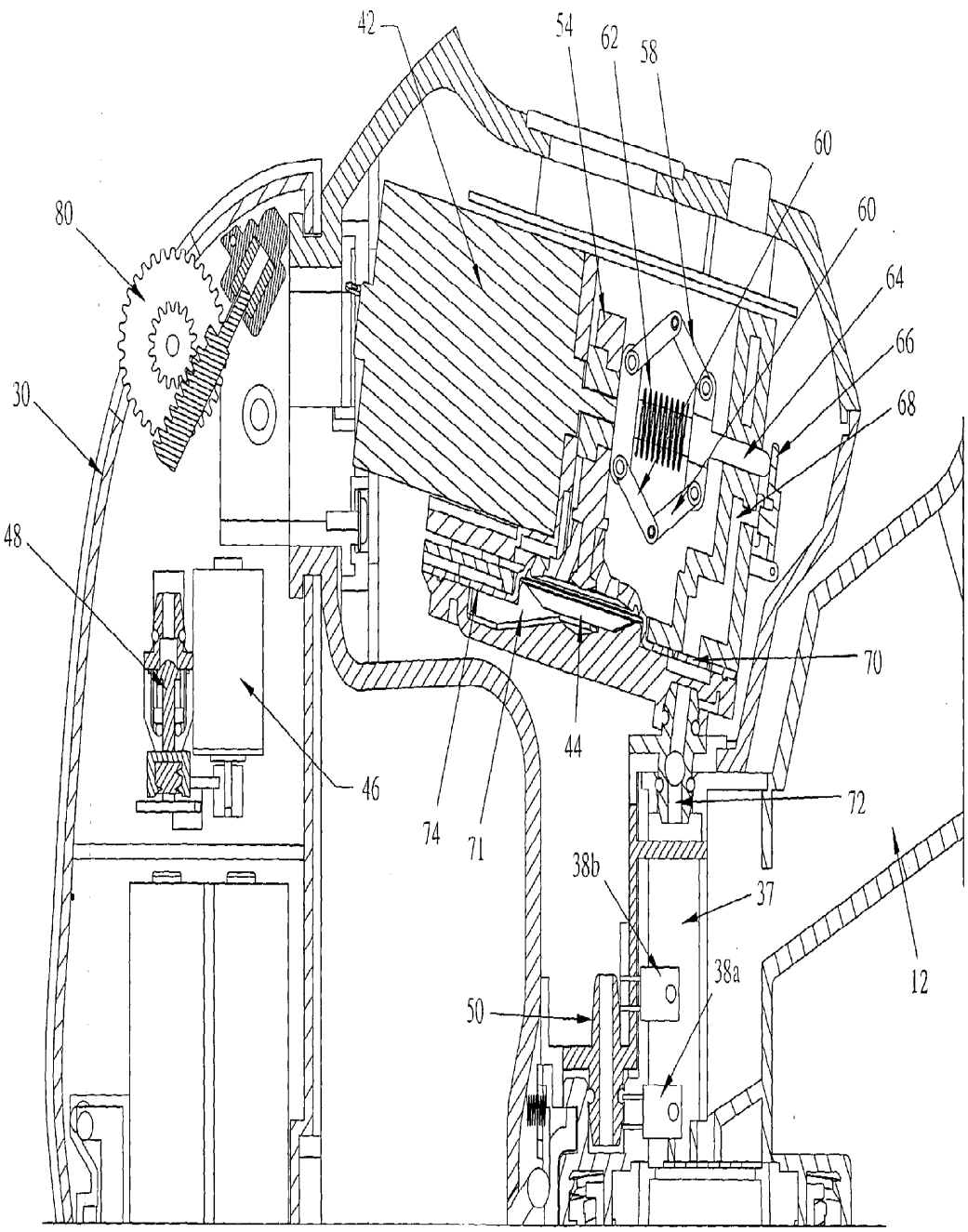


Fig. 10

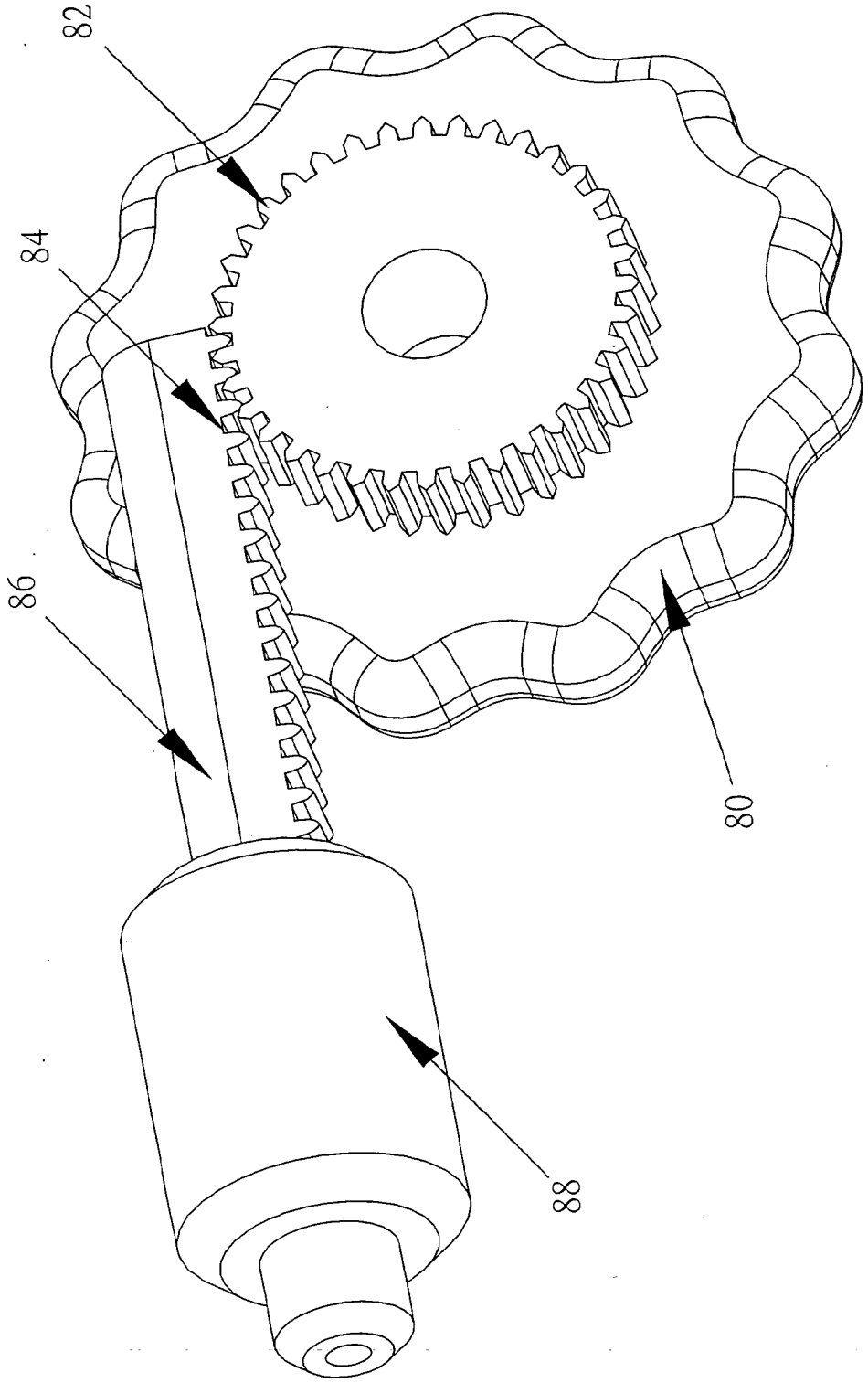


