Corrected Notice of Allowance - Correction of Issue Fee Amount

Due to a technical problem, the Notice of Allowance and Fee(s) Due mailed in this application specified an incorrect fee amount (the amount effective on January 19, 2025 for Notices of Allowance mailed on or after January 19, 2025). Corrected Notices of Allowance are being mailed to all applicants who are affected. This is necessary because the statute requires the applicant to pay the fee that is specified on the Notice of Allowance.

A Corrected Notice of Allowance is attached which specifies the correct issue fee. The time period for payment of the issue fee set forth in the previous Notice of Allowance and Fee(s) Due is being restarted to run THREE MONTHS from the "DATE MAILED" of the attached Corrected Notice of Allowance. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE

For applicants who replied prior to receiving the Corrected Notice of Allowance:

Applicant must still file a completed Part B – Fee(s) Transmittal, Form PTOL-85 Part B, or an equivalent, in reply to the Corrected Notice of Allowance since the Corrected Notice of Allowance sets forth a time period for reply. This applies to those situations in which applicant's reply was not processed before the Corrected Notice of Allowance was mailed (e.g., the reply crossed in the mail with the Corrected Notice of Allowance) and those situations in which applicant's reply was already processed. Applicants should check the appropriate box in section 4b of Form PTOL-85 Part B, such as the box authorizing the Director to "charge the required fee(s), any deficiency, or credit any overpayment" to a deposit account number. If this box is checked, the applicant will be refunded the amount of any overpayment to the designated deposit account. In addition, by checking the appropriate box in section 4b of Form PTOL-85, Part B, the applicant requests the Office to "first reapply any previously paid fee shown above," as stated on the form. Applicant may also include an explanatory cover letter, if desired. If, however, applicant prefers to file an equivalent of Form PTOL-85, Part B, and if applicant paid an increased issue fee amount as specified on the Notice of Allowance, applicant may request a refund of the difference between the incorrect amount specified on the Notice of Allowance and the correct amount specified on the Corrected Notice of Allowance.

For questions regarding the issue fee amount calculation, please contact the Application Assistance Unit at 888-786-0101 or *HelpAAU@uspto.gov.*.

For assistance with Patent Center or other Patent Electronic Systems, please contact the Patent EBC at 1-866-217-9197 or *ebc@uspto.gov*.

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

CORRECTED
NOTICE OF ALLOWANCE AND FEE(S) DUE

26111 7590 12/20/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 12/20/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	03/20/2025

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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 the USPTO patent electronic filing system.

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

26111 7590 12/20/2024
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

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 the USPTO patent electronic filing system 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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	03/20/2025

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/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 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)

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

☐ Electronic Payment via the USPTO patent electronic filing system ☐ 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

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.

☐ Applicant asserting small entity status. See 37 CFR 1.27

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.

☐ Applicant changing to regular undiscounted fee 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

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 12/20/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 12/20/2024

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) 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));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26111 7590 12/19/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 12/19/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1290	$0.00	$0.00	$1290	03/19/2025

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:

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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

26111 7590 12/19/2024
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

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 the USPTO patent electronic filing system 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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1290	$0.00	$0.00	$1290	03/19/2025

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/AIA/122 or PTO/SB/122) attached.

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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)

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

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

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☐ Applicant certifying micro entity status. See 37 CFR 1.29

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.

☐ Applicant asserting small entity status. See 37 CFR 1.27

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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
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 12/19/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
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EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 12/19/2024

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

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

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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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) 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));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/181,057	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 RCE and IDS filed.
   ☐ 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/
Primary Examiner, Art Unit 3783

Continuation of 3. The allowed claim(s) is/are: 1,3-22,24-25 and 28-34

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	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 SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf
Updated search	10/06/2023	cbf
Updated search	06/13/2024	cbf
Updated search based on submitted refs in IDS	12/06/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see SEARCH history	06/13/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					Type	Version
A61M	/	1	/	062	F	2014-02-04
A61M	/	1	/	067	I	2021-05-01
A61M	/	1	/	06935	I	2021-05-01
A61M	/	1	/	0697	I	2021-05-01
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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	06 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20241206

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC							
Symbol						**Type**	**Version**
A61M	/	2205	/	7536		A	2013-01-01
A61M	/	2205	/	80		A	2013-01-01
A61M	/	2205	/	8206		A	2013-01-01
A61M	/	2209	/	082		A	2013-01-01
A61M	/	2209	/	088		A	2013-01-01

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	06 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20241206

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	06 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20241206

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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		10		19		28								
	2		11		20		29								
	3		12		21		30								
	4		13		22		31								
	5		14		23		32								
	6		15		24		33								
	7		16		25		34								
	8		17		26										
	9		18		27										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	06 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6673036-B1	01-06-2004	BRITTO; James Joseph	
	002	US-6840918-B1	01-11-2005	BRITTO; James J. et al.	
	003	US-6887210-B2	05-03-2005	QUAY; Steven C.	
	004	US-7875000-B2	01-25-2011	KREBS; Yvonne et al.	
	005	US-8216179-B2	07-10-2012	BOSSHARD; Patrik et al.	
	006	US-9580863-B2	02-28-2017	BADER; Yves et al.	
	007	US-9919084-B2	03-20-2018	POLLEN; Ashia M. et al.	
	008	US-10046097-B2	08-14-2018	THOMPSON; Susan et al.	
	009	US-10149929-B2	12-11-2018	FURRER; Etienne et al.	
	010	US-10660995-B2	05-26-2020	MAKOWER; Joshua et al.	
	011	US-11717599-B2	08-08-2023	MILLER; Jared et al.	
	012	US-20080090444-A1	04-17-2008	LUZBETAK; Mark A. et al.	
	013	US-20110071466-A1	03-24-2011	SILVER; Brian H. et al.	
	014	US-20130123688-A1	05-16-2013	BOSMAN; Franciscus Jozef et al.	
	015	US-20140135683-A1	05-15-2014	HRADISKY; John L. et al.	
	016	US-20150217035-A1	08-06-2015	POLLEN; Ashia M. et al.	
	017	US-2015/0328380-A1	11-19-2015	FURRER; Etienne et al.	
	018	US-20150335800-A1	11-26-2015	YAMASHITA; Daisuke	
	019	US-20160213824-A1	07-28-2016	FRIDMAN; Ofer	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-105233355-A	01-13-2016	CHEN JUNBO.		☒

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	002	CN-205626591-U	10-12-2016	GUANGZHOU NANSHA DISTR DONGYONG YONGYI MOLD FACTORY.		☒
	003	CN-206473606-U	09-08-2017	SHANTOU HHQ ELECTRON TECH CO LTD.		☒
	004	CN-209033304-U	06-28-2019	SHANTOU HHQ ELECTRON TECH CO LTD.		☒
	005	CN-210096493-U	02-21-2020	WUXI XINZHONGRUI BABY SUPPLIES CO LTD.		☒
	006	JP-6292720-B2	03-14-2018	E. I. DU PONT DE NEMOURS AND COMPANY.		☒
	007	WO-2014094187-A1	06-26-2014	MEDELA HOLDING AG [CH]		☒
	008	WO-2015069095-A1	05-14-2015	SEE JING YEU [MY]		☐
	009	WO-2016108616-A1	07-07-2016	DOOSAN ENGINE CO LTD [KR]		☒
	010	WO-9636298-A1	11-21-1996	SCIMED LIFE SYSTEMS INC [US], et al.		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	CNET, "Pump on the go with the willow breast pump" 4 pages.	☐
	002	D'IGNAZIO, C., et al., "A Feminist HCI Approach to Designing Postpartum Technologies: "When I first saw a breast pump I was wondering if it was a joke," Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems, Association for Computing Machinery, San Jose, California, USA, 11 pages (May 2016).	☐
	003	FALCONE, J., "CES 2017: The final word" CNET, 18 pages (2017).	☐
	004	INGRAHAM, N., "How a smart breast pump won CES," Engadget, 11 pages.	☐
	005	LARSON, S., "Smart breast pump lets moms multitask," CES 2017: Willow's smart breast pump lets moms multitask, 16 pages.	☐
	006	LAUGHLIN, S., "Willow is among several companies at CES focused on meeting the needs of new moms," CES 2017: Maternal tech, 6 pages (January 2017).	☐
	007	MARTIN, C. E., AND CARY, J., "Shouldn't the Breast Pump Be as Elegant as an iPhone and as Quiet as a Prius by Now?" Motherlode: Adventures in Parenting, 3 pages (March 2014).	☐
	008	"Medela Pump In Style Advanced - Review" The Pumping mommy, 8 pages.	☐
	009	STRAUSS, E., "Breast Pumps Are Finally Getting Better. Here's How," Slate, 7 pages (May 2016).	☐
	010	"The Breast Pump Finally Joins the 21st Century," ARIELLE PARDES, 18 pages (2017).	☐
	011	The Willow smart breast pump could be a game-changer for moms, 2 pages.	☐
	012	Willow breast pump at CES 2017, 2 pages.	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	12/06/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 4 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

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.

☒ A certification statement is not submitted herewith.

FEE

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-12-03
Name/Print	Yangbeini Wang	Registration Number	800,005

23535945.1

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

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2022/01/01 01:04 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20120277636" OR "20130023821" OR "20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR				

		"8057425" OR "8118772" OR "8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2022/01/14

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				12:42 PM
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"20090281485" "20120165729" "5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2023/03/24

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				05:34 PM
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM
L34	1	1 AND (correct WITH nipple WITH align$6)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/06 02:29 PM
L35	9837	a61m1/06-0697.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:15 PM
L36	23049	breast WITH pump	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:16 PM
L37	61	(35 34) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4 correct$4 appropriat$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:17 PM
L38	69	(35 36) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO;	OR	ON	ON	2024/03/12 05:57 PM

		correct$4 appropriat$4))	JPO; DERWENT; IBM_TDB)				
L39	173	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/13 05:16 PM
L40	76	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:16 PM
L41	42	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:16 PM
L42	0	("16713099").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:20 PM
L43	1	("6328709").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:22 PM
L44	2	("16/713099").app.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:23 PM
L45	1	("20160022477").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:28 PM
L46	376301	breast.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L47	7245334	pump$4.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L48	1027289	shield.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L49	237305	interchang$6.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2024/06/13 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L50	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L51	1017372	spacing.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L52	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L53	4	("20120035559").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 07:07 PM
L54	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:05 PM
L55	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:06 PM
L56	7	(US-10987455-$ | US-20170080135-$ | US-20170136161-$ | US-	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM

		20190275222-$ | US-20210170080-$ | US-20220031918-$ | US-20220409782-$).DID.					
L57	4	("20070060873").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/07 12:07 PM
L58	1	("20070060873").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM
L59	17	53 54 55 56 58	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:07 PM
L60	11	59 AND ((fit$4 siz$4) WITH (shield nipple interface cup flange))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:10 PM
L61	1	("4000661").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:16 PM
L62	15	(("4000661").pn.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/07 12:16 PM
L63	39	(US-0328380-$ | US-10046097-$ | US-10149929-$ | US-10660995-$ | US-11717599-$ | US-6673036-$ | US-6840918-$ | US-6887210-$ | US-7875000-$ | US-8216179-$ | US-9580863-$ | US-9919084-$ | US-20080090444-$ | US-20110071466-$ | US-20130123688-$ | US-20140135683-$ | US-20150328380-$ | US-20150217035-$ | US-20150335800-$ | US-20160213824-$).DID.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/12/06 03:25 PM
L64	21	(US-0328380-$ | US-10046097-$ | US-10149929-$ | US-10660995-$ | US-11717599-$ | US-6673036-$ | US-	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/12/06 03:25 PM

		6840918-$ | US-6887210-$ | US-7875000-$ | US-8216179-$ | US-9580863-$ | US-9919084-$ | US-20080090444-$ | US-20110071466-$ | US-20130123688-$ | US-20140135683-$ | US-20150328380-$ | US-20150217035-$ | US-20150335800-$ | US-20160213824-$).DID.					

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	76349	breast.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N2	480637	pump$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N3	148822	shield.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N4	57138	interchang$6.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N5	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N6	250019	spacing.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N7	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N8	0	N1 AND N2 AND N3 AND N4 AND N5 AND N6 AND N7	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:35 PM

Bibliographic Data

Application No: 17/181,057

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.
02/22/2021	604	3783	4944.0120006
RULE			

APPLICANTS

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Adam ROLLO, London, UNITED KINGDOM

Andrew CARR, London, UNITED KINGDOM

CONTINUING DATA

This application is a CON of 16009547 06/15/2018 PAT 10926011

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

03/02/2021

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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B
Attorney Docket Number	4944.0120006

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. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. 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).

   a. ☐ 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.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ 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)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 19-0036 .

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

   d. ■ Payment by EFS-Web

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Yangbeini Wang #800,005/	Date	December 3, 2024
Name (Print/Type)	Yangbeini Wang	Registration No.	800,005

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**12/04/2024 04:13:26 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	68218236	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 26

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-12-04-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	168 KB
2024-12-04-RCE-Form-4944-0120006.pdf	2	Request for Continued Examination (RCE)	273 KB
Warning: This is not a USPTO supplied RCE fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
2024-12-04-sIDS-Pleading-4944-0120006.pdf	3	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-12-04-sIDS-SB08-4944-0120006.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	125 KB
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FOR_001_CN105233355A_EFS.pdf	13	Foreign Reference	607 KB
FOR_002_CN205626591U_EFS.pdf	9	Foreign Reference	378 KB
FOR_003_CN206473606U_EFS.pdf	7	Foreign Reference	286 KB
FOR_004_CN209033304U_EFS.pdf	12	Foreign Reference	803 KB
FOR_005_CN210096493U_EFS.pdf	15	Foreign Reference	937 KB
FOR_006_JP6292720B2_EFS.pdf	15	Foreign Reference	767 KB
FOR_007_WO2014094187A1_EFS.pdf	39	Foreign Reference	2143 KB
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NPL_001_CNET_Pump_4pgs_EFS.pdf	4	Non Patent Literature	140 KB
NPL_002_DIGNAZIO_Feminist_Proceedings_2016_11pgs_EFS.pdf	11	Non Patent Literature	193 KB
NPL_003_FALCONE_CES_2017_18pgs_EFS.pdf	18	Non Patent Literature	610 KB
NPL_004_INGRAHAM_Pump_11pgs_EFS.pdf	11	Non Patent Literature	191 KB
NPL_005_LARSON_Smart_16pgs_EFS.pdf	16	Non Patent Literature	835 KB
NPL_006_LAUGHLIN_Willow_CES_2017_6pgs_EFS.pdf	6	Non Patent Literature	108 KB
NPL_007_MARTIN_Elegant_Adventures_2014_3pgs_EFS.pdf	3	Non Patent Literature	44 KB
NPL_008_Medela_Pumping_8pgs_EFS.pdf	8	Non Patent Literature	119 KB

NPL_009_STRAUSS_Better_Slate_2016_7pgs_EFS.pdf	7	Non Patent Literature	197 KB
NPL_010_Pump_ARIELLE_2017_18pgs_EFS.pdf	18	Non Patent Literature	233 KB
NPL_011_Smart_2pgs_EFS.pdf	2	Non Patent Literature	49 KB
NPL_012_Willow_2pgs_EFS.pdf	2	Non Patent Literature	61 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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.

