UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

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
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	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

POWER OF ATTORNEY NOTICE

OC0000000133003112

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- The Power of Attorney to you in this application has been revoked by the applicant.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

OC000000133003147

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
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

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, Charo 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 cea4d66d805705bd3758de5e0ba4d38ffd63de63	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
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.

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.

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.	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.

IR103 (Rev. 10/09)

DocCode – SCORE

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.

Form Revision Date: March 1, 2019

33/44

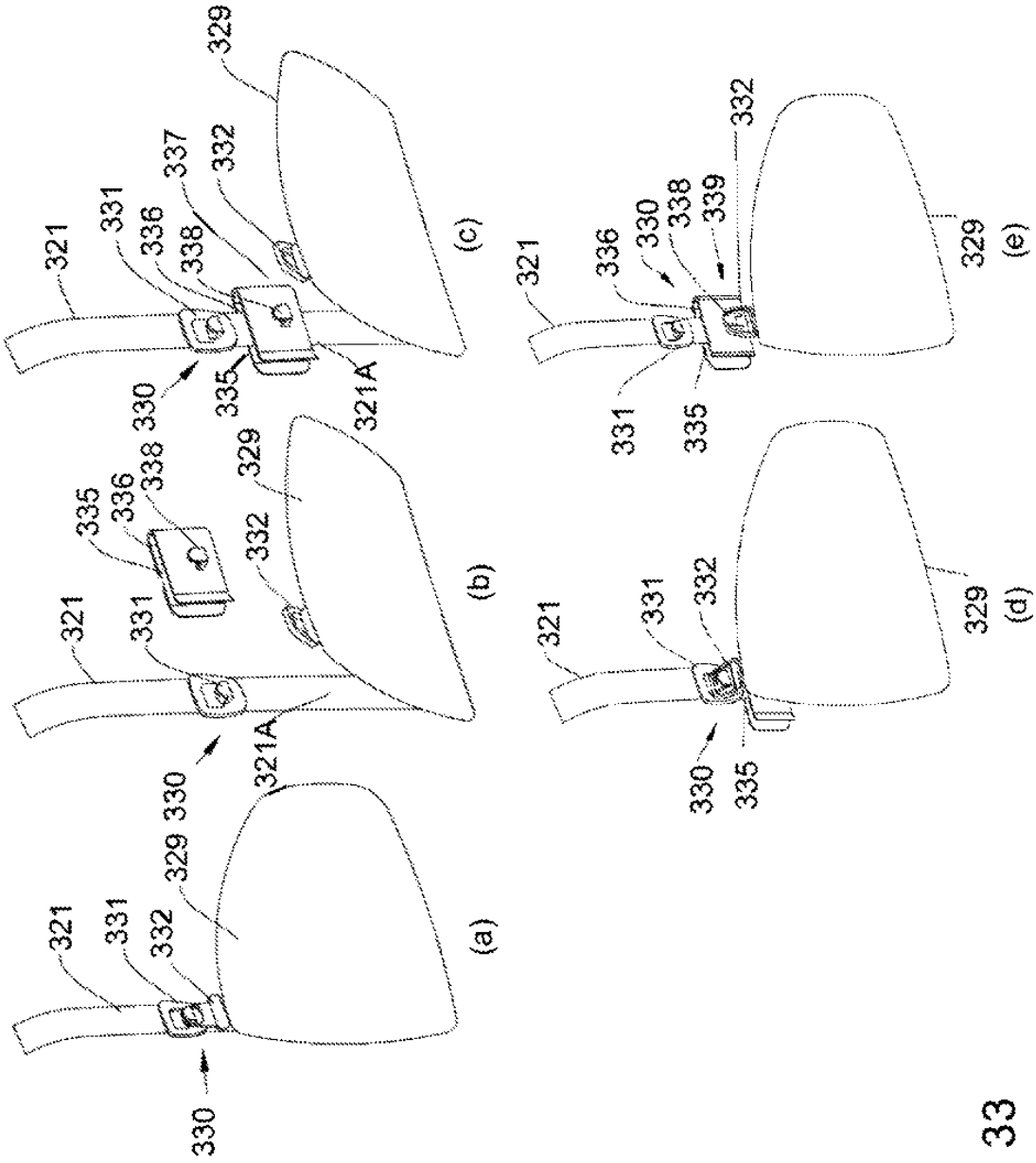


FIGURE 33

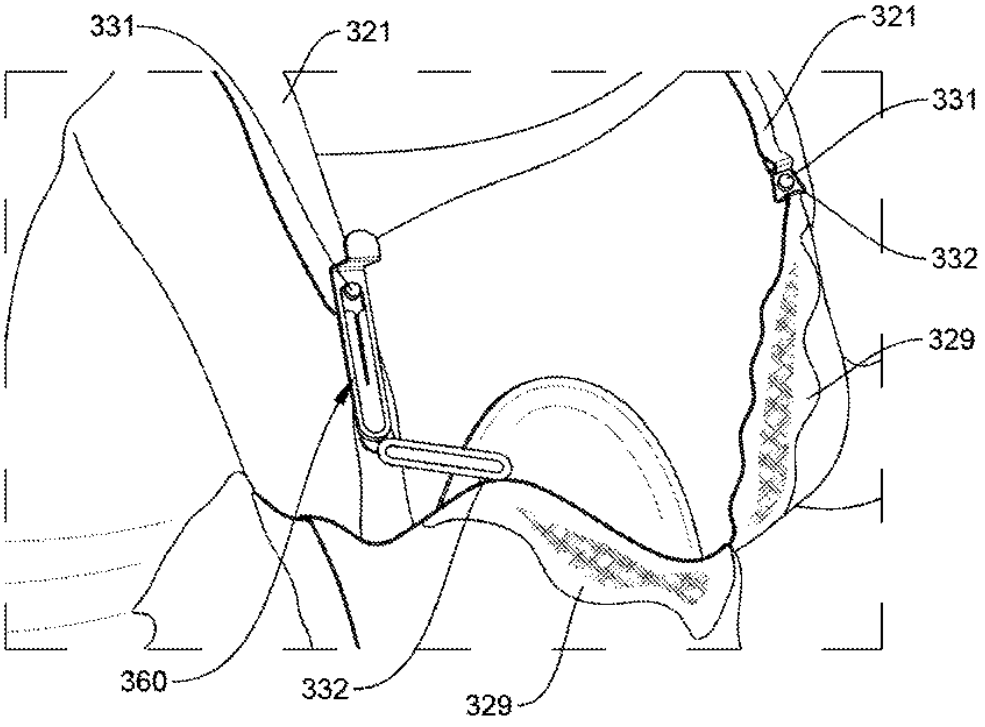


FIGURE 36

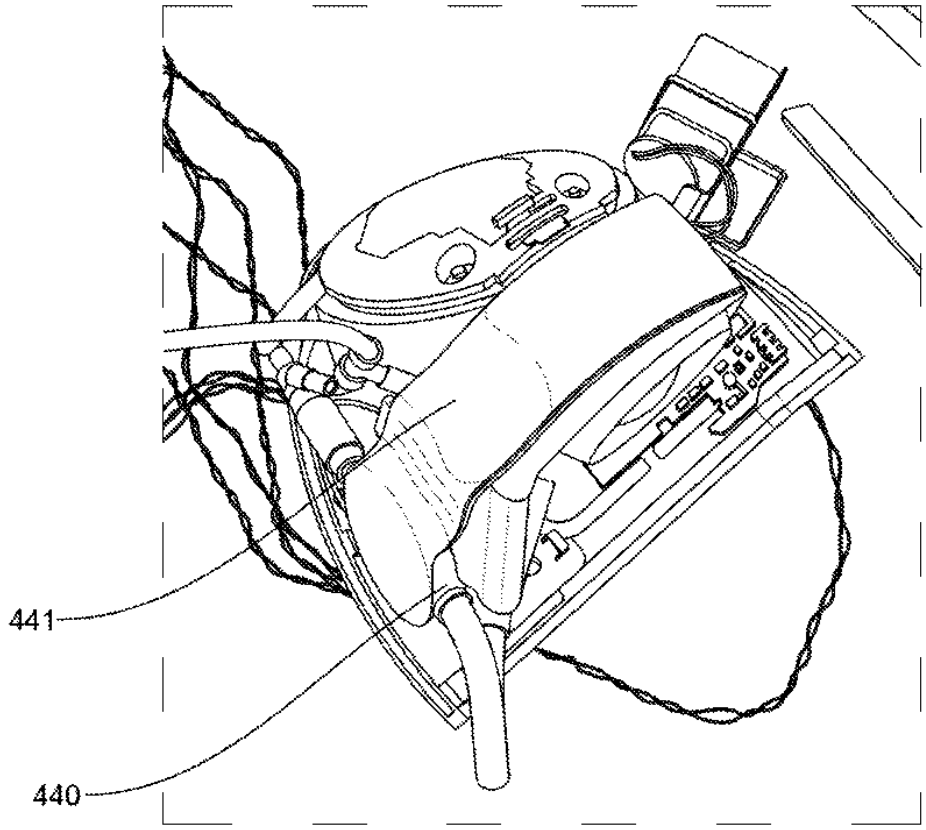


FIGURE 44

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 f32cde138ceb00e72c98b4cb35a2c9a3a2dcc36d	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 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 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
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.

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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.		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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]

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

	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)

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

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

*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)	2020-11-03
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.**

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

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 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.

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

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 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.

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

patents@saul.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
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".

/Kam Sin/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 16009547 **Drawings filed: 06/15/2018**

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)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] 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)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] 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)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [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:

PTO/SB/08a (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.

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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	2017108555	WO	A1	2017-06-29	KONINKLIJKE PHILIPS N.V.		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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]

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

	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)

If you wish to add additional non-patent literature document citation information please click the Add button Add

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)	2020-11-03
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.**

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 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.

(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/EP2016/081109

(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 2015 (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).

(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, DJ, 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, KH, KN, KP, KR, KW, 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,

[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 pressure sensor for determining volume changes in the system air volume in response to changes in vacuum pressure.

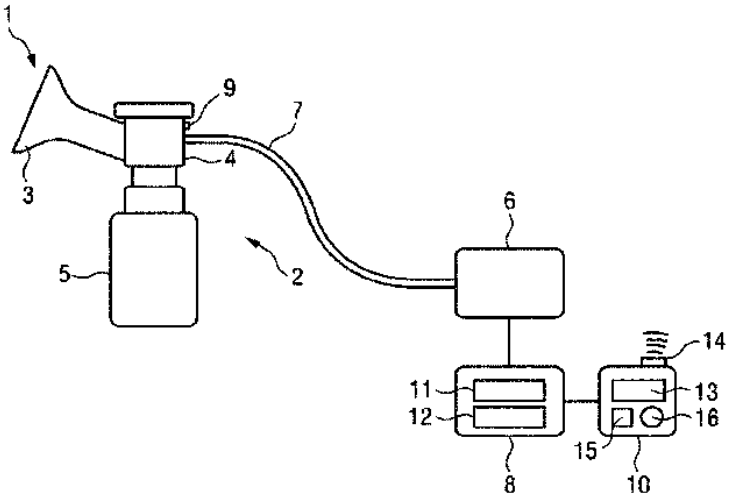


FIG.1

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(ii))*

Published:

— *with international search report (Art. 21(3))*

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 2015/0112298 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}, po and Qo 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):

$$\frac{dp}{dt} = \frac{dm}{dt}\frac{RT}{V}$$

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

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

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

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

The ODE can be solved which leads to:

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

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

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

wherein pi is the sensor signal received from the vacuum pressure sensor and wherein the parameters pmin, pO and QO 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.

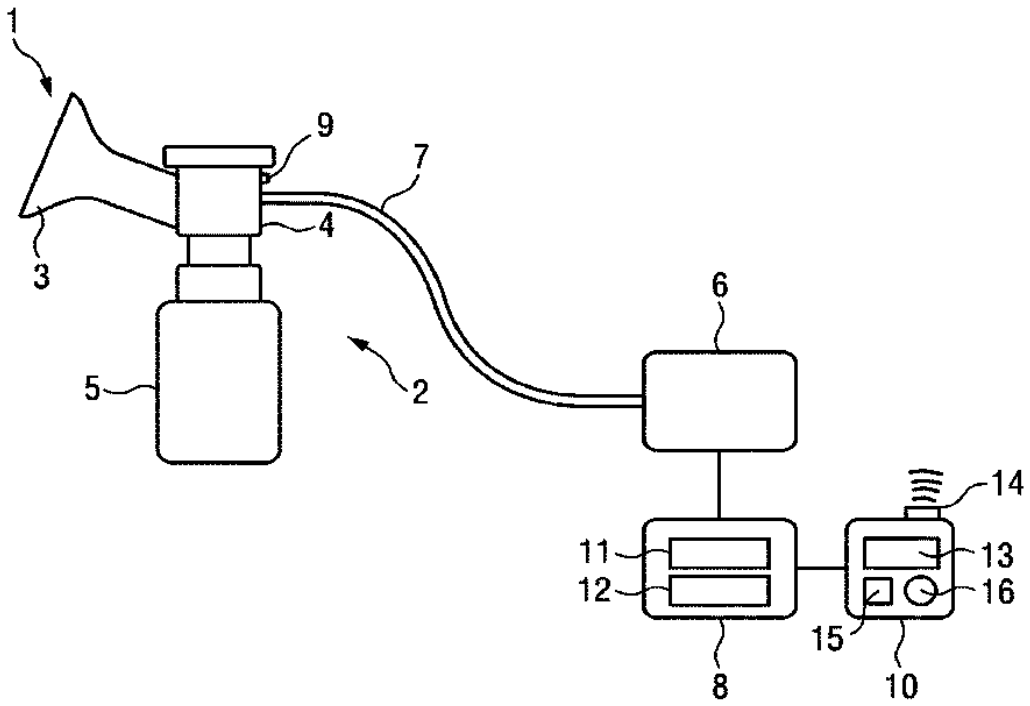


FIG.1

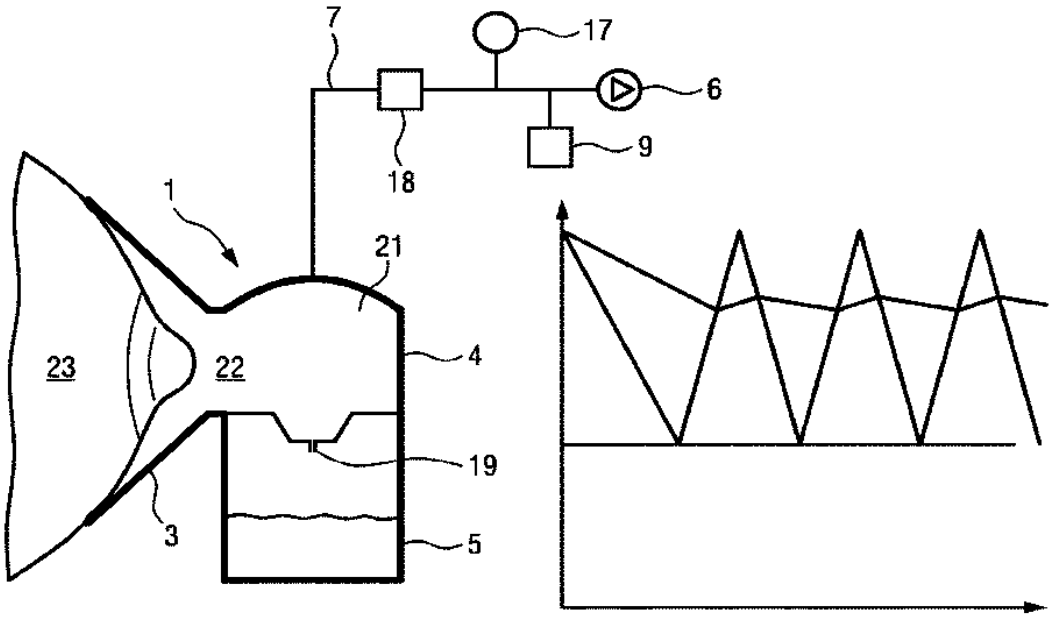


FIG.2A

FIG.2B

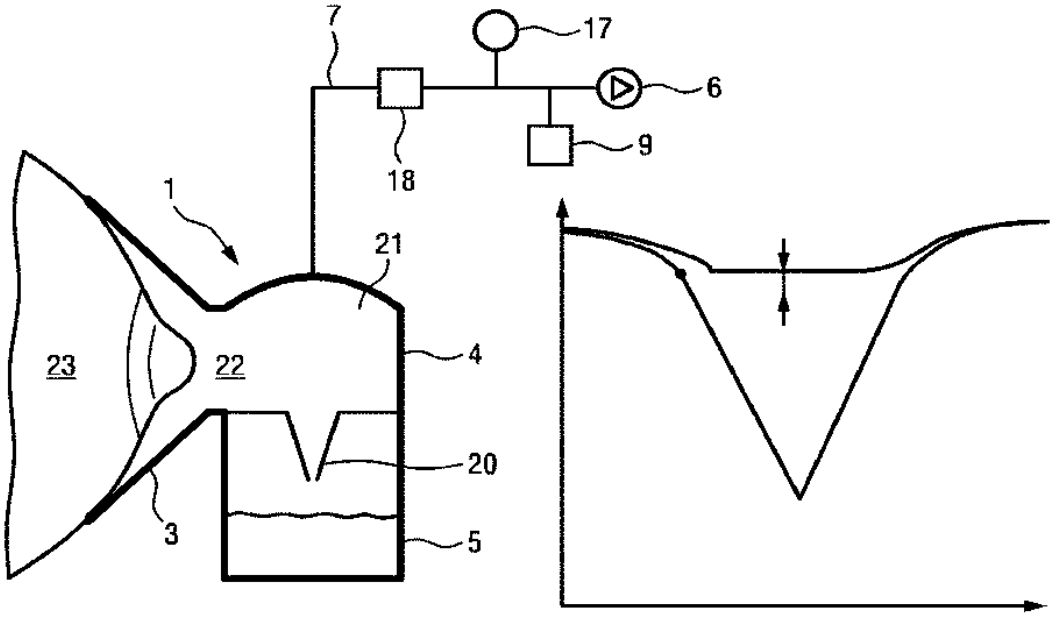


FIG.3A

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)

"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
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

1

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081109

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

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

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

Form PCT/ISA/210 (patent family annex) (April 2005)

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 3e7ed8ba72a3b33a18f5e2b2d3609595051 8d472	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

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.

(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.

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 _____ 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.** 16/009,547	**Applicant(s)** O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	**Art Unit** 3783	**AIA (FITF) Status** 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	✓	✓	✓	✓	✓				
10	13	✓	O	O	✓	✓				
12	14	✓	✓	✓	✓	✓				
13	15	✓	✓	✓	✓	✓				
14	16	✓	✓	✓	✓	✓				
15	17	✓	✓	✓	✓	✓				
16	18	✓	✓	✓	✓	✓				
17	19	✓	✓	✓	✓	✓				
18	20	✓	✓	✓	✓	✓				
19	21	✓	✓	✓	✓	✓				
	22	✓	-	-	-	-				
20	23	✓	✓	✓	✓	✓				
21	24	✓	✓	✓	✓	✓				
22	25	✓	✓	✓	✓	✓				
23	26	✓	✓	✓	✓	✓				
24	27	✓	✓	✓	✓	✓				
25	28	✓	✓	✓	✓	✓				
26	29	✓	✓	✓	✓	✓				
27	30	✓	✓	✓	✓	✓				
28	31				✓	✓				
29	32				✓	✓				
30	33				✓	✓				
31	34				✓	✓				
	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	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

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

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

☐ 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
1	1	8	10	17	19	25	28	32	37						
2	2	9	11	18	20	26	29	33	38						
3	3	11	12	19	21	27	30	34	39						
4	4	10	13		22	28	31	35	40						
5	5	12	14	20	23	29	32								
6	6	13	15	21	24	30	33								
	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

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)

<This search history is empty>

9/30/2020 3:17:56 PM
C:\Users\cfredrickson\Documents\EAST\Workspaces\16009547.wsp

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
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.

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	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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./

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.			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.**

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

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 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.

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

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 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

** SMALL ENTITY **

STATE OR COUNTRY

UNITED KINGDOM

ADDRESS

Saul Ewing Arnstein & Lehr LLP (Philadelphia)

Attn: Patent Docket Clerk

Centre Square West

1500 Market Street, 38th Floor

Philadelphia, PA 19102-2186

UNITED STATES

FILING FEE RECEIVED

$3,555

PTO/SB/08a (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.

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	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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.	

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.			

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.**

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 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.

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.

PATENT **Docket No. 373499.00002**

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.

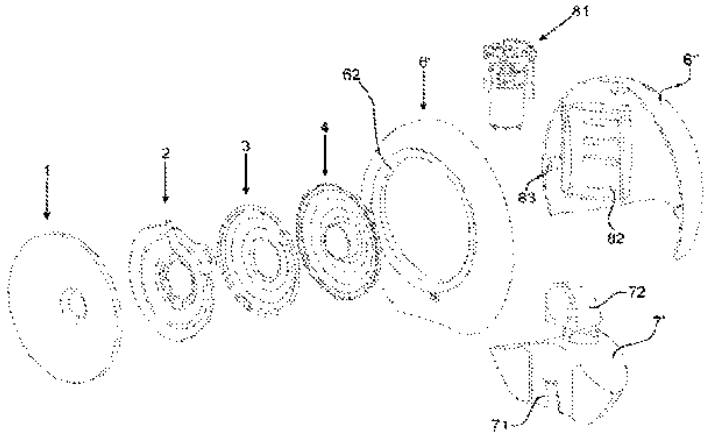


FIG. 11

Khalil, Fig. 11.

Therefore, amended claim 1 is novel over Khalil.

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

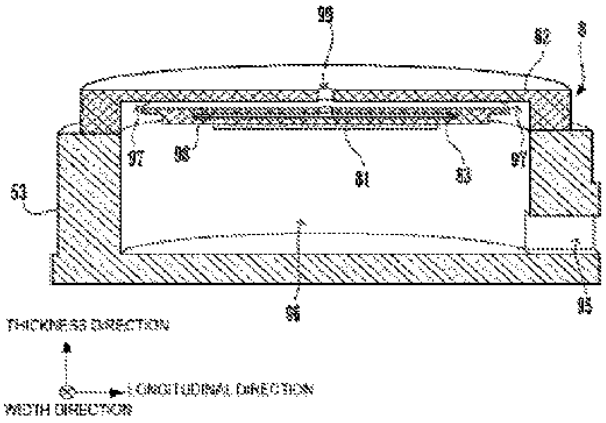
KSR (KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) requires that the Office provide "some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness." Further, the Office must "identify a reason that would have prompted a person 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/
Mark D. Simpson, Esquire
Registration No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Facsimile: 215 972 4169
Email: Mark.Simpson@saul.com

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
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.

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), (l), 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

AMENDMENT	06/22/2020	(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))	* 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

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 $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.

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 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-	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)

< This search history is empty>

1/ 15/ 2020 2:59:08 PM
C:\ Users\ cfredrickson\ Documents\ EAST\ Workspaces\ 16009547.wsp

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

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
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.

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.

PATENT **Docket No. 373499.00002**

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.

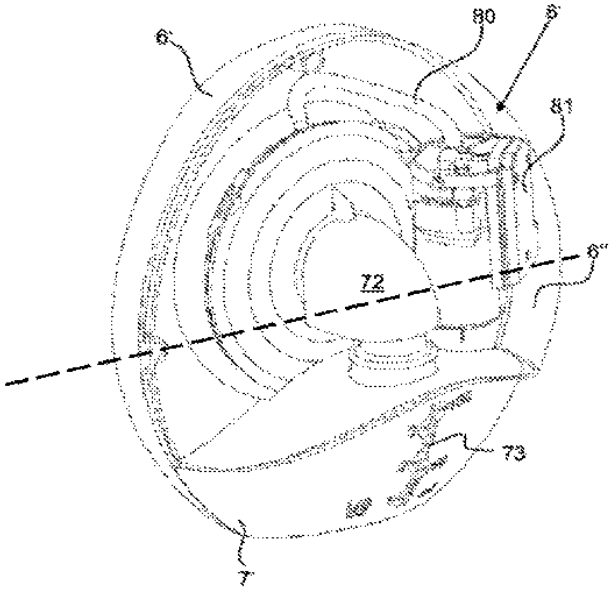
A *Prima Facie* Case of Obviousness Has Not Been Established

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."

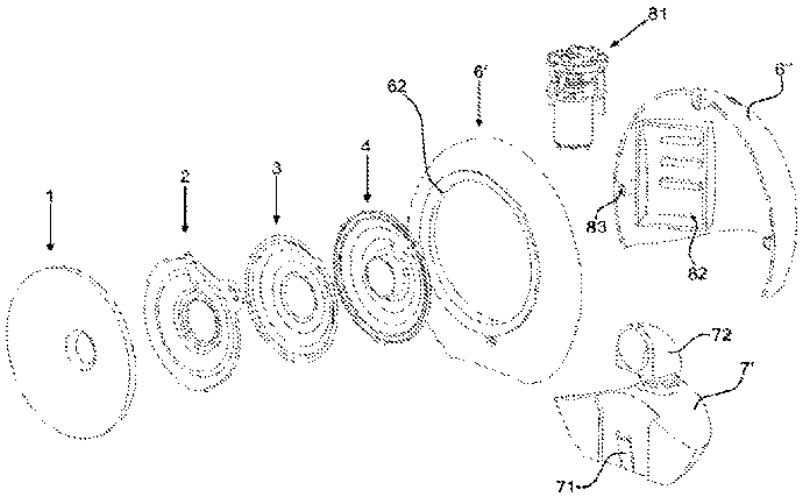
The words of a Claim describe and point out the invention by a series of limiting words or phrases – limitations (*Corning Glass Works v. Sumitomo Elec. USA Inc.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989)).

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/
Mark D. Simpson, Esquire
Registration No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Facsimile: 215 972 4169
Email: Mark.Simpson@saul.com

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
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-DEC-2019
Filing Date:	15-JUN-2018
Time Stamp:	11:34:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$900
RAM confirmation Number	E2019BMB34422055
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	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.

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 08/22/2019

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**
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.

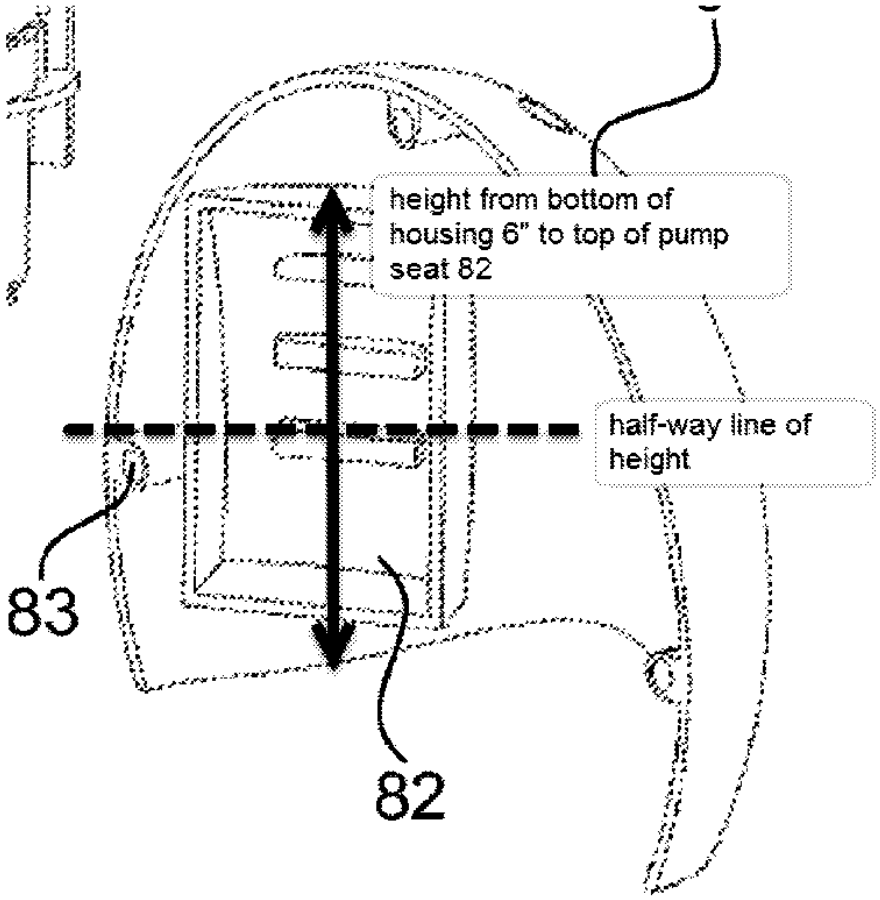
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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).

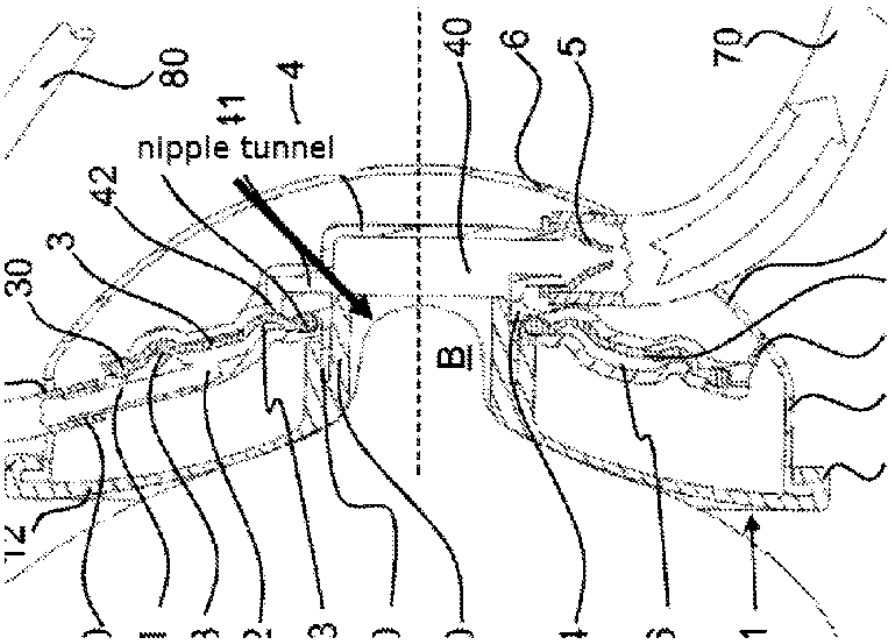
Regarding claim 17, in the modified system of Khalil, Khalil discloses a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container (73; paragraph 14-19 discloses that the container has a scale which can serve as a visual indicator if milk is flowing 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	✓	✓	✓						
	18	✓	✓	✓						
	19	✓	✓	✓						
	20	✓	✓	✓						
	21	✓	✓	✓						
	22	✓	-	-						
	23	✓	✓	✓						
	24	✓	✓	✓						
	25	✓	✓	✓						
	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
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;	OR	OFF	2018/08/07 13:59

			USOCR			
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
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			
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-	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.				
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;	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)

< This search history is empty>

3/ 14/ 2019 4:00:13 PM
C:\ Users\ cfredrickson\ Documents\ EAST\ Workspaces\ 16009547.wsp

PATENT **Docket No. 373499.00002**

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:

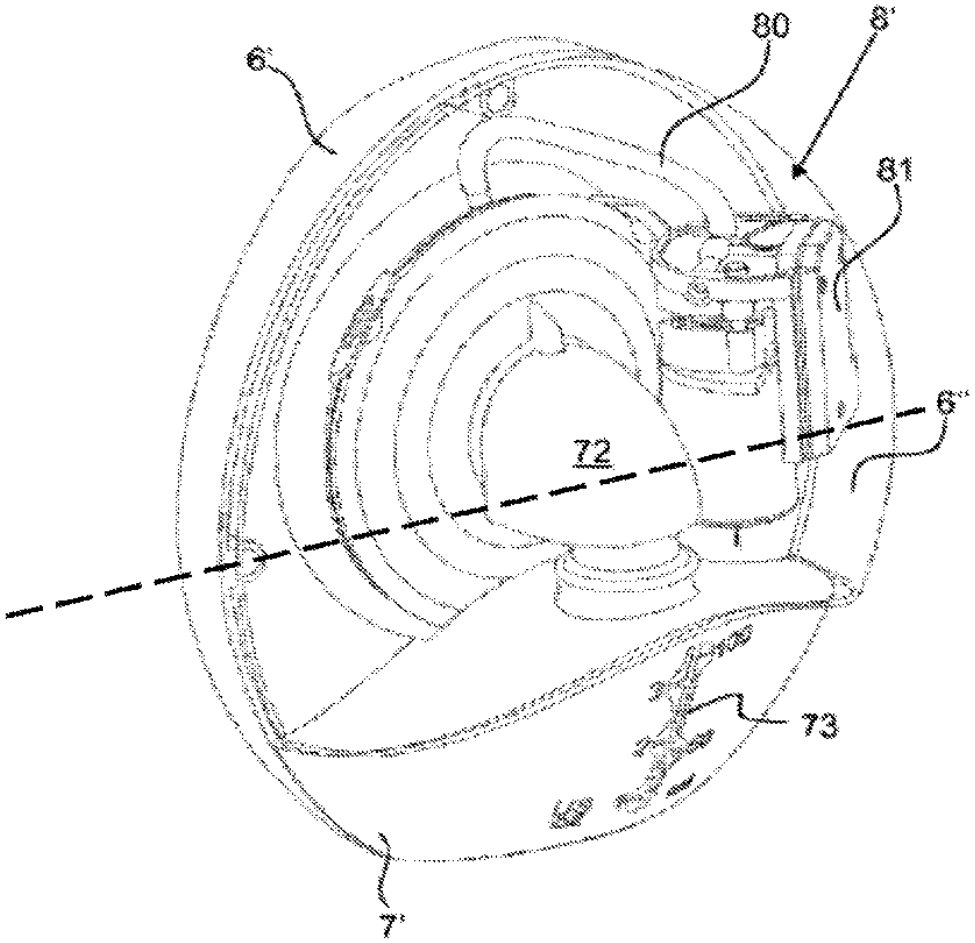
> "(see below; the examiner also notes that the "half-way height" line has not been defined by the claim, as such any line which is at or above the center of gravity is considered to read on the claimed limitation)" page 6.

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**"

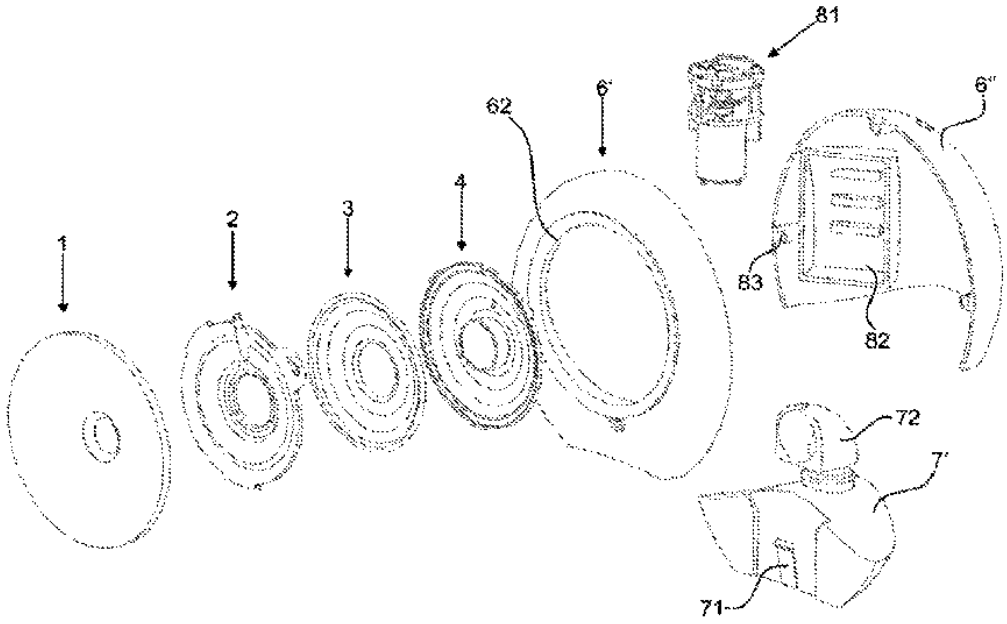
"the center of gravity of the breast pump system is, when the milk container is attached to the housing and is empty, substantially at or below the half-way **of the** height line of the housing"

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:



35575197.1 07/25/2019

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/
Mark D. Simpson, Esquire
Registration No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Facsimile: 215 972 4169
Email: Mark.Simpson@saul.com

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)

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		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
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.

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), (l), 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

AMENDMENT	07/25/2019	(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 $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.

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 04/26/2019

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**
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.

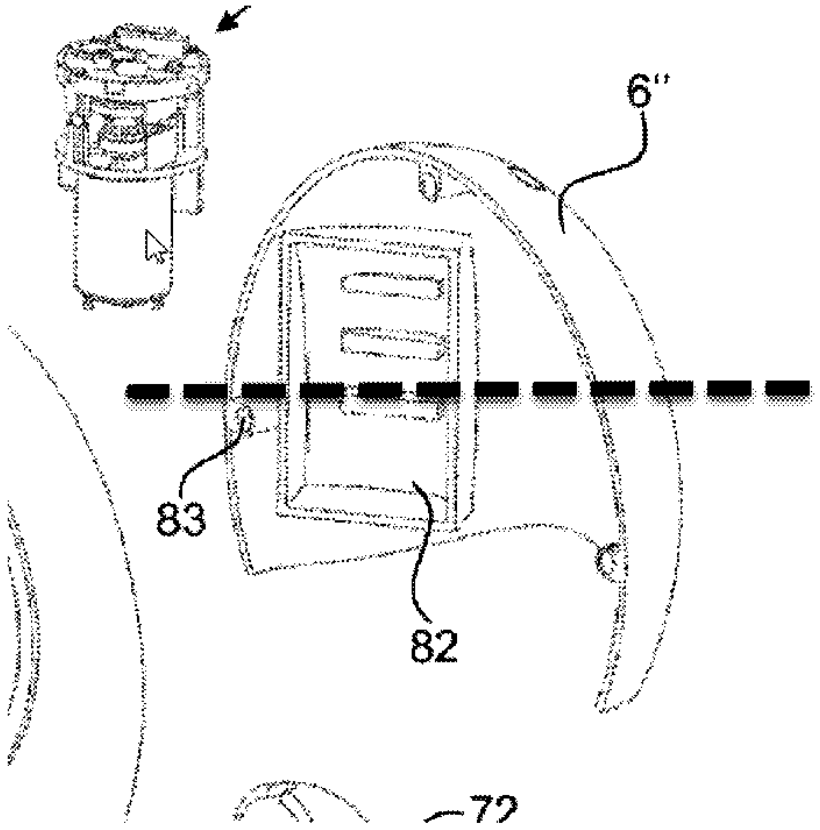
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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).

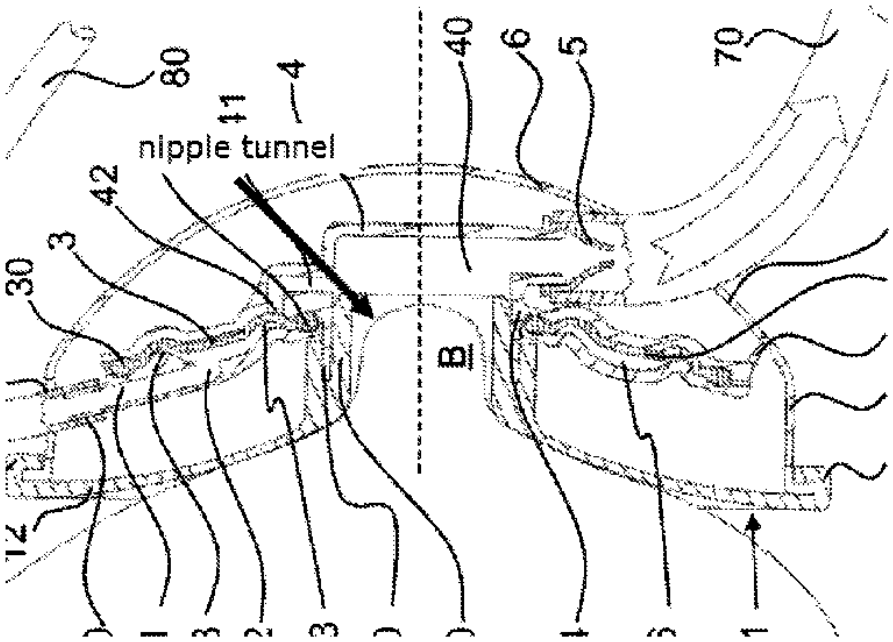
Regarding claim 17, in the modified system of Khalil, Khalil discloses a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container (73; paragraph 14-19 discloses that the container has a scale which can serve

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					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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	✓	✓							
	13	✓	O							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	✓	✓							
	19	✓	✓							
	20	✓	✓							
	21	✓	✓							
	22	✓	-							
	23	✓	✓							
	24	✓	✓							
	25	✓	✓							
	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
S12	143	a61j13/00.cpc.	US-	OR	OFF	2018/08/10

			PGPUB; USPAT			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-	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

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-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)

< This search history is empty>

3/ 14/ 2019 2:20:59 PM
C:\ Users\ cfredrickson\ Documents\ EAST\ Workspaces\ 16009547.wsp

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
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.

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)

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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	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)	X
	3	0 503 280	EP	A2	1992-02-08	Pierburg GmbH	(English abstract only)	☒

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

	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)	☒

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	03/14/2019

*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.

EFS Web 2.1.18

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)	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.**

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

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 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.

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

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	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

PUBLICATION NOTICE

OC000000104613491

Title:BREAST PUMP SYSTEM

Publication No.US-2018-0361040-A1
Publication Date:12/20/2018

NOTICE OF PUBLICATION OF APPLICATION

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/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/08a (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.

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)

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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	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)		
	Application Number	16009547
	Filing Date	2018-06-15
	First Named Inventor	Jonathan OTOOLE
	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)	☒

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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		

If you wish to add additional non-patent literature document citation information please click the Add button Add

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)	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.**

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 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.

Espacenet

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

FIG 2A

FIG 2B

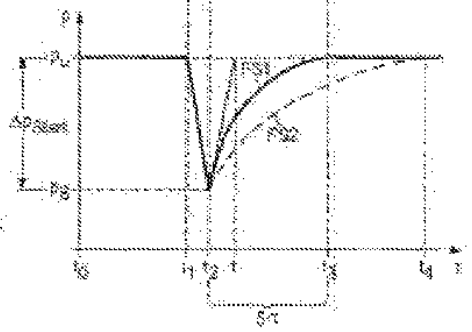


FIG 2C

Espacenet

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.

Espacenet

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.

Espacenet

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

Espacenet

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

Espacenet

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 06987eea1c37258e45174c91f16a8be715eca939	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 9f6f642d9774233b2e5a413bf65bed4a62af5ca	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2532494	

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.

PATENT **Docket No. 373499.00002**

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 1~~1~~, 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."

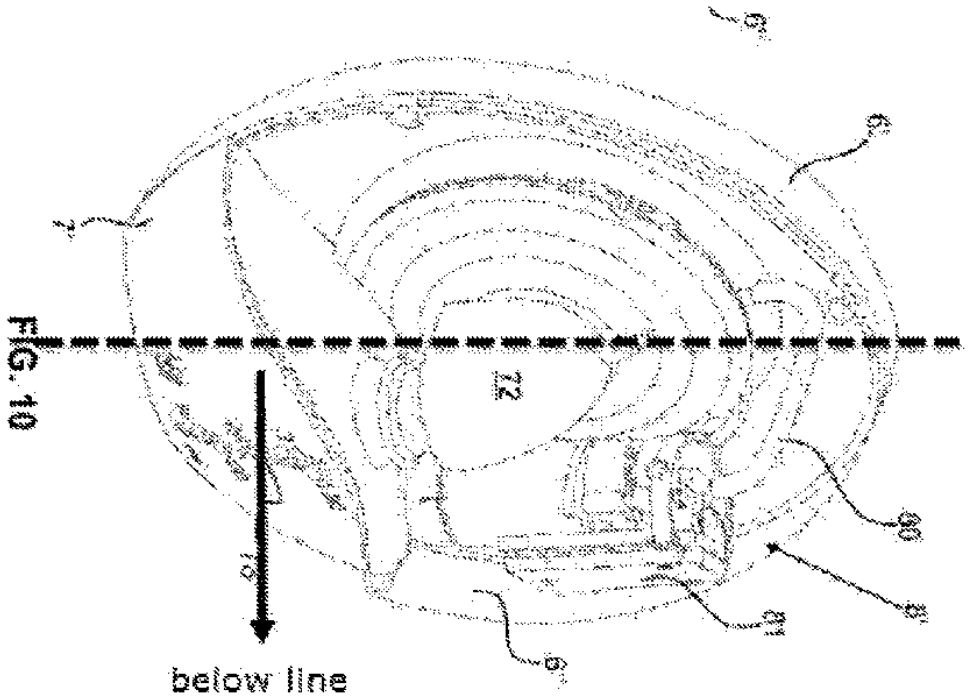


FIG. 10

Amended Claim 1 includes the limitation "in normal upright use".

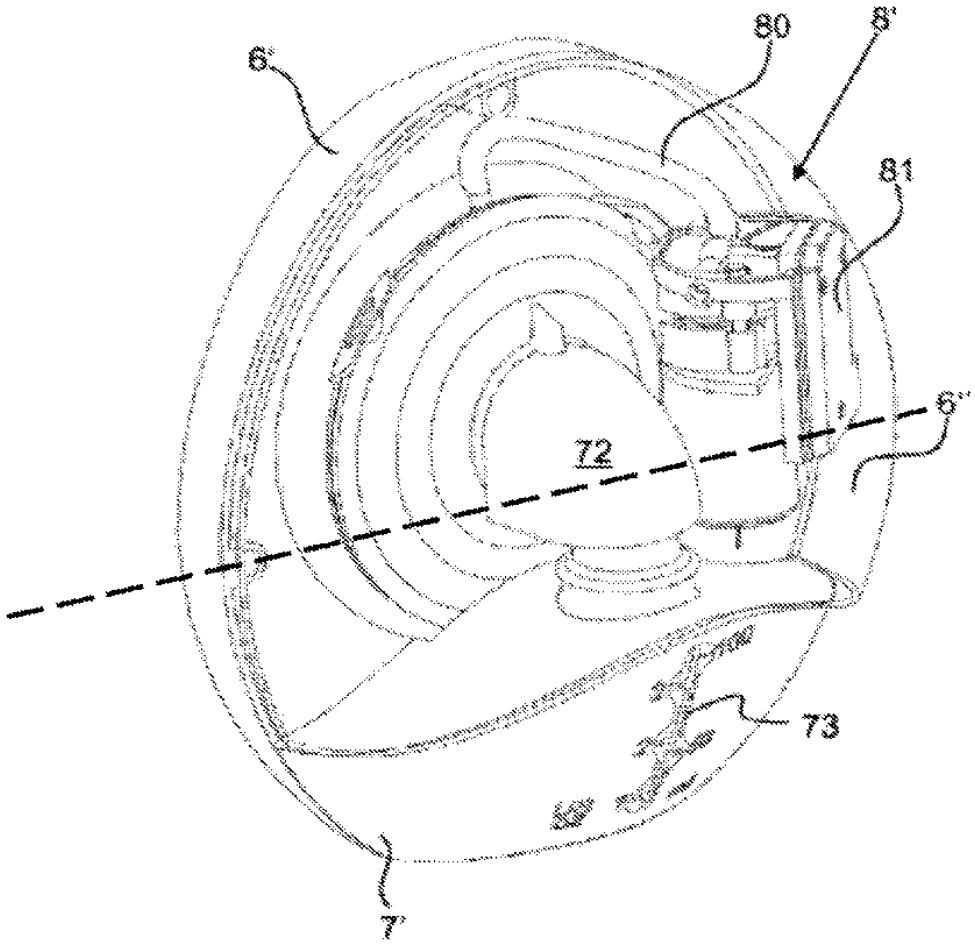
Regarding amended dependent Claim 29, which includes the limitation "in normal upright use", on pages 4 and 8 of the Office Action, the Office rejected former Claim 29 under 35 U.S.C. §103 as being unpatentable over U.S. Patent Application Publication No. 2013/0023821 to Khalil in view of U.S. Patent 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

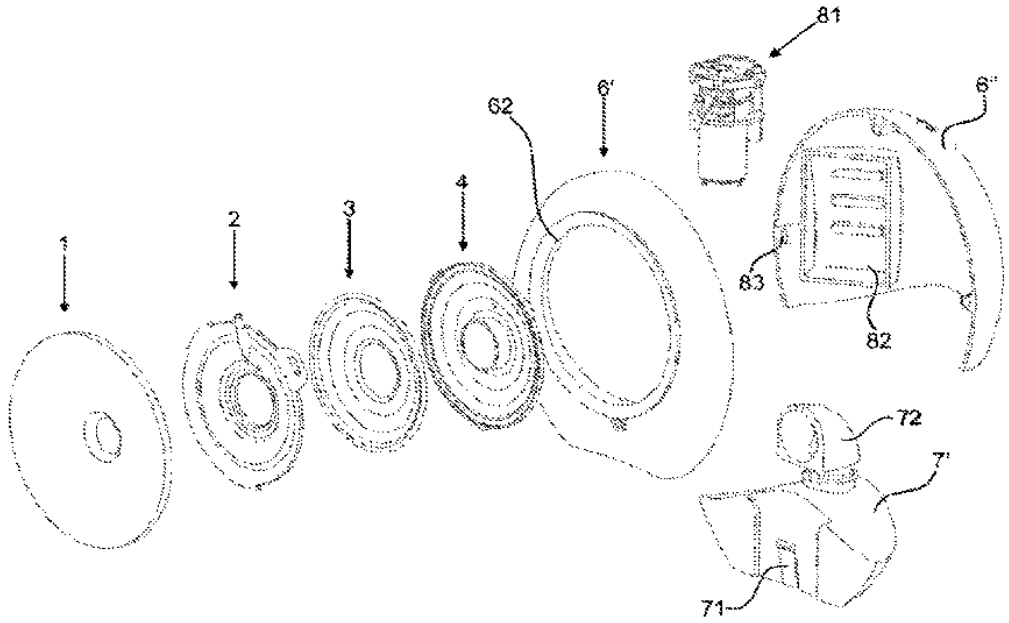
> reused) that when connected to the housing is positioned entirely below the opening or the milk flow path (fig. 10 shows the container positioned below the opening), when the breast pump is positioned or oriented for normal use."

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/
Mark D. Simpson, Esquire
Registration No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2189
Telephone: 215 972 7880
Facsimile: 215 972 4169
Email: Mark.Simpson@saul.com

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
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.

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), (l), 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.

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 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.

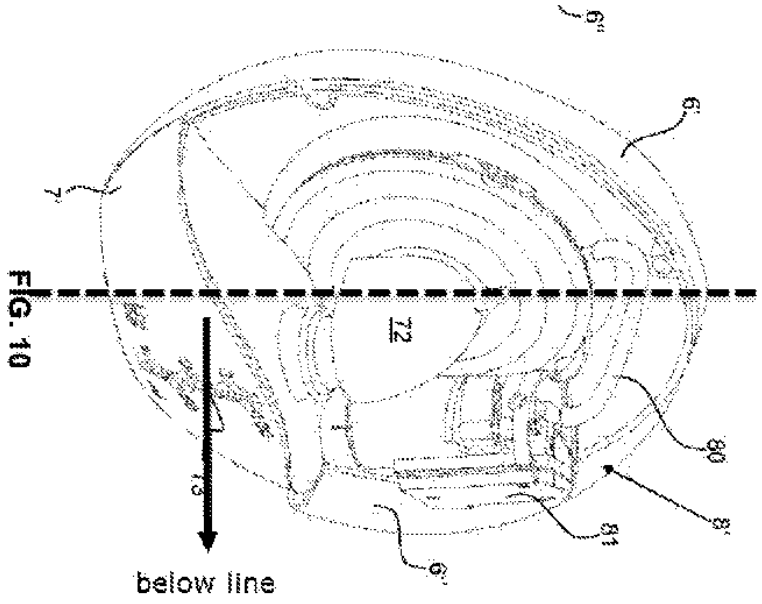


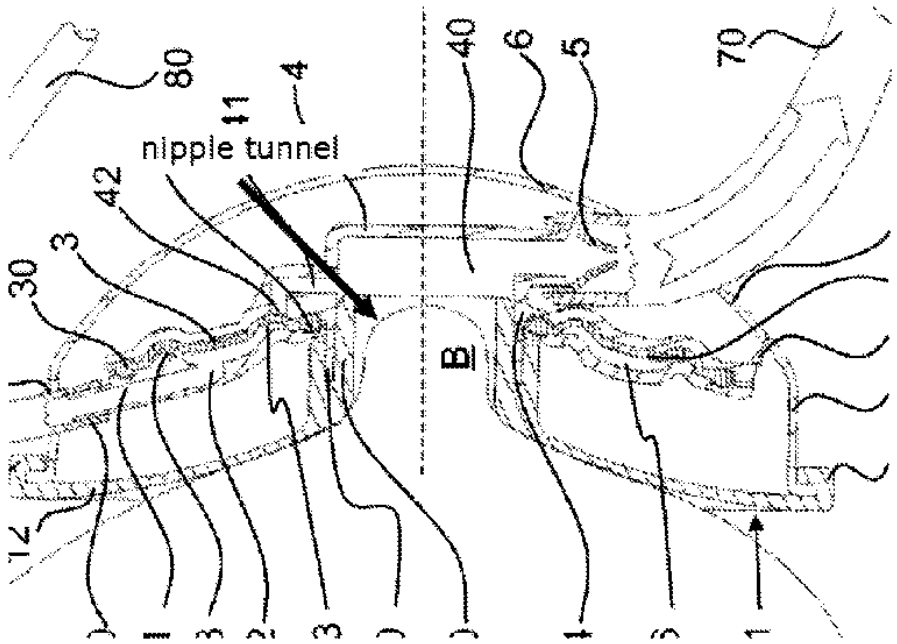
FIG. 10

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
	D	US-				
	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	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	✓								
	22	✓								
	23	✓								
	24	✓								
	25	✓								
	26	✓								
	27	✓								
	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

		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-	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)

< This search history is empty>

8/ 25/ 2018 6:35:38 PM
C:\ Users\ cfredrickson\ Documents\ EAST\ Workspaces\ 16009547.wsp

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

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
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.

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.	

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	
	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	

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	
	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	

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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.	

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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.	

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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.	

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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		

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	
Filing Date	
First Named Inventor	Jonathan O'TOOLE
Art Unit	
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.		

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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~~	~~105268759~~	~~CN~~	~~A~~	~~2016-02-03~~			

EFS Web 2.1.17

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	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		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00002

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	

If you wish to add additional non-patent literature document citation information please click the Add button Add

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.

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	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.**

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

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 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.

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	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

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/02/2018

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED KINGDOM

ADDRESS

Saul Ewing Arnstein & Lehr LLP (Philadelphia)

Attn: Patent Docket Clerk

Centre Square West

1500 Market Street, 38th Floor

Philadelphia, PA 19102-2186

UNITED STATES

FILING FEE RECEIVED

$3,555

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	

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	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

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.

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.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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	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

POA ACCEPTANCE LETTER

OC000000101445024

Date Mailed: 08/03/2018

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/01/2018.

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**.

/hnguyen/

Digital Access Service
(DAS)

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

CERTIFICATE OF AVAILABILITY OF A CERTIFIED PATENT DOCUMENT IN A DIGITAL LIBRARY

The International Bureau certifies that a copy of the patent application indicated below has been available to the WIPO Digital Access Service since the date of availability indicated, and that the patent application has been available to the indicated Office(s) as of the date specified following the relevant Office code:

Document details: Country/Office: GB
Filing date: 01 Jun 2018 (01.06.2018)
Application number: 1809036.5

Date of availability of document: 13 Jul 2018 (13.07.2018)

The following Offices can retrieve this document by using the access code:
JP, US, SE, NZ, KR, EA, IN, BR, GB, AU, ES, NL, IB, EE, CN, MA, FI, DK

Date of issue of this certificate: 03 Aug 2018 (03.08.2018)

34, chemin des Colombettes
1211 Geneva 20, Switzerland
www.wipo.int

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 GB1809036.5 filed on 01 June 2018, 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 07 June 2018

Intellectual Property Office

2018013286

01/06/2018 0.00 NONE

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 GB1809036.5

1.	Your reference	**Elvie Pump (UK)**
2.	Full name, address and postcode of the applicant or of each applicant Patents ADP number *(if you know it)*	**CHIARO TECHNOLOGY LIMITED** **63 - 66 Hatton Garden** **London EC1N 8LE** **United Kingdom** 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)* Patents ADP number *(if you know it)*	**Langley, Mr Peter** **Origin Limited** **Twisden Works** **Twisden Road** **London NW5 1DN** **United Kingdom** 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

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?	**No**	

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **121**

Claim(s): **n/a**

Abstract: **n/a**

Drawing(s): **44**

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): **0**

Request for search (Patents Form 9A): **0**

Request for 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.

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
Telephone: 02074241952
Fax: 02072090643

Warning

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 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.

A portion of the disclosure of this patent document contains material, which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

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.

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. 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/Ir 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.