Fig. 11

Fig. 12

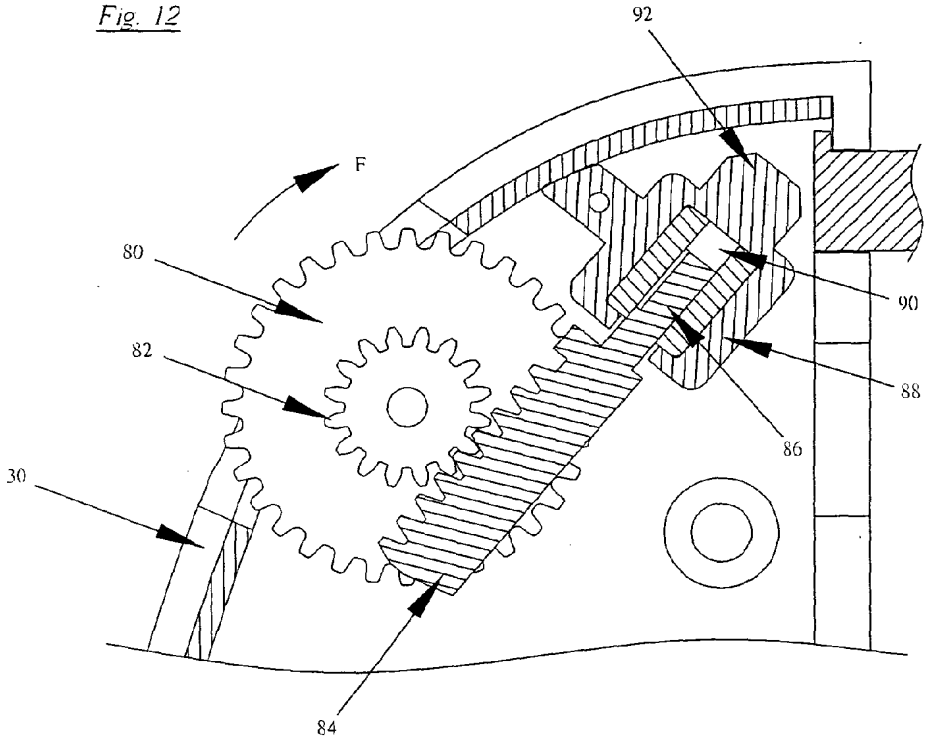
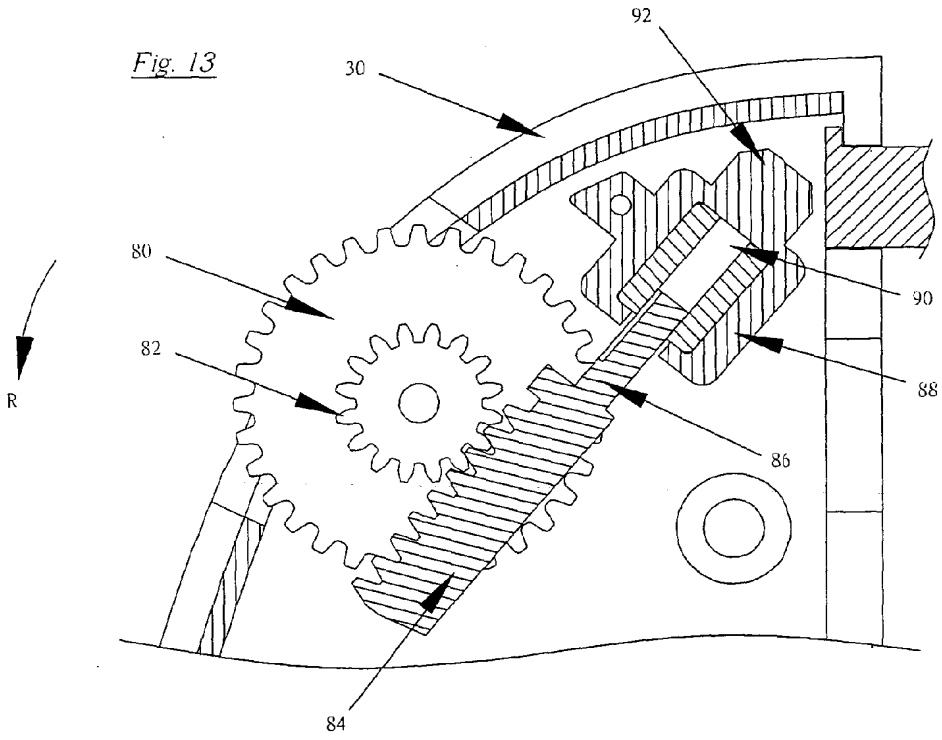