Bibliographic data

Title:	Breast pump
Pub/Pat no:	CN205626591U
Pub/Issue Date:	2016-10-12
Inventor(s):	JIAN ZHONGRONG|
Applicant(s):	GUANGZHOU NANSHA DISTR DONGYONG YONGYI MOLD FACTORY
Classification:	A61M1/06AI
Application number:	CN201620276943U 2016-04-01
Priority number:	CN201620276943U 20160401;

Abstract of CN205626591U

The utility model discloses a breast pump, including the feeding bottle, feeding bottle upper end opening is equipped with the pumping part, the pumping part still includes the mounting base including breast cover that is located the front end and the negative pressure connector who is located the rear end, the bottom of mounting base has the collet of supporting feeding bottle, but mounting base upper portion is equipped with matches sealing connection negative pressure connector's suction joint, be equipped with vacuum device in the mounting base, vacuum device's output is connected the suction and is connected. The utility model discloses with vacuum device integrative integrated to the mounting base in, simultaneously the mounting base have can direct sealing connection negative pressure connector the suction connect, as long as hold the mounting base during use, place feeding bottle and pumping part and can directly inhale milk on the collet, and need not additionally to dispose the hose, also need not external power facility, equipment, consequently the operation get up simply more, convenient. The utility model discloses the milk of inhaling that can be used to lactating women is operated.

(19)中华人民共和国国家知识产权局

(12)实用新型专利

(10)授权公告号 CN 205626591 U
(45)授权公告日 2016.10.12

(21)申请号 201620276943.1

(22)申请日 2016.04.01

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代理人 冯剑明

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

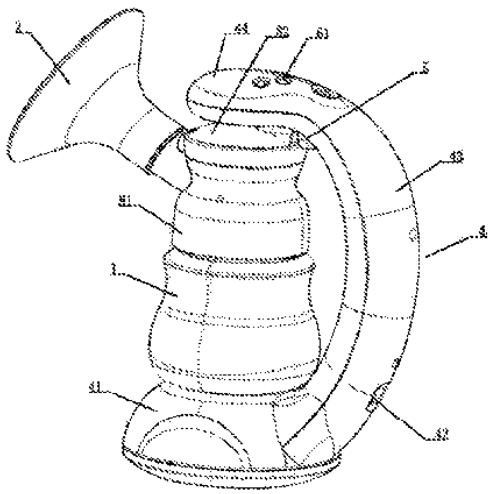
权利要求书1页 说明书3页 附图3页

(54)实用新型名称

一种吸奶器

(57)摘要

本实用新型公开了一种吸奶器，包括奶瓶，所述奶瓶上端开口设有抽吸部件，所述抽吸部件包括位于前端的乳房罩以及位于后端的负压接口，还包括安装基座，所述安装基座的底部具有支承奶瓶的底托，所述安装基座上部设有匹配并可密封连接负压接口的抽吸接头，所述安装基座内设有负压装置，所述负压装置的输出端连接抽吸接头。本实用新型将负压装置一体集成至安装基座内，同时安装基座具有可直接密封连接负压接口的抽吸接头，使用时只要拿着安装基座，将奶瓶以及抽吸部件放置在底托上即能直接吸奶，而无需额外配置软管，也无需外置动力设施、设备，因此操作起来更加简单、方便。本实用新型可用于哺乳妇女的吸奶操作。



CN 205626591 U

1.一种吸奶器，包括奶瓶(1)，所述奶瓶(1)上端开口设有抽吸部件，所述抽吸部件包括位于前端的乳房罩(2)以及位于后端的负压接口(3)，其特征在于：还包括安装基座(4)，所述安装基座(4)的底部具有支承奶瓶(1)的底托(41)，所述安装基座(4)上部设有匹配并可密封连接负压接口(3)的抽吸接头(5)，所述安装基座(4)内设有负压装置，所述负压装置的输出端连接抽吸接头(5)。

2.根据权利要求1所述的吸奶器，其特征在于：所述安装基座(4)的顶部设有照明部件。

3.根据权利要求2所述的吸奶器，其特征在于：所述照明部件的光源朝向底托(41)方向。

4.根据权利要求2所述的吸奶器，其特征在于：所述安装基座(4)上设有可外接电源的供电插头(42)，所述供电插头(42)通过线路连接照明部件和负压装置。

5.根据权利要求2所述的吸奶器，其特征在于：所述安装基座(4)内设有为负压装置以及照明部件供电的电池组件。

6.根据权利要求2或3或4或5所述的吸奶器，其特征在于：所述负压装置包括固定在底托(41)内部的负压泵，所述负压泵的输出端通过安装基座(4)内的管路连接抽吸接头(5)。

7.根据权利要求2或3或4或5所述的吸奶器，其特征在于：所述安装基座(4)顶部的内腔设有控制线路板(6)，所述控制线路板(6)电性连接负压装置和照明部件，所述安装基座(4)顶部的外壁设有与控制线路板(6)匹配的控制按钮(61)，所述控制线路板(6)配套设有显示屏(7)。

8.根据权利要求1或2或3或4或5所述的吸奶器，其特征在于：所述抽吸部件包括与奶瓶(1)上端开口螺纹连接的三通连接件(81)，所述乳房罩(2)接于三通连接件(81)的侧端开口，所述三通连接件(81)的顶部开口接有顶盖(82)，所述负压接口(3)设置在顶盖(82)上，所述三通连接件(81)内部还设置有抽吸用的隔膜(83)。

9.根据权利要求8所述的吸奶器，其特征在于：所述三通连接件(81)通向奶瓶(1)的通道中设有单向阀(84)。

一种吸奶器

技术领域

[0001] 本实用新型涉及哺乳器材领域，特别是涉及一种吸奶器。

背景技术

[0002] 目前的吸奶器一般为手持式，如CN 204033881U的吸奶器，包括一个奶瓶，奶瓶上端开口设有抽吸部件，抽吸部件包括位于前端的乳房罩以及位于后端的负压接口，使用时用手握持奶瓶，在负压接口上套接软管，软管连接负压泵以进行吸奶。但是，这种类型的吸奶器普遍存在着使用不便的问题。每次吸奶都要外接一套的负压装置和配套的软管，操作起来略显麻烦，而且各零散的部件也会占用更多的空间。

实用新型内容

[0003] 为了解决上述问题，本实用新型的目的在于提供一种吸奶器，其使用方便。

[0004] 本实用新型所采用的技术方案是：

[0005] 一种吸奶器，包括奶瓶，所述奶瓶上端开口设有抽吸部件，所述抽吸部件包括位于前端的乳房罩以及位于后端的负压接口，还包括安装基座，所述安装基座的底部具有支承奶瓶的底托，所述安装基座上部设有匹配并可密封连接负压接口的抽吸接头，所述安装基座内设有负压装置，所述负压装置的输出端连接抽吸接头。

[0006] 作为本实用新型的进一步改进，所述安装基座的顶部设有照明部件。

[0007] 作为本实用新型的进一步改进，所述照明部件的光源朝向底托方向。

[0008] 作为本实用新型的进一步改进，所述安装基座上设有可外接电源的供电插头，所述供电插头通过线路连接照明部件和负压装置。

[0009] 作为本实用新型的进一步改进，所述安装基座内设有为负压装置以及照明部件供电的电池组件。

[0010] 作为本实用新型的进一步改进，所述负压装置包括固定在底托内部的负压泵，所述负压泵的输出端通过安装基座内的管路连接抽吸接头。

[0011] 作为本实用新型的进一步改进，所述安装基座顶部的内腔设有控制线路板，所述控制线路板电性连接负压装置和照明部件，所述安装基座顶部的外壁设有与控制线路板匹配的控制按钮，所述控制线路板配套设有显示屏。

[0012] 作为本实用新型的进一步改进，所述抽吸部件包括与奶瓶上端开口螺纹连接的三通连接件，所述乳房罩接于三通连接件的侧端开口，所述三通连接件的顶部开口接有顶盖，所述负压接口设置在顶盖上，所述三通连接件内部还设置有抽吸用的隔膜。

[0013] 作为本实用新型的进一步改进，所述三通连接件通向奶瓶的通道中设有单向阀。

[0014] 本实用新型的有益效果是：本实用新型将负压装置一体集成至安装基座内，同时安装基座具有可直接密封连接负压接口的抽吸接头，使用时只要拿着安装基座，将奶瓶以及抽吸部件放置在底托上即能直接吸奶，而无需额外配置软管，也无需外置动力设施、设备，因此操作起来更加简单、方便。

附图说明

[0015] 下面结合附图和实施方式对本实用新型进一步说明。

[0016] 图1是吸奶器的结构示意图；

[0017] 图2是安装基座的结构示意图；

[0018] 图3是安装基座的分解示意图；

[0019] 图4是奶瓶的分解示意图。

具体实施方式

[0020] 如图1至图4所示的吸奶器，包括奶瓶1，奶瓶1上端开口设有抽吸部件，抽吸部件包括位于前端的乳房罩2以及位于后端的负压接口3。吸奶器还包括一个安装基座4，该所述安装基座4为一空心的壳体，安装基座4的底部为支承奶瓶1的底托41，中部为弧形臂43，上部为盖结构44，位于底托41的正上方。在安装基座弧形臂43的顶端设置有与抽吸部件的负压接口3匹配并可密封连接负压接口3的抽吸接头5，当奶瓶1放置在底托41上时，抽吸接头5可直接密封连接负压接口3。另外，安装基座4内设有负压装置，负压装置的输出端连接抽吸接头5。负压装置可以通过通电而启动并产生抽吸的动力，通过负压接口3将抽吸力传递至抽吸部件中。

[0021] 上述的吸奶器将产生动力的负压装置一体集成至安装基座4内，同时安装基座4具有可直接密封连接负压接口3的抽吸接头5，使用时只要拿着安装基座4，将奶瓶1以及抽吸部件放置在底托41上即能直接吸奶，而无需额外配置软管，也无需外置动力设施、设备，因此操作起来更加简单、方便。

[0022] 另外，若觉得整体安装基座4负载太重，也可以将抽吸接头5和负压接口3通过软管连接，仅握持奶瓶1以进行吸奶，一举两得。

[0023] 进一步优选的，安装基座4顶部的盖结构44中安装设有照明部件。因为一般来说因为哺乳期是有限的，吸奶器的使用期是与哺乳期相关，当加入照明部件后，底托41、弧形臂43、盖结构44和照明部件构成了一个台灯的结构，当无需要使用吸奶功能时，将奶瓶1和抽吸部件移走，那么即可成为一个照明的器具。

[0024] 进一步优选的，参考图2，照明部件实质为一配有灯罩的LED灯9，LED灯9的照射方向朝向底托41方向。

[0025] 进一步优选的，参考图1，安装基座4的弧形臂43上设有可外接电源的供电插头42，供电插头42通过安装基座4内的供电线路连接照明部件和负压装置，可以在供电插头42上连接配套的电线，之后接上交流电，以直接供电使用吸奶功能和照明功能。

[0026] 进一步优选的，参考图4，也可以使用内置的电池组件为吸奶、照明供电。具体来说，安装基座4的弧形臂43内设有电池组件，一般来说是蓄电池10，能同时为负压装置以及照明部件供电。而且，外接的交流电还能为该蓄电池10充电，避免了需要更换电池的麻烦。

[0027] 进一步优选的，负压装置包括固定在底托41内部的负压泵31，负压泵31的输出端通过安装基座4内的管路连接抽吸接头5，这些管路并未在附图中体现。负压泵31也可以配置电磁阀32等控制的零部件。

[0028] 进一步优选的，参考图1和图4，安装基座4顶部盖结构44的内腔设有控制线路板6，

控制线路板6电性连接负压装置和照明部件，安装基座4的盖结构44设有与控制线路板6匹配的控制按钮61，譬如是控制照明部件启闭的按钮，以及控制负压装置启闭的按钮，以及控制负压装置抽吸速度的按钮等。另外，控制线路板6配套设有显示屏7，显示吸奶器运行的状态。显示屏7可以突出于盖结构44，也可以是盖结构44位于显示屏7的上方且由透明材质制成，用户视线穿过盖结构44后观察显示屏7。

[0029] 本实施例中的抽吸部件结构如下。

[0030] 具体参考图3，抽吸部件包括与奶瓶1上端开口螺纹连接的三通连接件81，乳房罩2接于三通连接件81的侧端开口，三通连接件81的顶部开口接有顶盖82，负压接口3设置在顶盖82上，三通连接件81内部还设置有抽吸用的隔膜83。