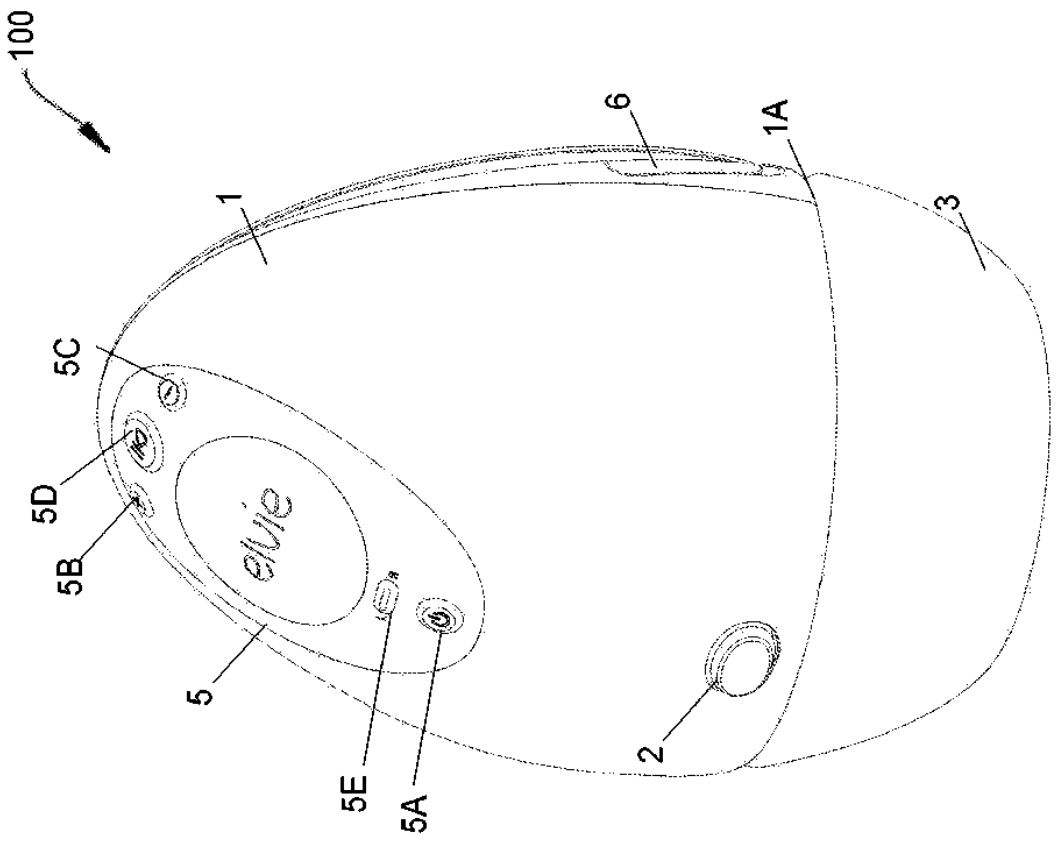


FIGURE 1

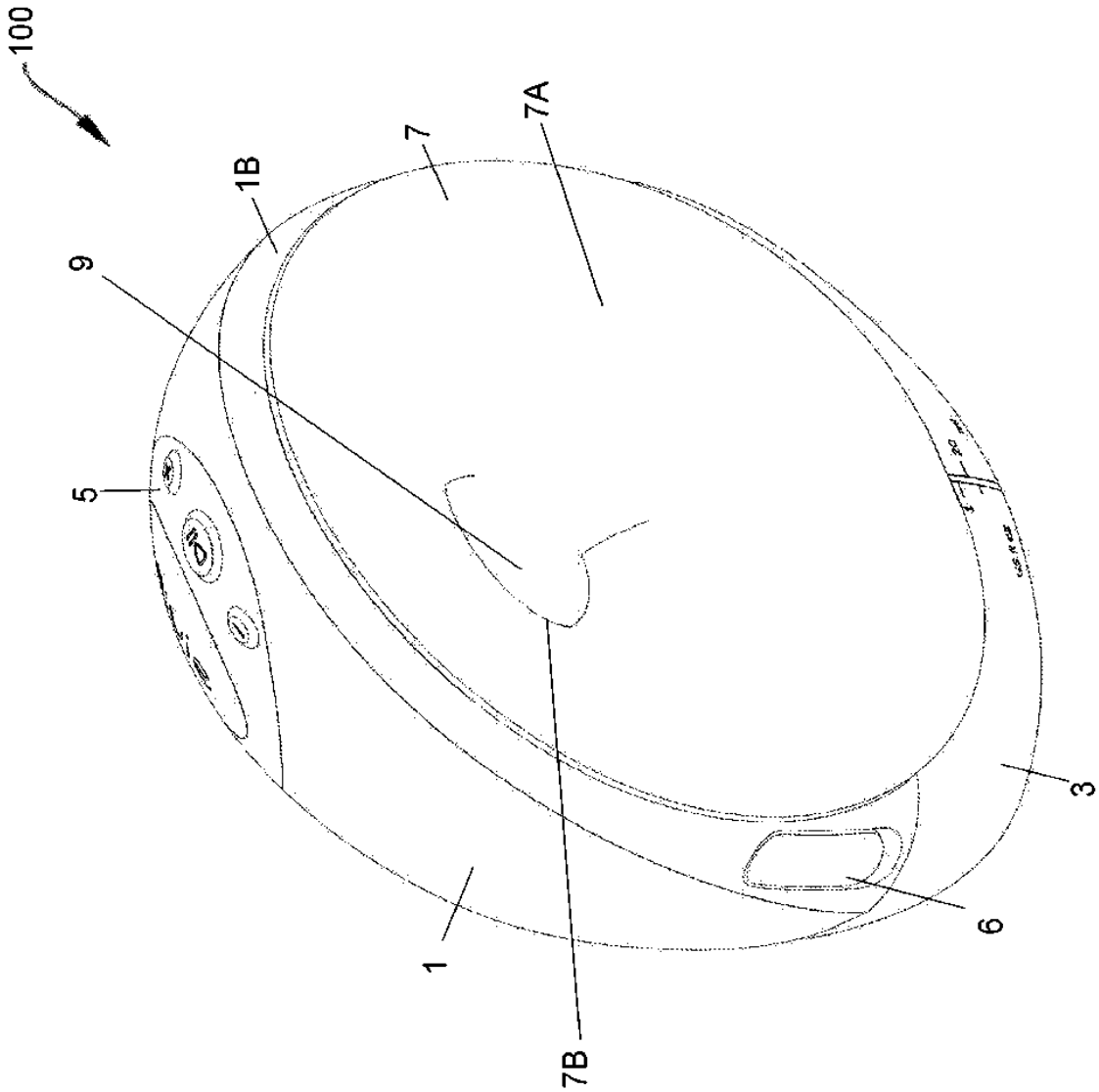


FIGURE 2

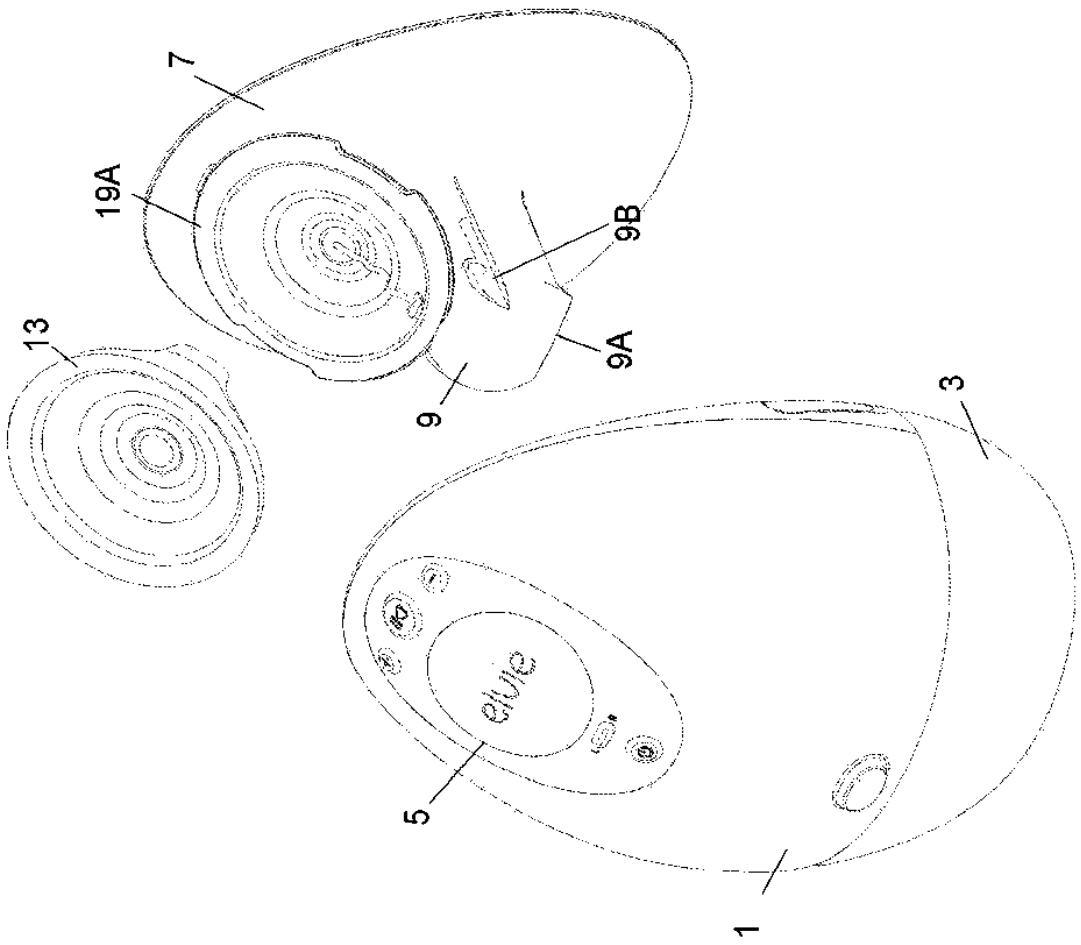


FIGURE 3

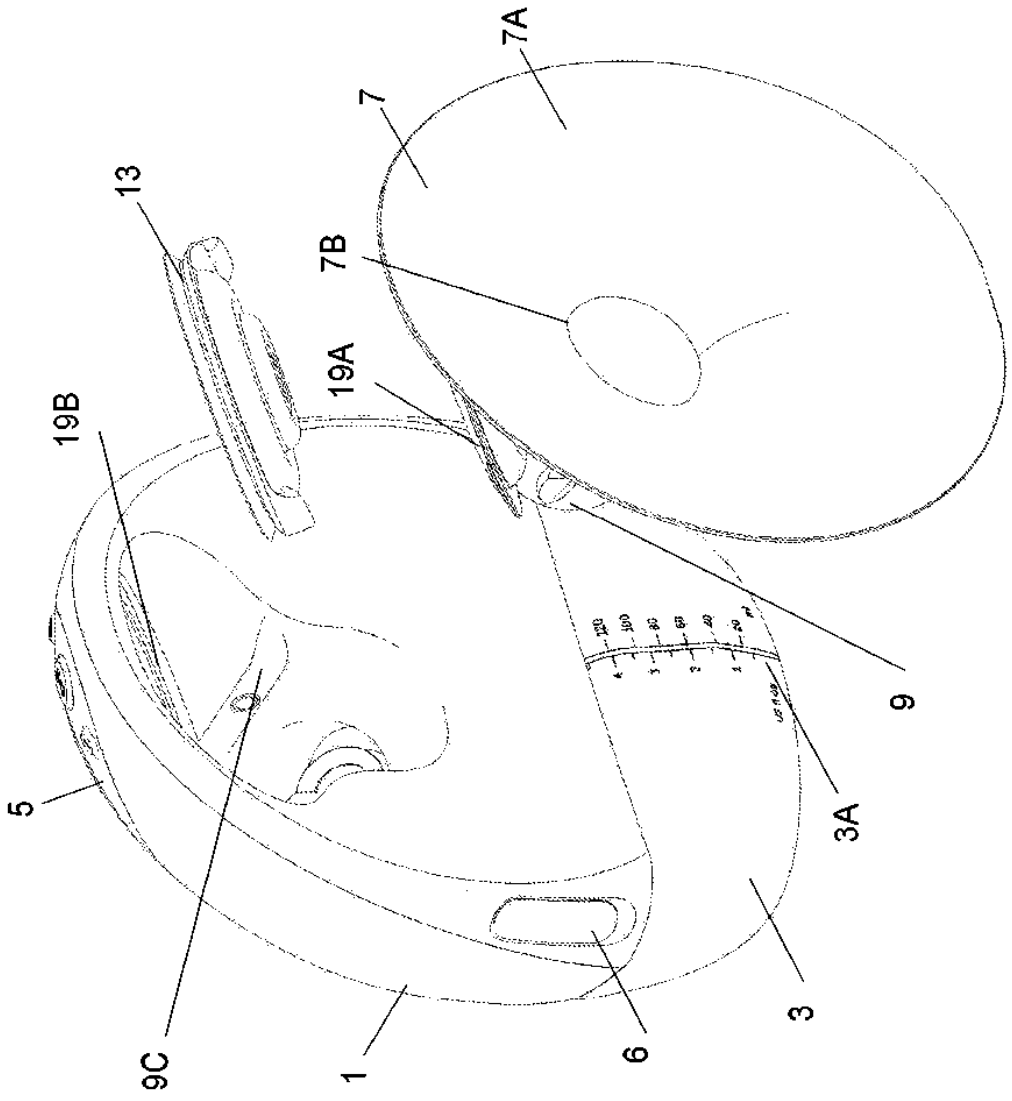


FIGURE 4

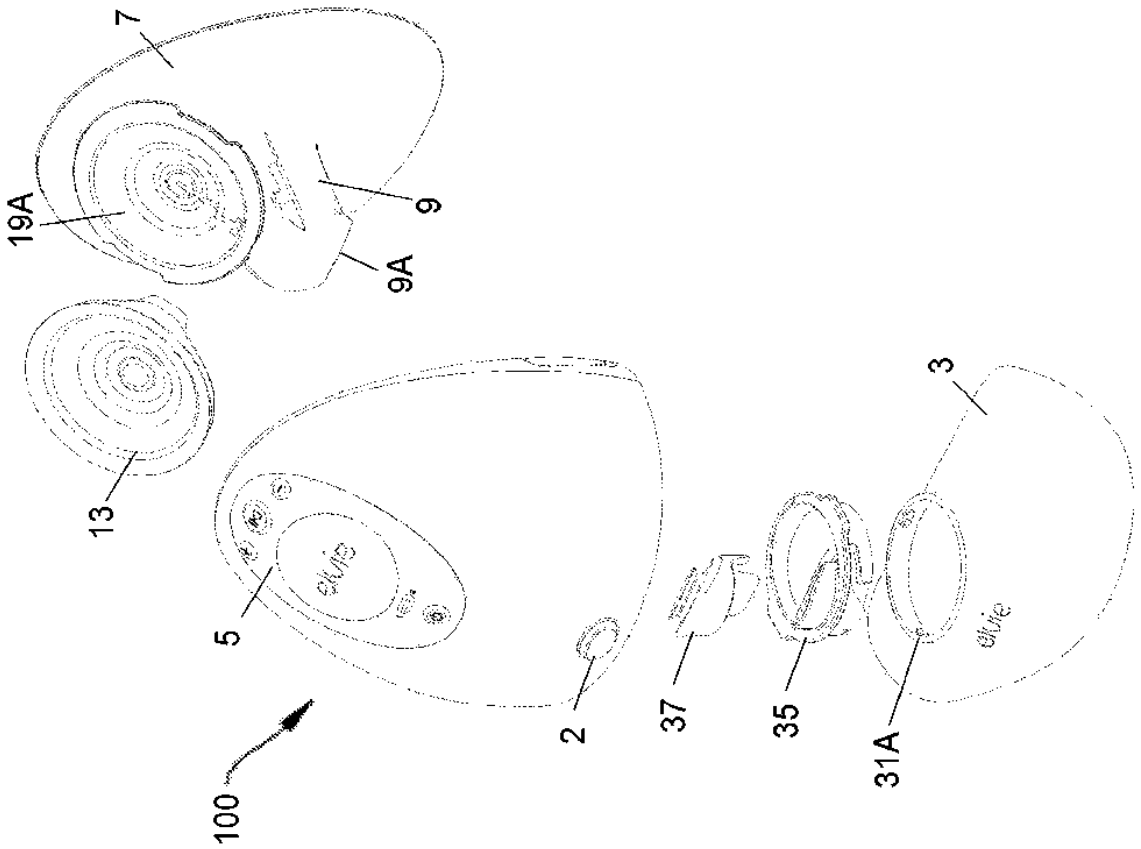


FIGURE 5

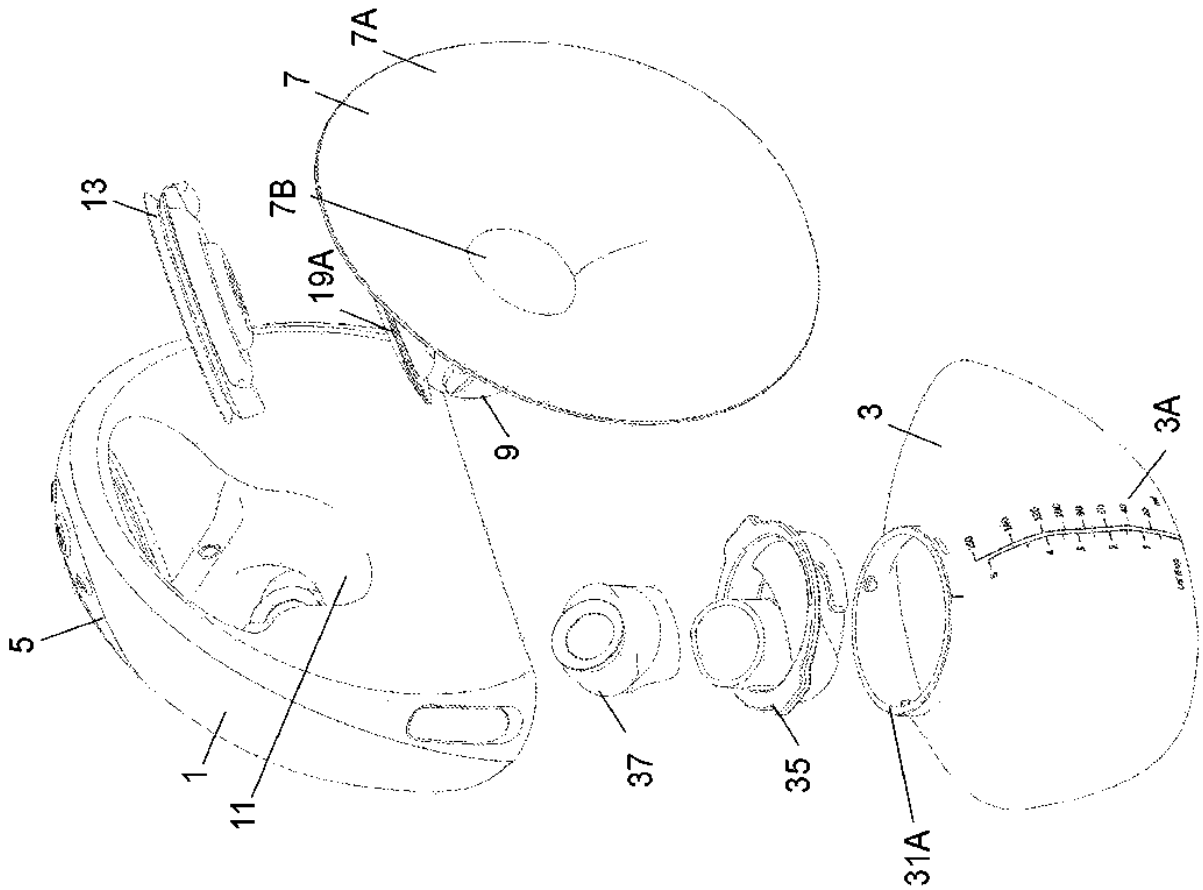


FIGURE 6

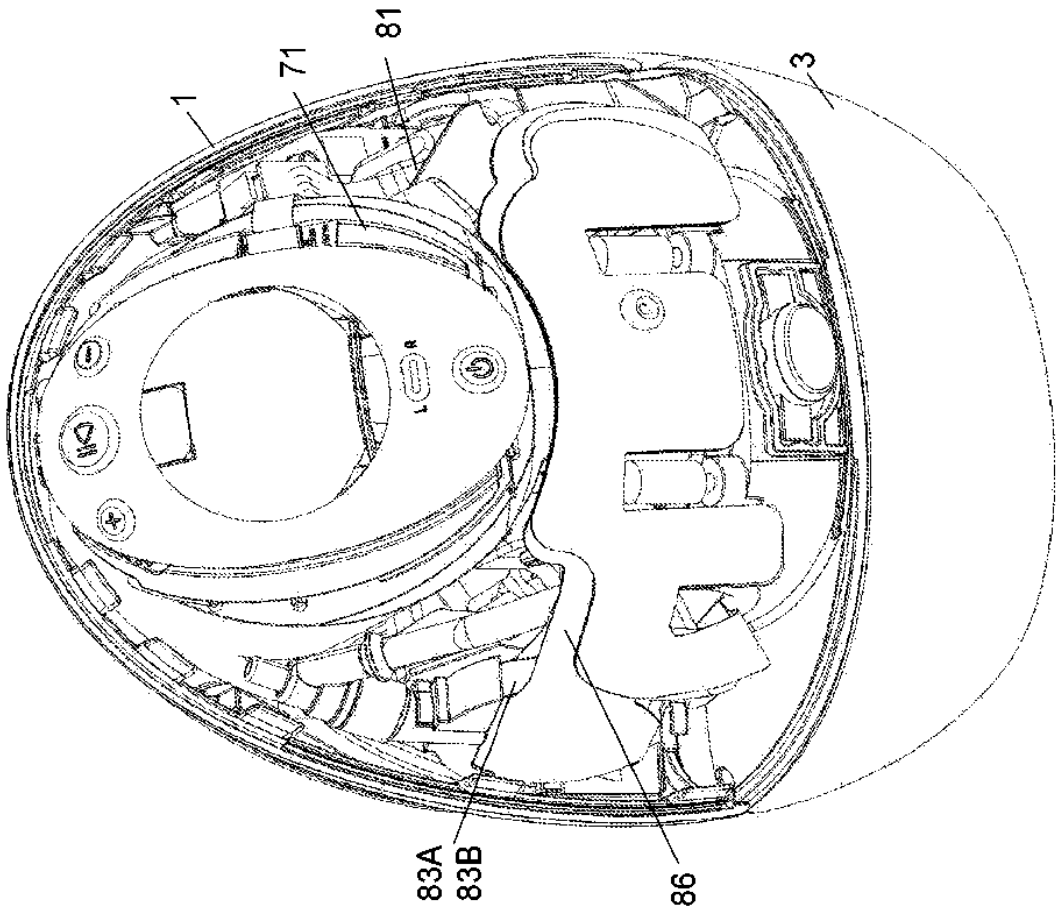


FIGURE 7

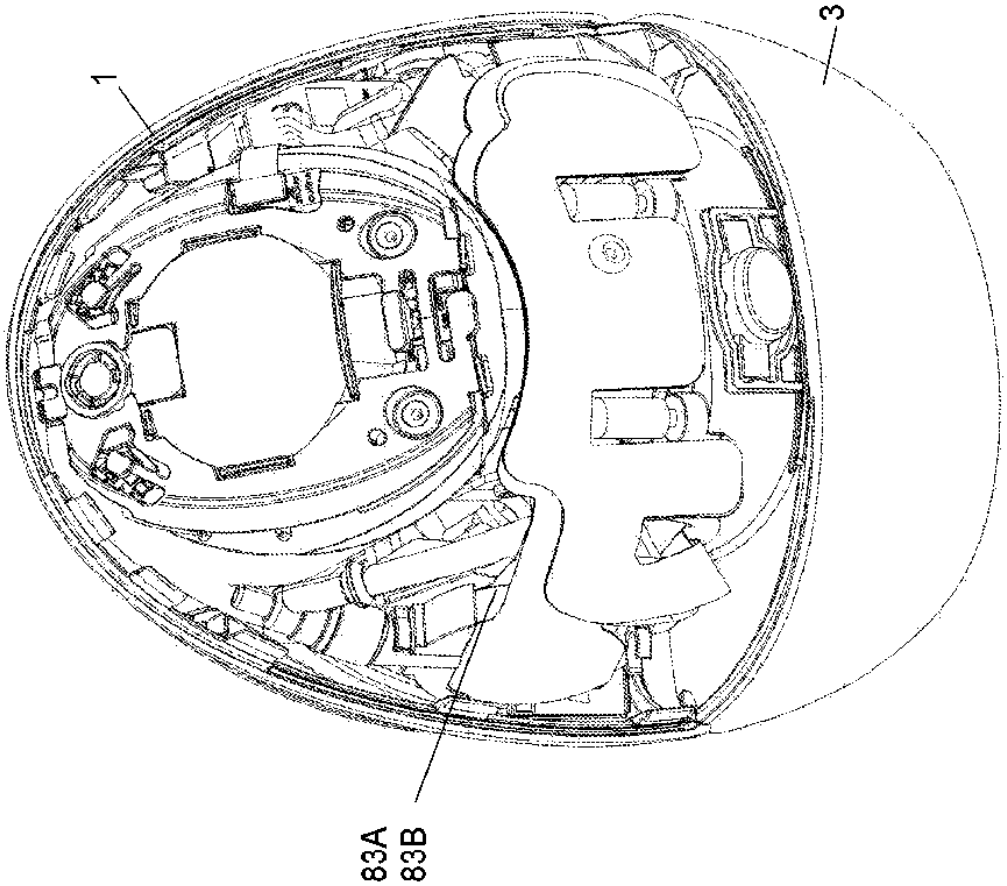


FIGURE 8

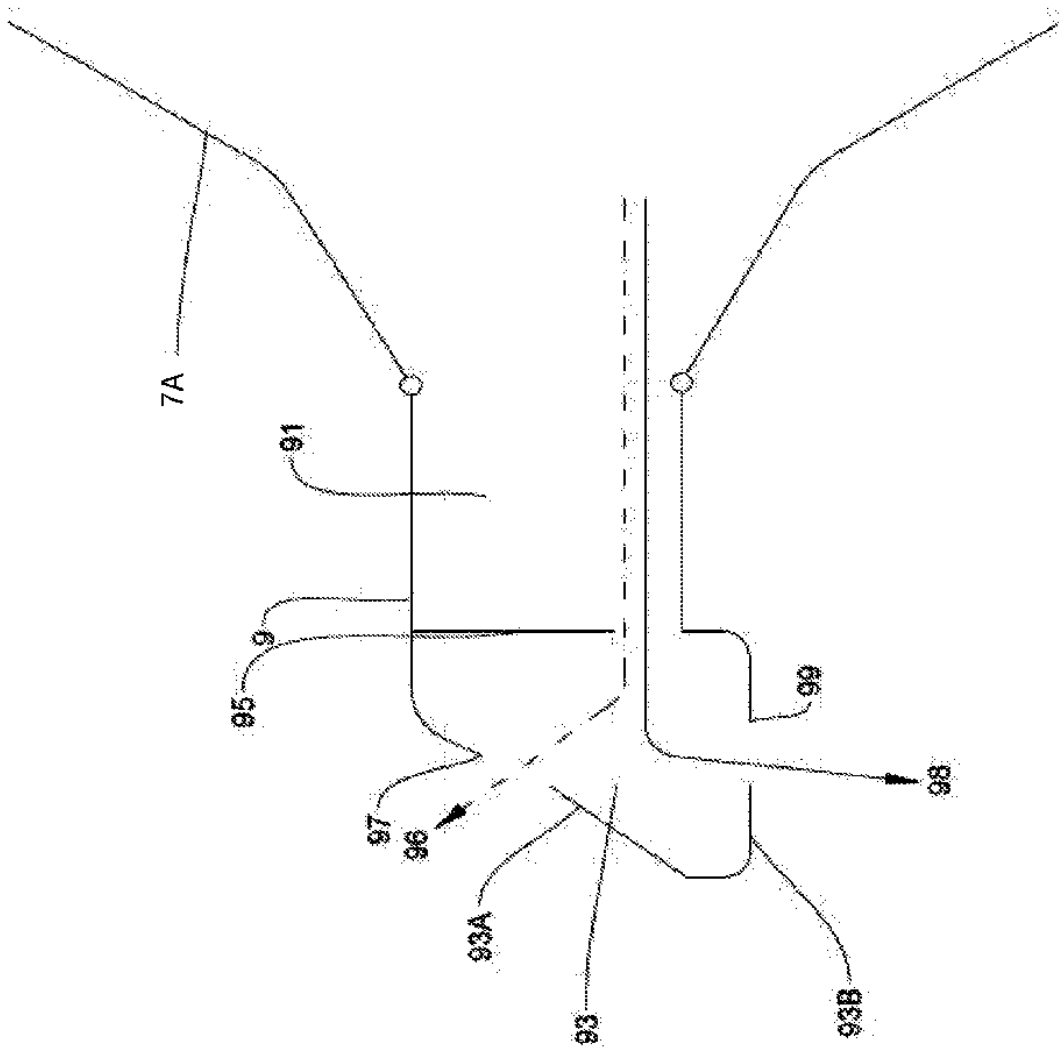


FIGURE 9

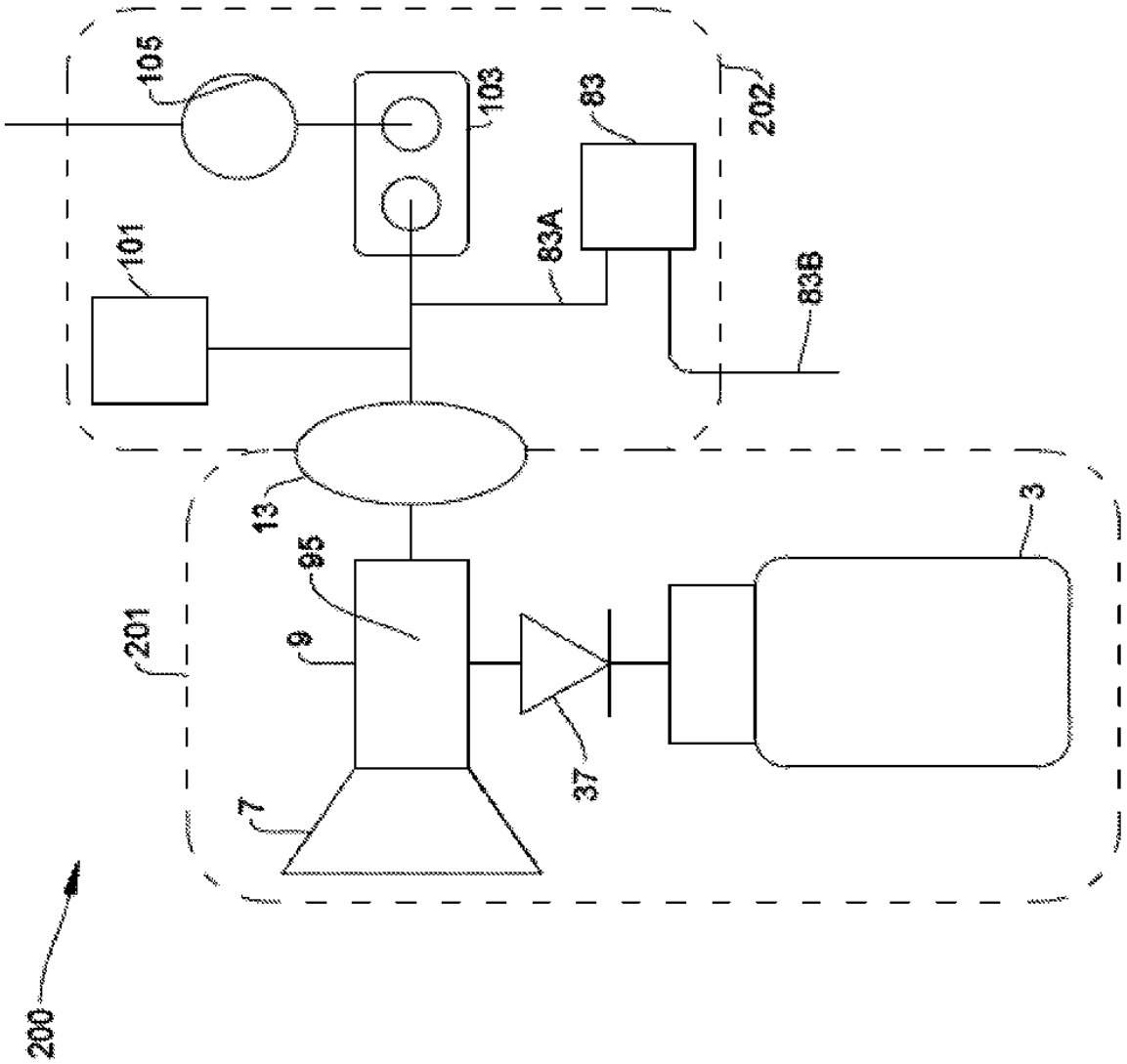


FIGURE 10

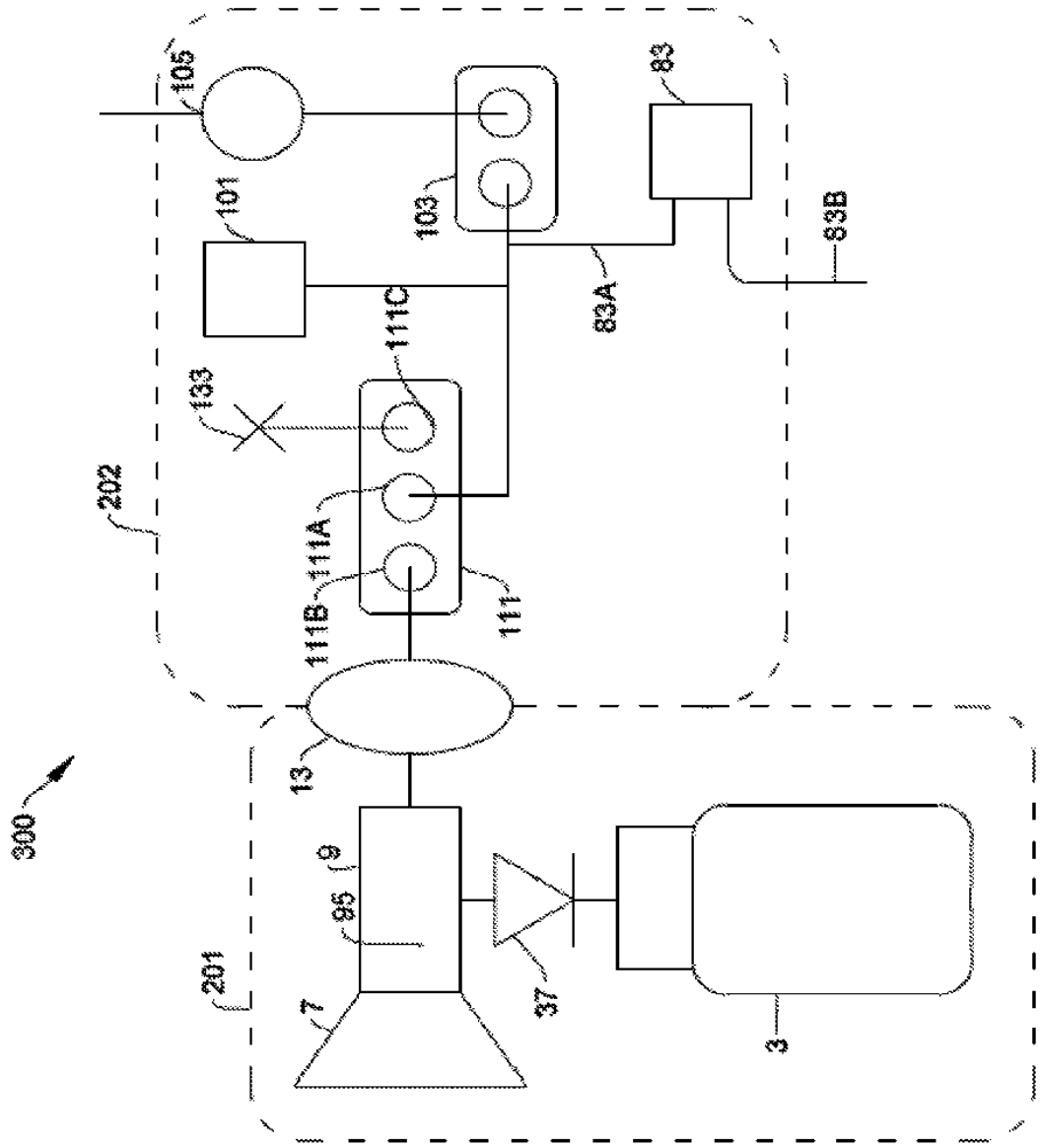

300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

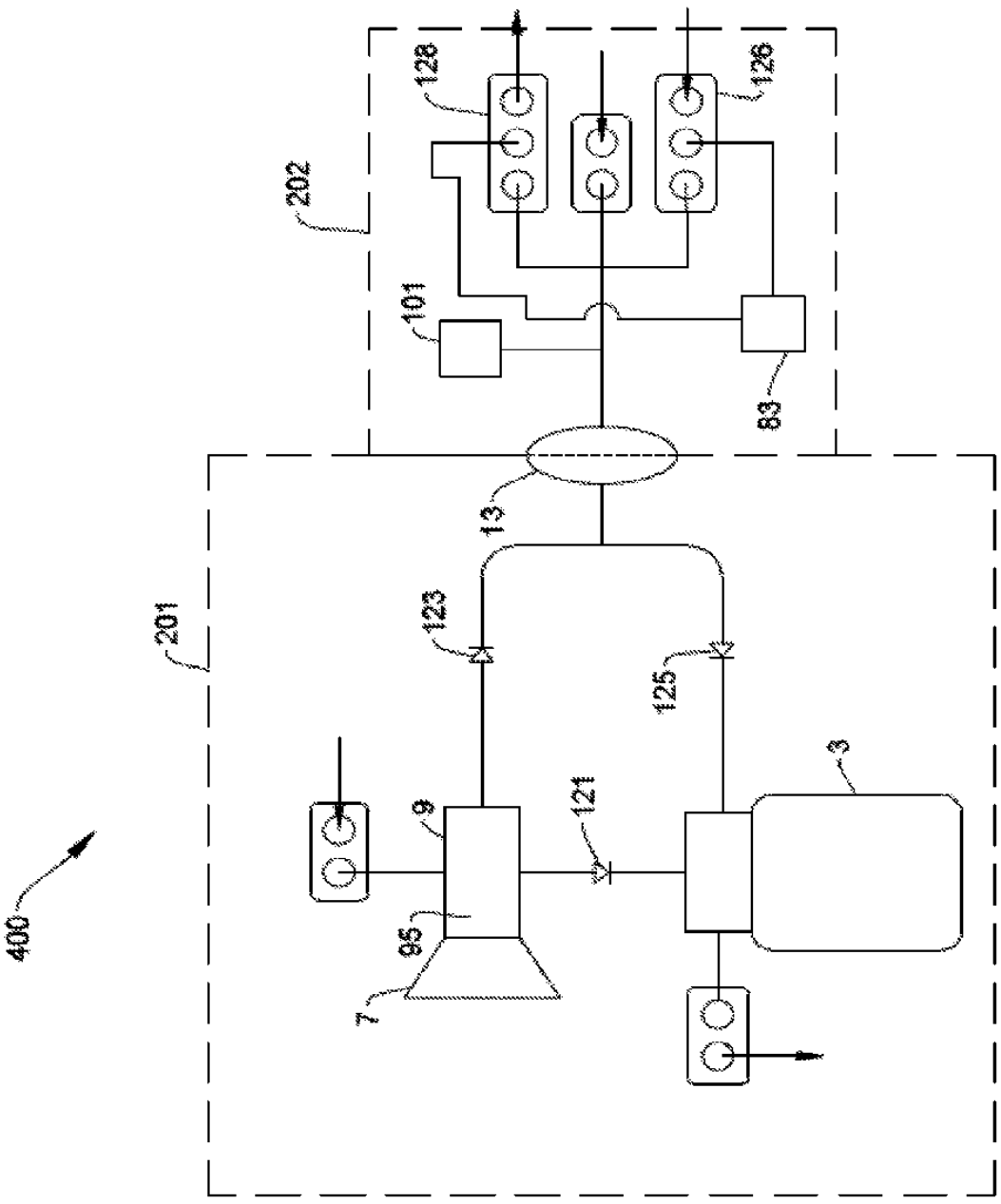


FIGURE 12

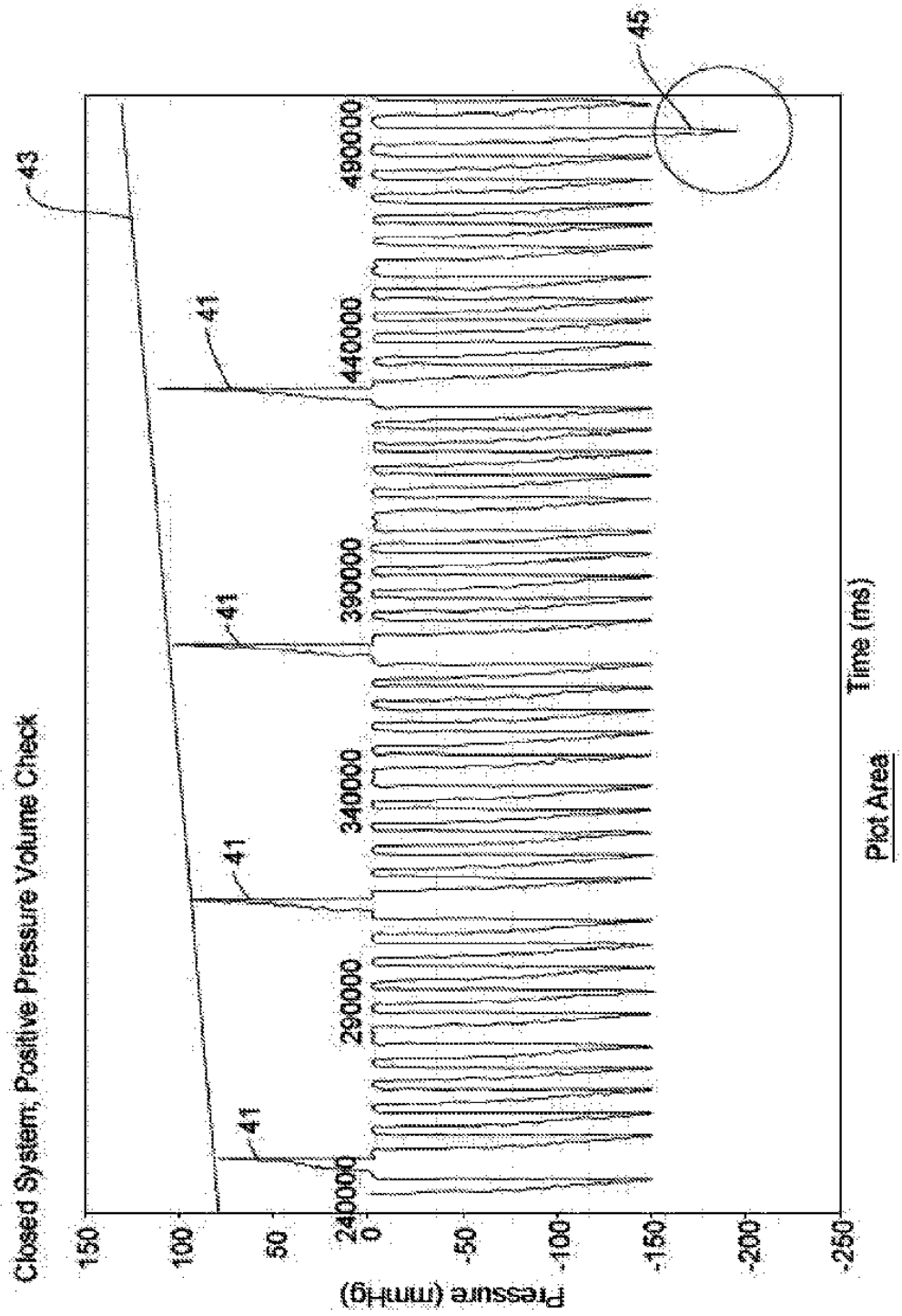

Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

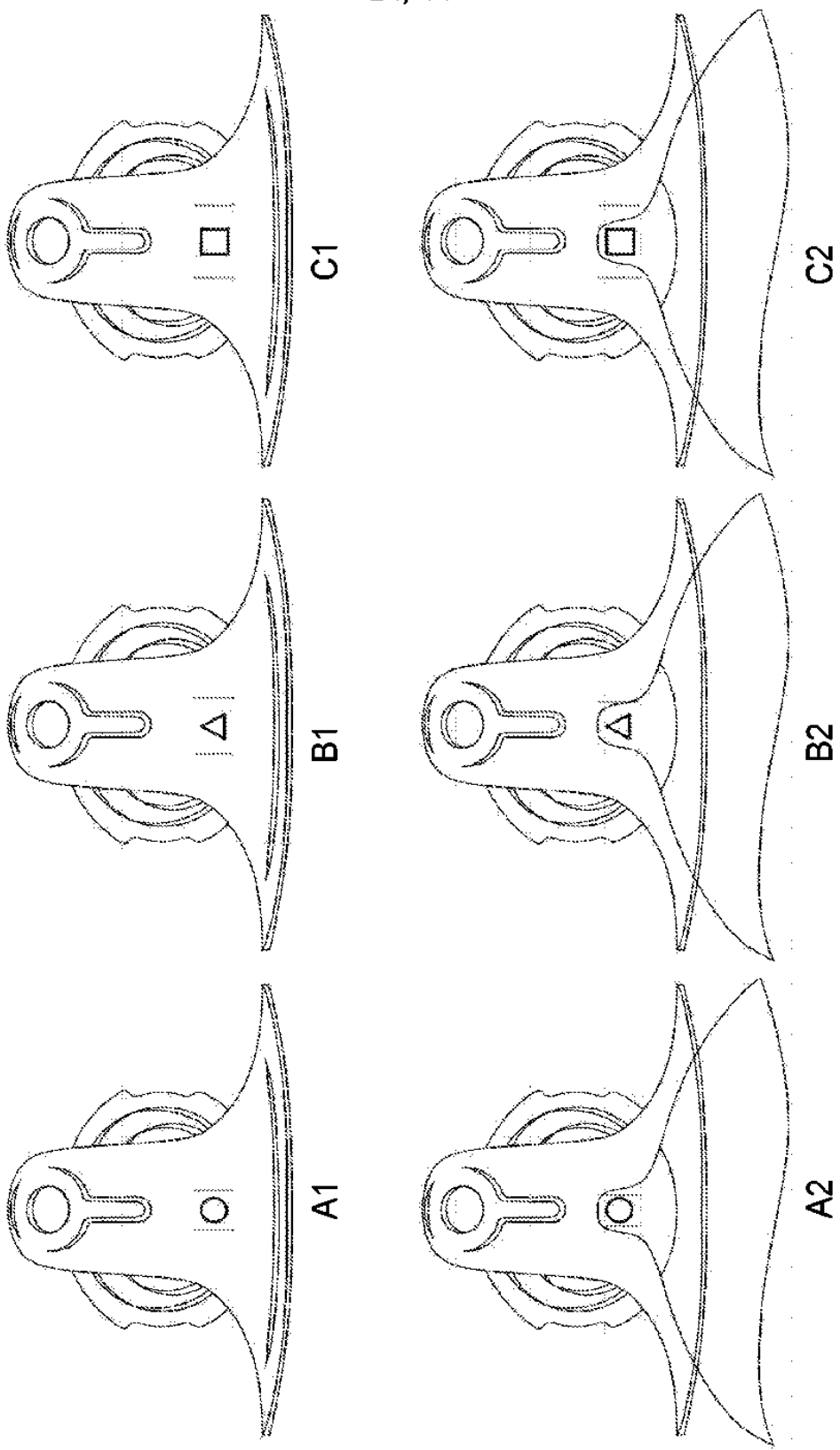


FIGURE 14

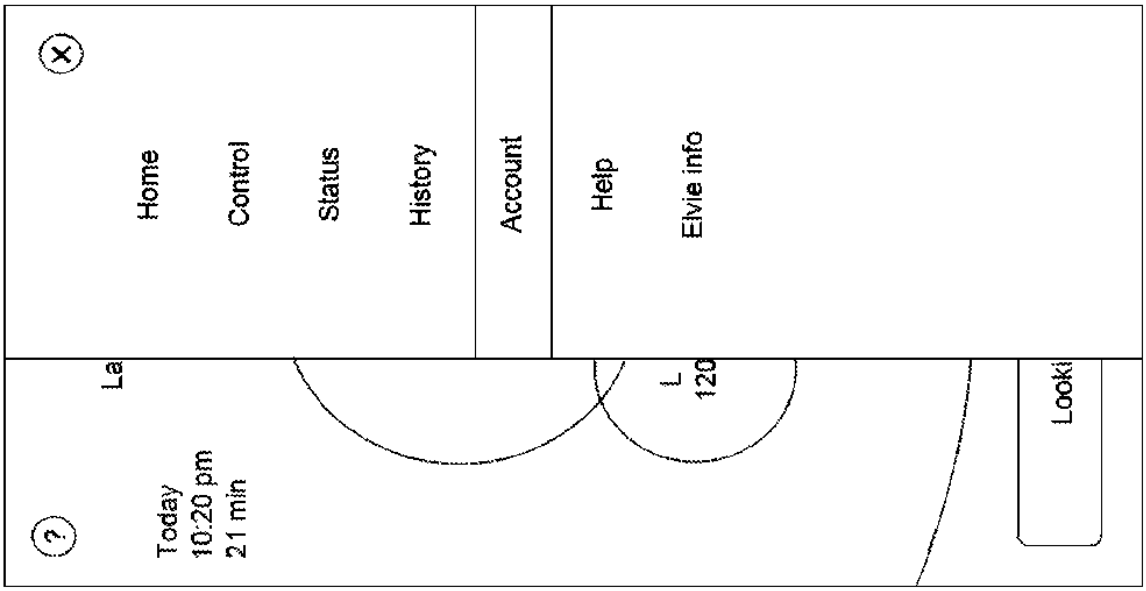

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

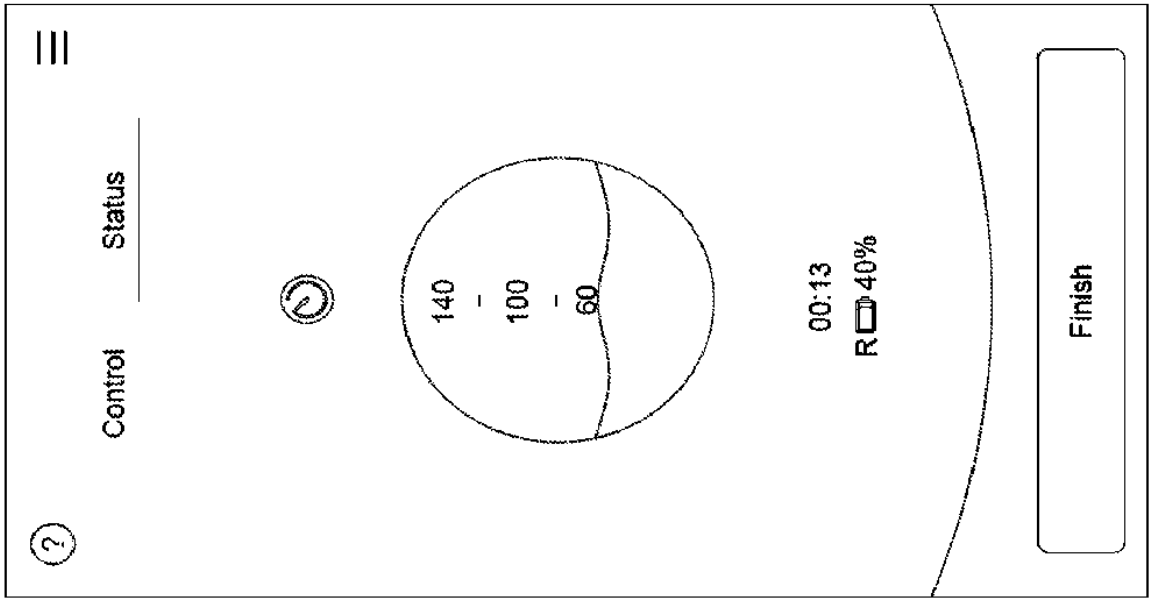


FIGURE 16

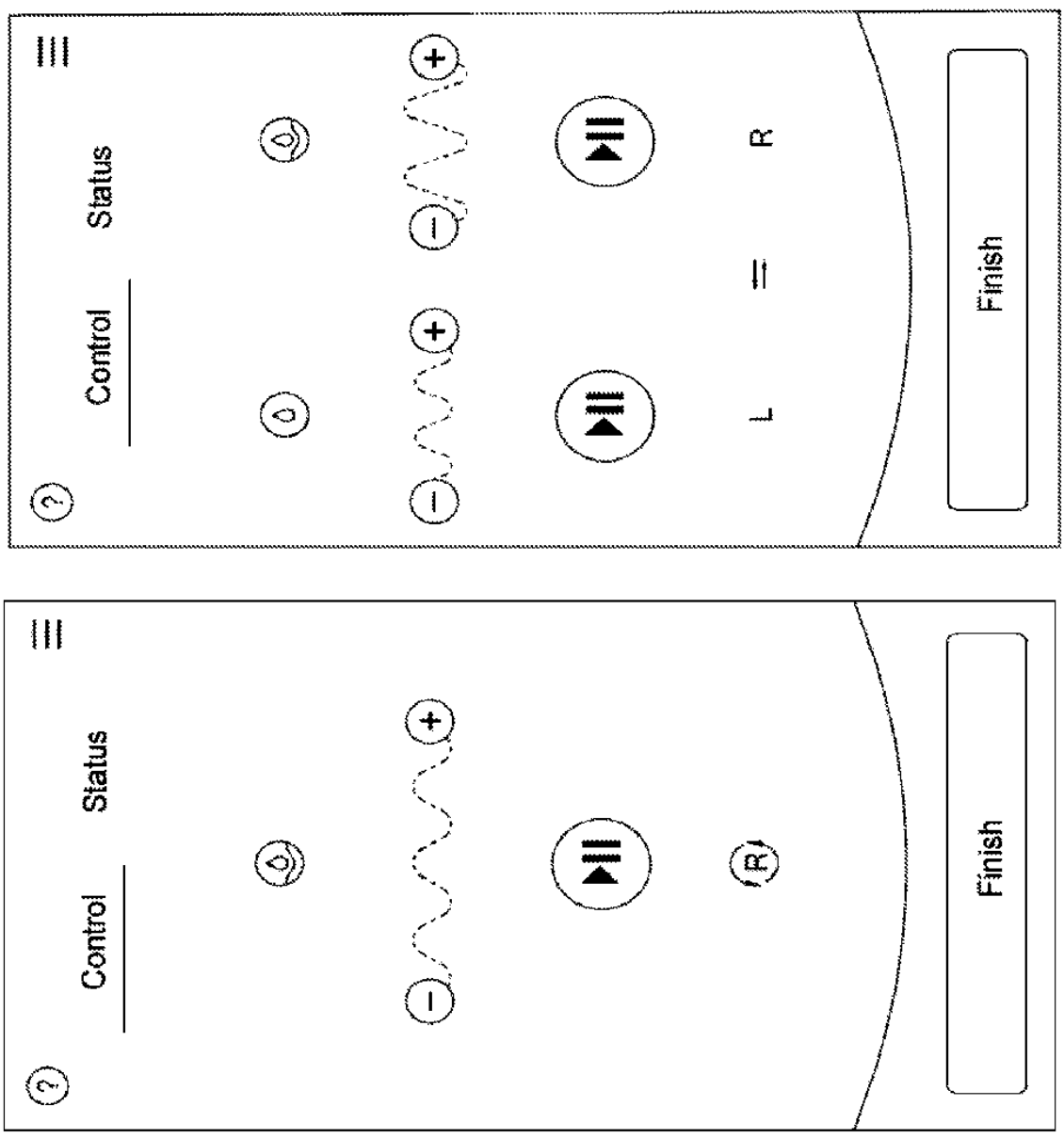


FIGURE 17

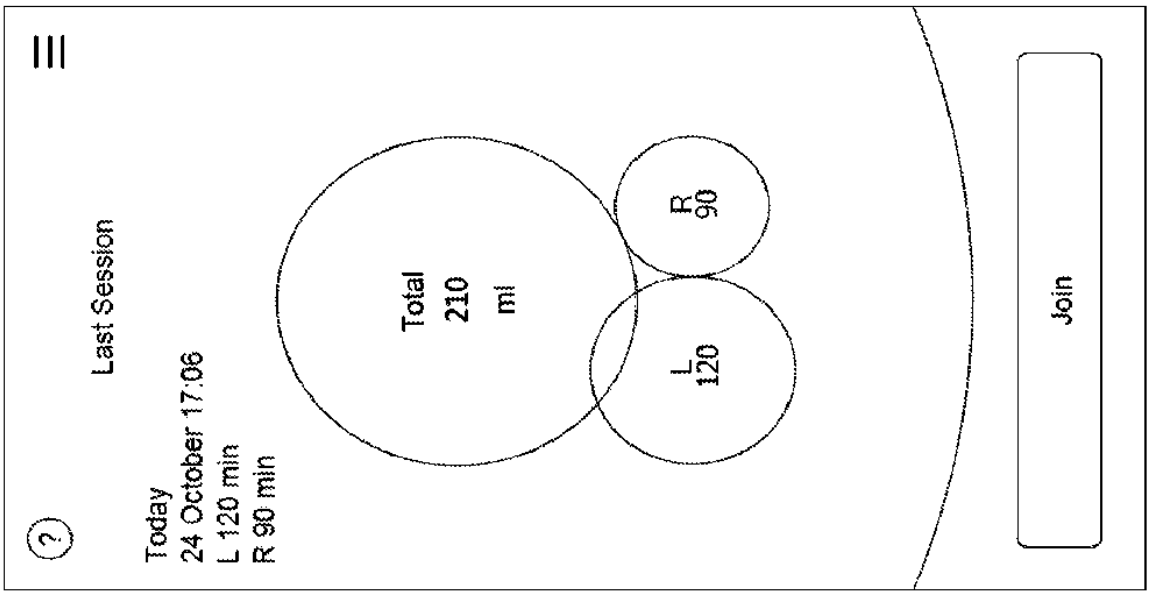

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
mi
L
120
R
90
Join

FIGURE 18

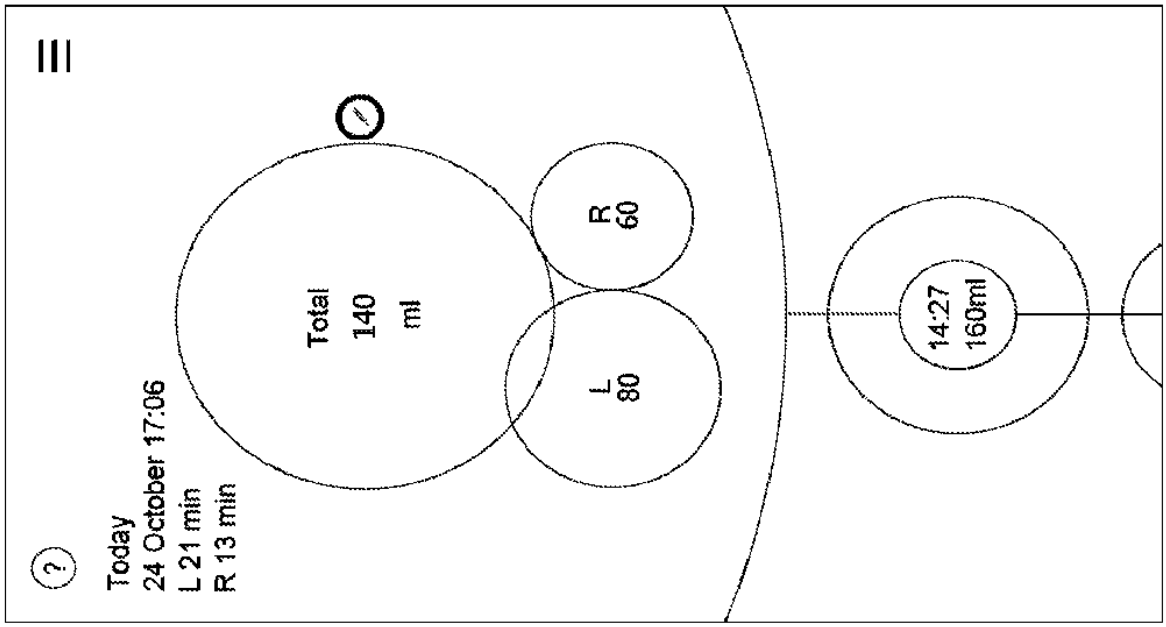

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

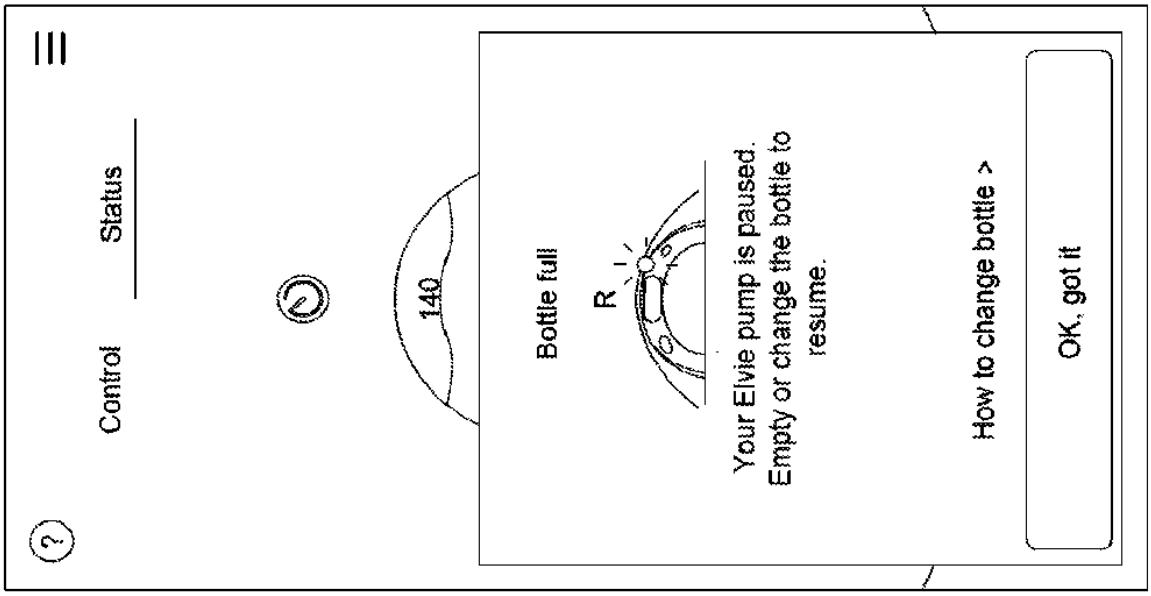

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

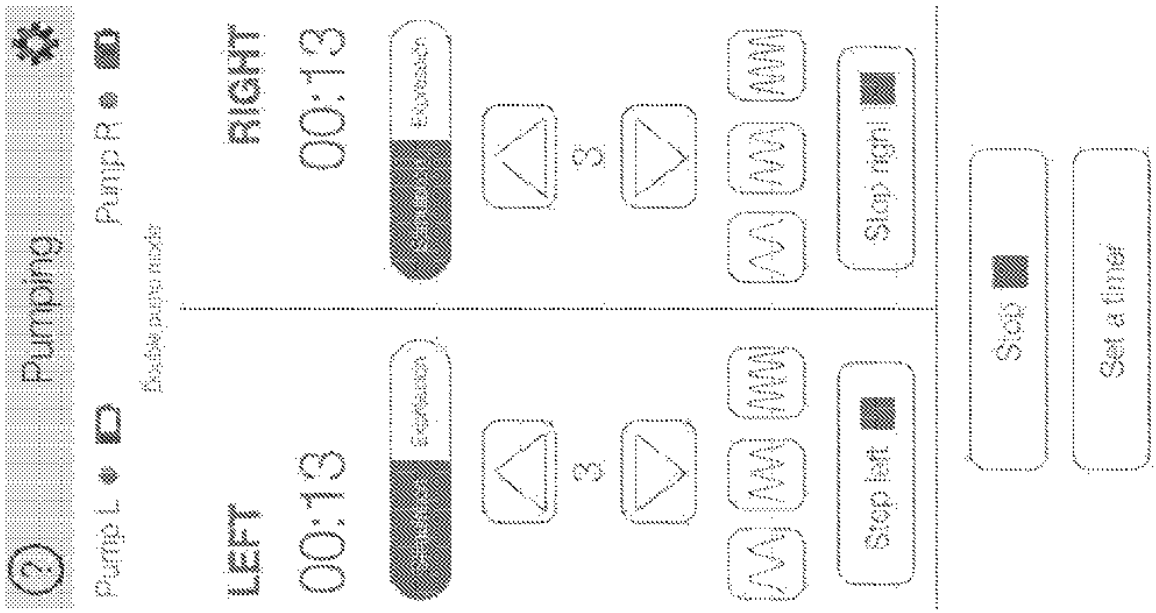

Pumping
Pump L
Pump R
Auto suction mode
LEFT
00:13
Suction
Expulsion
RIGHT
00:13
Suction
Expulsion
Stop left
Stop right
Stop
Set a timer

FIGURE 21

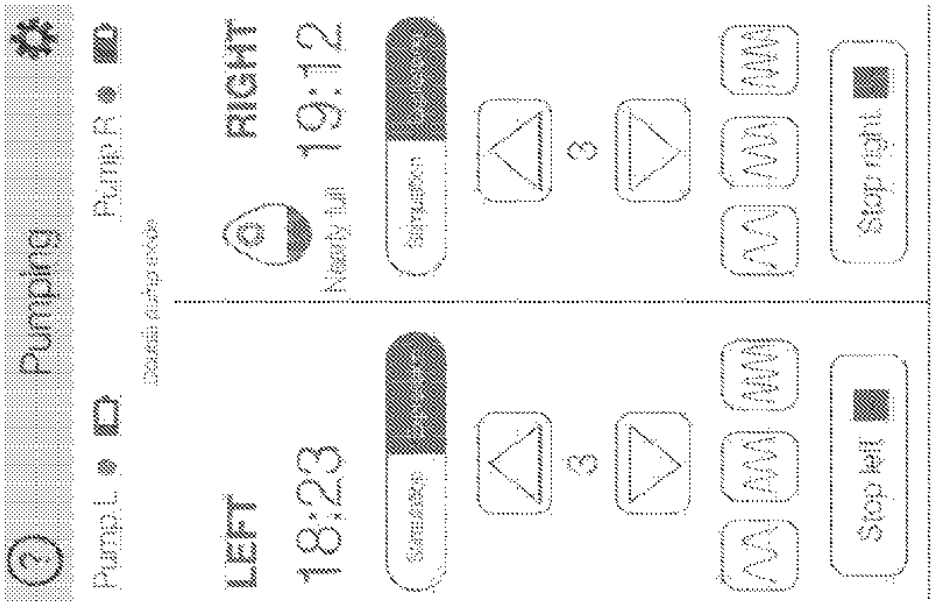

Pumping
Pump L
Pump R
Quick actions
LEFT
18:23
Sensation
Custom
3
3
Stop left
RIGHT
19:12
Sensation
Custom
3
3
Stop right
Stop
Set a timer

FIGURE 22

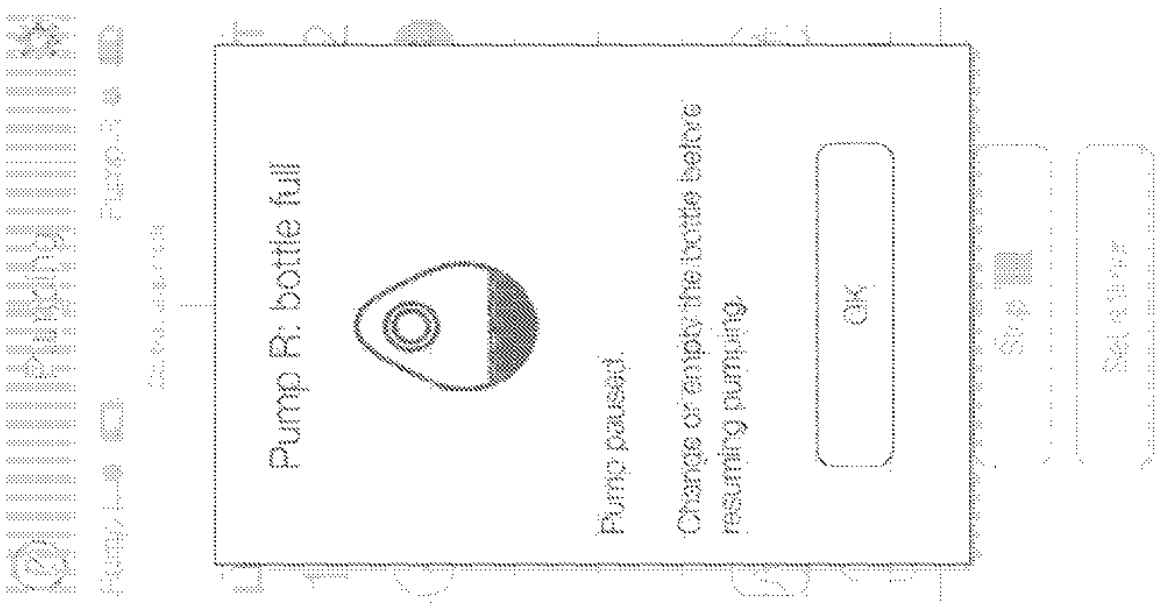

Pump R: bottle full
Pump paused
Change or empty the bottle before resuming pumping
OK

FIGURE 23


Stopped
Pump L
Pump R
Order in use now
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle
Total volume in bottle
60 ml
65 ml
Tick if you emptied the bottle
Tick if you emptied the bottle
Resume left
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
Pump R
Check pump cycle
LAST SESSION
Start time: 3:30pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

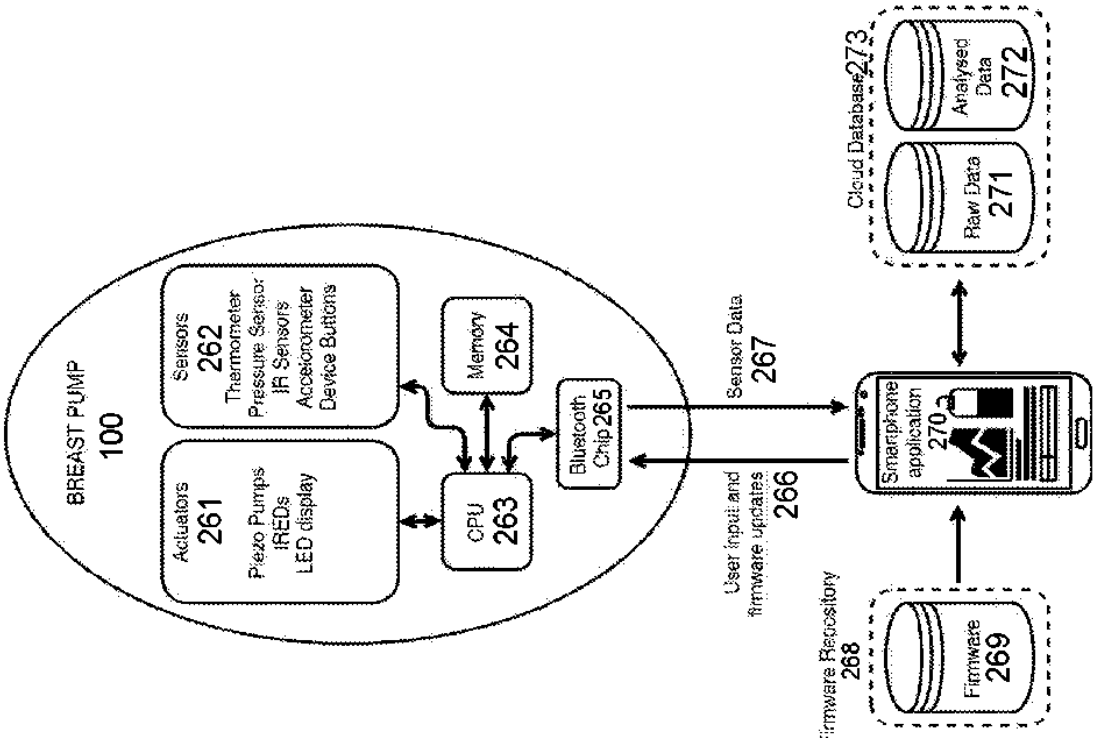

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

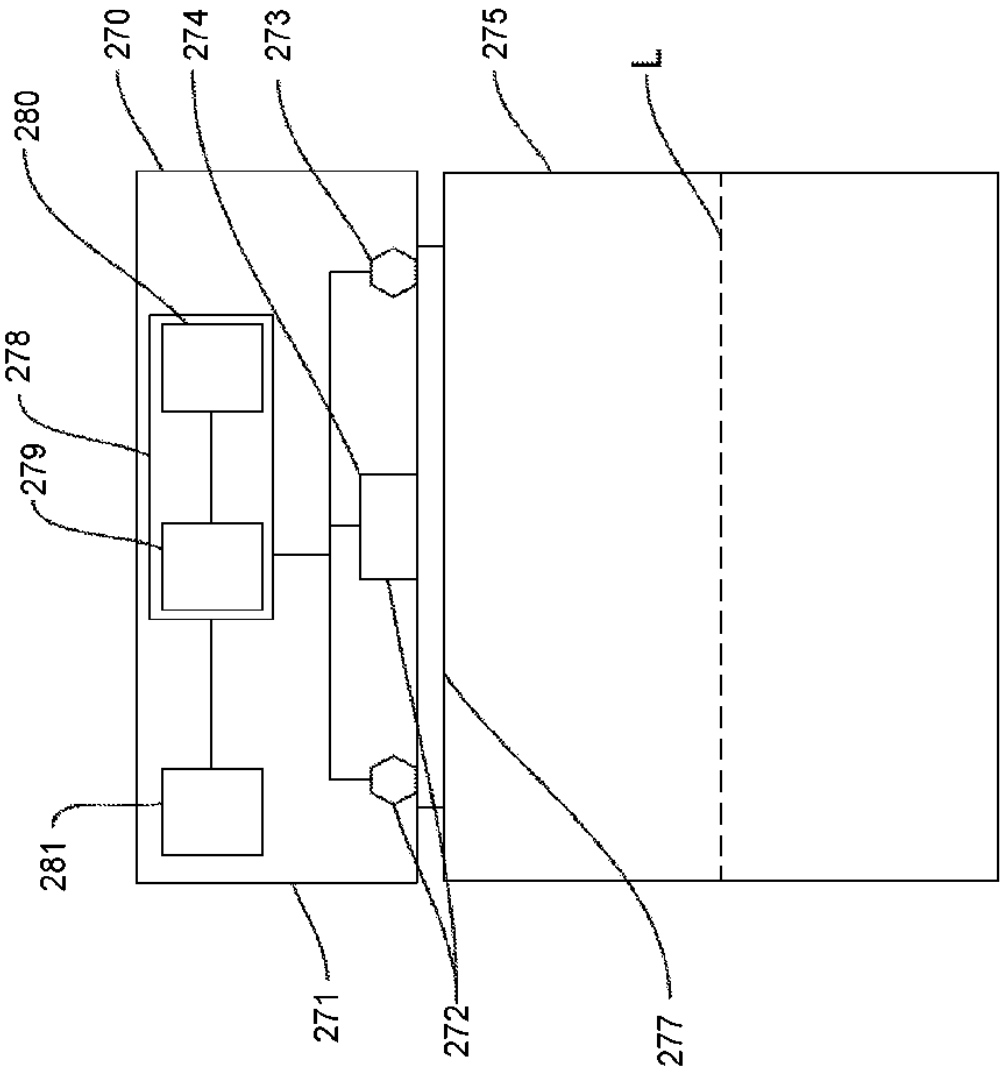


FIGURE 27

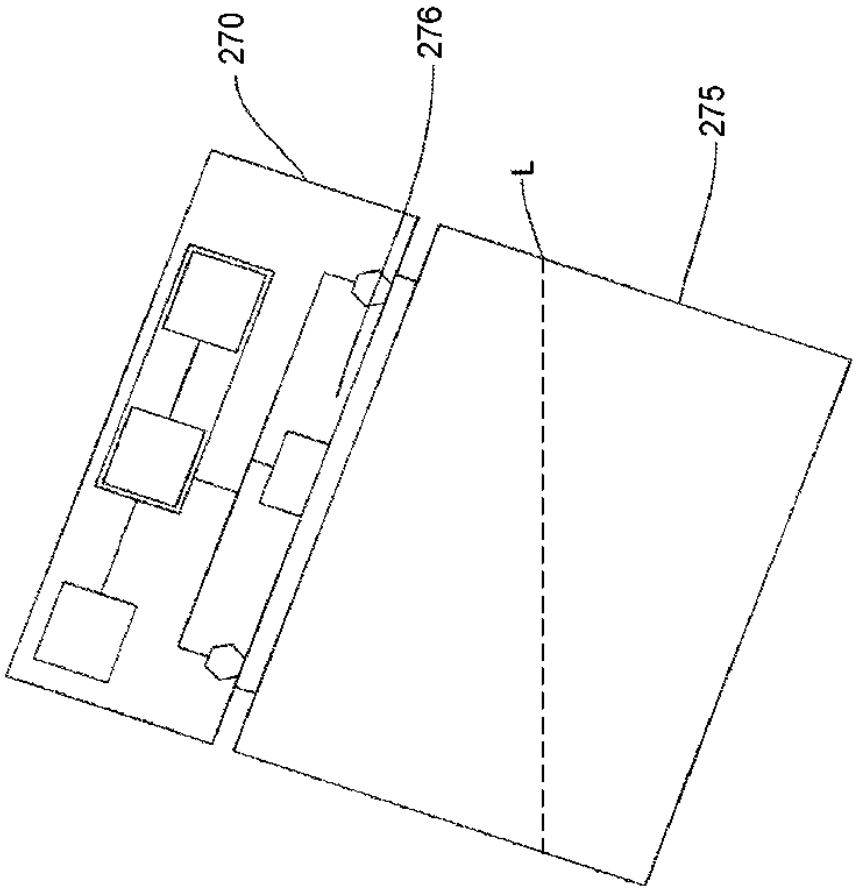


FIGURE 28

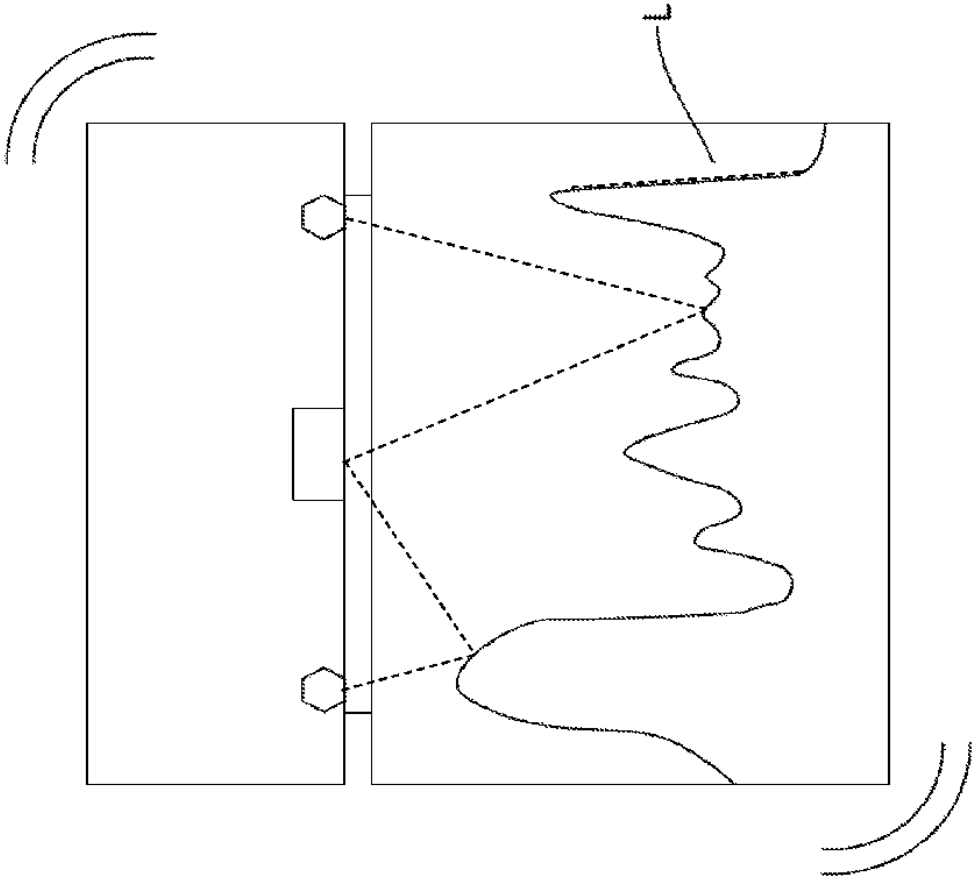


FIGURE 29

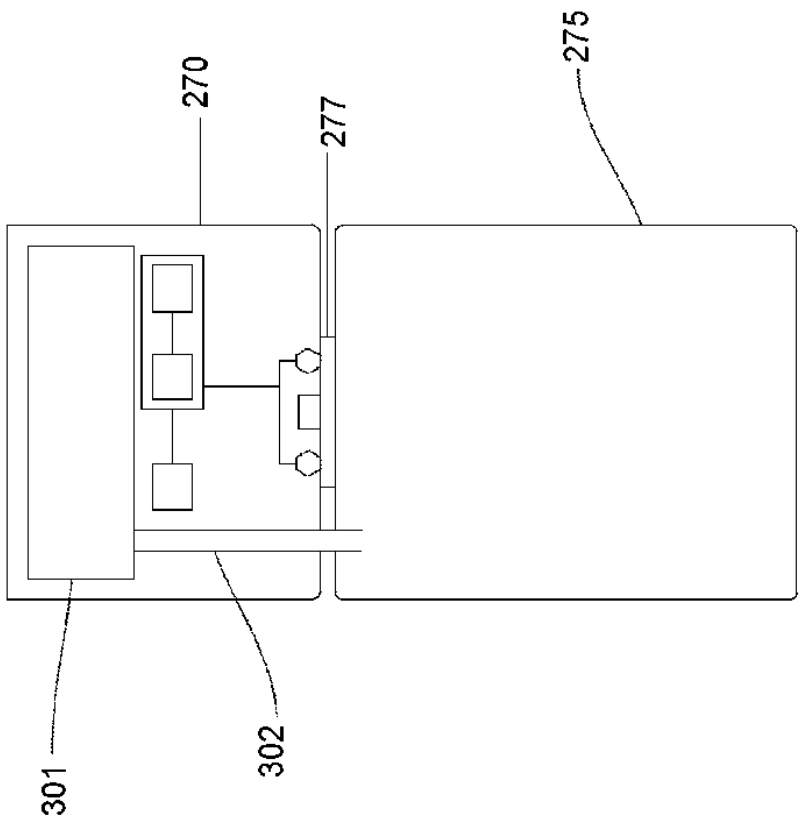


FIGURE 30

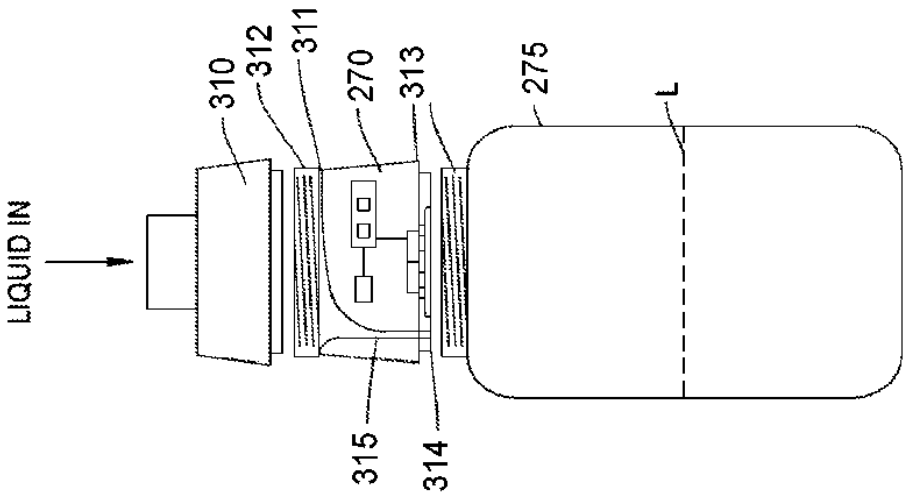


FIGURE 31

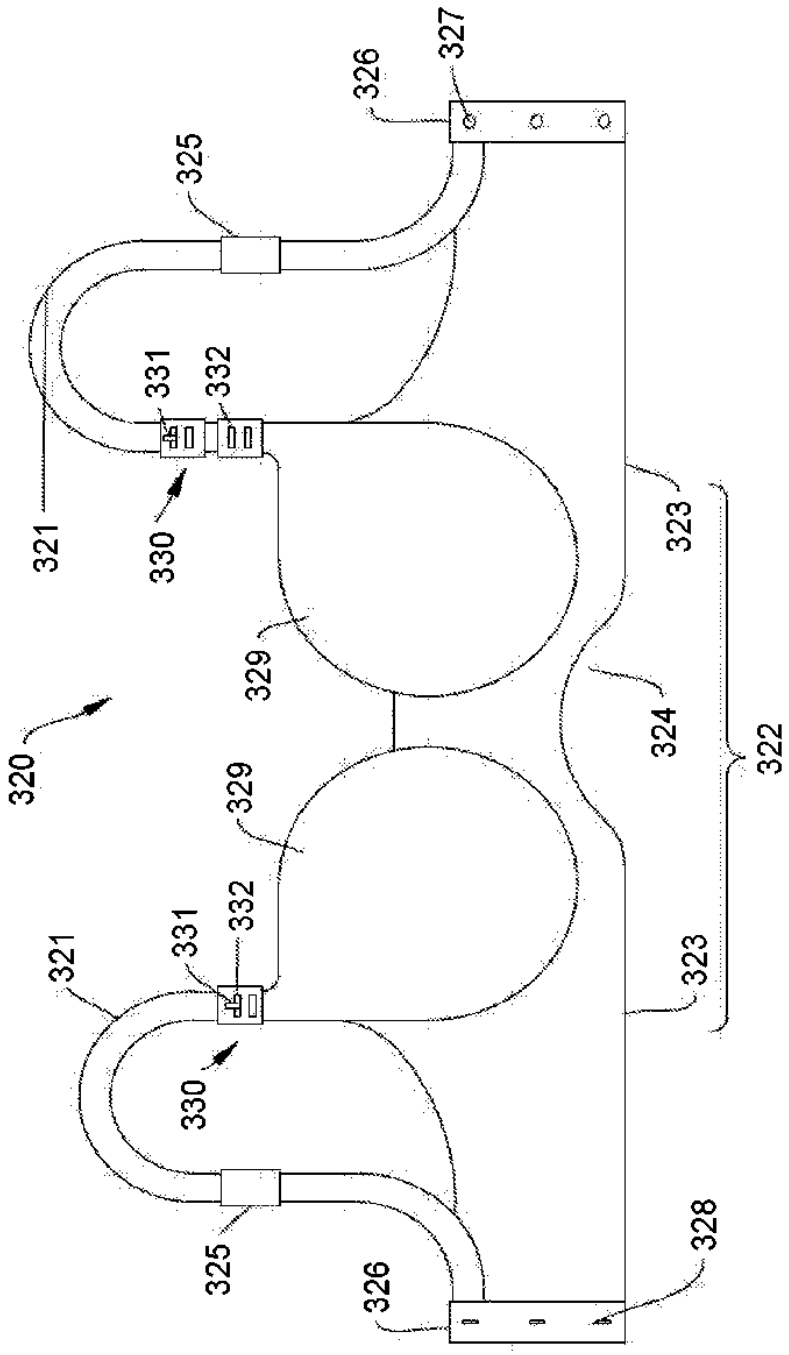


FIGURE 32

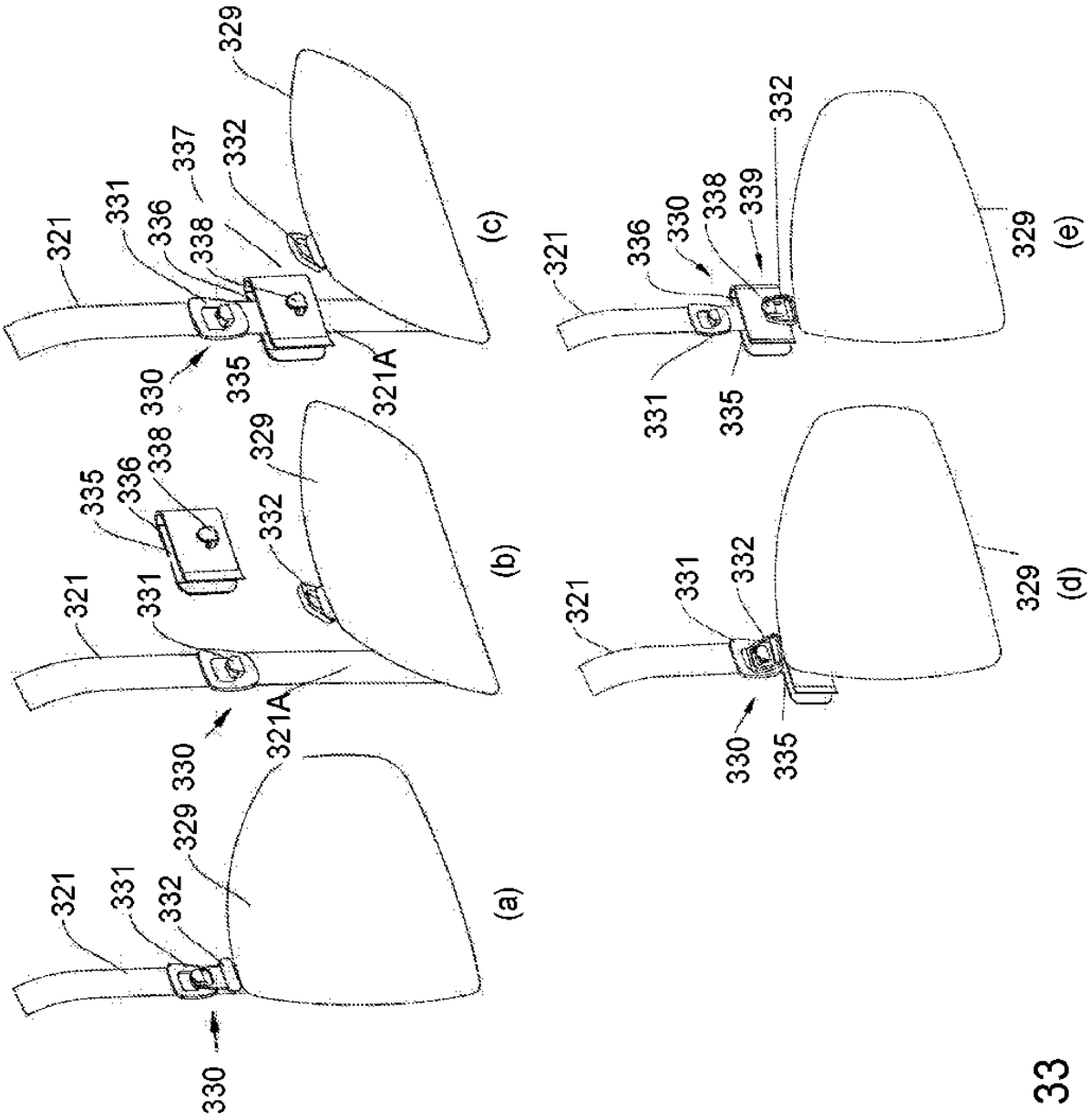

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
338
337
332
329
330
335
321A
(c)
321
336
330
338
339
332
329
331
335
(e)
321
331
332
329
330
335
(d)