Fig. 13



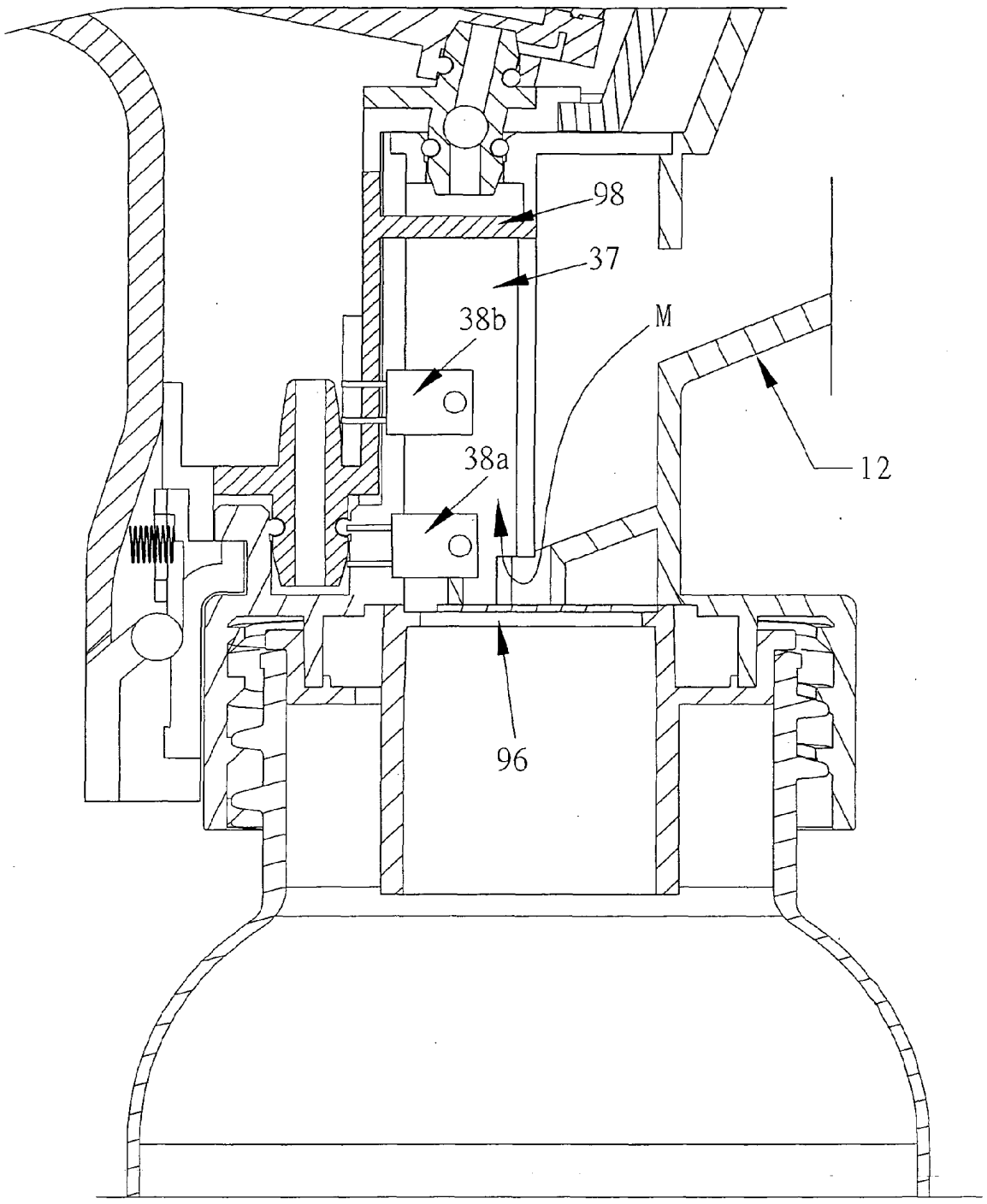


Fig. 14

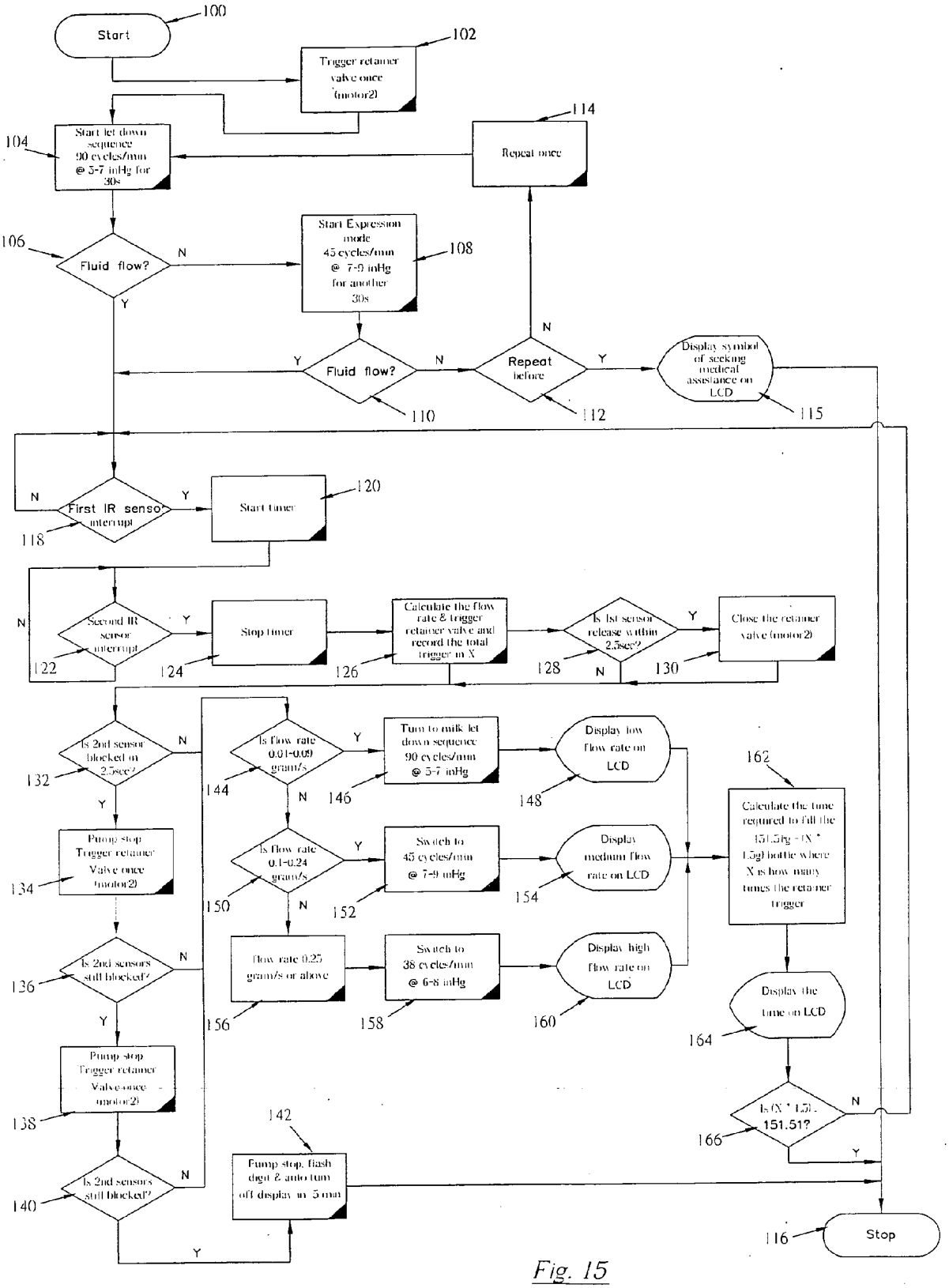

Start
100
Trigger retainer valve once (motor2)
102
Start let down sequence 90 cycles/min @ 5-7 inHg for 30s
104
Repeat once
114
Fluid flow?
106
N
Y
Start Expression mode 45 cycles/min @ 7-9 inHg for another 30s
108
Fluid flow?
110
Repeat before
112
Display symbol of seeking medical assistance on LCD
115
First IR sensor interrupt
118
Start timer
120
Second IR sensor interrupt
122
Stop timer
124
Calculate the flow rate & trigger retainer valve and record the total trigger in X
126
Is 1st sensor release within 2.5sec?
128
Close the retainer valve (motor2)
130
Is 2nd sensor blocked in 2.5sec?
132
Pump stop Trigger retainer Valve once (motor2)
134
Is 2nd sensors still blocked?
136
Pump stop Trigger retainer Valve once (motor2)
138
Is 2nd sensors still blocked?
140
Pump stop, flash digit & auto turn off display in 5 min
142
Is flow rate 0.01~0.09 gram/s
144
Turn to milk let down sequence 90 cycles/min @ 5-7 inHg
146
Display low Flow rate on LCD
148
Is flow rate 0.1~0.24 gram/s
150
Switch to 45 cycles/min @ 7-9 inHg
152
Display medium Flow rate on LCD
154
Flow rate 0.25 gram/s or above
156
Switch to 38 cycles/min @ 6-8 inHg
158
Display high Flow rate on LCD
160
Calculate the time required to Fill the 151.5fg - (X * 1.5g) bottle where X is how many times the retainer trigger
162
Display the time on LCD
164
Is (X * 1.5) = 151.5?
166
Stop
116

Fig. 15

РОССИЙСКАЯ ФЕДЕРАЦИЯ

(19) **RU** (11) **2 441 367** (13) **C2**

(51) МПК
A01J 7/00 (2006.01)

ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

(12) ОПИСАНИЕ ИЗОБРЕТЕНИЯ К ПАТЕНТУ

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(54) СПОСОБ ИЗМЕРЕНИЯ ОБЪЕМА МОЛОКА В РЕЗЕРВУАРЕ

(57) Реферат:

Изобретение относится к измерительной и холодильной технике. Предложенный способ заключается в том, что предварительно перемешивают молоко, после чего регистрируют расстояние от бесконтактного датчика, закрепленного на верхнем упоре, в качестве которого используют съемный цифровой лазерный дальномер со встроенными батареями питания, до поверхности молока. Затем это расстояние вычитают из расстояния до дна пустого резервуара и определяют объем молока в резервуаре по индивидуальной тарировочной таблице уровней, полученной при последовательном заполнении резервуара от нуля до максимума через эталонный счетчик-расходомер с дискретностью 50 л. Изобретение повышает точность и удобство измерения объема молока, просто в применении. 4 ил.

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RUSSIAN FEDERATION

FEDERAL SERVICE
FOR INTELLECTUAL PROPERTY

(19) **RU** (11) **2 441 367** (13) **C2**

(51) Int. Cl.
A01J 7/00 (2006.01)

(12) ABSTRACT OF INVENTION

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(54) METHOD OF MILK VOLUME MEASURING IN TANK

(57) Abstract:

FIELD: measuring and refrigeration engineering.

SUBSTANCE: milk is mixed in advance. Then distance from a proximity sensor mounted on an overhead gauge to milk surface is measured. Removable ranging laser with integrated battery power can be used as an overhead gauge. Further, this value is deducted from the distance to the bottom of an empty tank, and milk volume in tank is calculated according to an individual rating table, composed by sequential tank filling from zero to max. level using reference volumeter with 50 litre increment.

EFFECT: increase in accuracy and convenience of milk volume measuring, easy to apply.

6 dwg