[0031] 另外，三通连接件81通向奶瓶1的通道中设有单向阀84，防止奶的回流。

[0032] 以上所述只是本实用新型优选的实施方式，其并不构成对本实用新型保护范围的限制。

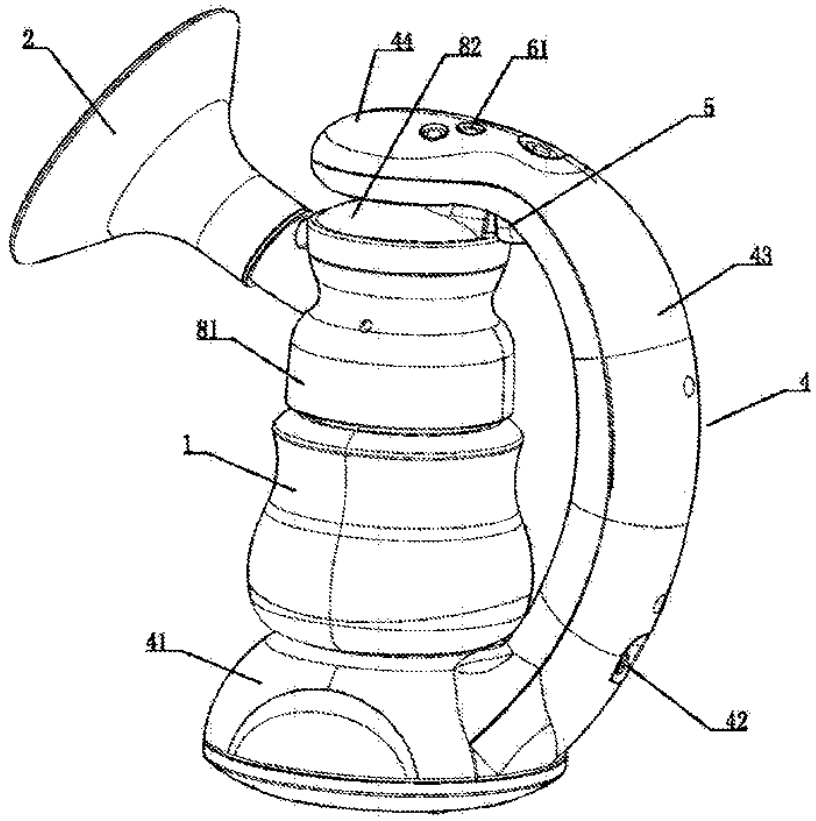


图1

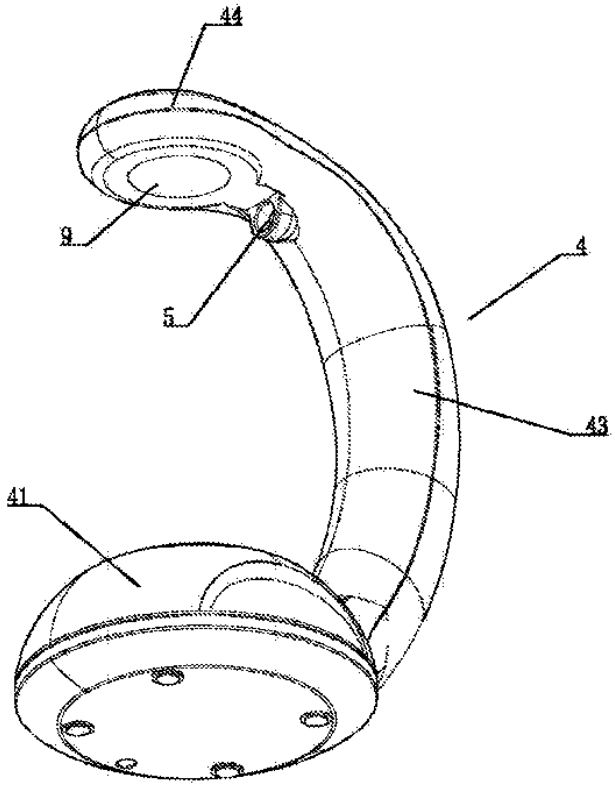


图2

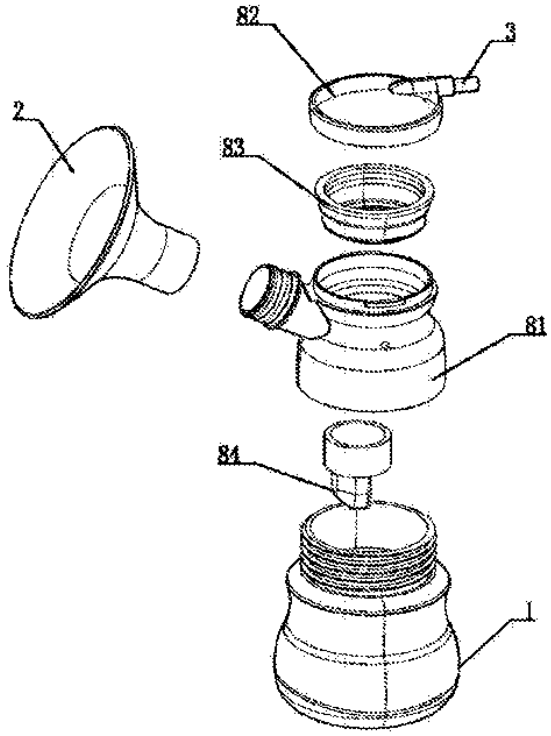


图3

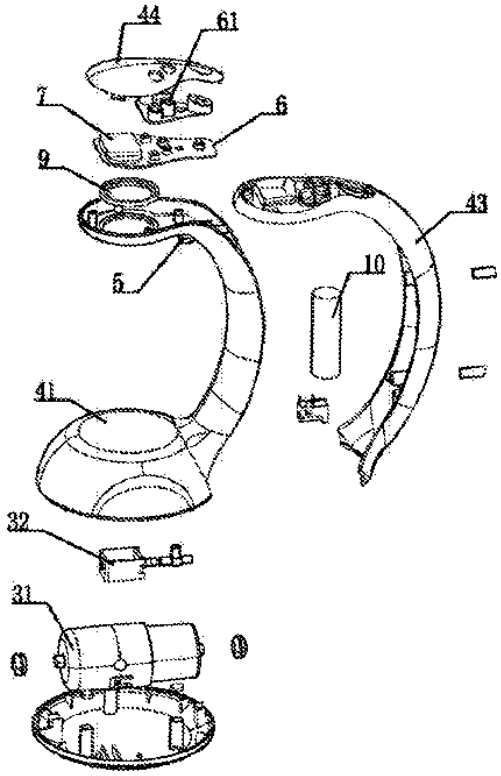


图4

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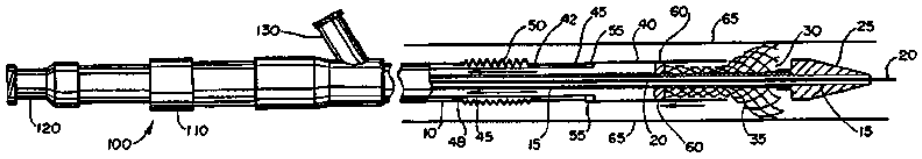
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(57) Abstract

The present invention provides an improved stent delivery catheter. The stent delivery system comprises a catheter having a stent receiving portion adapted to receive a stent near the distal end of the catheter and a stent concentrically arranged around the catheter within the stent receiving portion. The stent delivery system further comprises a proximal outer sheath, a retractable distal sheath surrounding at least a portion of the stent and containing the stent in its reduced delivery configuration and a pull back means connected to the retractable distal sheath. The system further comprises a collapsible sheath concentrically arranged around the catheter and located between the retractable distal sheath and the proximal outer sheath, whereby when the pull back means is pulled proximally the distal sheath is retracted, causing the collapsible sheath to collapse and freeing the stent for delivery.

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STENT DEPLOYMENT CATHETER WITH COLLAPSIBLE SHEATH

Field of the Invention

This invention relates to a stent delivery catheter system, such as the kind used in percutaneous transluminal coronary angioplasty (PTCA) procedures. More particularly, it relates to a stent delivery catheter employing a collapsible sheath which collapses during the retraction of a distal sheath during the release of a self-expanding or balloon expandable stent.

Background of the Invention

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the vascular system of a patient and advanced through the aorta until the distal end is in the ostium of the desired coronary artery. Using fluoroscopy, a guide wire is then advanced through the guiding catheter and across the site to be treated in the coronary artery. An over the wire (OTW) balloon catheter is advanced over the guide wire to the treatment site. The balloon is then expanded to reopen the artery. The OTW catheter may have a guide wire lumen which is as long as the catheter or it may be a rapid exchange catheter wherein the guide wire lumen is substantially shorter than the catheter. Alternatively, a fixed wire balloon catheter could be used. This device features a guide wire which is affixed to the catheter and cannot be removed.

To help prevent arterial closure, repair dissection, or prevent restenosis, a physician can implant an intravascular prosthesis, or a stent, for maintaining vascular patency inside the artery at the lesion. The stent may either be a self-expanding stent or a balloon expandable stent. For the latter type, the stent is often delivered on a balloon and the balloon is used to the expand the stent. The self-expanding stents may be made of shape memory materials such as NITINOL or constructed of regular metals but of a design which exhibits self expansion characteristics.

In certain known stent delivery catheters, a stent and an optional balloon are positioned at the distal end of the catheter, around a core lumen. The stent and balloon are held down and covered by a sheath or sleeve. When the distal

portion is in its desired location of the targeted vessel the sheath or sleeve is retracted to expose the stent. After the sheath is removed, the stent is free to self-expand or be expanded with a balloon.

In a coronary stent deployment system which utilizes a retractable sheath one problem which is encountered is the interaction of the sheath and guide catheter upon retraction. The traditional way of dealing with this is to make the retractable sheath long enough so that it will be contained in the guide catheter at all times. This increases system profile, reduces flexibility and creates excess friction upon sheath retraction. The invention disclosed reduces the sheath length, maintains a reduced system profile and provides good flexibility.

Summary of the Invention

The present invention provides an improved stent delivery system. The stent delivery system comprises a catheter having a proximal outer, a stent receiving portion adapted to receive a stent near the distal end of the catheter, a retractable distal sheath concentrically arranged around the stent receiving portion and a pull back means connected to the distal sheath. The catheter further comprises a collapsible sheath located between and adhered to the proximal outer and the retractable distal sheath. During retraction of the distal sheath the collapsible sheath collapses upon itself, or accordions upon its preformed pleats or creases, providing room for the distal sheath to retract unencumbered, thereby freeing the loaded stent. The inclusion of the collapsible sheath significantly reduces the required sheath length, maintains a reduced system profile, provides good flexibility and provides a protective covering to the wire pull back mechanism.

Other objects, features, embodiments and characteristics of the present invention, as well as the methods of operation and functions of the related elements of the structure, and the combination of parts and economics of manufacture, will become more apparent upon consideration of the following description with reference to the accompanying drawings, all of which form a part of this specification.

Brief Description of the Figures

Figure 1 shows a side view of a catheter according to the invention having a loaded stent including a cross-sectional view of the distal portion thereof and a side view of the proximal end of a catheter according to the invention showing the manifold portion thereof.

Figure 2 shows a side view of a catheter according to the invention having a loaded self-expanding stent including a cross-sectional view of the distal portion thereof, wherein the loaded stent is shown as partially deployed, and a side view of the proximal end of a catheter according to the invention showing the manifold portion thereof.

Figure 3 shows a side view of a catheter according to the invention having a loaded stent including a cross-sectional view of the distal portion thereof, wherein the loaded stent is shown as fully deployed and a side view of the proximal end of a catheter according to the invention showing the manifold portion thereof.

Figure 4 shows a side view of a catheter according to an alternative embodiment of the invention having a loaded stent including a cross-sectional view of the distal portion thereof.

Figure 5 shows a side view of a catheter according to an alternative embodiment of the invention having a loaded stent including a cross-sectional view of the distal portion thereof, wherein the loaded stent is shown as fully deployed.

Figure 6 shows a side view of a catheter according to an alternative embodiment of the invention having a loaded stent including a cross-sectional view of the distal portion thereof.

Figure 7 is a sectional view of the catheter thereof, taken along line 7-7 in Figure 6.

Figure 8 shows a side view of a catheter according to an alternative embodiment of the invention having a loaded stent including a cross-sectional view of the distal portion thereof.

Figure 9 shows a side view of a catheter according to an alternative embodiment of the invention having a loaded stent including a cross-sectional view of the distal portion thereof.

Figure 9a shows a partial exploded view of Fig. 9.

Figure 9b shows a partial exploded view of Fig. 9.

Figure 9c shows a partial exploded view of Fig. 9.

Detailed Description of the Invention

Figure 1 shows a cross-section of the distal portion of a specific embodiment of the stent delivery catheter, generally designated as 5, that is the subject of the present invention. The device generally comprises a proximal outer 10 which covers the majority of the catheter 5 excluding a portion of the distal end of the catheter 5. This outer 10 is characterized by a flexible tube which contains a pull wire lumen and a guide wire lumen. Preferably the outer 10 is comprised of a high density polyethylene (HDPE), SURLYN, a combination of HDPE and low density polyethylene (LDPE) or NYLON material. The proximal outer 10 encloses an optional guide wire lumen 15 which extends through and terminates with the distal tip 25 of the catheter 5. Preferably the guide wire lumen 15 encloses a guide wire 20 which aids in the navigation of the catheter 5 through the appropriate vessel. The guide wire lumen 15 is made of flexible, but incompressible construction such as a polymer encapsulated braid or coil. The flexibility of the braid/coil allows the catheter 5 to navigate through body lumens and the incompressibility of the braid/coil aids in maintaining the integrity of the catheter and aids in deployment accuracy when the sheath is being retracted during stent release. The braid/coil may be comprised of stainless steel or NITINOL, but preferably stainless steel encased in a polymer such as a polyimide, HDPE, TEFLON or urethane, but preferably polyimide and TEFLON.

Situated just proximal to the distal tip 25 is the portion 30 of catheter 5 around which the stent is concentrically carried. The stent 35 surrounds the guide wire lumen 25. The stent 35 is preferably a NITINOL™ or mesh self-expanding stent, but may also be a balloon expandable stent carried by an expansion balloon. Self-expanding and balloon expandable stents are well known in the art and require no further instruction.

The present invention further comprises a retractable distal sheath 40 which covers and contains the loaded stent 35. The retractable distal sheath 40 will hold a self-expanding stent in its reduced delivery configuration. The retractable

distal sheath will merely contain a balloon expandable stent which was positioned over an expansion balloon. The distal sheath 40 is connected to a retracting member 45, or pull wire, which allows a physician to retract the distal sheath 40 from the proximal end of the catheter 5, thus releasing the stent 35 in the targeted area of the vessel. The retractable sheath 40 may be flexible or rigid, and is generally used to retain the stent 35 and protect the vessel wall during delivery. The distal sheath is preferably formed of a material which provides tensile strength, but is flexible, such as a braid, coil, a super elastic alloy, polymer, stainless steel or other similar composites. The retracting member 45 may be a rod, a cable, a tube which may also be used to transport fluids, a pull back wire, guide wire or the like, but is preferably a wire. In addition, the retracting member 45 may be tapered along its length to impart varying flexibility. Those skilled in the art will recognize other suitable materials and constructions may be employed to serve substantially the same function. The figures show two pull wires, but one is preferred. It should be understood that any desired number of pull wires could be utilized. The retracting member 45 extends longitudinally within the proximal outer 10, optionally through a retracting member lumen (not shown), such as a HDPE, nylon or polyether block amide (PEBAX) tube. In one embodiment, the retracting member lumen extends longitudinally under the proximal outer 10, and houses the pull back wire 45. The retracting member lumen that houses the pull back wire 45 may also carry fluid for purging air from the catheter 5.