FIGURE 33

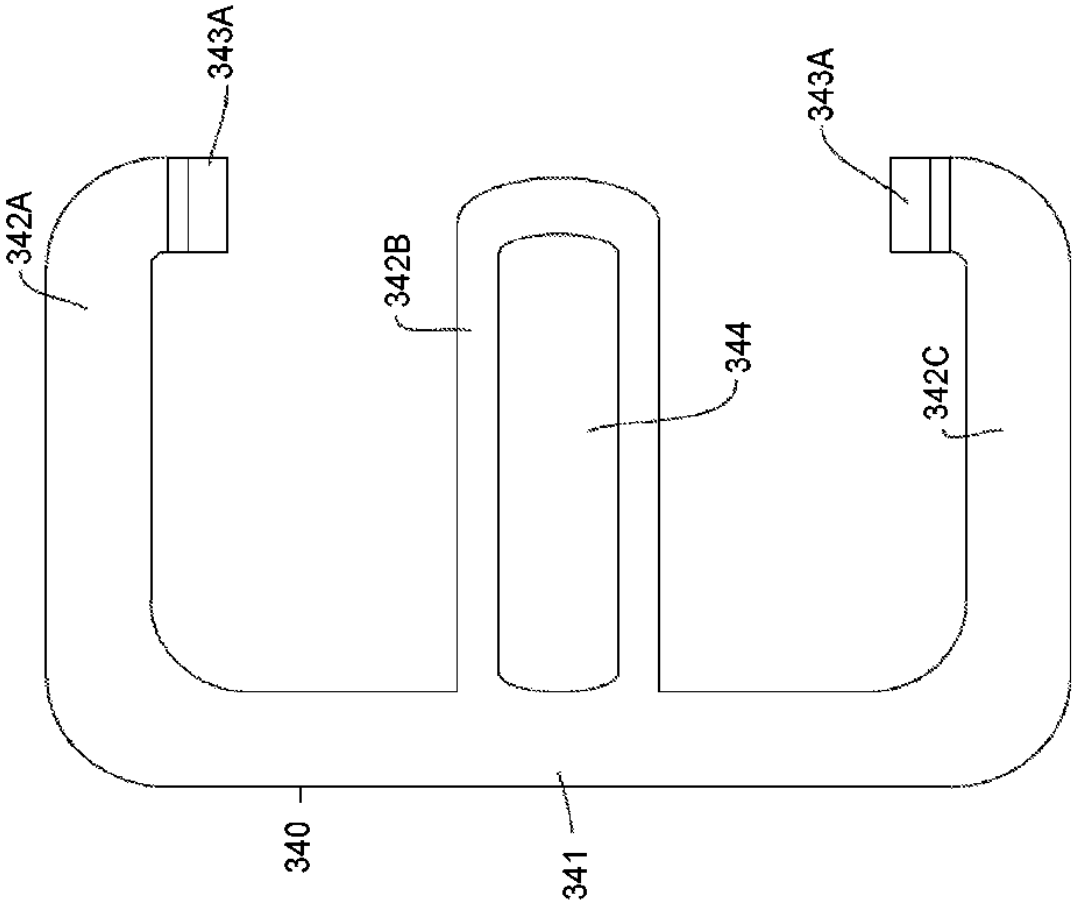


FIGURE 34

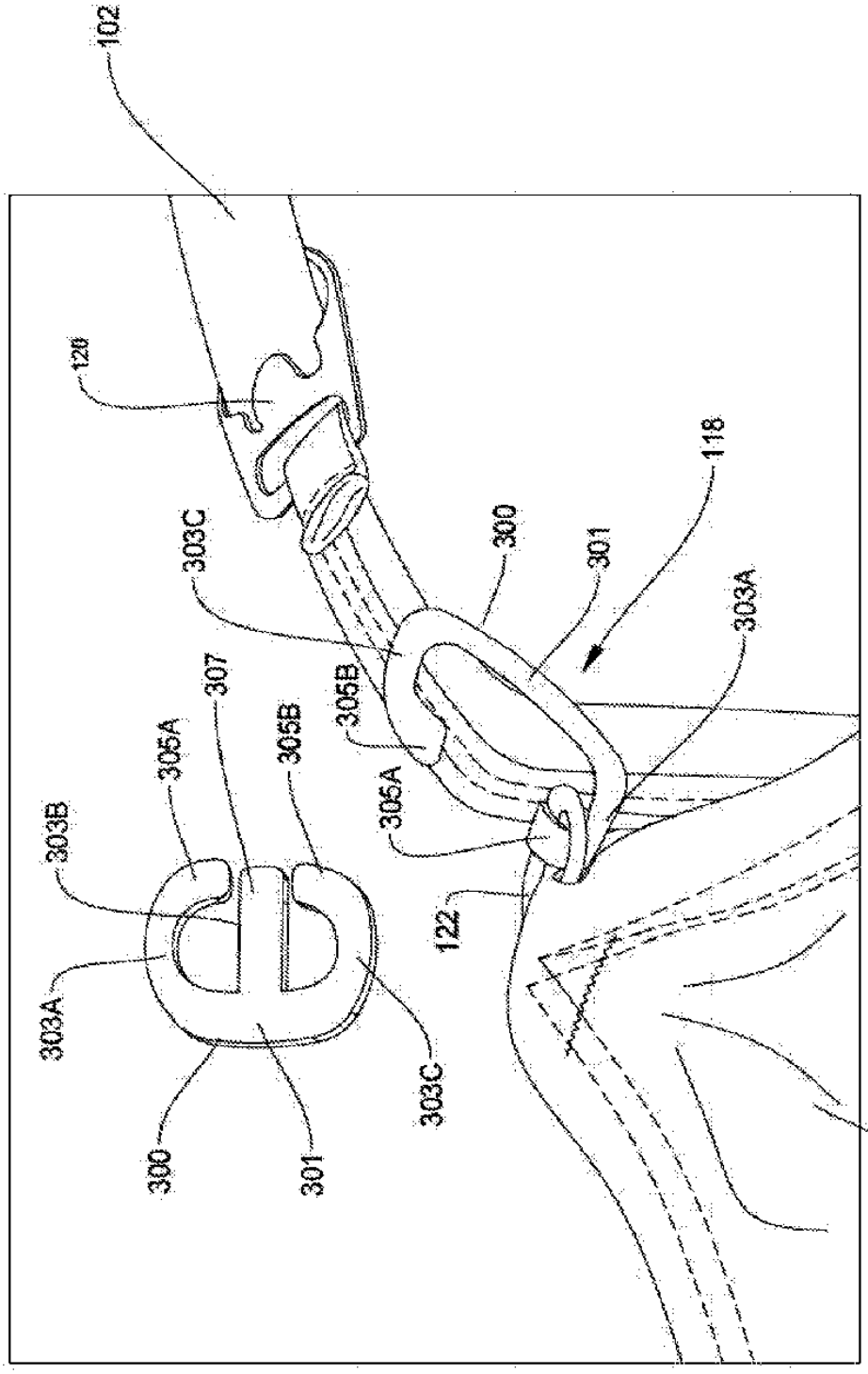

102
120
303C
300
301
118
303A
307
305B
305A
305B
305A
303B
303A
122
303C
300
301
116

FIGURE 35

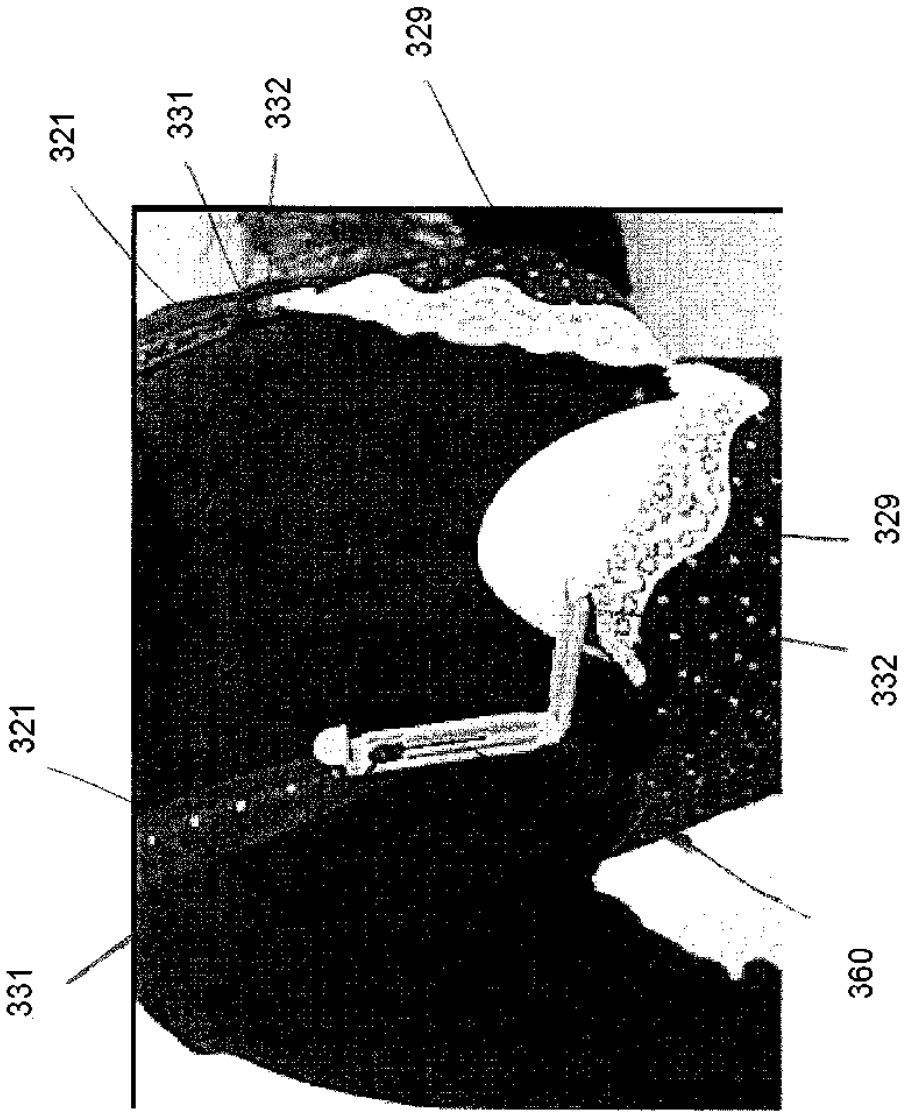


FIGURE 36

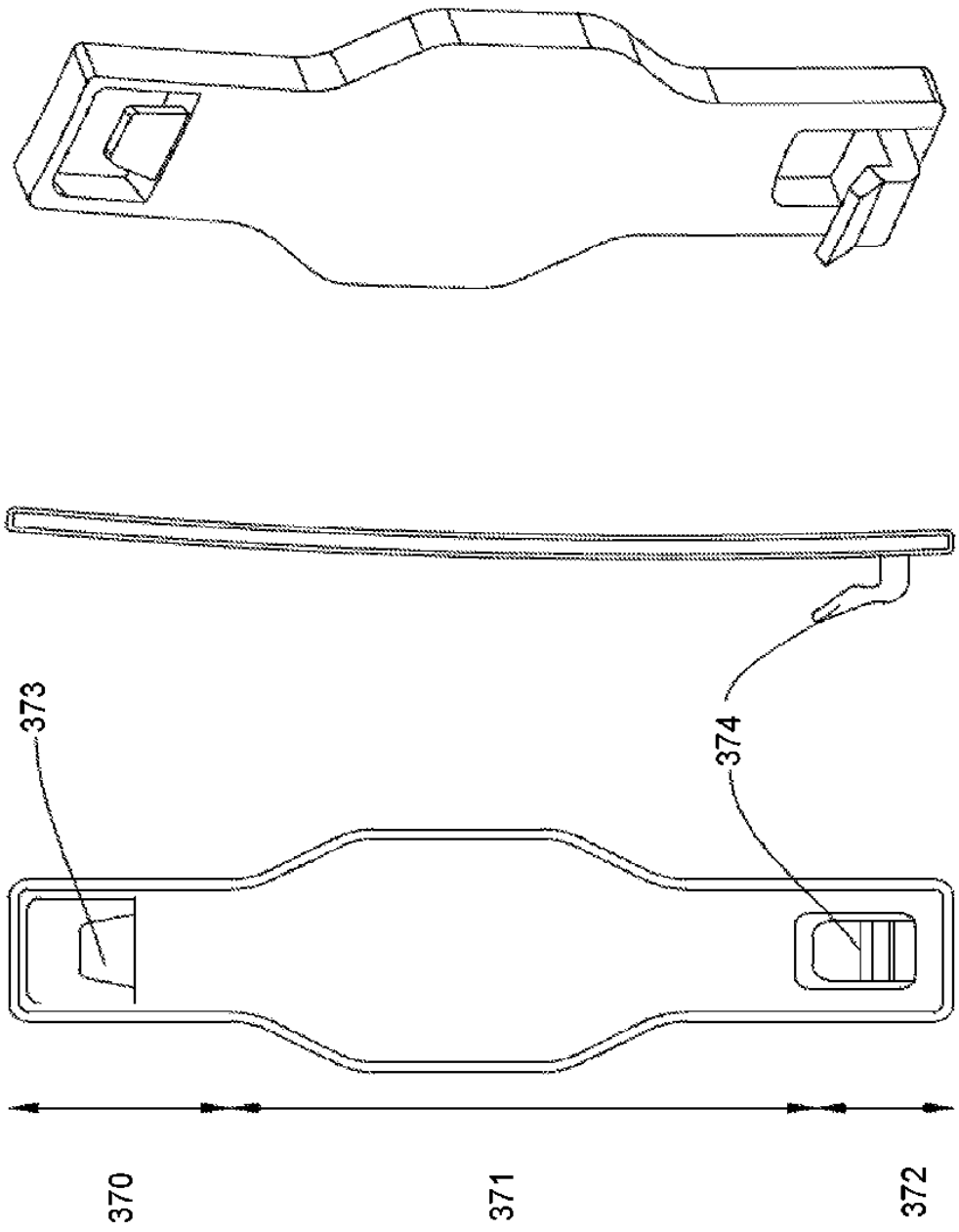


FIGURE 37

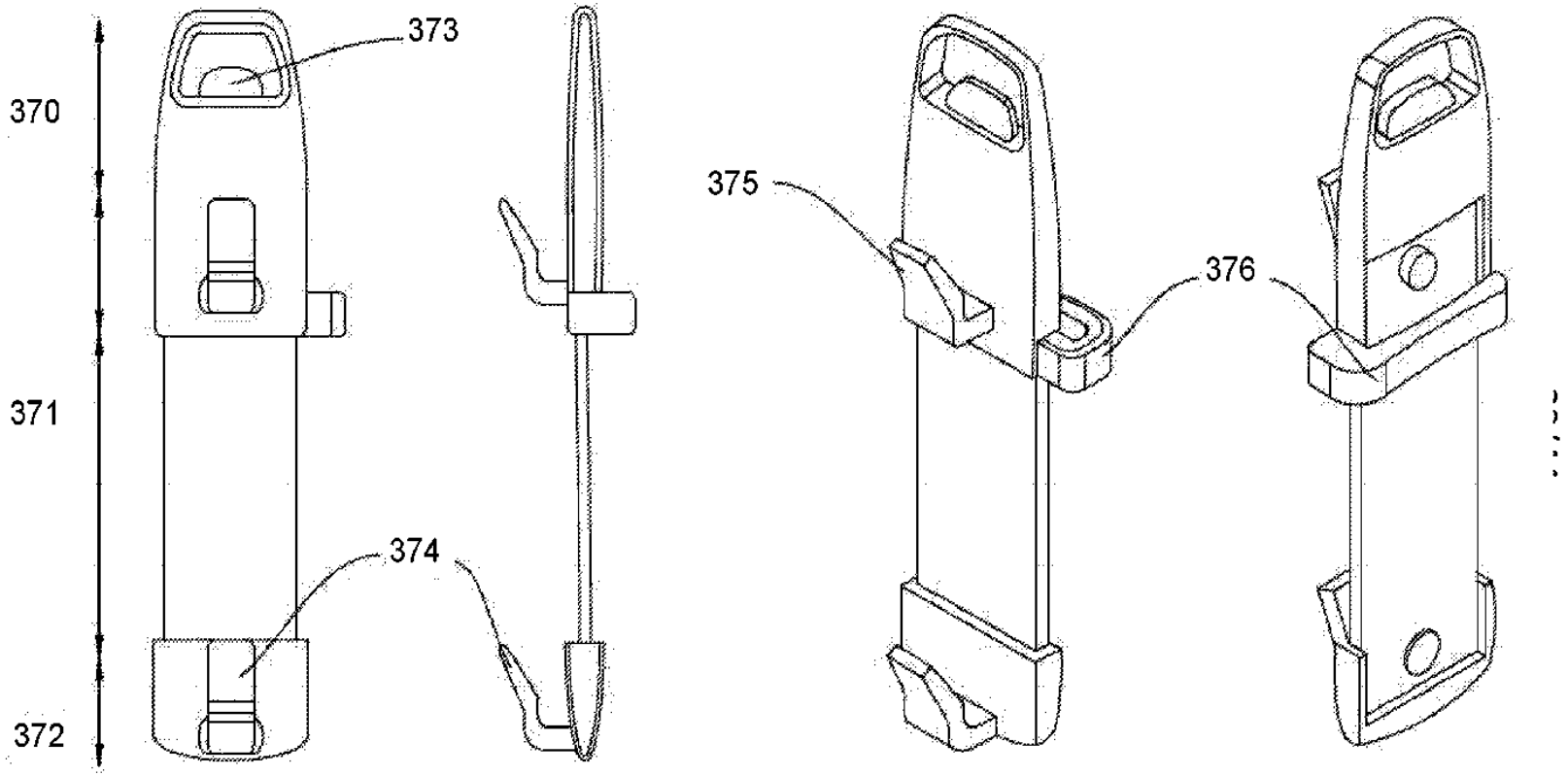


FIGURE 38

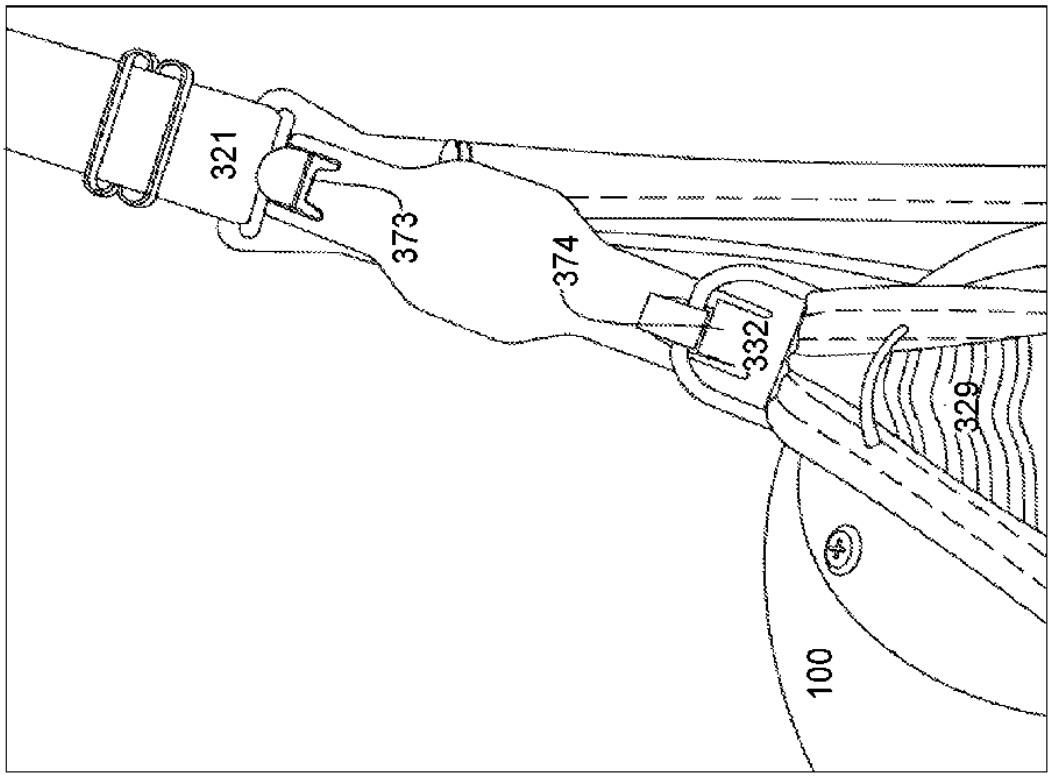


FIGURE 39

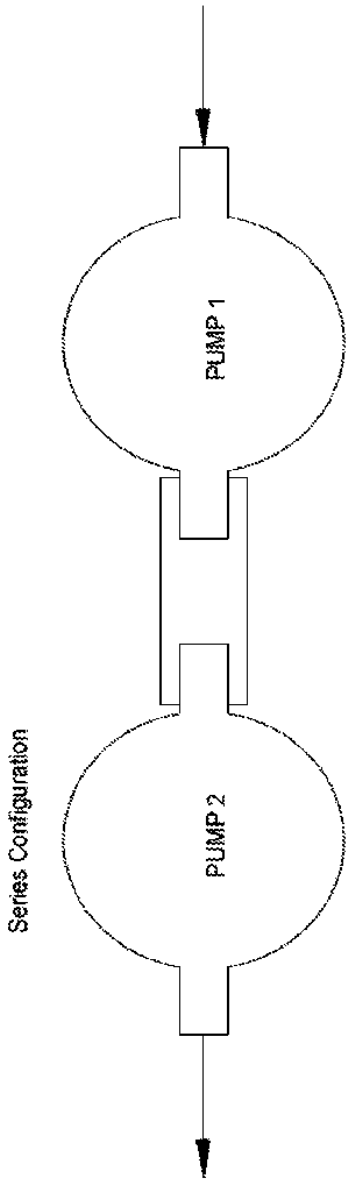


FIGURE 40

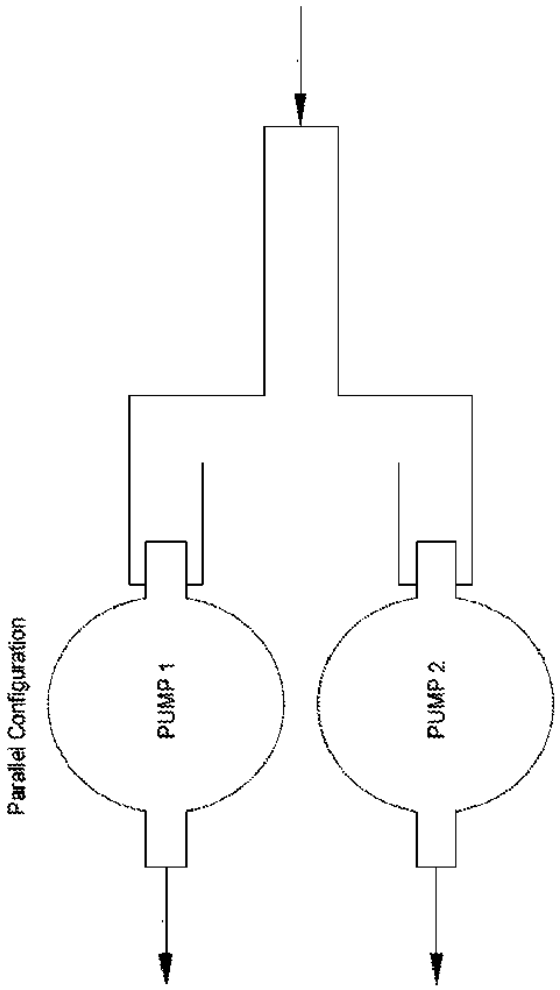


FIGURE 41

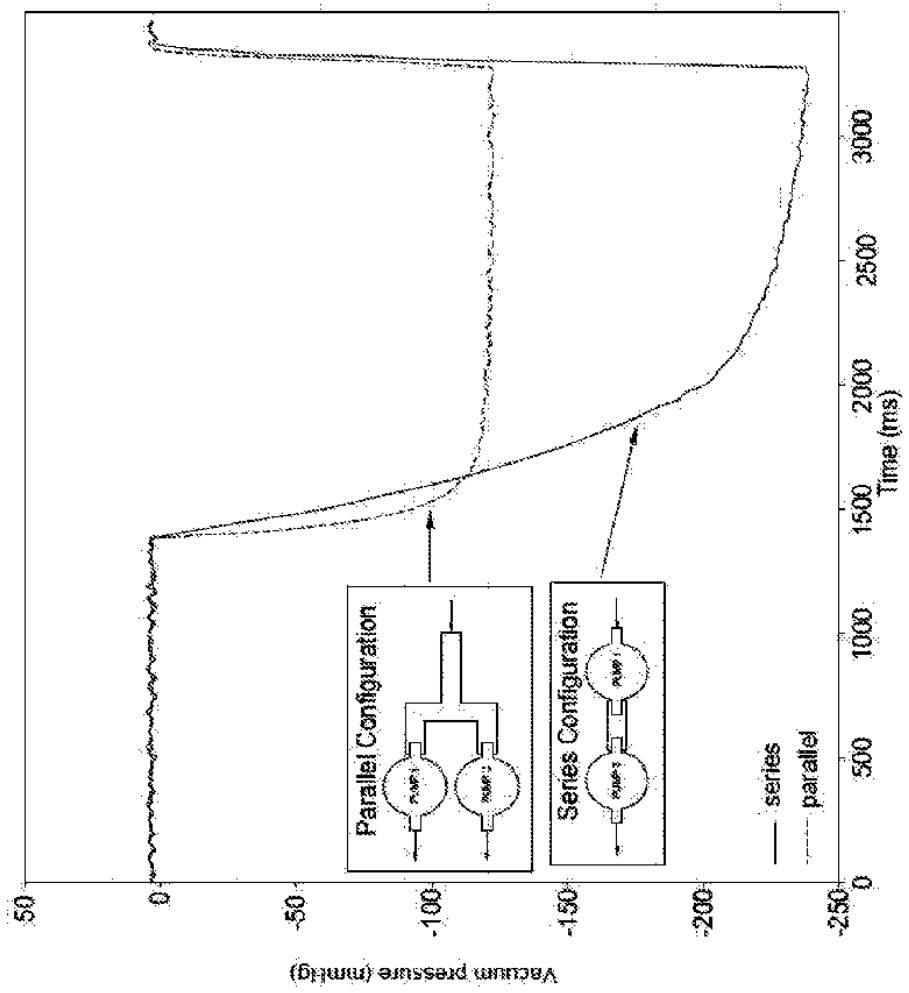

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

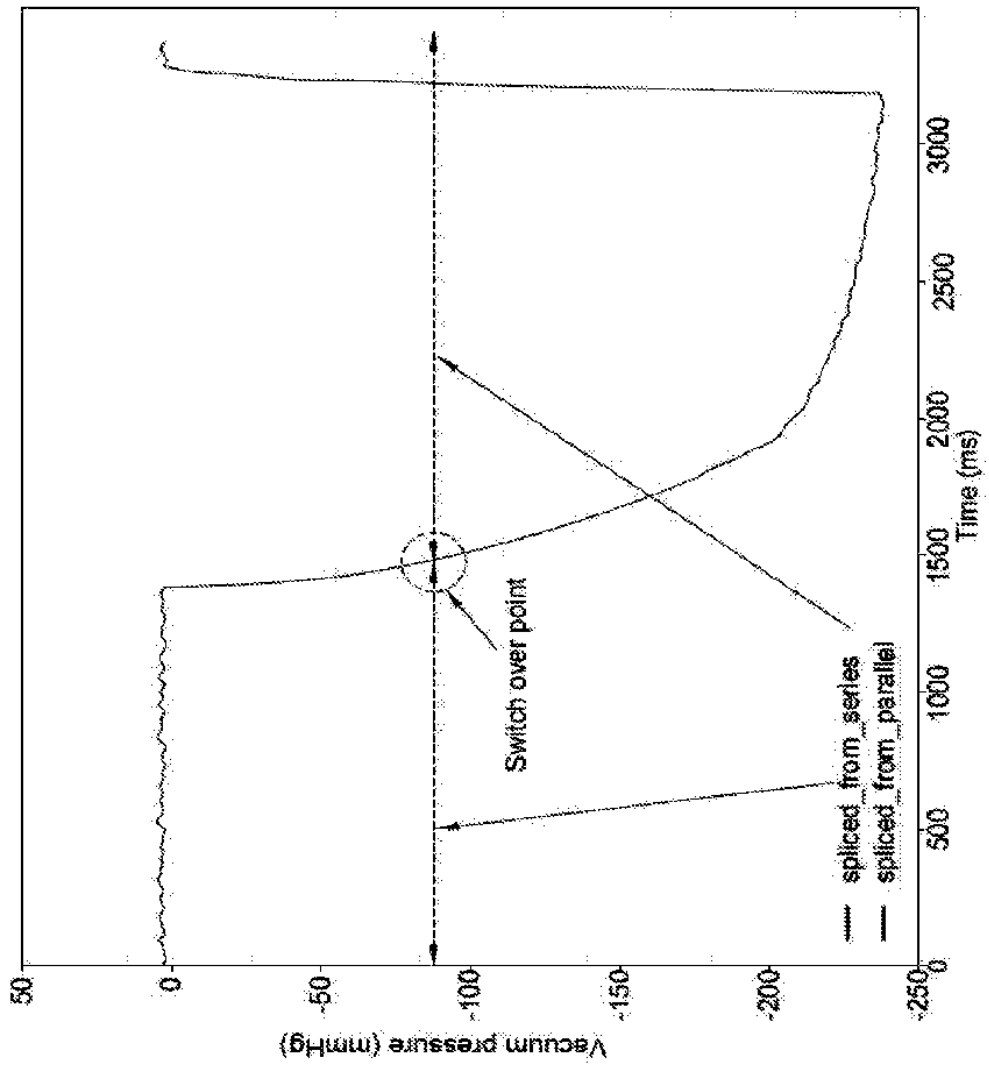

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

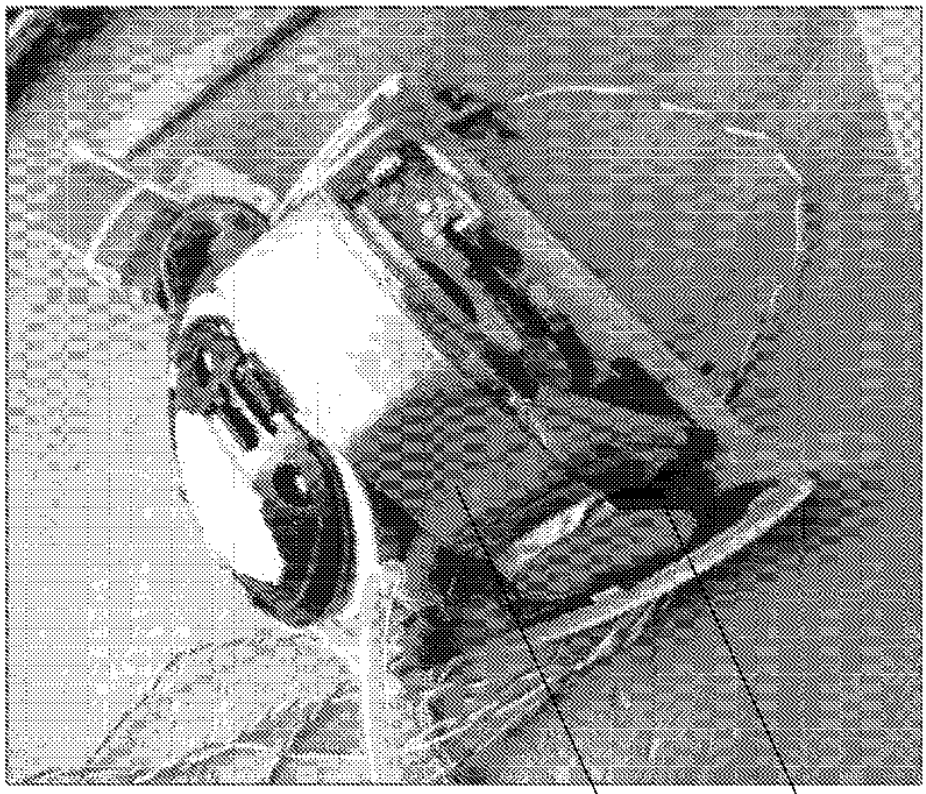


FIGURE 44

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
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

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)
Approved for use through 01/31/2014. OMB 0651-0032
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.

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
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.

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: 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.

PTO/AIA/01 (05-12)
Approved for use through 01/31/2014. OMB 0651-0032
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.

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: 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

Doc Code: PD.REQ.RETR
Document Description: Request for USPTO to retrieve priority docs

PTO/SB/38 (10-14)
Approved for use through 05/31/2016. 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 displays a valid OMB control number.

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.**

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.

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		

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

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

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

GRANT

Decision Type: 643 - Track One request

643

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

Digital Access Service
(DAS)

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

CERTIFICATE OF AVAILABILITY OF A CERTIFIED PATENT DOCUMENT IN A DIGITAL LIBRARY

The International Bureau certifies that a copy of the patent application indicated below has been available to the WIPO Digital Access Service since the date of availability indicated, and that the patent application has been available to the indicated Office(s) as of the date specified following the relevant Office code:

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)

The following Offices can retrieve this document by using the access code:
JP, US, SE, NZ, KR, EA, IN, BR, GB, AU, ES, NL, IB, EE, CN, MA, FI, DK

Date of issue of this certificate: 27 Jul 2018 (27.07.2018)

34, chemin des Colombettes
1211 Geneva 20, Switzerland
www.wipo.int

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**

Patents Form 1

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

Warning
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 the diaphragm; and the other throw 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;

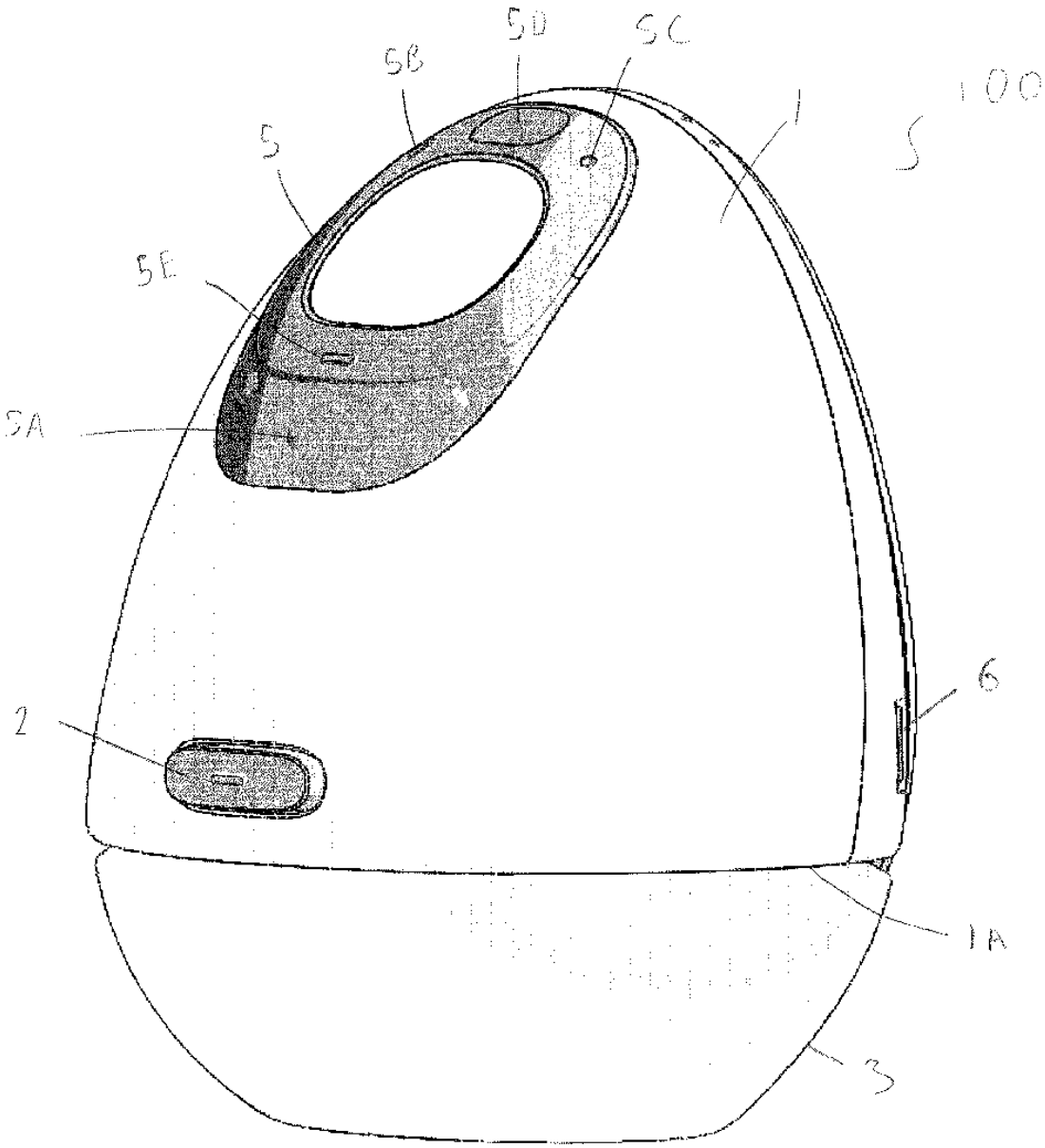
generating a positive pressure with the pump;

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.

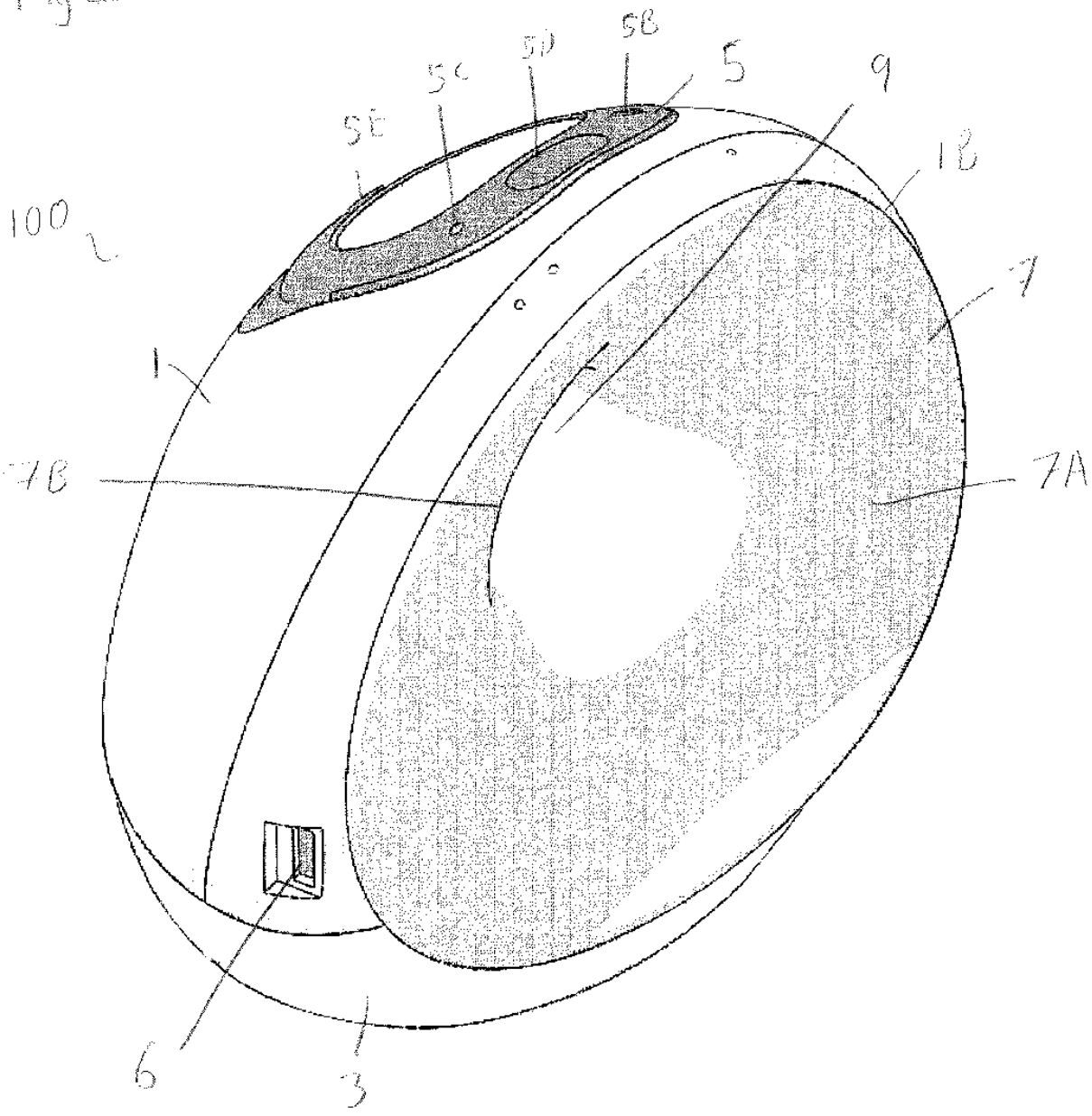
P153992GB00



7397102, JCP2, JCP2

P153992GB00

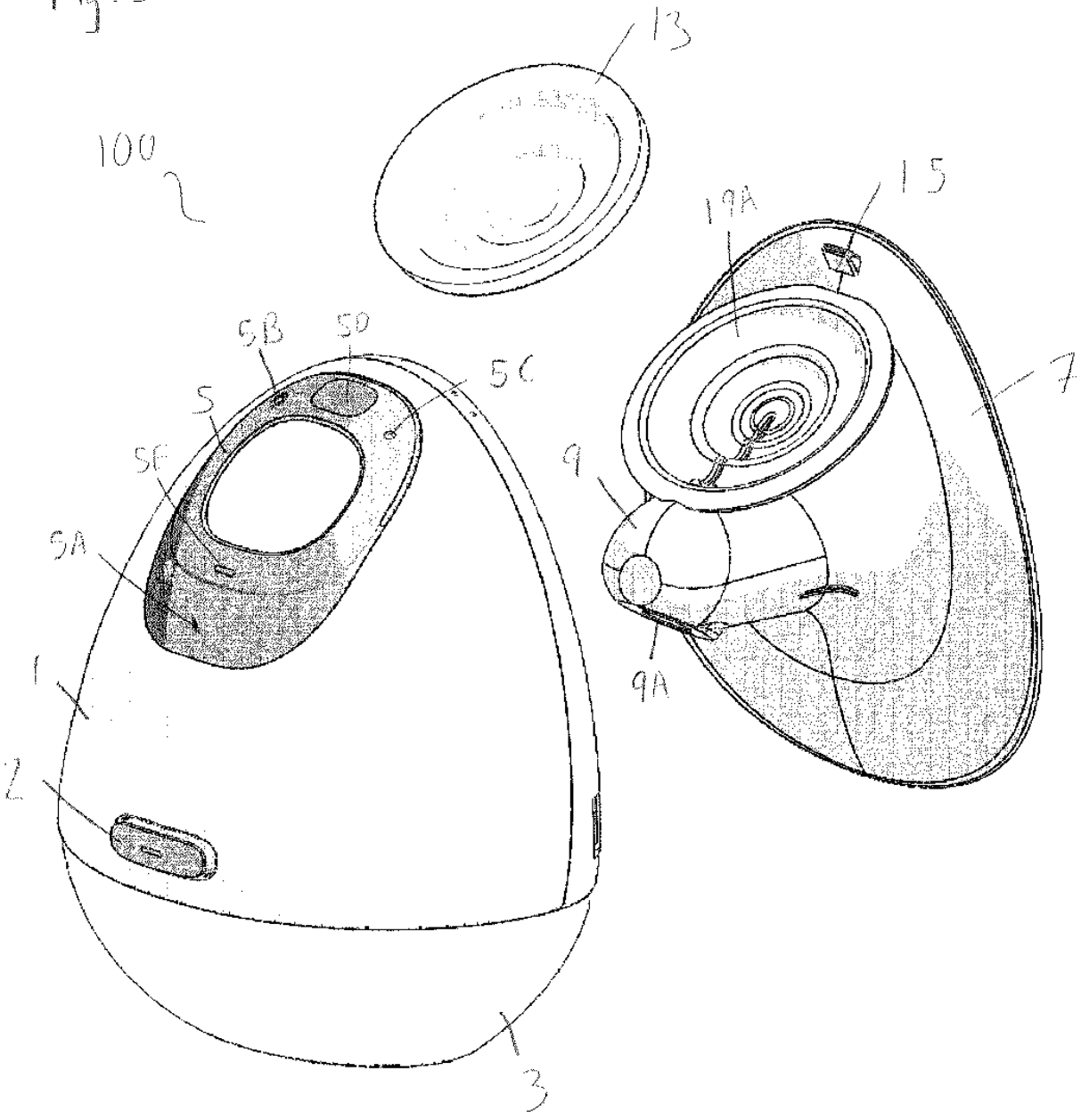
Fig 2



7397102; JCP2; JCP2

P153992GB00

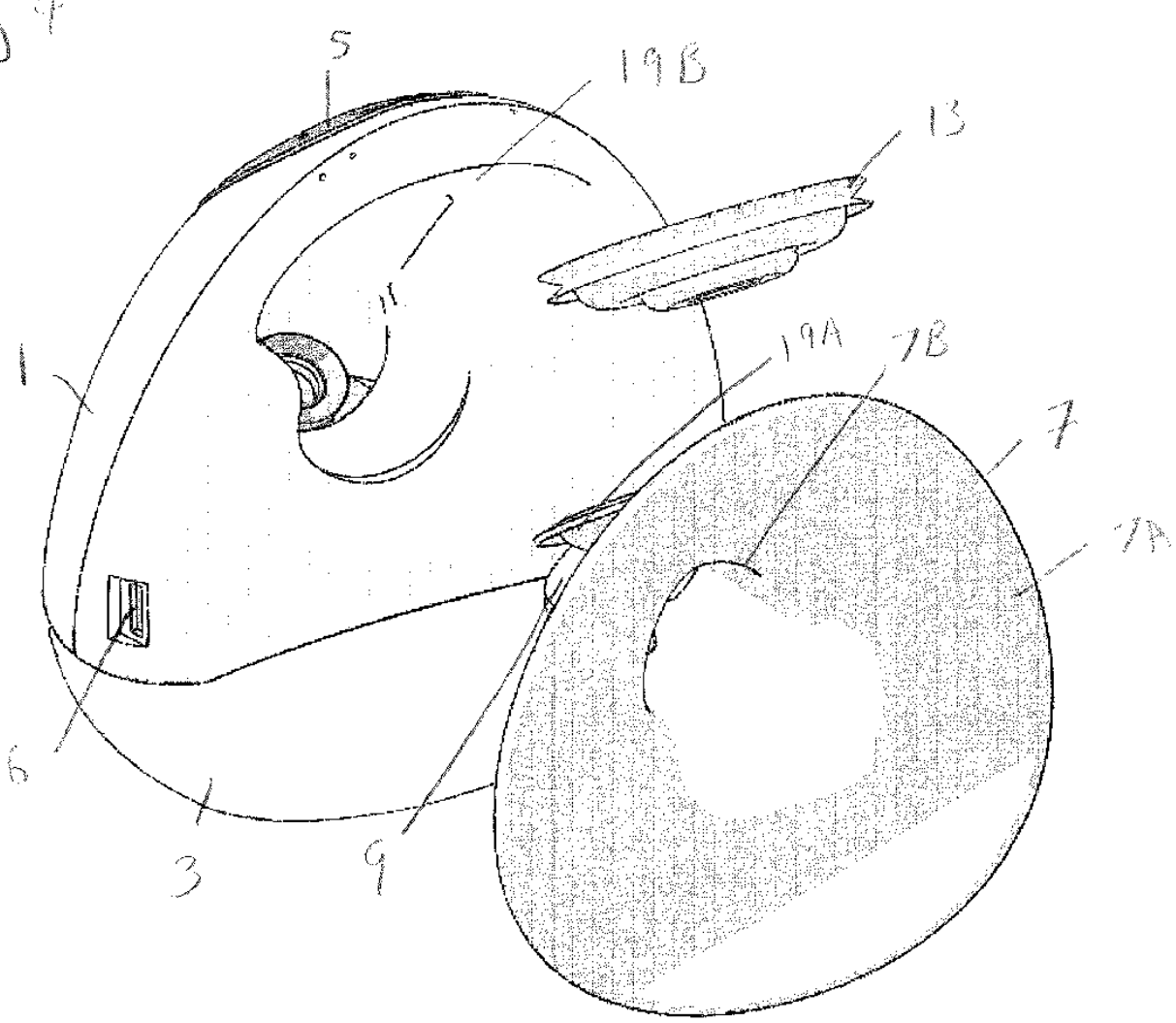
Fig. 3



7397102; JCP2; JCP2

P153992GB00

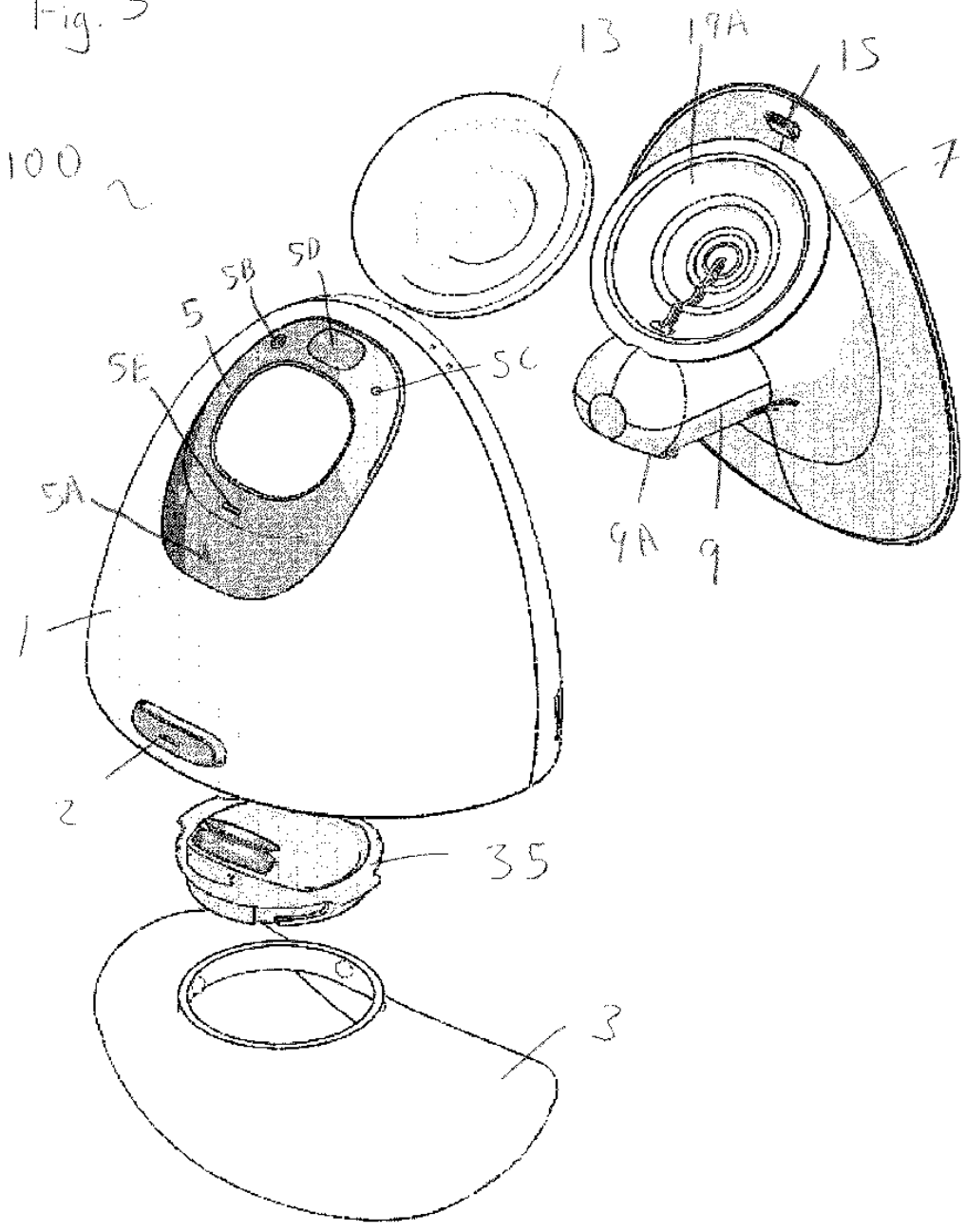
Fig 4



7397102; JCP2; JCP2

P153992GB00

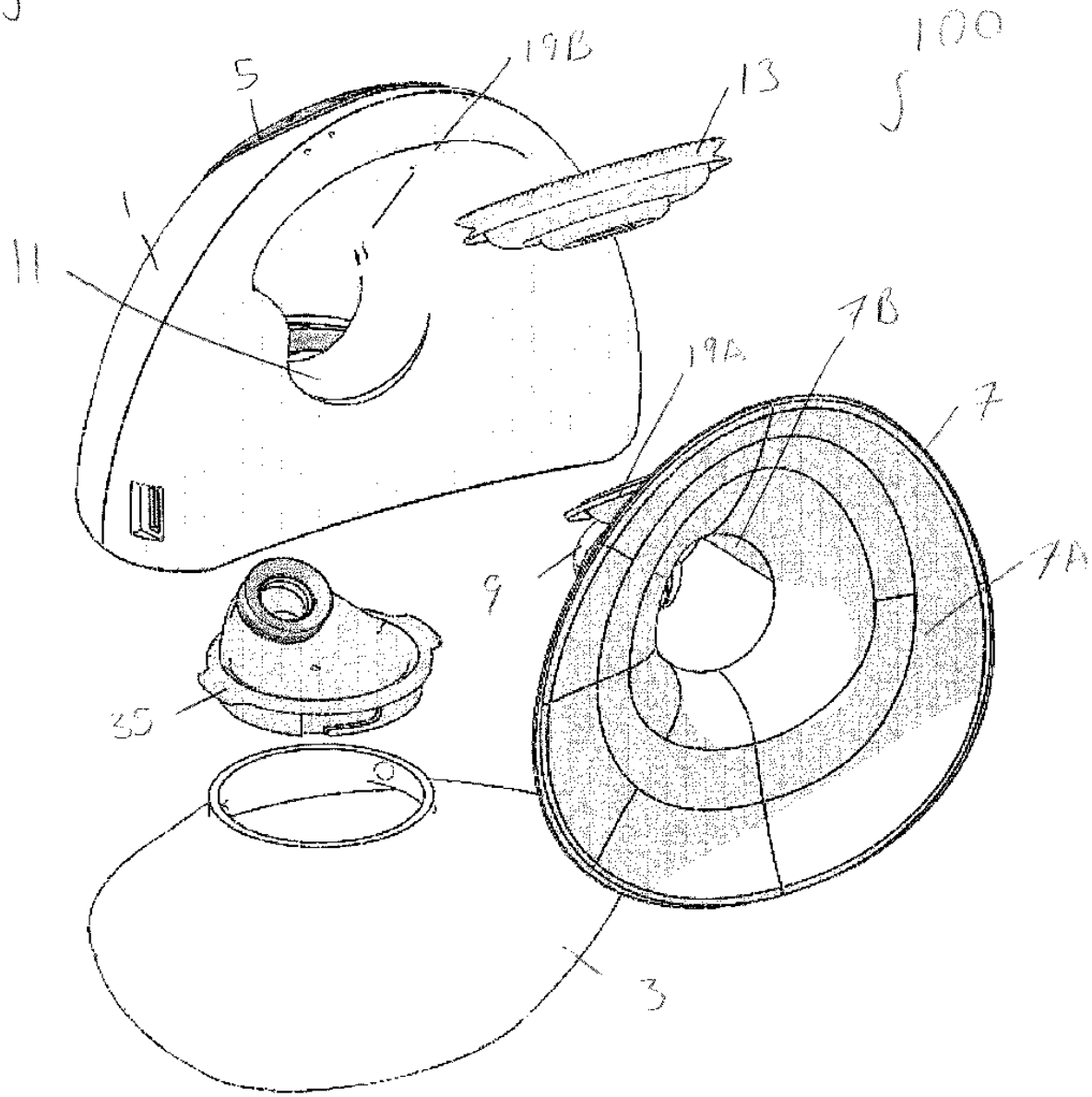
Fig. 5



7397102, JCP2, JCP2

P153992GB00

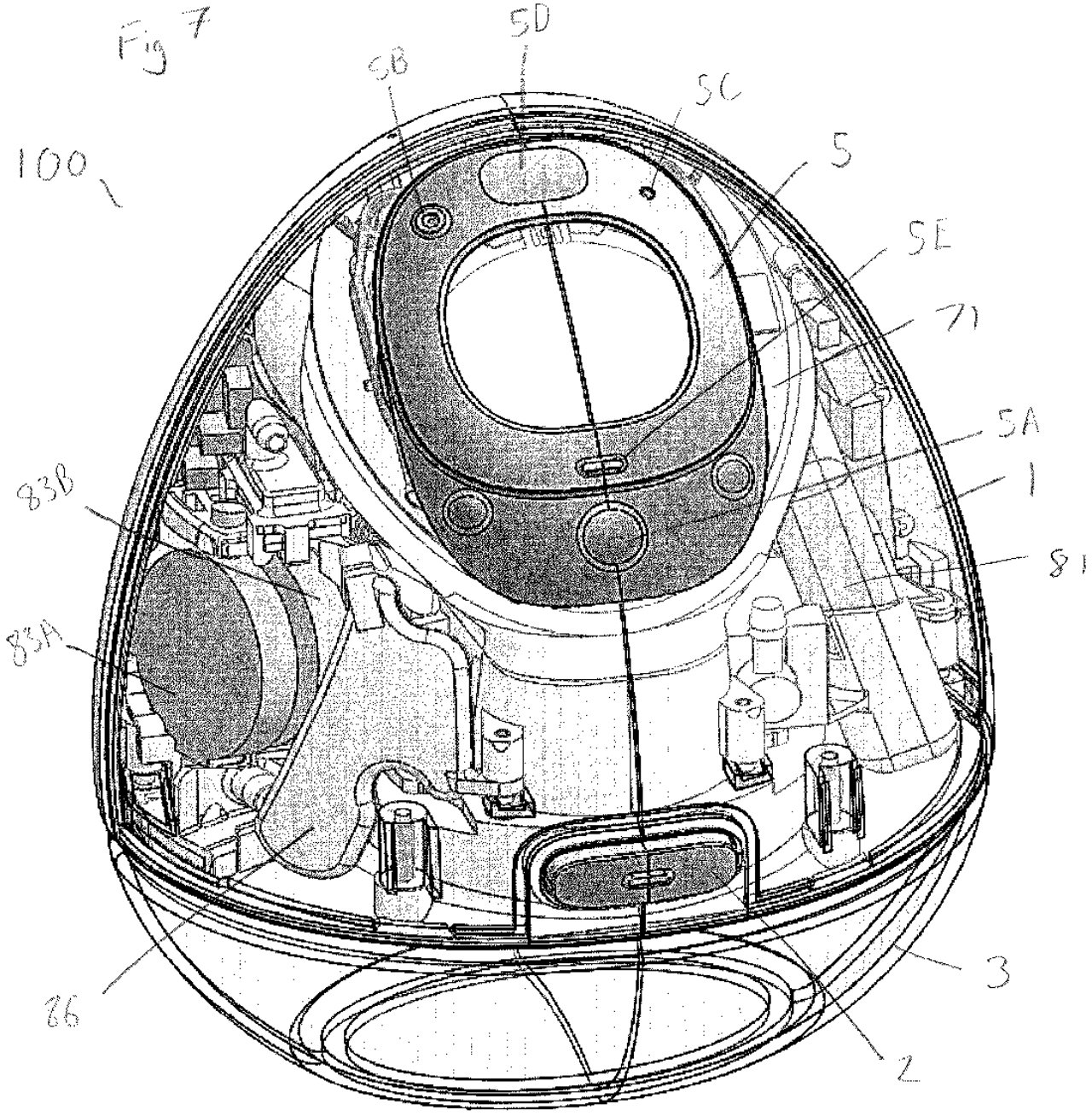
Fig 6



7397102, JCP2; JCP2

P153992GB00

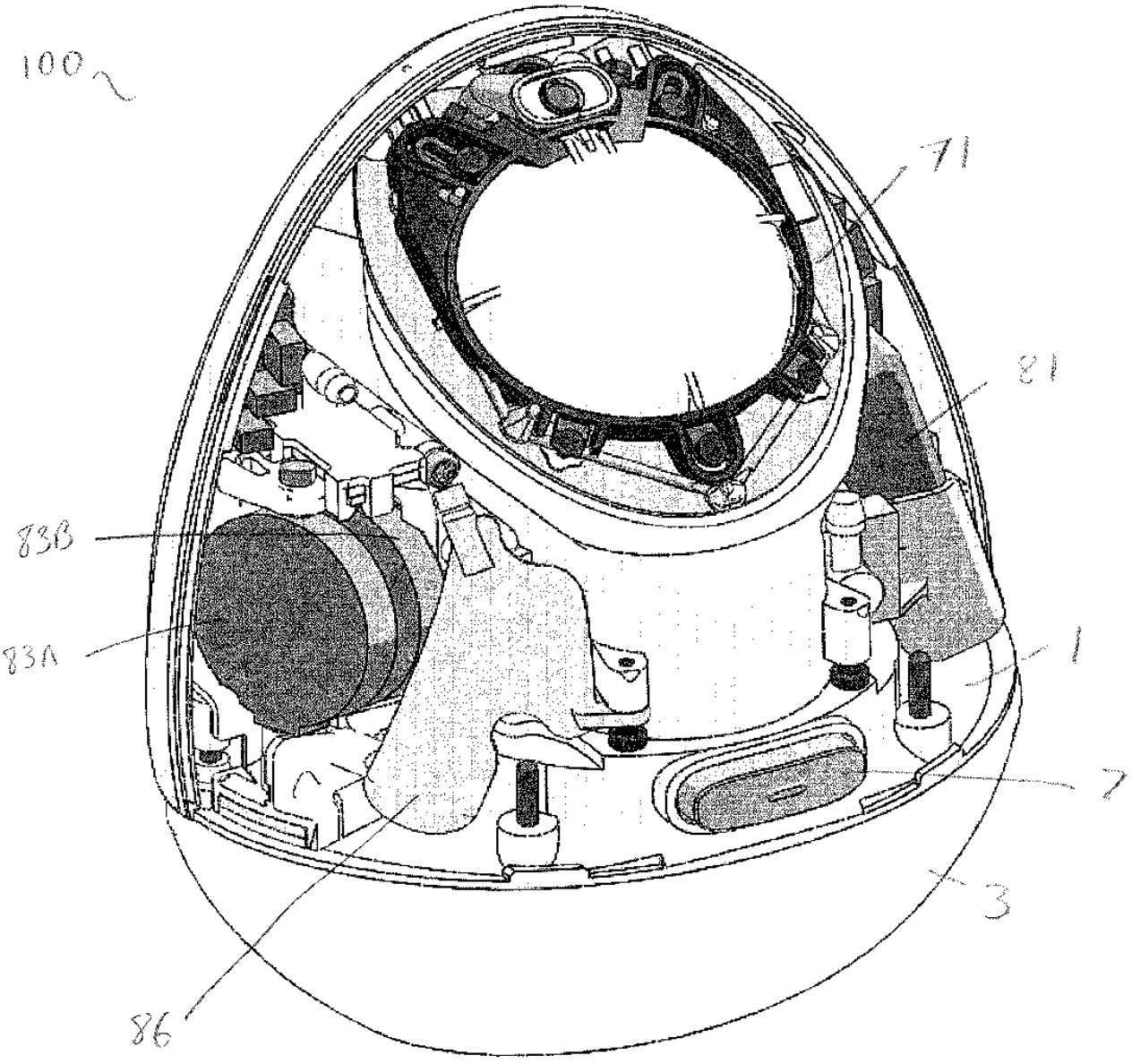
Fig 7



7397102; JCP2; JCP2

P153992GB00

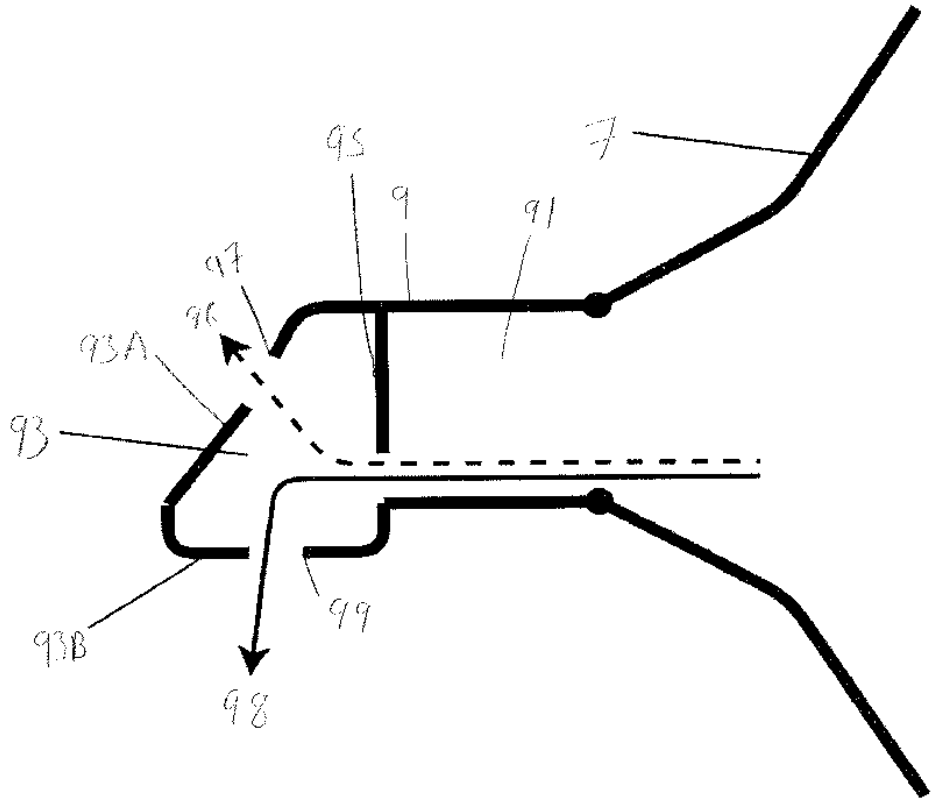
Fig 8



7397102; JCP2. JCP2

P153992GB00

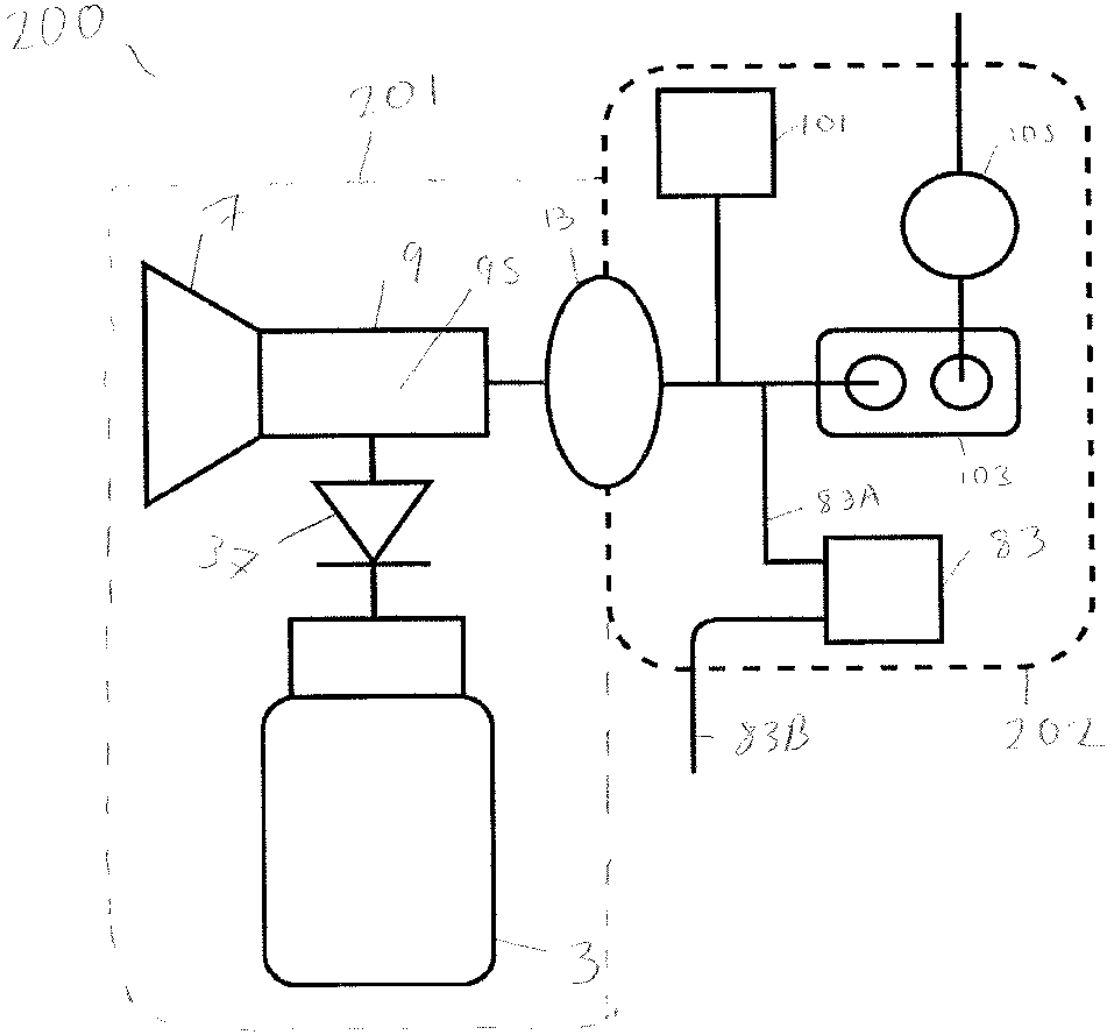
Fig 9



7397102; JCP2; JCP2

P153992GB00

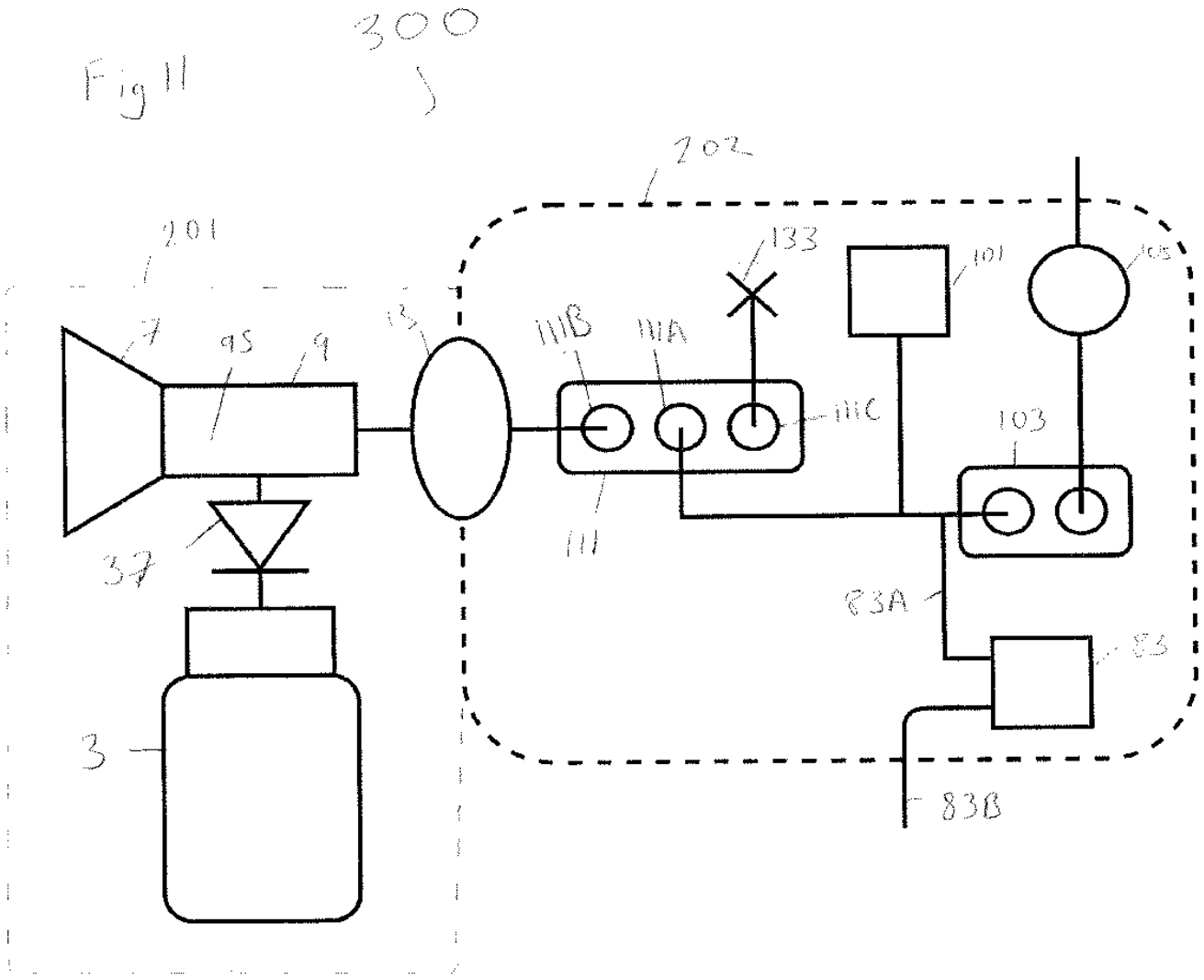
Fig 10



7397102; JCP2; JCP2

P153992GB00

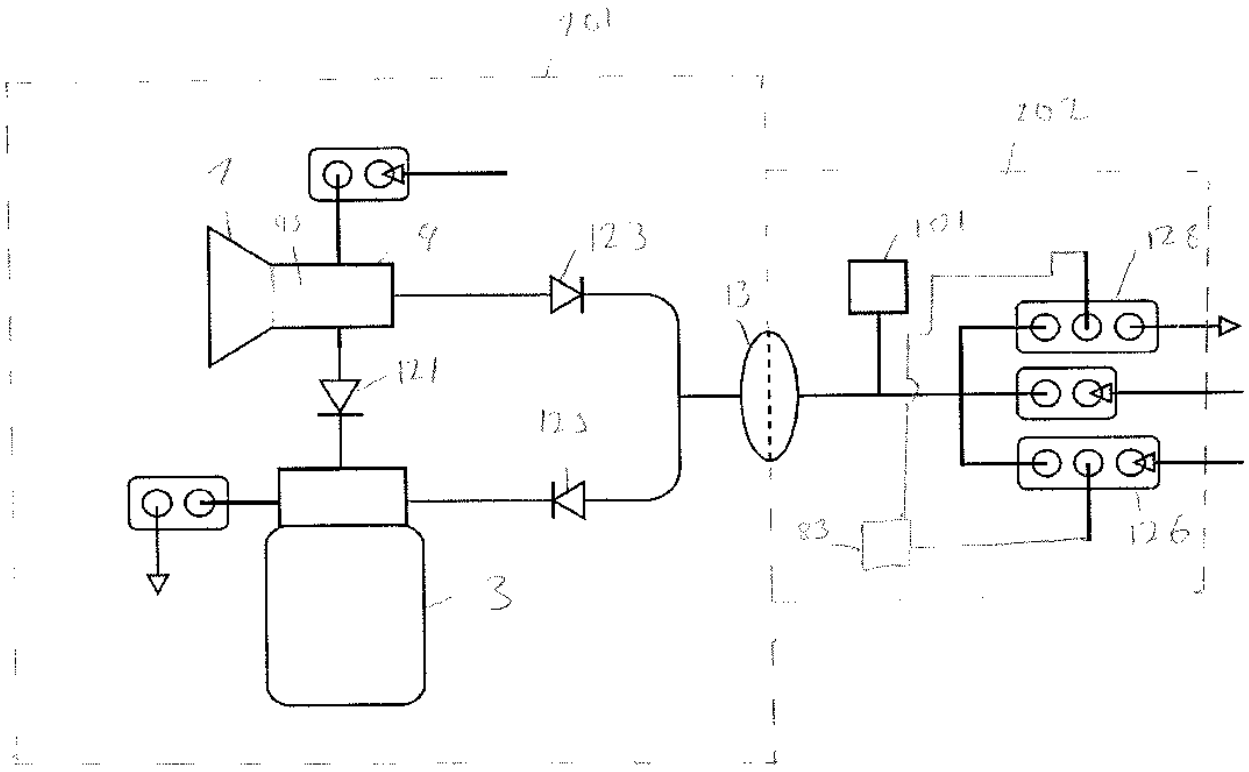
Fig 11



7397102; JCP2; JCP2

P153992GB00

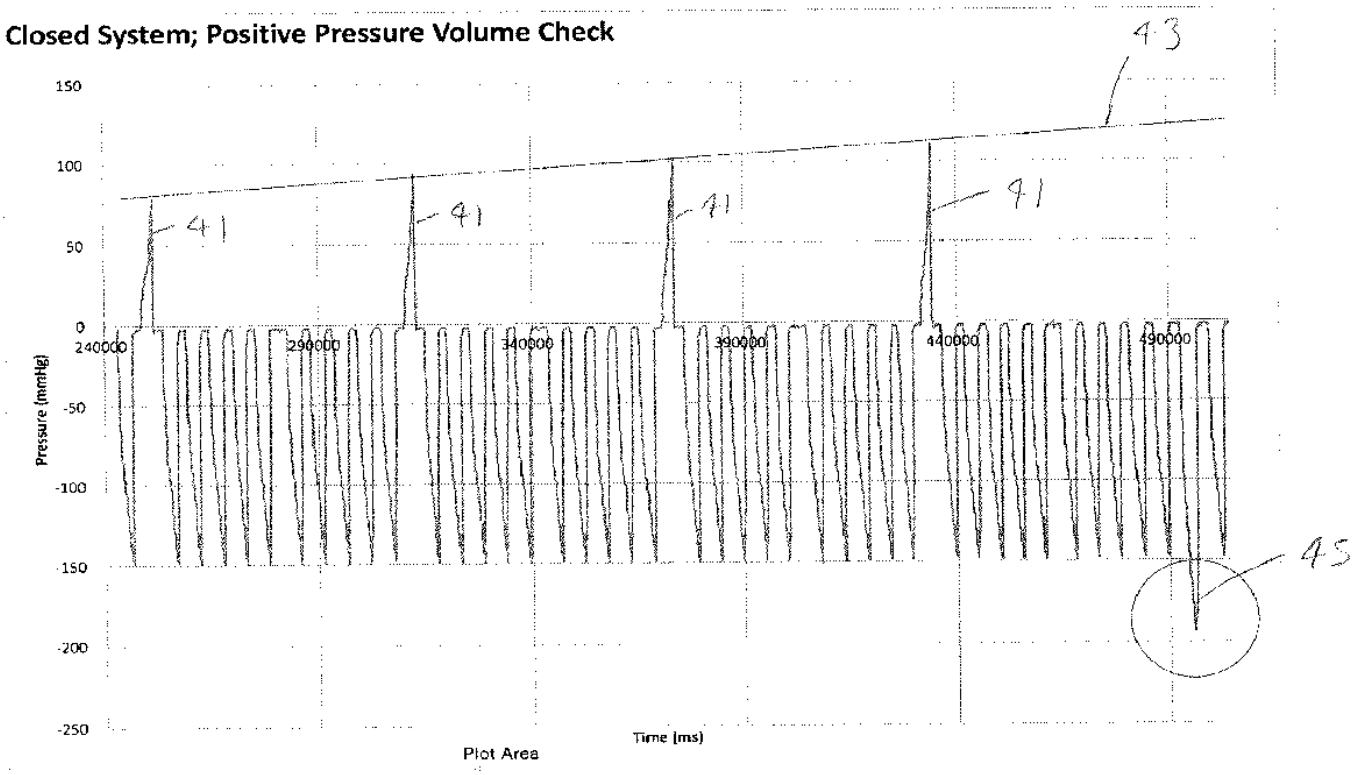
Fig 12



7397102; JCP2; JCP2

P153992GB00

Fig 13



7397102. JCP2; JCP2

Digital Access Service
(DAS)

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

CERTIFICATE OF AVAILABILITY OF A CERTIFIED PATENT DOCUMENT IN A DIGITAL LIBRARY

The International Bureau certifies that a copy of the patent application indicated below has been available to the WIPO Digital Access Service since the date of availability indicated, and that the patent application has been available to the indicated Office(s) as of the date specified following the relevant Office code:

Document details: Country/Office: GB
Filing date: 15 Jun 2017 (15.06.2017)
Application number: 1709564.7

Date of availability of document: 27 Jul 2017 (27.07.2017)

The following Offices can retrieve this document by using the access code:
JP, US, SE, NZ, KR, EA, IN, BR, GB, AU, ES, NL, IB, EE, CN, MA, FI, DK

Date of issue of this certificate: 27 Jul 2018 (27.07.2018)

34, chemin des Colombettes
1211 Geneva 20, Switzerland
www.wipo.int

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 GB1709564.7 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

1200242970
1017015613 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 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**
8.	Are you paying the application fee with this form?	**Yes**

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **12**

Claim(s): **3**

Abstract: **n/a**

Drawing(s): **4**

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

Warning
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.

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.

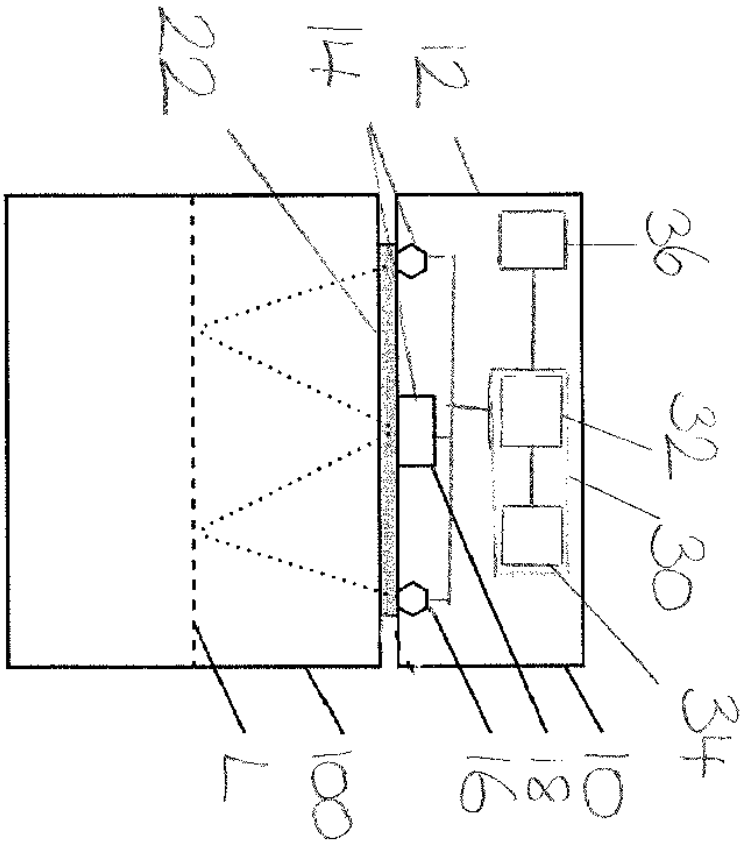


FIG 1A

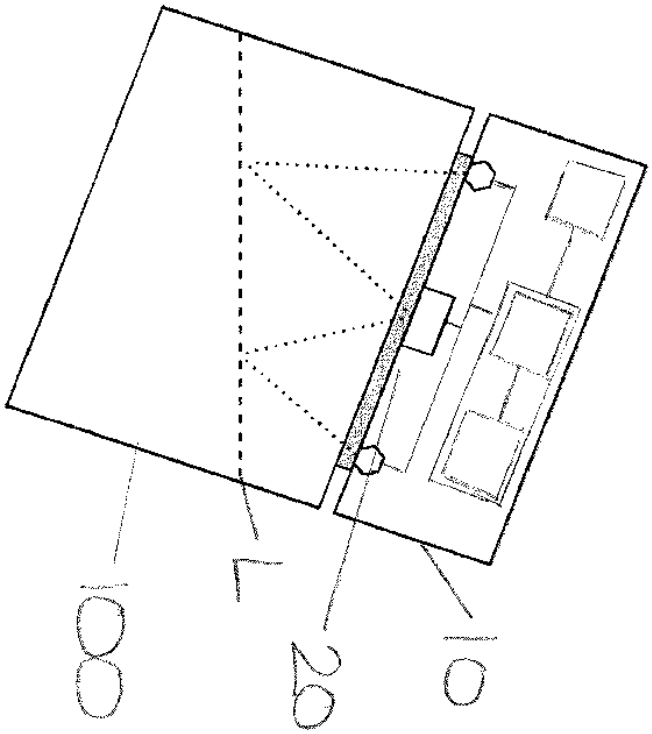


FIG 1B

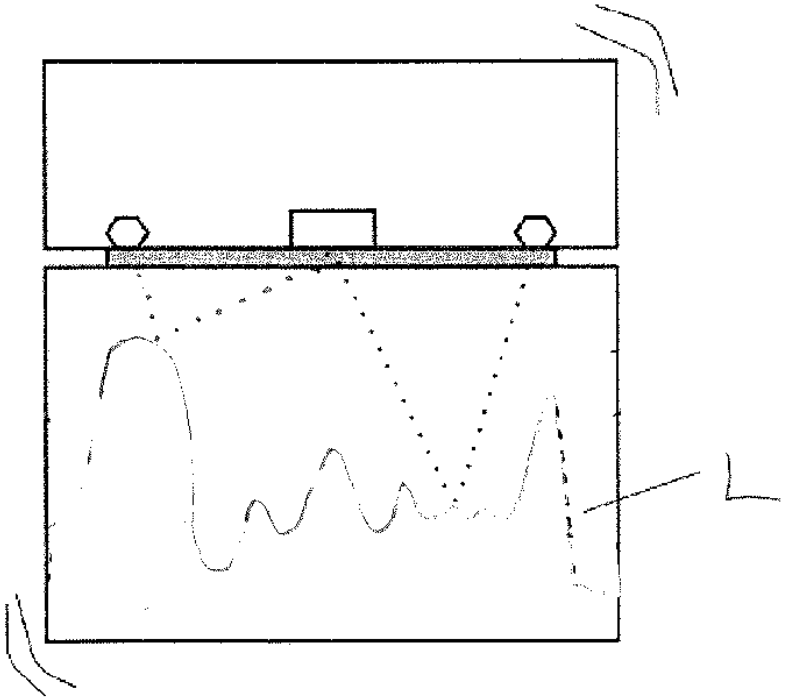


FIG 2

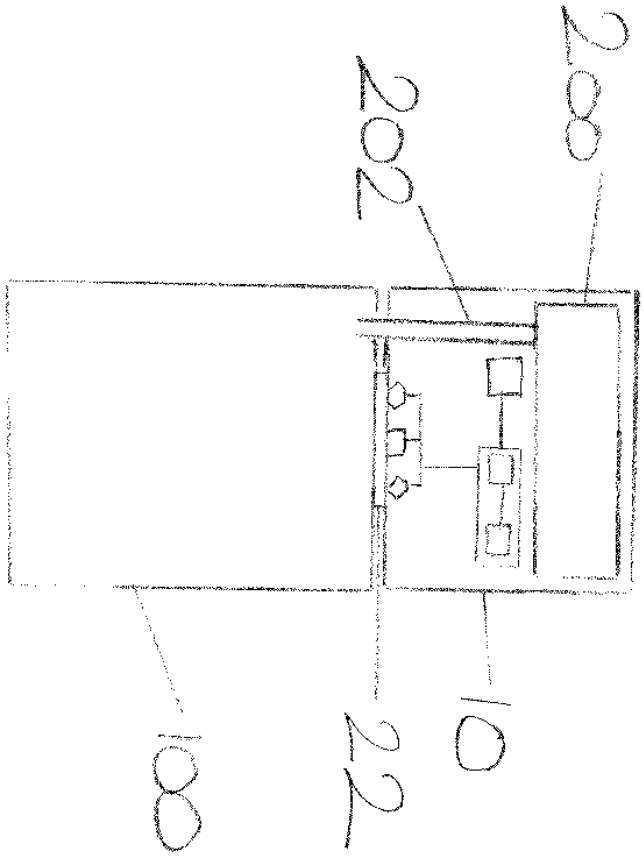


FIG 3

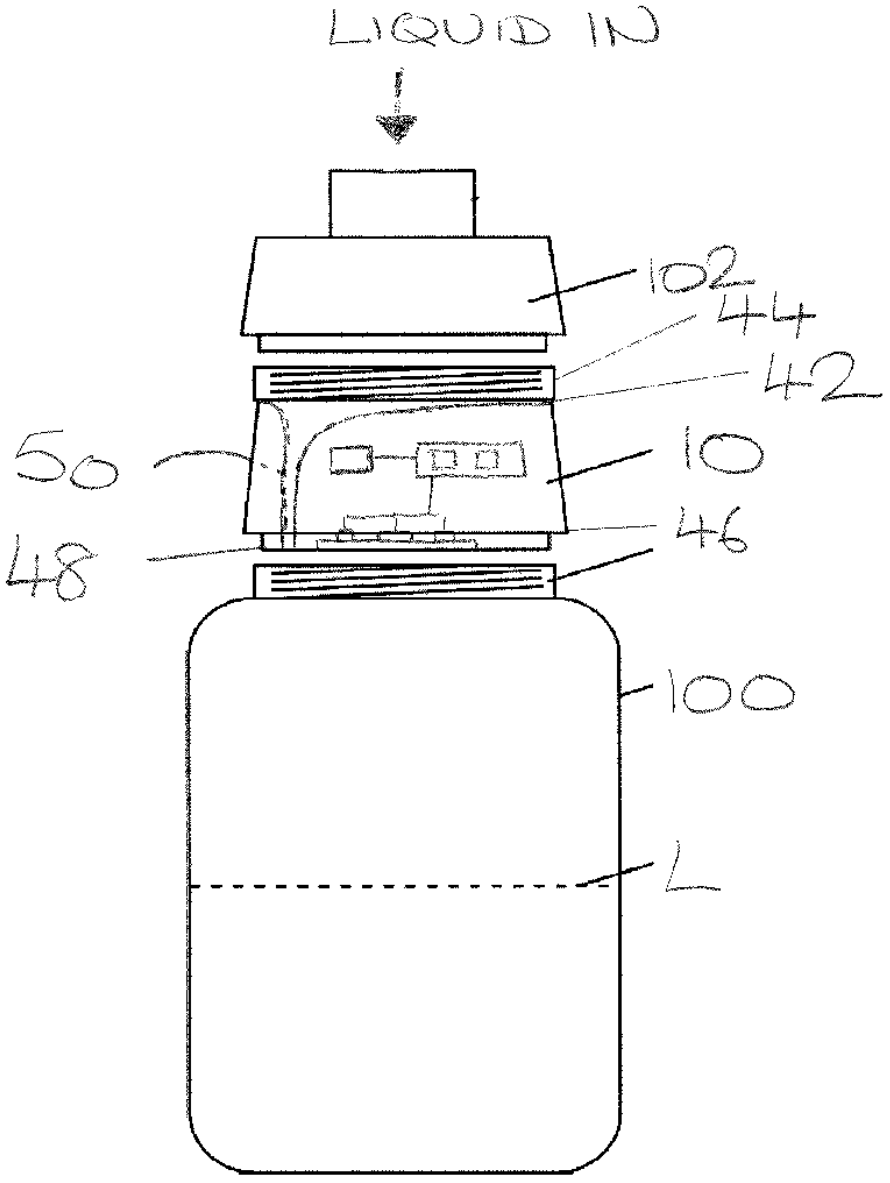


FIG 4.

Digital Access Service
(DAS)

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

CERTIFICATE OF AVAILABILITY OF A CERTIFIED PATENT DOCUMENT IN A DIGITAL LIBRARY

The International Bureau certifies that a copy of the patent application indicated below has been available to the WIPO Digital Access Service since the date of availability indicated, and that the patent application has been available to the indicated Office(s) as of the date specified following the relevant Office code:

Document details: Country/Office: GB
Filing date: 15 Jun 2017 (15.06.2017)
Application number: 1709561.3

Date of availability of document: 27 Jul 2017 (27.07.2017)

The following Offices can retrieve this document by using the access code:
JP, US, SE, NZ, KR, EA, IN, BR, GB, AU, ES, NL, IB, EE, CN, MA, FI, DK

Date of issue of this certificate: 27 Jul 2018 (27.07.2018)

34, chemin des Colombettes
1211 Geneva 20, Switzerland
www.wipo.int

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 GB1709561.3 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

1200242967
1017015610 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 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**
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**

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **9**

Claim(s): **3**

Abstract: **n/a**

Drawing(s): **7**

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

Warning
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.

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.