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Изобретение относится к области измерительной и холодильной техники и может быть использовано в пищевой промышленности, в агропромышленном комплексе и предназначено для бесконтактного измерения объема преимущественно охлажденного молока при продажах отгрузках и покупках на молокозаводах, молочнотоварных фермах и фермерских хозяйствах для коммерческого учета.

Известны приборы фирмы Endress+Hauser: микроволновые радарные уровнемеры для жидкостей Micropilot S FMR531, использующие регистрацию расстояния от бесконтактного датчика с измерительным преобразователем. непосредственно закрепленного на верхнем кронштейне вертикальных цилиндрических резервуаров, которые вычитают из расстояния от датчика до дна пустого резервуара [1]. Также известны ультразвуковые бесконтактные уровнемеры Prosonic M FMU 40/45 [2]. состоящие из датчика и измерительного преобразователя, выполненных в едином корпусе, работающие по такому же принципу. В танках-охладителях молока Kryos фирмы Westfalia Surge [3] используется погружной электронный датчик уровня, с измерительным поплавком и стержнем, ценой 1690 €.

Молочная холодильная установка по патенту RU 2265322, A01J 9/04, 2005 г в качестве простейшего измерителя объема молока в резервуаре использует мерную линейку из нержавеющей стали, отградуированную через 50 литров [4]. Опуская ее через люк до упора, отмечают уровень и объем продукта по глубине погружения в молоко на соответствующем делении. Аналогичный простейший измеритель объема применяется в вариантном исполнении резервуаров Westfalia Surge (без электронного датчика уровня). С другой стороны, известен портативный цифровой лазерный дальномер (ЦЛД) DLL 50 Professional фирмы BOSCH [5], габаритные размеры которого 58×100×32 мм. масса 0.18 кг. цена деления 1 мм, со встроенными батареями питания, стоимостью 150 €, предназначенный для измерения дальностей, длин, высот от датчика до непрозрачных, непористых поверхностей, с помощью узконаправленного лазерною луча. Он применяется преимущественно для строительных работ - своеобразная «лазерная рулетка».

Стационарные бесконтактные уровнемеры для жидкостей Micropilot S FMR 531 и Prosonic M FMU 40/45 используют принцип соответственно радиолокации и эхолокации, поставляются с протоколами калибровки и программным обеспечением, а также возможностью задания собственной таблицы линеаризации для пересчета уровня в единицы объема. Они содержат отдельно излучатель и программируемый ЖК-дисплей, являются сложными, габаритными и дорогими для использования в резервуарах охладителях молока, особенно учитывая невысокую квалификацию обслуживающего персонала ферм. К тому же ультразвуковой уровнемер FMU 40 усложнен встроенным датчиком температуры для коррекции точности. Аналогичными недостатками (сложностью и малой ремонтопригодностью) обладает емкостной поплавковый датчик уровня резервуара Kryos [3]. К тому же он является погружным и требует периодической очистки стержня и поплавка для сохранения точности.

Недостатком погружных мерных линеек [4] является невысокая точность и жесткая расчетная градуировка в литрах при нанесении шкалы, не позволяющая учесть реальный технологический разброс (допуск) размеров индивидуально каждого резервуара при его изготовлении и калибровке. Реальные отклонения диаметра, длины, высоты и ширины внутренней поверхности резервуаров [3, 4] до 10 мм приводят к погрешностям в десятки литров, которые необходимо учитывать дополнительными корректирующими таблицами. Длина мерной линейки

цилиндрического резервуара на 6000 л составляет 2 м, что требует высоких потолков в молокоприемном пункте (до 4,5 м) чтобы была возможность извлечь двухметровую линейку из резервуара высотой 2,3 м через люк. Это приводит к дополнительным неудобствам в эксплуатации.