The invention additionally comprises a collapsible sheath 50 situated between the proximal outer 10 and the distal sheath 40. The collapsible sheath 50 covers the exposed area between the proximal outer 10 and the distal sheath 40, serving to protect the guide wire lumen 15 and the retracting member 45 in this area. The collapsible sheath 50 is adhered to the proximal end of the distal sheath 40 at point 42 and the distal end of the proximal outer 10 at point 48. These connections between components are preferably made using adhesives such as urethane or cyanoacrylate, and other suitable adhesives that are well known in the art. Connections between polymer components can also be made using other bonding techniques such as thermal welding, ultrasonic welding and the like.

The collapsible sheath 50 is manufactured to induce collapsibility by winding a coil around the collapsible sheath material, such as a tube of SURLYN.

The coil winder controls the pitch or distance between adjacent wraps of wire. After the tube is wound, the tube is pressurized, causing the material to expand between the gaps in the wire and creating the pleats or creases which allow it to collapse. The coil is then removed producing the collapsible sheath 50 behind.

As the distal sheath 40 is retracted, the collapsible sheath 50 is forced back, collapsing upon itself into an accordion type configuration to give the distal sheath 40 room to retract. The collapsible sheath 50 is longer than the distal sheath 40 and is made from a highly flexible material such as SURLYN, PEBAX, or polyethylene, including both HDPE and LDPE, but preferably SURLYN. The distal sheath 40 and the collapsible sheath 50 may be two separate sheaths/components adhered to one another, or they may form one continuous sheath.

In the preferred embodiment, the distal sheath 40 is connected via a collar comprised of a short section of hypotube 55, configured as an annular ring, to the pull back wire 45. The proximal end of the distal sheath 40 is attached by adhesive or heat bond to the annular ring 55 and the distal end of the pull back wire 45 is connected, preferably brazed, to the inside of the annular ring 55. Although one pull back wire 45 is preferred, a plurality of pull back wires may be connected to the collar 55. The illustrative figures 1-5 enclosed herein utilize two pull back wires.

Proximal to the stent 35 is a stopper 60. The stopper 60 is preferably HDPE and is attached to the guide wire lumen 15, or whatever may comprise the rigid inner core, and is used to prevent the stent 35 from moving proximally when the distal sheath 40 is retracted.

Preferably, the catheter 5 further comprises an optional neck portion 62 located just proximal to the collar 55. This portion 62 is a slight reduction in diameter of the catheter 5 just behind the collar 55. The neck portion 62 aids in containing the collar 55 and supplies added leverage to the collar 55 as it retracts the distal sheath 40. It additionally aids in compressing the collapsible sheath 50 by providing an added brace for the collar 55 as the collar pushes back collapsing the collapsible sheath 50.

In an alternative embodiment a stiffening wire 60, preferably stainless steel but optionally NITINOL may also be incorporated longitudinally along the axis of the catheter 5 for extra stability and control.

In a fixed wire embodiment the guide wire lumen 15 may be replaced with just a guide wire, wherein the distal portion of the guide wire 20 is bonded to the distal tip 25.

The proximal portion of the catheter 5, as shown in Figures 1-3, comprises of a manifold system, generally designated 100, which includes a sliding member 110 slidably integrated between the distal and proximal end of the manifold. By retracting the sliding member 110 of the manifold 100, distal to proximal, the distal sheath 40 is retracted exposing the stent 35. The manifold 100 may further comprise a hydrating luer 130, which is preferably located on the distal end of the manifold 100 and is used to purge air from the catheter.

To prepare the stent delivery catheter 5 the stent 35 is compressed and loaded into the stent receiving portion 30 and covered by protective distal sheath 40. The distal sheath 40 remains covering the underlying stent 35 during the placement of the stent 35 by the delivery catheter 5 through the patient's vasculature. During the placement of the stent 35, the distal sheath 40 protects the patient's vasculature from the stent 35.

Figures 1-3 illustrate three stages of the deployment of a self-expanding stent 35 using the preferred embodiment of the catheter of the present invention. Figure 1 represents a loaded deployment catheter 5, with the stent 35 covered by the distal sheath 40 and the collapsible sheath 50 in its extended state. Figure 2 shows the stent 35 partially deployed, with the distal sheath retracted to cause the collapsible sheath to partially collapse. In the preferred embodiment the pull wire is attached to sliding member 110, which is used to retract sheath 40. As the sliding member 110 is pulled back, the distal sheath 40 begins to retract. The stent is prevented from moving proximally with the sheath by the stopper and therefore, the stent 35 begins to release and expand while the collapsible sheath 50 begins to collapse upon itself in an accordion fashion. Since the distal sheath 40 does not slide back over the proximal outer, but rather the collapsible sheath 50 collapses in place, the profile of the catheter 5 remains nearly the same. Figure 3 shows the stent fully released. At this point the distal sheath 40 is fully retracted and the collapsible sheath 50 is compressed releasing the stent 35 to allow it to self-expand against the vessel wall 65. After the stent 35 is expanded and in place, the catheter 5 is withdrawn. It should be understood that a

balloon expandable stent could also be utilized by arranging the stent around an optional placement balloon (not shown). Once the sheath 40 is fully retracted the placement balloon would be inflated through its inflation lumen (not shown) to deploy the stent.

Preferably the stent 35 is self expanding, such as a NITINOL™ stent, or it may be expanded by means of an internal balloon positioned under the stent 35 on the distal end of the inner core 40. Those skilled in the art will recognize other suitable materials and constructions which may be employed to serve substantially the same function.

The collapsible sheath is formed such that upon retraction of the distal sheath 40 the collapsible sheath 50 is compressed to a state approximately 1/5 of its longitudinally expanded state. The collapsible sheath 50 provides covering of the wire mechanism, eliminates the relative motion of the proximal edge of the distal sheath 40 and reduces the friction involved in retraction the distal sheath 40. Unlike known retractable systems, the distal sheath does not retract over or under the proximal outer, which results in an increase in the profile of the catheter, an increase in friction as the distal sheath resists being pulled back over the proximal outer and a higher likelihood of hang ups due to the faulty engagement between the proximal end of the distal sheath and the guide catheter or vessel. In the present invention the collapsible sheath 50 compresses thereby providing space for the distal sheath 40 to retract without any encumbrances.

Figures 4 and 5 illustrate an alternative embodiment of the present invention. In this case the proximal outer 70 extends distally over the catheter, generally designated 90, up to a position in close proximity with the stopper 60 and the collapsible sheath 75 performs as the distal sheath. The distal end of the proximal outer 70 is adhered the proximal end of the collapsible sheath 75 at point 80. In this embodiment the collar 55 is connected to collapsible sheath 75 at the distal end at point 85. As the pull back wire 45 is drawn proximally, the collapsible sheath 75 is retracted, collapsing upon itself, and begins to release. As discussed earlier, stopper 60 prevents the stent from moving proximally with the retracting sheath 75. Figure 5 illustrates the fully retracted collapsible sheath 75 and the release of the stent 35 to its fully expanded position urging against the inner wall of the vessel 65.

Figure 6 discloses an alternative embodiment of the present invention. In this case the stent delivery system is generally designated 145 and the catheter 155 is comprised of a guide wire lumen 15 and a pull back lumen 150. The pull back lumen is axially connected to the guide wire lumen, traveling along the length of the guide wire lumen 15 up to the distal tip 25 at point 153, as the guide wire lumen continues through the distal tip 25. Figure 7 illustrates the configuration of the catheter 155 from a cross-section perspective along lines 7-7 in Figure 6. A stent 35 may be concentrically arranged around the catheter 15 near the distal end on the stent receiving portion 30. The device further comprises a retractable distal sheath 40 surrounding at least a portion of the stent 35. Figure 6 shows the retractable distal sheath 40 partly retracted. The proximal end of the retractable distal sheath 40 is attached to the collapsible sheath 50 at point 143. The collapsible sheath 50 is concentrically arranged around the catheter 155 and is shown in Figure 6 as partially collapsed. The proximal end of the collapsible sheath 50 is connected, preferably adhered, to a fixed anchoring device 140, preferably an annular collar, which is affixed to the catheter 155 at point 160. The fixed anchoring device 140 stabilizes the proximal end of the collapsible sheath 50 allowing it to collapse upon itself during retraction of the distal sheath 40. The pull back wire 45 travels, proximal to distal, through the pull back lumen 150 and exits through an axial slit (not shown) in the surface of the pull back lumen 150. The distal end of the pull back wire is attached to annular ring 55, which is in turn attached to the retractable distal sheath 40. During the application of the device the pull back wire 45 is retracted, sliding proximally through the axial slit in the pull back lumen, proximally retracting the distal sheath 40 causing the collapsible sheath 50 to collapse, freeing the stent 35 for delivery. The stopper 60 prevents the stent from moving proximally with the retracting sheath 75.

Figure 8 illustrates a rapid exchange embodiment of the invention. The distal end of the catheter is structured and functions in the same fashion as that of device shown in Figure 1. The overall length of the catheter is approximately 135 cm, while the length of the guide wire lumen 15 is between approximately 5 cm to 35 cm from the distal tip 25 to a point where the guide wire lumen 15 and the guide wire 20 exit the catheter.

It should be understand that other mechanical methods of retracting the pull back wire, besides the manifold apparatus disclosed herein, may be employed.

It should also be understood that the retractable distal sheath 40 and the collapsible sheath 50 may comprise one continuous sheath, wherein the preform creases or pleats are incorporated only into the intended collapsible portion.

The design disclosed herein also aids in flushing the catheter. Since the catheter essentially is sealed to the distal tip 25 and has only one opening in the distal segment, that being the end portion of the guide wire lumen 15 at the distal tip 25, flushing is made easier and more efficient.

The present invention may be incorporated into both of the two basic types of catheters used in combination with a guide wire, commonly referred to as over-the-wire (OTW) catheters and rapid-exchange (RX) catheters. The construction and use of both over-the-wire and rapid-exchange catheters are well known in the art. The usable length of the delivery catheter is approximately 135 cm. For a rapid exchange catheter the distance from where the guide wire accesses the guide wire lumen to the distal tip will be approximately 5 cm to 35 cm.

The key features of the longitudinally collapsible sheath include, without limitation: low profile both proximally and distally when extended, relatively thin walls for low profile and large interior lumens, efficient packing upon collapse, flexible, pushable and trackable.

A further embodiment of the invention is shown in Figures 9, 9a, 9b and 9c. This catheter, generally designated 162, is similar to the above embodiments in that it focuses on a retractable sheath portion and an accordion portion, and it comprises many of the same materials and elements, which function in substantially the same manner.

As shown in Fig. 9, the catheter 162 includes a hand manifold, generally designated 164, which comprises a handle 161, a sheath actuator (sliding member) 163, a safety lock 198, which secures the sheath actuator 164 in place and is preferably made of polyethylene, a guide wire inlet 165 for controlling the guide wire from the proximal end, and a hydrating luer 167, for flushing. The manifold 164 also comprises a strain relief tubing 190 which is connected to the distal end of the handle. The proximal outer shaft 166 extends distally through the strain relief tubing 190. The

strain relief tubing 190 protects the proximal outer shaft 166 at the shaft's 166 joining with the manifold 164. Such protection is needed because of the distinct size difference between the manifold 164 and the proximal outer shaft 166.

The catheter 162 further comprises a proximal outer shaft, or proximal outer, 166, preferably made of a polyimide braid, a distal outer shaft 168, preferably made of polyethylene, connected to the proximal outer shaft 166 at an adhesive point 192, preferably by means of a urethane adhesive. The distal outer shaft 168 is similarly connected to a collapsible sheath/shaft 174, which is collapsible in the longitudinal direction in an accordion manner at a second adhesive point 200 (preferably using a urethane adhesive) and which is most preferably made of HDPE, best shown in Fig. 9a. The collapsible shaft 174 is in turn connected to a proximal sheath, or spacer sheath, 176, which is preferably made of polyethylene, at a third adhesive point 202 (preferably using a urethane adhesive). The distal end of the proximal sheath 176 is adhered at point 204 (preferably using a urethane adhesive) to the proximal end of a retractable distal sheath, or deployment sheath, 184, which is preferably made of polyethylene, which encloses a loaded stent 196, preferably a NITINOL self expanding stent.

The catheter 162 also further comprises an internal guide wire lumen 170, preferably made of a polyimide braid, which may house a guide wire and which extends within the catheter 162 from the guide wire inlet 165 to and through a distal tip 186, which is preferably made of polyethylene, at the distal end of the catheter 162, to which it is connected to the distal tip 186, best seen in Fig. 9c, preferably using a urethane adhesive 206. The deployment sheath 184 overlaps the distal tip 186 in a manner which provides the smoothest profile possible. In Fig. 9c, this "smooth profile" is achieved by a notch in the outer surface of the distal tip 186 in which the distal end of the deployment sheath abuts.

Also housed within the catheter is a pull (back) wire lumen 172, preferably made of polyethylene, which in turn houses the pull (back) wire 182, which is preferably stainless steel. The pull wire lumen 172, best seen in Figs. 9a and b, is optional and can be adhered and separate from the outer wall of the catheter 162, or can share common inner surfaces with the outer wall of the catheter 162. The pull wire lumen 172 extends from a point just distal to the sheath actuator 163, through the

catheter 162, to a point at the distal end of the proximal sheath 176, best seen in Fig. 9b. As seen in Fig. 9a, the pull wire lumen may discontinue and recontinue when within the collapsible shaft 174. This is to allow the shaft 174 room to collapse when the deployment sheath 184 is retracted.

The pull wire 182 is housed within the pull wire lumen 172. The proximal end of the pull wire 182 is attached to the sheath actuator 163 and the distal end of the pull wire 182 is connected to a pull collar (annular ring) 178, preferably made of stainless steel, which, as seen in Fig. 9b, is connected, preferably adhered, to the inner wall of the proximal end of the deployment sheath 184. This collar, as in the above embodiments, can be positioned anywhere along the catheter distal to the collapsible portion, as long as it is connected so that the sheath covering the stent is retracted. As in the other embodiments, when the sheath actuator 163 is retracted, the deployment sheath is similarly retracted, pushing back the proximal sheath 176, which in turn applies reward pressure on the collapsible shaft, which collapses onto itself, resulting in the release of a stent 196.

Fig. 9b further illustrates a stopper/bumper 180, preferably made of polyethylene, positioned just proximal to the stent 196 used to prevent the stent 196 from slipping proximally during the retraction of the deployment sheath 184. The bumper is preferably adhered to the guide wire lumen 170 using a urethane adhesive 208 just distal to the pull collar 178 within the deployment sheath 184.