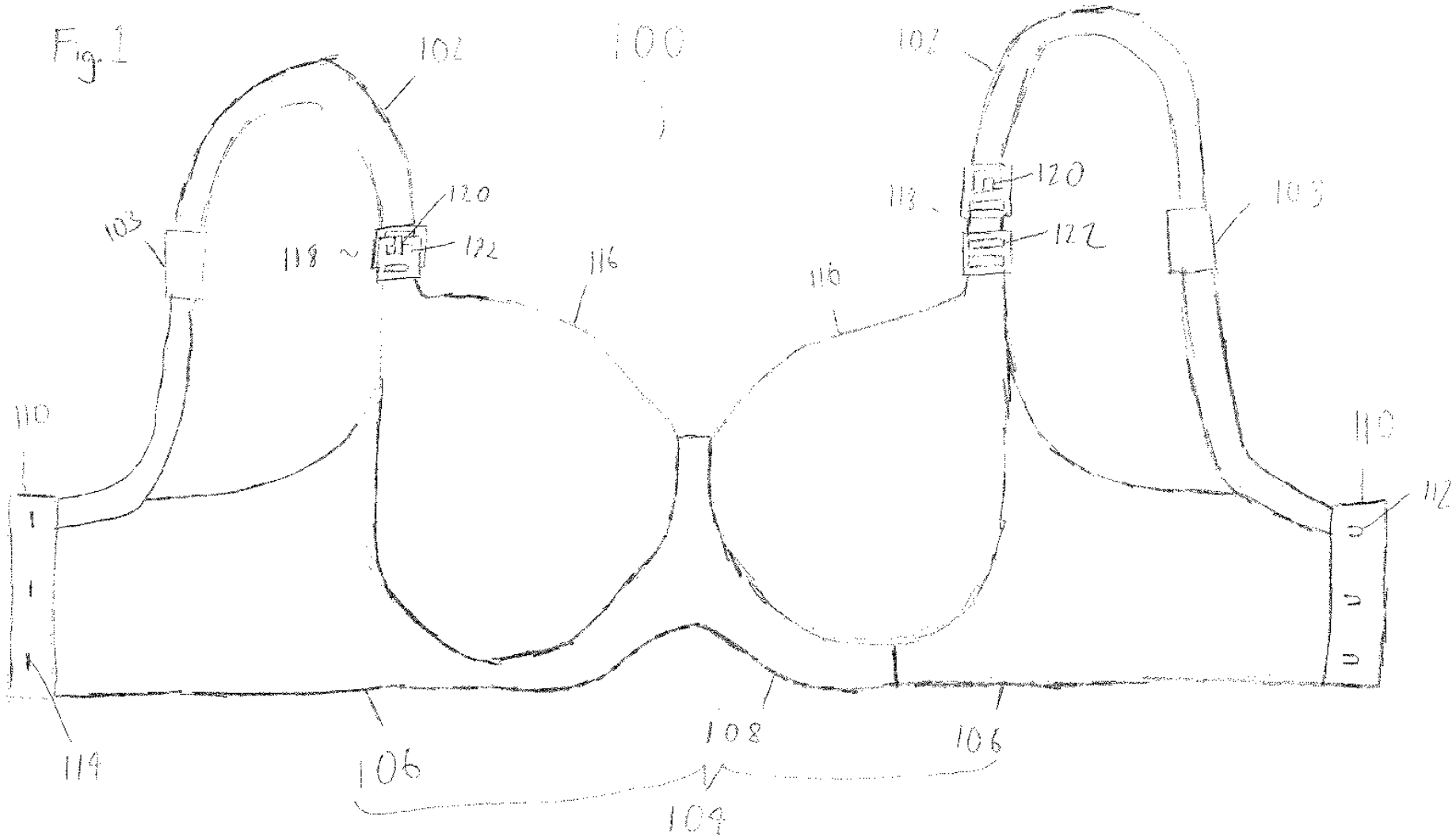
17. The method of claim 15 or 16, further comprising the steps of:

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



708

PRIOR ART

Fig. 2A

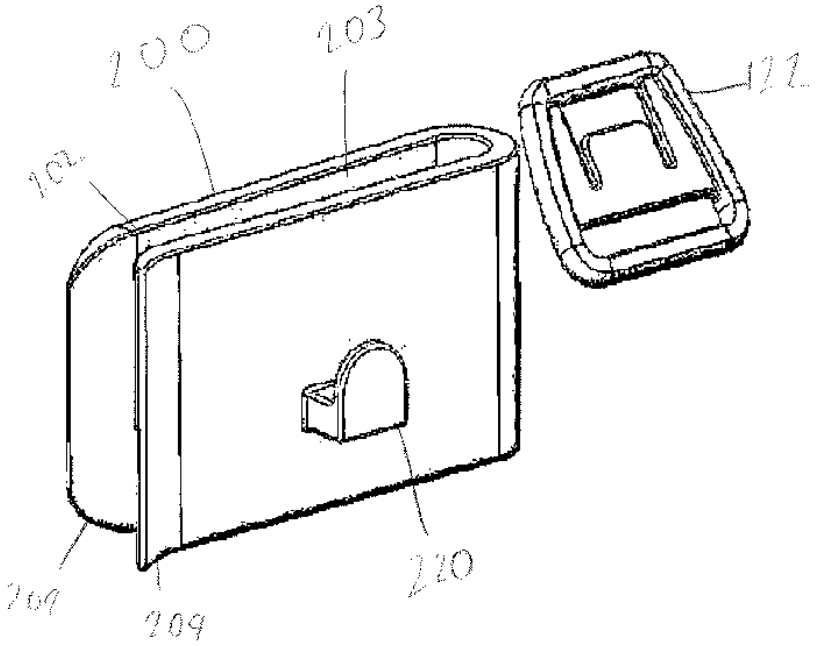
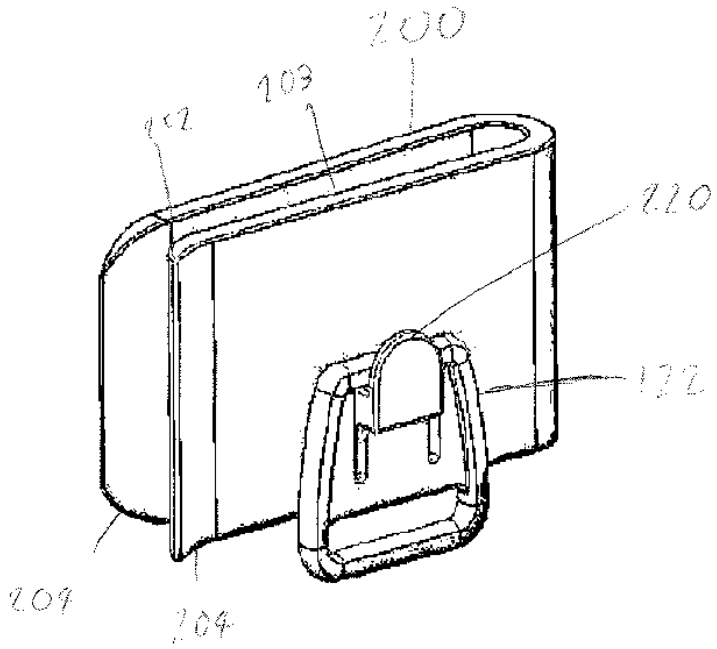


Fig 2B



709

Fig. 3A

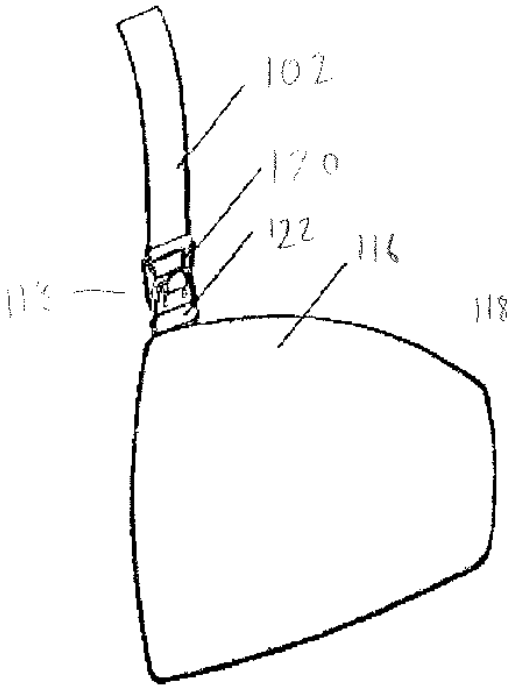


Fig. 3B

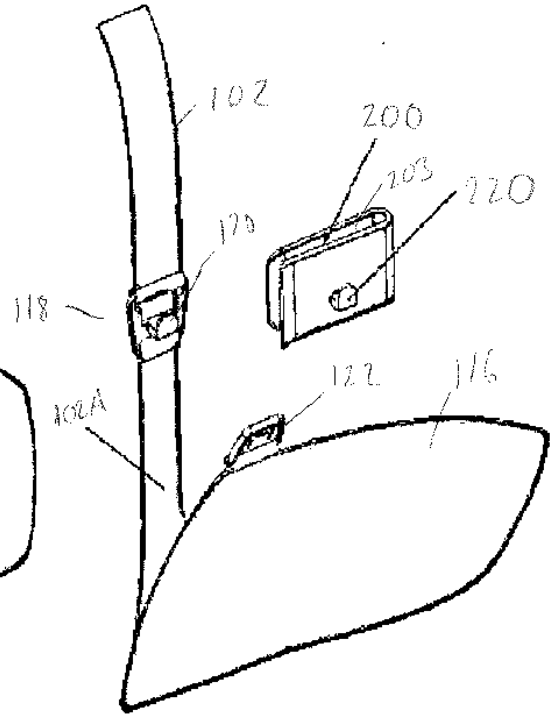
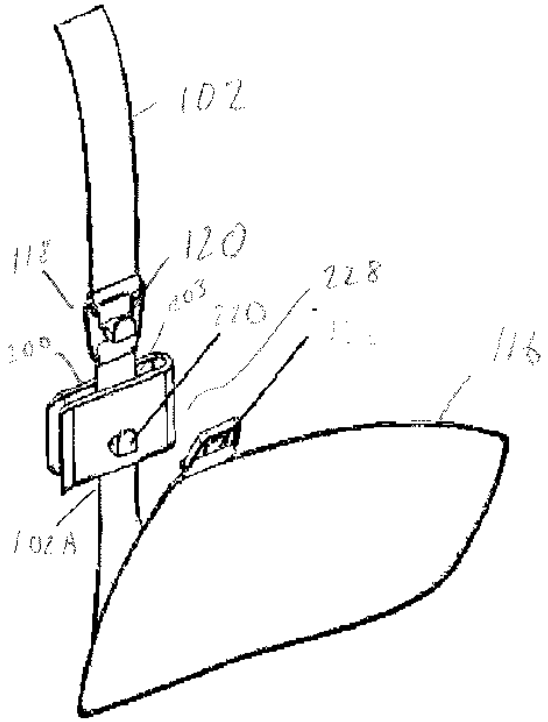


Fig. 3C



710

Fig. 4A

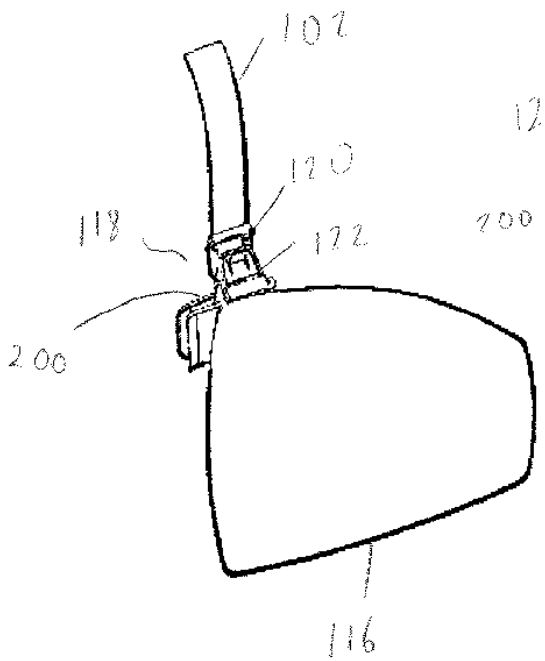
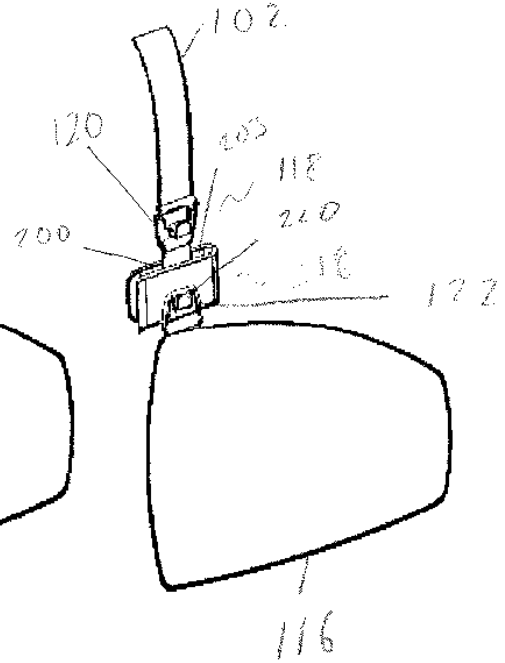
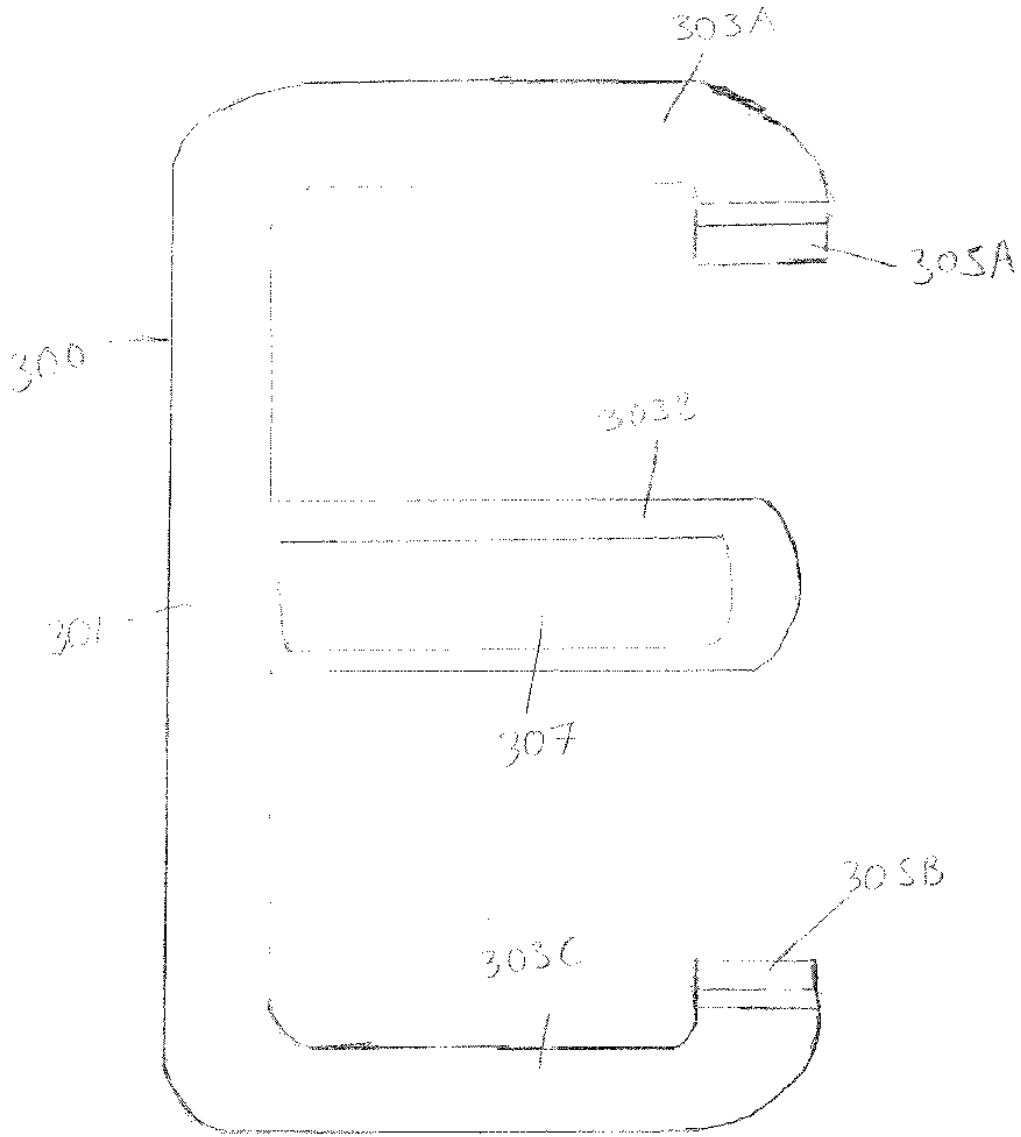


Fig. 4B



711

Fig. 5



712

Fig 6

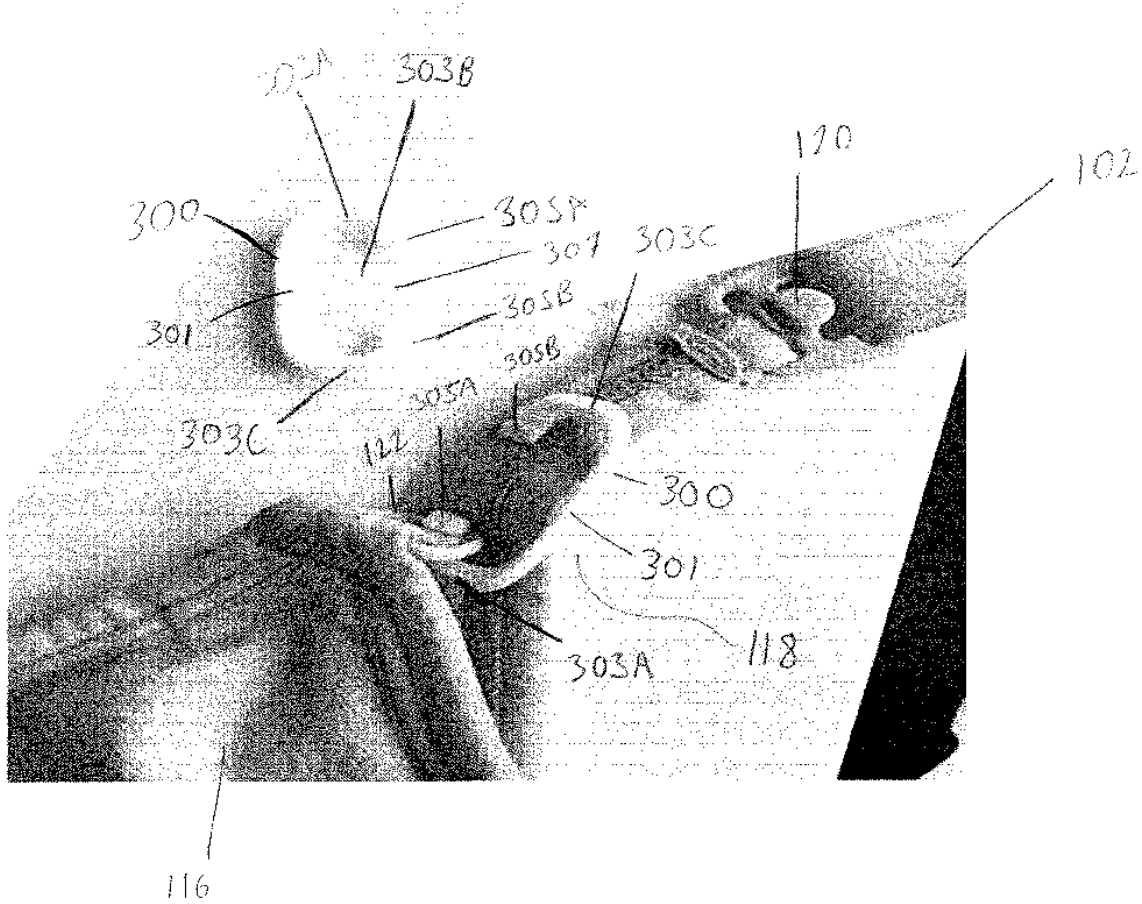
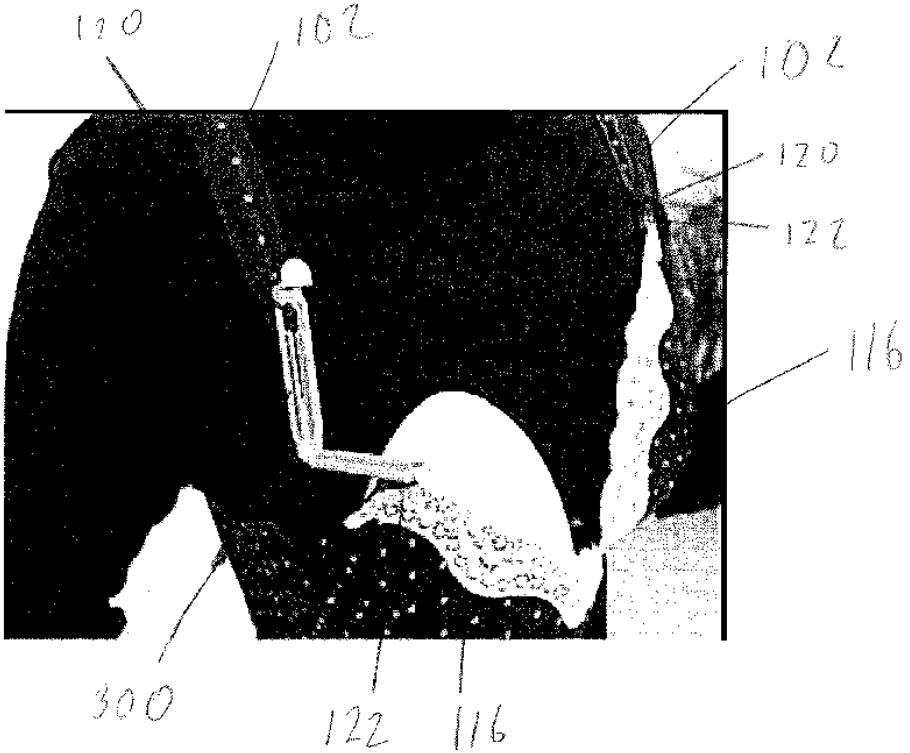

303B
300
305A
301
303C
170
102
305B
301
303C
305A
305B
122
300
301
118
303A
116

Fig 7



714

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	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), (l), 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.

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	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

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

FILING RECEIPT

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.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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.

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.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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
	Jonathan		O'TOOLE	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country [i]	GB

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Adam		ROLLO	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country [i]	GB

Inventor 3 Remove

Legal Name

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited		
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

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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).

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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
1709564.7	GB	2017-06-15	B3B5
1709566.2	GB	2017-06-15	D6F6
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.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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.

Remove

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	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

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

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

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.**

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 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.

A portion of the disclosure of this patent document contains material, which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

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/Ir 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.

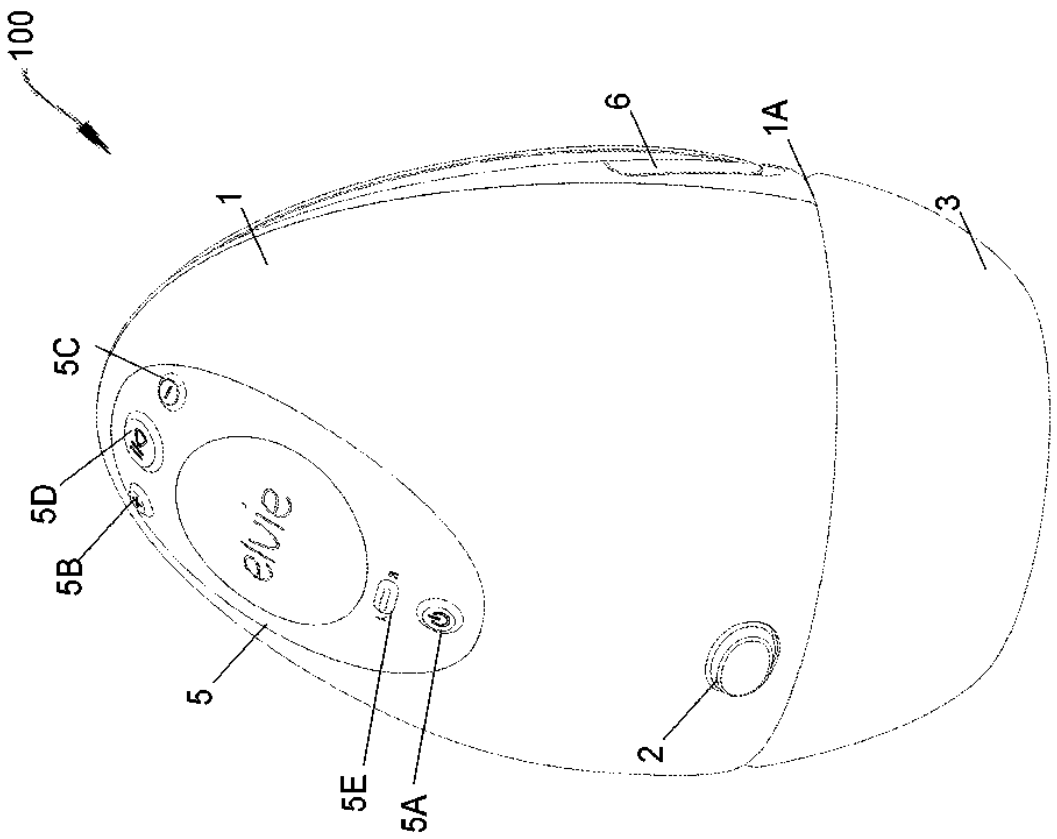


FIGURE 1

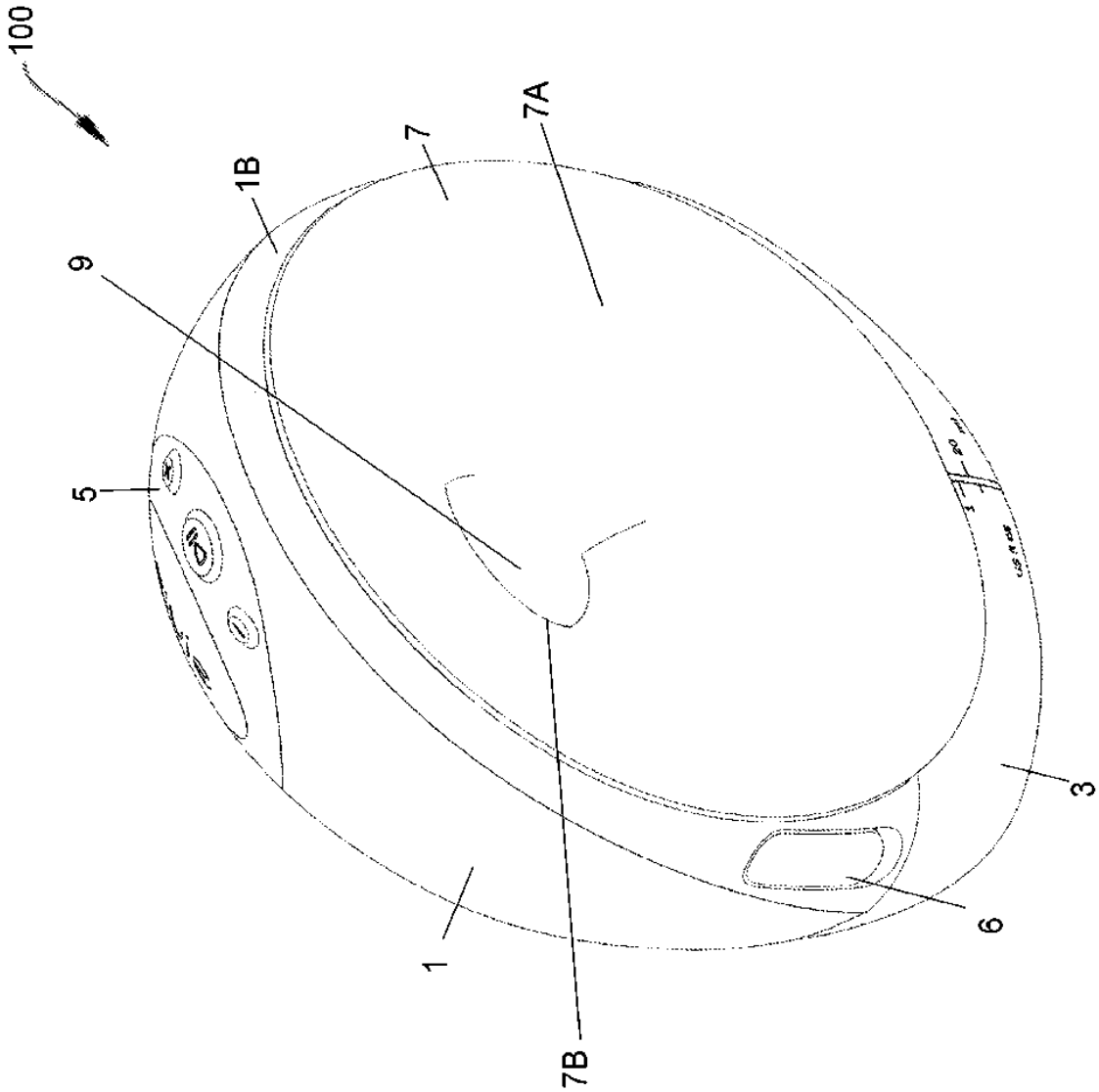


FIGURE 2

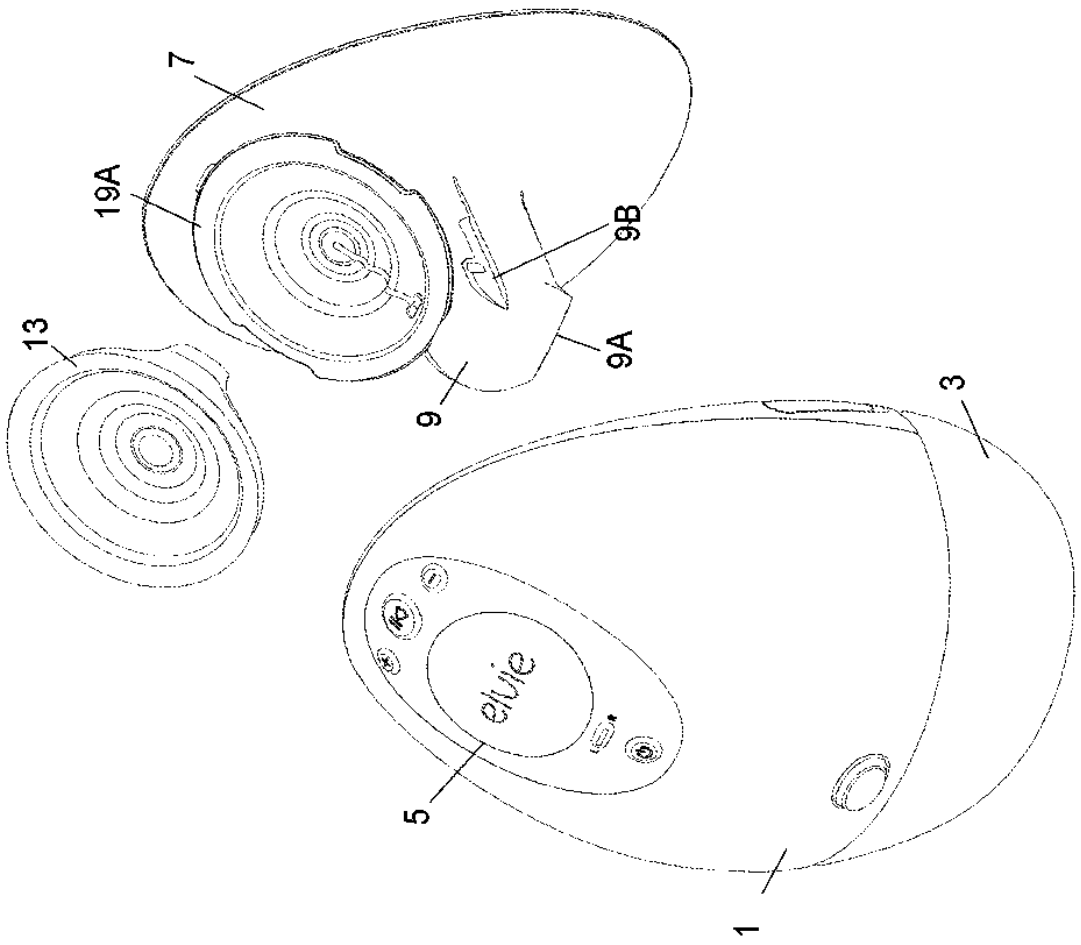


FIGURE 3

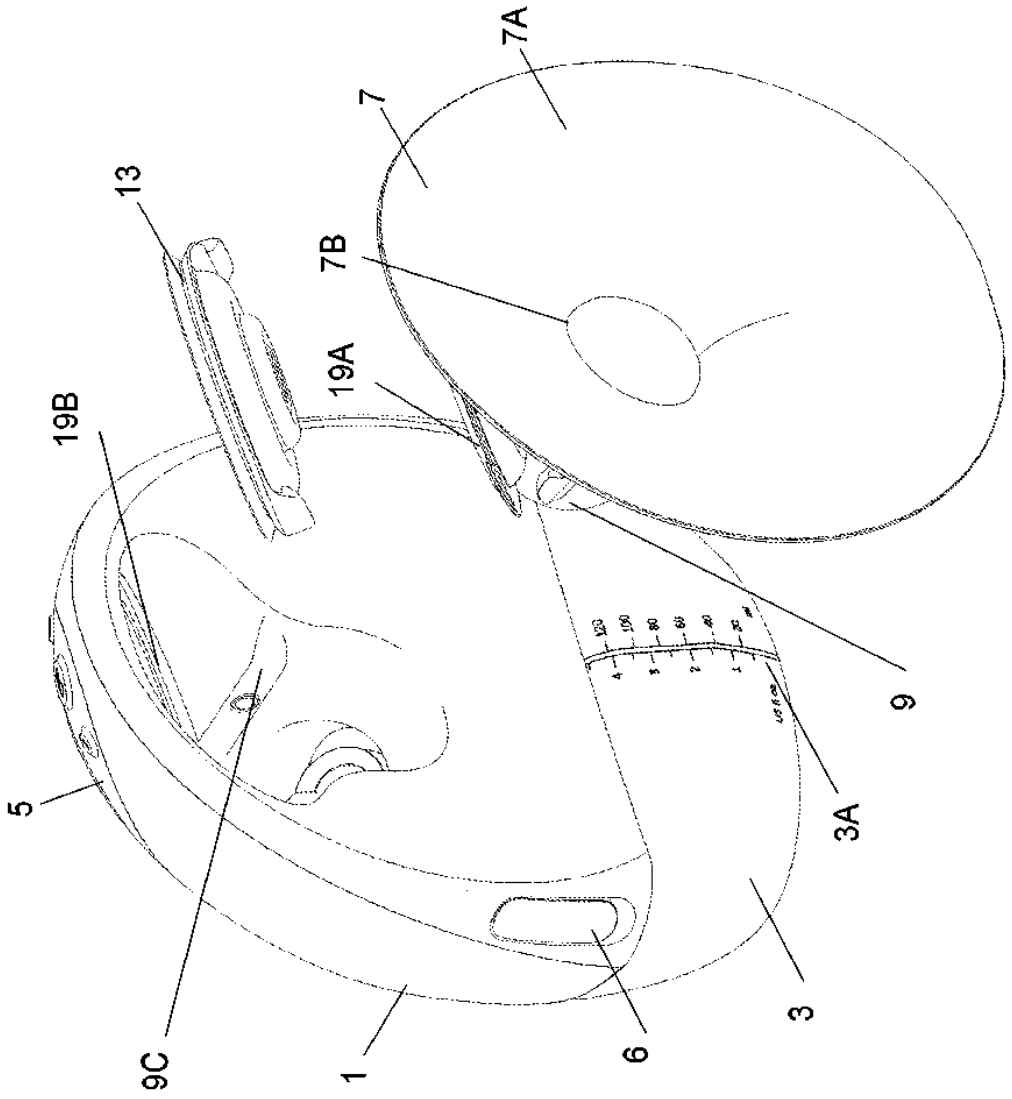


FIGURE 4

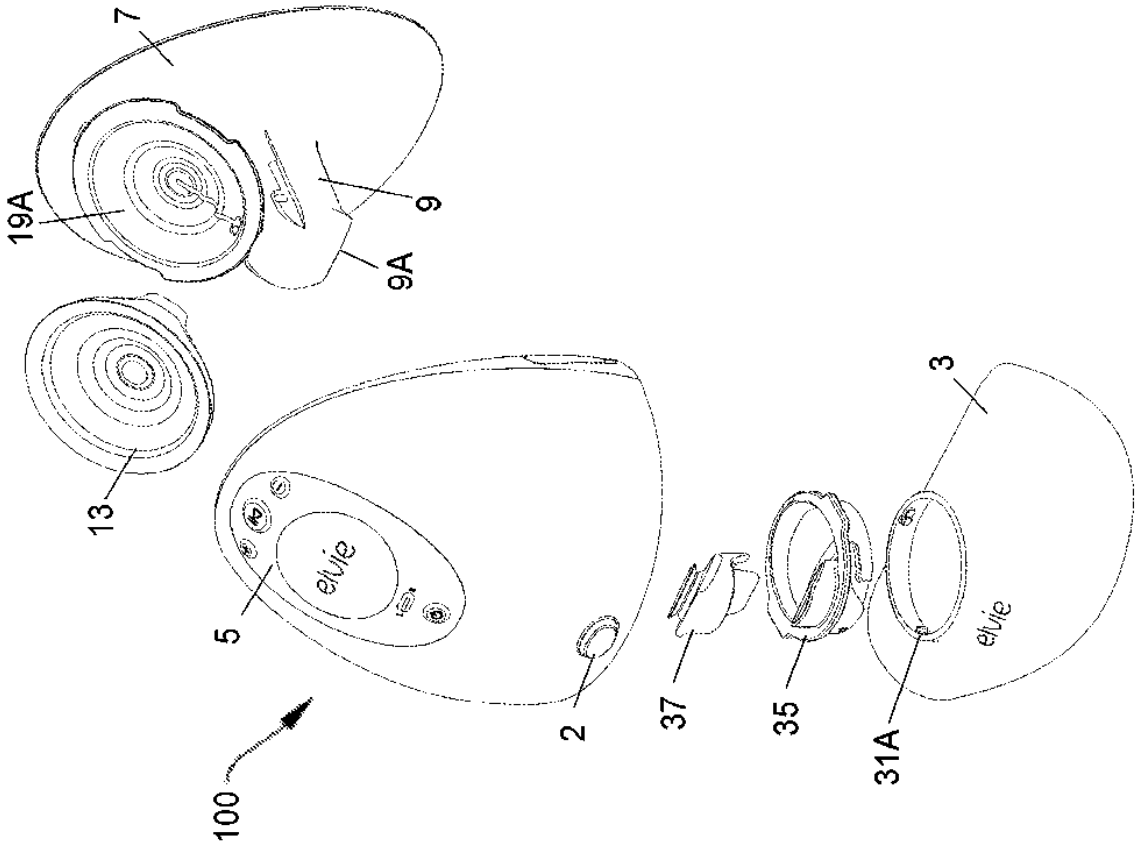


FIGURE 5

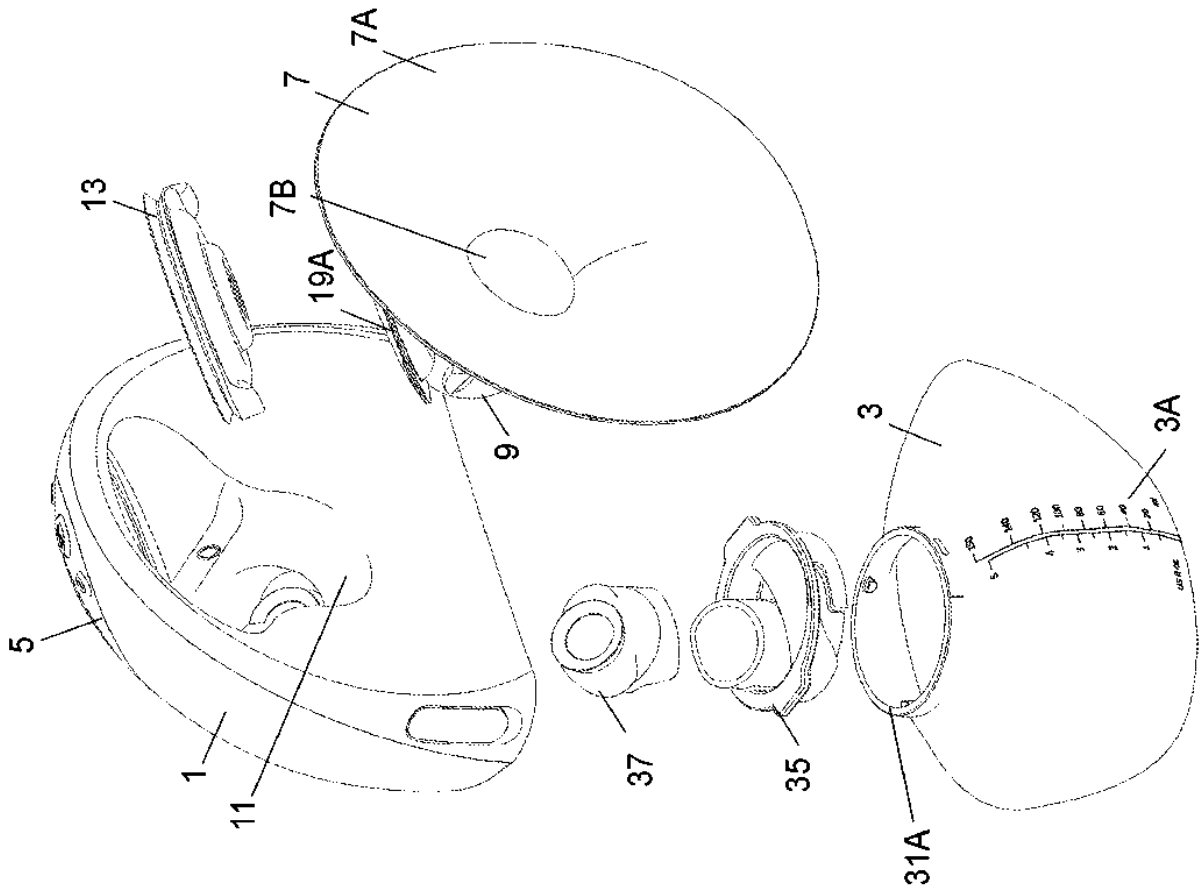


FIGURE 6

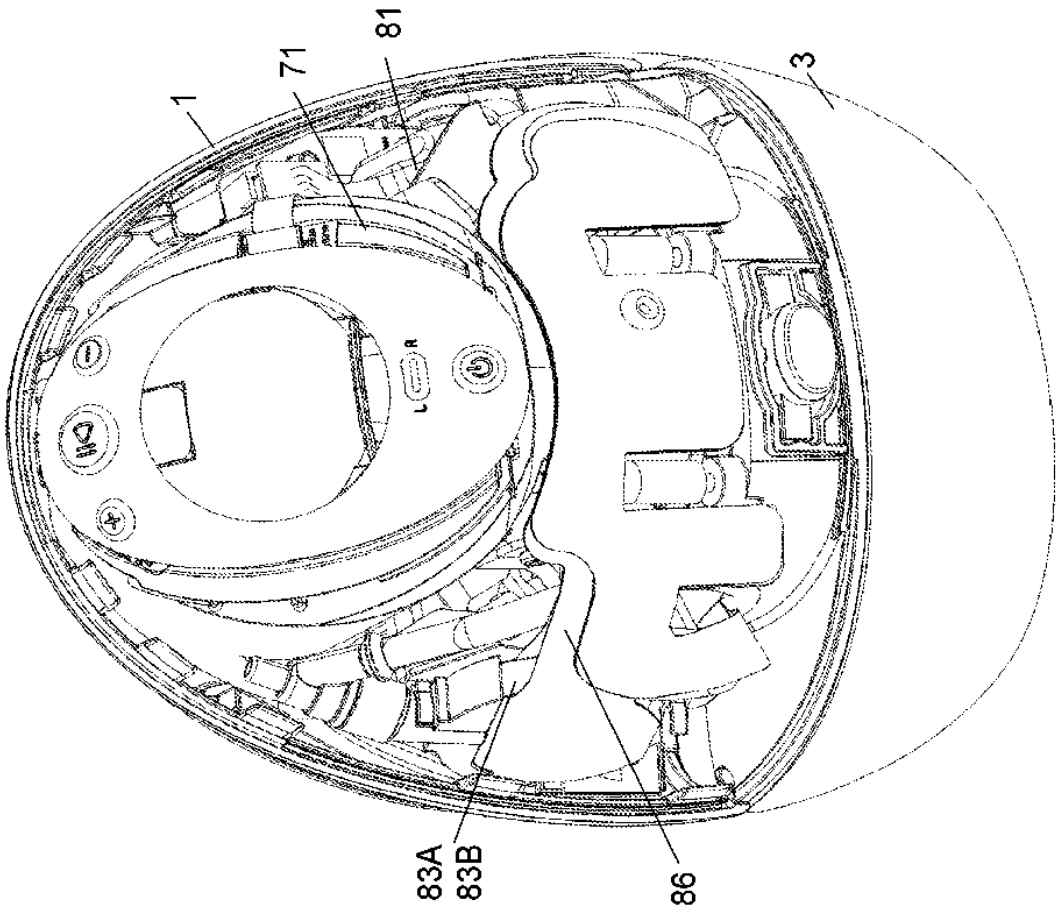


FIGURE 7

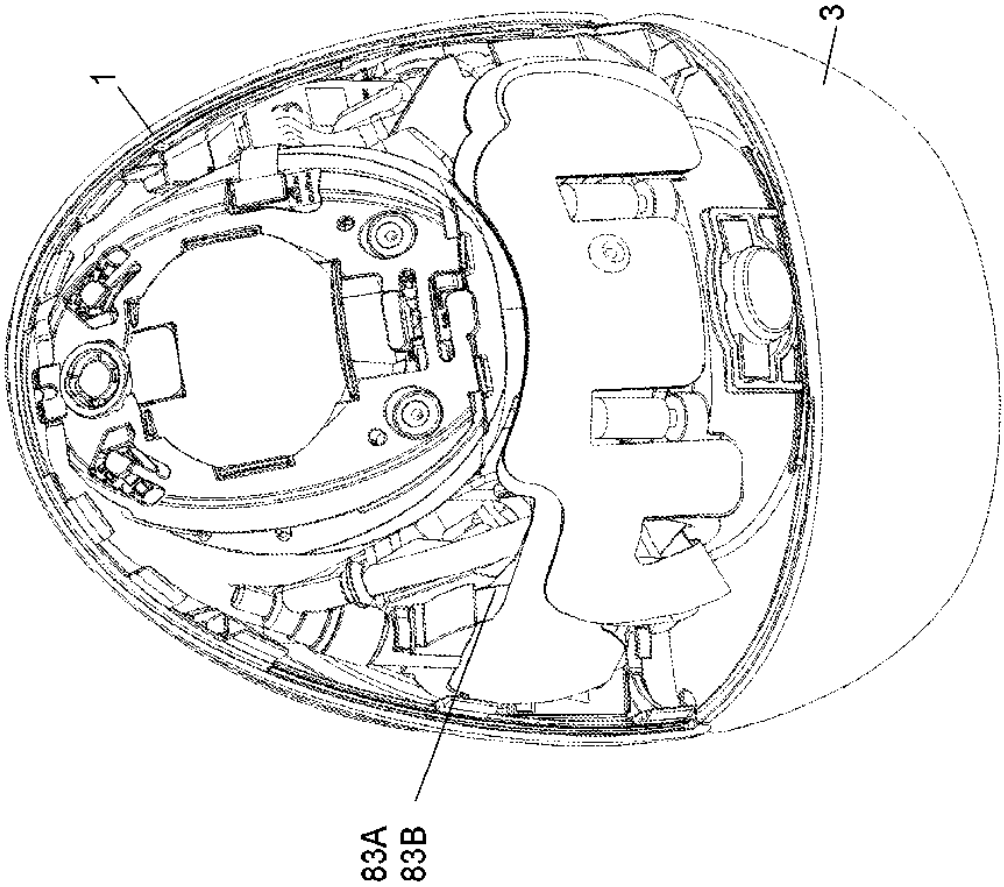


FIGURE 8

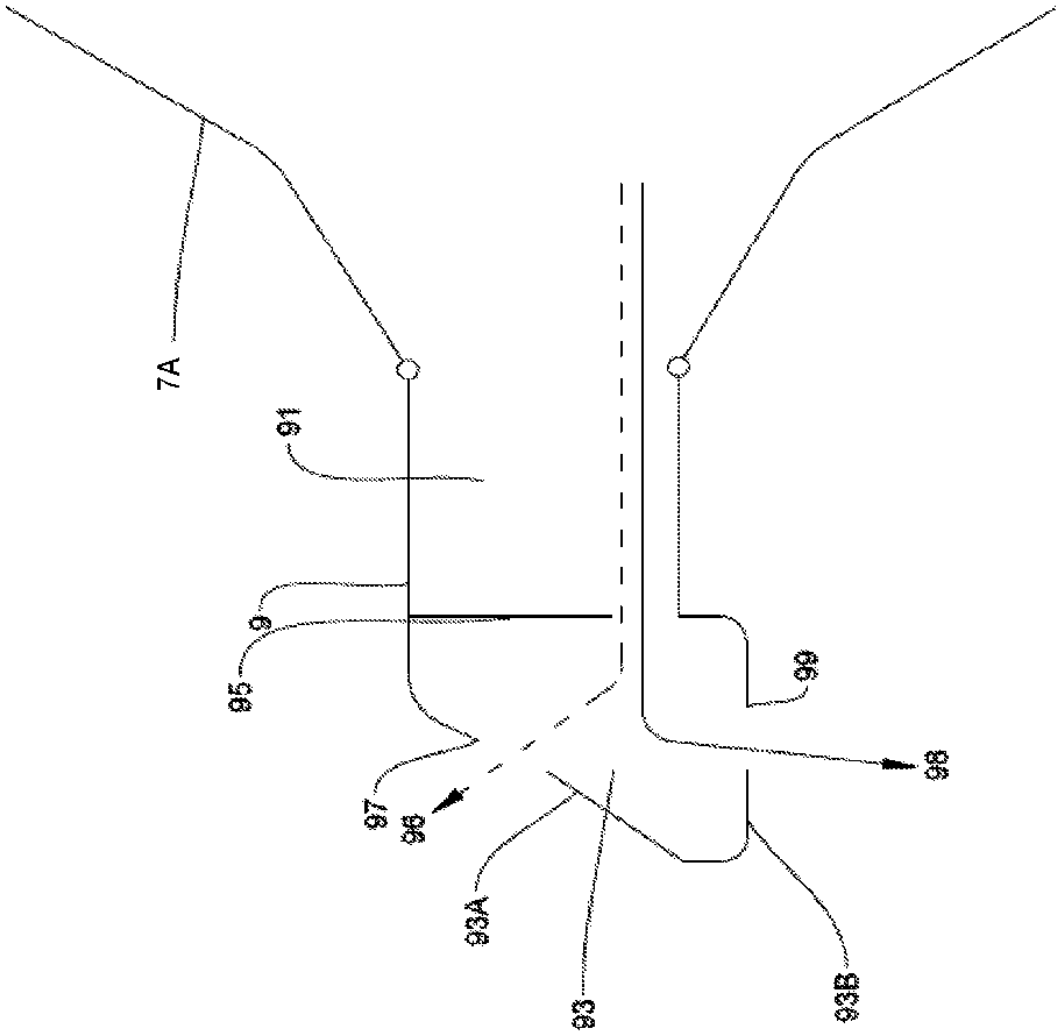


FIGURE 9

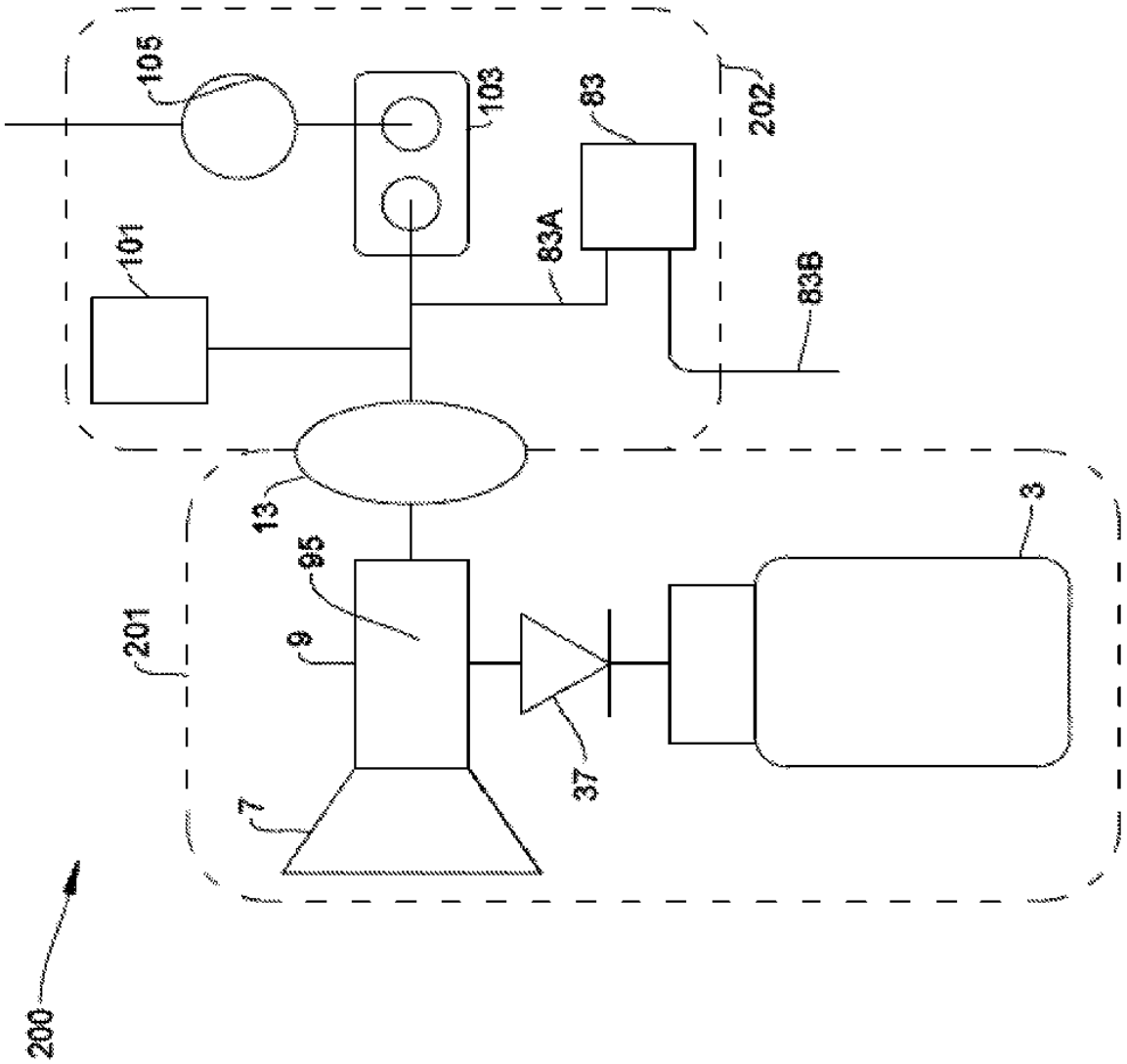


FIGURE 10

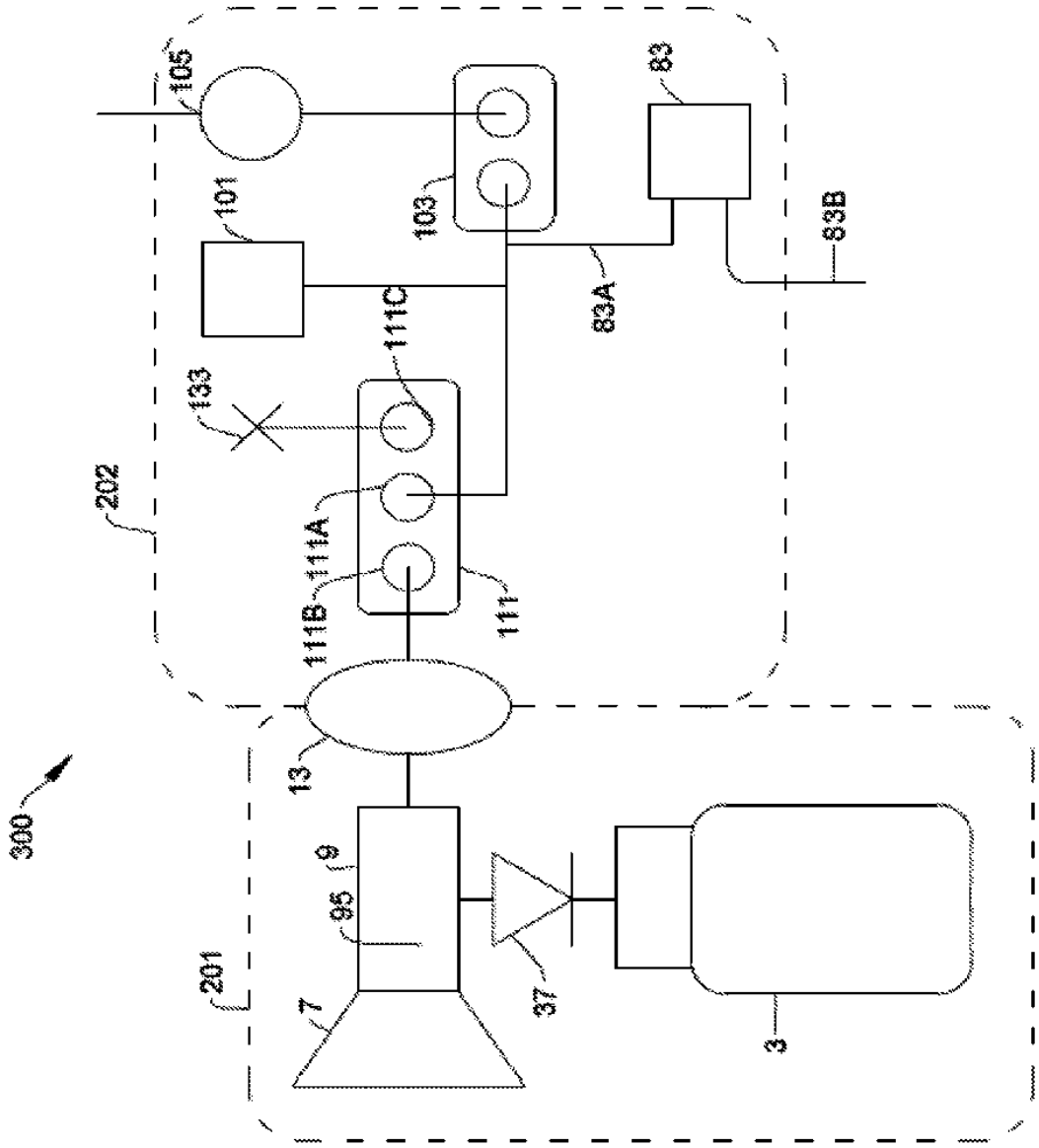

300
202
201
105
101
103
83
83B
83A
111C
133
111A
111B
111
13
9
95
7
37
3

FIGURE 11

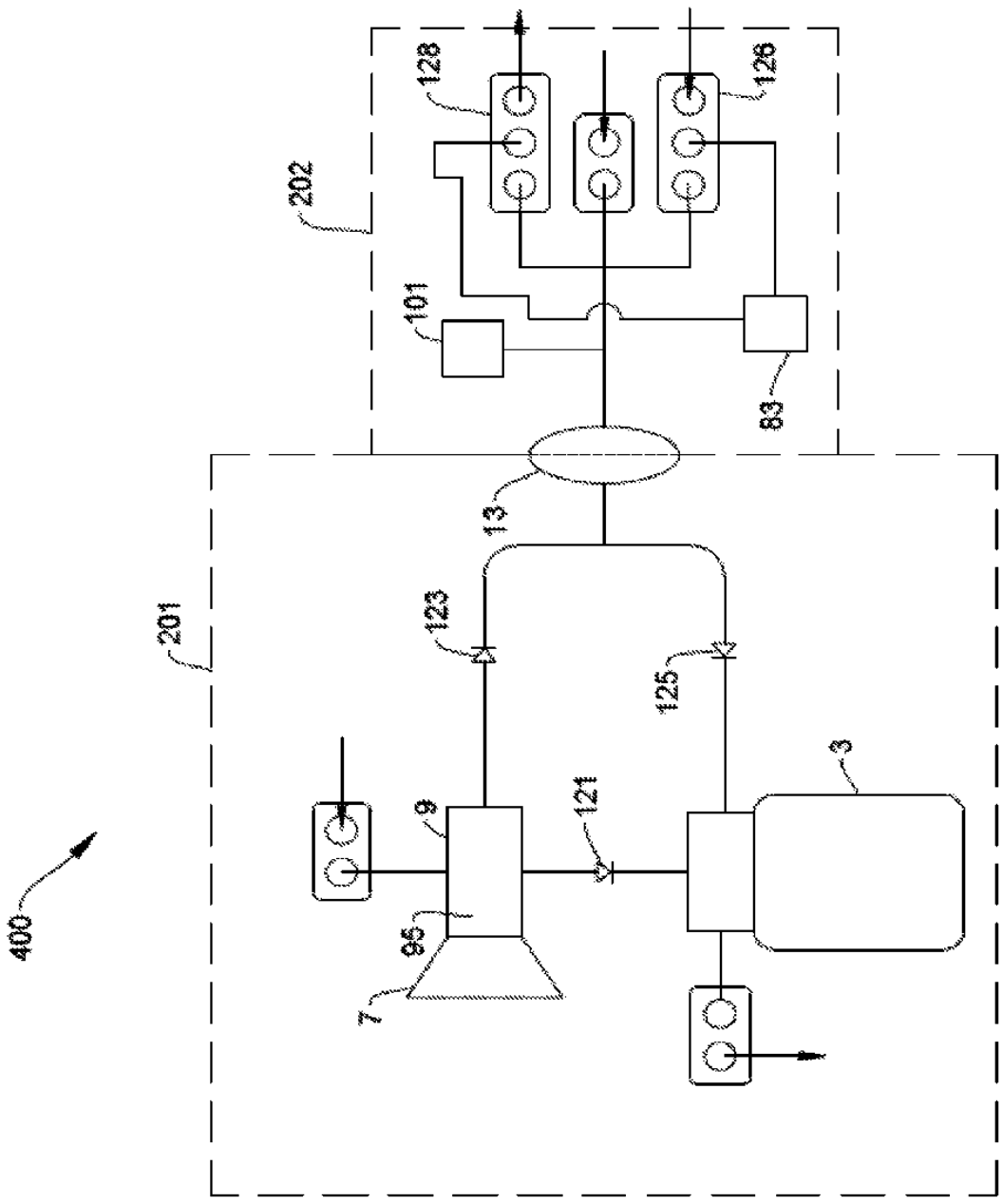


FIGURE 12

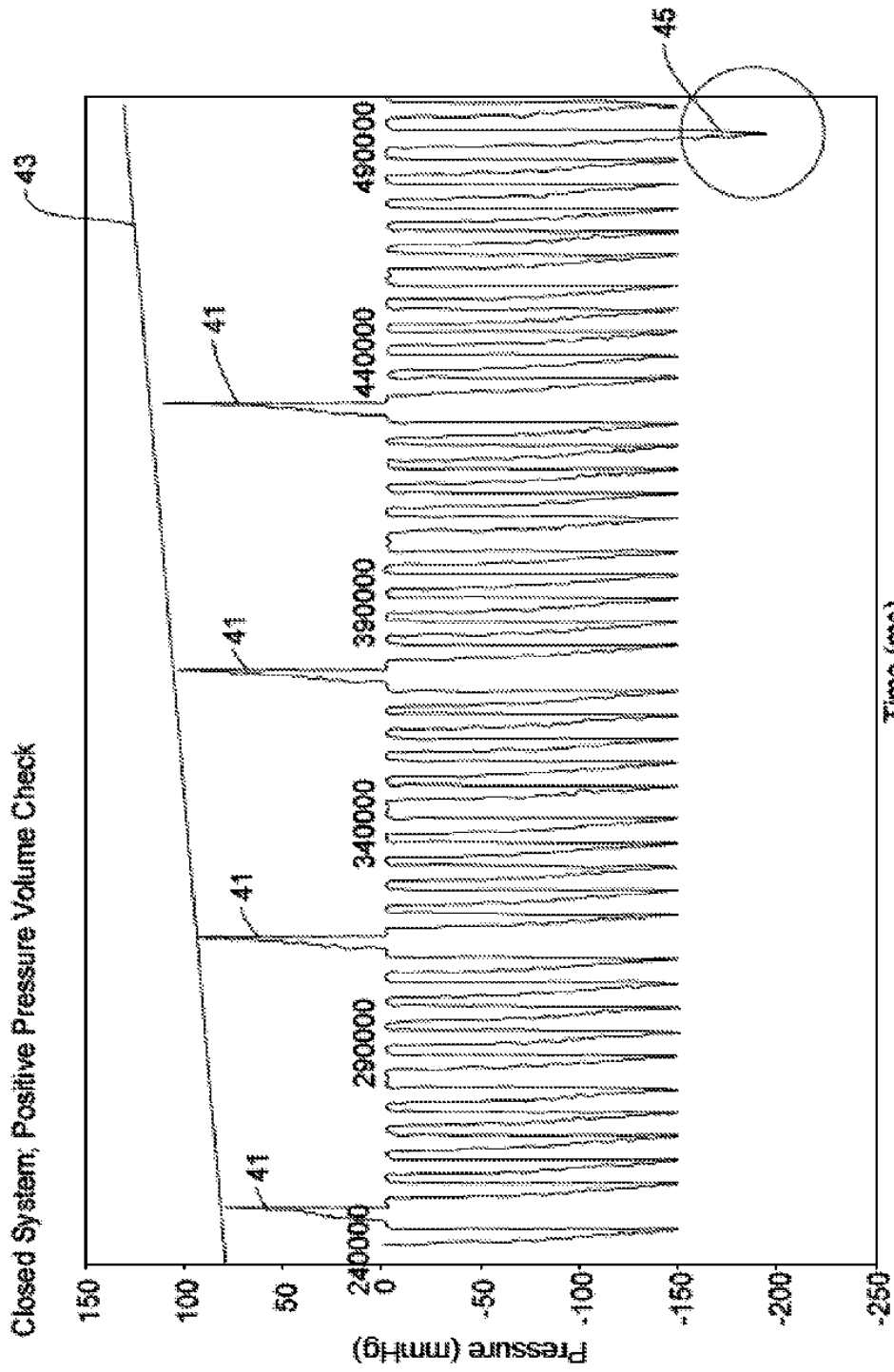
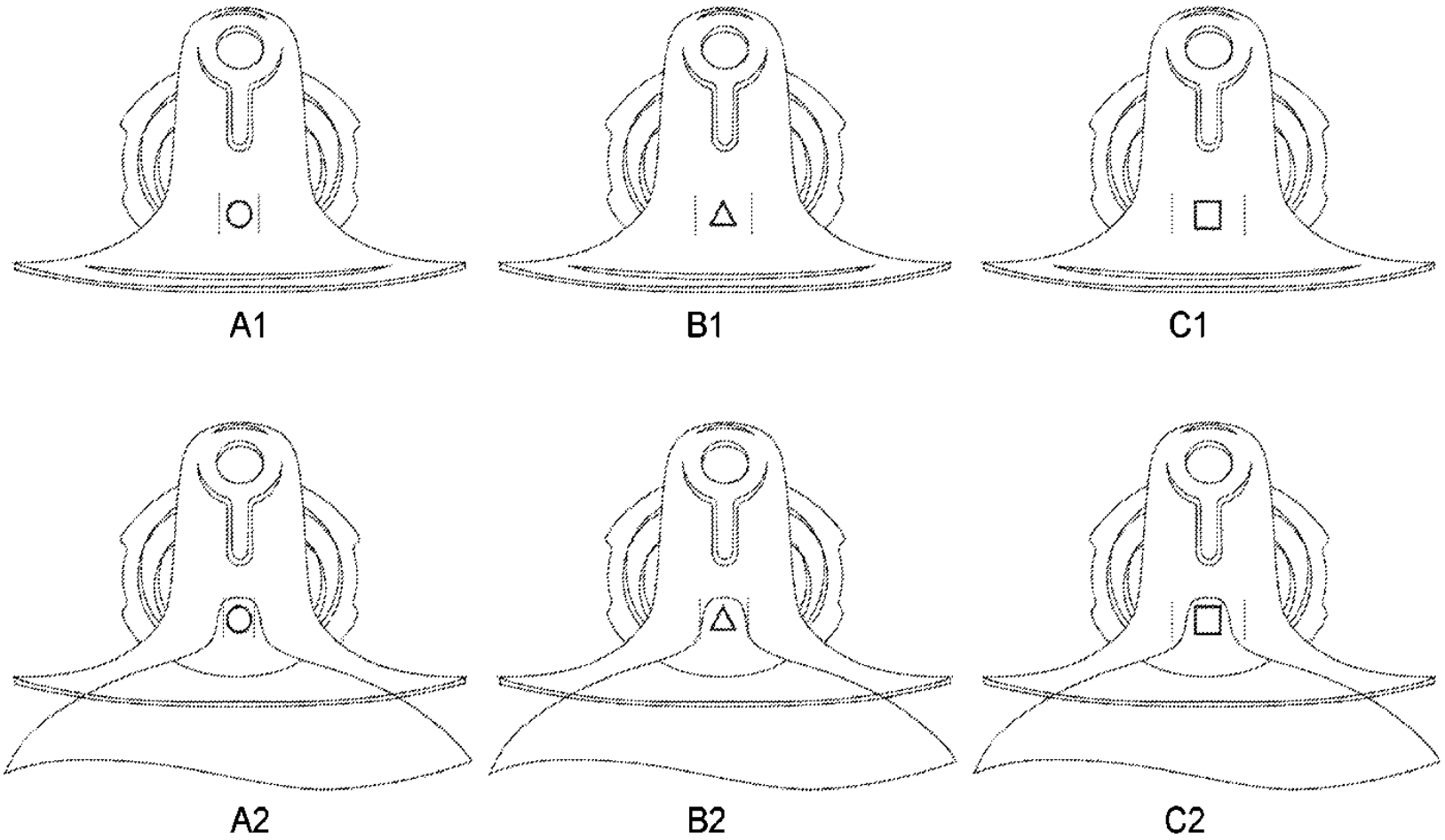

Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13



871

FIGURE 14

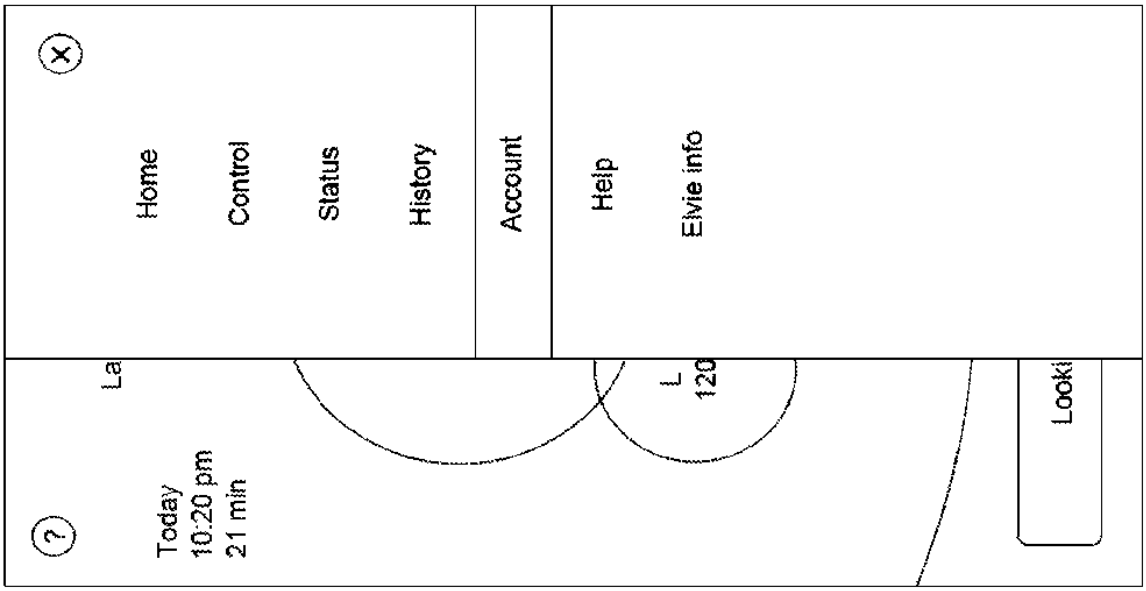

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

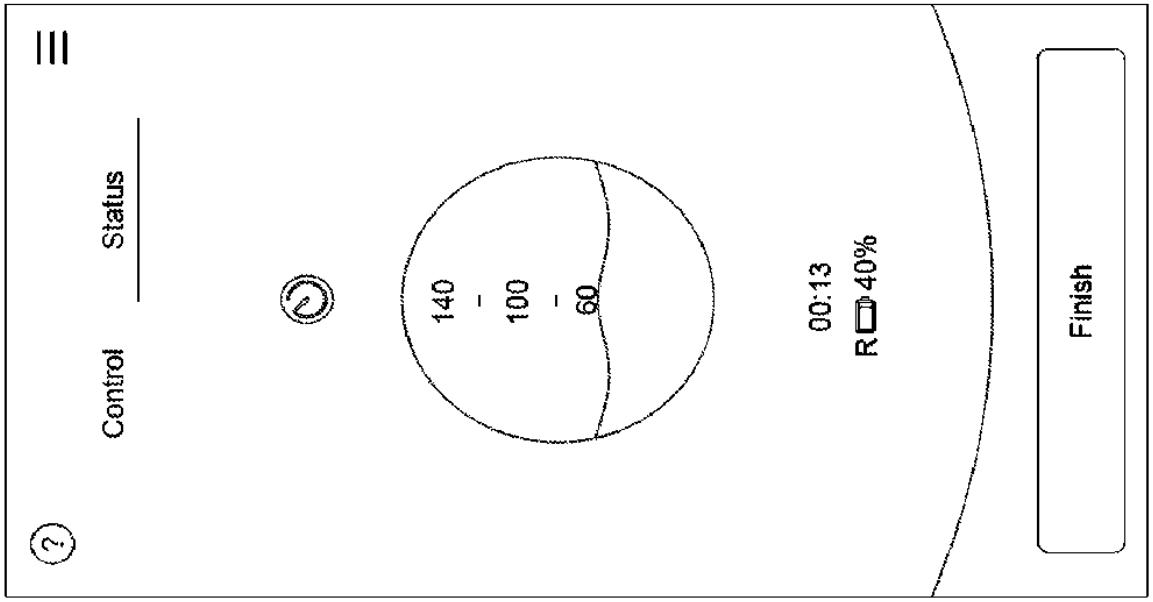


FIGURE 16

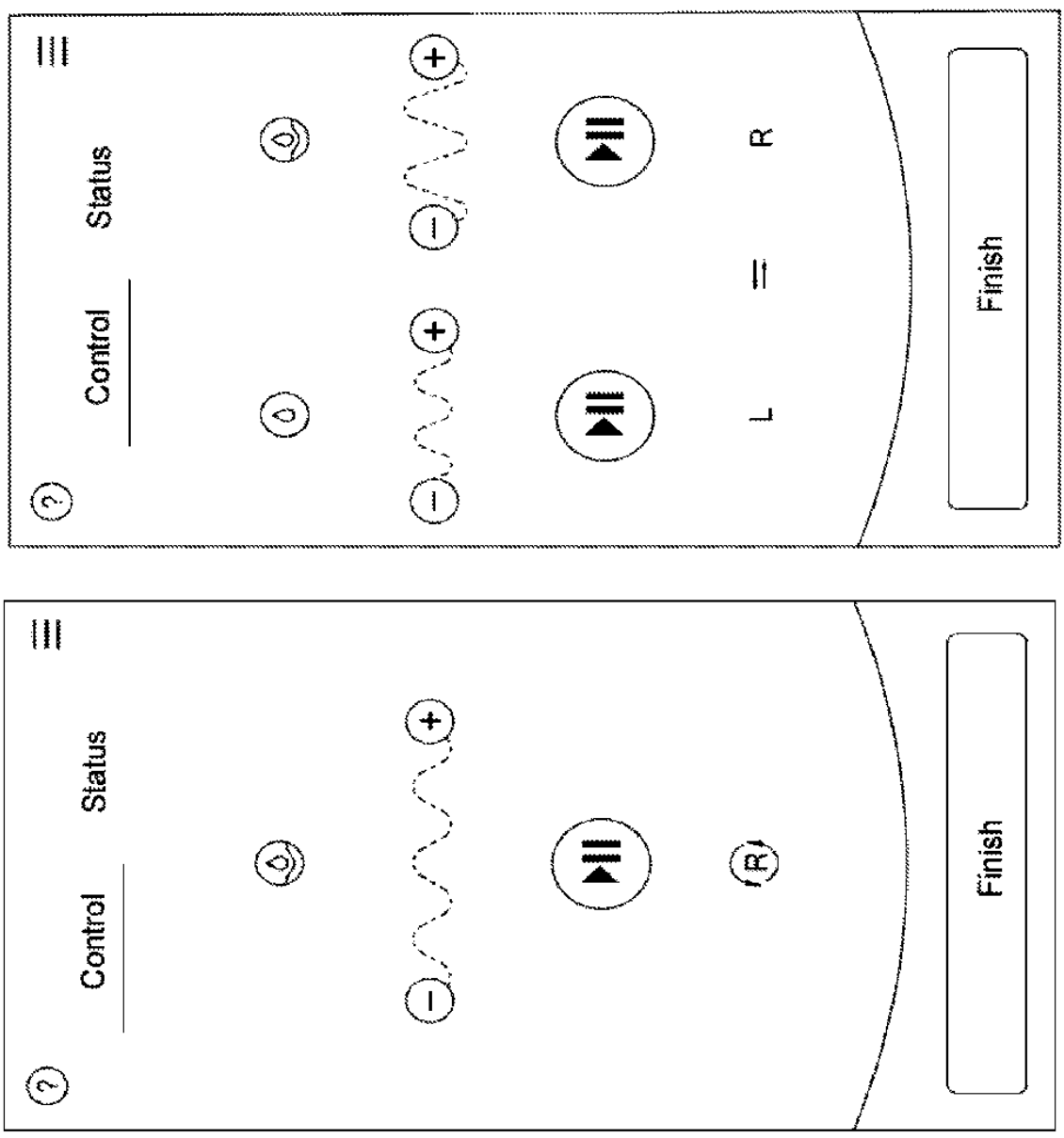


FIGURE 17

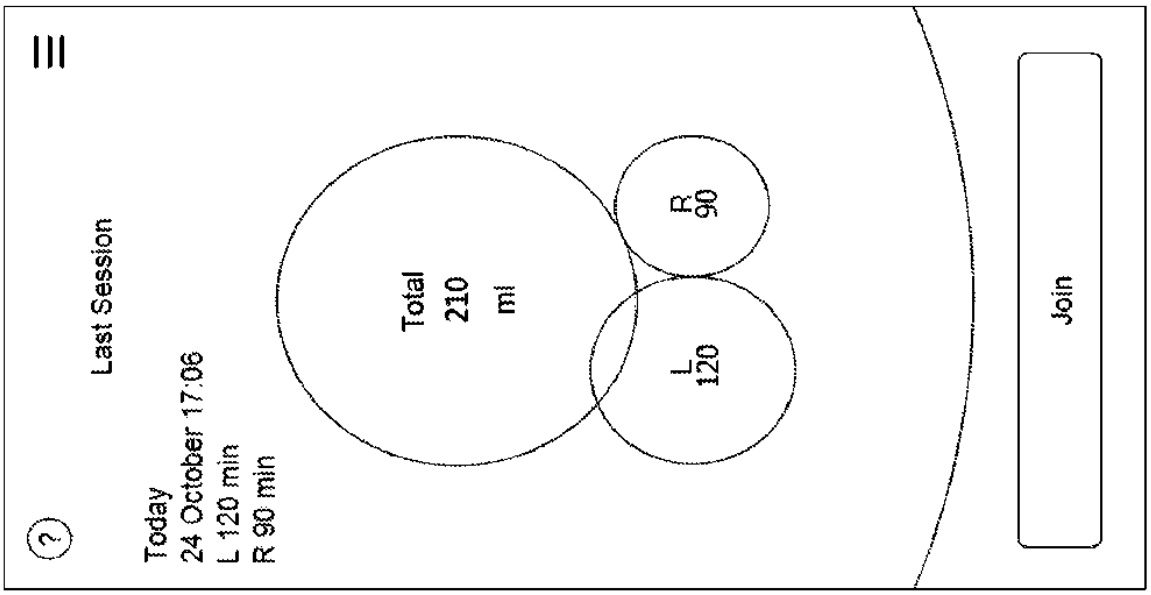

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
mi
L
120
R
90
Join

FIGURE 18

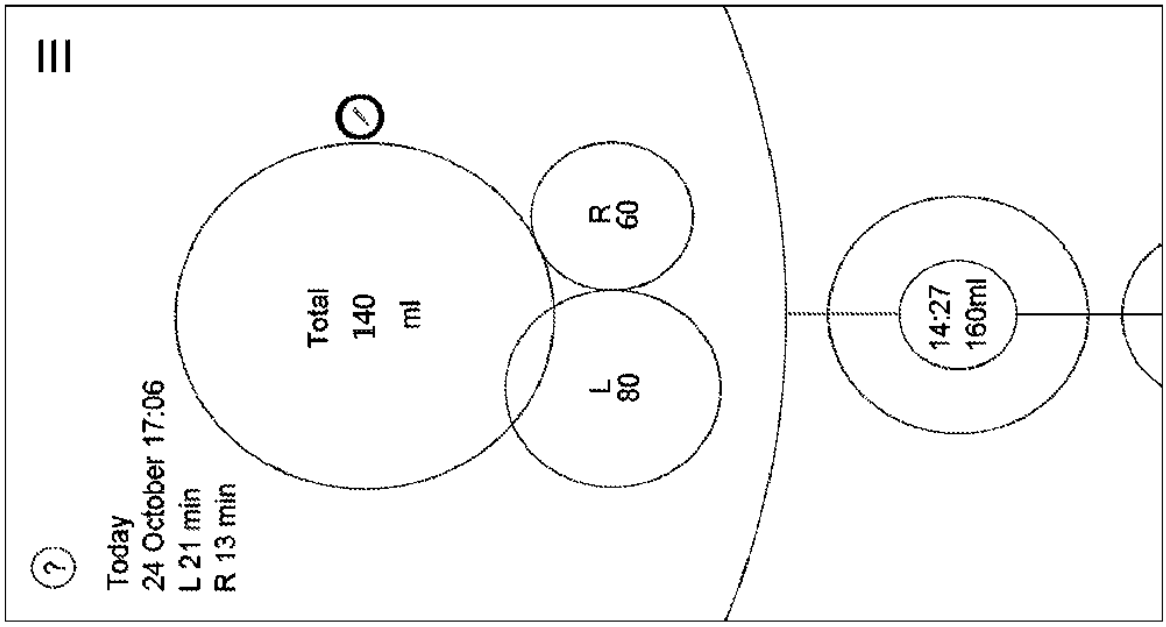

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

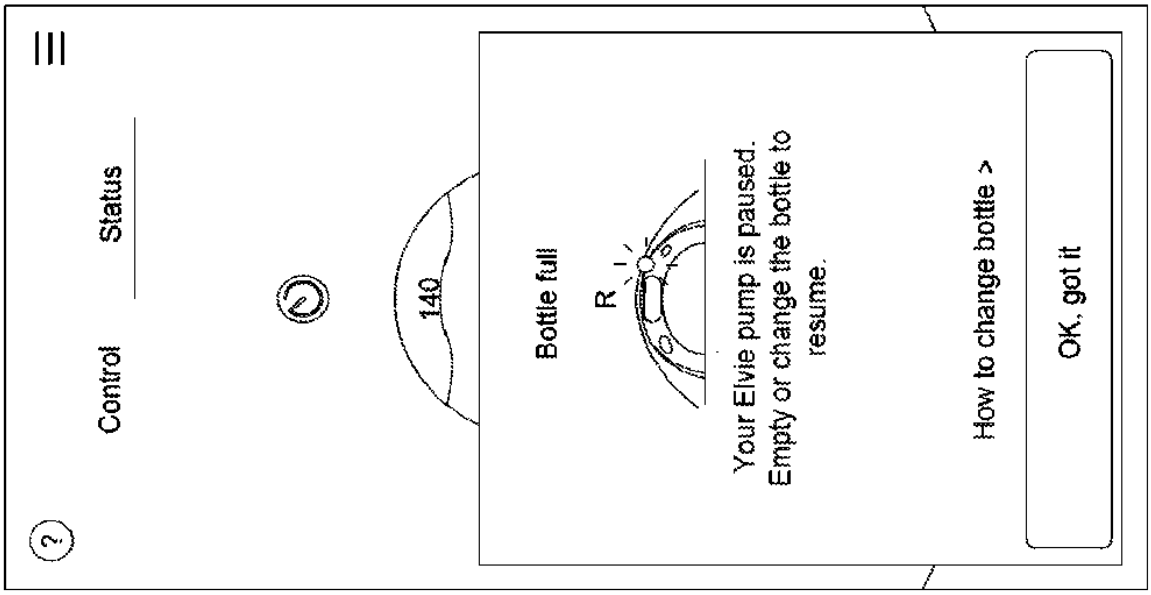

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

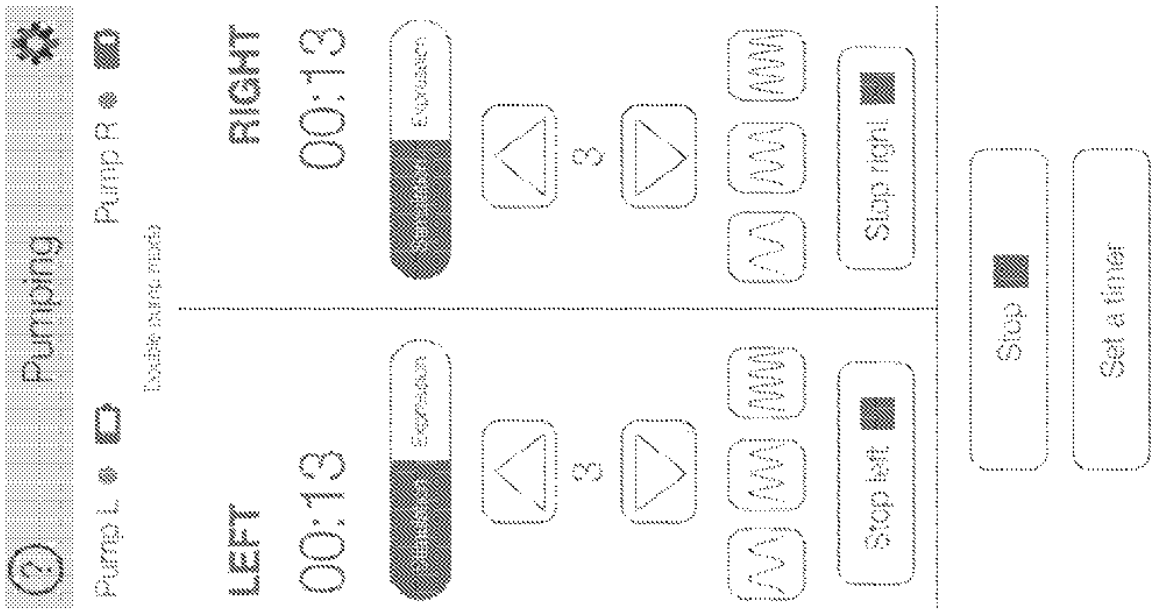

Pumping
Pump L
Pump R
LEFT
00:13
Expression
RIGHT
00:13
Expression
Stop left
Stop right
Stop
Set a timer

FIGURE 21

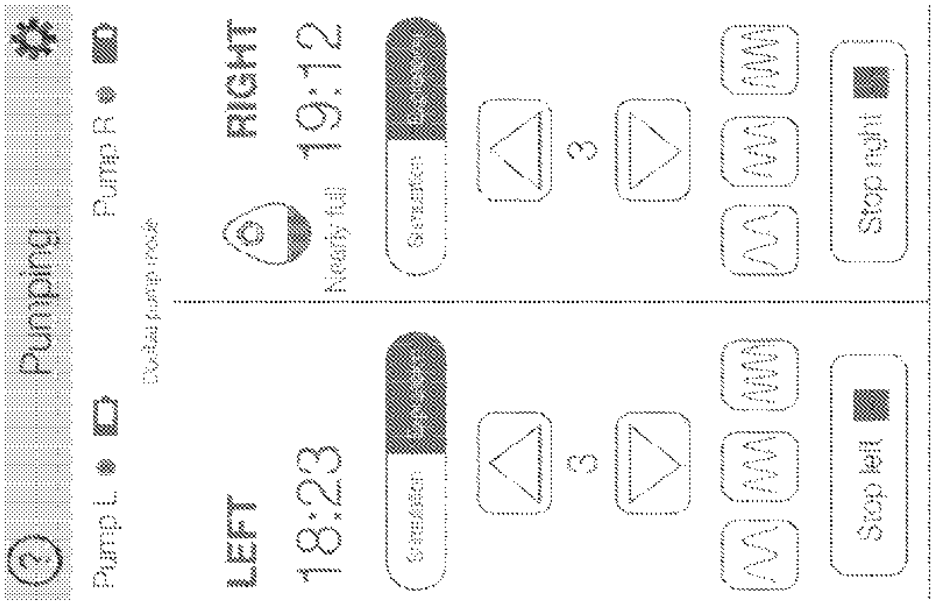

Pumping
Pump L
Pump R
Default pump mode
LEFT
18:23
Sensation
Duration
3
Stop left
RIGHT
Nearly full
19:12
Sensation
Duration
3
Stop right
Stop
Set a timer

FIGURE 22

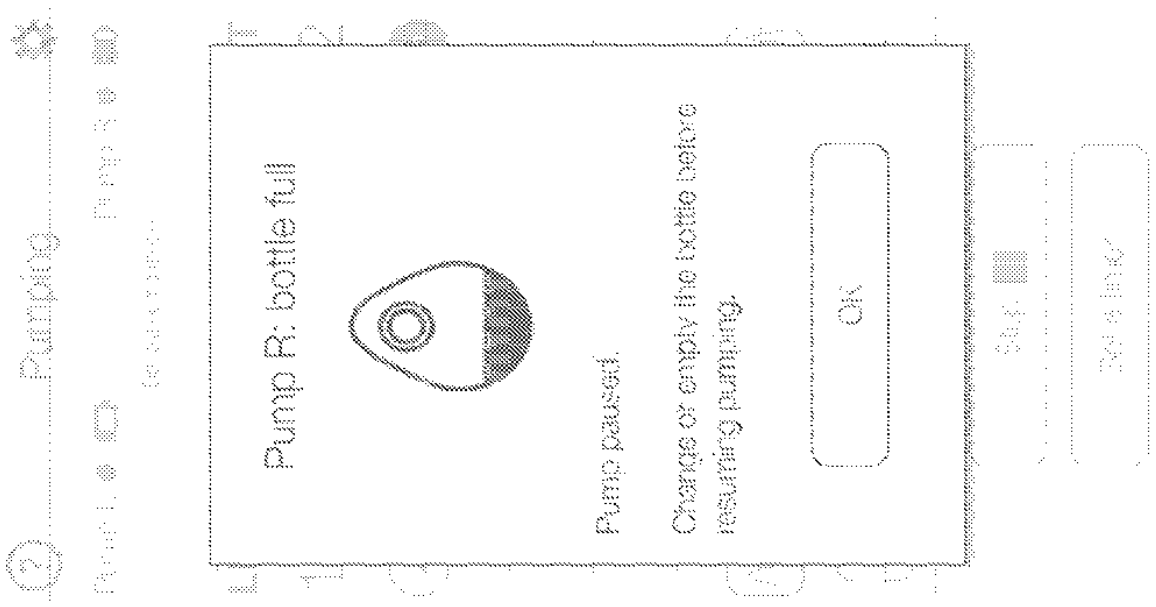


FIGURE 23


Stopped
Pump L
Pump R
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
25%
Pump R
Basal pump rate
LAST SESSION
Start time: 3:30pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
19mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