Наиболее близким по технической сущности к заявляемому изобретению (прототипом) является способ измерения уровня (объема) молока в резервуаре. реализованный в уровнемере Micropilot S FMR 531, заключающийся в регистрации расстояния от микроволнового радарного датчика со стержневой антенной, стационарно закрепленного на верхнем упоре резервуара, до поверхности молока, которое вычитают из расстояния от датчика до дна пустого резервуара. Датчик (рабочая частота 6 ГГц) и измерительный преобразователь прибора выполнены в едином корпусе, содержат четырехстрочный жидкокристаллический дисплей с полноцветным текстовым меню, программным обеспечением для задания собственной таблицы пересчета измеренного уровня в литры, настройки и линейной калибровки, сделанной на заводе-изготовителе. Базовая стоимость микроволнового датчика FMR 531 составляет с НДС 4543 €, что определяется его сложностью и соразмерно с ценой молочной холодильной установки [4], состоящей из резервуара и холодильного агрегата. Стационарное закрепление датчика на верхнем упоре резервуара, работающего в агрессивных средах, вынуждает изготовителей к пылевлагозащищенному исполнению узлов, что также усложняет и удорожает прибор. Масса датчика (без учета фланца) составляет 4 кг, а четырехпроводное соединение датчика с дисплеем обусловливает стационарное раздельное размещение датчика и дисплея на резервуаре, что также удорожает монтаж и усложняет прибор.

Изобретение направлено на упрощение и удешевление измерения объема молока в резервуаре для коммерческого учета при одновременном повышении точности и удобства.

Указанный технический результат достигается тем, что при регистрации расстояния от бесконтактного датчика, закрепленного на верхнем упоре резервуара, до поверхности молока, которое вычитают из расстояния до дна пустого резервуара, СОГЛАСНО ИЗОБРЕТЕНИЮ, в качестве датчика используют съемный цифровой лазерный дальномер со встроенными батареями питания, причем перед измерением молоко перемешивают, а после измерения определяют объем по индивидуальной тарировочной таблице уровней, полученной при последовательном заполнении резервуара от нуля до максимума через эталонный счетчик-расходомер с дискретностью, например, 50 литров.

Изобретение поясняется чертежами. На фиг.1 представлена схема регистрации уровня молока в цилиндрическом резервуаре, на фиг.2 - индивидуальная тарировочная таблица цилиндрического резервуара с номинальным объемом 3000 л, на фиг.3 - чертеж размещения верхнего упора при измерении уровня (объема) молока через закрытый люк, на фиг.4 - сборочный чертеж съемного цифрового лазерного дальномера (ЦЛД) с упорным флажком.

Способ измерения объема, V [л]: молока в резервуаре (фиг.1) основан на регистрации фактического расстояния $H_ф$ от цифрового лазерного дальномера ЦЛД 1 (его верхнего торца 2) до поверхности молока 3 лучом лазера 4, и вычитании этого значения из начального расстояния В между ЦЛД 1 и дном пустого резервуара. Для получения объема молока в резервуаре V [л] используют индивидуальную тарировочную таблицу перевода показаний ЦЛД 1 $H_ф$ [мм] в объем молока V [л], например, для трехтонного цилиндрического резервуара фиг.2 с размерами: D=2R=

1274 мм - диаметр внутренней полоста резервуара, L=2560 мм - ее длина.

Расчетные значения H [мм] на фиг.2 даны для идеального цилиндра с горизонтальным расположением резервуара на регулируемых опорах без учета выноса отсчетного торца 2 ЦЛД 1 над срезом люка на расстояние a=298 мм, включающее высоту установки упора в обечайке люка, размер упорного флажка и длину самого датчика (100 мм). Расчетные зависимости V (H) и H (V) получены численными методами из тригонометрического уравнения объема молока в резервуаре с уровнем h=2R-H:

$$V = R^2 L\left[\arccos(HR-1) - (H/R-1)\sqrt{2H/R - H^2/R^2}\right], \quad H>R$$

Фактические показания ЦЛД $H_ф$ должны быть получены по результатам калибровки объемов молока в резервуаре эталонным счетчиком - расходомером, например, счетчиком холодной воды (СХВ), паспорт ПДЕК.407223.002 ПС, производитель г.Арзамас, ЗАО «Росавиаспецкомплект», номинальный расход 25 л/мин, цена деления младшего разряда 1 л стоимостью - 400 рублей. Замеры $H_ф$ проводятся через 50 л при последовательном заполнении резервуара вплоть до среза люка.

Для удобства измерения при закрытом люке, положение которого может изменяться в пределах податливости эластичной манжеты обечайки, на съемный ЦЛД 1 (фиг.3. фиг.4) неподвижно установлен упорный флажок 5, закрепленный на корпусе ЦЛД 1 винтом-фиксатором 6. При замерах и тарировке упорный флажок 5 съемного ЦЛД 1 сквозь щель 7 с резиновой шторкой в крышке люка 8 вставляют в упор 9, приваренный к обечайке 10. Тем самым жестко фиксируют расстояние от ЦЛД 1 до уровня молока. Для герметичности измерительные отверстия 11 в крышке люка 8 закрыты прозрачным оргстеклом 12, приклеенным к верхней плоскости крышки 8. Измерения сквозь прозрачное стекло 12, выполняемые ЦЛД 1, показывают идентичные результаты по сравнению с открытыми отверстиями 11, т.е. прозрачное стекло 12 не искажает результатов измерения. ЦЛД 1 питается от четырех штатных батарей 13 4×1.5 В, устанавливаемых под крышку корпуса.

При замерах согласно руководству по эксплуатации трижды нажимают на кнопку 14 (измерение), после чего на дисплее 15 появляется фиксируемый результат, например, 0.821 м ЦЛД 1 можно вынуть из щели 7 и снять показания, которые будут удерживаться 5 минут. Для выключения ЦЛД 1 можно обесточить нажатием на кнопку 16.

При оценке точности способа необходимо отметить, что лазерный луч 4, в связи с некоторой прозрачностью молока, проникает вглубь поверхности уровня 3 на расстояние Δ=5 мм (фиг.1) при нормальной жирности 3,6…3,8%

Замеры датчиком DLE 50 Professional BOSCH с длиной волны 635 нм показывают, что снижение жирности молока до 1,5% и 1% соответственно увеличивают глубину проникновения луча Δ до 9 мм и даже до 13 мм соответственно. Отстой молока и выделение на поверхности сливок с жирностью 15…20% уменьшают проникновение луча в поверхность 3 до Δ=1 мм. Поэтому для повышения точности перед измерением молоко необходимо перемешивать в течение 1…2 минут. Для этой цели в резервуарах-охладителях молока применяется мешалка (фиг.1), обеспечивающая его равномерную плотность (гомогенизацию) по всему объему в процессе хранения. Нормальная жирность охлажденного или парного гомогенизированного молока 3,6…3,8% обеспечивает стабильное проникновение луча Δ=5 мм при любых уровнях h и фактических показаниях $H_ф$, независимо от температуры, что гарантирует высокую

точность и стабильность $H_ф$ в сочетании с другими константами, жестко определяющими положение отсчетного торца 2 ЦЛД 1 над срезом люка в момент измерения (a=298 мм).