Figs. 9b and 9c also illustrate a pair of optional markerbands 188 positioned at either end of the loaded stent 196 to provide the physician means to accurately position the stent within the vascular lumen at the targeted problem area where the stent is to be deployed. Any number, or size, of markerbands may be incorporated, as long as it aids the physician in accurately positioning the stent. Preferably, there are two, positioned as seen in Figs. 9b and 9c, and are adhered to the guide wire lumen at the proximal and distal ends 194 of the stent 196, preferably using an cyanoacrylate adhesive.

The distal outer shaft 168, preferably made of polyethylene, and the proximal sheath 176, have reduced diameters as compared to the proximal outer shaft 166 and the deployment sheath 184, respectively, in order to reduce the profile of the collapsible shaft 174. As can be seen in Figs. 9, 9a and 9b, the outside of the distal

end of the proximal outer shaft 166 is adhered to the inside of the proximal end of the distal outer shaft 168. Just distal to this connection, the diameter of the distal outer shaft 168 is decreased. Similarly, the outside of the distal end of the distal outer shaft 168 is adhered to the inside of the proximal end of the collapsible shaft 174. The inside of the distal end of the collapsible shaft 174, in turn, is adhered to the outside of the proximal end of the proximal sheath 176, which has approximately the same diameter of the distal outer shaft 168. The outside of the distal end of the proximal sheath 176, finally, is adhered to the inside of the proximal end of the deployment sheath, which is notched down so as to be compatible with the outer diameter of the distal end of the proximal sheath 176 and to aid in maintaining the position of the pull collar 178 during retraction, best seen in Fig. 9b. This type of construction reduces the profile of the collapsible shaft 174 when the shaft 174 is collapsed. The distal outer shaft 168 and the proximal sheath 176 could be removed so that the distal end of the proximal outer shaft 166 is extended and is adhered to the proximal end of the collapsible shaft 174, while the proximal end of the deployment sheath 184 is extended and is adhered to the distal end of the collapsible shaft 174, but the overall profile would be compromised.

It should be further noted that the collapsible portion of the catheter can be located anywhere along the catheter distal to the manifold and proximal to the retractable portion in the above embodiments. The collapsible portion can also be any length, as long as it is longer than the length of the loaded stent so as to allow for clean deployment of the stent.

Any part of the above sheaths of the catheter distal to the collapsible portion is considered the retractable portion. The retractable portion proximal to the pull collar and the shaft/sheath portions proximal to the collapsible portion must be rigid enough to resist collapsing upon itself during the sheath retracting process. The guide wire lumen also must be rigid enough to resist the reward pressure during the retraction of the retractable portion. See the Applicant's copending U.S. application titled PULL BACK SLEEVE SYSTEM WITH COMPRESSION RESISTANT INNER SHAFT, serial number 08/484,006, filed June 7, 1995, which is incorporated herein by reference.

The collapsible shaft is constructed so as to collapse upon retraction of the retractable portion. The following are descriptions of example methods used in creating a polyethylene collapsible sheath and a SURLYN collapsible sheath:

Example 1

Process for Polyethylene (PE) Collapsible

Shaft Forming

Materials needed:

1. PE tubing 0.041/0.046 (inches) inner/outer diameter
2. Mandrel stock 0.040 (inches)
3. Coil winder
4. Blade with 0.003 radius edge (inches).
5. Rubber Gloves

Protocol:

Step 1.	Place the PE tubing onto the mandrel and into coilwinder.
Step 2.	Turn coilwinder on at speed 4, with a .020 pitch and set blade at 35 degree angle.
Step 3.	Set blade down on PE tube and plow, or contour, the PE tube. The resulting PE tube will have a small indent circumferentially around the tube, preferably in a helical fashion.
Step 4.	Hold the PE tube on outside of indent and push together so tube will accordion, preferably with rubber gloves.
Step 5.	Leave accordion tube on mandrel for annealing process. Anneal tube in an oven at 70 degrees C. for a minimum of 4 hours.

The resulting shaft is then prepared to be incorporated into the catheter.

Example 2:

Process for SURLYN Collapsible

Shaft Forming

Materials needed:

1. Razor blades
2. Balloon Mold (preferably 1.5mm)
3. Spring
4. Cold water bath and hot water bath (80° C)
5. Mandrel (preferably TEFLON coated)
6. SURLYN sleeve (blank)
7. Alcohol (99%)

8. Grooved accordion mold
9. Air pressure station (preferably 95-100 PST)

Protocol:

Step 1.

Load the blank tubing into the mold using the following method:

Load spring into the balloon mold (note: no spring is required with the grooved accordion mold). Insert tubing blank into mold until approximately ½ protrudes from proximal end. Place balloon mold into holding bracket. Insert end of tubing blank into the Y adapter connector and tighten. Pressurize tube.

Step 2.

Mold the accordion assembly using the following method:

Lower mold into hot water bath up to the Y adapter and then raise until top edge of mold reaches surface of water. Hold mold in hot water for 25-30 seconds. Lift mold out of water bath and insert into cold water bath for 3-5 seconds. Remove mold from water and close air stopcock. Open Y adapter valve and remove tubing. Remove balloon mold from bracket. Open mold and pull out tubing with spring (if present). Trim proximal end of tubing to 5mm and remove spring (if present).

Step 3.

Heat set the folds of the accordion assembly using the following method:

Slide accordion assembly over mandrel. Slide black sleeve over mandrel and under shaft of accordion assembly up to the folds. Push both ends of the folds together from each end and place a clamp onto the sleeve to hold it in place. Dip assembly into hot water bath a maximum of 2mm past folds and hold for 10-15 seconds (note: ensure folds are submerged in the water). Remove and dip mandrel into cold water bath for 2-5 seconds. Remove from cold water bath and slide back sleeve and clamp. Slide accordion assembly off mandrel. Rinse with alcohol and dry with nitrogen.

The resulting shaft is then prepared to be incorporated into the catheter.

It should also be noted that the part of the retractable portion which covers the loaded stent can also be contoured to increase its flexibility, preferably in a helical fashion.

The above disclosure is intended to be illustrative and not exhaustive.

These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A stent delivery system comprising:

a catheter with a distal end and a proximal end;

a retractable distal sheath surrounding at least a portion of the catheter;

a pull back means having a distal end connected to the retractable distal sheath for retraction of the retractable distal sheath; and

a collapsible sheath concentrically arranged around the catheter positioned on the catheter proximal to the retractable distal sheath,

whereby when the pull back means is retracted proximally the distal sheath is retracted, causing the collapsible sheath to collapse.

2. The stent delivery system as in claim 1, further comprising a proximal outer sheath positioned on the catheter proximal to the collapsible sheath, wherein the collapsible sheath has a distal end and a proximal end, the distal end being adhered to the retractable distal sheath and the proximal end being adhered to the proximal outer sheath.

3. The stent delivery system as in claim 2, further comprising a self-expanding stent loaded on the distal end of the catheter, wherein the stent is held in its collapsed state by the retractable distal sheath and when the pull back means is retracted proximally the distal sheath is retracted, causing the collapsible sheath to collapse and freeing the stent for delivery.

4. A stent deliver system as in claim 3, wherein the pull back means comprises a pull back wire.

5. The stent delivery system as in claim 4, wherein the pull back means further comprises an annular collar surrounding the catheter and longitudinally movable along the catheter, wherein the proximal end of the retractable distal sheath is connected to the annular collar and the distal end of the pull back wire are connected to the annular collar.

6. The stent delivery system as in claim 5, further comprising a stopper positioned on the catheter to prevent the stent from moving proximally as the distal sheath is retracted to expose the stent.

7. A stent delivery system as in claim 6, wherein the catheter comprises a guide wire lumen, the guide wire lumen being incompressible and flexible.

8. A stent delivery system as in claim 6, wherein the catheter comprises a guide wire, the guide wire being bonded to the distal end.

9. The stent delivery system as in claim 7, further comprising a pull back wire lumen which partially encloses the pull back wire and is at least partially covered by the proximal outer sheath.

10. The stent delivery system as in claim 8, further comprising a stiffening wire positioned longitudinally along the catheter.

11. The stent delivery system as in claim 7, wherein the guide wire lumen is a polymer encapsulated braid.

12. The stent delivery system as in claim 7, wherein the guide wire lumen is a polymer encapsulated coil.

13. The stent delivery system as in claim 11, further comprising a guide wire enclosed within the guide wire lumen.

14. The stent delivery system as in claim 13, comprising a plurality of pull back wires attached to the annular collar.

15. The stent delivery system as in claim 14, wherein the retractable distal sheath further includes a neck portion just proximal to the connection between the retractable distal sheath and the annular collar, which frictionally engages the annular collar and aids in retraction of the distal sheath.

16. The stent delivery system as in claim 14, wherein the proximal outer sheath comprises a high density polyethylene.

17. The stent delivery system as in claim 7, wherein the stent delivery system is an over-the wire catheter.

18. The stent delivery system as in claim 7, wherein the guide wire lumen is shorter than the catheter.

19. The stent delivery system of claim 18 wherein the catheter is 135 cm and the guide wire lumen is between 5 cm and 35 cm.

20. The stent delivery system as in claim 2, further comprising a balloon disposed under the stent, whereby after the retractable distal sheath is retracted the stent is expanded by inflating the balloon.

21. A stent delivery system comprising:

a catheter with a distal end and a proximal end, the catheter having a stent receiving portion adapted to receive a stent near the distal end of the catheter and a distal tip arranged distal to the stent receiving portion;

a retractable distal sheath surrounding at least a portion of the stent receiving portion, the retractable distal sheath being collapsible; and

a pull back means having a distal end connected to the retractable distal sheath, the pull back means being longitudinally movable,

whereby when the pull back means is pulled proximally, the distal sheath collapses upon itself in accordion fashion.

22. The stent delivery system as in claim 21, further comprising a proximal outer sheath positioned on the catheter proximal to the collapsible sheath, wherein the retractable distal sheath comprises a proximal end, the proximal end being adhered to the proximal outer sheath.

23. The stent delivery system as in claim 22, further comprising a self-expanding stent loaded on the distal end of the catheter, wherein the stent is held in its collapsed state by the retractable distal sheath and when the pull back means is retracted proximally the distal sheath is retracted, causing the collapsible sheath to collapse and freeing the stent for delivery.

24. The stent delivery system as in claim 23, further comprising an annular collar, wherein the proximal end of the retractable distal sheath and the distal end of the pull back means are connected to the collar.

25. The stent delivery system as in claim 24, further comprising a stopper positioned to prevent the stent from moving proximally as the retractable distal sheath is retracted to expose the stent.

26. A stent deliver system as in claim 25, wherein the pull back means is a pull back wire.

27. A stent delivery system as in claim 26, wherein the catheter comprises a guide wire lumen, the guide wire being incompressible and flexible.

28. A stent delivery system as in claim 26, wherein the catheter comprises a guide wire, the guide wire being bonded to the distal tip.

29. The stent delivery system as in claim 27, further comprising a pull back wire lumen which partially encloses the pull back wire and is at least partially covered by the proximal outer sheath.

30. The stent delivery system as in claim 28, further comprising a stiffening wire positioned longitudinally along the catheter.

31. The stent delivery system as in claim 27, wherein the guide wire is a polymer encapsulated braid.

32. The stent delivery system as in claim 27, wherein the guide wire lumen is a polymer encapsulated coil.

33. The stent delivery system as in claim 31, further comprising a guide wire enclosed within the guide wire lumen.

34. The stent delivery system as in claim 33 comprising a plurality of pull back wires.

35. The stent delivery system as in claim 34, further comprising a neck portion situated in the retractable distal sheath just proximal to the attachment between the retractable distal sheath and the annular collar.

36. The stent delivery system as in claim 34, wherein the proximal outer sheath comprises a high density polyethylene.

37. The stent delivery system as in claim 27, wherein the stent delivery system is an over-the wire catheter.

38. The stent delivery system as in claim 27, wherein the catheter is 135 cm and the guide wire lumen is between 5 cm and 35 cm.

39. The stent delivery system as in claim 21, further comprising a balloon disposed under the stent within the stent receiving portion, whereby after the retractable distal sheath is retracted the stent is expanded by inflating the balloon.

40. A stent delivery system comprising:

a catheter with a distal end and a proximal end, the catheter including a guide wire lumen and a pull back lumen;

a stent concentrically arranged around the catheter near the distal end;

a retractable distal sheath surrounding at least a portion of the stent;

a pull back means, a portion of the pull back means housed in the pull back lumen, the pull back means having a distal end connected to the retractable distal sheath for retraction of the retractable distal sheath;

an anchoring device fixedly attached to the catheter; and

a collapsible sheath having proximal and distal ends and concentrically arranged around the catheter, the proximal end of the collapsible sheath being attached to the anchoring device and the distal end of the collapsible sheath being attached to the retractable distal sheath proximal to the retractable distal sheath,

whereby when the pull back means is retracted proximally the distal sheath is retracted, causing the collapsible sheath to collapse and freeing the stent for delivery.

41. The stent delivery system as in claim 1, further comprising proximal outer shaft positioned on the catheter proximal to the collapsible sheath.

42. The stent delivery system as in claim 41, wherein the retractable distal sheath comprises a proximal sheath and a deployment sheath, both the proximal sheath and the deployment sheath being distal to the collapsible sheath and the proximal sheath being proximal to the deployment sheath, and wherein the proximal sheath is connected to the collapsible sheath and the deployment sheath.

43. The stent delivery system as in claim 42, further comprising a distal outer shaft, the distal outer shaft being positioned on the catheter between, and connected to, the proximal outer shaft and the collapsible sheath.

44. The stent delivery system as in claim 43, further comprising a guide wire lumen internally extending from the proximal end of the catheter to the distal end of the catheter.

45. The stent delivery system as in claim 44, further comprising a distal tip position and attached to the distal end of the guide wire lumen.

46. The stent delivery system as in claim 45, wherein the pull back means is a pull wire, and further comprising a pull collar connected to the retractable distal sheath, the distal end of the pull wire being connected to the pull collar.

47. The stent delivery system as in claim 46, further comprising a manifold positioned at the proximal end of the catheter, the manifold comprising a sheath actuator, wherein the proximal end of the pull wire is connected thereto.

48. The stent delivery system as in claim 47, further comprising a pull wire lumen internally extending from just distal to the manifold to just proximal to the pull collar.

49. The stent delivery system as in claim 48, wherein the pull collar is attached to the proximal end of the deployment sheath.

50. The stent delivery system as in claim 49, wherein the pull wire lumen is discontinued and recontinued at the proximal end and the distal end of the collapsible sheath, respectively.

51. The stent delivery system as in claim 50, further comprising a self expanding stent loaded on the distal end of the guide wire lumen, just proximal to the distal tip, under the deployment sheath, wherein the stent is held in its collapsed state by the deployment sheath and when the pull back wire is retracted proximally, the distal sheath is retracted, causing the collapsible sheath to collapse and freeing the stent for delivery.