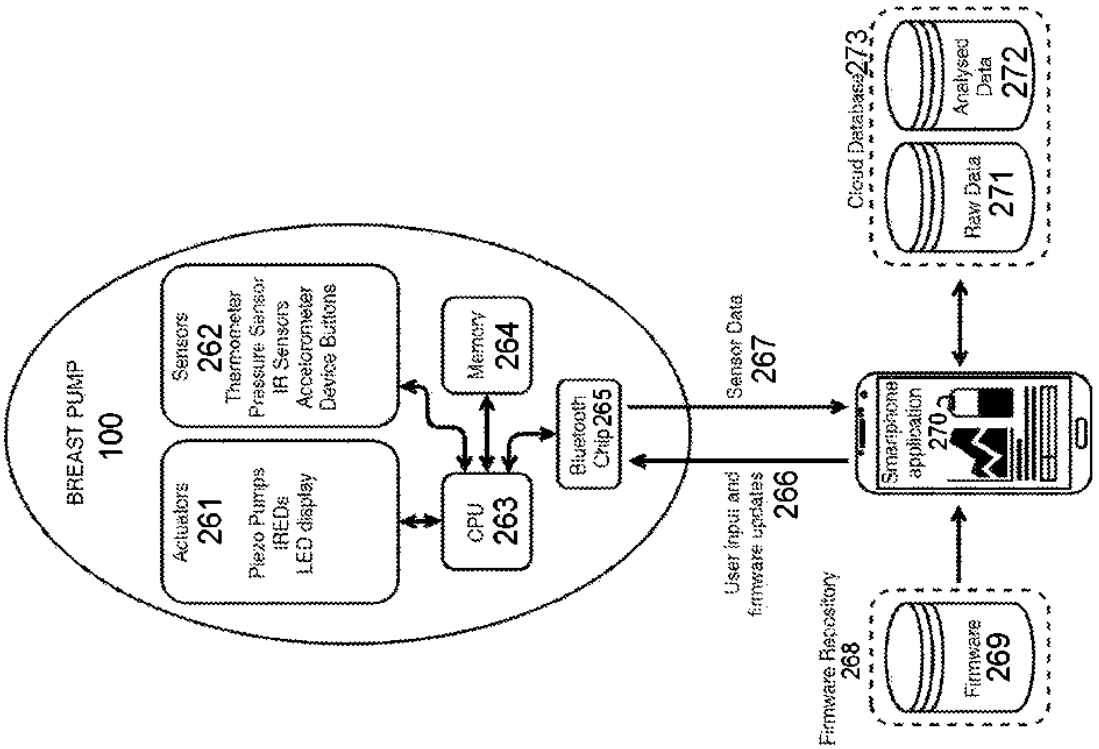

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

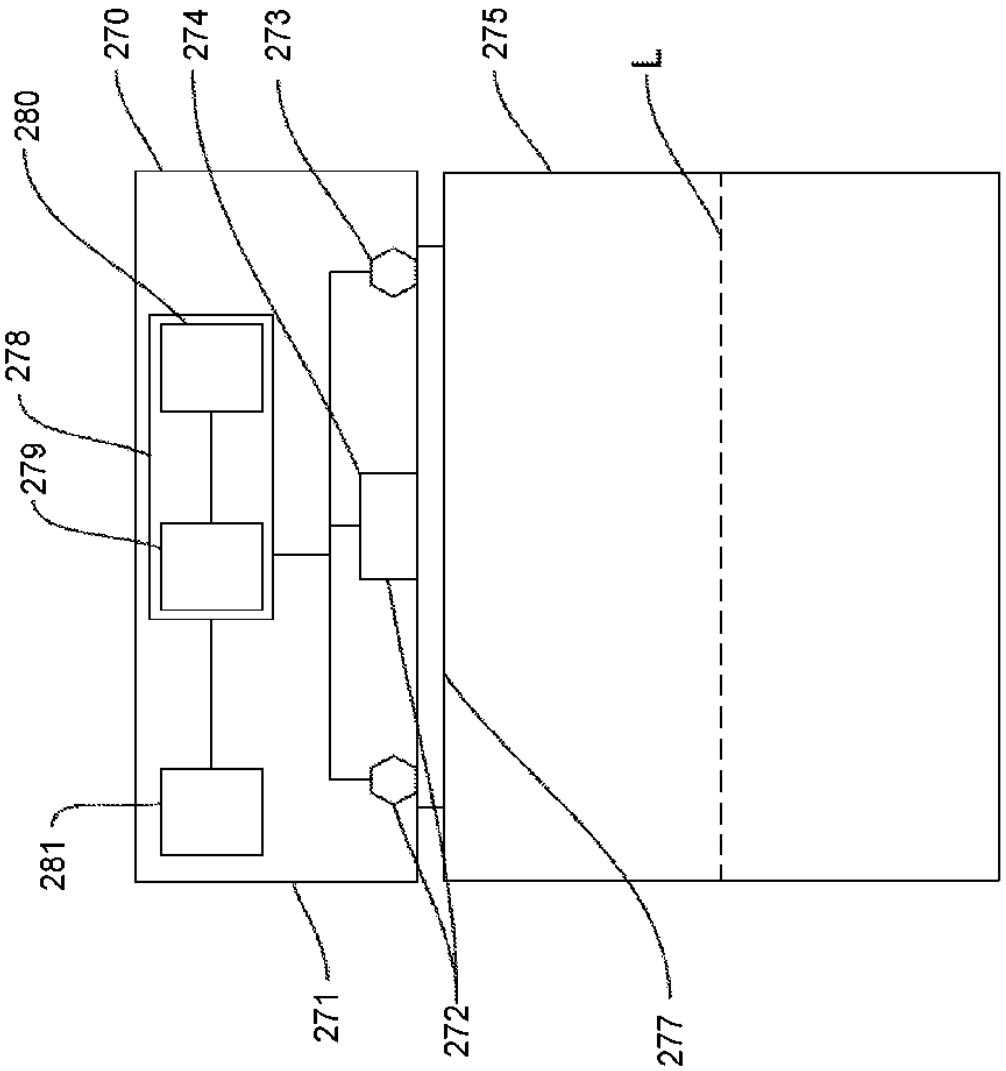


FIGURE 27

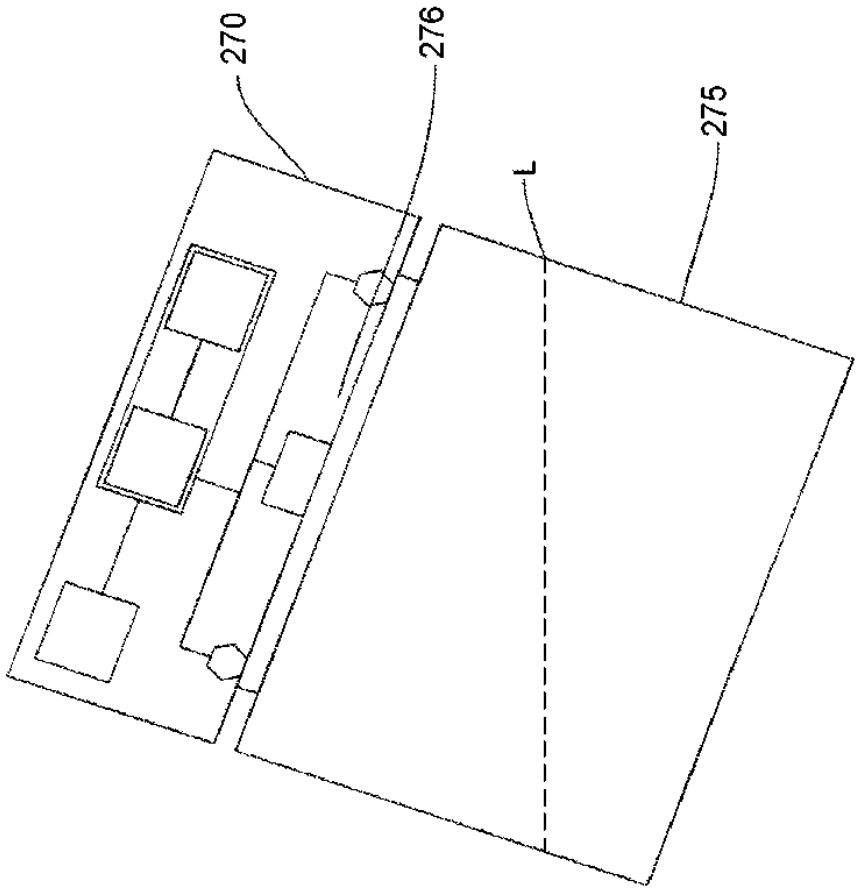


FIGURE 28

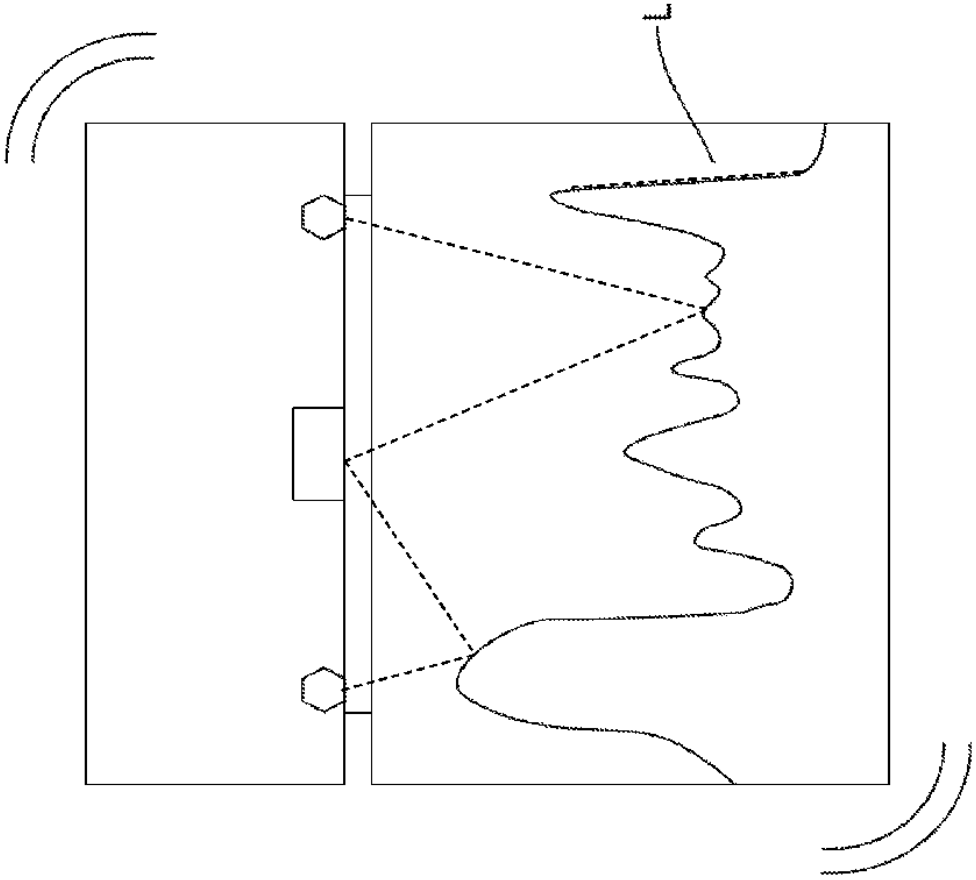


FIGURE 29

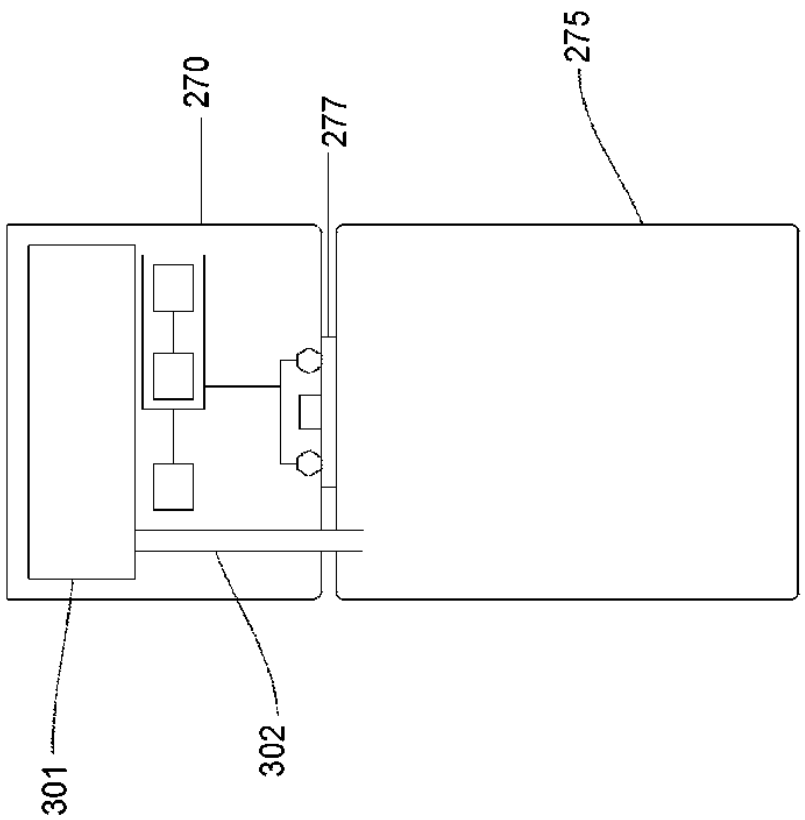


FIGURE 30

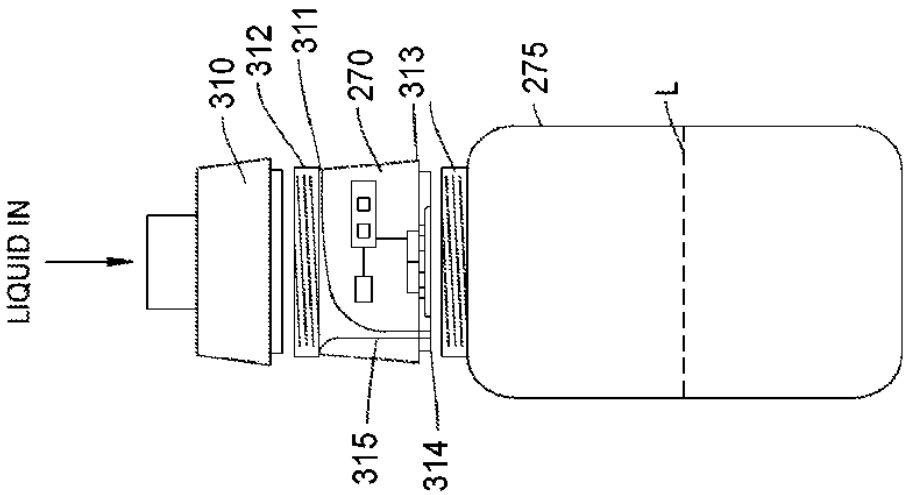


FIGURE 31

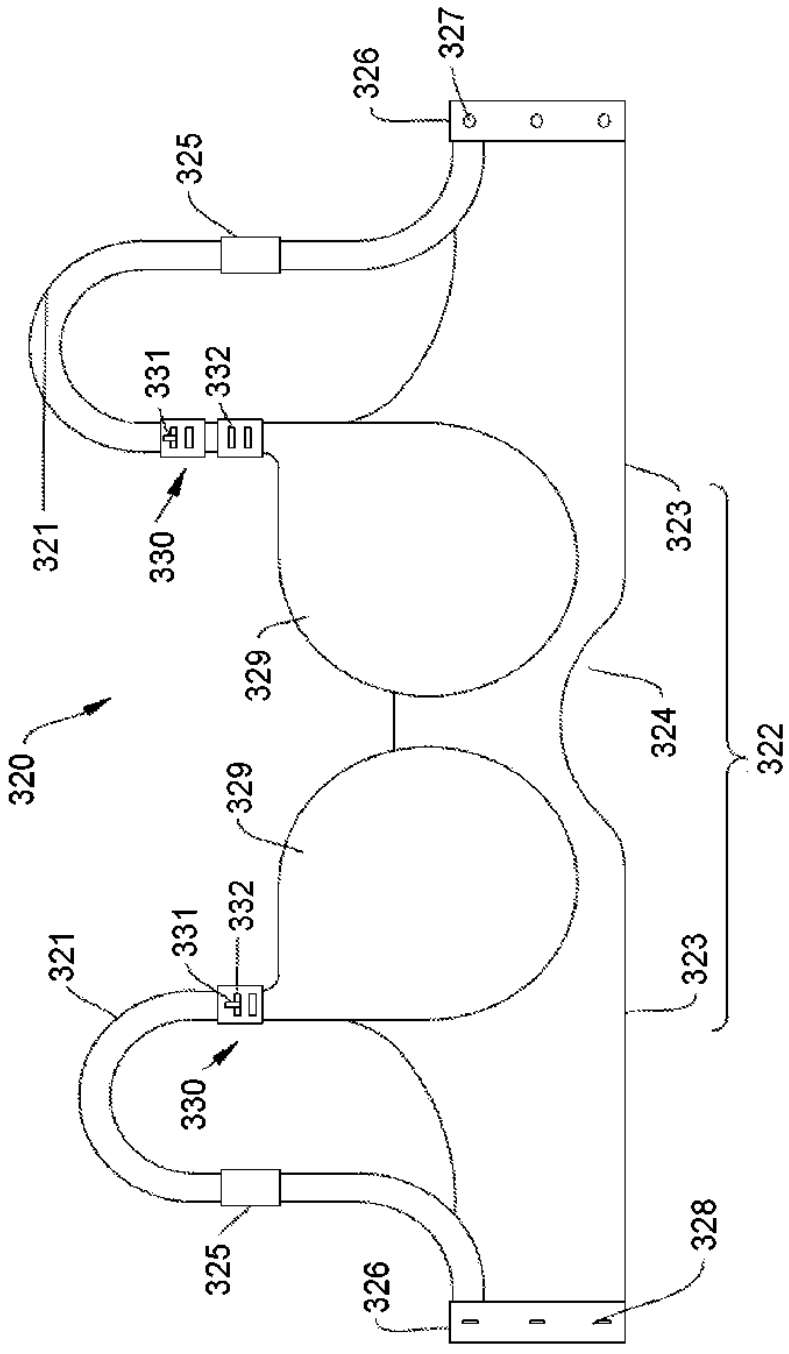


FIGURE 32

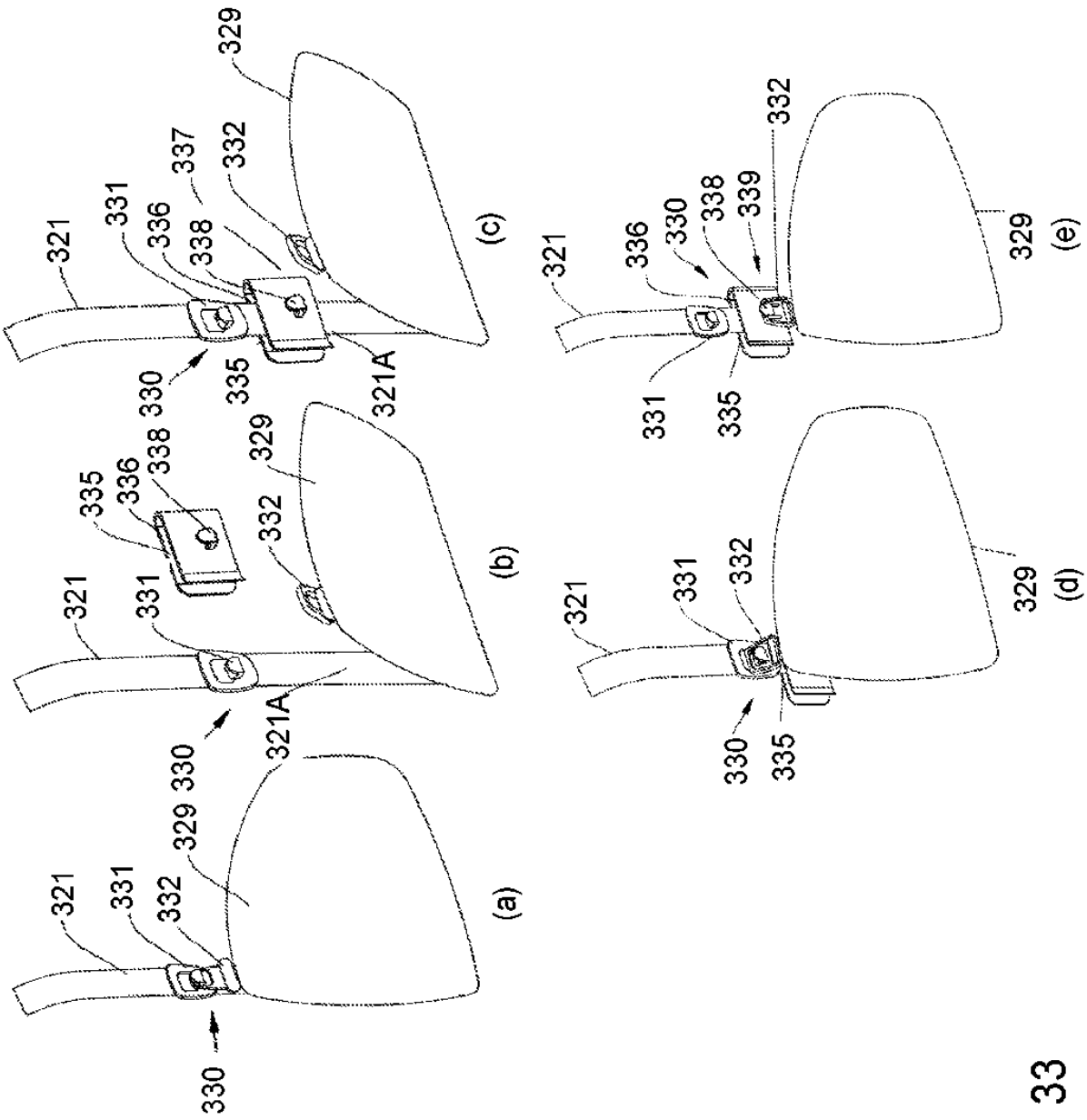

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
338
337
332
329
330
335
321A
(c)
321
336
330
338
339
332
329
331
335
(e)
321
331
332
329
330
335
(d)

FIGURE 33

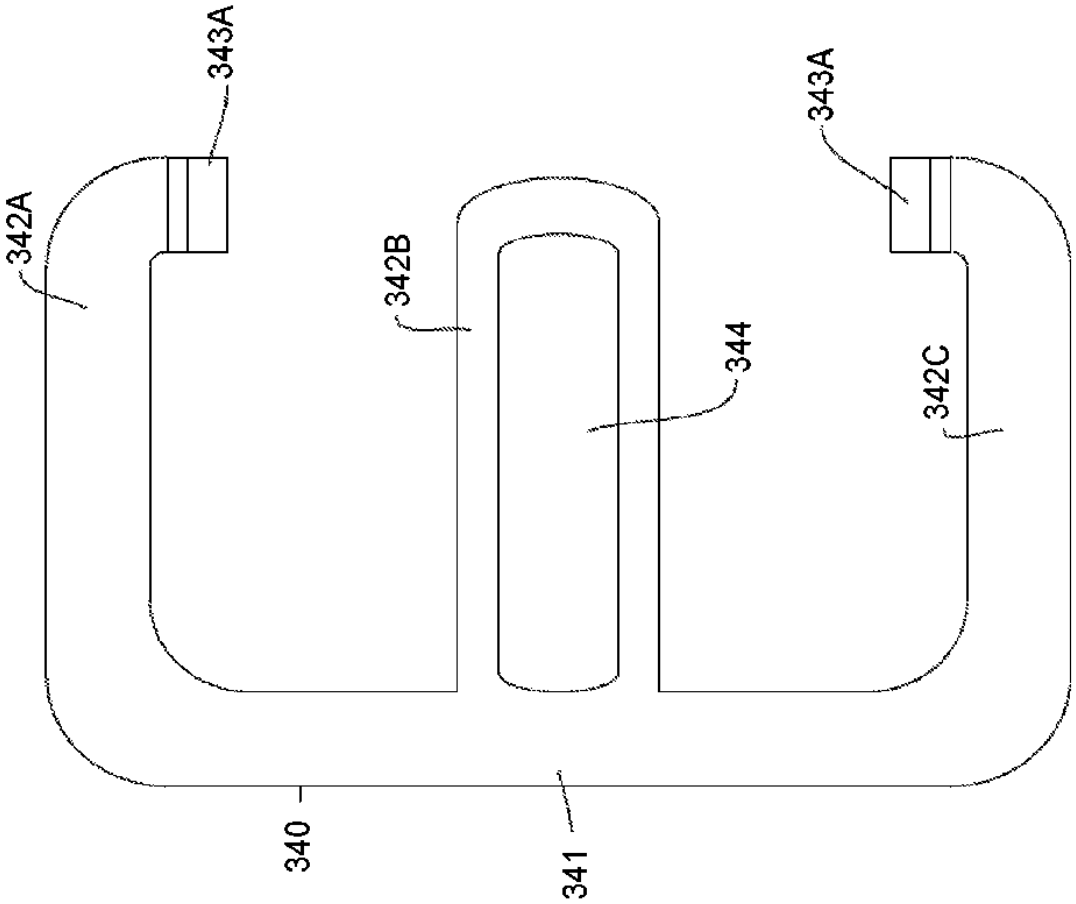


FIGURE 34

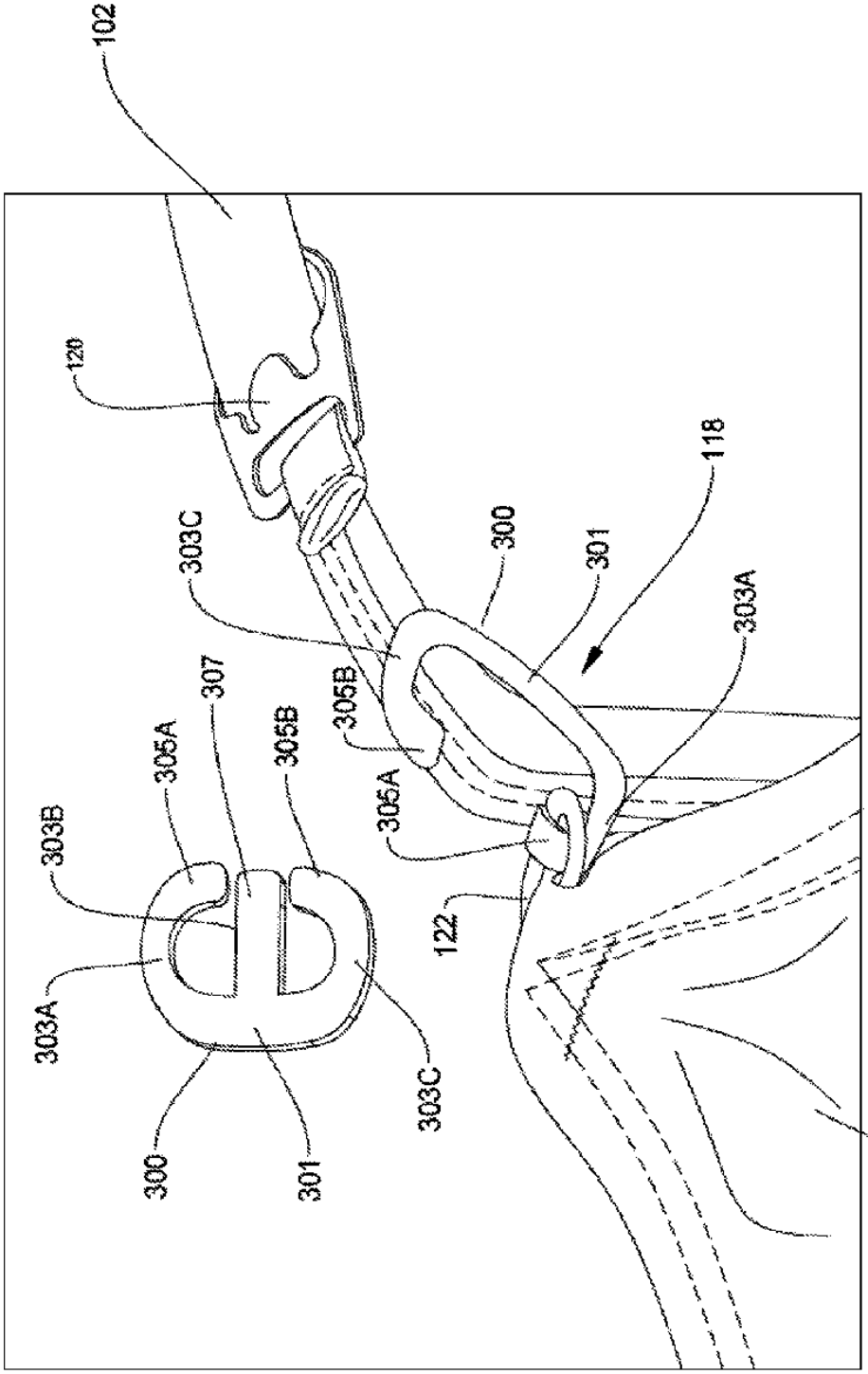

102
120
303C
300
301
118
303A
307
305B
305A
305B
305A
303B
303A
122
303C
300
301
116

FIGURE 35

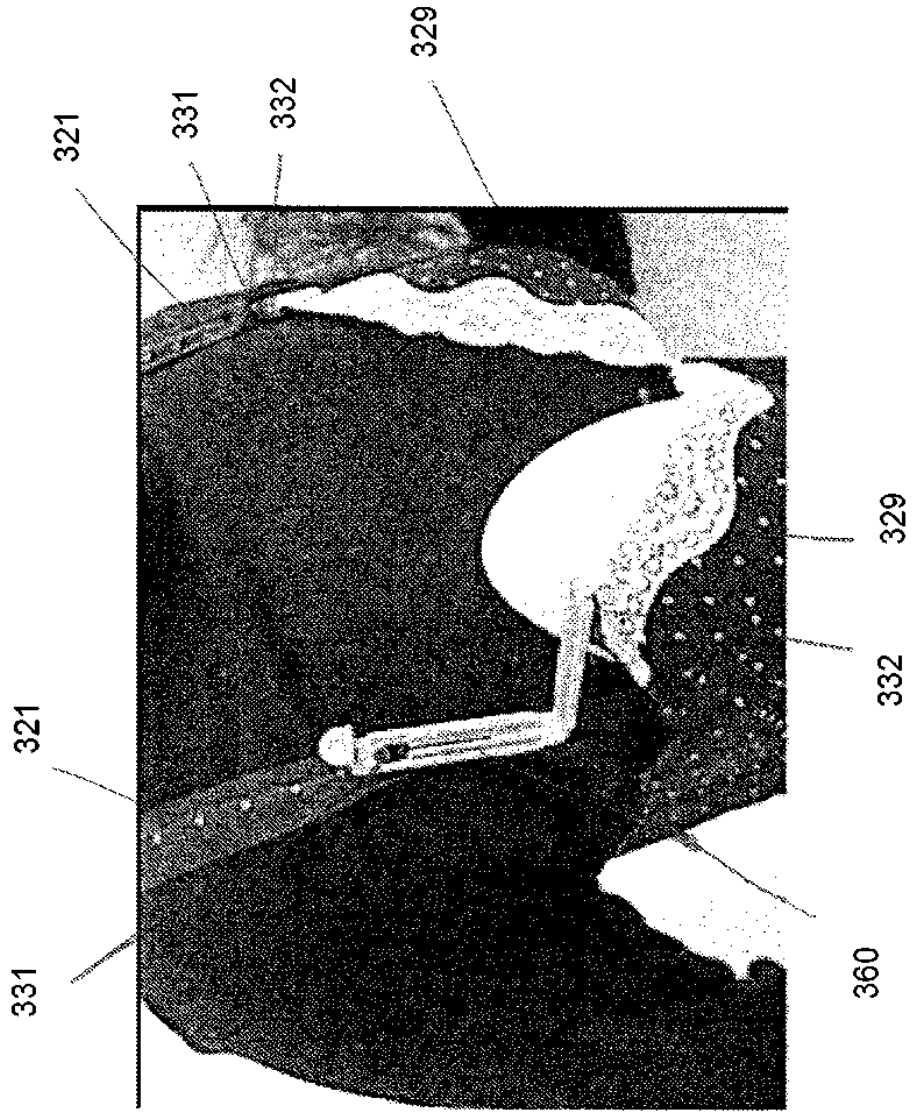


FIGURE 36

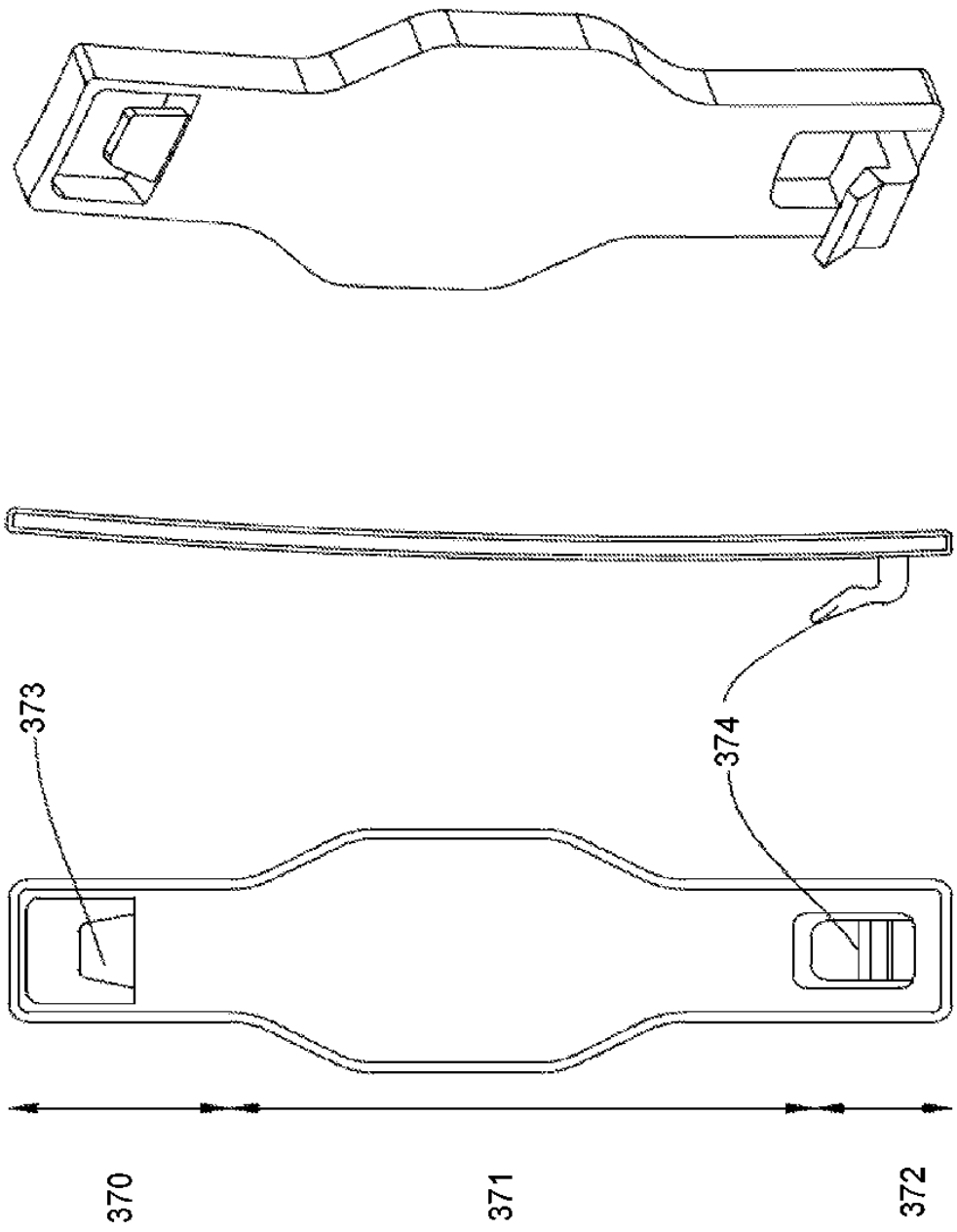
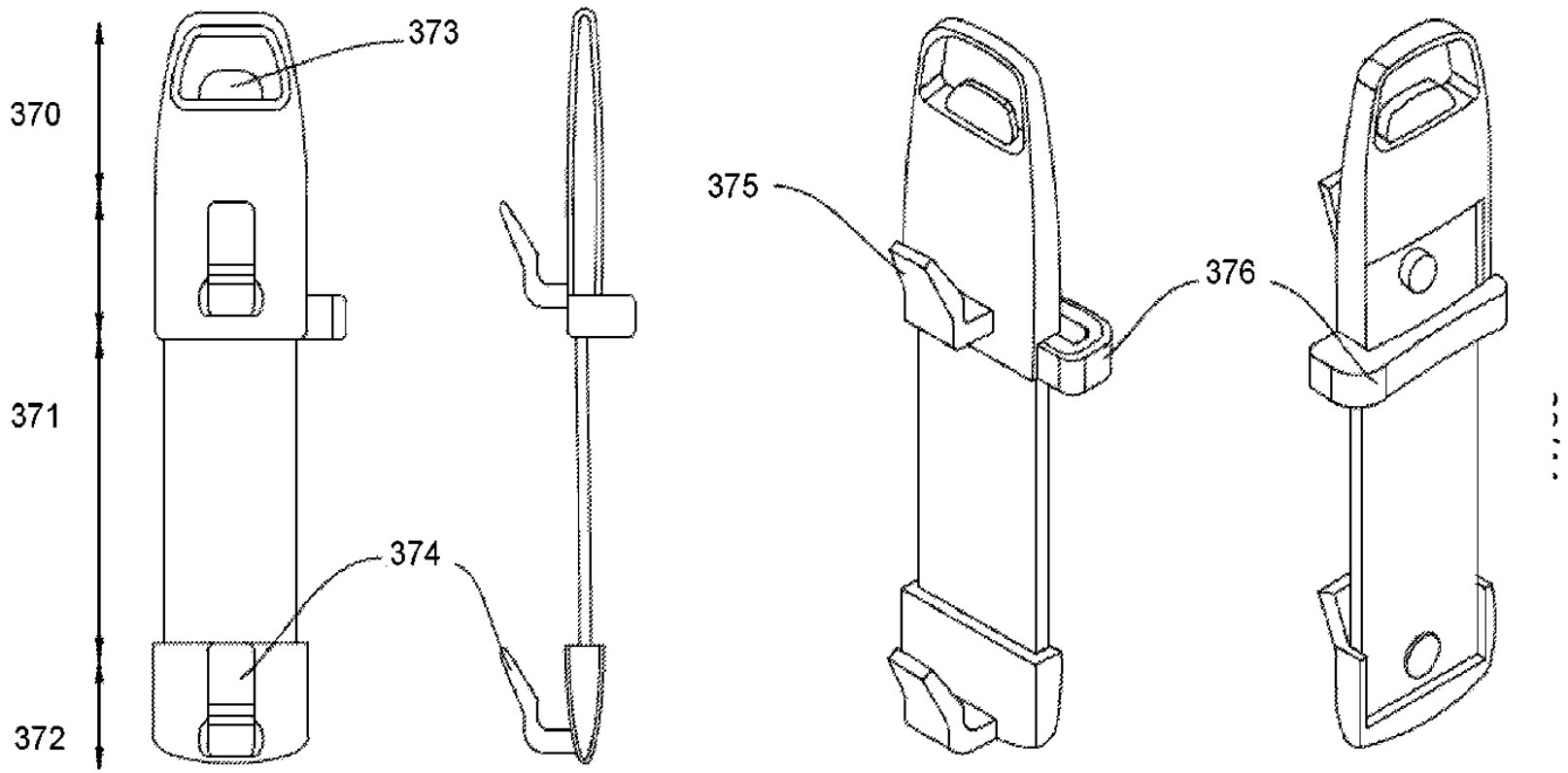


FIGURE 37



895

FIGURE 38

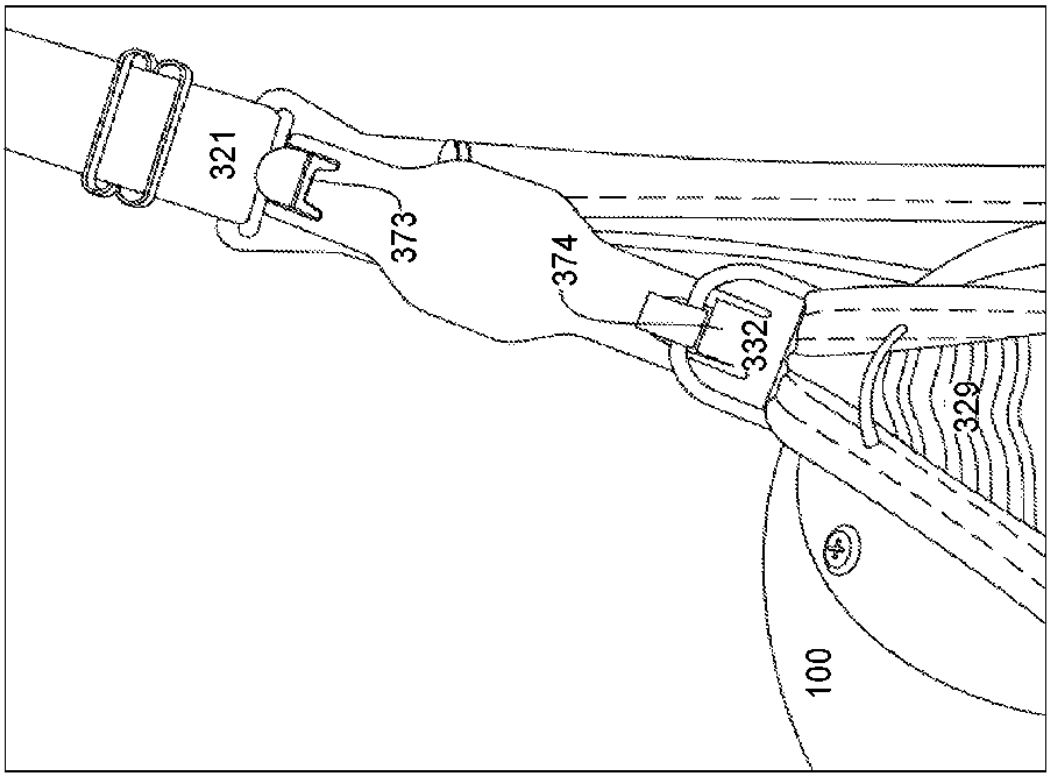


FIGURE 39

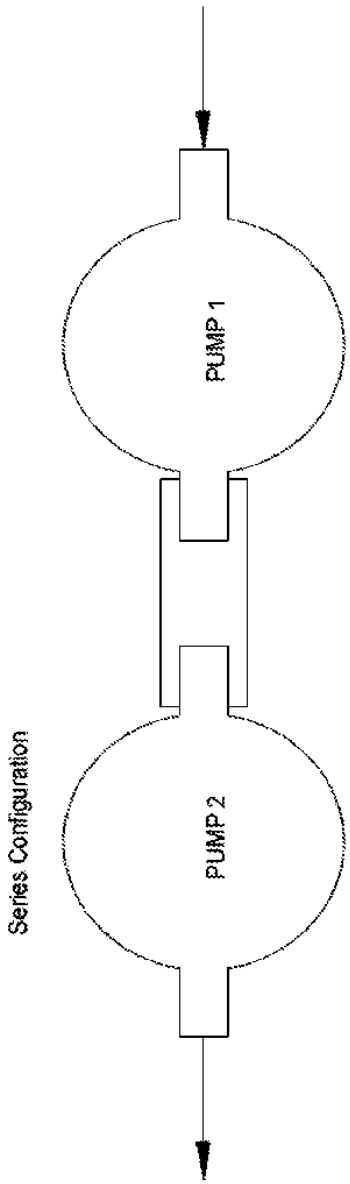


FIGURE 40

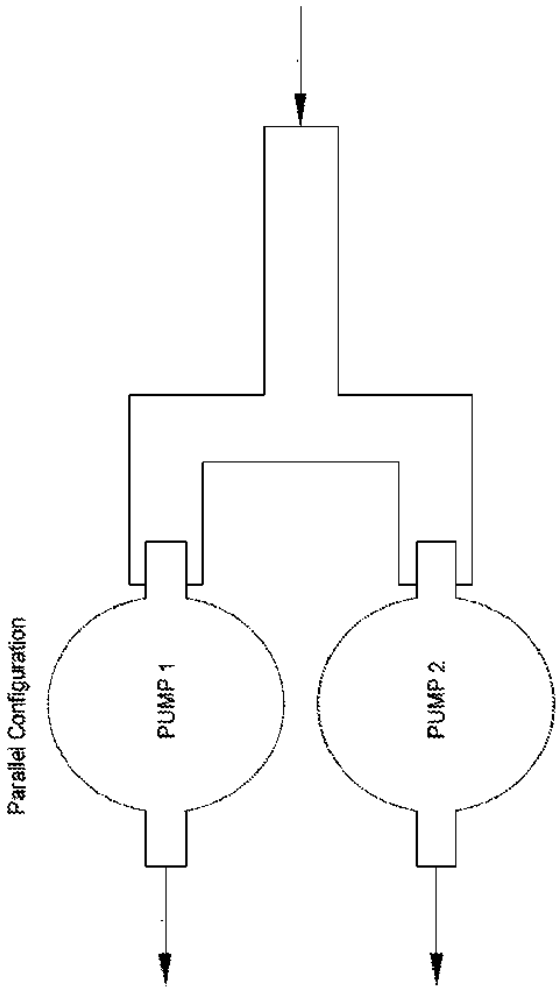


FIGURE 41

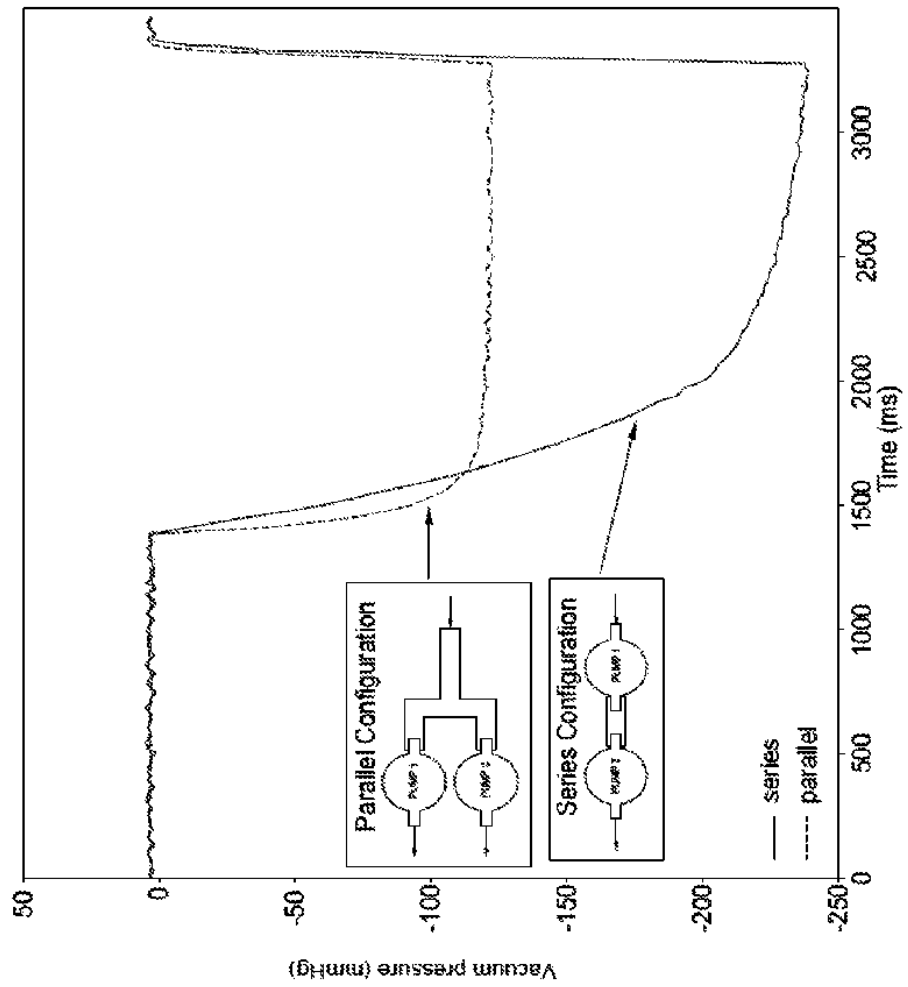

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

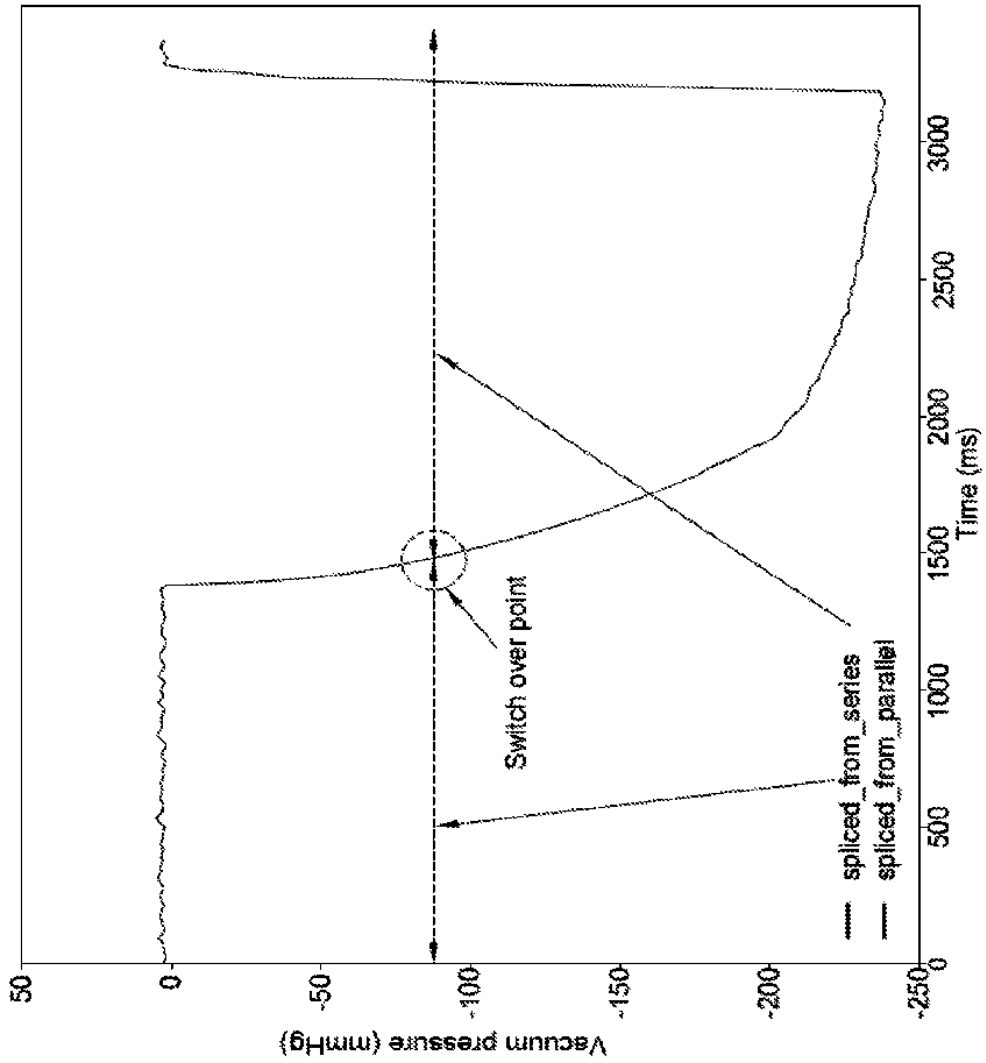

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

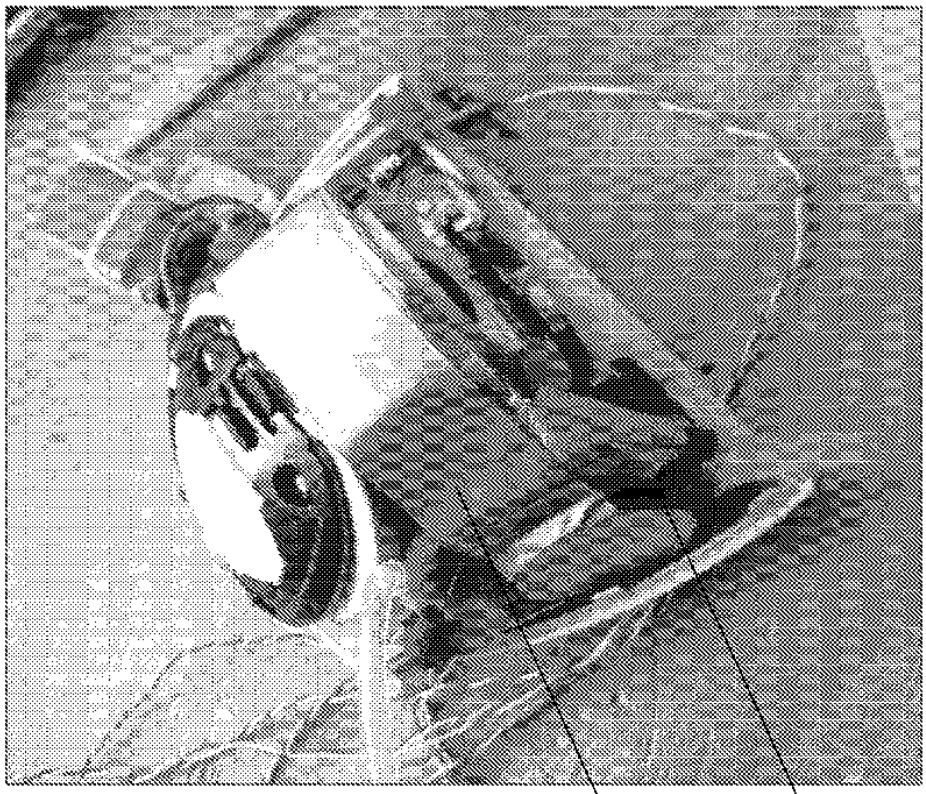


FIGURE 44

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

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.

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)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

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
	Art Unit	
	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	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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
	Art Unit	
	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.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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		

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

	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	
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	
	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			

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

	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		

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add]

NON-PATENT LITERATURE DOCUMENTS [Remove]

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

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	

If you wish to add additional non-patent literature document citation information please click the Add button Add

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	
	Filing Date	
	First Named Inventor	Jonathan O'TOOLE
	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.**

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 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.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 263 487 B2

(12) **NEW EUROPEAN PATENT SPECIFICATION**
After opposition procedure

(45) Date of publication and mention of the opposition decision:
23.11.2016 Bulletin 2016/47

(45) Mention of the grant of the patent:
01.12.2010 Bulletin 2010/48

(21) Application number: **00993020.7**

(22) Date of filing: **07.12.2000**

(51) Int Cl.:
A61M 1/06 *(2006.01)*

(86) International application number:
PCT/US2000/042659

(87) International publication number:
WO 2001/047577 (05.07.2001 Gazette 2001/27)

(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**
30.12.1999 US 475426
30.12.1999 US 475681
30.12.1999 US 476075
30.12.1999 US 476076

(43) Date of publication of application:
11.12.2002 Bulletin 2002/50

(60) Divisional application:
04017140.7 / 1 468 705
10004173.0 / 2 218 467
10004174.8 / 2 218 468
10004299.3 / 2 210 628
10011009.7 / 2 260 885

(73) Proprietor: **Medela Holding AG**
6340 Baar (CH)

(72) Inventors:
- **SILVER, Brian, H.**
Cary, IL 60013 (US)
- **GRETER, Andy**
CH-6312 Steinhausen (CH)
- **LARSSON, Michael**
CH-6300 Zug (CH)
- **ANNIS, Larry, D.**
Elgin, IL 60123 (US)
- **DETTLING, Michael**
CH-6424 Lauerz (CH)
- **WESTON, Richard, S.**
Calrsbad, CA 92002 (US)
- **EIXLER, Jurgen**
CH-6330 Cham (CH)

(74) Representative: **Clerc, Natalia et al**
Isler & Pedrazzini AG
Gotthardstrasse 53
Postfach 1772
8027 Zürich (CH)

(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

EP 1 263 487 B2

Printed by Jouve, 75001 PARIS (FR)

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 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.

[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 output from 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

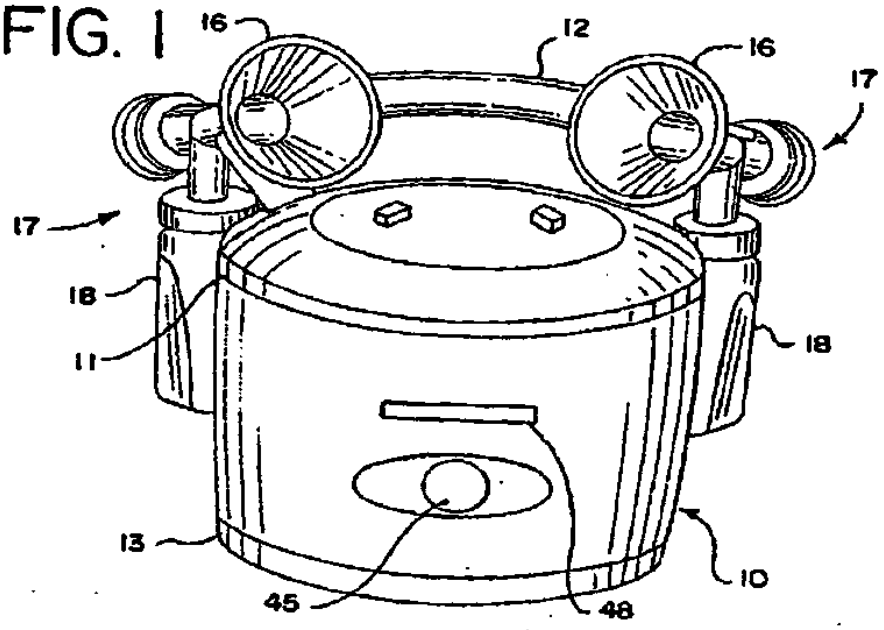


FIG. 2

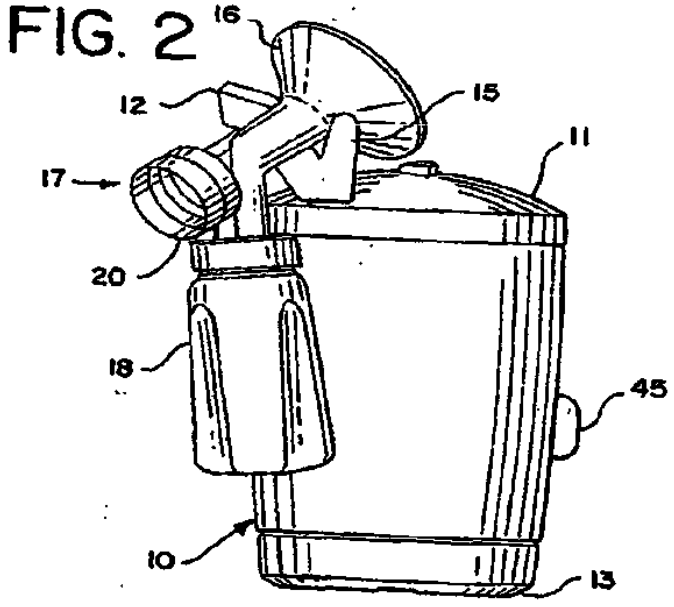


FIG. 3

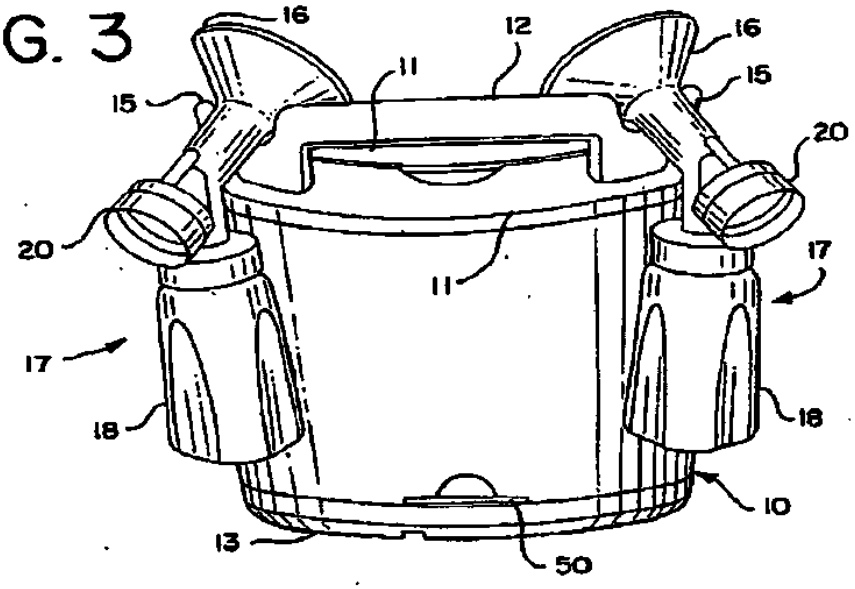

16
12
16
11
15
15
20
20
17
11
17
18
18
10
13
50

FIG. 4

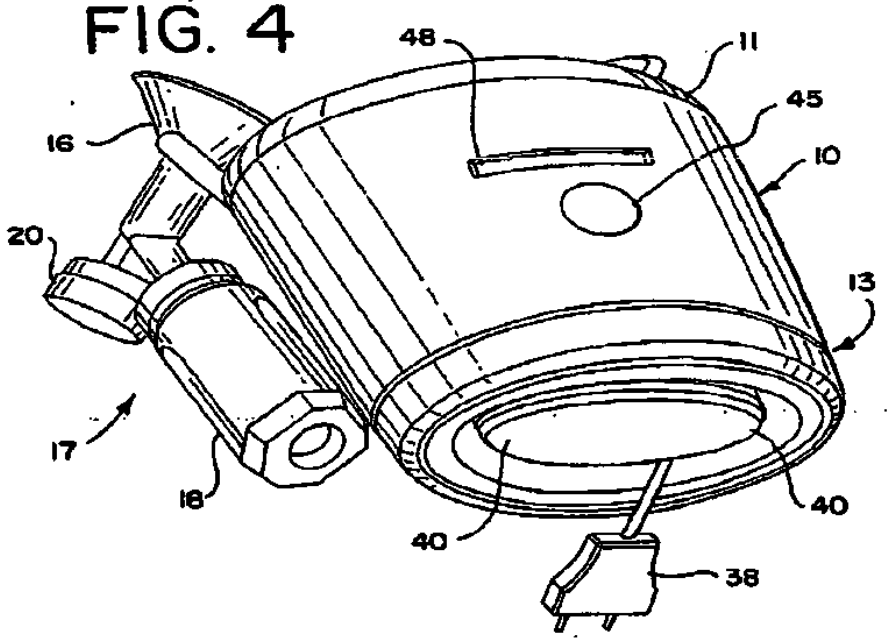

48
11
45
16
10
20
13
17
18
40
40
38

FIG. 5

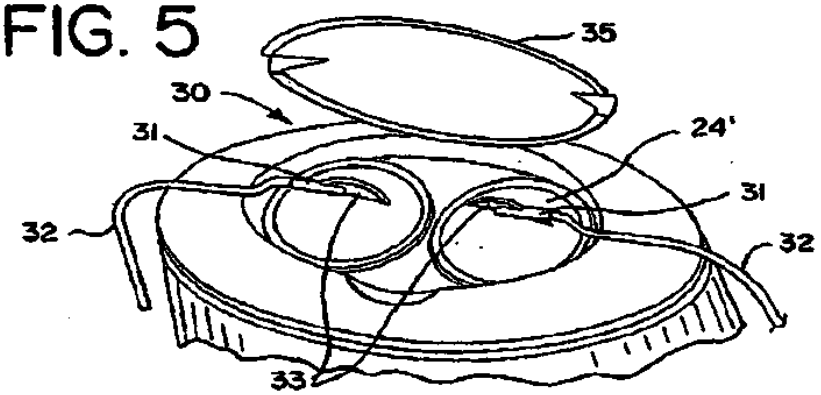


FIG. 6

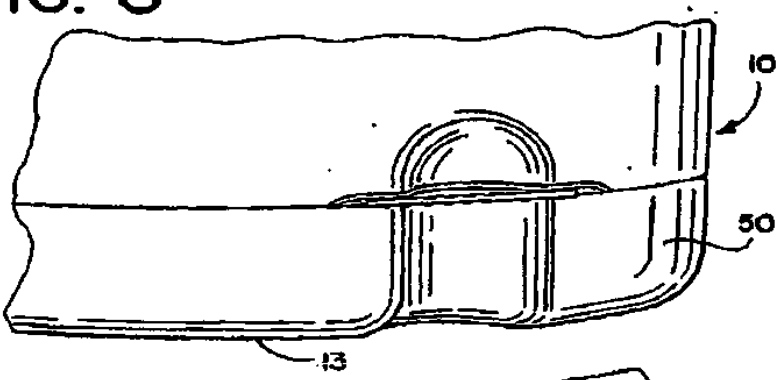


FIG. 7

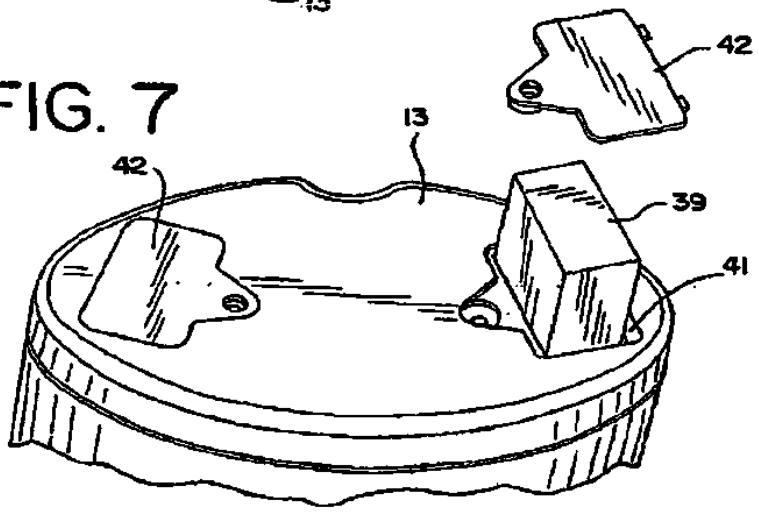


FIG. 8

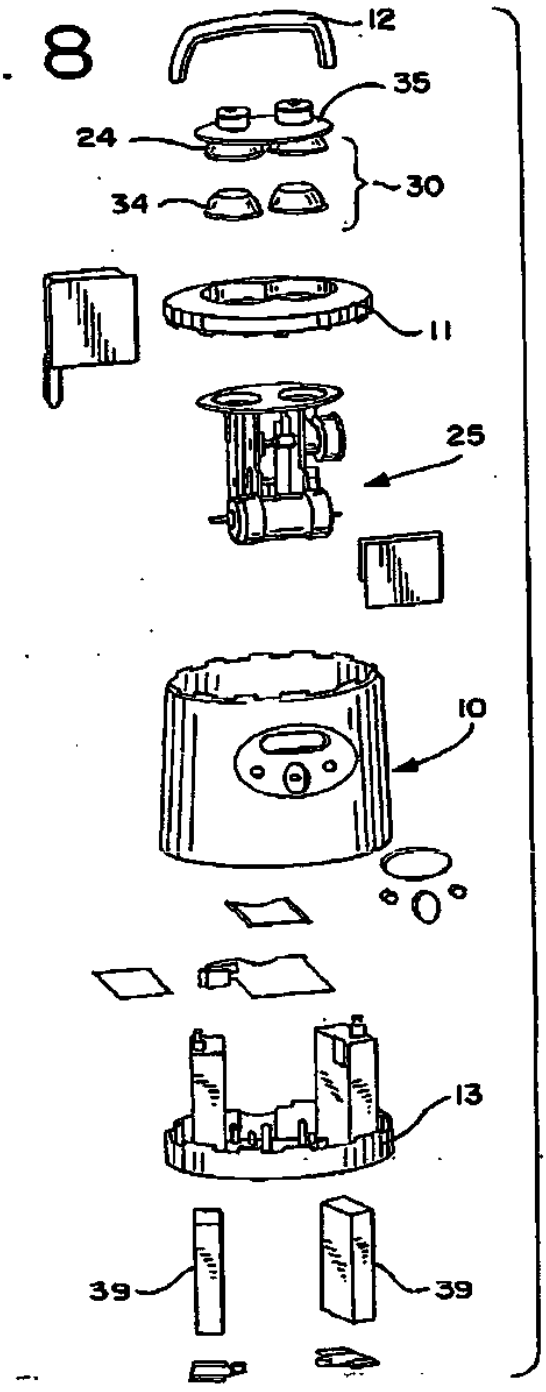


FIG. 9

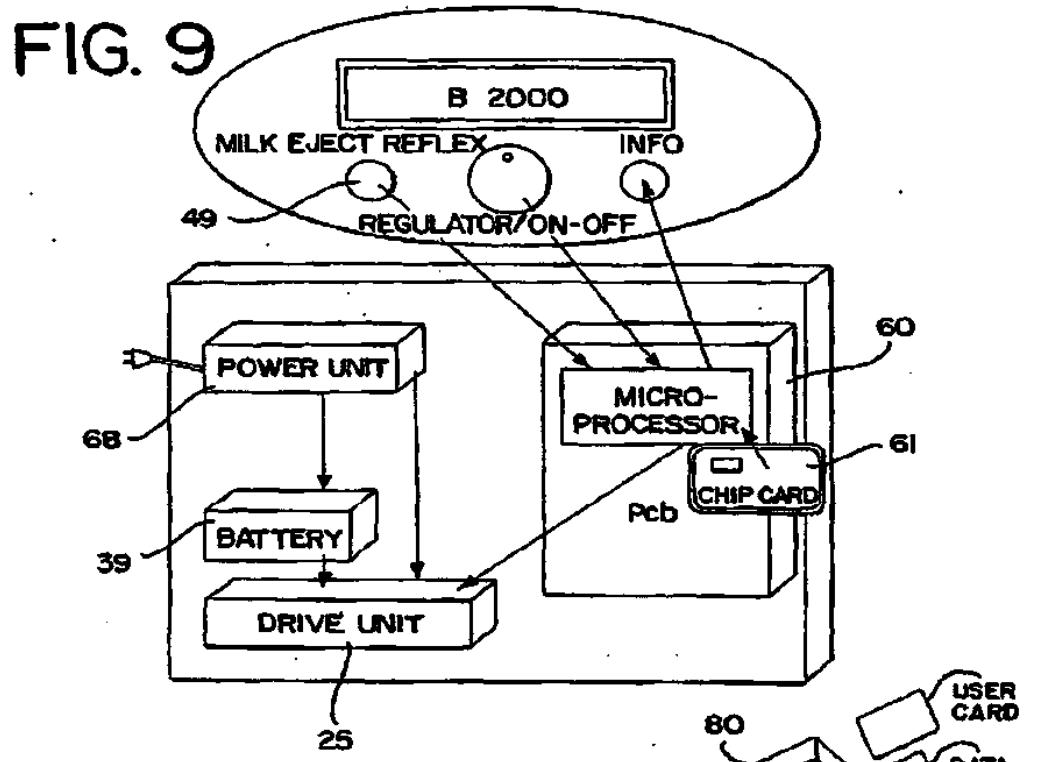

B 2000
MILK EJECT REFLEX
INFO
49
REGULATOR/ON-OFF
POWER UNIT
68
MICRO-PROCESSOR
60
61
CHIP CARD
Pcb
BATTERY
39
DRIVE UNIT
25
80
USER CARD
DATA CARD
RESEARCH CARD

FIG. 10

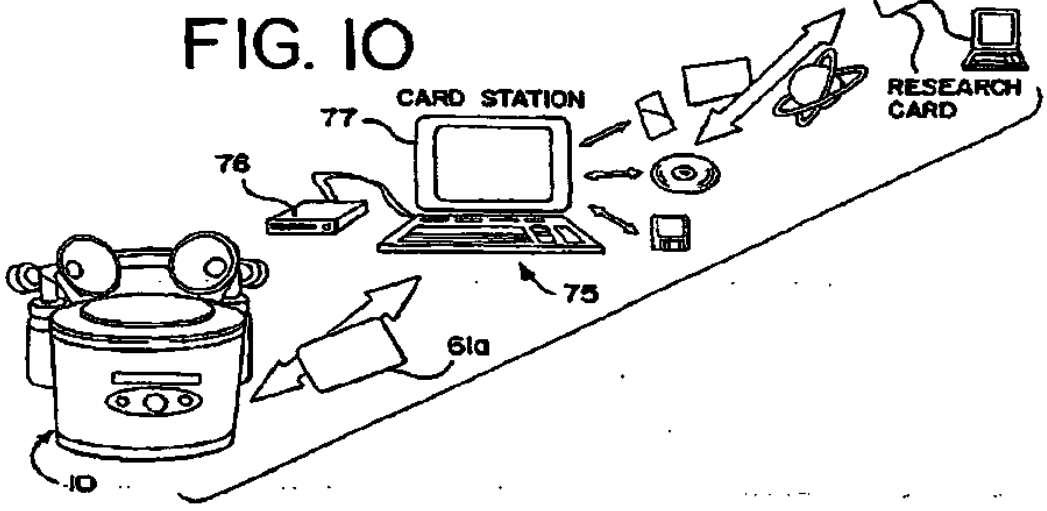
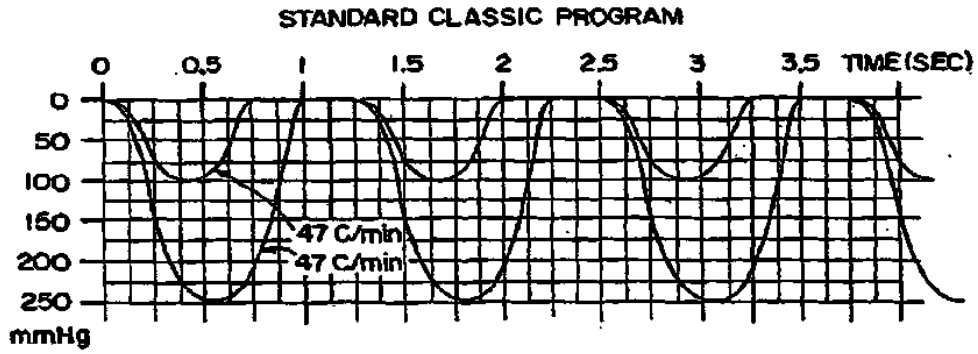
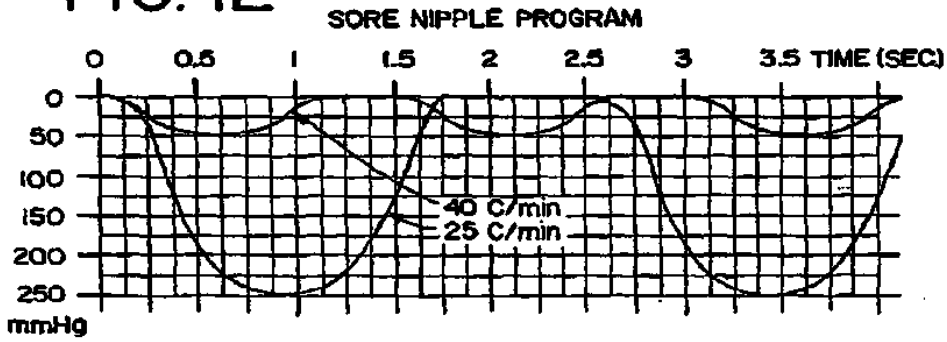

CARD STATION
77
76
75
61a
10

FIG. 11



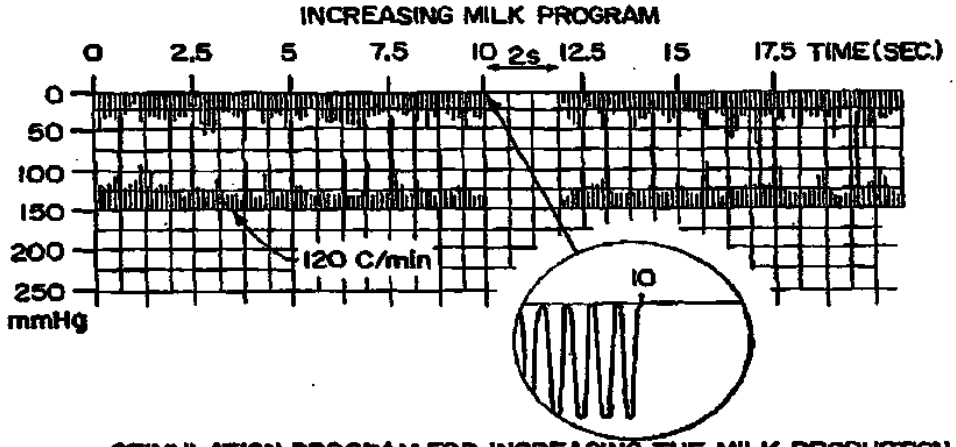
SUCTION CURVES AND CYCLES EQUAL TO CLASSIC
VACUUM RANGE: 100-250mmHg
CYCLES: 47/min (NOT ADJUSTABLE)

FIG. 12



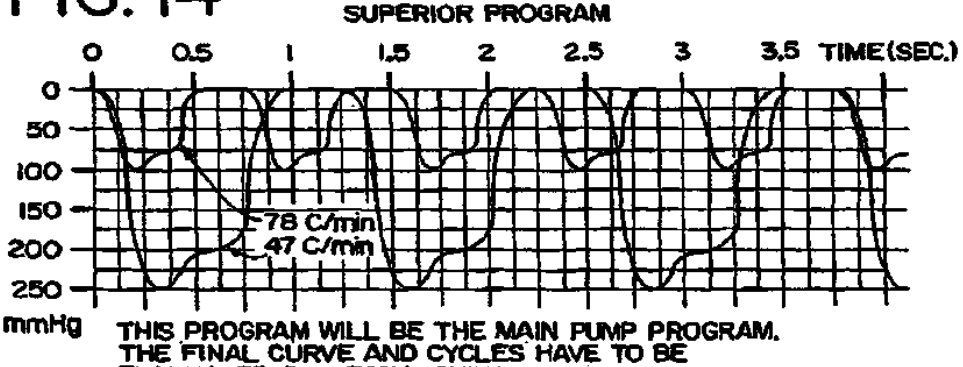
EXTREMELY GENTLE AND SLOW SUCTION
DECREASED VACUUM YIELDS GENTLER AND SLOWER SUCTION
VACUUM RANGE: 20-250
CYCLES: 25-40/min (CONTROLLED BY VACUUM LEVEL)

FIG. 13



STIMULATION PROGRAM FOR INCREASING THE MILK PRODUCTION
IT IS USED BETWEEN THE PUMP SESSIONS A FEW TIMES A DAY
VACUUM RANGE: 50-150mmHg
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