При поставках в хозяйства столбец $H_ф$ тарировочной таблицы (фиг.2) содержит пустые графы и только после монтажа резервуара с уклоном 1…2° проводится его калибровочное заполнение через эталонный счетчик-расходомер, поэтому все отклонения от идеальной расчетной зависимости $H_ф$ (V), обусловленные уклоном, а также полями допусков на изготовление внутренней полости цилиндров диаметром D=2R и длиной L, не влияют на точность измерения объема.

Рассмотрим измерение уровня и объема молока между узловыми (табличными) точками, например, при $H_ф$=821 мм на промежуточном уровне. Отметим по тарировочной таблице (фиг.2) ближайшие значения, например, $H_ф$=832 мм и $H_ф$=87, полученные в результате калибровки, что соответствует расчетным уровням h=736 мм и h=751 мм в реальном резервуаре, а также объем V=1950 л и V=2000 л. С учетом кусочно-линейной аппроксимации между узловыми точками измеренный объем составит

$$1950 + 50 \times \frac{832 - 821}{832 - 817} = 1982 \text{ л}$$

Для снижения начальной погрешности метода Δ, обусловленной проникновением лазерного луча 4 вглубь поверхности молока на Δ=5 мм, при регулировке положения изгиба упорного флажка 5 в щели 9 следует приблизить пятно луча 4 к сливному патрубку резервуара на 150…200 мм по продольной оси. В этом случае уже первый литр молока при изначальном заполнении резервуара, с учетом уклона на 1…2° в сторону сливного патрубка, даст уровень h порядка 9…12 мм. Все последующие заполнения уровня h будут линейно с высокой точностью (до 1 мм) фиксироваться убывающими показаниями ЦЛД 1.

Таким образом, уровень h учитывается с точностью до 1 мм, а объем V - с точность до 1 л. Следовательно, фактическая точность метода определения объема молока в резервуаре обусловлена точностью эталонного счетчика-расходомера, поскольку замеры точности работы ЦЛД DLE 50 Professional (лазерной «рулетки») на эталонном расстоянии показывают погрешность не более 1 мм в пределах 0…3,000 м.

При поставках в фермерские хозяйства резервуаров с ЦЛД каждое изделие комплектуется СХВ - счетчиком-расходомером ПДЕК и тарируется по таблице (фиг.2) для коммерческого учета в присутствии покупателя и продавца. Паспортная погрешность СХВ ПДЕК.407223.002 ПС не превышает 3%. В спорных случаях погрешность метода может быть уменьшена за счет ручного заполнения резервуара эталонной емкостью с молоком 50 л.

Учитывая ограниченный расход (25 л/мин) через эталонный счетчик-расходомер СХВ, последовательное заполнение трехтонного резервуара через 50 л согласно таблицы (фиг.2) с 64 контрольными точками регистрации $H_ф$ с помощью ЦЛД 1 займет порядка трех часов (каждая точка - 2…3 минуты). Поэтому заполнение молоком трехтонного резервуара из-за возможных потерь (прокисления) нецелесообразно. Для упрощения калибровки резервуара в комплект также поставляется пластмассовая тарелка из полистирола толщиной 3 мм, глубиной 20 мм и диаметром 200 мм, которая наполняется на 6…8 мм цельным парным молоком. Она устанавливается на дно пустого резервуара под лазерный луч 4 датчика ЦЛД 1, который проникает вглубь цельного молока на упомянутую константу Δ=5 мм. Последовательно заполняя резервуар водой через СХВ с расходами 25 л/мин,

каждые 2 минуты перекрывают кран и снимают показания с ЦЛД 1 через 50 л. Тарелка на воде всплывает, при этом уровень молока в тарелке до долей миллиметра совпадает с уровнем воды, а измерение лазерным лучом 4 с помощью ЦЛД полностью имитирует заполненный молоком резервуар. Таким образом, в процессе калибровки резервуара задают точный объем воды через 50 л с помощью СХВ и замеряют уровень молока $H_ф$ в плавающей тарелке высокоточным ЦЛД 1, с регистрацией результатов в таблицу (фиг.2). Мы получаем точное соответствие уровня $H_ф$ [мм] объему молока V [л] в резервуаре, причем погрешности изготовления резервуара и регулировка его уклона не влияют на точность измерения.

К достоинствам способа можно отнести отсутствие в закрытых резервуарах-охладителях молока прямых солнечных лучей, которые могут искажать результаты лазерных измерений.

Преимущество предлагаемого способа измерения перед простейшей мерной линейкой с нанесенной через 50 л гравировкой уровней заключается в высокой точности, исключающей при замерах погрешности изготовления резервуара и регулировки его уклона при монтаже в хозяйствах. Габаритные размеры ЦЛД с упорным флажком значительно меньше мерной линейки и не требуют высоких потолков при замерах. Кроме того, нет необходимости в открытии люка в режиме регистрация уровня объема молока, при этом не нарушается герметичность резервуара.

По сравнению с прототипом (микроволновым радарным уровнемером FMR 531), преимущества предлагаемого способа заключаются в значительном упрощении конструкции, уменьшении габаритов, снижении стоимости на порядок, удобстве измерения, калибровки и обслуживания. Очевидно, что прототип, как и предлагаемый способ, с целью повышения точности, нуждается в эталонной калибровке, однако, для реализации этого он еще требует соответствующего программного обеспечения, встроенных перепрограммируемых запоминающих устройств, соответствующей квалификации персонала и микрокомпьютерной поддержки, что нереально в условиях российских ферм. Большим преимуществом предлагаемого способа является быстросъемное исполнение датчика в отличие от встроенной стержневой антенны прототипа, которое позволяет между замерами хранить ЦЛД в нормальных климатических условиях.

Таким образом, использование предлагаемого способа измерения объема молока в резервуарах-охладителях позволяет существенно повысить точность его коммерческого учета при хранении и сдаче. Реализовать это удается простейшими средствами и по доступным для крестьян ценам (порядка 1...3% от стоимости комплектной поставки).

Вот почему немедленно после внедрения этого способа в продукцию ООО «НИИ «Автомат» (г. Ковров), 30% заказов открытых и закрытых резервуаров-охладителей молока с декабря 2007 г комплектуются лазерными цифровыми дальномерами DLE 50 Professional со счетчиками-расходомерами СХВ ПДЕК.407223.002 ПС, тарировочной таблицей и пластмассовой тарелкой-поплавком.