52. The stent delivery system as in claim 51, further comprising a bumper attached to the guide wire lumen just proximal to the loaded stent to prevent the stent from moving proximally as the deployment sheath is retracted to expose the stent.

53. The stent delivery system as in claim 52, further comprising markerbands attached to the guide wire lumen in close proximity to the loaded stent so as to allow the user to accurately position the stent within a targeted vascular lumen.

54. The stent delivery system as in claim 1, wherein the method of making the collapsible sheath comprises:

contouring a piece of tubing;

longitudinally compressing the tubing; and

annealing the tubing,

wherein the resulting tubing is accordion-like.

55. A method for preparing a collapsible shaft for a stent delivery system comprising the steps:

contouring a piece of tubing;

longitudinally compressing the tubing; and

annealing the tubing,

wherein the resulting tubing is accordion-like.

56. The method for preparing a collapsible shaft as in claim 55, wherein the tubing is contoured in a helical fashion.

57. The method for preparing a collapsible shaft as in claim 56, the tubing being comprised of polyethylene.

58. The method for preparing a collapsible shaft as in claim 56, the tubing being comprised of SURLYN.

59. The method for preparing a collapsible shaft as in claim 57, wherein the tubing is contoured by:

placing the tubing onto a mandrel; and

plowing the tubing while on the mandrel in a coilwinder.

60. The method for preparing a collapsible shaft as in claim 59, wherein the tubing is annealed by:

placing the tubing, while on the mandrel, in an oven at about 70° C. for about 4 hours.

61. The method for preparing a collapsible shaft as in claim 58, wherein the tubing is contoured by:

loading the tubing into a mold, wherein the mold has a helical projection arranged on its inner surface;

pressurize the tubing;

dipping the mold into a hot water bath;

dipping the mold into a cold water bath; and

removing the tubing from the mold.

62. The method for preparing a collapsible shaft as in claim 61, wherein the tubing is longitudinally compressed by:

placing the tubing onto a mandrel; and

pushing both ends of the tubing together from each end and securing the tubing in place,

and is annealed by:

dipping the tubing, while on the mandrel, into a hot water bath;

dipping the tubing, while on the mandrel, into a cold water bath;

removing the tubing from the mandrel;

rinsing with alcohol; and

drying with nitrogen.

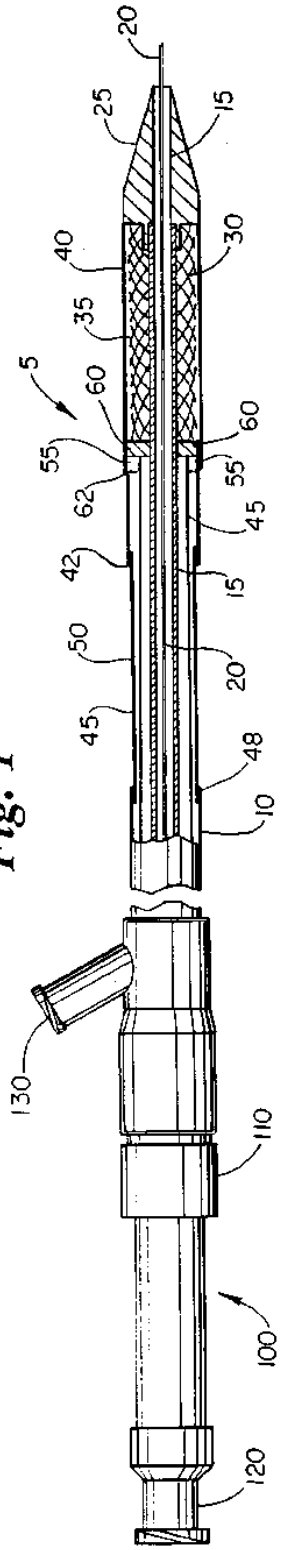


Fig. 1

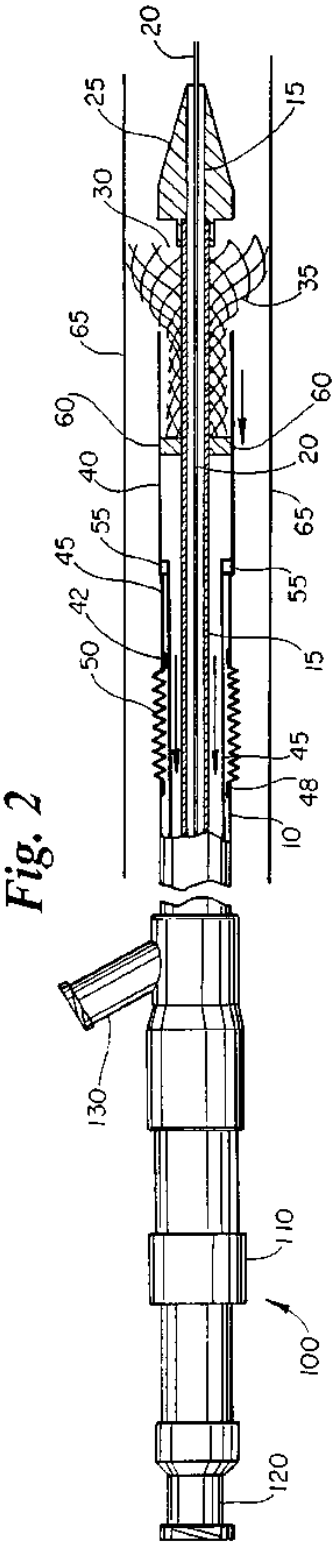


Fig. 2

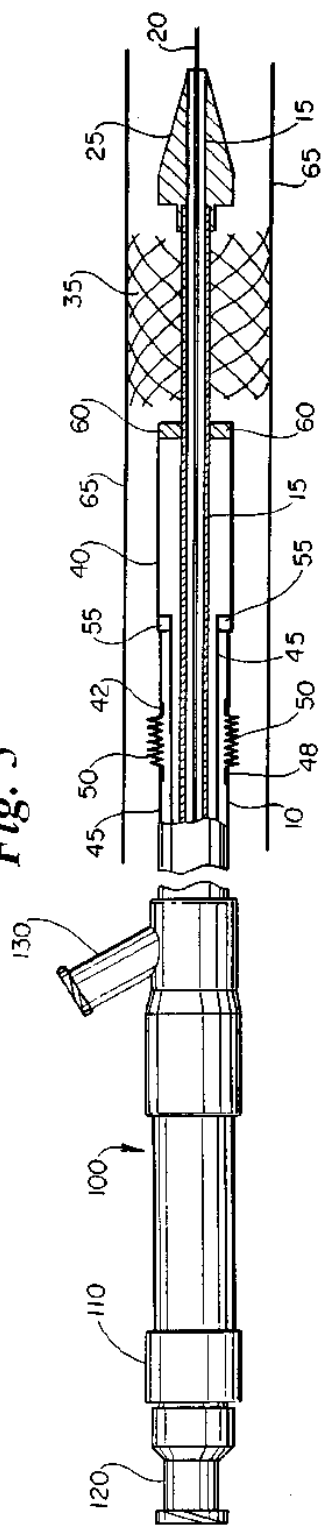


Fig. 3

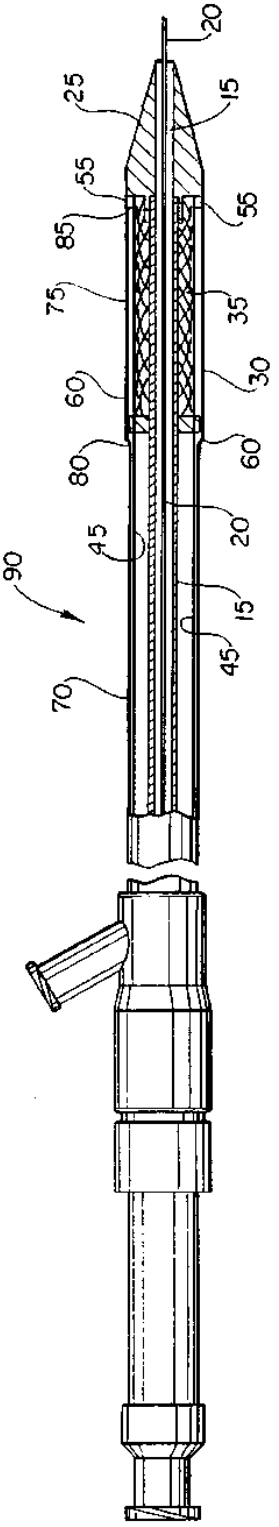

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Fig. 4

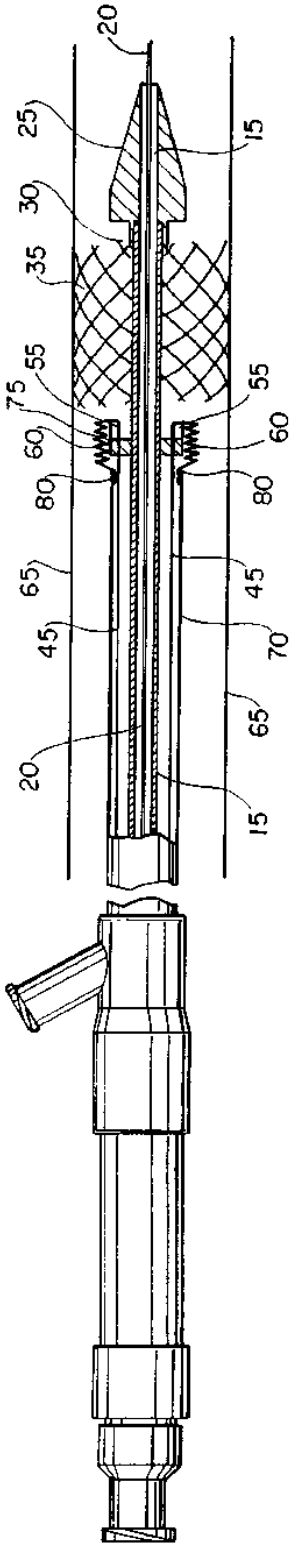

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Fig. 5

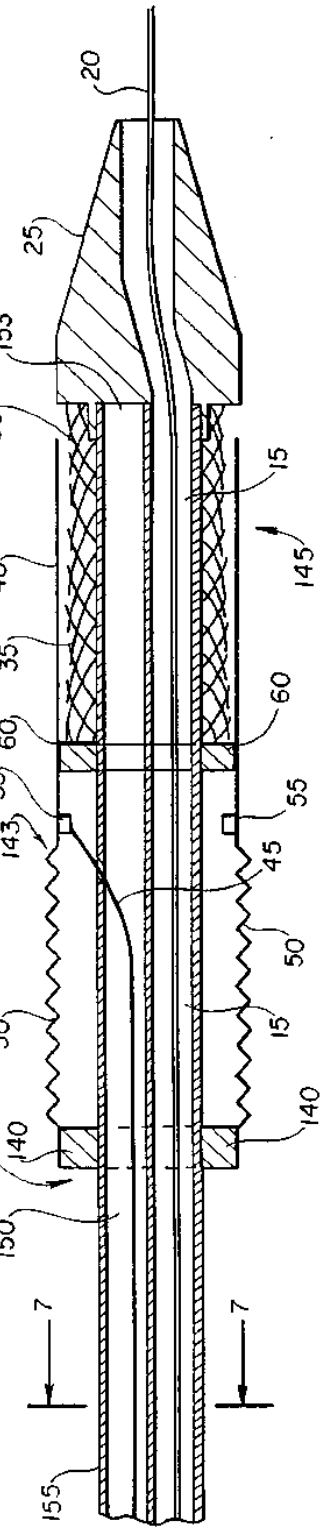


Fig. 6

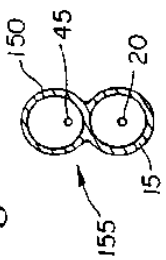


Fig. 7

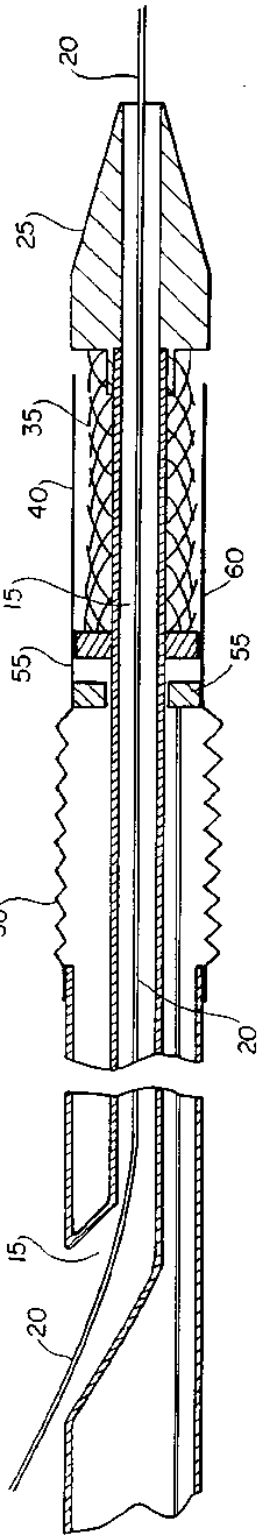


Fig. 8

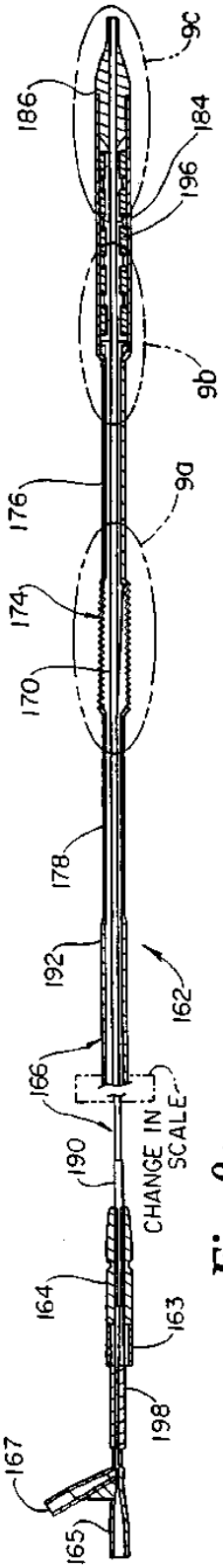


Fig. 9

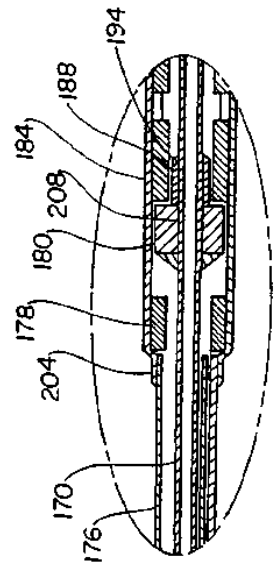


Fig. 9b

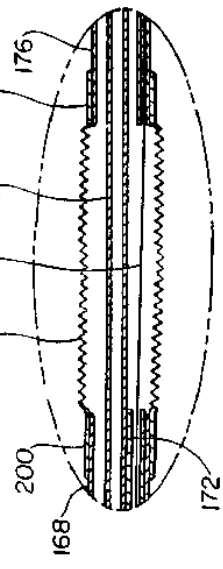


Fig. 9a

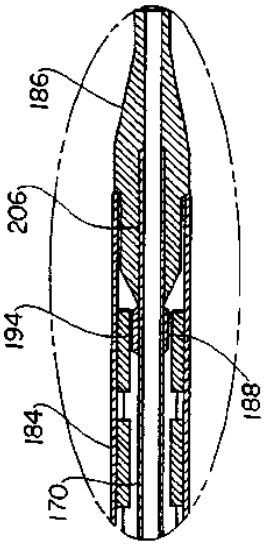


Fig. 9c

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 96/07143

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F 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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 611 556 (ADVANCED CARDIOVASCULAR SYSTEM, INC.) 24 August 1994 see abstract; figures 1-6 ---	1-62
A	US,A,3 894 540 (BONNER) 15 July 1975 see abstract; figures 1,2 ---	1-3, 21-23, 40-42,54
A	US,A,4 580 568 (GIANTURCO) 8 April 1986 see abstract; figures 4,5,9,10 ---	1-19, 21-38, 40-51
A	US,A,5 158 548 (LAU ETAL.) 27 October 1992 ---	
A	EP,A,0 247 559 (STERIMED GESELLSCHAFT FÜR MEDIZINISCHEN BEDARF MBH) 2 December 1987 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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