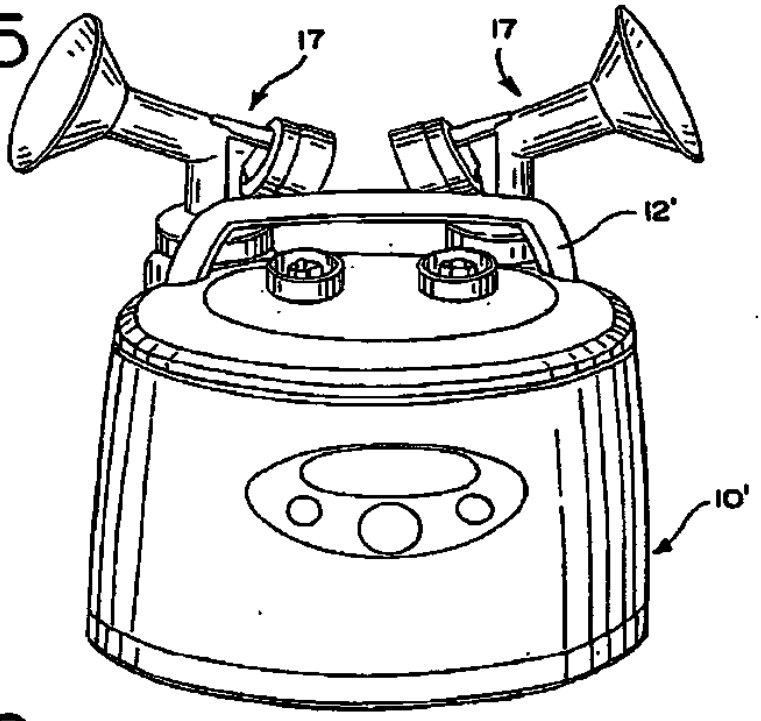


FIG. 16

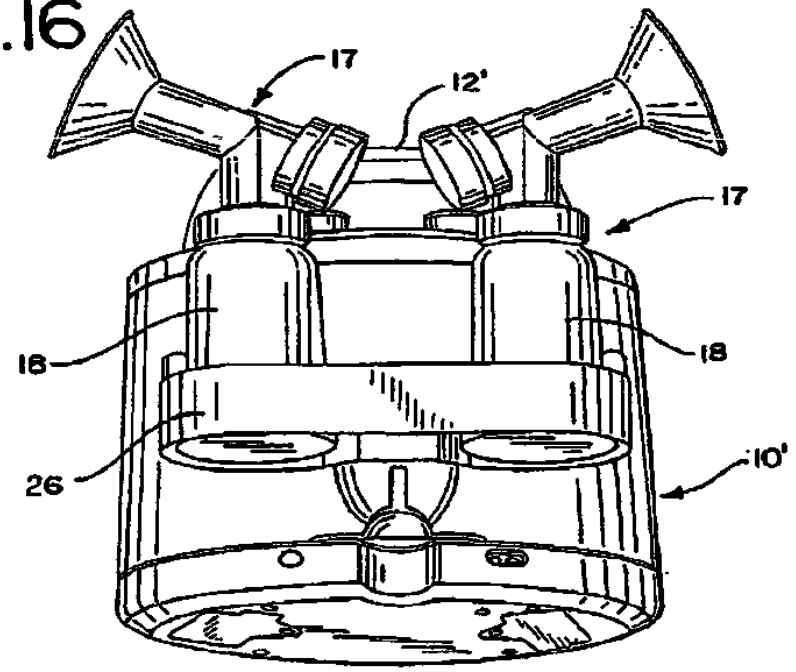


FIG. 17

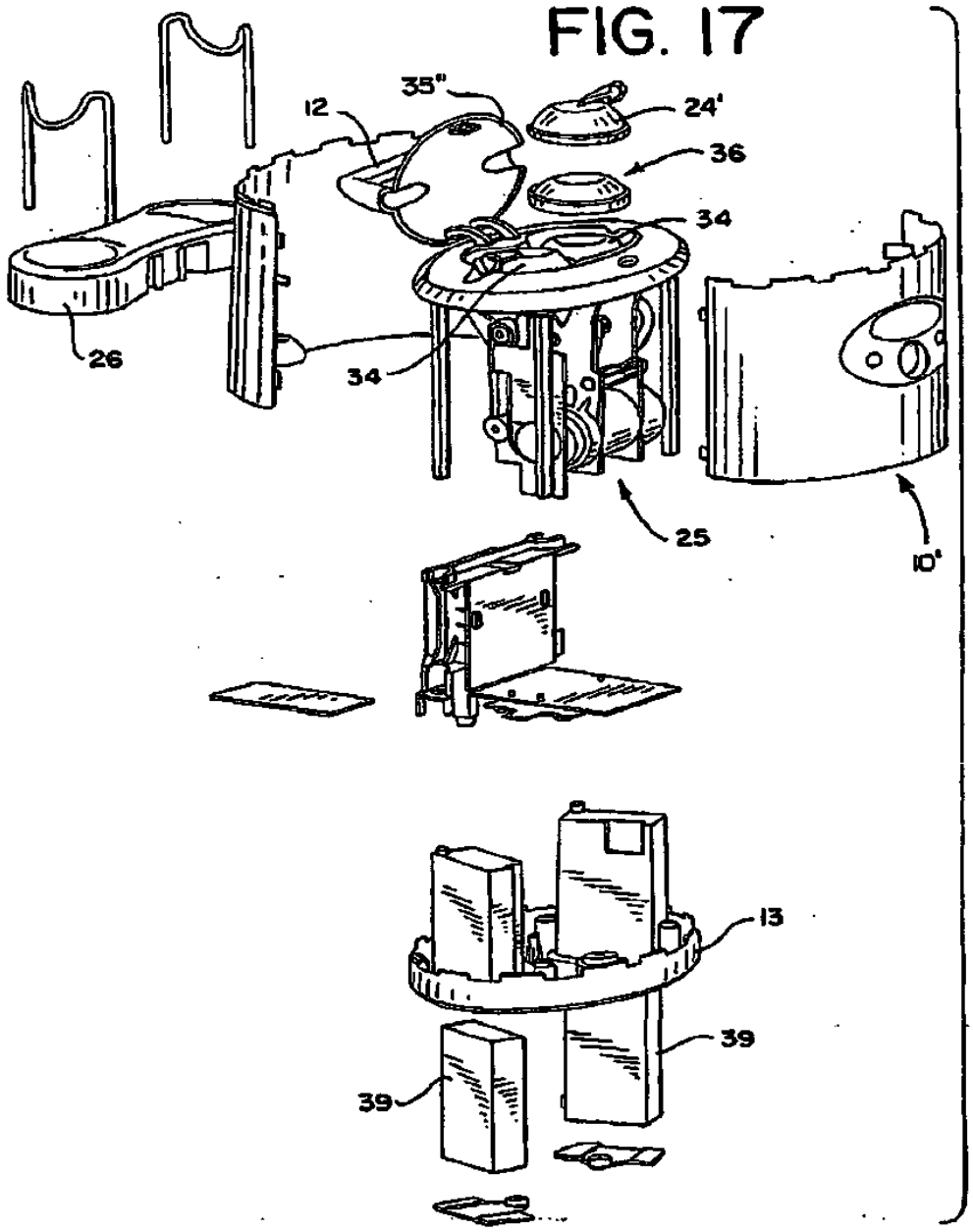


FIG. 19

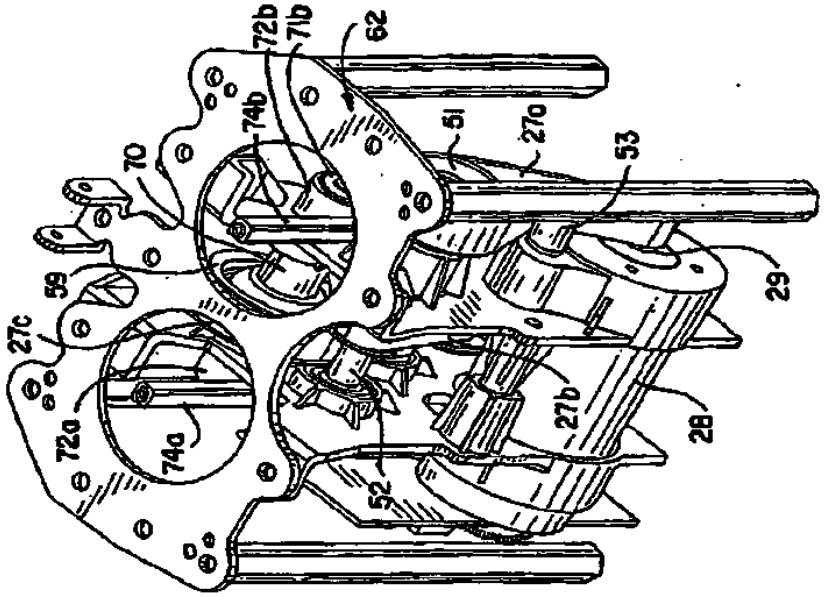

72b
71b
62
74b
51
27a
53
70
59
27c
72a
74a
52
27b
28
29

FIG. 18

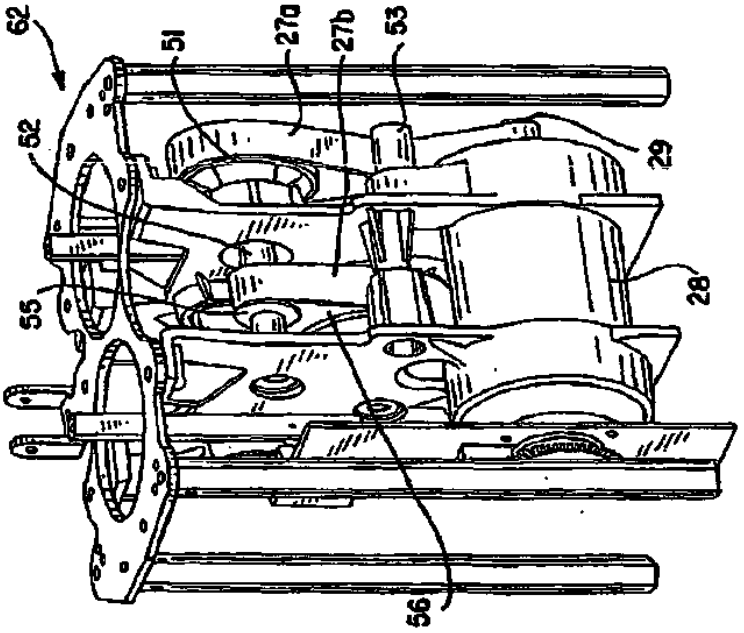

62
51
27a
27b
53
52
29
28
55
56

FIG. 20

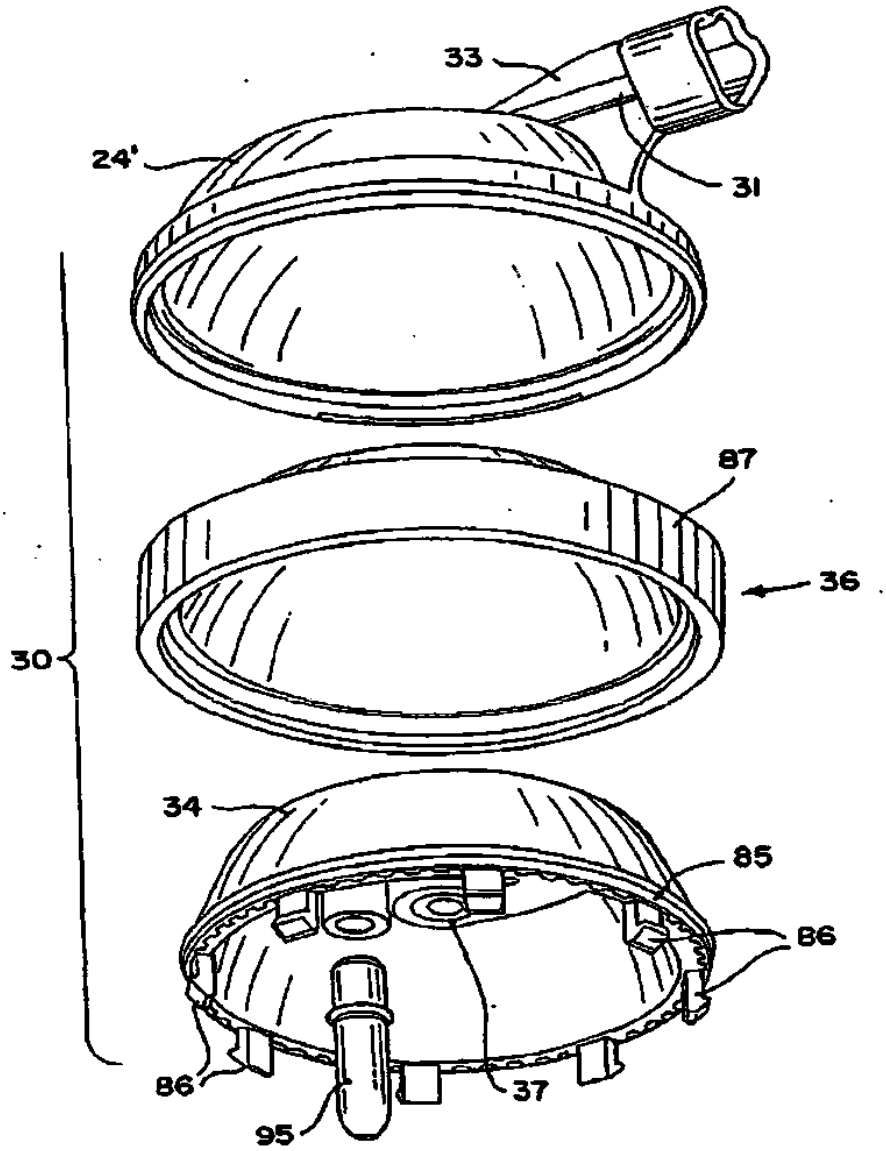


FIG. 21a

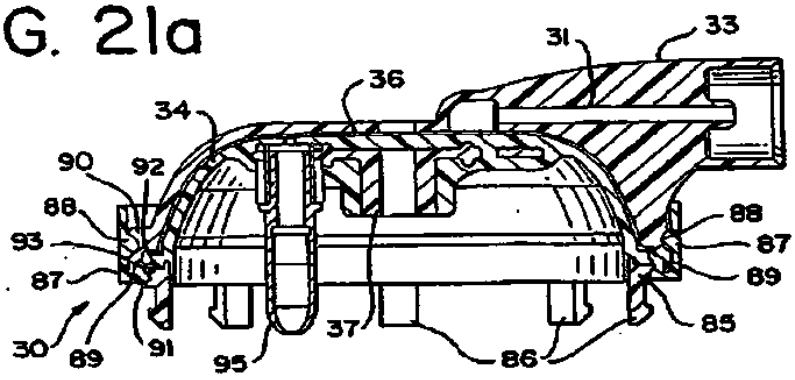


FIG. 21b

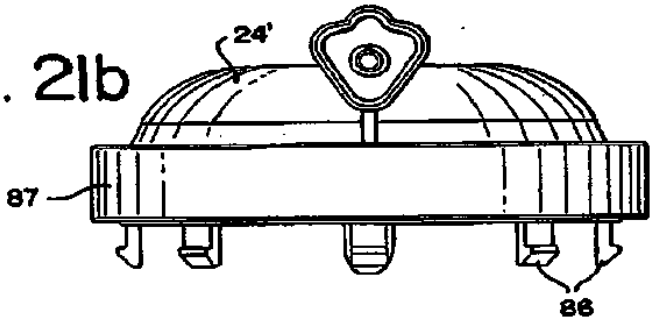


FIG. 21c

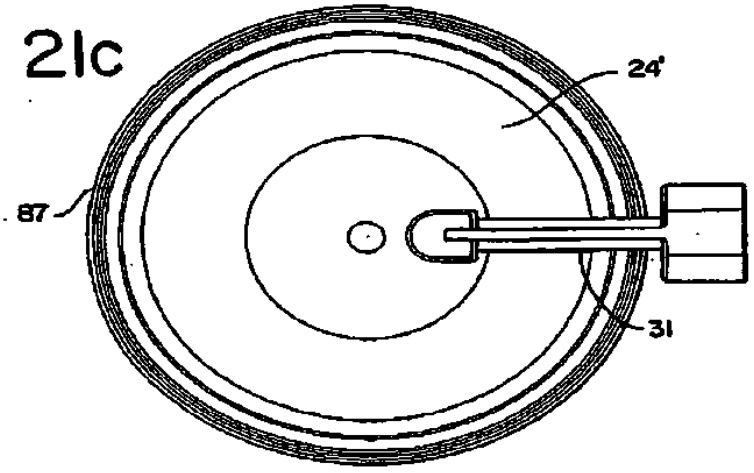


FIG. 22

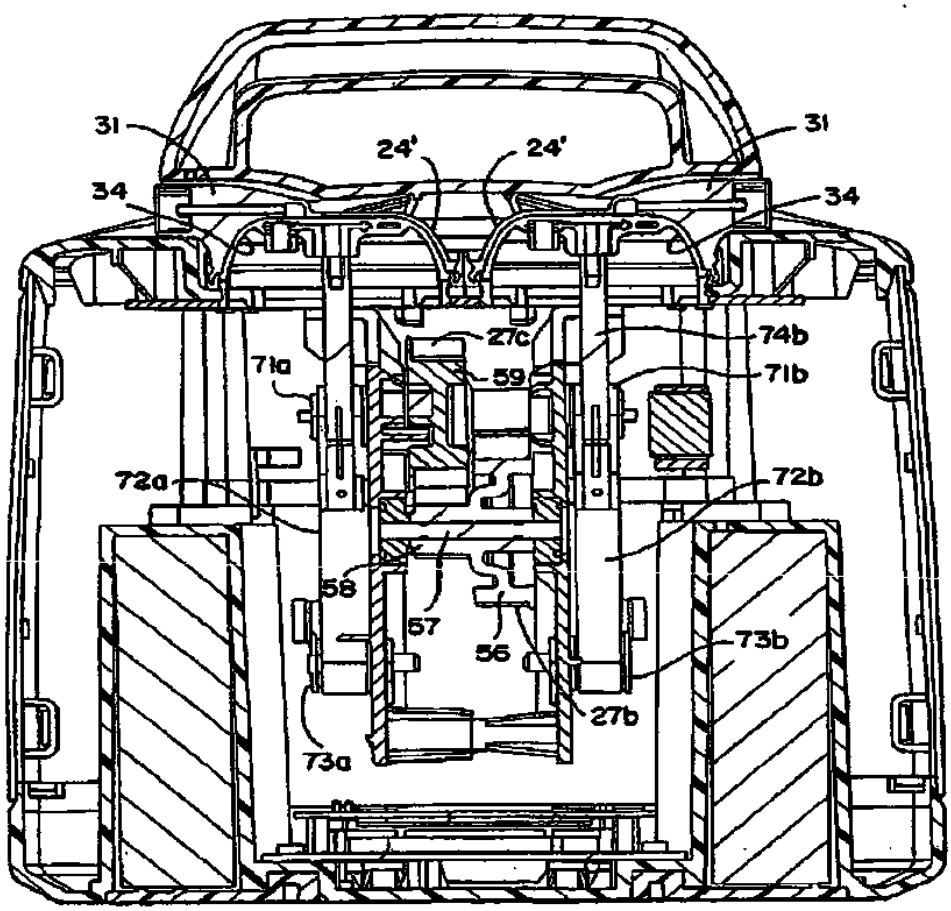


FIG. 23

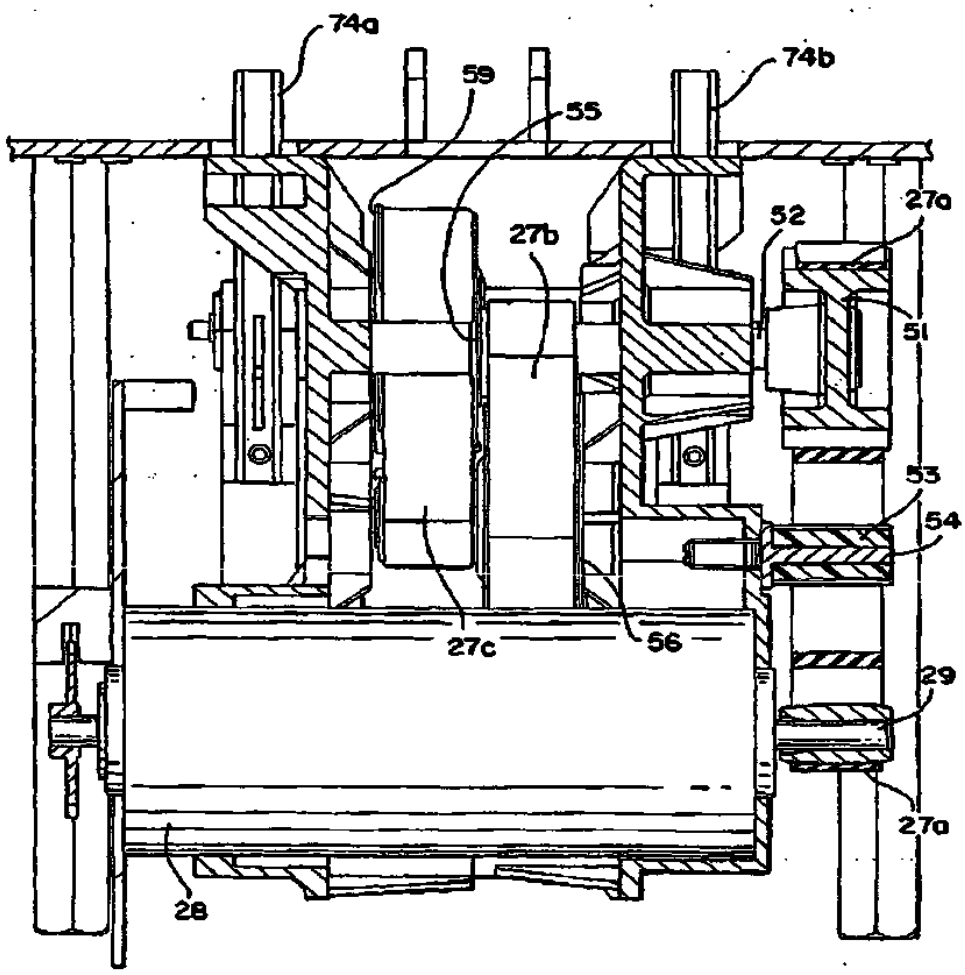
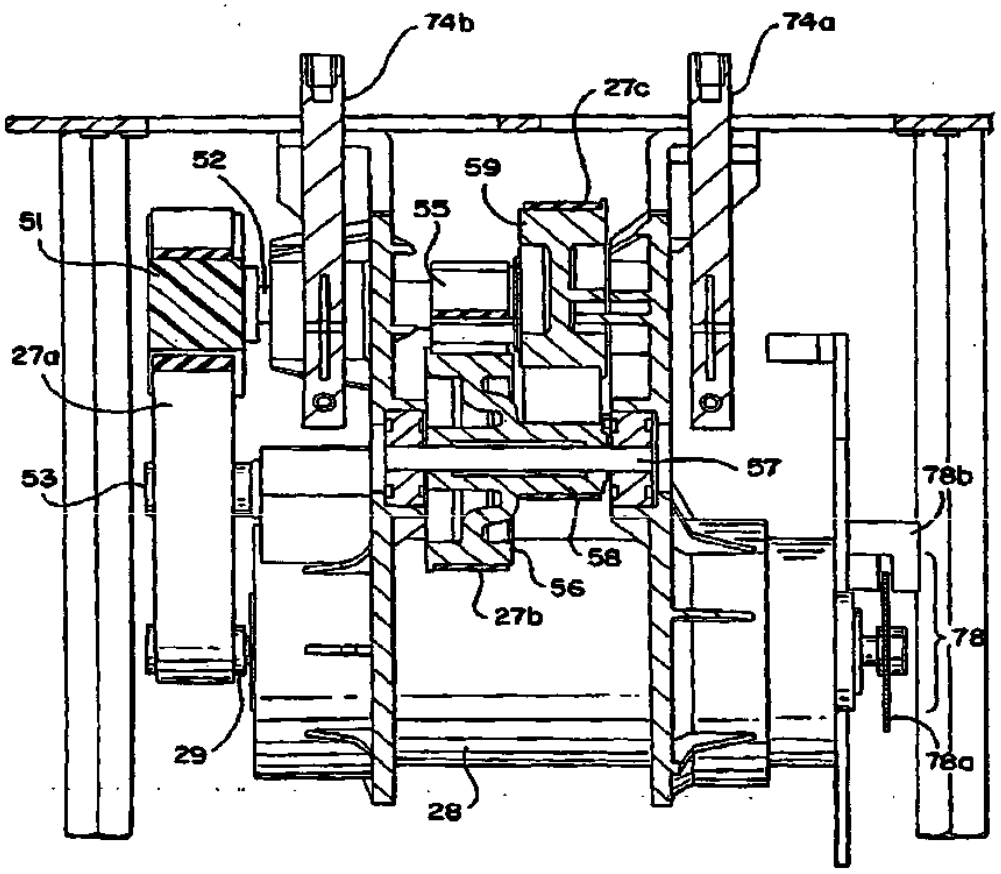


FIG. 24



REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
14.05.2008 Bulletin 2008/20

(51) Int Cl.:
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

(43) Date of publication of application:
23.06.2004 Bulletin 2004/26

(73) Proprietor: **Medela Holding AG**
6340 Baar (CH)

(72) Inventors:
- **Kent, Jacqueline Coral**
  Nedlands, WA 6009 (AU)
- **Mitoulas, Leon Robert**
  Osborne Park, WA 6017 (AU)
- **Ramsay, Donna Tracy**
  Forrestfield, WA 6058 (AU)
- **Hartmann, Peter Edwin**
  Gooseberry Hill, WA 6076 (AU)
- **Cregan, Mark Derek**
  Doubleview, WA 6018 (AU)
- **Sadleir, Rosalind Jane**
  Gainsville, FL 32601-4352 (US)

(74) Representative: **Clerc, Natalia et al**
Isler & Pedrazzini AG
Gotthardstrasse 53
Postfach 1772
8027 Zürich (CH)

(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**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Printed by Jouve, 75001 PARIS (FR)

EP 1 430 918 B1

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.

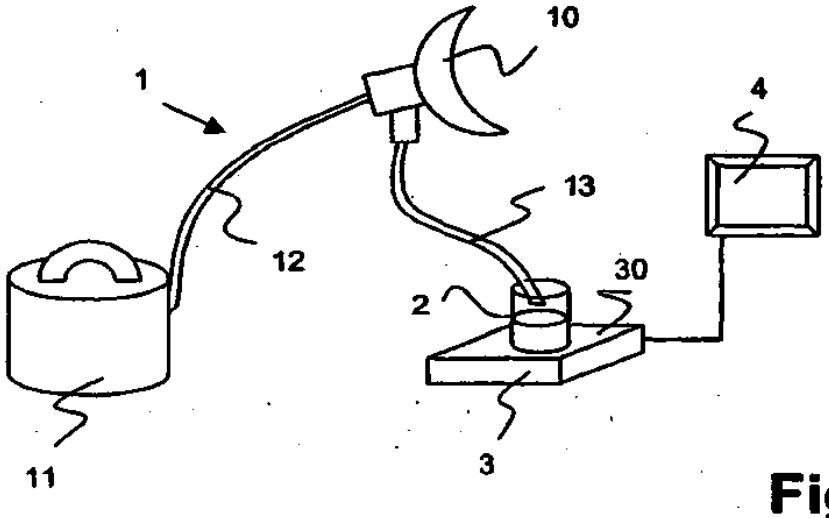


Fig. 1

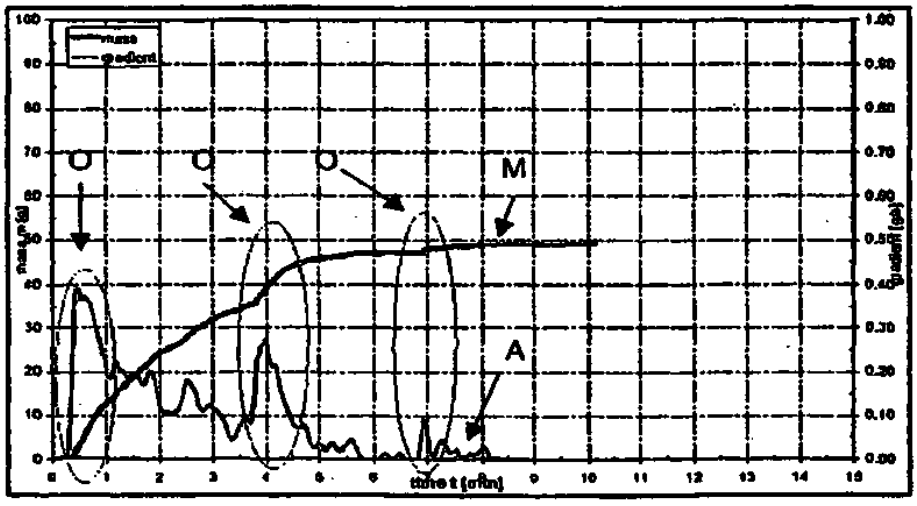


Fig. 2

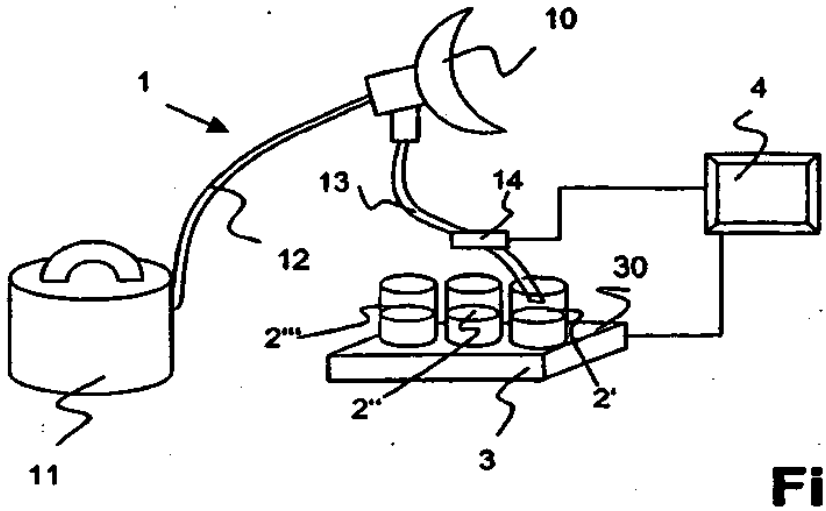


Fig. 3

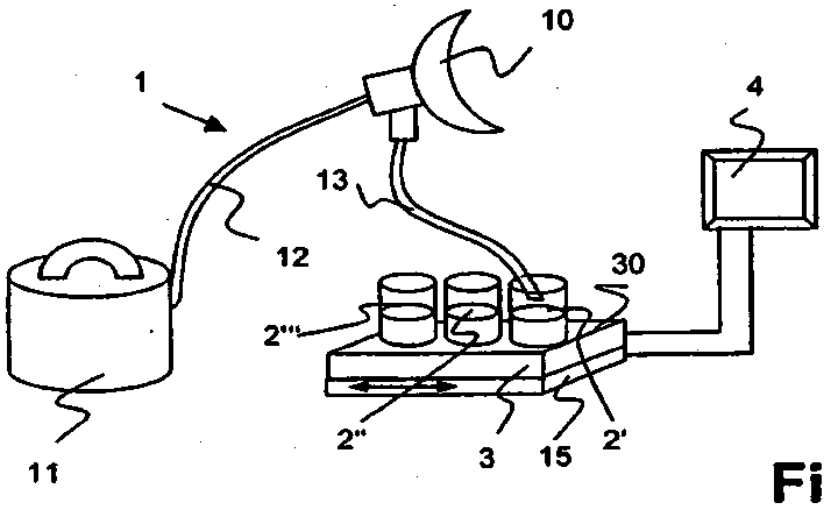


Fig. 4

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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]**

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 077 868 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
27.07.2016 Bulletin 2016/30

(21) Application number: **07861485.6**

(22) Date of filing: **24.10.2007**

(51) Int Cl.:
A61M 1/06 *(2006.01)* ***A61M 31/00*** *(2006.01)*

(86) International application number:
PCT/US2007/022507

(87) International publication number:
WO 2008/057218 (15.05.2008 Gazette 2008/20)

(54) **SELF-RETURNING CONTAMINATION BARRIER**

SELBSTZURÜCKKEHRENDE KONTAMINATIONSBARRIERE

BARRIÈRE ANTI-CONTAMINATION À RETOUR AUTOMATIQUE

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC MT NL PL PT RO SE SI SK TR

(30) Priority: **01.11.2006 US 591276**

(43) Date of publication of application:
15.07.2009 Bulletin 2009/29

(73) Proprietor: **Medela Holding AG**
6340 Baar (CH)

(72) Inventors:
- **LUZBETAK, Mark A.**
  Kildeer, IL 60047 (US)
- **SUTRINA, Thomas A.**
  Rockford, IL 61108 (US)
- **PFENNIGER, Erich**
  6030 Ebikon (CH)
- **BOSSHARD, Patrik**
  6343 Buonas (CH)

(74) Representative: **Clerc, Natalia et al**
Isler & Pedrazzini AG
Gotthardstrasse 53
Postfach 1772
8027 Zürich (CH)

(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

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Printed by Jouve, 75001 PARIS (FR)

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 pre-loaded 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.

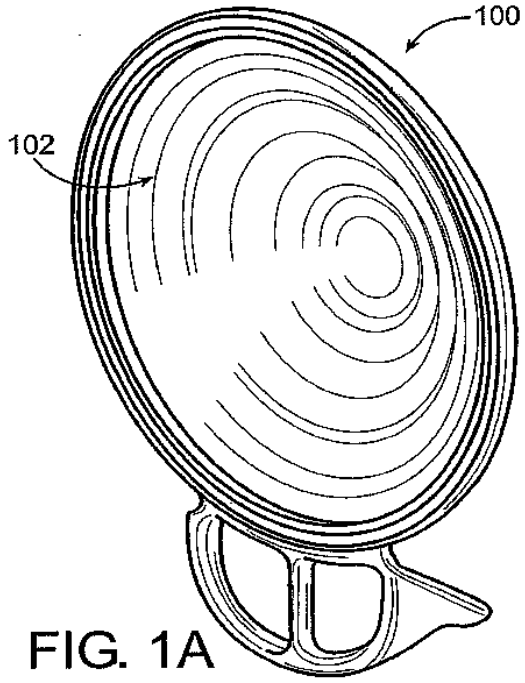


FIG. 1A

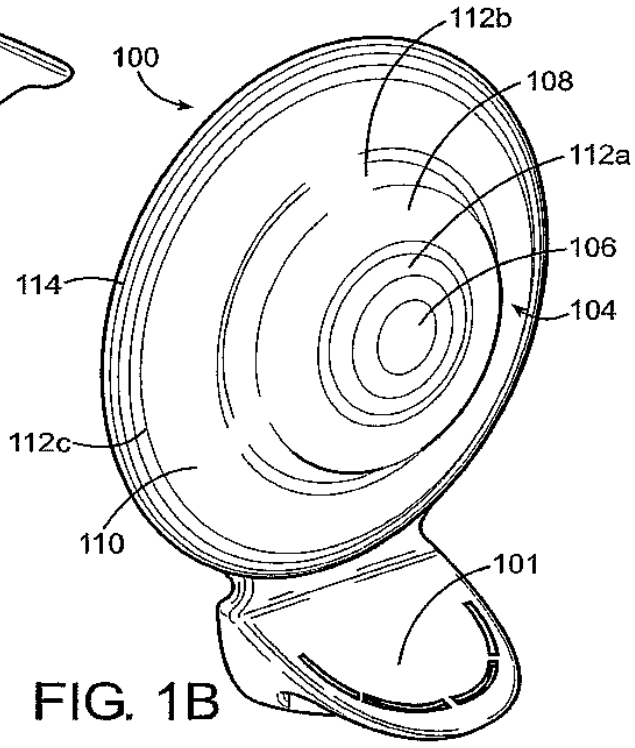


FIG. 1B

Free / As Molded

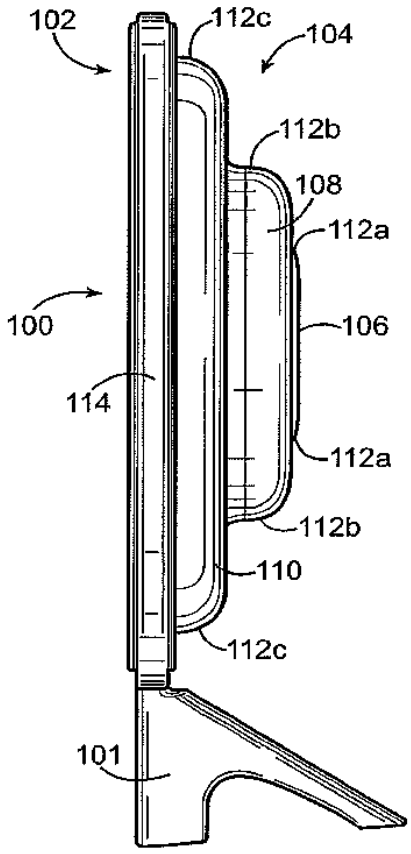


FIG. 2

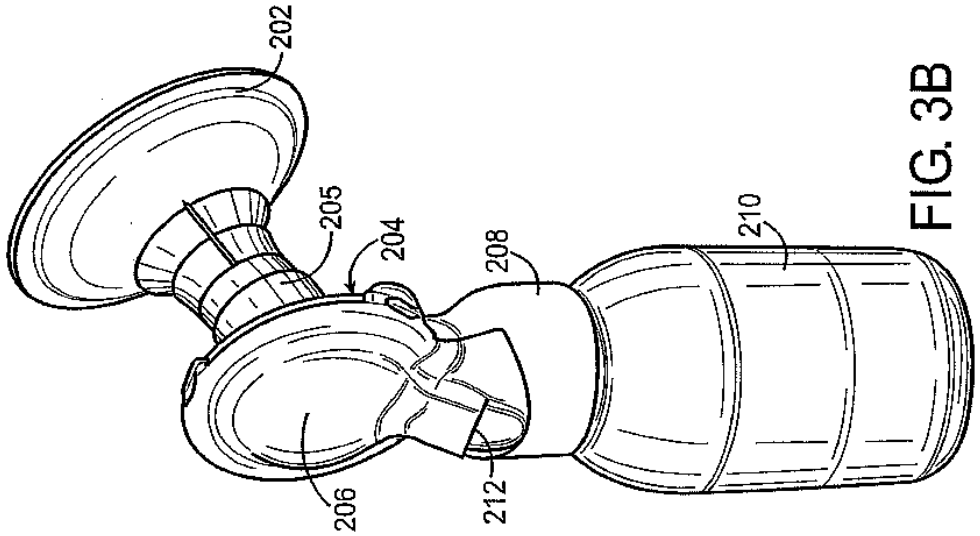


FIG. 3B

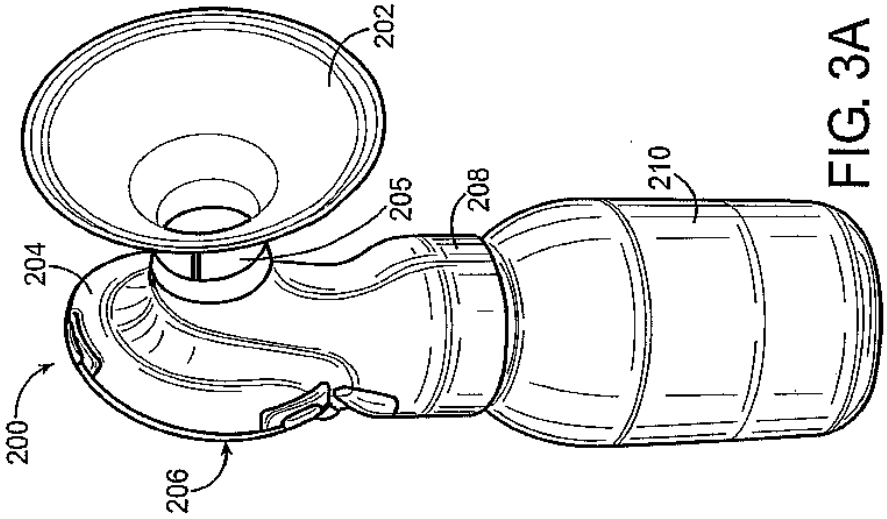


FIG. 3A

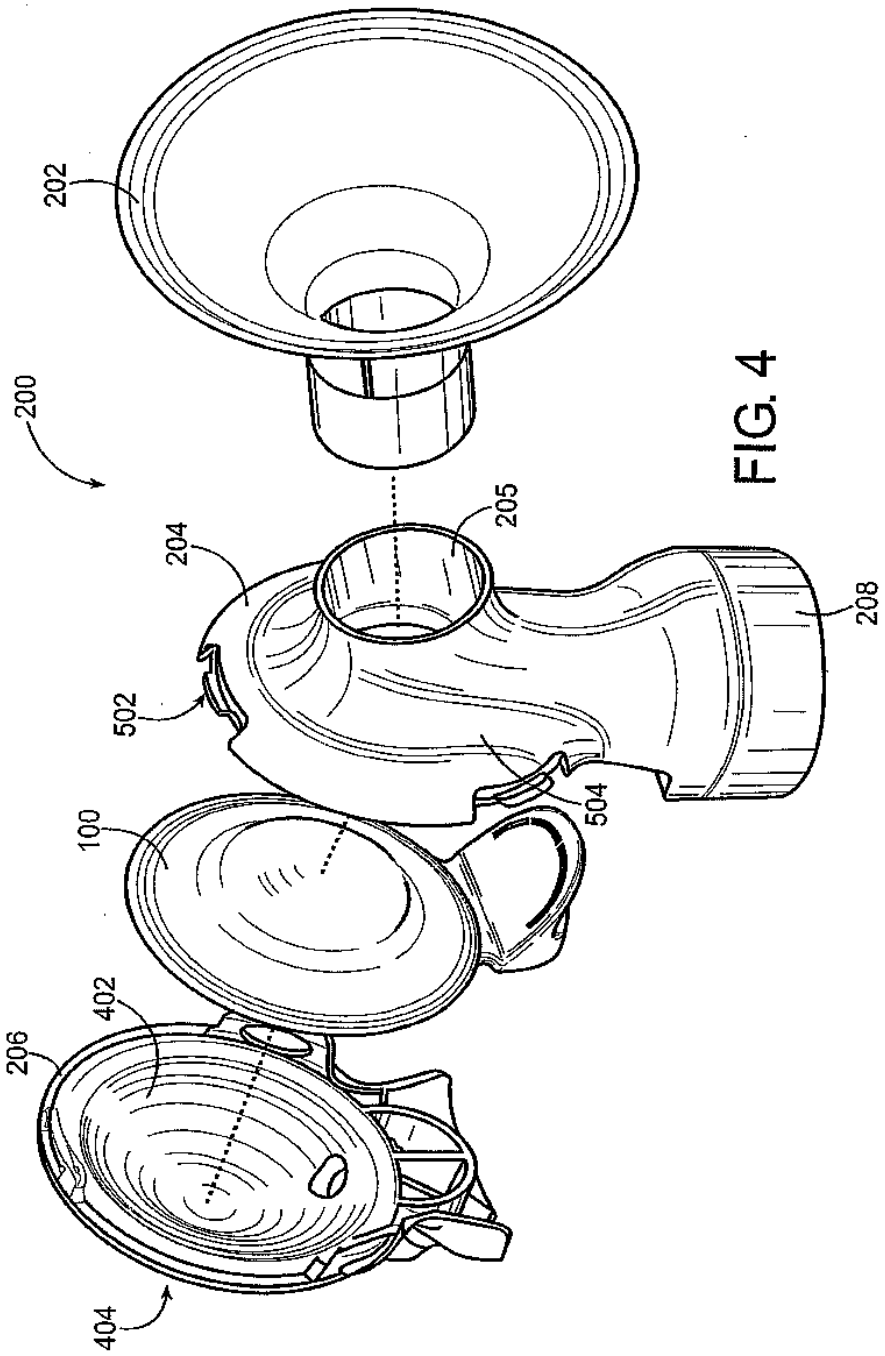


FIG. 4

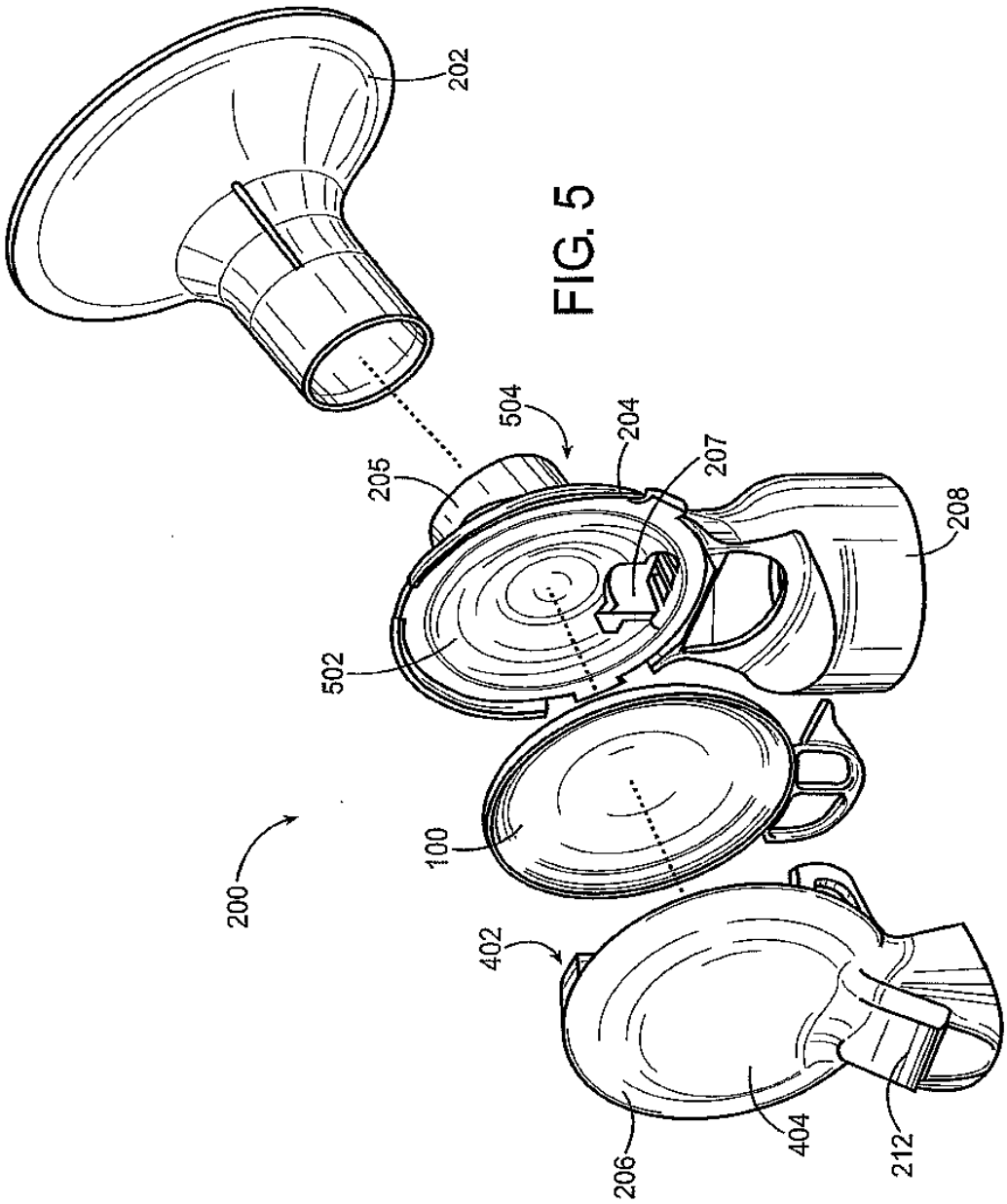


FIG. 5

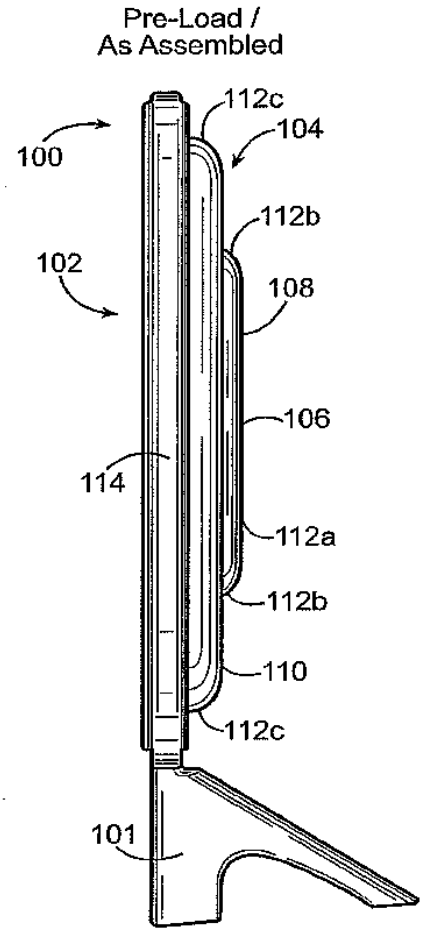

Pre-Load /
As Assembled
100
102
112c
104
112b
108
106
114
112a
112b
110
112c
101

FIG. 6A

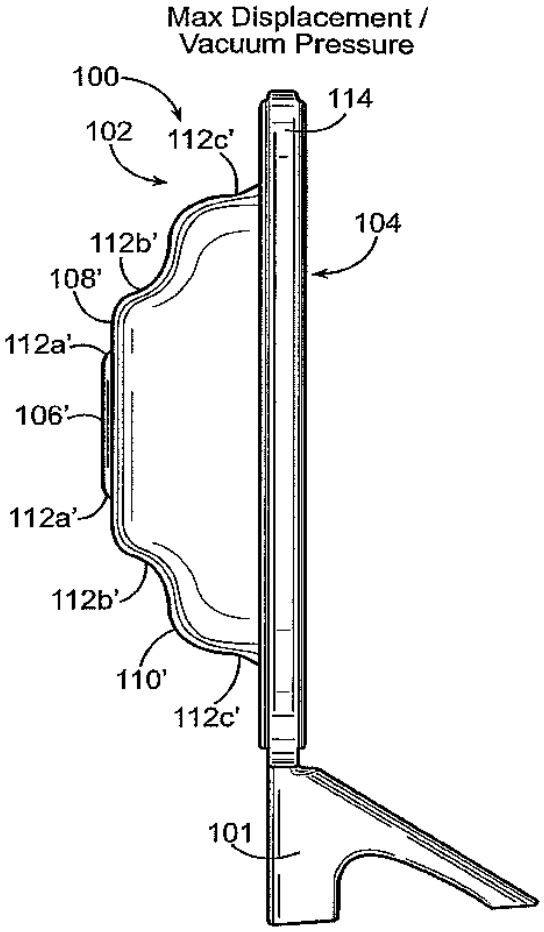

Max Displacement /
Vacuum Pressure
100
102
112c'
114
104
112b'
108'
112a'
106'
112a'
112b'
110'
112c'
101

FIG. 6B

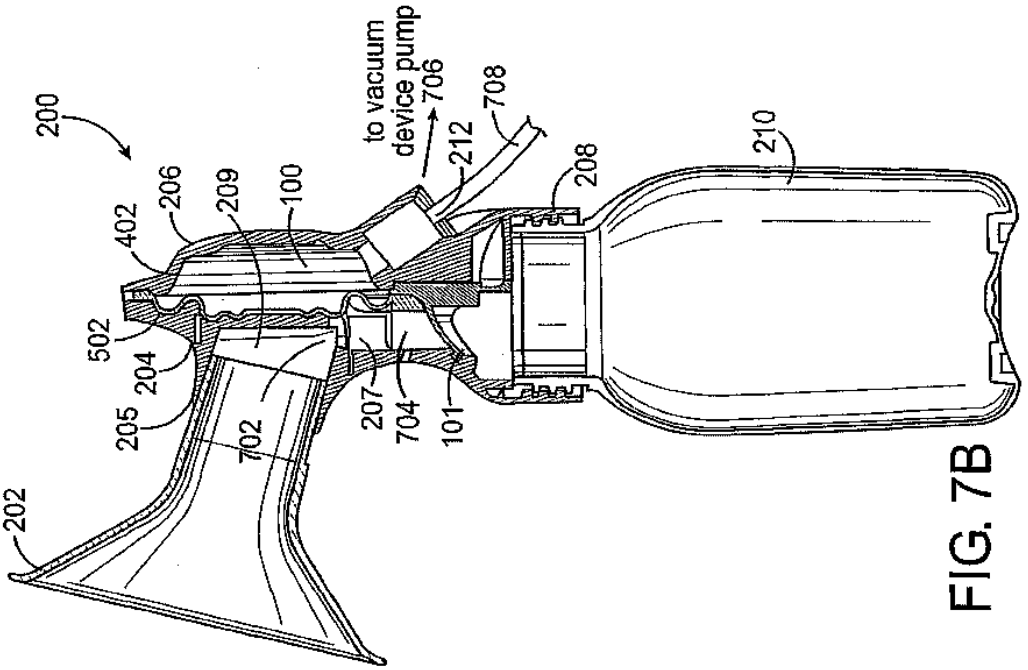

200
206
209
100
402
502
204
205
202
702
207
704
101
to vacuum
device pump
706
212
708
208
210

FIG. 7B

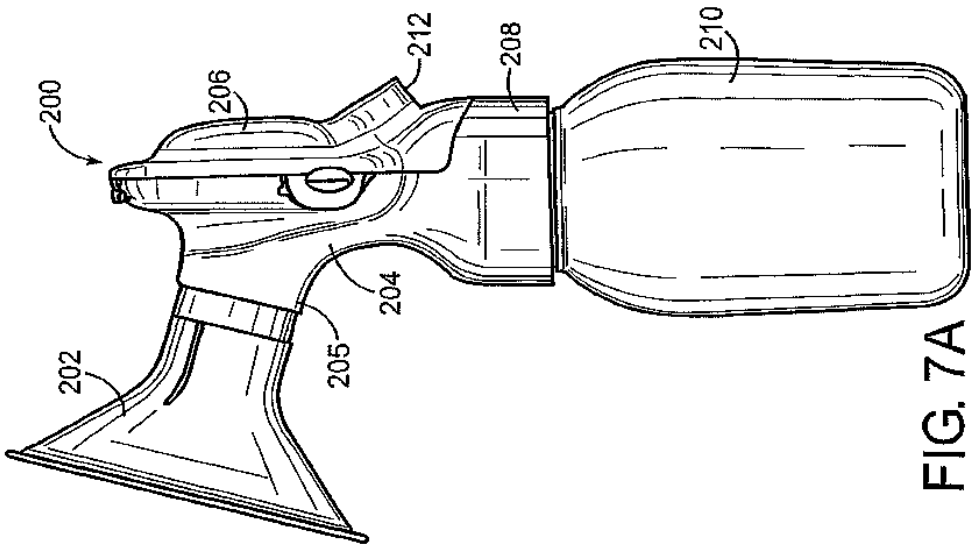

200
206
212
208
210
204
205
202

FIG. 7A

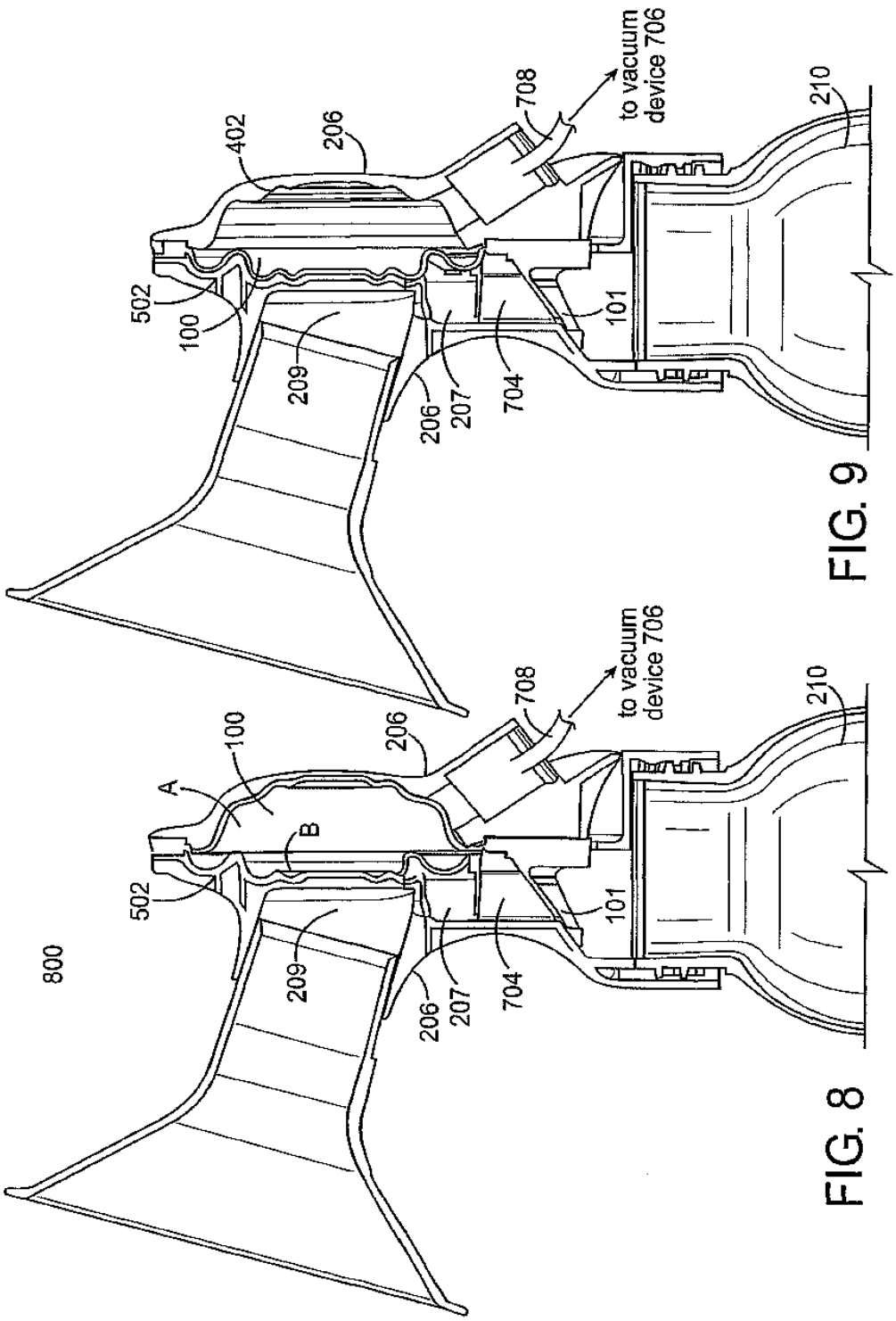

800
502
100
A
B
209
206
207
704
101
206
708
to vacuum device 706
210
402
206
708
to vacuum device 706
210
502
100
209
206
207
704
101

FIG. 8

FIG. 9

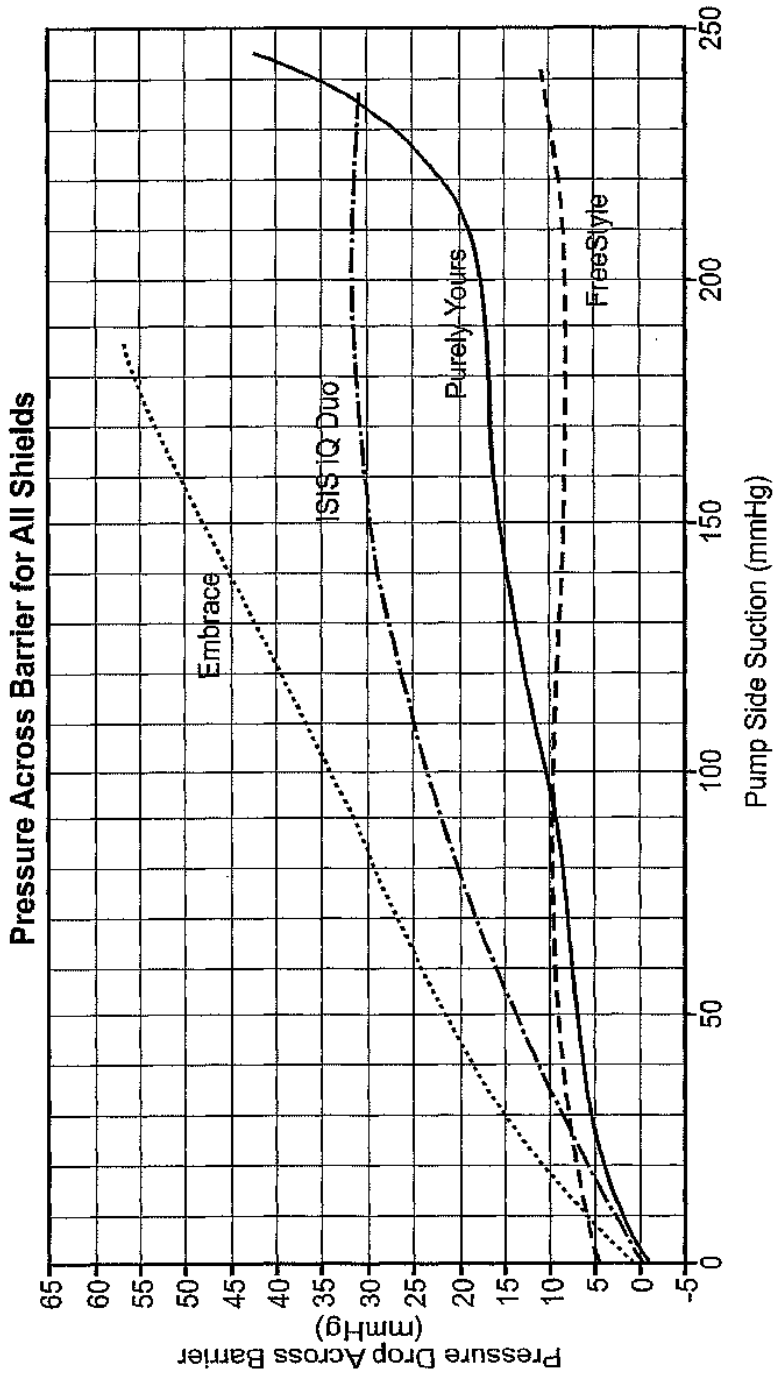

Pressure Across Barrier for All Shields
Pressure Drop Across Barrier (mmHg)
65
60
55
50
45
40
35
30
25
20
15
10
5
0
-5
0
50
100
150
200
250
Pump Side Suction (mmHg)
Embrace
ISIS iQ Duo
Purely Yours
FreeStyle

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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]**

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 210 628 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
13.02.2013 Bulletin 2013/07

(51) Int Cl.:
A61M 1/06 *(2006.01)*

(21) Application number: **10004299.3**

(22) Date of filing: **07.12.2000**

(54) **Breastpump**

Brustpumpe

Tire-lait

(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**
30.12.1999 US 475426
30.12.1999 US 475681
30.12.1999 US 476075
30.12.1999 US 476076

(43) Date of publication of application:
28.07.2010 Bulletin 2010/30

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
00993020.7 / 1 263 487

(73) Proprietor: **Medela Holding AG**
6340 Baar (CH)

(72) Inventors:
- **Silver, Brian H.**
  Cary, IL 60013 (US)
- **Larsson, Michael**
  6300 Zug (CH)
- **Dettling, Michael**
  6424 Lauerz (CH)
- **Eixler, Jürgen**
  6330 Cham (CH)
- **Greter, Andy**
  6340 Baar (CH)
- **Annis, Larry D.**
  Elgin, IL 60123 (US)
- **Weston, Richard S.**
  Encinitas, CA 92024 (US)

(74) Representative: **Clerc, Natalia et al**
Isler & Pedrazzini AG
Postfach 1772
8027 Zürich (CH)

(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

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Printed by Jouve, 75001 PARIS (FR)

EP 2 210 628 B1

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-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.

[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

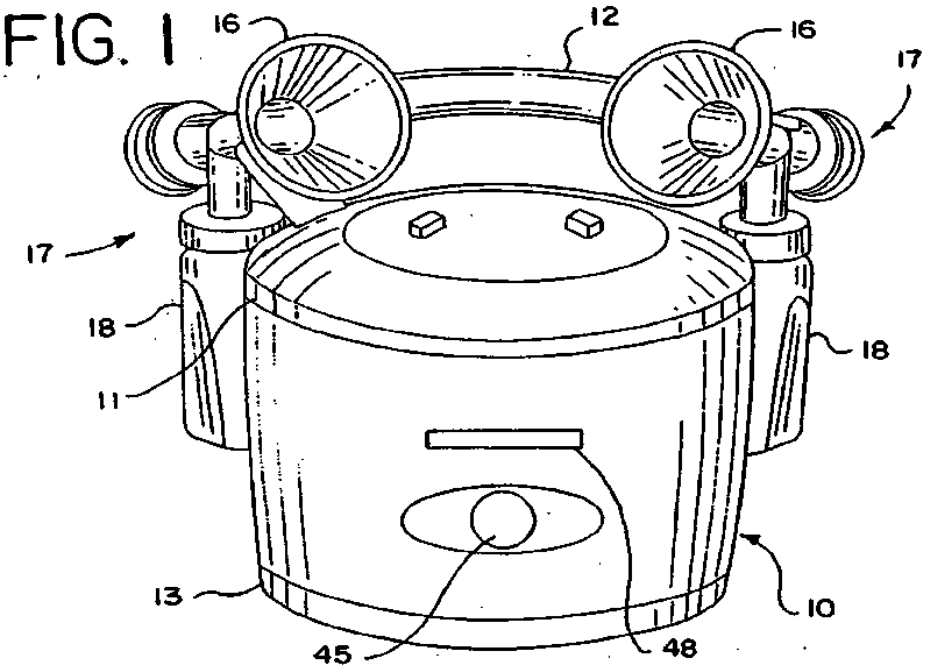


FIG. 2

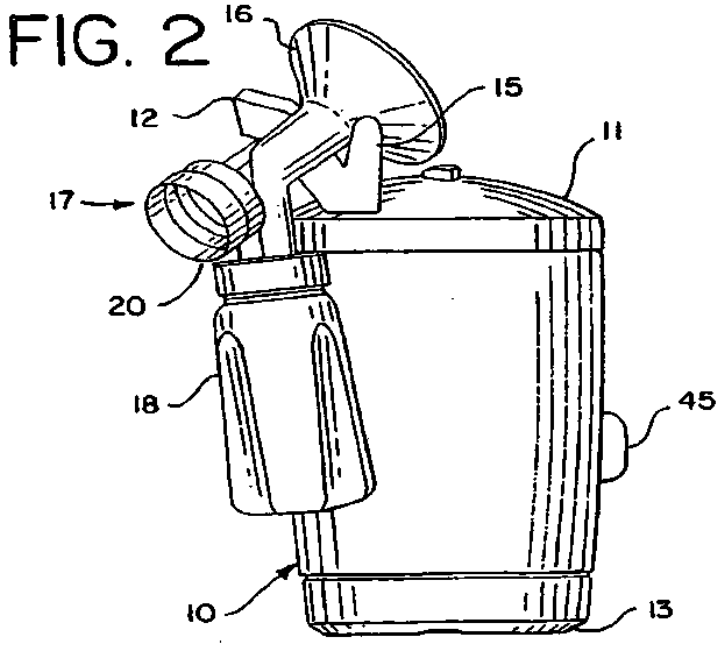


FIG. 3

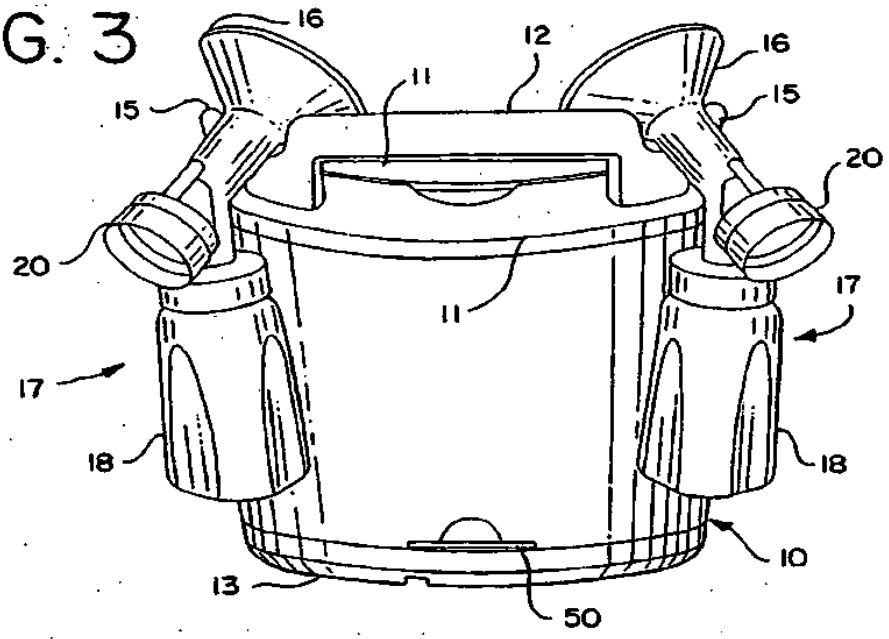

16
12
16
11
15
15
20
20
11
17
17
18
18
10
13
50

FIG. 4

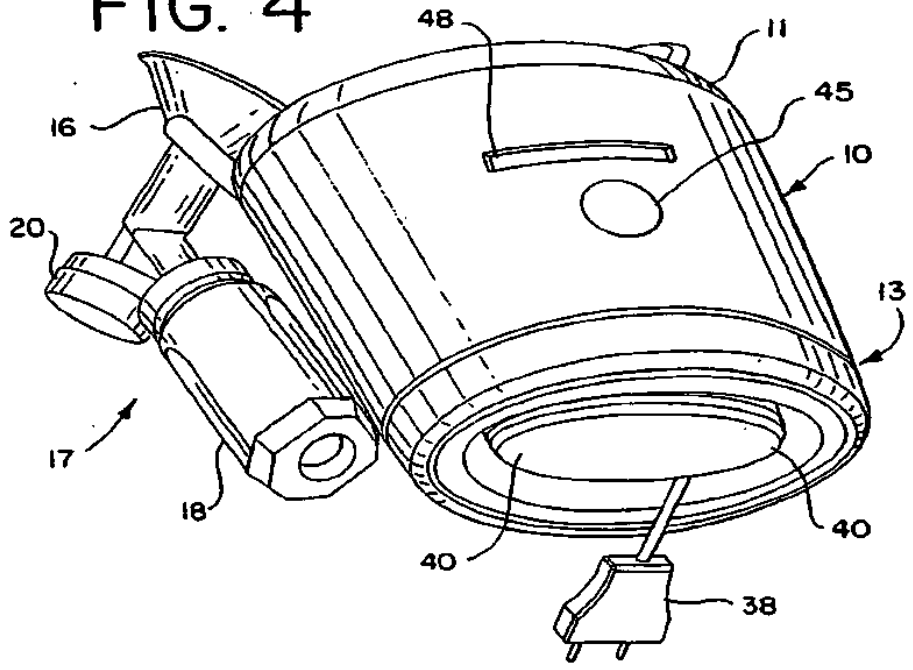

48
11
45
16
10
20
13
17
18
40
40
38

FIG. 5

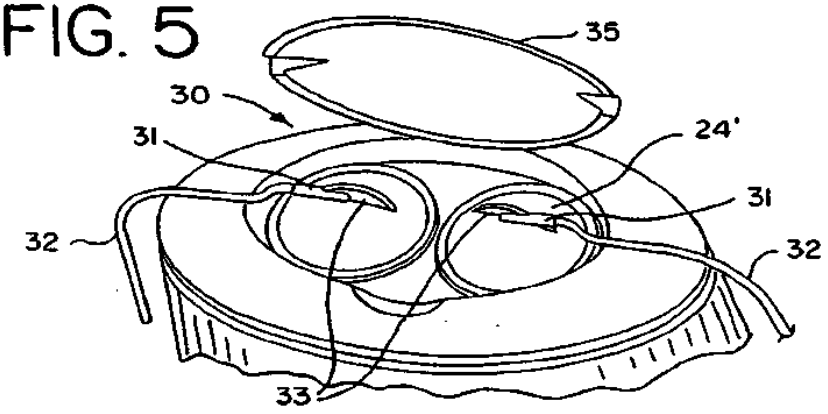


FIG. 6

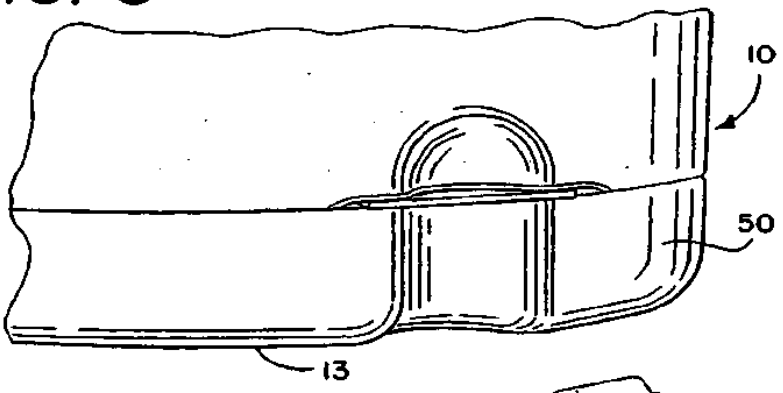


FIG. 7

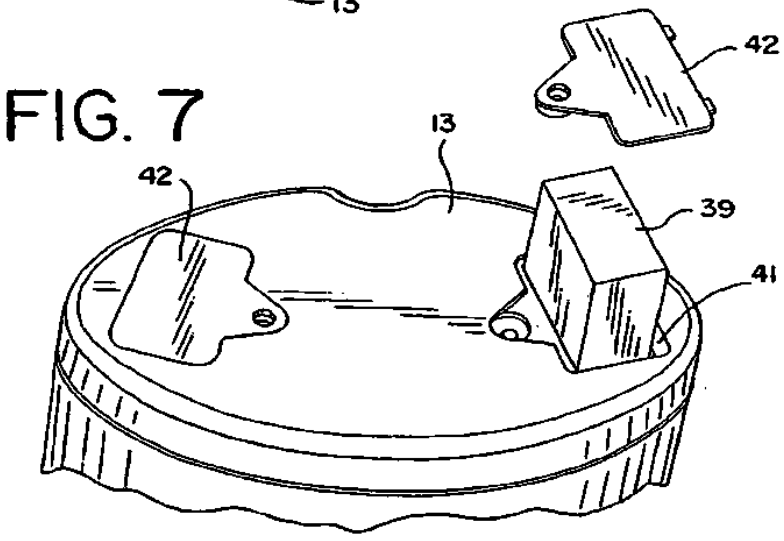


FIG. 8

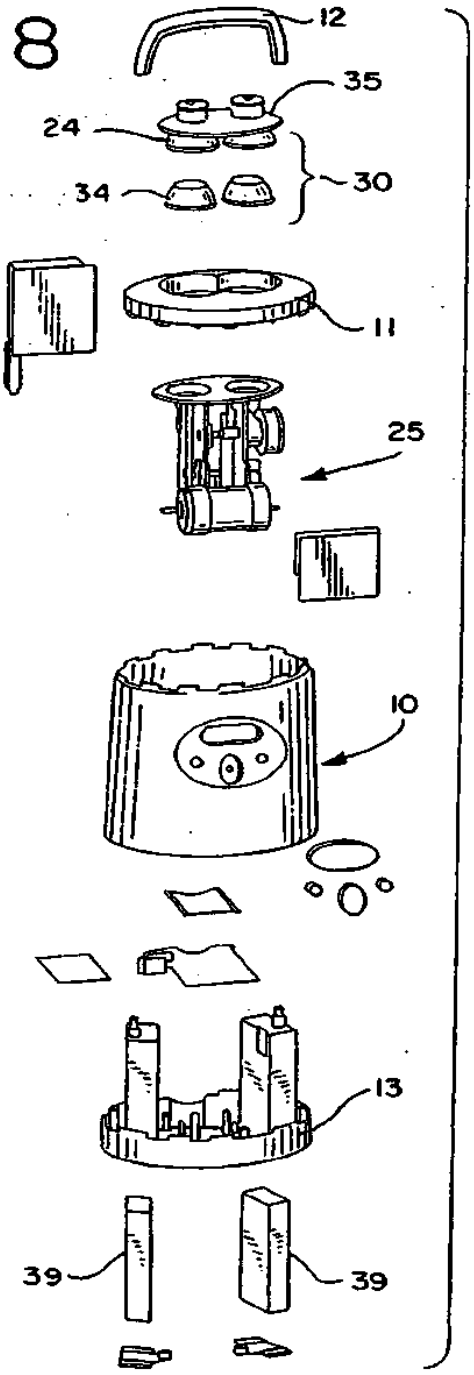


FIG. 9

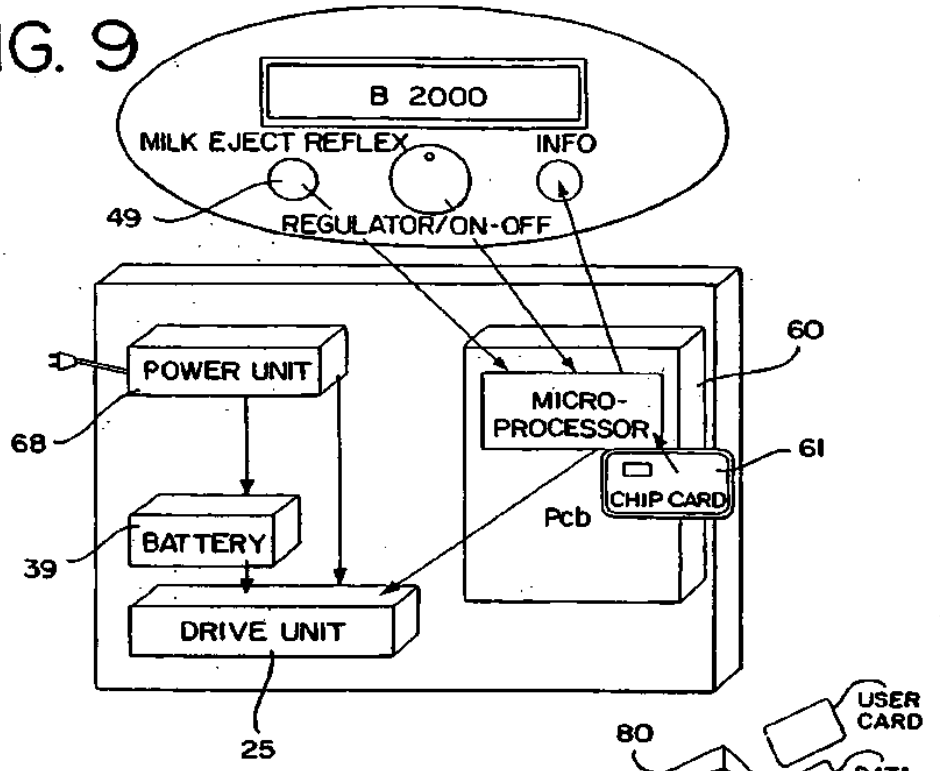

B 2000
MILK EJECT REFLEX
INFO
49
REGULATOR/ON-OFF
60
POWER UNIT
MICRO-
PROCESSOR
68
61
CHIP CARD
Pcb
BATTERY
39
DRIVE UNIT
25
80
USER
CARD
DATA
CARD
RESEARCH
CARD

FIG. 10

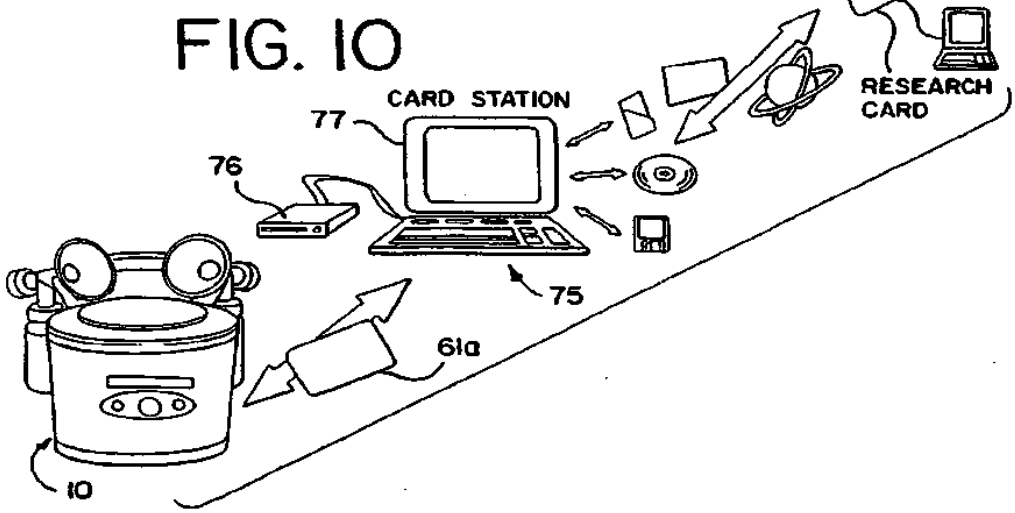
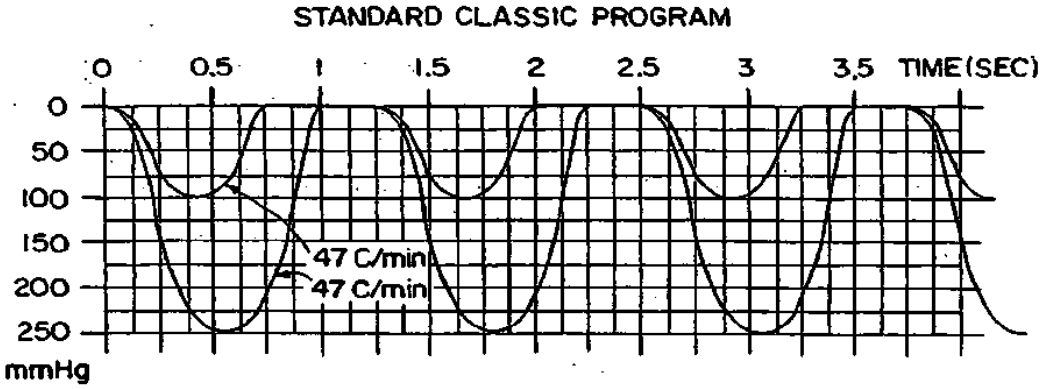
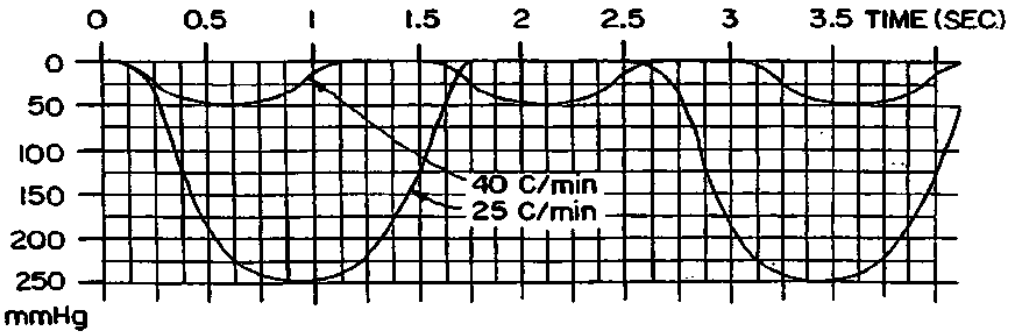

CARD STATION
77
76
75
61a
10

FIG. 11



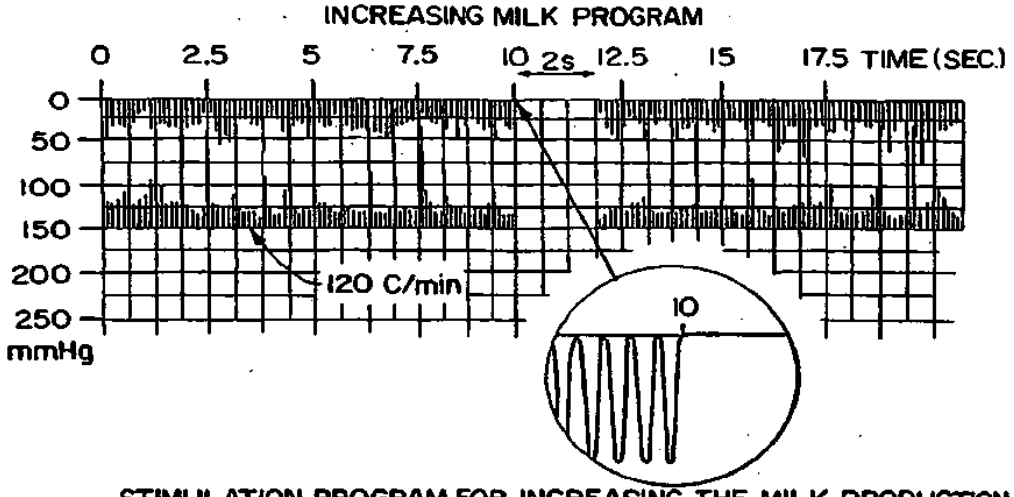
SUCTION CURVES AND CYCLES EQUAL TO CLASSIC
VACUUM RANGE: 100 - 250mmHg
CYCLES: 47/min (NOT ADJUSTABLE)

FIG. 12



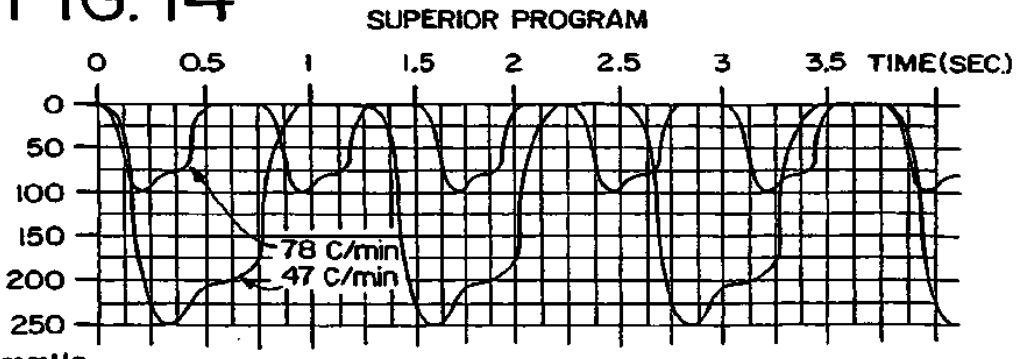
EXTREMELY GENTLE AND SLOW SUCTION
DECREASED VACUUM YIELDS GENTLER AND SLOWER SUCTION
VACUUM RANGE: 20 - 250
CYCLES: 25 - 40/min (CONTROLLED BY VACUUM LEVEL)