Литература

1. Микроволновый радарный уровнемер для бесконтактного измерения уровня жидкостей Micropilot SFMR 531. В книге ОАО «Челябинский завод теплоприбор»: 2006 г., 454047, г.Челябинск, ул. 2-я Павелецкая, 36: дилерский центр ENDRESS+HAUSRR. стр.267-269; сайт http: www.tpchel.ru.

2. Компактный ультразвуковой уровнемер для жидкостей Prosonic M FME 40. Книга

ОАО «Челябинский завод теплоприбор»: 2006 г., 454047, г.Челябинск, ул. 2-я Павелецкая, 36: дилерский центр ENDRESS+HAUSER. стр.271-272: сайт: www.tpchel.ru.

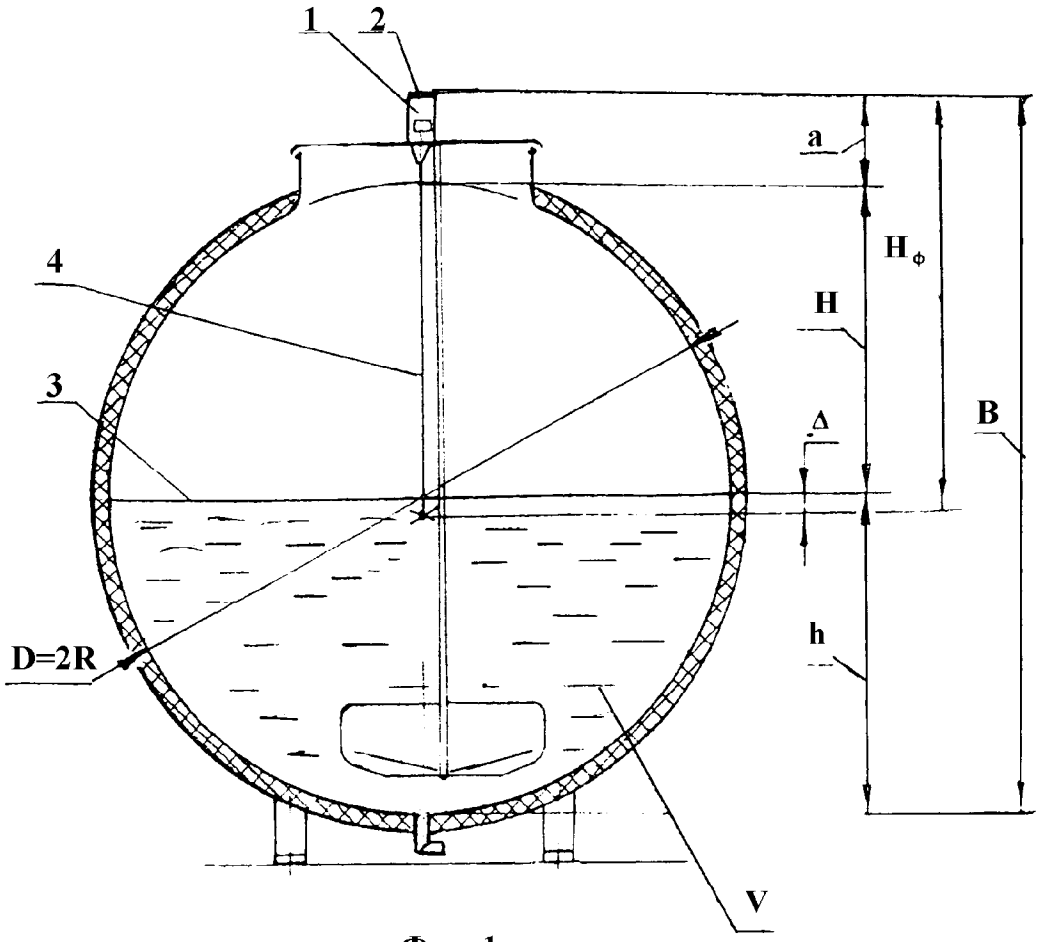
3. Танк охладитель молока Kryos Westfalia Surge. Рекламный буклет 2006 г. стр.2. 3, 6, сайт: www.westfalia surge.ru. Москва, ул.Семеновский Вал, 6, строение 1, тел.937-57-63.

4. Молочная холодильная установка. Патент RU №2265322, A01J 9/04, 2005 г.

5. Цифровой лазерный дальномер DLE 50 Professional. BOSCH. Руководство по эксплуатации, стр.143-150. На русском языке. ООО «Роберт Бош». Сервисный центр по обслуживанию электроинструмента. 129515, Москва, ул.Академика Королева. 13, строение 5, тел. 935-71-93, сайт: www.bosch-pt.com.

Формула изобретения

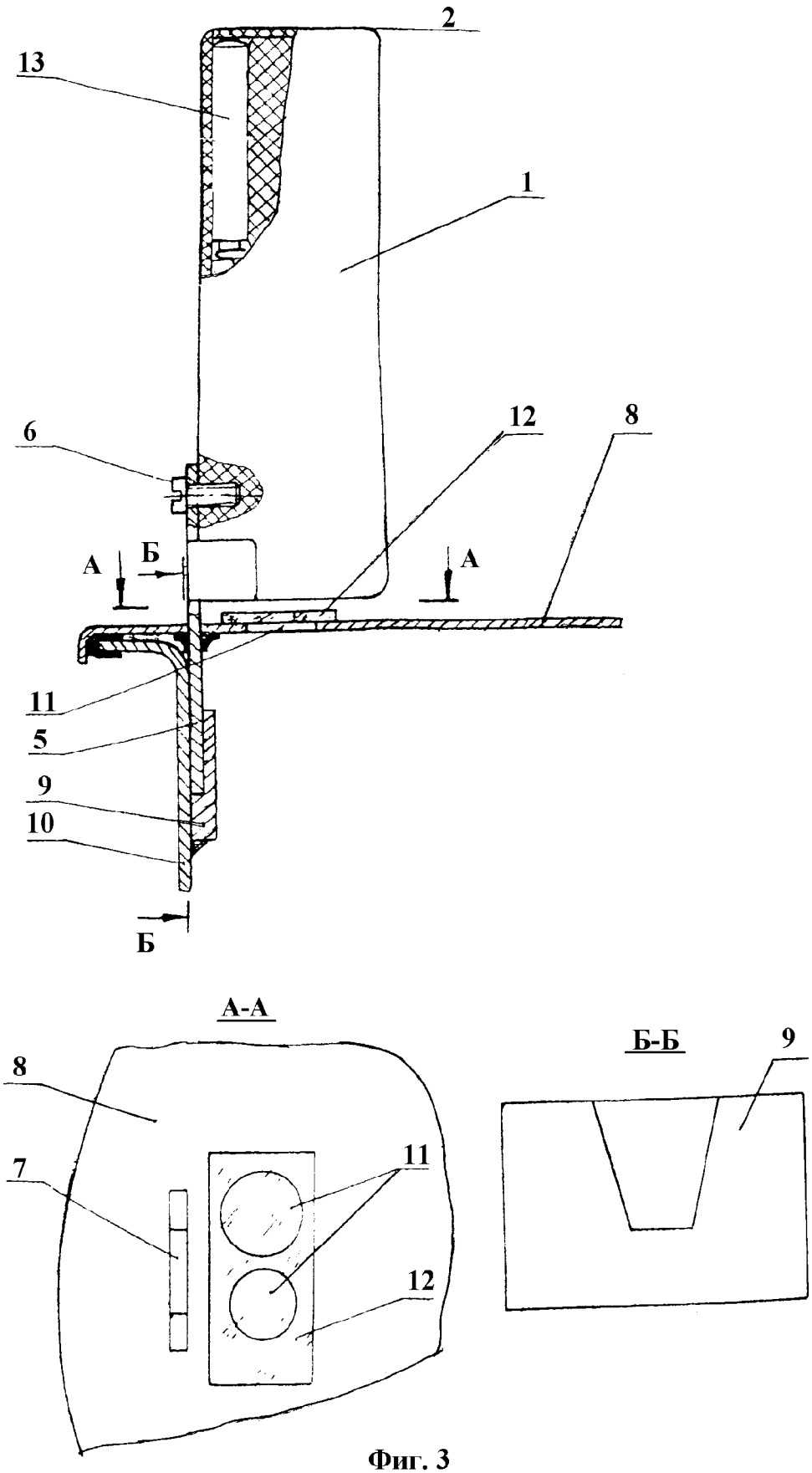
Способ измерения объема молока в резервуаре, заключающийся в регистрации расстояния от бесконтактного датчика, закрепленного на верхнем упоре, до поверхности молока, которое вычитают из расстояния до дна пустого резервуара, отличающийся тем, что в качестве датчика используют съемный цифровой лазерный дальномер со встроенными батареями питания, причем перед измерением молоко перемешивают, а после измерения определяют объем по индивидуальной тарировочной таблице уровней, полученной при последовательном заполнении резервуара от нуля до максимума через эталонный счетчик-расходомер с дискретностью, например, 50 л.