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

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

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 August 1996	19. 09. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Michels, N

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter ial Application No
PCT/US 96/07143

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-611556	24-08-94	US-A-	5360401	01-11-94
		CA-A-	2115887	19-08-94
		JP-A-	7047133	21-02-95
US-A-3894540	15-07-75	AU-A-	7860375	26-08-76
		US-A-	4062363	13-12-77
US-A-4580568	08-04-86	AU-B-	581464	23-02-89
		AU-B-	4811385	10-04-86
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		JP-C-	1748182	25-03-93
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		DE-U-	8707450	24-09-87
		WO-A-	8707163	03-12-87

Form PCT/ISA/210 (patent family annex) (July 1992)

Espacenet

Bibliographic data: JP6292720 (B2) — 2018-03-14

PROCESS FOR OBTAINING LOW RESIDUAL ARAMID MATERIALS

Inventor(s): Bader Yves, Weiss Kurt Hans, de Cuendias Herrero Bienvenido

Applicant(s): E. I. du Pont de Nemours and Company

Classification: - **international:** ***A41D31/00; D01F6/60; D02G3/04; D03D15/00; D03D15/12; D06L1/22***
- **cooperative:** **D01D10/06 (EP, CN, US)**; **D01F13/04 (EP, CN, US)**; **D01F6/605 (EP, CN, US)**; **D01F6/805 (EP, CN, US)**; **D06M11/65 (EP, CN, US)**; **D06M13/144 (EP, CN, US)**; **D06M13/188 (EP, CN, US)**; **D06M15/59 (US)**; **D06M7/00 (EP, CN, US)**; D06M2101/36 (EP, CN, US); Y02P70/62 (EP, US)

Application number: JP20150510400 20130501 Global Dossier

Priority number(s): US201261641945P 20120503 ; WO2013US38971 20130501

Also published as: BR112014027324 (A2) CA2870565 (A1) CN104471120 (A) EP2844787 (A1) JP2015520808 (A) more

Abstract not available for JP6292720 (B2)
Abstract of corresponding document: WO2013166086 (A1)

The present invention provides for a process for reducing the content of one or more residuals in aramid fibers or filaments, comprising, in this order, the steps of introducing the aramid fiber or filaments into a extraction solution adjusted to a pH ranging from of 2 to 7, adjusting the extraction solution and the aramid fibers or filaments to a temperature of from 80C to 140C, removing the aramid fibers or filaments from the extraction solution, introducing the aramid fiber or filaments into a first rinsing solution adjusted to a pH ranging from of 2 to 7, optionally comprising a detergent, adjusting the first rinsing solution and the aramid fibers and filaments to a temperature of from 70C to 100C, removing the aramid fibers or filaments from the first rinsing solution.

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D06L	1/22	(2006.01)	D06L	1/22	
D01F	6/60	(2006.01)	D01F	6/60	371F
D02G	3/04	(2006.01)	D02G	3/04	
D03D	15/12	(2006.01)	D03D	15/12	Z
D03D	15/00	(2006.01)	D03D	15/00	A

請求項の数 7　(全 14 頁)　最終頁に続く

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(86)(22)出願日　平成25年5月1日(2013.5.1)
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(54)【発明の名称】低残留物のアラミド材料を得るプロセス

(57)【特許請求の範囲】

【請求項１】

アラミド繊維又はアラミドフィラメントにおける１つ以上の残留物の含有量を低減する方法であって、

ａ．前記アラミド繊維又は前記アラミドフィラメントを、２～７の範囲のｐＨに調整した、着色成分を含まない抽出用の溶液に導入する工程と、

ｂ．前記抽出用の溶液と、前記アラミド繊維又は前記アラミドフィラメントを、８０℃～１４０℃の温度に調整する工程と、

ｃ．前記抽出用の溶液から前記アラミド繊維又は前記アラミドフィラメントを取り除く工程と、

ｄ．前記アラミド繊維又は前記アラミドフィラメントを、２～７の範囲のｐＨに調整した第１のリンス液（洗剤を含んでもよい）に導入する工程と、

ｅ．前記第１のリンス液と、前記アラミド繊維及び前記アラミドフィラメントを、７０℃～１００℃の温度に調整する工程と、

ｆ．前記第１のリンス液から前記アラミド繊維又は前記アラミドフィラメントを取り除く工程と

をこの順序にて含み、

前記抽出用の溶液は０ｇ／ｌより多く４０ｇ／ｌ以下の塩成分と、０ｇ／ｌより多く４０ｇ／ｌ以下の担体成分とを含む水溶液であり、且つ、

前記塩成分及び前記担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌである、方法。

【請求項２】
前記アラミド繊維又は前記アラミドフィラメントは、メタ－アラミド繊維又はメタ－アラミドフィラメントである、請求項１に記載の方法。
【請求項３】
前記メターアラミド繊維又は前記メターアラミドフィラメントは、乾式紡糸によって得られる乾燥した結晶性メターアラミド繊維又はメターアラミドフィラメントであり、工程ｆの後の結晶性メターアラミド繊維又はメターアラミドフィラメントが０．１重量パーセント未満のオルトージクロロベンゼンを含む、請求項２に記載の方法。
【請求項４】
前記メターアラミド繊維又は前記メターアラミドフィラメントは、乾式紡糸によって得られる乾燥した結晶性メターアラミド繊維又はメターアラミドフィラメントであり、工程ｆの後の結晶性メターアラミド繊維又はメターアラミドフィラメントが０．１重量パーセント未満のＮ－メチル－２－ピロリドン又はＮ，Ｎ－ジメチルアセトアミドを含む、請求項２に記載の方法。
【請求項５】
メターアラミド繊維又はメターアラミドフィラメントと、少なくとも１つの静電気防止繊維とを含む糸条の製造方法であって、請求項３又は４に記載の方法でメターアラミド繊維又はフィラメントを得る工程を含む、製造方法。
【請求項６】
アラミド繊維又はアラミドフィラメントを含む、熱、火炎、及びアークに対して耐性のある衣服の製造方法であって、アラミド繊維又はアラミドフィラメントを衣服に組み込む工程を含み、アラミド繊維又はアラミドフィラメントが請求項３又は４に記載の方法によって得られる、製造方法。
【請求項７】
アラミド繊維又はアラミドフィラメントを含む、熱、火炎、及びアークに対して耐性のある布地の製造方法であって、アラミド繊維又はアラミドフィラメントを布地に組み込む工程を含み、アラミド繊維又はアラミドフィラメントが請求項３又は４に記載の方法によって得られる、製造方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、アラミド繊維又はアラミドフィラメント、及びこれから１つ以上の残留物を抽出するプロセスに関する。
【背景技術】
【０００２】
アラミド繊維又はアラミドフィラメントから作製される衣服は、放射熱、燃焼、及び電気アークに対する優れた防護性を付与すること、並びに、その優れた機械的特性に関して、個人防護用品の当技術分野において知られている。
【０００３】
このため、前述のアラミド材料を含む衣服は、産業用防護衣服、消防士服、警察又は軍隊の制服などの、多くの防護衣服において広範囲にわたって使用される。
【０００４】
このような衣服又は制服におけるアラミド繊維又はアラミドフィラメントの使用は、こうした繊維又はフィラメントは、美的目的だけでなく、多くの場合、はっきりと目で見えることができる必要性からも、広範囲にわたって着色されなければならないことがあることを示している。その他の例としては、例えば、偽装、及び、特定の赤外線反射の必要性などの、軍事目的の衣服に対する着色が挙げられる。
【０００５】
アラミド材料を着色する場合、複数の染色手順が存在し、そのうちのほとんどは合成染料を使用する。一般的に、こうした染色プロセスは、カチオン染料、担体物質、及び無機

塩の水溶液において、アラミド材料を加熱し、その後、１回以上、濯ぐ工程を伴う。その他の着色ルートとしては、ｓｐｕｎ－ｉｎ色素として知られる、紡糸プロセスの前に色素をポリマー溶液に取り込むことが挙げられる。

【発明の概要】

【発明が解決しようとする課題】

【０００６】

しかしながら、このような合成染料及び色素は、工業規模において生産され、その結果、このような染料の合成において使用された残留量の望ましくない化合物を含む場合がある。こうした残留化合物は、一般的に、少ない量で存在し、例えば、ジクロロベンゼン及びその誘導体の種々の異性体を含む。

【０００７】

例えば、フッ素化仕上げ剤などの、意図的にアラミド材料に加えられた仕上げ剤に悪影響を与える又は仕上げ剤を洗い流すことなく、最終のアラミド材料におけるこうした化合物の水準を低下させることが望ましい。

【０００８】

更に、アラミド材料の機械的特性に悪影響を与えることなく、アラミド材料におけるこうした化合物の水準を低下させることが望ましく、又、アラミド材料の機械的特性を同時に向上させることによって、アラミド材料におけるこうした水準の濃度を低下させることが更により望ましい。

【０００９】

更に、アラミド材料の同一の量を使用するとともに、より効果的に防護する改善した個人防護用品を製造するために、アラミド材料の熱、火炎、及び電気アークに対する耐性特性を増加させるという恒常的な要望が存在する。更に又、例えば、機械的及び熱的安定性に直接影響する繊維の結晶化度を増加させることなど、アラミド材料の寸法安定性、並びにその他の望まれる特質を維持すること、又は更に強化することが望ましい。

【００１０】

アラミド繊維の結晶化度は、国際公開第２０１１０１１３９５号パンフレットに記載のラマン分光法によって測定される場合、例えば、そのガラス転移点を超える温度で繊維を伸ばすことによってなどの、熱及び張力を繊維に加えることによって、又は、ベンジルアルコール及びベンゾフェノンなどの、染料担体を用いて、着色、染色、又は疑似染色のプロセスにおいて、繊維を化学的に処理することによって、１５％を超えて増加させることができる。こうした方法の例は、米国特許第４６６８２３４号明細書、米国特許第４７５５３３５号明細書、米国特許第４８８３４９６号明細書、及び米国特許第５０９６４５９号明細書において見られ得る。通常、こうした疑似染色方法は、かなりの濃度の担体成分及び塩成分を使用し、このため、こうした方法は経済的に望ましくなくなる。従って、より費用に対して効果的なプロセスを提供するために、こうした高い費用の成分の使用を低減する必要が存在し、又、環境的に持続可能な方法で廃棄される必要が存在する。

【００１１】

メターアラミドにおける結晶化度を増加させるその他の周知の方法は、１４０℃～１６５℃の温度における蒸気にて、好ましくはトウの形態において、繊維を加熱する工程を含む。アラミド繊維及び特にメターアラミド繊維が、良好な耐熱特性を有する一方、アラミド繊維を染色するために通常使用される染料は、この特性を有さない。従って、染料を熱的に分解させることなく、染色されたアラミド繊維において、熱によって結晶化度を増加させることは、これまでのところ実際には実現可能ではない。

【課題を解決するための手段】

【００１２】

本発明は、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整した抽出溶液に導入する工程と、抽出溶液とアラミド繊維又はアラミドフィラメントを８０℃～１４０℃の温度に調整する工程と、抽出溶液からアラミド繊維又はアラミドフィラメントを取り除く工程と、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整

した第１のリンス液に導入する工程と、場合により洗剤を含む工程と、第１のリンス液とアラミド繊維及びアラミドフィラメントを７０℃～１００℃の温度に調整する工程と、第１のリンス液からアラミド繊維又はアラミドフィラメントを取り除く工程と、をこの順序にて含み、この場合に、抽出溶液は、０～４０ｇ／ｌの塩成分と、０～４０ｇ／ｌの担体成分とを含む水溶液であり、且つ、塩成分及び担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌである、アラミド繊維又はアラミドフィラメントにおける１つ以上の残留物の含有量を低減するプロセスを提供する。