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

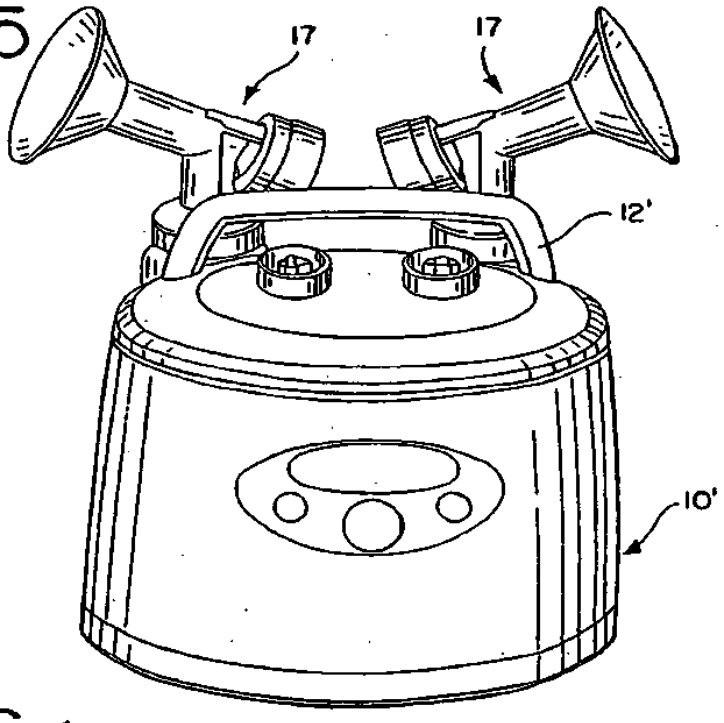


FIG. 16

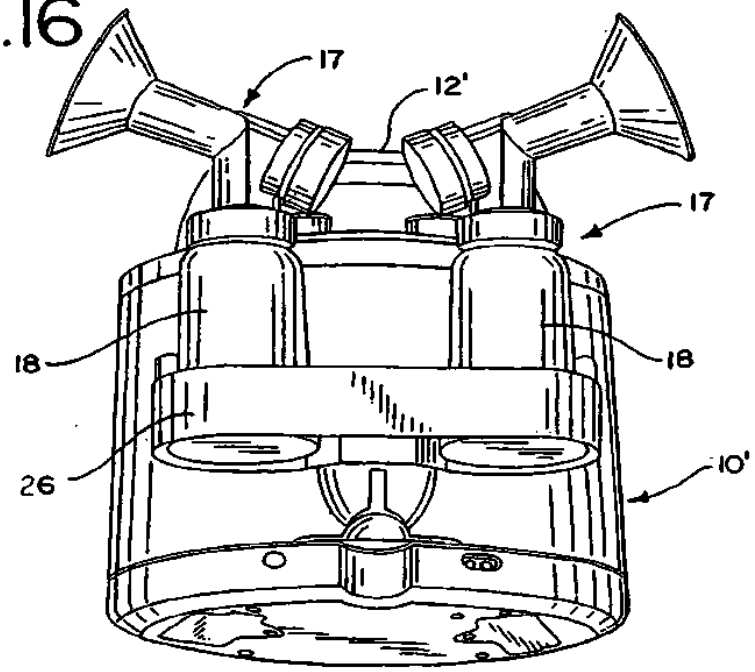


FIG. 17

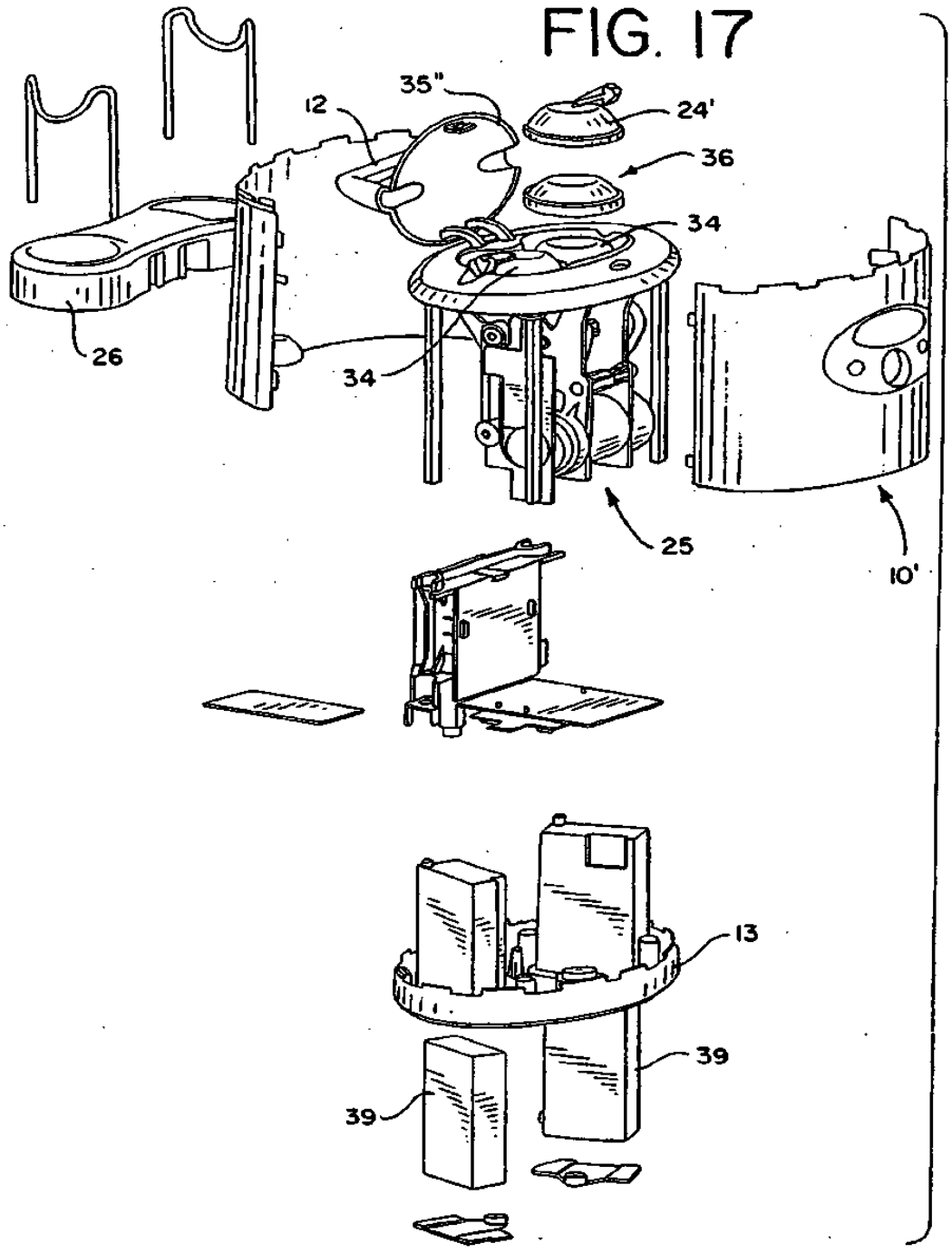


FIG. 19

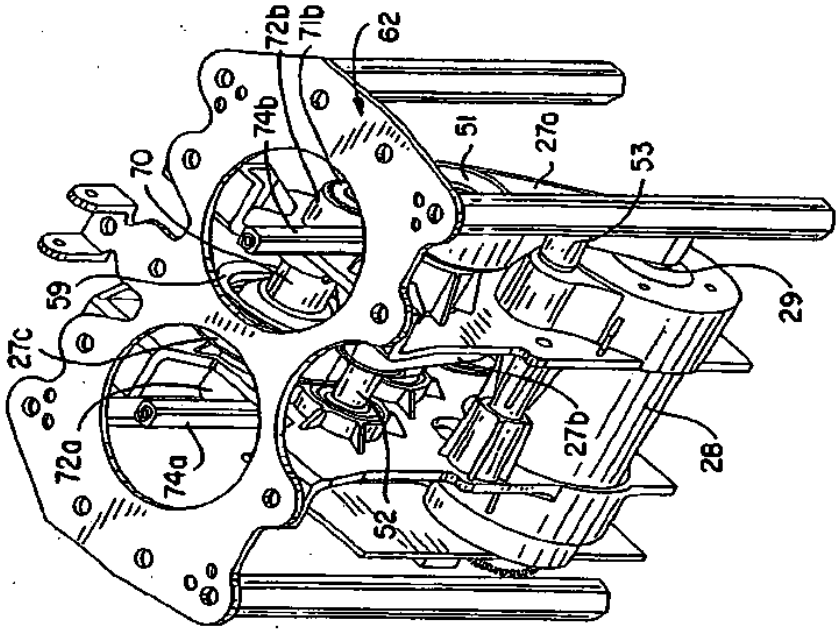

72b
71b
62
74b
70
51
27a
53
59
29
27c
72a
74a
27b
28
52

FIG. 18

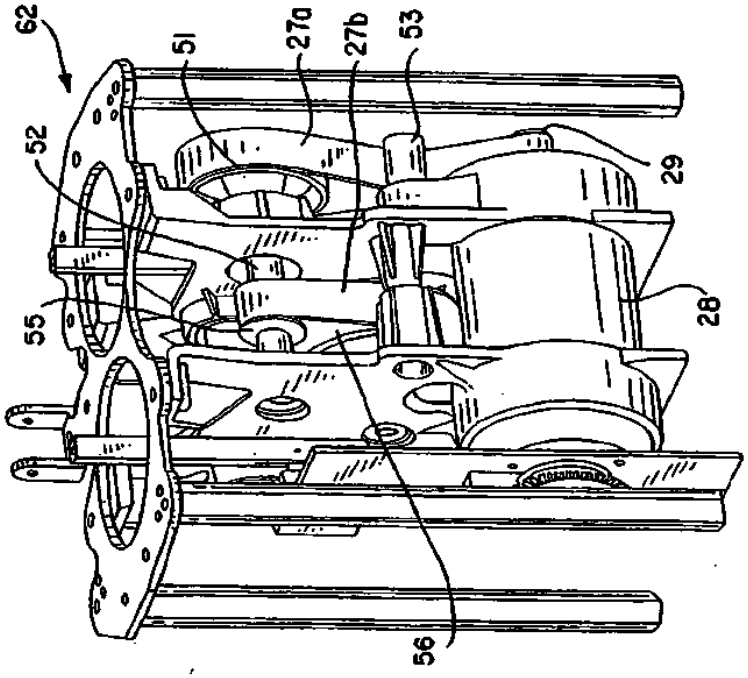

62
51
27a
27b
53
52
29
55
28
56

FIG. 20

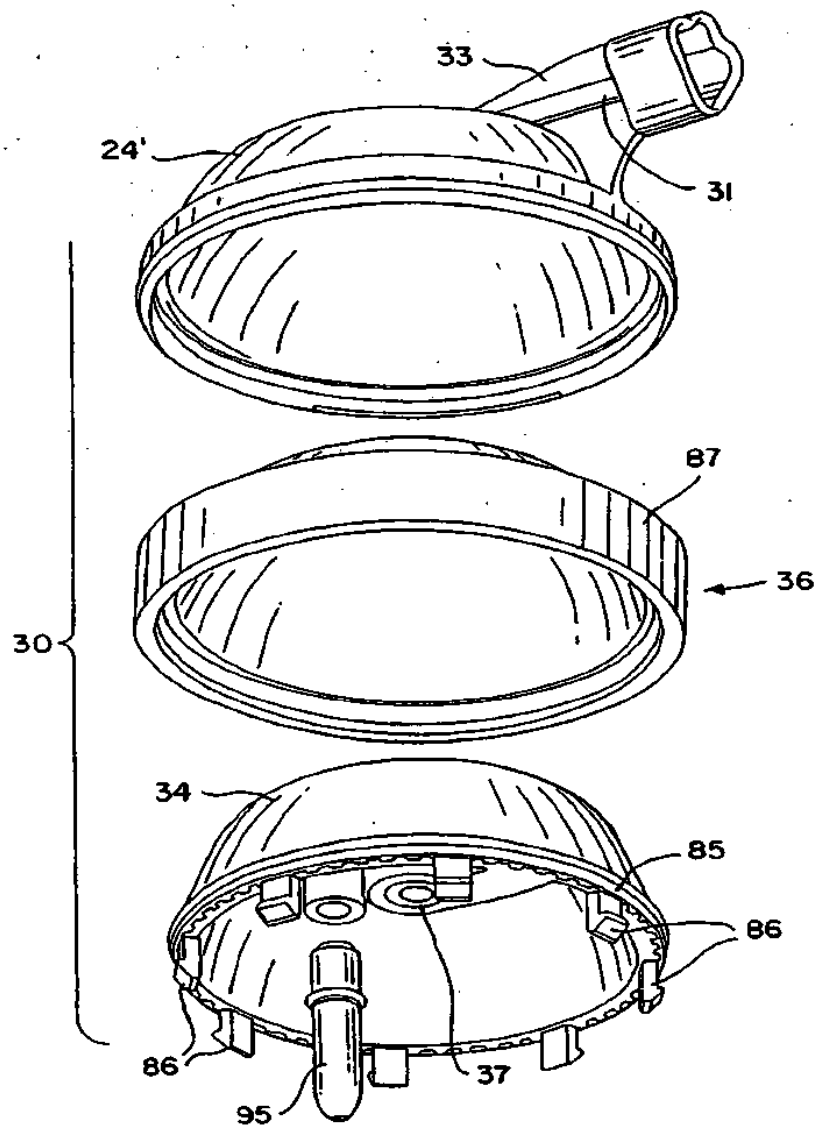


FIG. 21a

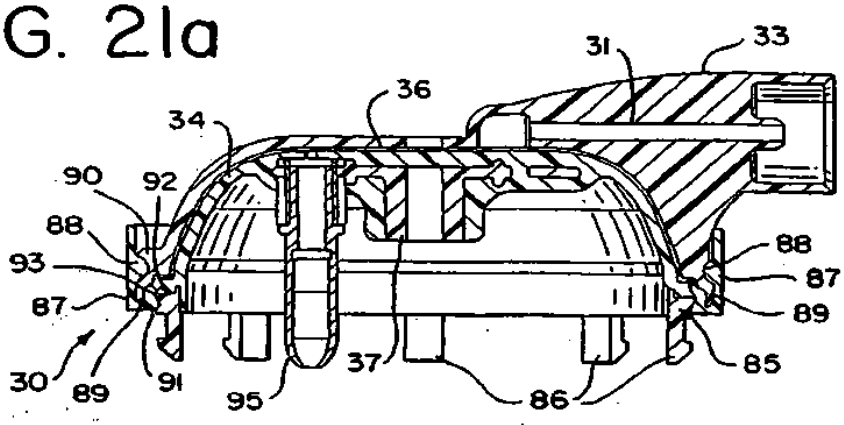


FIG. 21b

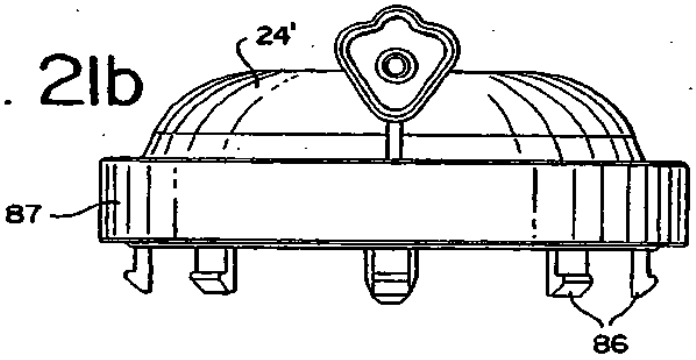


FIG. 21c

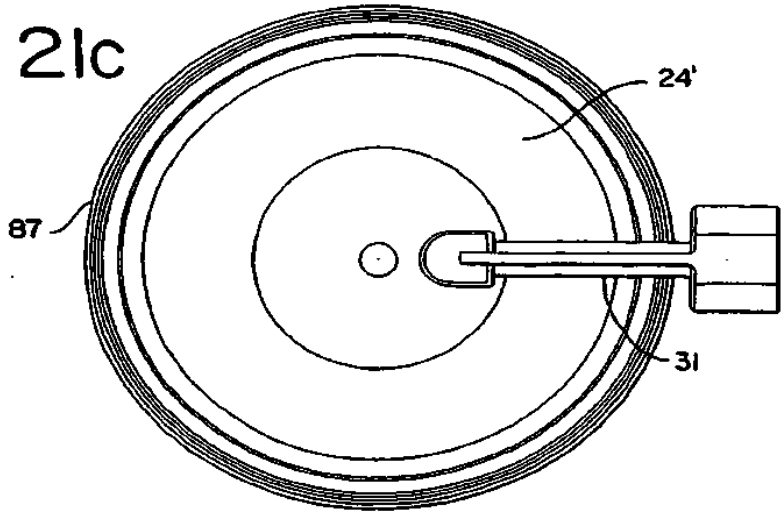


FIG. 22

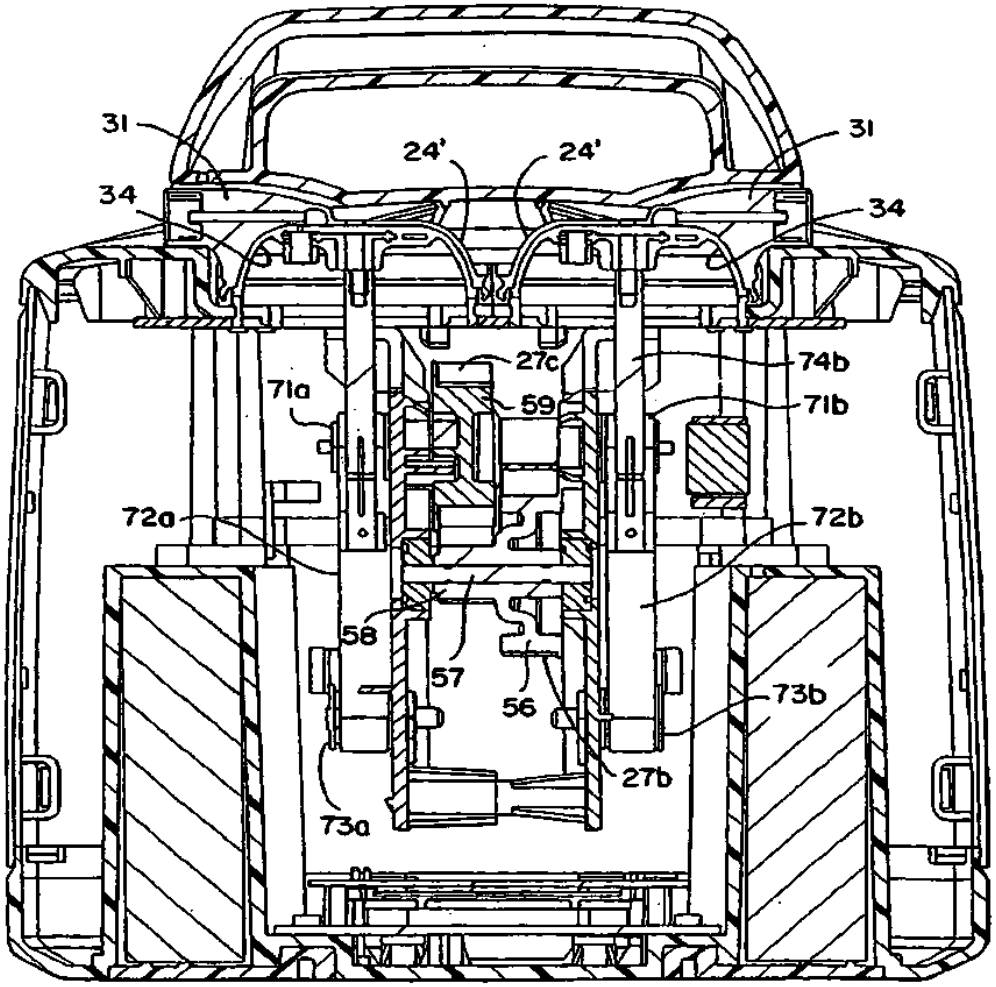


FIG. 23

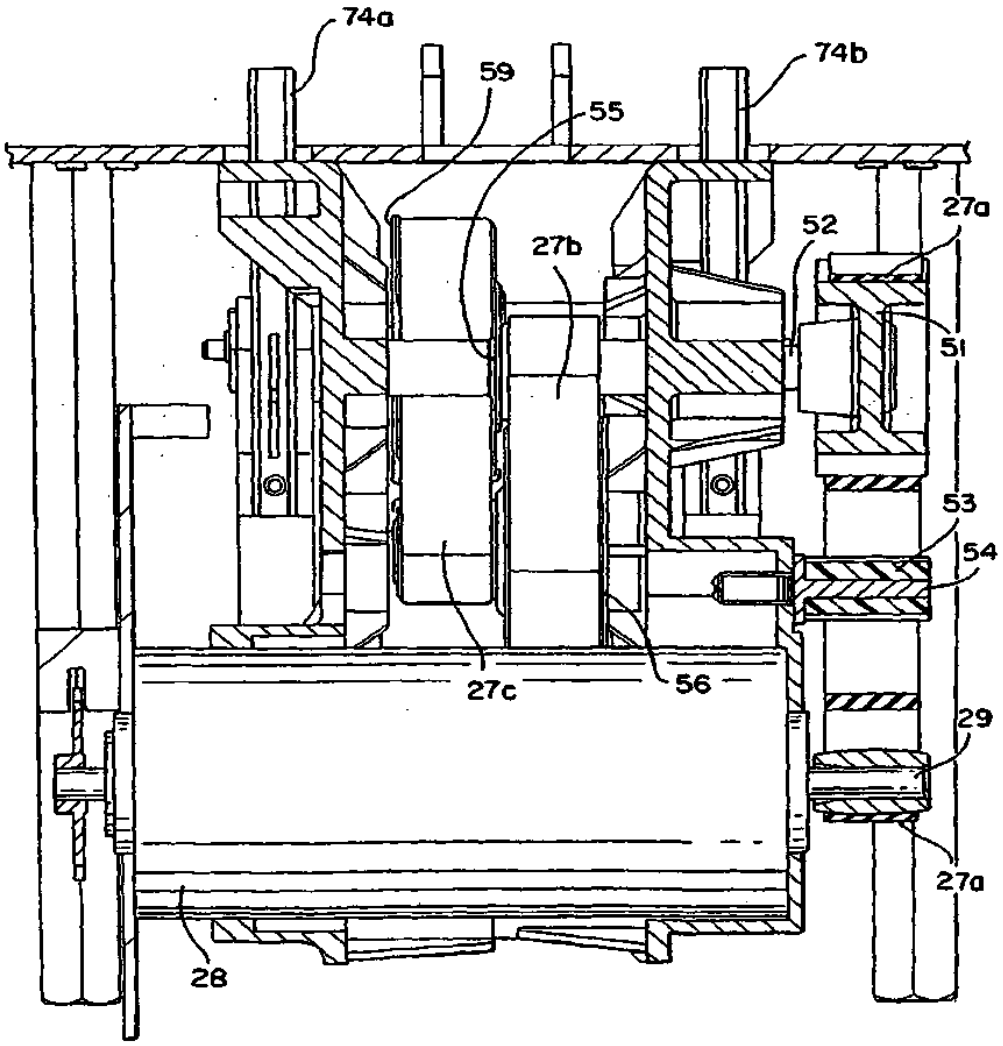
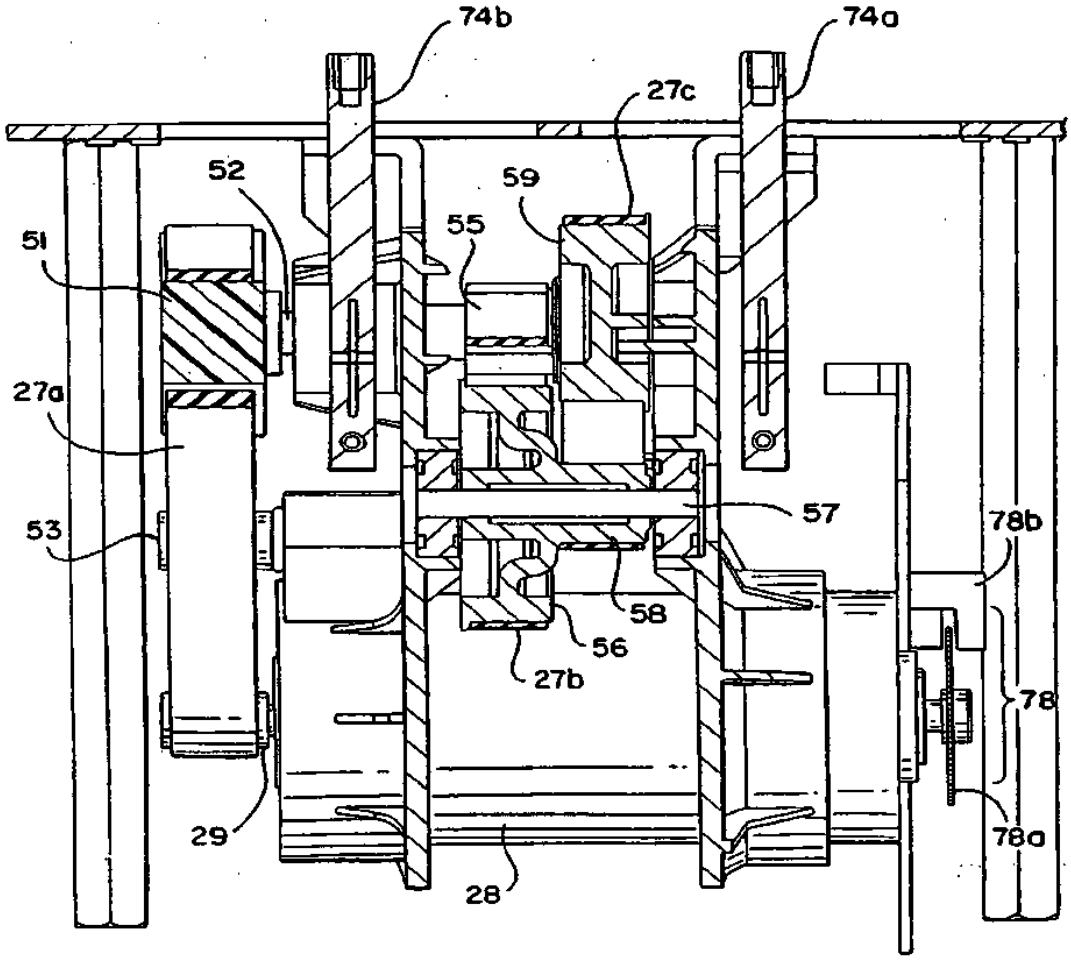


FIG. 24



REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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]**

(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 2016/014469 A1

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

(21) International Application Number:
PCT/US2015/041257

(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

(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). **DONOHOE, Brendan, M.**; 105 Forrest Avenue, Fairfax, CA 94930 (US). **WANG, Sharon, Lam**; 10650 Magdalena Road, Los Altos Hills, CA 94024 (US). **TOROSIS, Michele**; 1262 Nightingale Court, Los Altos, CA 94024 (US). **BRIGHT, Earl, II**; 1590 Julie Lane, Los Altos, CA 94024 (US).

(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

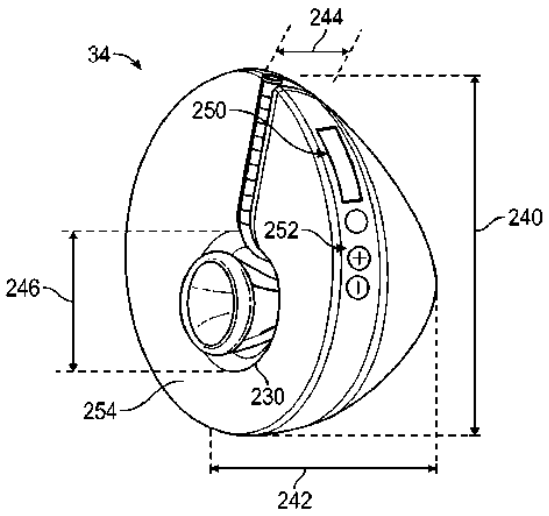


FIG. 6

(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.

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 described 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.

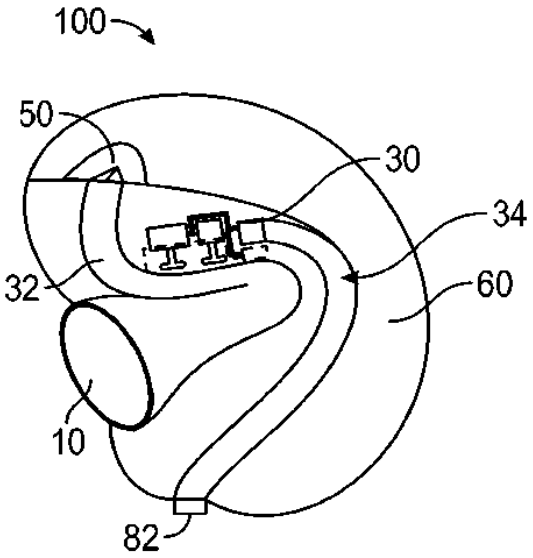


FIG. 1

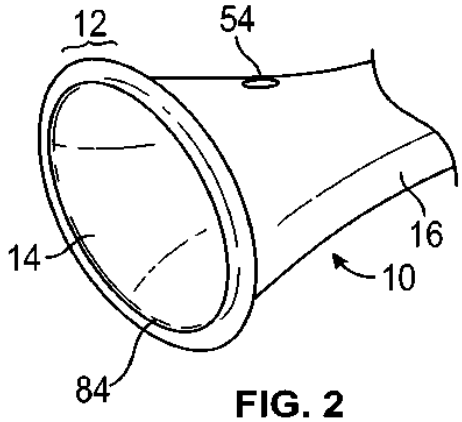


FIG. 2

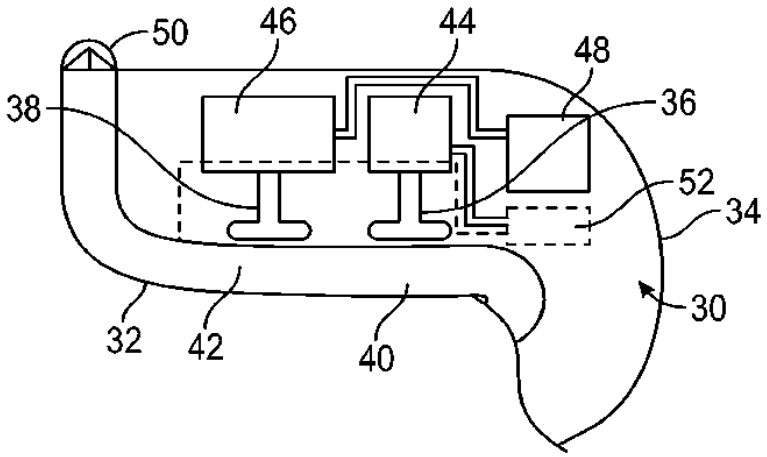


FIG. 3

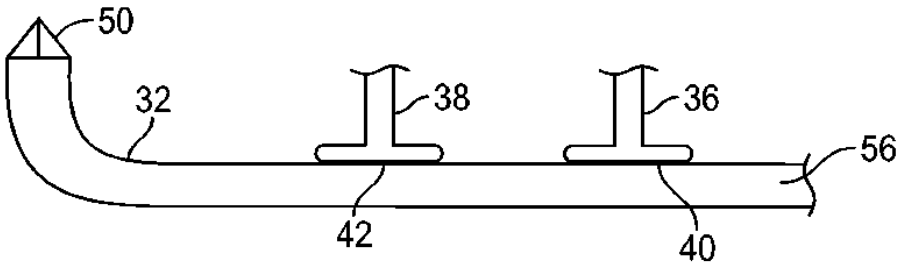


FIG. 4A

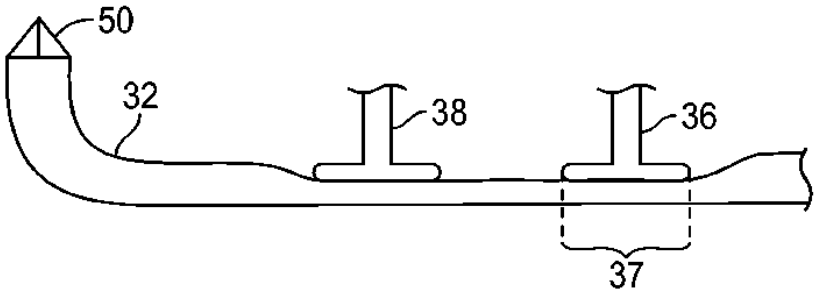


FIG. 4B

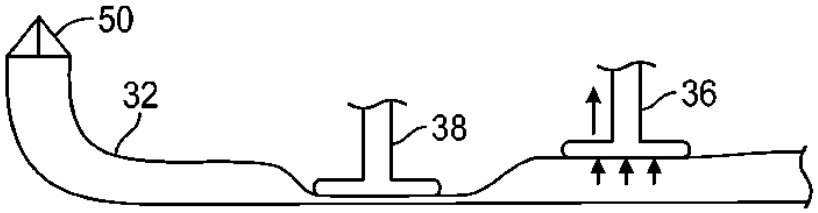


FIG. 4C

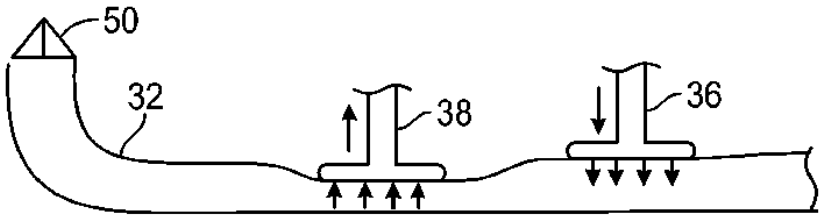


FIG. 4D

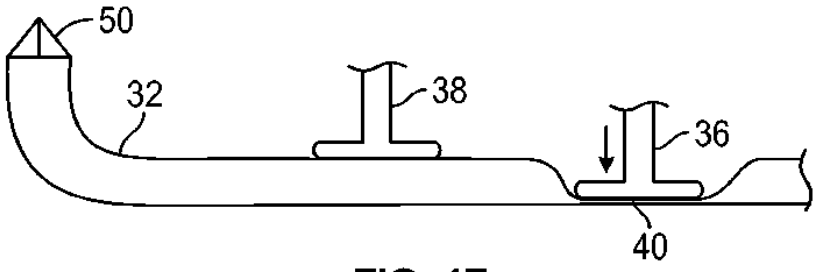


FIG. 4E

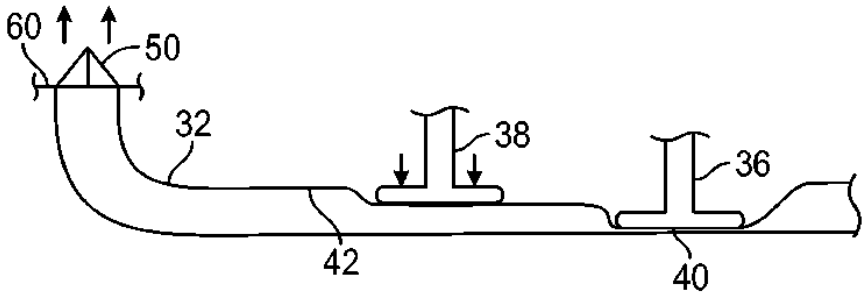


FIG. 4F

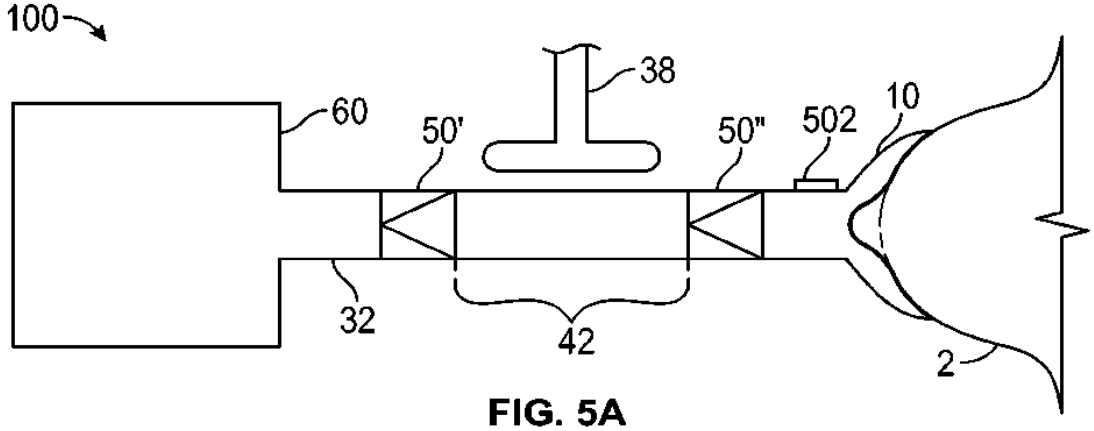


FIG. 5A

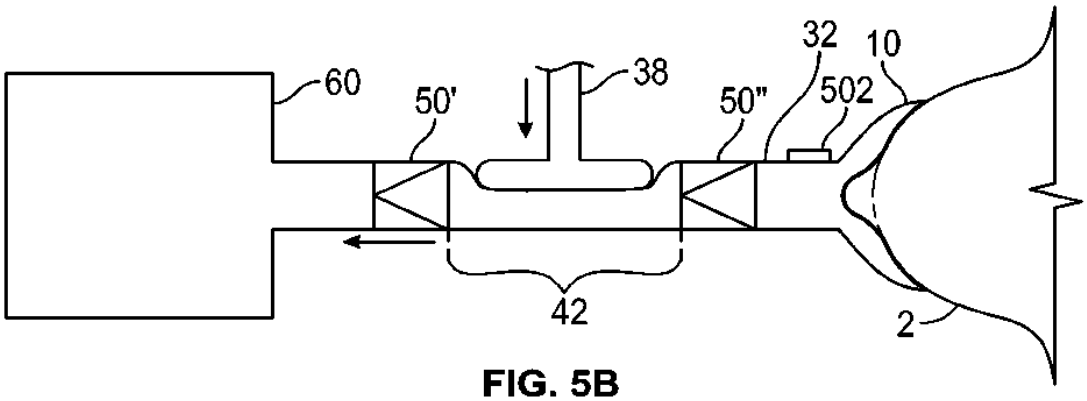


FIG. 5B

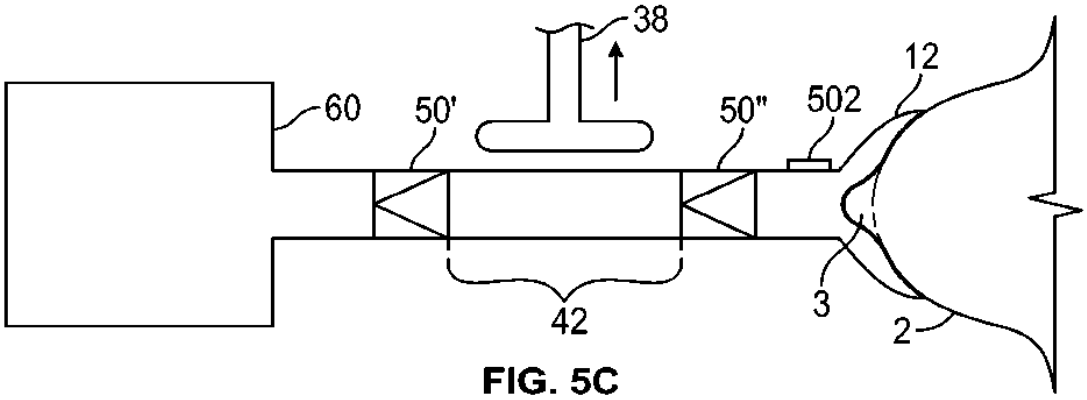


FIG. 5C

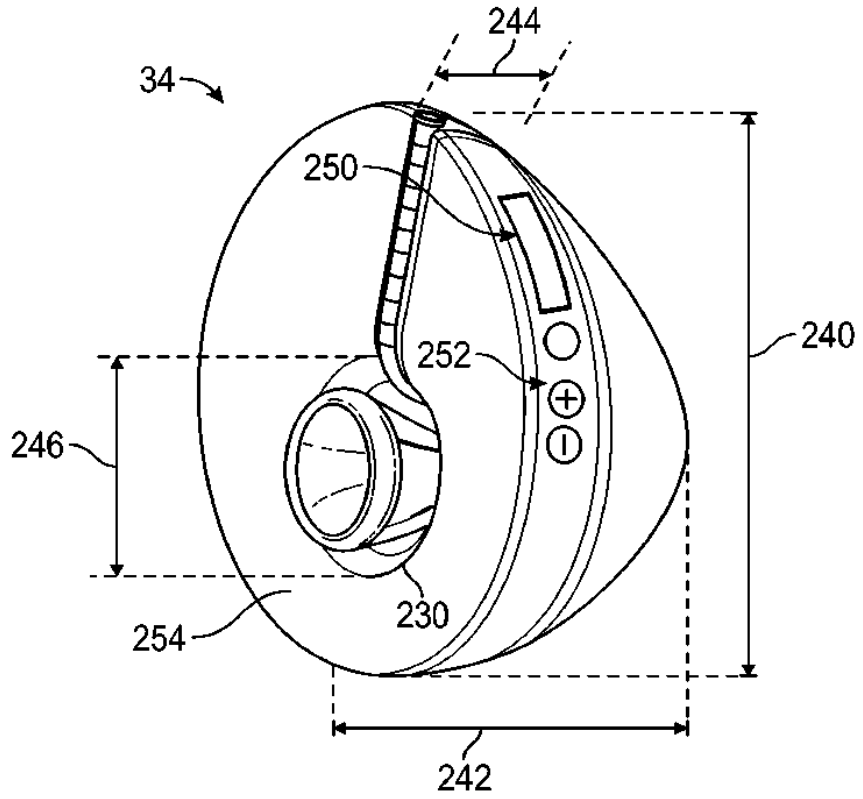


FIG. 6

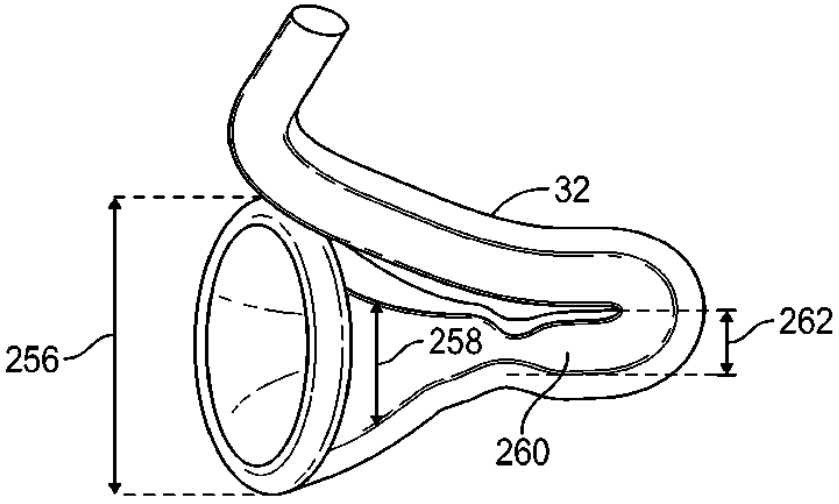


FIG. 7A

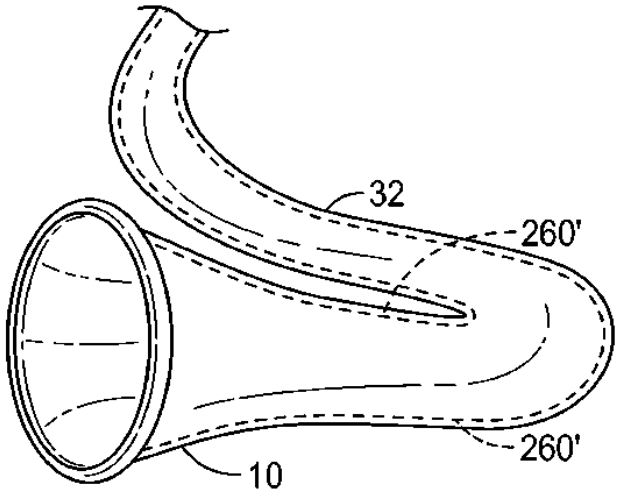


FIG. 7B

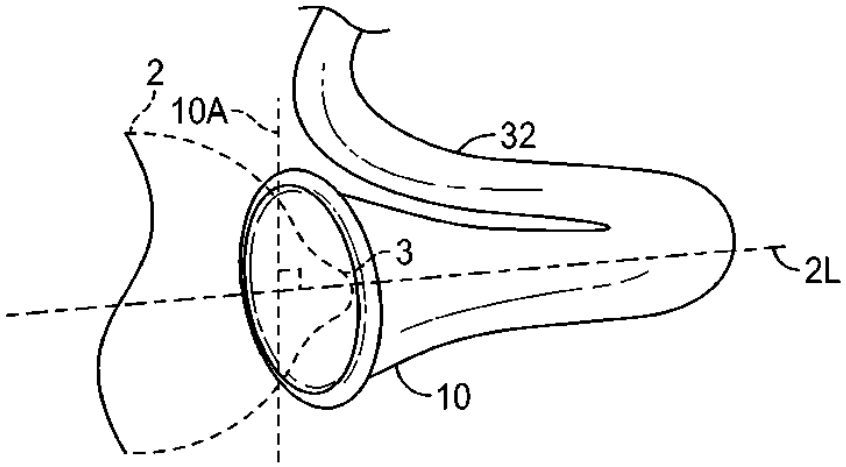


FIG. 7C

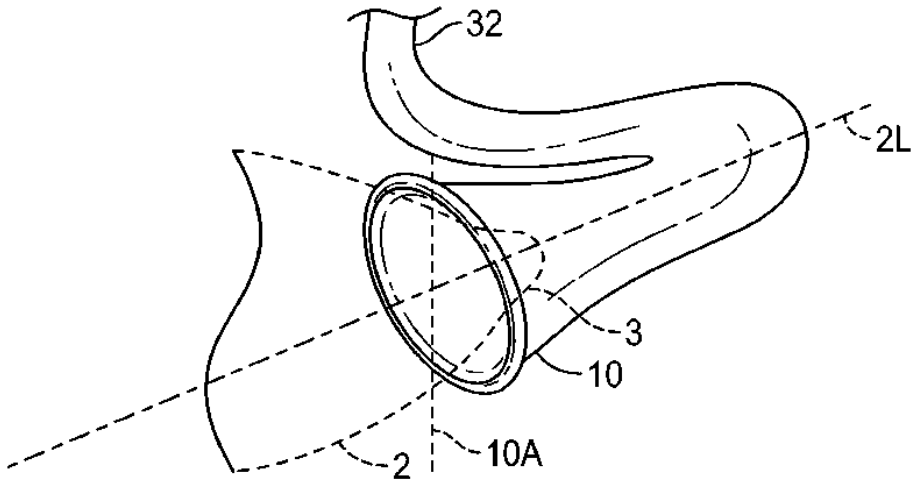


FIG. 7D

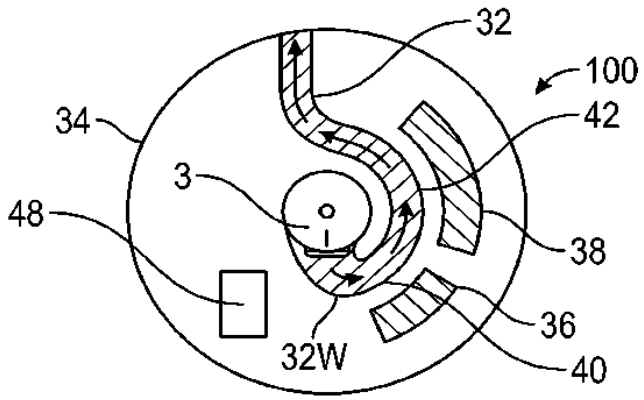


FIG. 8A

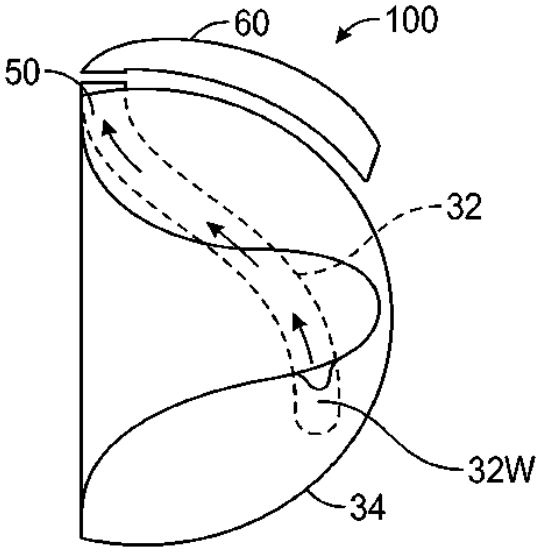


FIG. 8B

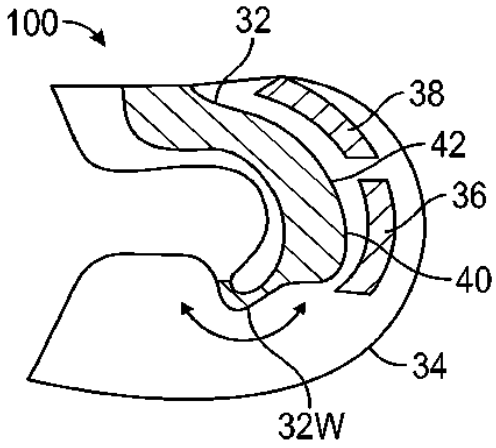


FIG. 9

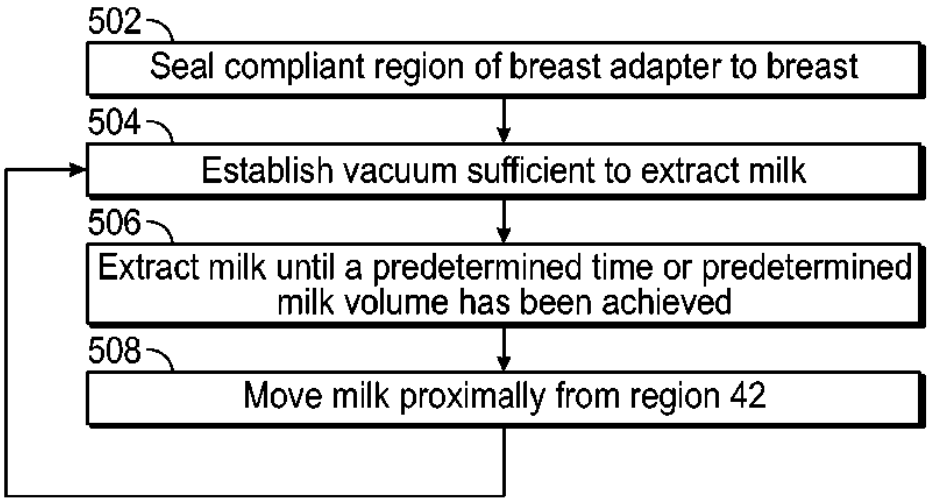


FIG. 10

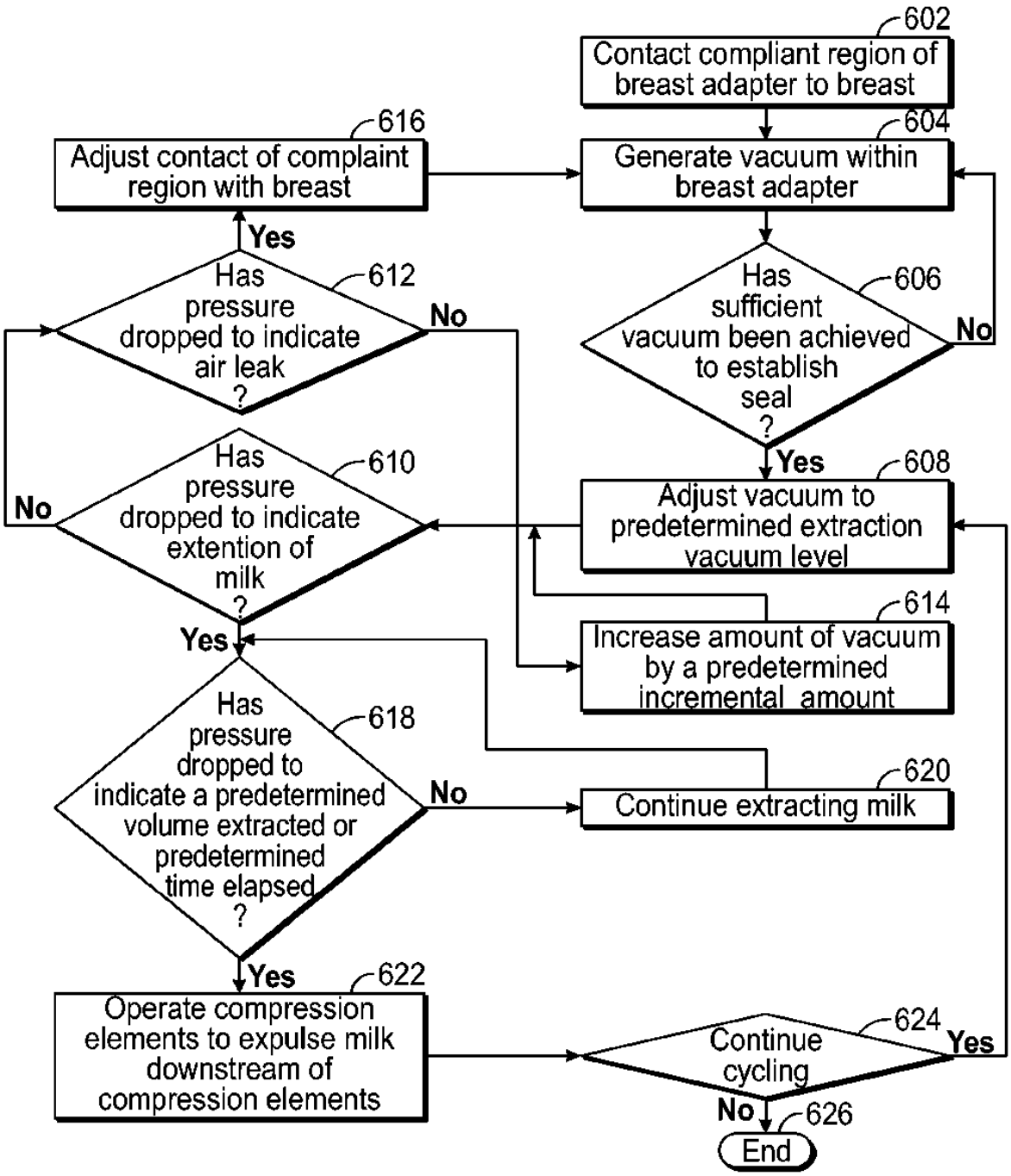

602
Contact compliant region of breast adapter to breast
604
Generate vacuum within breast adapter
606
Has sufficient vacuum been achieved to establish seal ?
No
Yes
608
Adjust vacuum to predetermined extraction vacuum level
610
Has pressure dropped to indicate extention of milk ?
No
Yes
612
Has pressure dropped to indicate air leak ?
No
Yes
614
Increase amount of vacuum by a predetermined incremental amount
616
Adjust contact of complaint region with breast
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