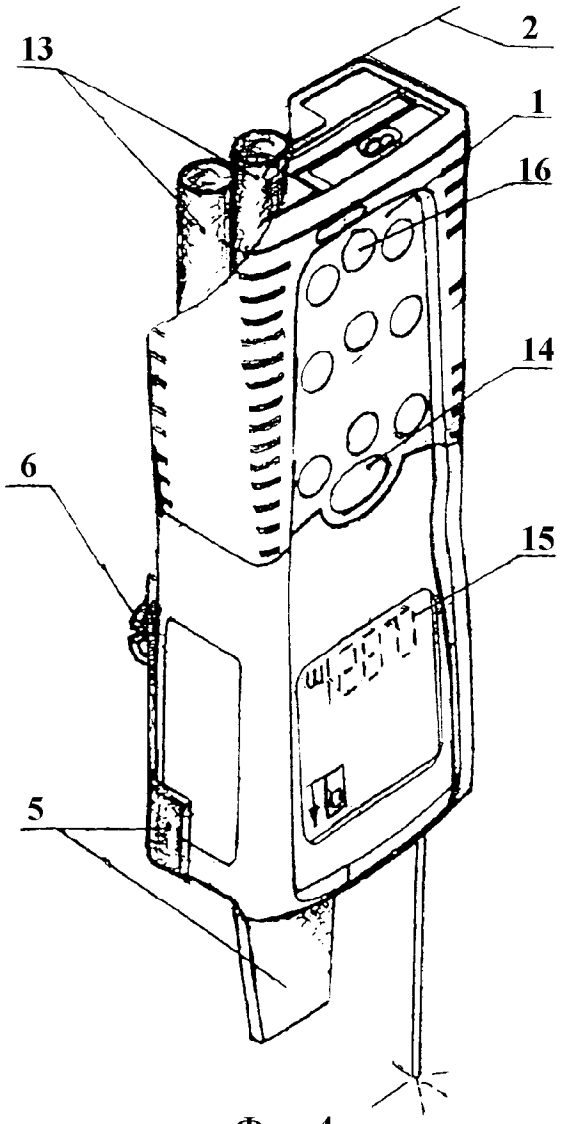
Фиг. 1

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100	90	1184		1750	673	601	
150	117	1157		1800	689	585	
200	143	1131		1850	703	571	
250	167	1107		1900	720	554	
300	188	1086		1950	736	538	832
350	209	1065		2000	751	523	816
400	229	1045		2050	767	507	
450	250	1024		2100	782	492	
500	268	1006		2150	798	476	
550	286	988		2200	814	460	
600	306	968		2250	830	444	
650	323	951		2300	846	428	
700	340	934		2350	864	410	
750	360	914		2400	879	395	
800	374	900		2450	897	377	
850	391	883		2500	912	362	
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1350	551	723		3000	1102	172	
1400	766	708		3050	1126	148	
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1500	597	677		3150	1170	104	
1550	612	662		3200	1208	66	
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Фиг. 2



Фиг. 3



Фиг. 4

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
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UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	2081	1	200	200
Claims:				
CLAIMS IN EXCESS OF 20	2202	10	50	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous-Filing:				
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3555**

Electronic Acknowledgement Receipt

EFS ID:	32910084
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	15-JUN-2018
Filing Date:	
Time Stamp:	13:12:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3555
RAM confirmation Number	061518INTEFSW13140300
Deposit Account	504364
Authorized User	Mark Simpson

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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3		T1_2_as_filed.PDF	937035 005395c6523f1648d33823967cc35c4c21be968d	yes	126

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	121
Claims	122	125
Abstract	126	126

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4	Drawings-only black and white line drawings	Elvie_Pump_US_figs_as_filed.PDF	6476970 15aca1b7780bd336acb53dbe1ee5b87eb865d73c	no	44
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Total Files Size (in bytes):	69055781

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Patent Application Fee Transmittal

Application Number:	16009547
Filing Date:	
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00002

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**80**

Electronic Acknowledgement Receipt

EFS ID:	32910167
Application Number:	16009547
International Application Number:	
Confirmation Number:	5958
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Correspondence Address:	Saul Ewing Arnstein & Lehr LLP (Philadelphia) Attn: Patent Docket Clerk Centre Square West 1500 Market Street, 38th Floor Philadelphia PA 19102-2186 US 215-972-7880 patents@saul.com
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00002
Receipt Date:	15-JUN-2018
Filing Date:	
Time Stamp:	13:16:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$80

RAM confirmation Number	061518INTEFSW13170700
Deposit Account	504364
Authorized User	Mark Simpson

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

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Warnings:

Information:

Total Files Size (in bytes):	30469

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

SCORE Placeholder Sheet for IFW Content

Application Number: 16009547 Document Date: 06/15/2018

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