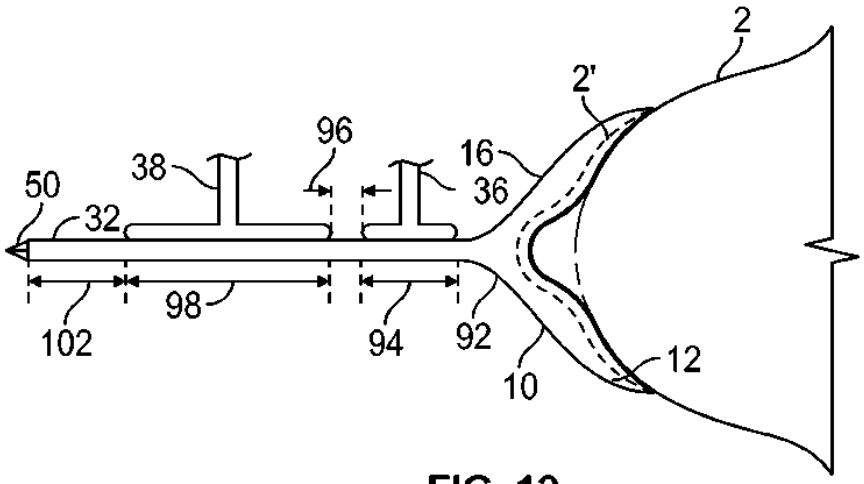


FIG. 12

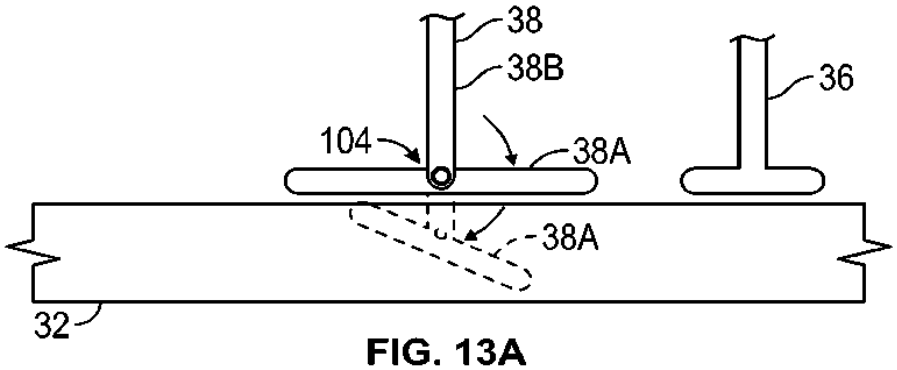


FIG. 13A

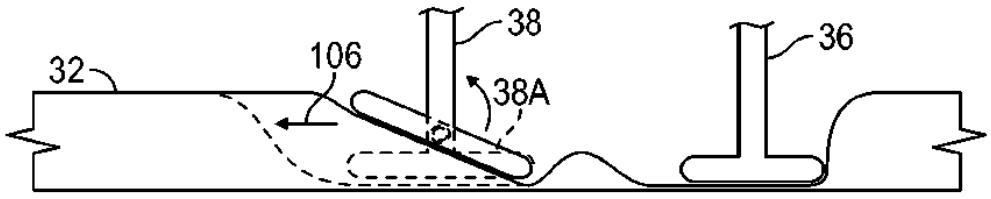


FIG. 13B

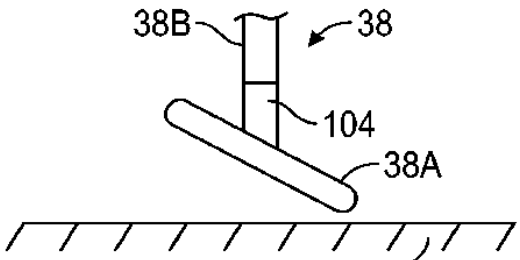


FIG. 13C

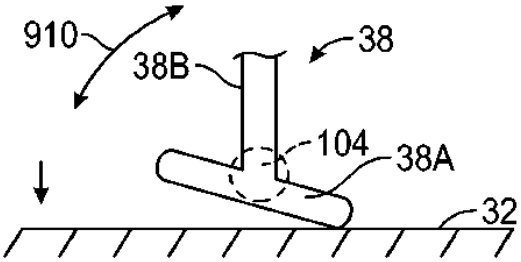


FIG. 13D

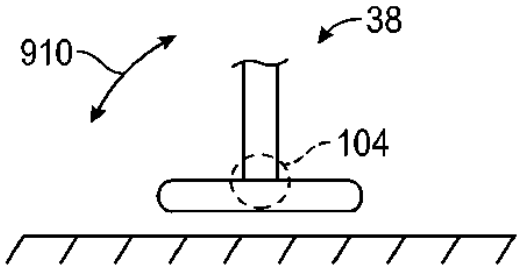


FIG. 13E

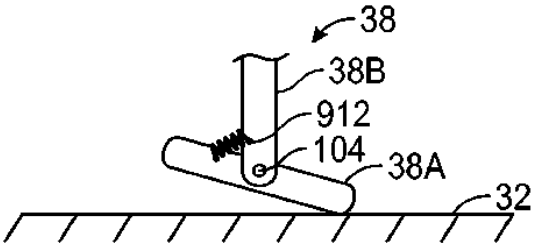


FIG. 13F

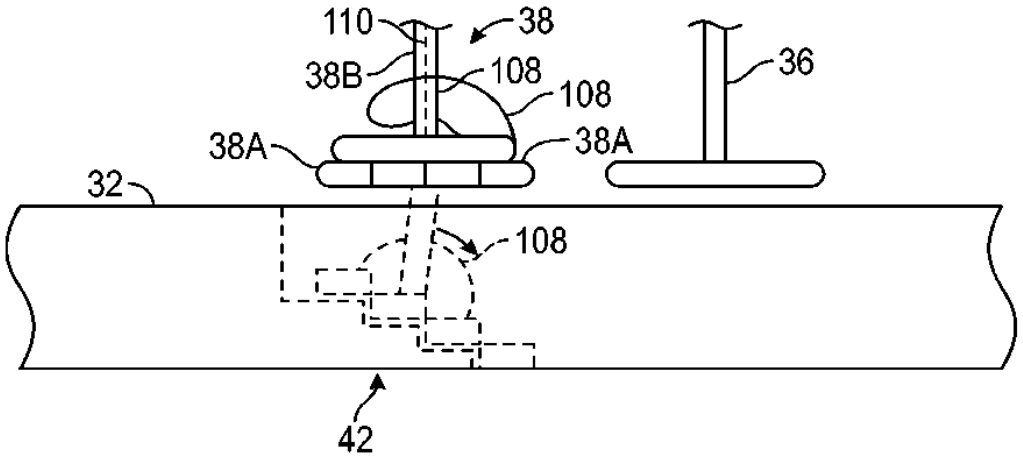


FIG. 14

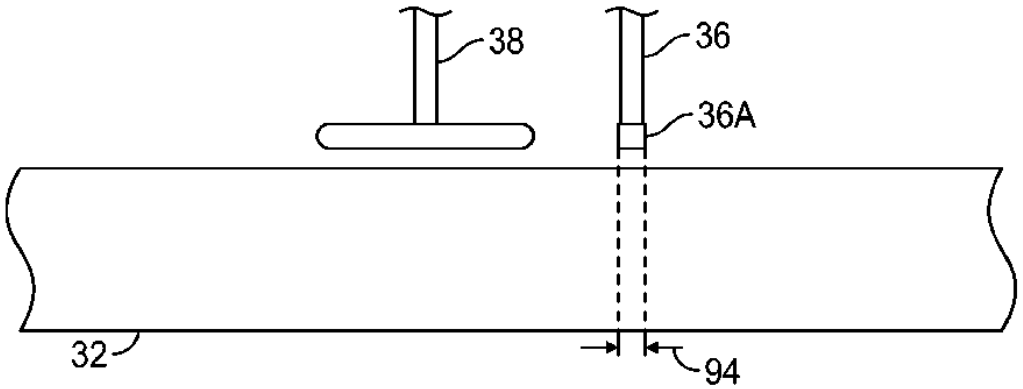


FIG. 15

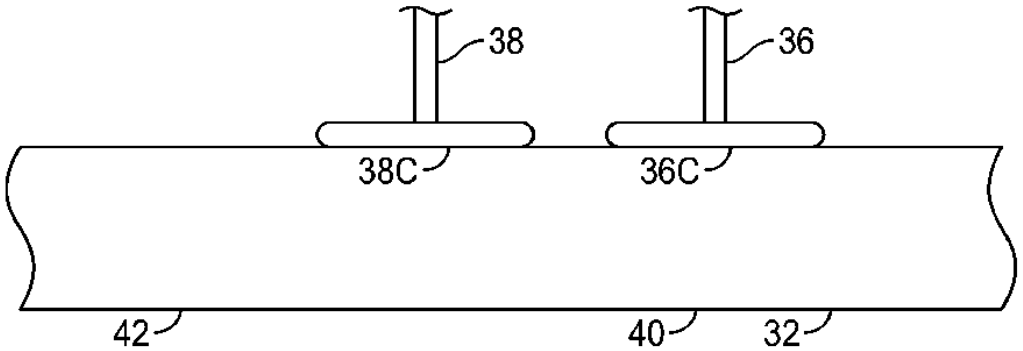


FIG. 16A

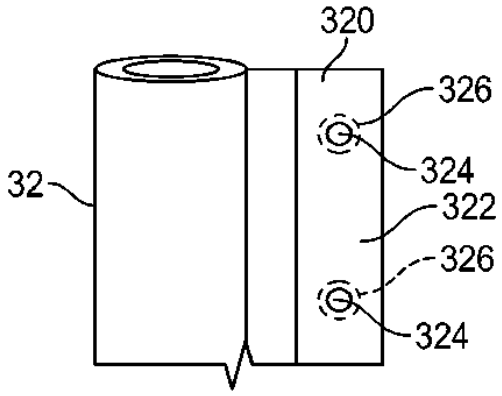


FIG. 16B

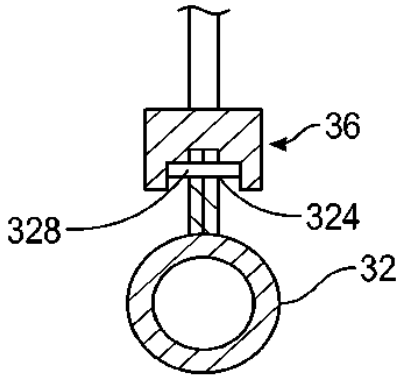


FIG. 16C

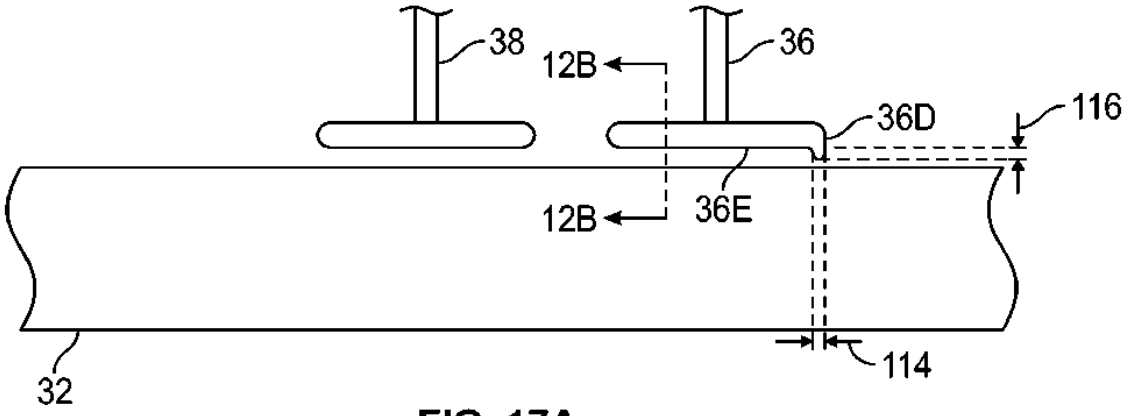


FIG. 17A

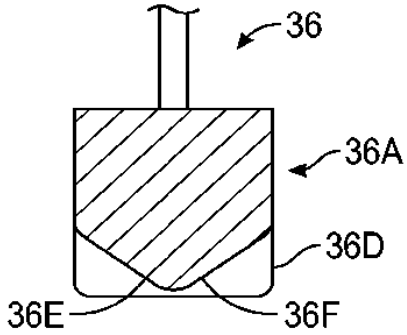


FIG. 17B

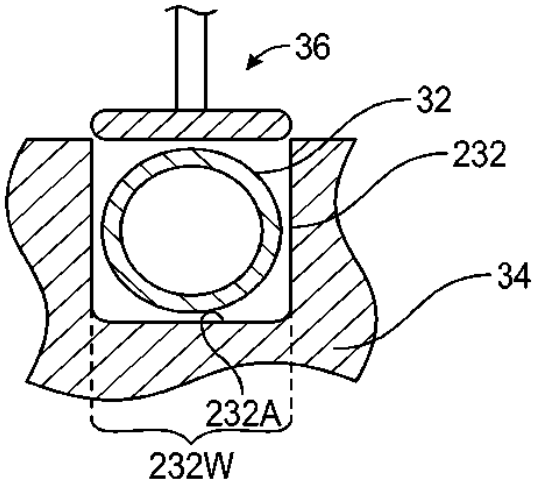


FIG. 17C

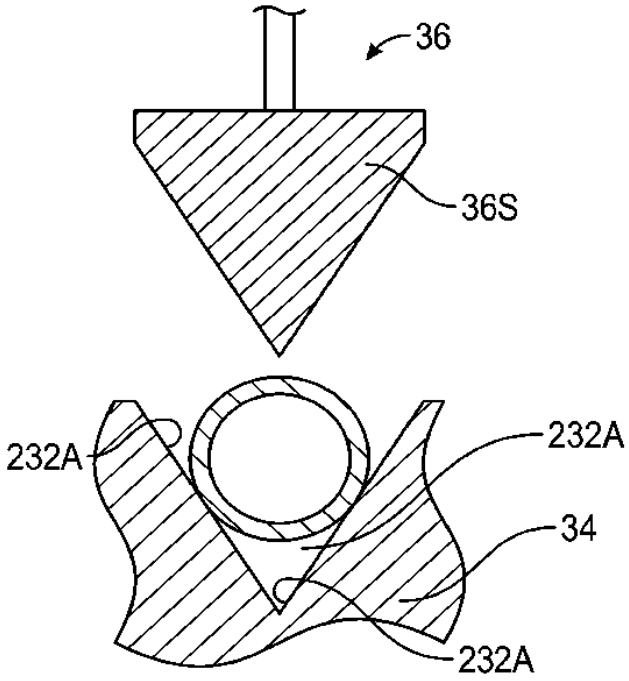


FIG. 17D

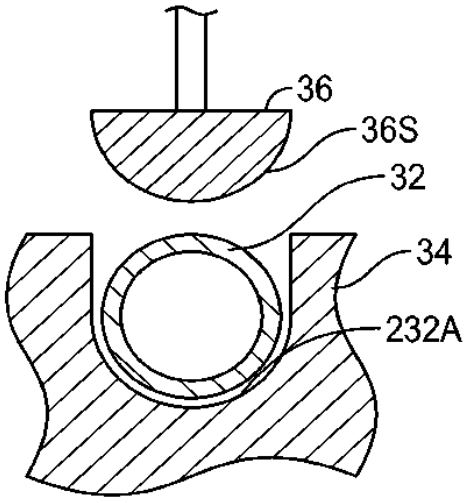


FIG. 17E

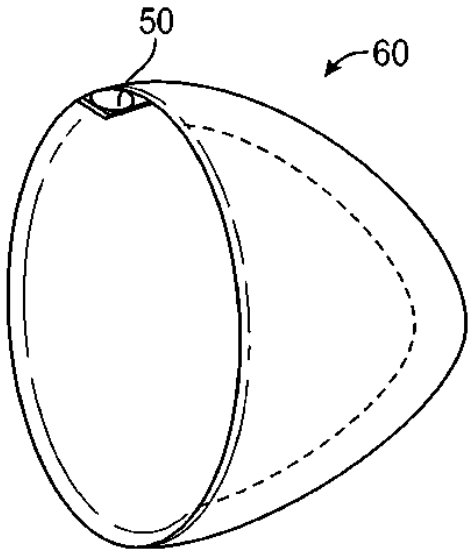


FIG. 18

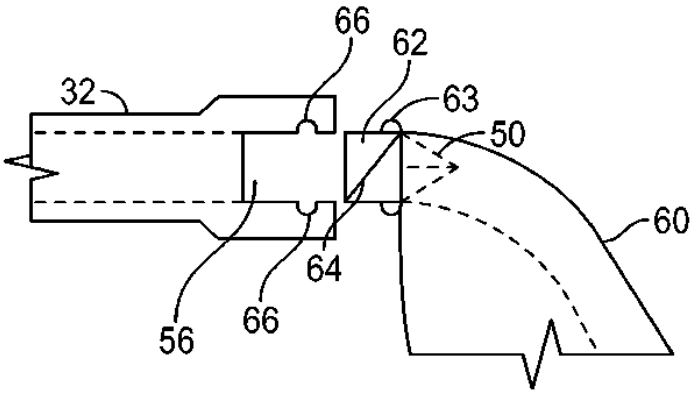


FIG. 19

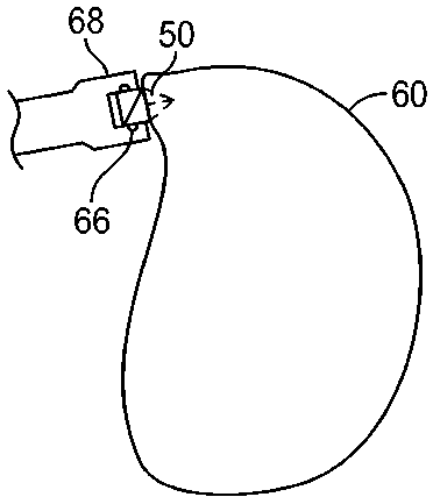


FIG. 20

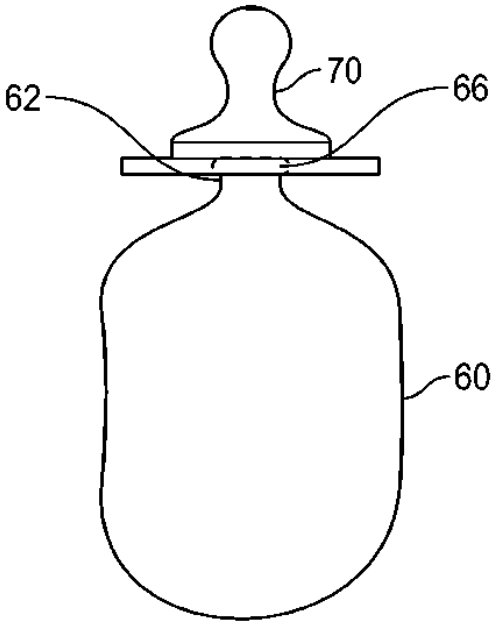


FIG. 21

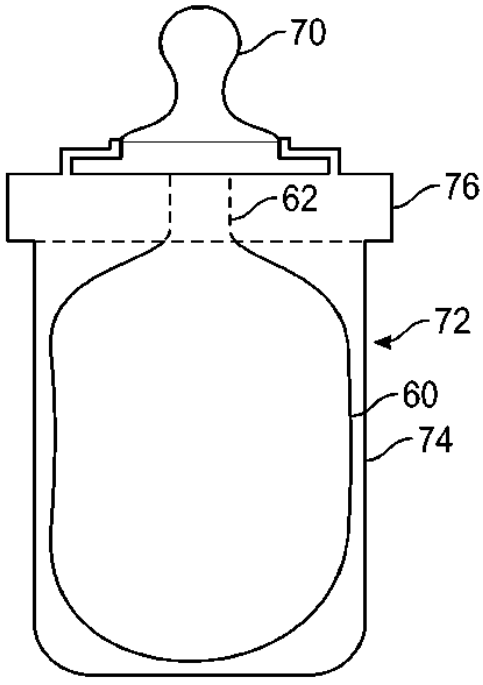


FIG. 22

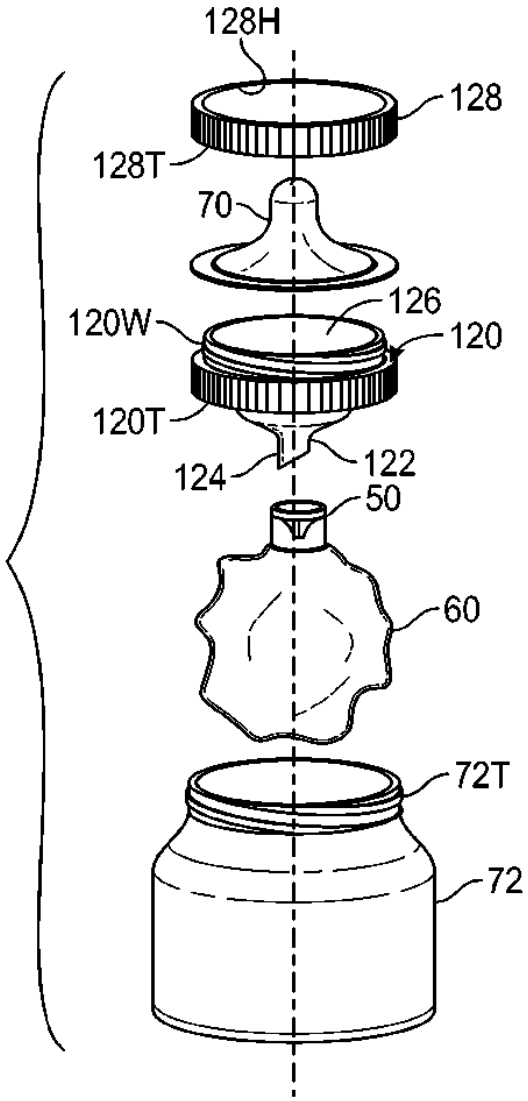

128H
128
128T
70
126
120W
120
120T
124
122
50
60
72T
72

FIG. 23

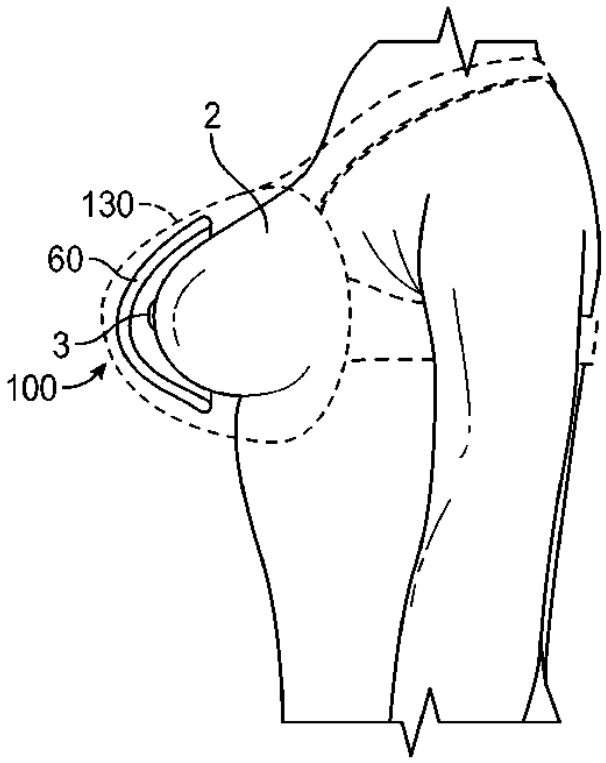

2
130
60
3
100

FIG. 24

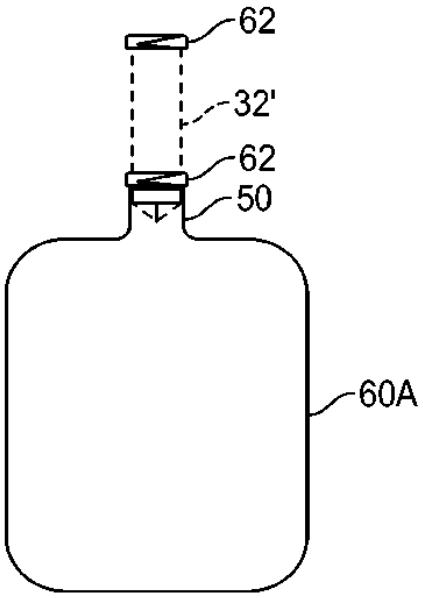


FIG. 25

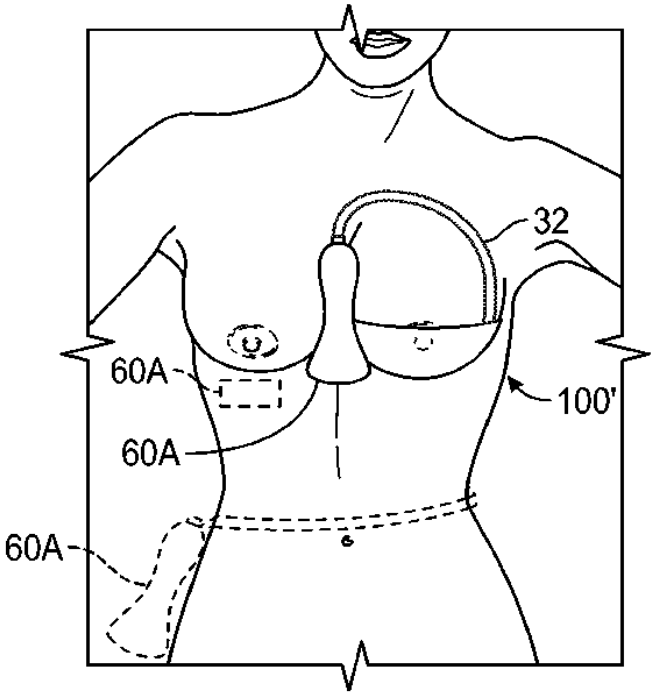


FIG. 26

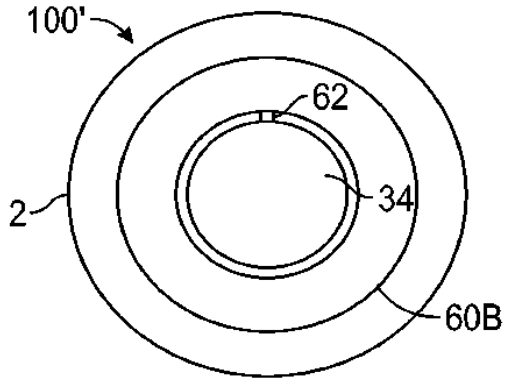


FIG. 27A

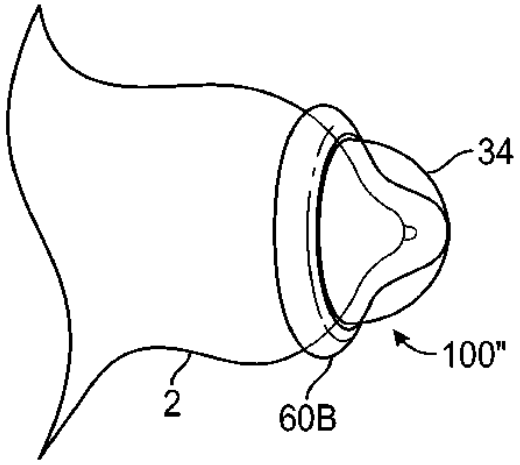


FIG. 27B

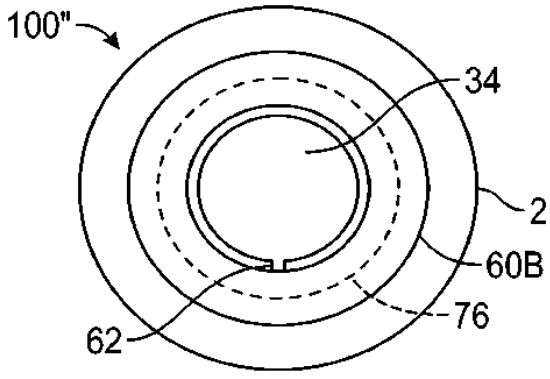


FIG. 28A

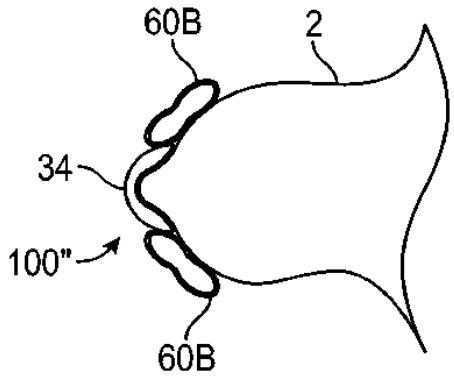


FIG. 28B

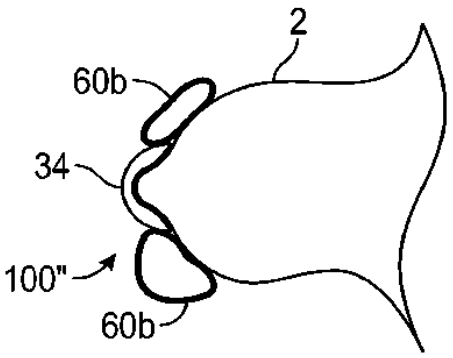


FIG. 28C

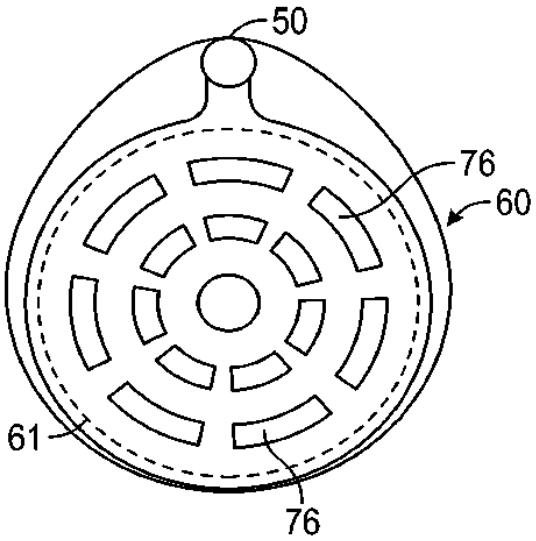


FIG. 28D

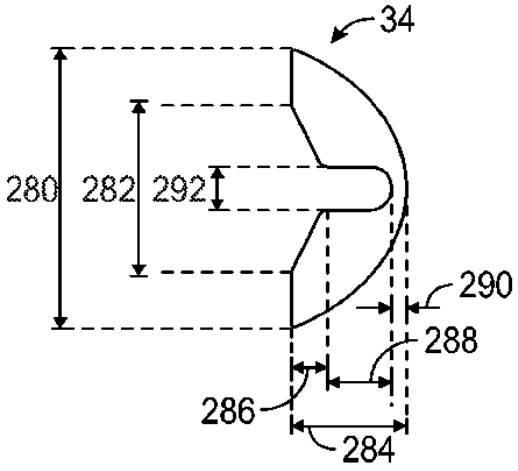


FIG. 28E

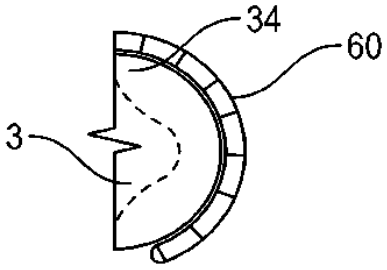


FIG. 28F

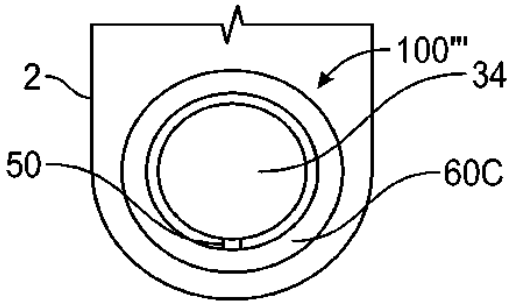


FIG. 29A

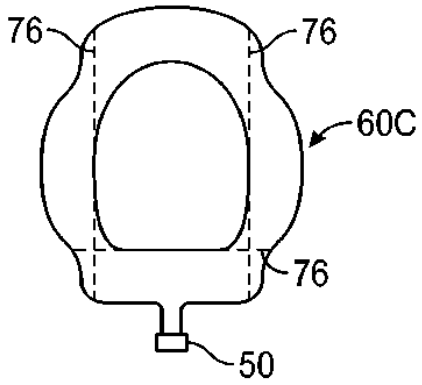


FIG. 29B

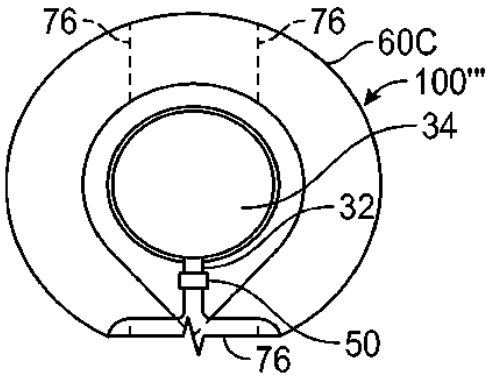


FIG. 29C

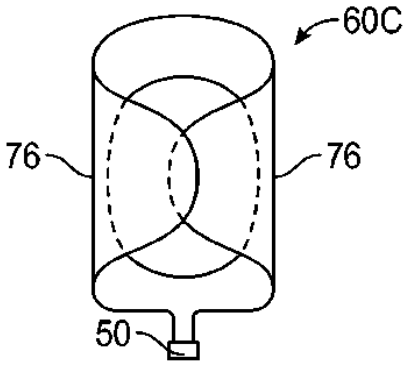


FIG. 29D

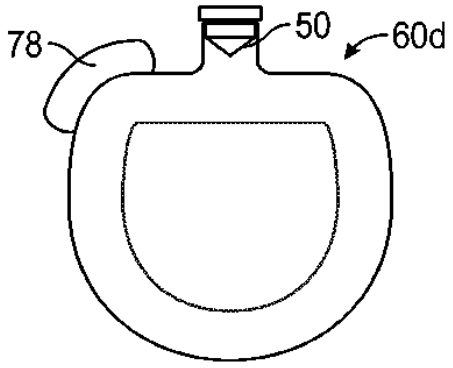


FIG. 30

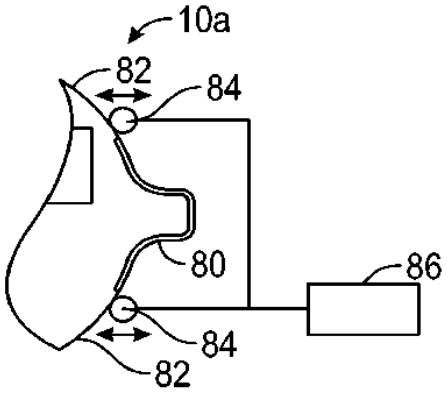


FIG. 31A

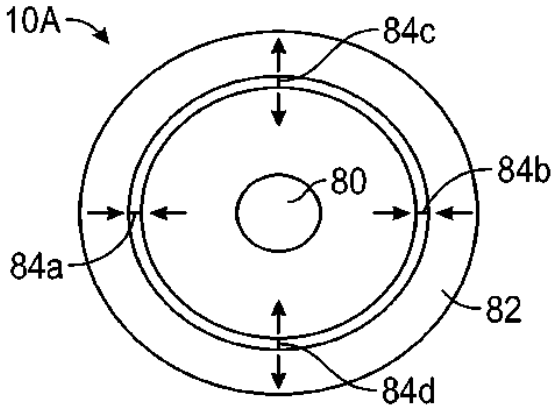


FIG. 31B

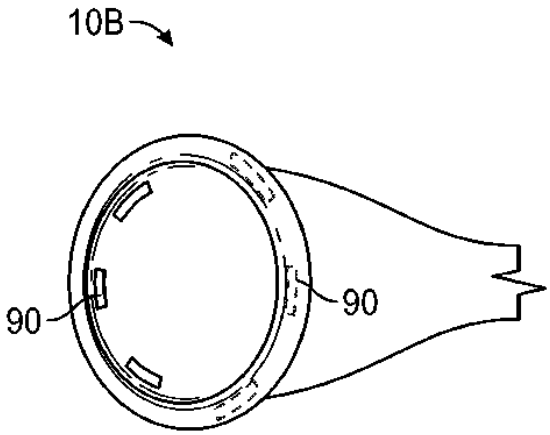


FIG. 32A

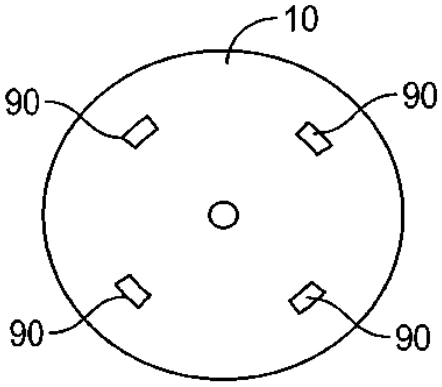


FIG. 32B

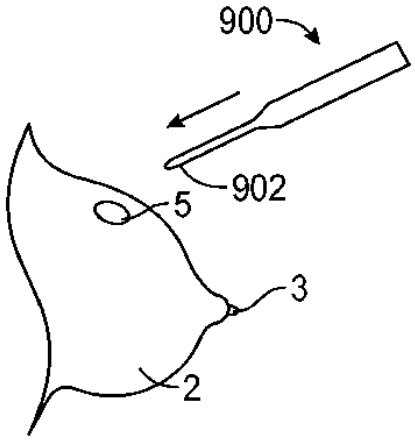


FIG. 32C

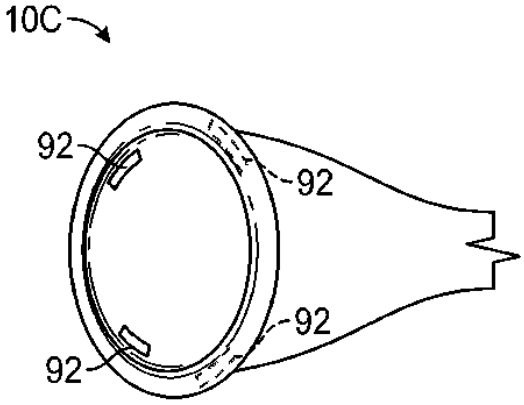


FIG. 33

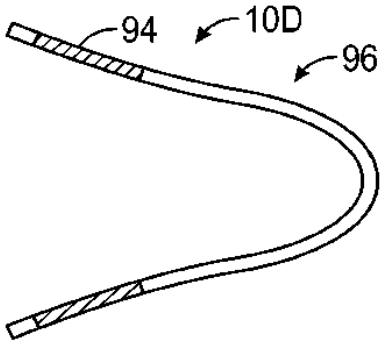


FIG. 34

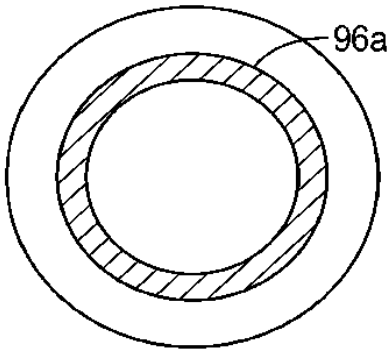


FIG. 35A

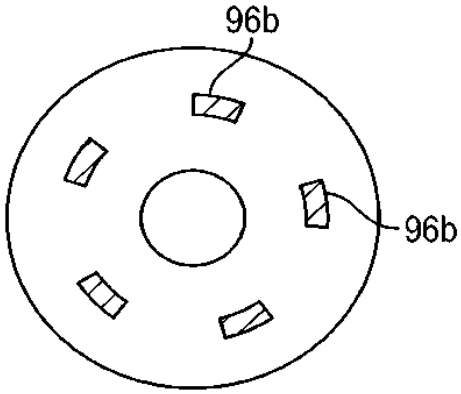


FIG. 35B

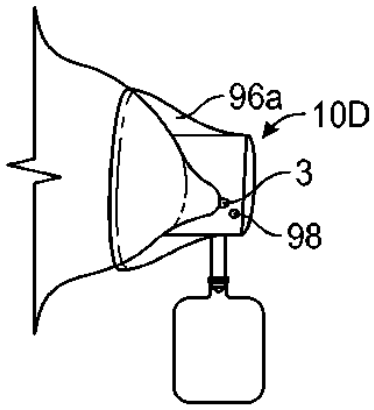


FIG. 36

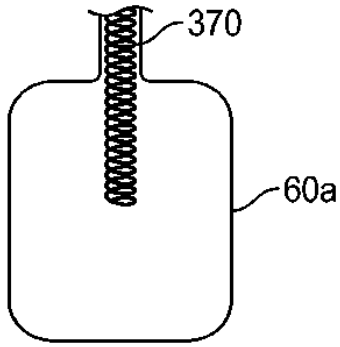


FIG. 37A

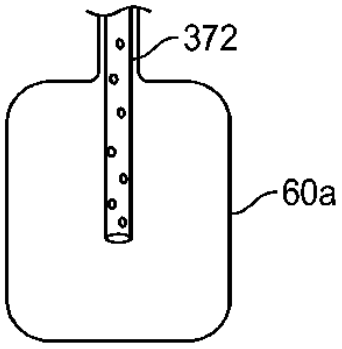


FIG. 37B

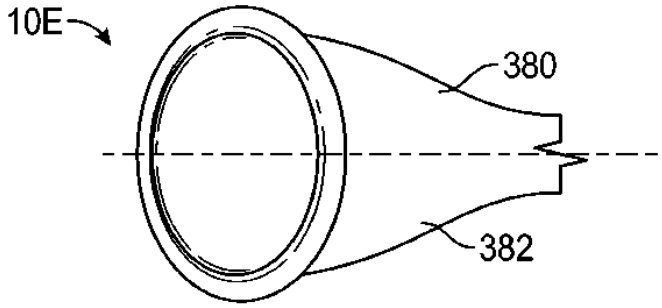


FIG. 38

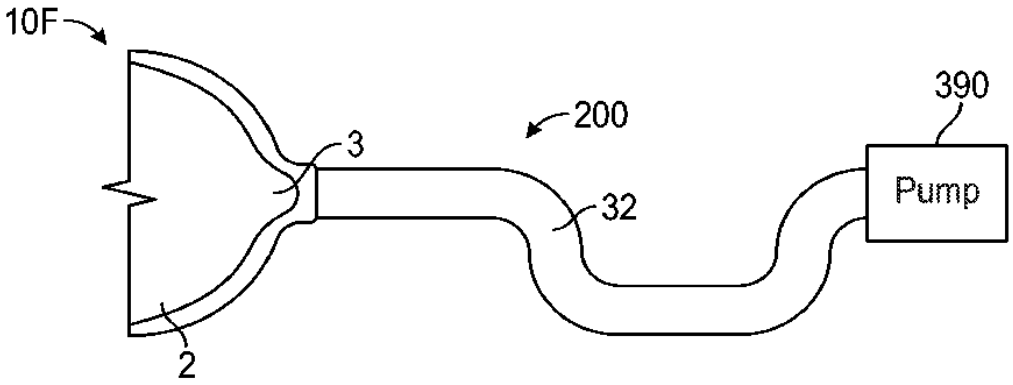


FIG. 39A

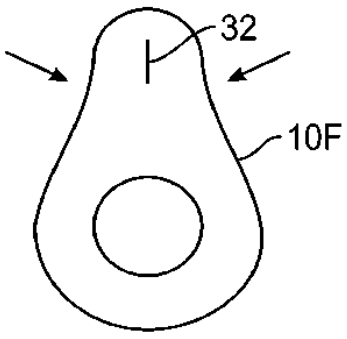


FIG. 39B

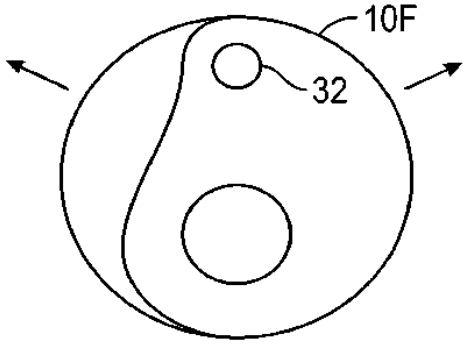


FIG. 39C

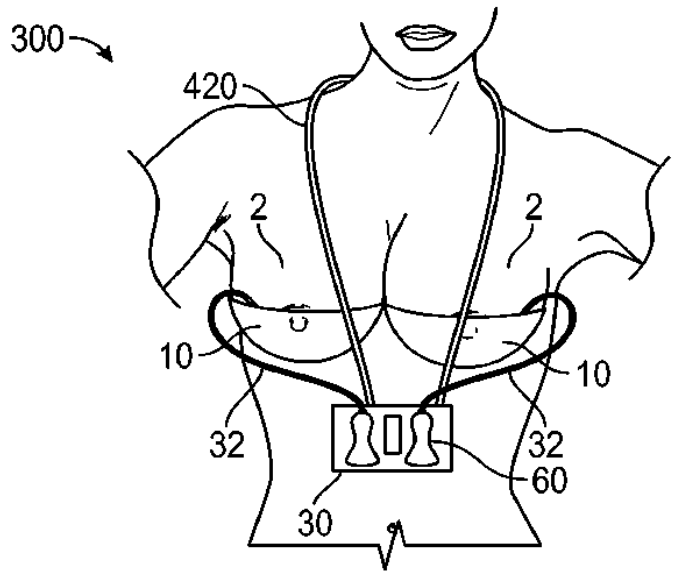


FIG. 40

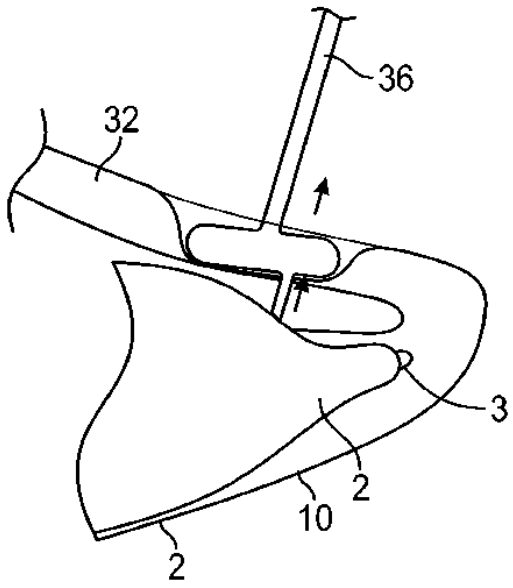


FIG. 41

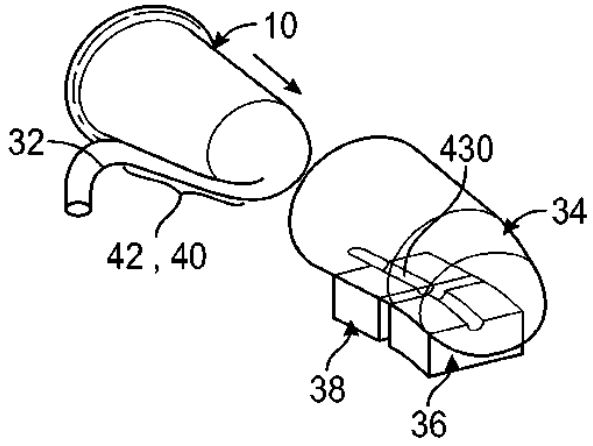

10
32
430
34
42 , 40
38
36

FIG. 42

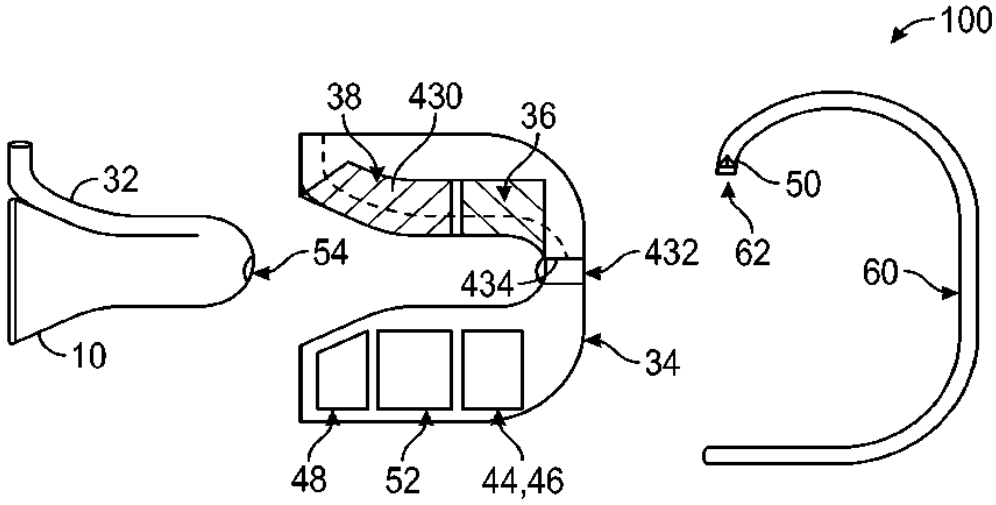

100
38
430
36
32
50
54
432
62
60
434
10
34
48
52
44,46

FIG. 43

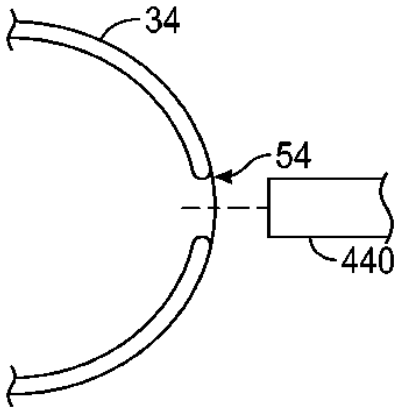


FIG. 44A

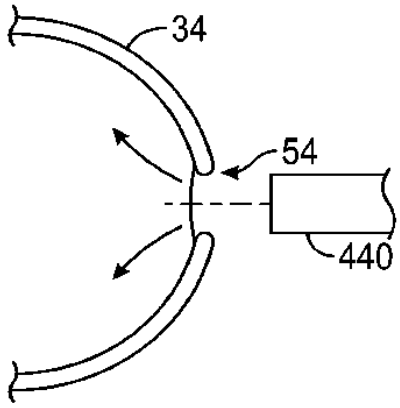


FIG. 44B

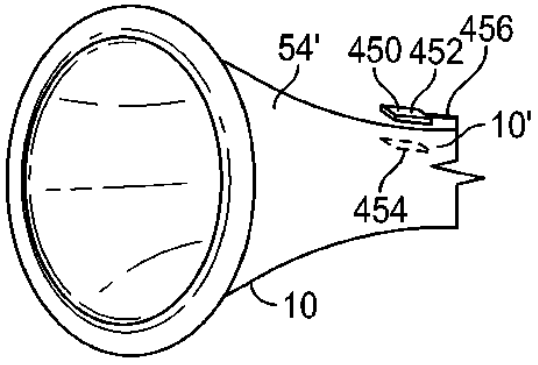


FIG. 45A

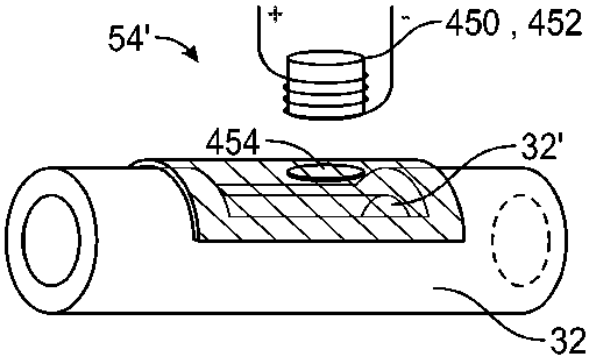


FIG. 45B

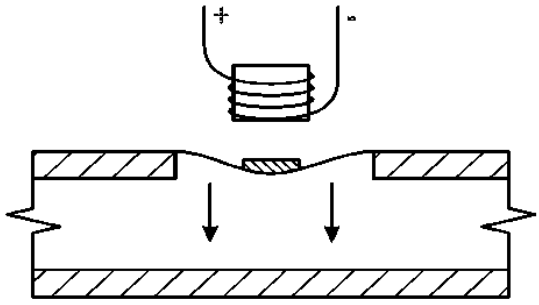


FIG. 45C

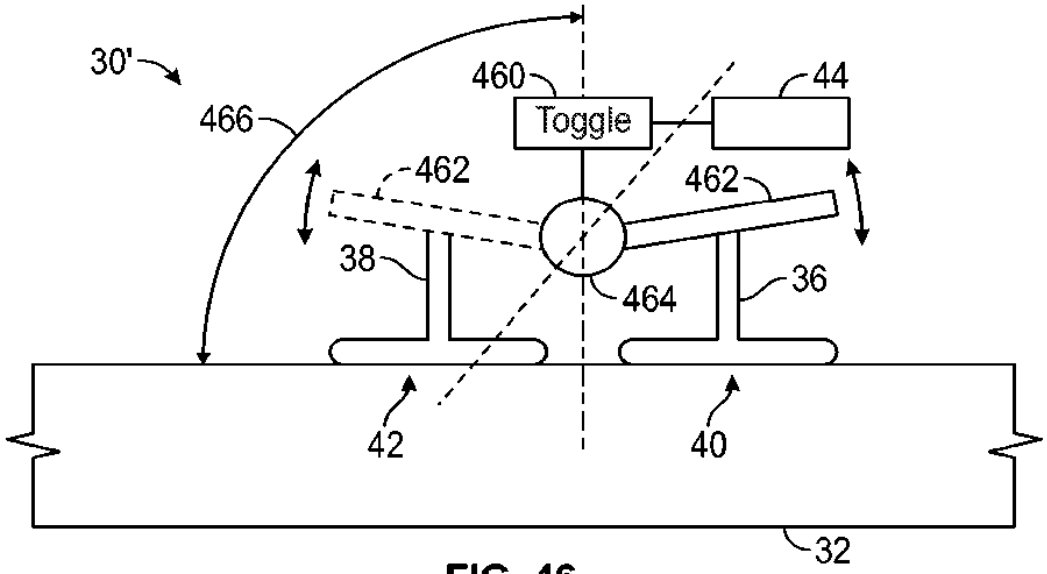


FIG. 46

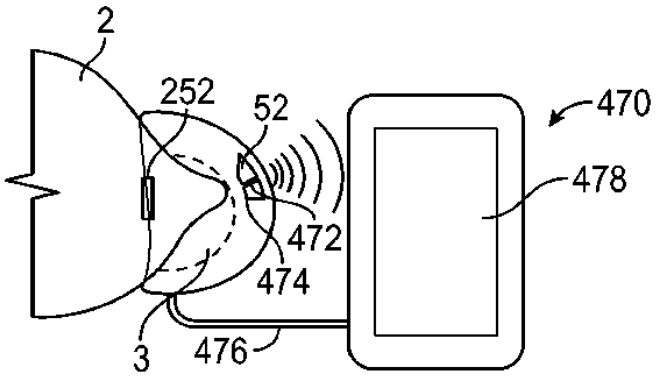


FIG. 47

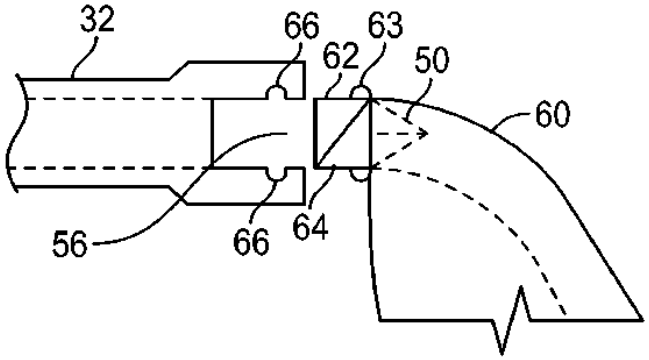


FIG. 48

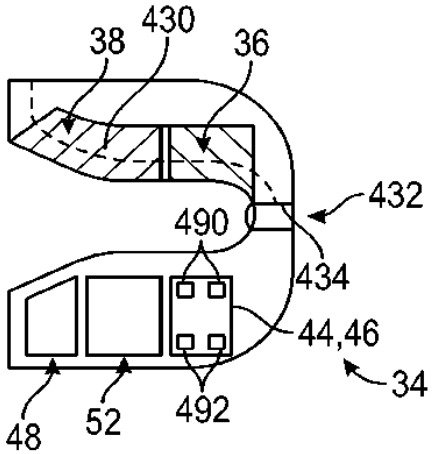


FIG. 49

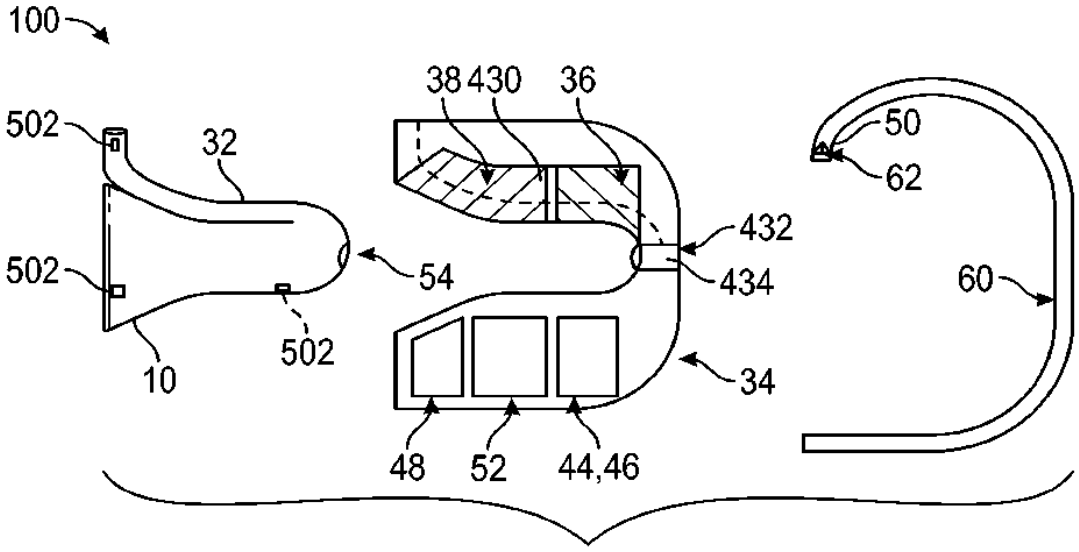

100
38
430
36
502
32
50
62
502
54
432
434
60
502
10
34
48
52
44,46

FIG. 50

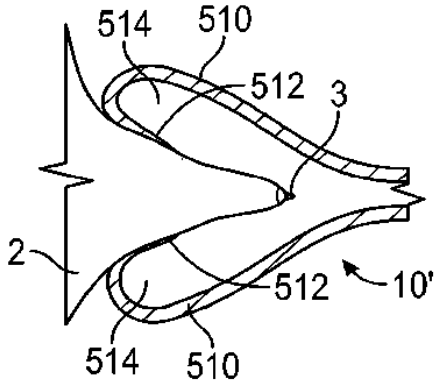

514
510
512
3
2
512
10'
514
510

FIG. 51

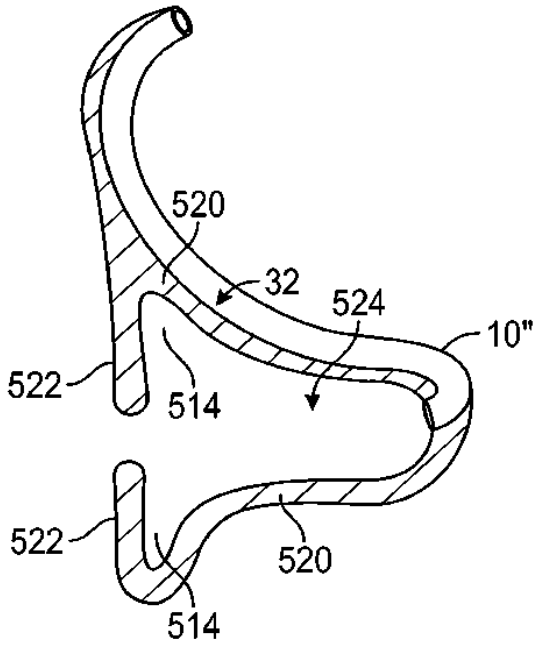


FIG. 52A

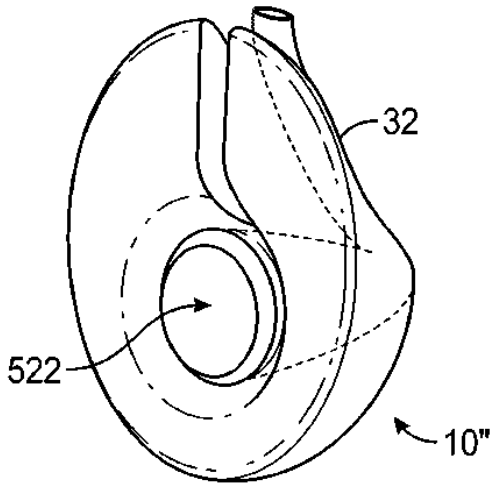


FIG. 52B

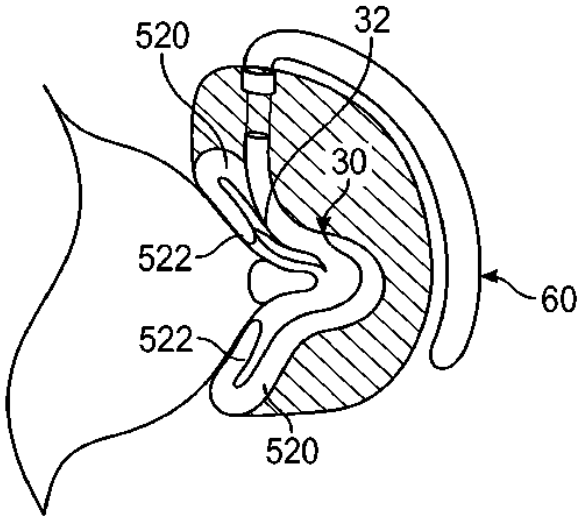


FIG. 52C

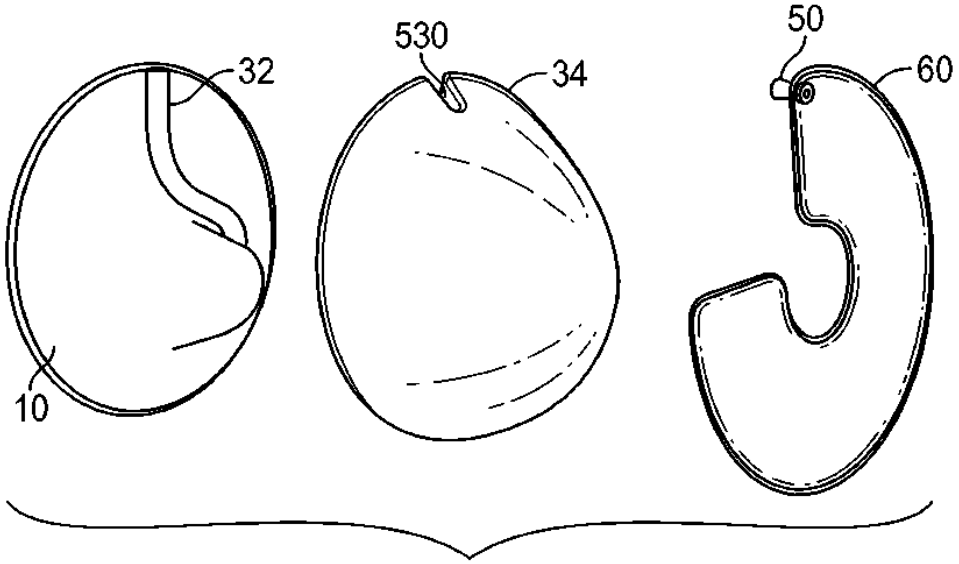


FIG. 53A

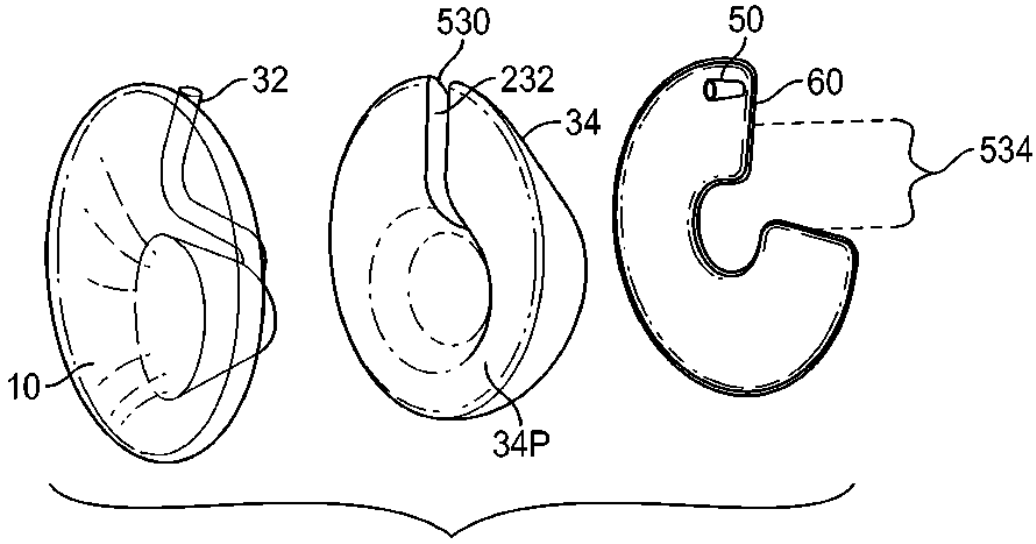


FIG. 53B

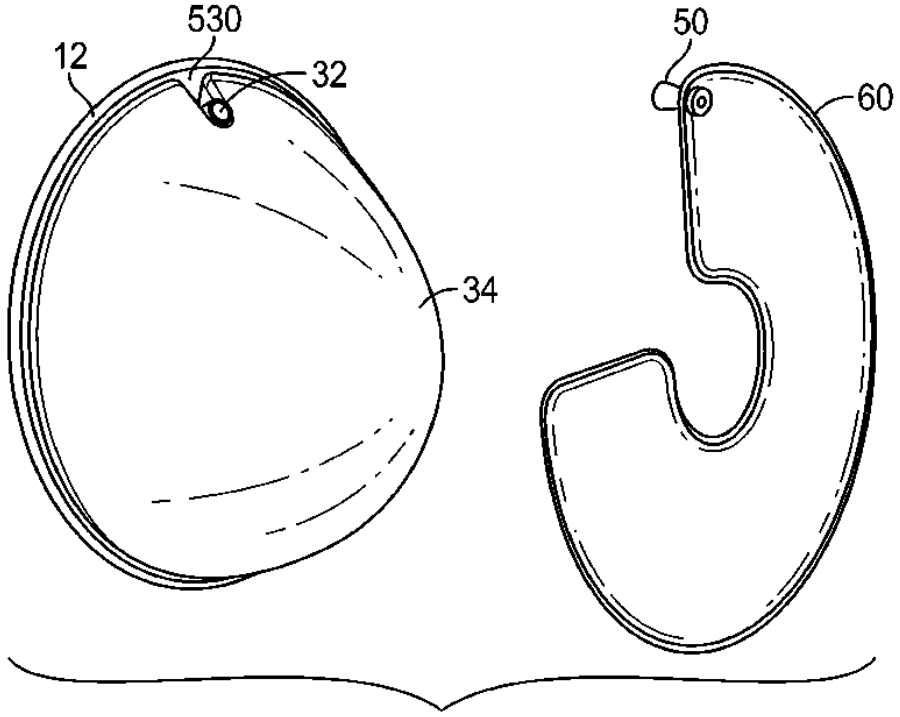


FIG. 53C

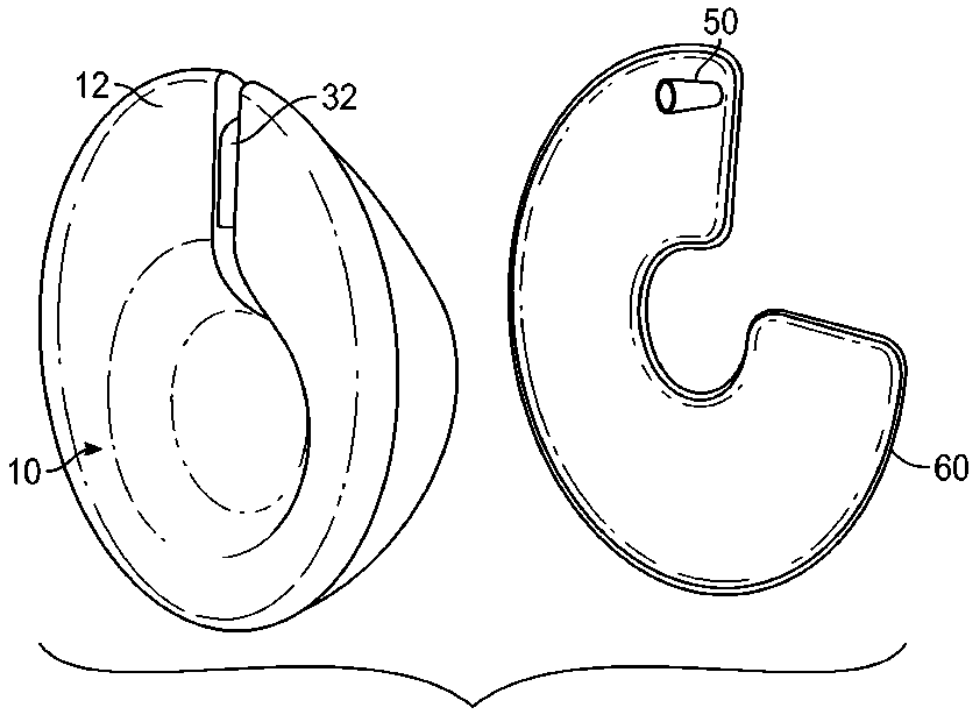


FIG. 53D

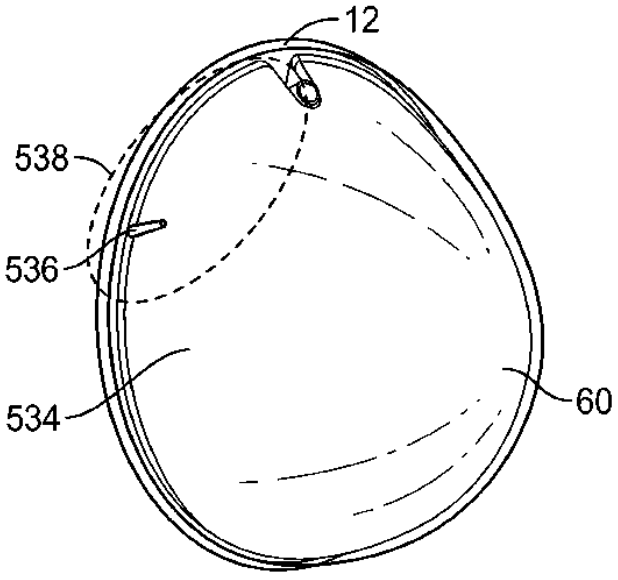


FIG. 53E

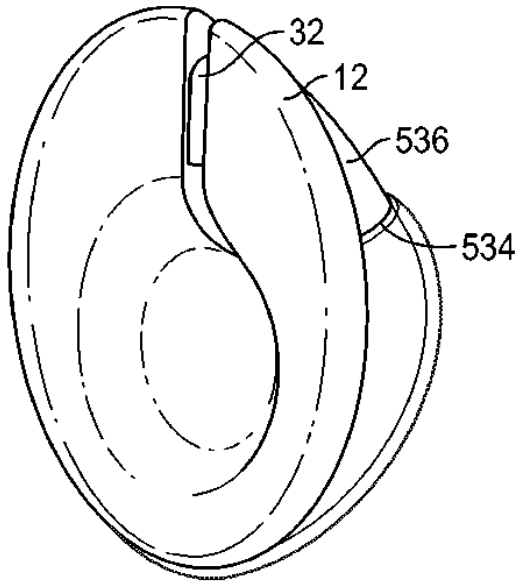


FIG. 53F

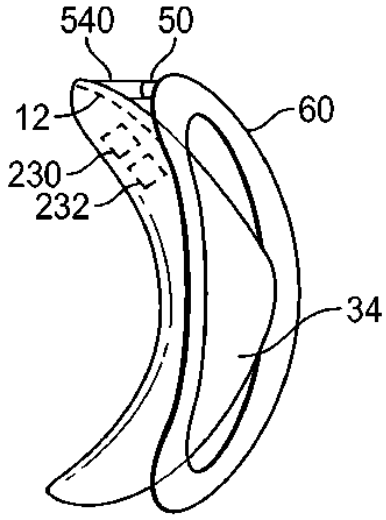


FIG. 53G

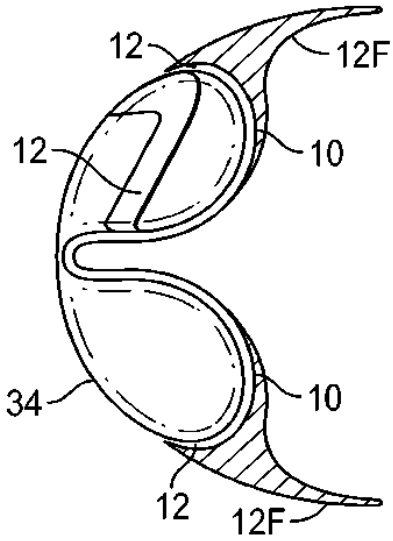


FIG. 54

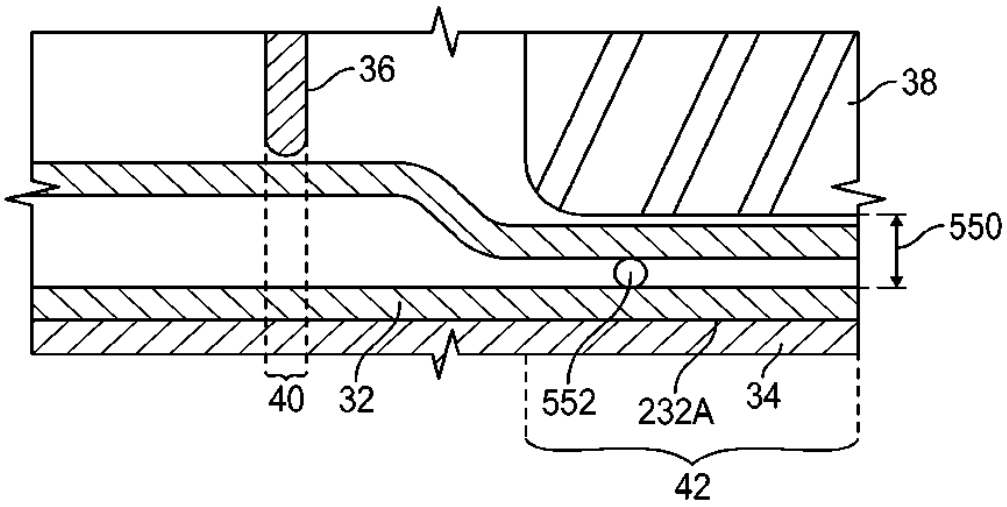


FIG. 55A

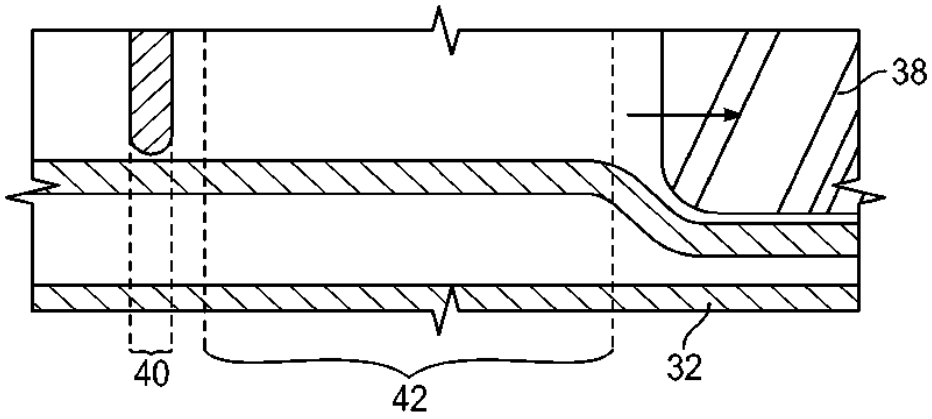


FIG. 55B

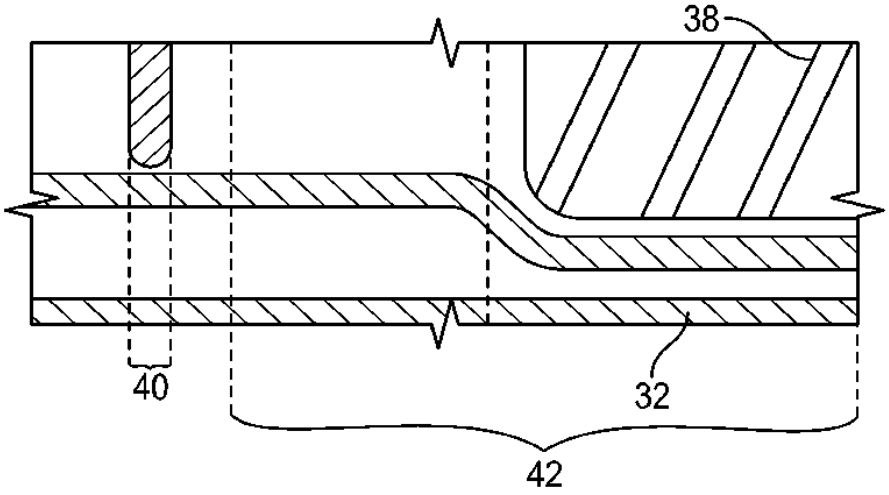


FIG. 55C

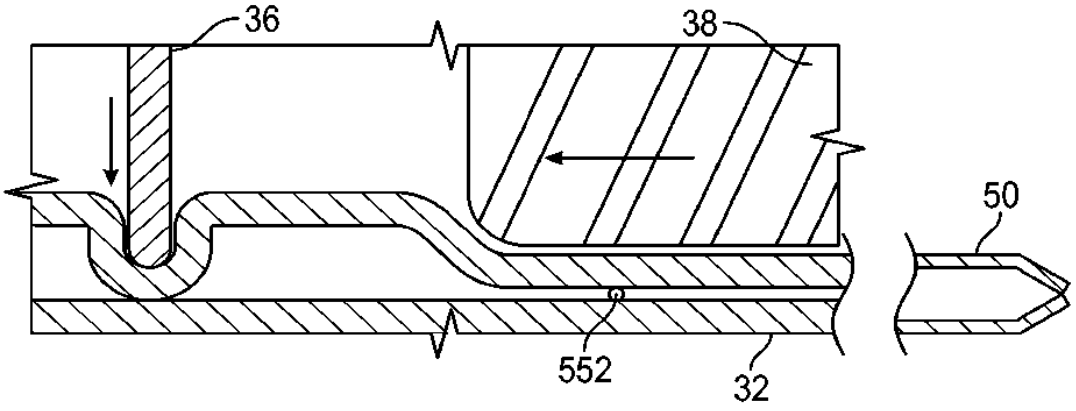


FIG. 55D

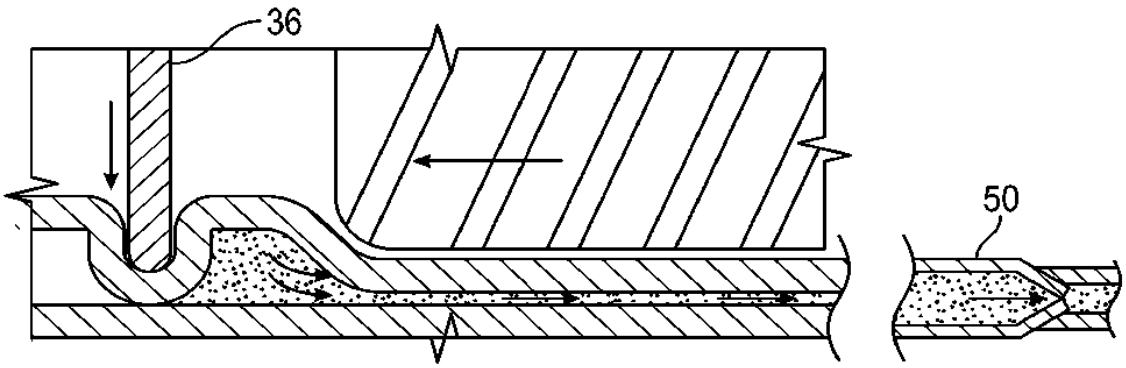


FIG. 55E

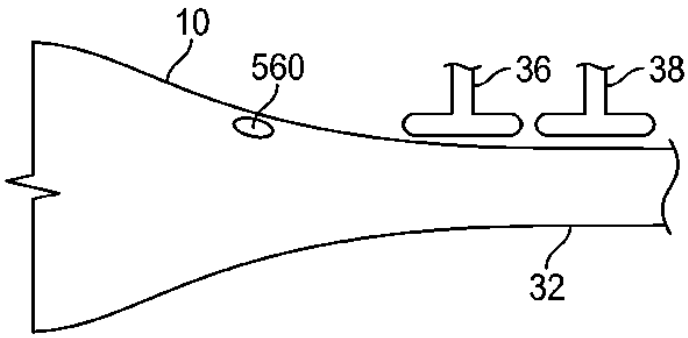


FIG. 56

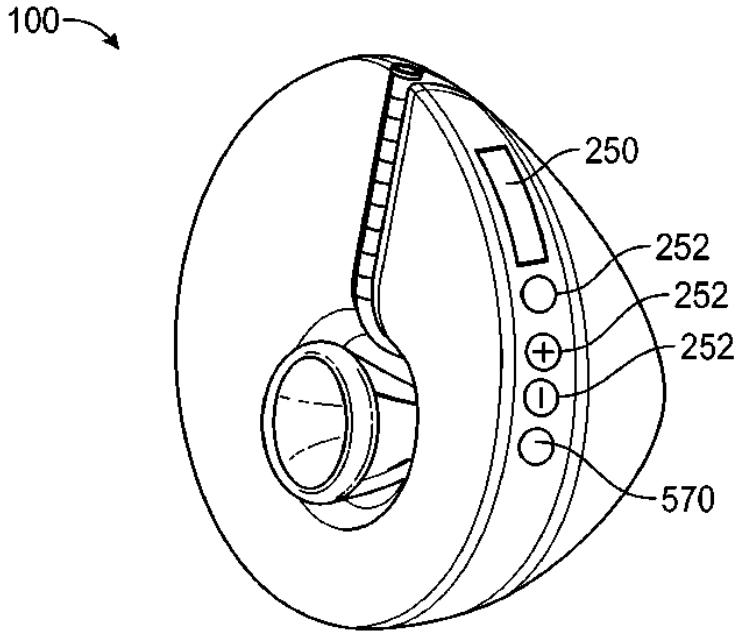


FIG. 57

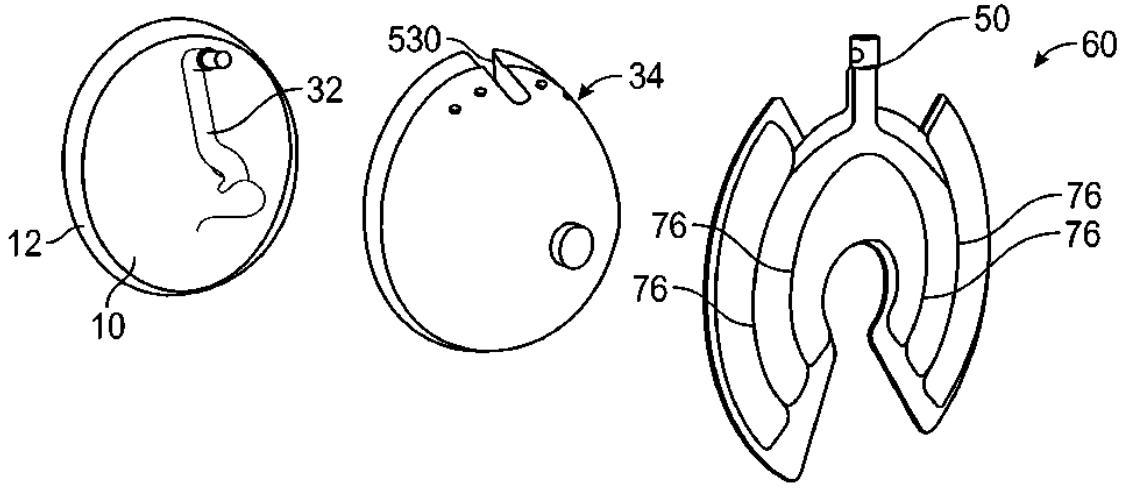


FIG. 58A

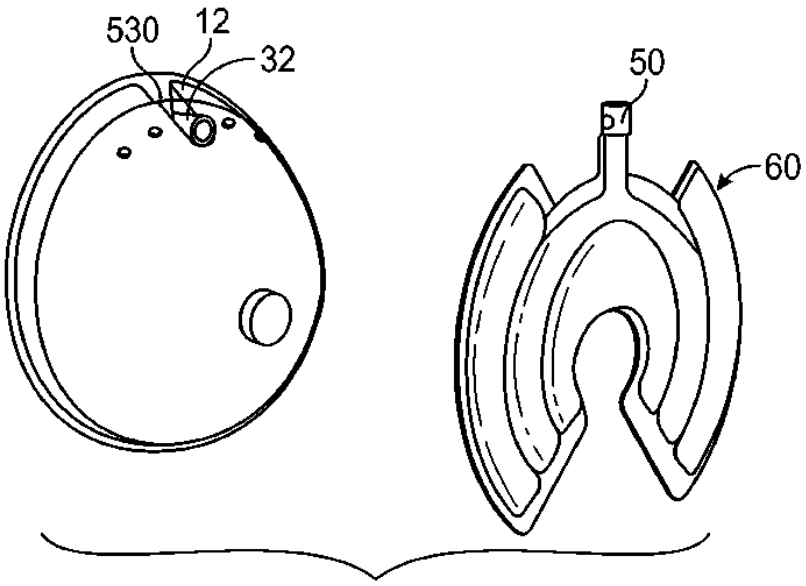


FIG. 58B

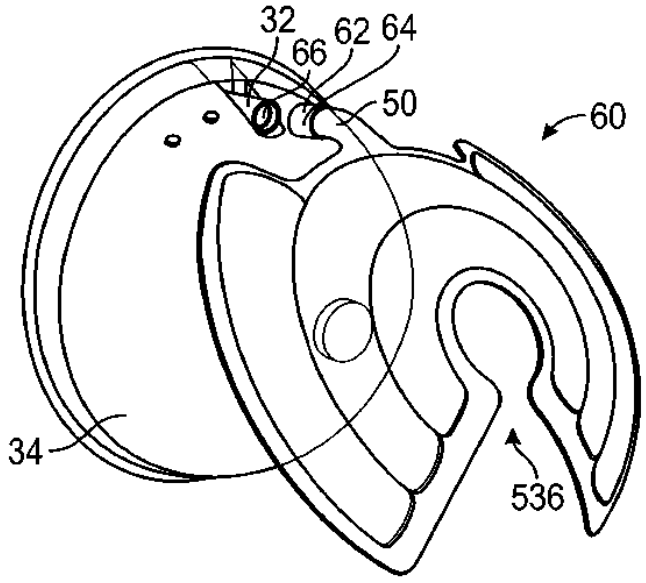


FIG. 58C

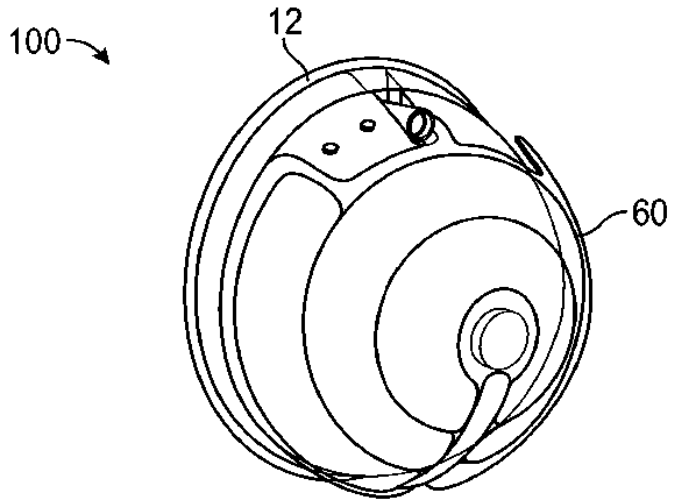


FIG. 58D

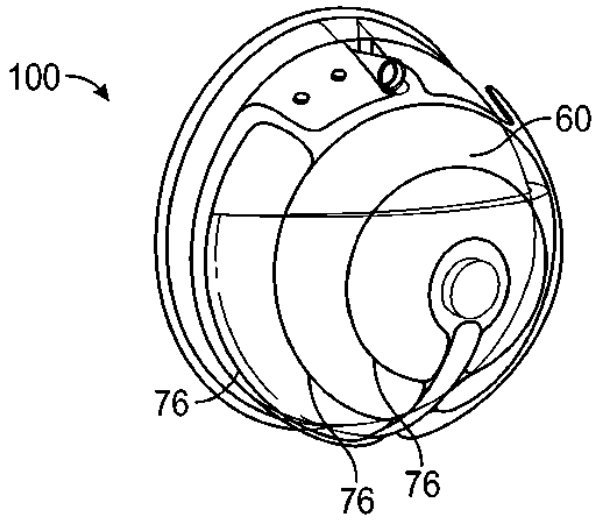


FIG. 58E

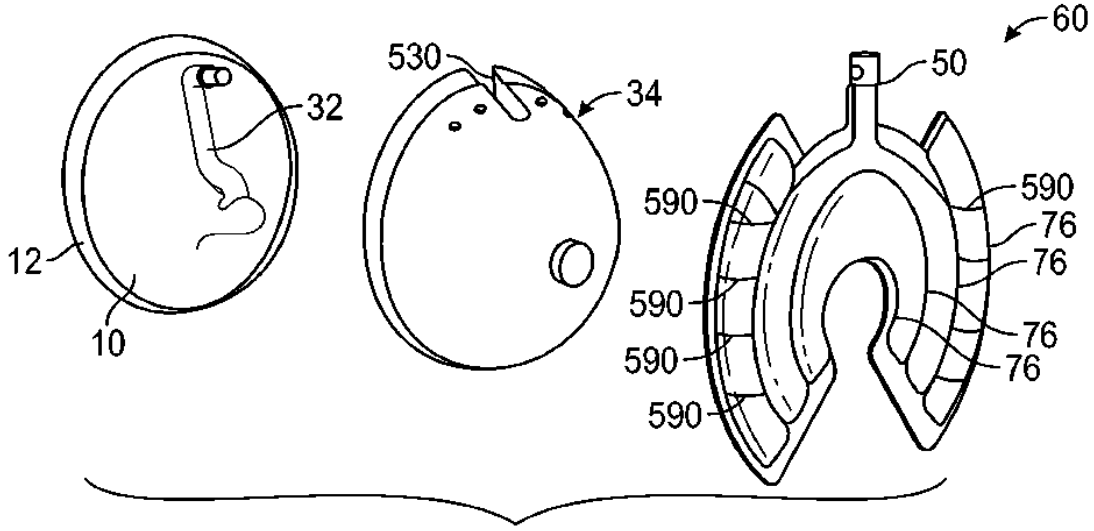


FIG. 59A

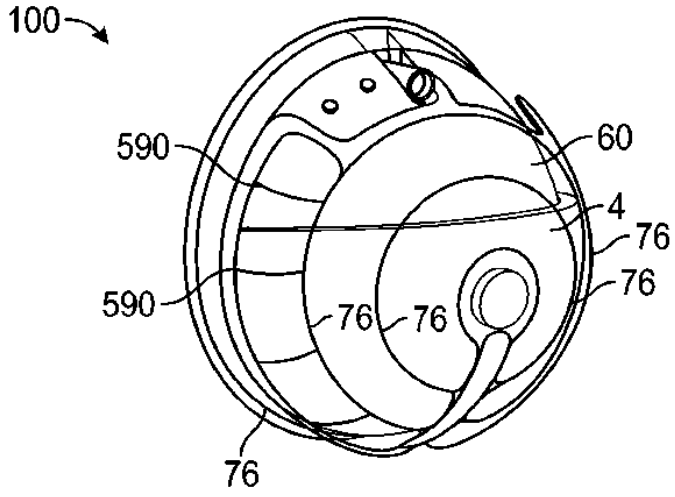


FIG. 59B

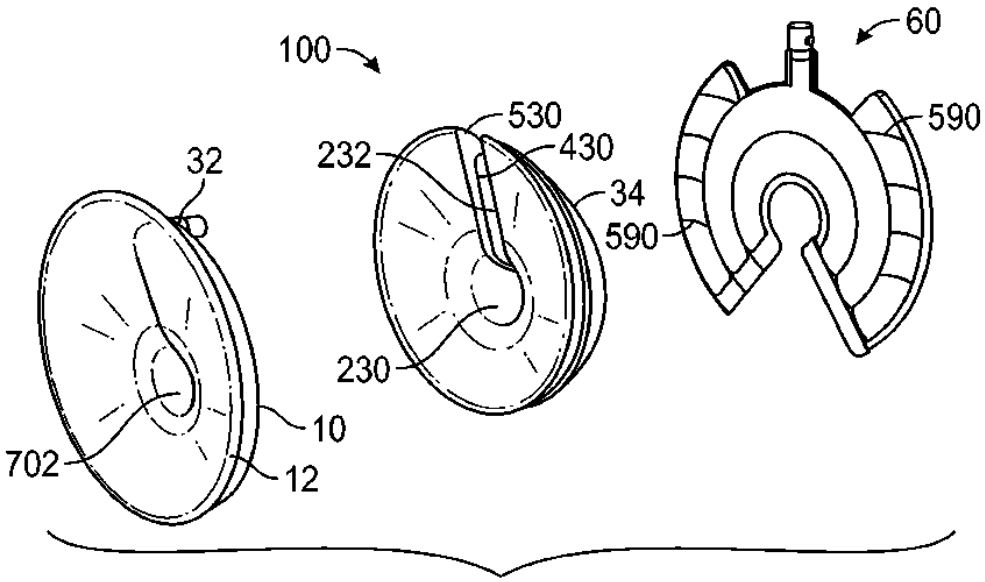


FIG. 59C

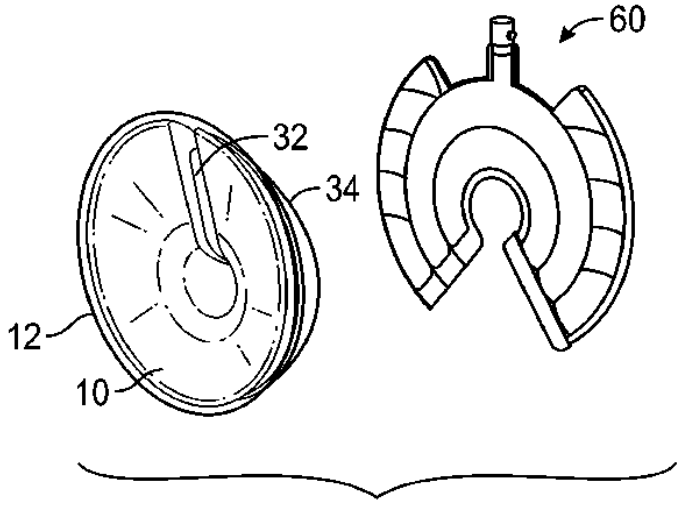


FIG. 59D

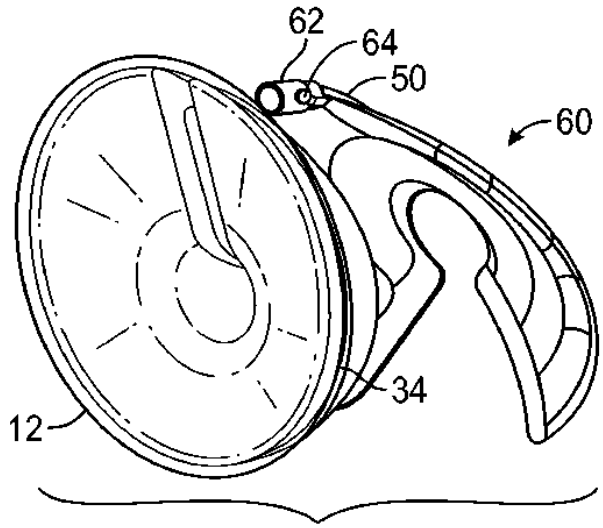


FIG. 59E

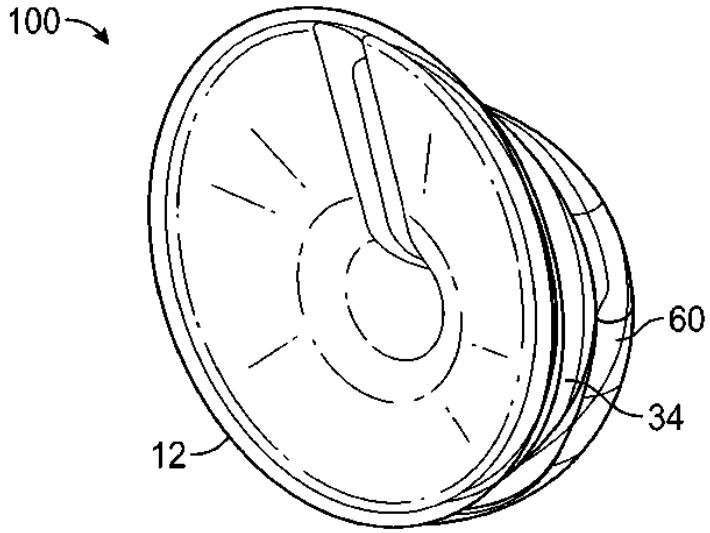


FIG. 59F

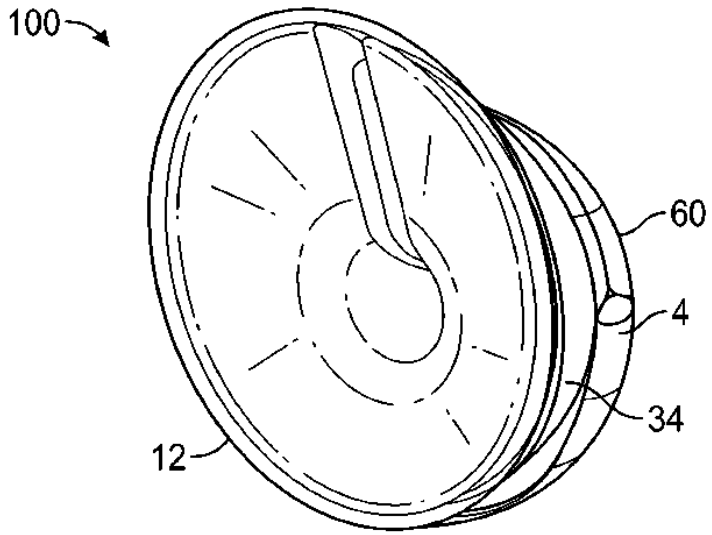


FIG. 59G

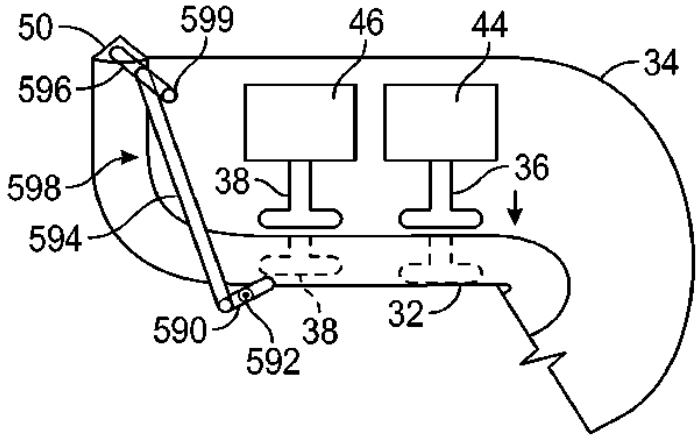


FIG. 60

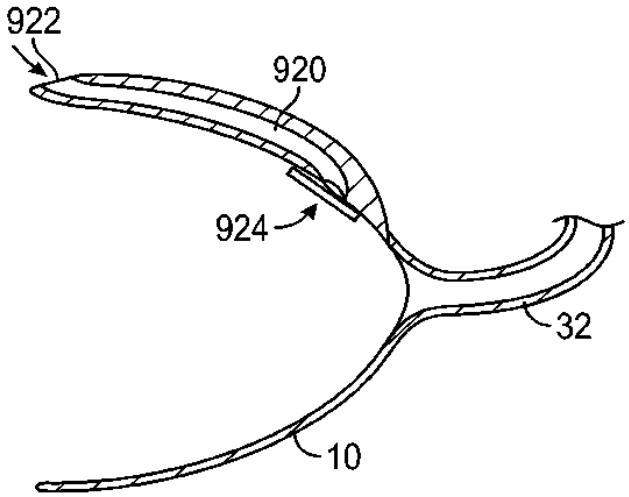


FIG. 61

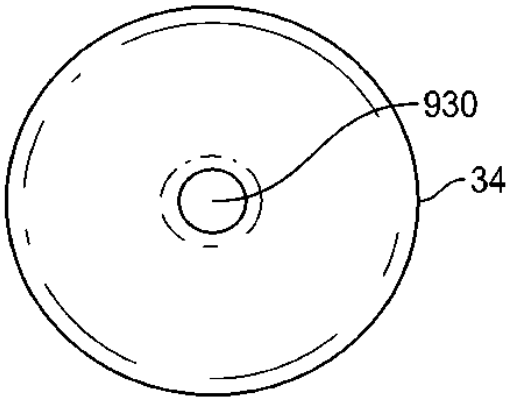


FIG. 62

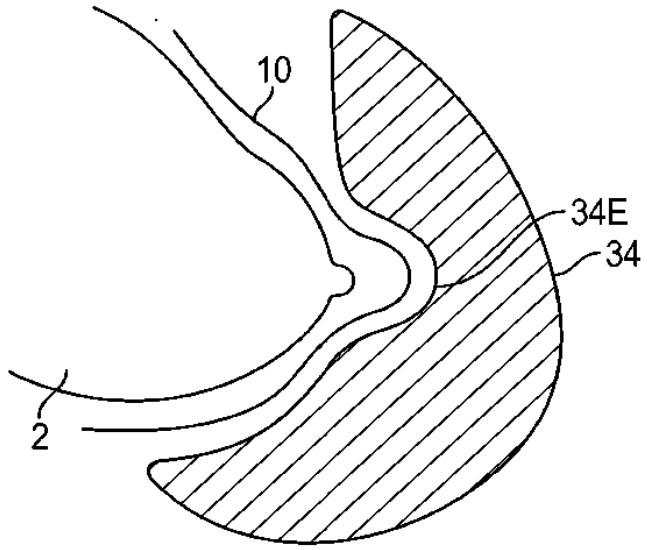


FIG. 63

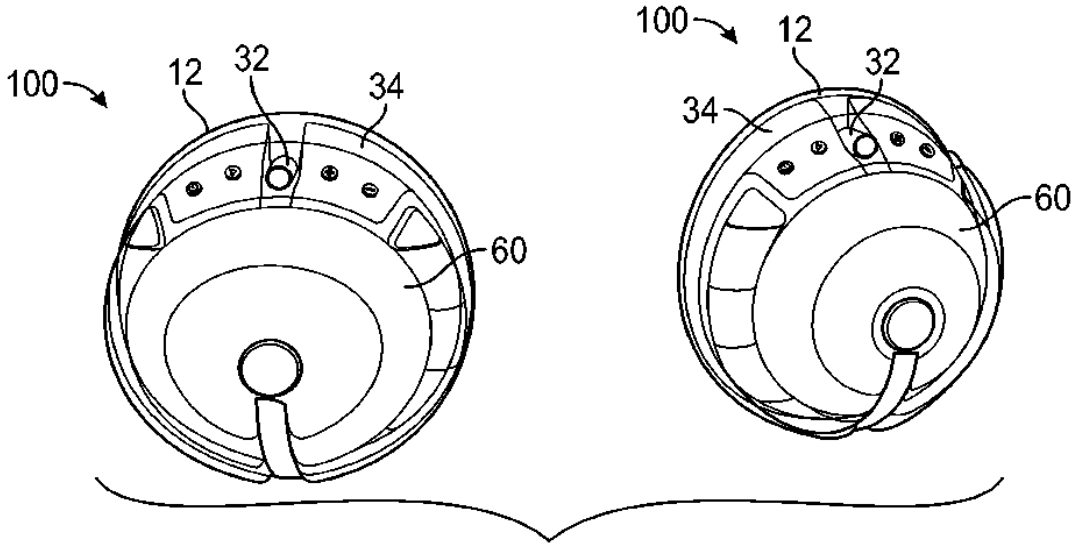


FIG. 64

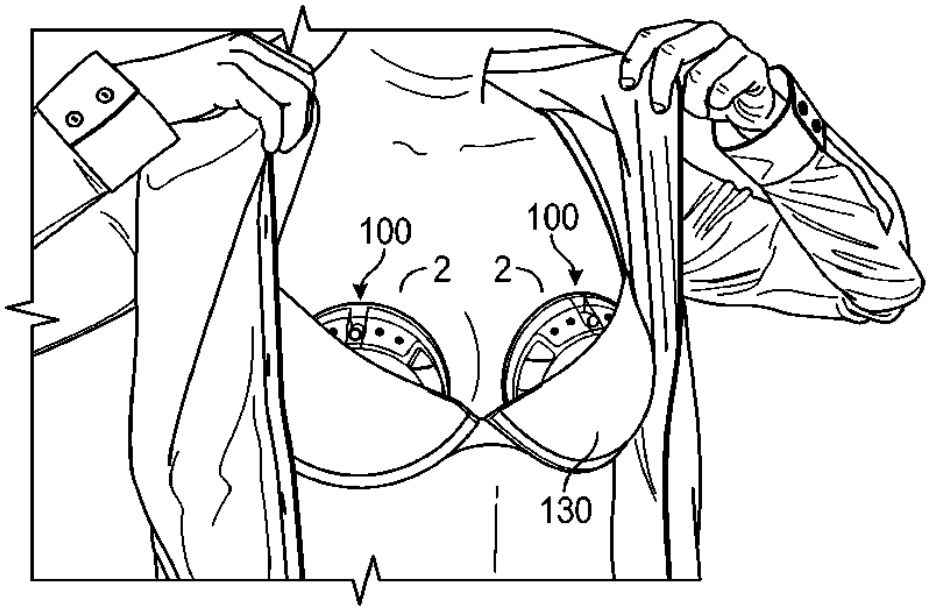


FIG. 65

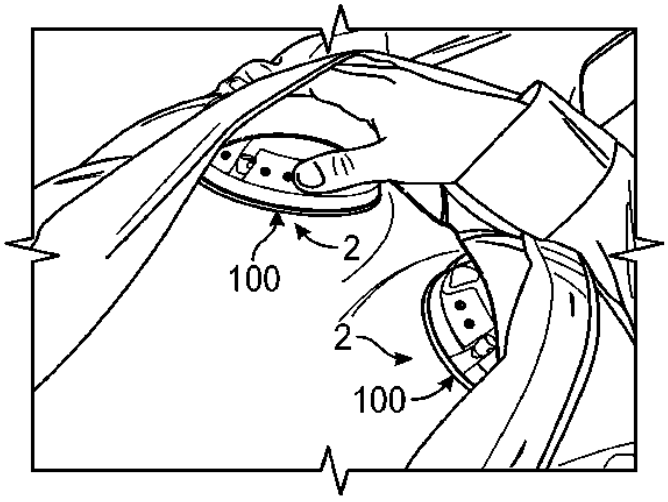


FIG. 66

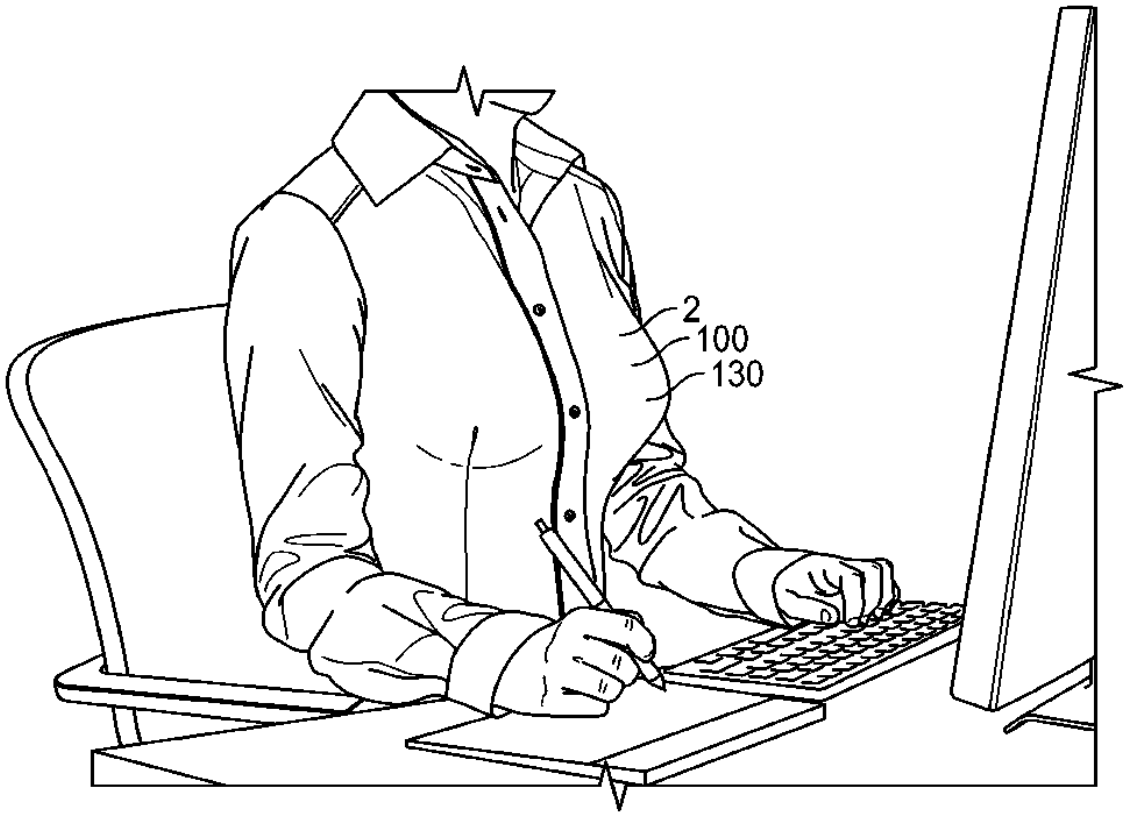


FIG. 67

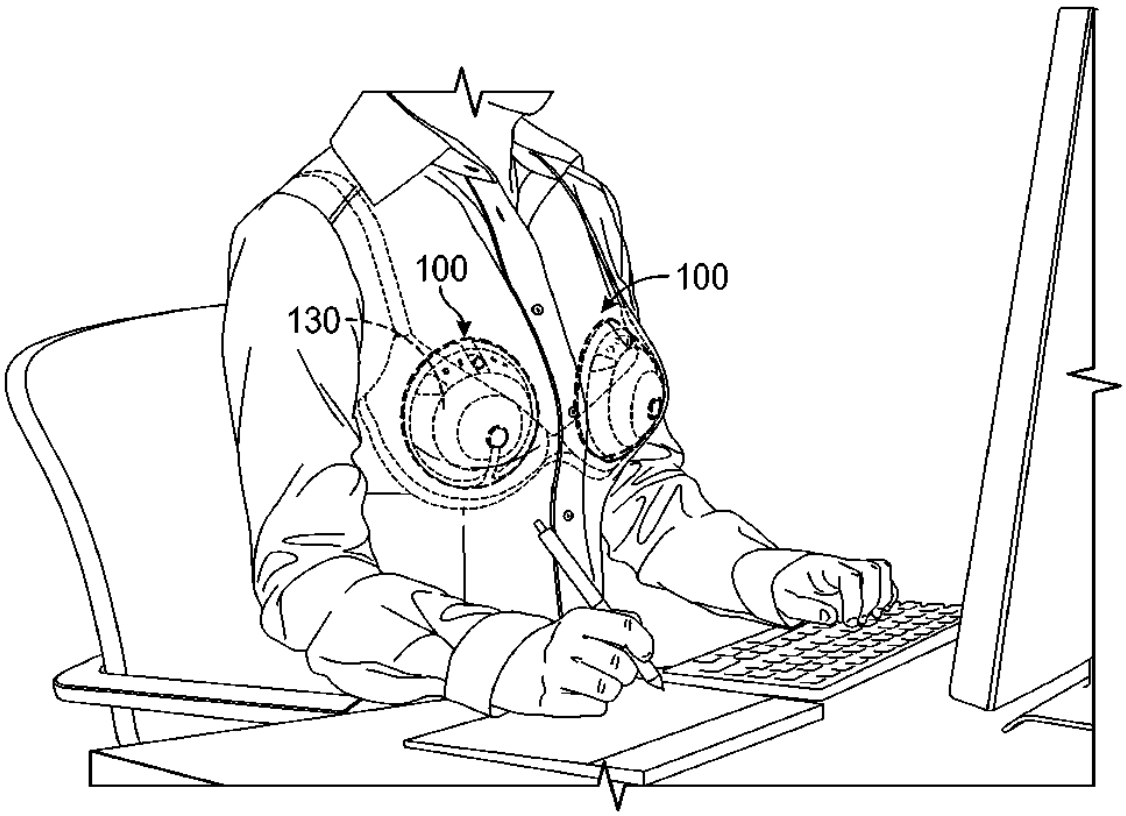


FIG. 68

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: 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. 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).

(74) Agent: **HANLEY, John**; 2570 W. 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

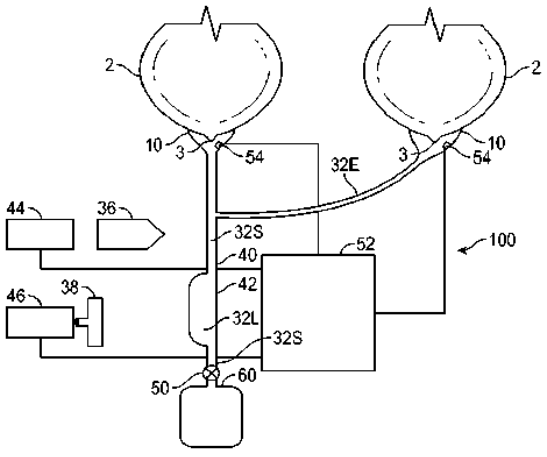


FIG. 24

(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.

WO 2016/014488 A1

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