【００１３】

本発明は、前記プロセスによって得られるメターアラミド繊維又はメターアラミドフィラメント、並びにこれから作製される糸条及び衣服を更に提供する。

【発明を実施するための形態】

【００１４】

本開示との関連において、用語「アラミド」は、アミド（－ＣＯＮＨ－）結合の少なくとも８５％が、２つの芳香環に直接結合したポリアミドを意味する。添加剤がアラミドとともに使用可能であり、実際に、１０重量％と同量までのその他のポリマー材料がアラミドとブレンド可能であり、又は、アラミドのジアミンに置き換わる１０パーセントと同量のその他のジアミン、又は、アラミドの二酸塩化物に置き換わる１０パーセントと同量のその他の二酸塩化物を有するコポリマーが使用可能であることが判明した。適切なアラミド繊維は、Ｍａｎ－Ｍａｄｅ　Ｆｉｂｅｒｓ－Ｓｃｉｅｎｃｅ　ａｎｄ　Ｔｅｃｈｎｏｌｏｇｙ，Ｖｏｌｕｍｅ　２，Ｓｅｃｔｉｏｎ　ｔｉｔｌｅｄ　Ｆｉｂｅｒ－Ｆｏｒｍｉｎｇ　Ａｒｏｍａｔｉｃ　Ｐｏｌｙａｍｉｄｅｓ，ｐａｇｅ　２９７，Ｗ．Ｂｌａｃｋ　ｅｔ　ａｌ．，Ｉｎｔｅｒｓｃｉｅｎｃｅ　Ｐｕｂｌｉｓｈｅｒｓ，１９６８．に記載されている。又、アラミド繊維は、米国特許第４，１７２，９３８号明細書、米国特許第３，８６９，４２９号明細書、米国特許第３，８１９，５８７号明細書、米国特許第３，６７３，１４３号明細書、米国特許第３，３５４，１２７号明細書、及び米国特許第３，０９４，５１１号明細書に開示されている。メターアラミドは、アミド結合が互いに対してメタ位にあるアラミドであり、且つ、パラーアラミドは、アミド結合が互いに対してパラ位にあるアラミドである。ほとんどの場合に使用されるアラミドは、メターアラミドポリ（メタフェニレンイソフタルアミド）及びパラーアラミドポリ（パラフェニレンテレフタルアミド）である。

【００１５】

本開示との関連において、値Ａ：値Ｂとして表される、用語「液体比」は、処理されたアラミドの重量（値Ａ）と使用された抽出溶液の重量（値Ｂ）との間の比に関する。

【００１６】

本開示との関連において、用語「結晶性」は、国際公開第２０１１０１１３９５号パンフレットに記載のラマン分光法によって測定される場合、１５％を超える、好ましくは２０％を超える、より好ましくは２５％を超える又は２５～４０％の結晶化度に関する。

【００１７】

本発明によるプロセスは、染色された、着色された、又は色素着色されたアラミド材料における残留物の低減のみに限定されず、加工していない、即ち、染色されていないアラミド材料における残留物の低減にも有用である。

【００１８】

本発明は、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整した抽出溶液に導入する工程と、抽出溶液とアラミド繊維又はアラミドフィラメントを８０℃～１４０℃の温度に調整する工程と、抽出溶液からアラミド繊維又はアラミドフィラメントを取り除く工程と、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整した第１のリンス液に導入する工程と、場合によって洗剤を含む工程と、第１のリンス液とアラミド繊維及びアラミドフィラメントを７０℃～１００℃の温度に調整する工程と、第１のリンス液からアラミド繊維又はアラミドフィラメントを取り除く工程と、をこの順序にて含み、この場合に、抽出溶液は、０～４０ｇ／ｌの塩成分と、０～４０ｇ／ｌの担

体成分とを含む水溶液であり、且つ、塩成分及び担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌである、アラミド繊維又はアラミドフィラメントにおける１つ以上の残留物の含有量を低減するプロセスを提供する。

【００１９】

本発明によるプロセスは、８０℃～１４０℃の温度で実行されることから、本プロセスは更に、アラミド繊維又はアラミドフィラメントにおいてだけでなく、アラミド繊維又はアラミドフィラメントと、例えば、導電性炭素系成分及びポリマー成分を有する繊維などの少なくとも１つの静電気防止繊維とを含む糸条においても、残留物を低減することに特に適している。

【００２０】

本発明によるプロセスは、アラミド繊維又はアラミドフィラメントが、乾式紡糸又は湿式紡糸によって、好ましくは乾式紡糸によって得られる、乾燥した結晶性メターアラミド繊維又はメターアラミドフィラメントである場合に、特に効果的である。

【００２１】

乾燥した結晶性メターアラミド繊維又はメターアラミドフィラメントは、繊維又はフィラメントの結晶化度を増加させるために、従来の乾燥方法によって紡糸したままの状態の繊維又はフィラメントを乾燥させ、その後、例えば、加熱ロール又は蒸気などの加熱環境において繊維又はフィラメントを延伸することによって得られ得る。こうした方法は、アラミド材料の当技術分野において周知であり、従って、簡潔にするために、更に詳細に記載しないものとする。

【００２２】

乾式紡糸によって得られるメターアラミド繊維又はメターアラミドフィラメントは、その典型的な「犬の骨形状」断面、及びその滑らかな外皮表面によって、顕微鏡下にて容易に認識され得る。

【００２３】

本発明によるプロセスを実施することによってアラミド繊維又はアラミドフィラメントにおいて低減され得る残留物は、アラミド繊維又はアラミドフィラメントの製造プロセス及び／又は染色プロセスにおいて本質的に存在する残留物である。

【００２４】

製造プロセスに存在するこうした残留物の非限定的な例は、Ｎ，Ｎ－ジメチルアセトアミド及びＮ，Ｎ－ジメチルホルムアミド、Ｎ－メチル－２－ピロリドン及びジメチルスルホキシドなどの非プロトン性溶媒である。

【００２５】

通常は製造プロセスに存在しないが、染色したアラミド繊維又はアラミドフィラメントにおいて存在する場合があるその他の残留物は、例えばオルトージクロロベンゼンなどのクロロベンゼン及びその誘導体である。

【００２６】

オルトージクロロベンゼン（ＯＤＣＢ）は、オキサジン色素、ピラントロン染料、及びアントラキノン染料の生産におけるプロセス溶媒として使用され、本発明のプロセスにより、例えば色素の熱劣化などの着色特性に悪影響を与えることなく、前述の色素及び染料で染色されるアラミド繊維又はアラミドフィラメントにおけるオルトージクロロベンゼンの含有量を低減することができる。本プロセスによってアラミド繊維又はアラミドフィラメントにおいて低減され得るその他の残留物は、例えば塩化カルシウムなどの金属イオン及び無機塩である。

【００２７】

しかしながら、本発明によるプロセスは、前述の化合物の低減のみに限定されず、代わりに、染色される又は染色されないにかかわらず、アラミド繊維又はアラミドフィラメントにおけるいかなる種類の残留物をも除去するのにも有用であることができる。

【００２８】

本発明によるアラミド繊維又はアラミドフィラメントにおける１つ以上の残留物の含有

量を低減するプロセスは、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整した抽出溶液に導入する工程と、抽出溶液とアラミド繊維又はアラミドフィラメントを８０℃～１４０℃の温度に調整する工程と、抽出溶液からアラミド繊維又はアラミドフィラメントを取り除く工程と、アラミド繊維又はアラミドフィラメントを２～７の範囲のｐＨに調整した第１のリンス液に導入する工程と、場合により洗剤を含む工程と、第１のリンス液とアラミド繊維及びアラミドフィラメントを７０℃～１００℃の温度に調整する工程と、第１のリンス液からアラミド繊維又はアラミドフィラメントを取り除く工程と、をこの順序にて含み、この場合に、抽出溶液は、０～４０ｇ／ｌ の塩成分と、０～４０ｇ／ｌ の担体成分とを含む水溶液であり、且つ、塩成分及び担体成分の合計は、２０ｇ／ｌ ～８０ｇ／ｌ である。

【００２９】

アラミド繊維又はアラミドフィラメントは、本発明によるプロセスを実施するために、バッチ毎に又は連続的に、抽出溶液に導入され得る。

【００３０】

本プロセスが実行され得る適切な機械は、部分染色機、ジェット染色機、パッケージ染色機、ジグ及びビーム染色機、又は連続染色機などの、繊維製品の染色の当技術分野において周知の機械の中から選択され得る。

【００３１】

アラミド繊維又はアラミドフィラメントが糸条の形態である場合には、好ましい機械は、パッケージ染色機であり、一方、アラミド繊維又はアラミドフィラメントが、繊維製品の形態である場合には、好ましい機械は、ビーム染色機である。

【００３２】

本発明によるプロセスが、パッケージ染色機において実行される場合、抽出溶液は、パッケージの内側からパッケージの外側への抽出溶液の加圧された流れを利用することによって、アラミド繊維又はアラミドフィラメントのパッケージ（通常、糸条の糸巻き）を圧力によって強制的に通され得る。他の方法の中でも、これは、ラックにおいて穿孔されたロッドの上に糸条の糸巻きを積み重ね、抽出溶液がその後加圧下にてロッドの穿孔から外側に押し出されるタンクにて浸漬させることによってなされ得る。

【００３３】

本発明によるプロセスに有用な抽出溶液は、酸性のｐＨ、好ましくは２～７のｐＨ、より好ましくは３～５のｐＨに調整され得る。

【００３４】

所望のｐＨが得られるまで、ｐＨは、酸を抽出溶液に加えることによって調整され得る。適切な酸は、ギ酸、酢酸及びそのハロゲン化誘導体、プロパン酸、クエン酸、硫酸、硝酸、及びその他のものなどの、有機酸及び無機酸、及び／又はそれらの誘導体から選択され得る。好ましくは、酸は、酢酸又はギ酸である。

【００３５】

抽出溶液は、例えば、着色剤、染料、及び色素などのいかなる着色成分をも基本的に含まない。

【００３６】

本発明によるプロセスに有用である抽出溶液は、０～４０ｇ／ｌ の塩成分と、０～４０ｇ／ｌ の担体成分とを含む水溶液であることができ、この場合に、塩成分及び担体成分の合計は、２０ｇ／ｌ ～８０ｇ／ｌ であり、好ましくは２０ｇ／ｌ ～６０ｇ／ｌ 、より好ましくは２０ｇ／ｌ ～４０ｇ／ｌ である。

【００３７】

好ましくは、本発明によるプロセスに有用である抽出溶液は、水、０～４０ｇ／ｌ の塩成分、及び０～４０ｇ／ｌ の担体成分からなる水溶液であり、この場合に、塩成分及び担体成分の合計は、２０ｇ／ｌ ～８０ｇ／ｌ であり、好ましくは２０ｇ／ｌ ～６０ｇ／ｌ 、より好ましくは２０ｇ／ｌ ～４０ｇ／ｌ である。

【００３８】

本発明によるプロセスにおいては、液体比は、１：１～１：６０又は１：１～１：１８０であることができる。

【００３９】

抽出溶液の塩成分は、安息香酸ナトリウムなどの有機塩、及び無機塩から選択されてもよく、好ましくは、例えば$NaNO_3$、Na_2SO_4、NaCl、$NaHCO_3$等のアルカリ塩又はアルカリ土類塩などの無機塩から選択される。或いは、尿素、及び安息香酸ナトリウム又は安息香酸カリウムなどの有機化合物も、同様に使用できる。

【００４０】

塩成分及び担体成分の合計は、２０ｇ／ｌ～６０ｇ／ｌであり、好ましくは２０ｇ／ｌ～４０ｇ／ｌであるという条件で、液体比が、１：１～１：２０である場合、好ましくは、抽出溶液の塩成分は、０～２０ｇ／ｌの範囲の量で抽出溶液に含まれ得る。

【００４１】

塩成分及び担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌであり、好ましくは２０ｇ／ｌ～６５ｇ／ｌ、より好ましくは２０ｇ／ｌ～４５ｇ／ｌであるという条件で、液体比が、１：２０～１：６０又は１：２０～１：１８０である場合、好ましくは、抽出溶液の塩成分は、２０～４０ｇ／ｌの範囲の量で抽出溶液に含まれ得る。

【００４２】

塩成分及び担体成分の合計は、２０ｇ／ｌ～５０ｇ／ｌであり、より好ましくは２０ｇ／ｌ～４０ｇ／ｌであるという条件で、液体比が、１：６０～１：１８０又は１：１００～１：１８０である場合、より好ましくは、抽出溶液の塩成分は、２０～４０ｇ／ｌの量で存在することができる。

【００４３】

特に好ましい実施形態においては、塩成分及び担体成分の合計は、２０ｇ／ｌ～４０ｇ／ｌであり、且つ、担体成分の量は、基本的に０ｇ／ｌ、即ち、抽出溶液は担体成分を含まないという条件で、液体比が、１：６０～１：１８０又は１：１００～１：１８０である場合、抽出溶液の塩成分は、２０～４０ｇ／ｌの量で存在することができる。

【００４４】

抽出溶液の担体成分は、アリールエーテル、アセトフェノン、ベンジルアルコール、ｏ－フェニルフェノール、ビスフェニル、ブチルベンゾエート、フタル酸ジアリル、安息香酸、トルエン、及び／又はそれらの混合物などの、有機溶媒から選択され得る。好ましくは、担体成分は、アリールエーテル、アセトフェノン、ベンジルアルコール、及び／又はそれらの混合物から選択され、最も好ましくは、ベンジルアルコールである。

【００４５】

塩成分及び担体成分の合計は、２０ｇ／ｌ～６０ｇ／ｌであり、好ましくは２０ｇ／ｌ～４０ｇ／ｌであるという条件で、液体比が、１：１～１：２０である場合、抽出溶液の担体成分は、２０～４０ｇ／ｌの範囲の量で抽出溶液に含まれ得る。

【００４６】

塩成分及び担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌであり、好ましくは２０ｇ／ｌ～６５ｇ／ｌ、より好ましくは２０ｇ／ｌ～４５ｇ／ｌであるという条件で、液体比が、１：２０～１：６０又は１：６０～１：１８０である場合、抽出溶液の担体成分は、０～４０ｇ／ｌ、より好ましくは０～２５ｇ／ｌの範囲の量で抽出溶液に含まれ得る。

【００４７】

塩成分及び担体成分の合計は、２０ｇ／ｌ～５０ｇ／ｌであり、より好ましくは２０～４０ｇ／ｌであるという条件で、液体比が、１：６０～１：１８０又は１：１００～１：１８０である場合、より好ましくは、抽出溶液の担体成分は、０～１０ｇ／ｌの量で存在することができる。

【００４８】

場合により、抽出溶液は、例えば、当技術分野において周知の有用な濃度にて、分散剤、洗剤、又は界面活性剤などの、当技術分野において周知の添加剤を含んでもよい。

【００４９】

本発明によるプロセスにおいては、抽出溶液が、アラミド繊維又はアラミドフィラメントの膨張又は開繊を引き起こし、このため、１つ以上の残留物が抽出溶液に拡散することが可能になり、従って、処理されているアラミド繊維又はアラミドフィラメントにおける残留物の濃度を著しく低減させることが可能になると考えられる。残留物がアラミド繊維から拡散した後、アラミド繊維又はアラミドフィラメントは、残留物が再び入ることができないように、再び固まる、即ち、閉じる。

【００５０】

アラミド繊維又はアラミドフィラメントが、本発明のプロセスにおける工程ａ）に従って前述の抽出溶液に導入された後、次いでアラミド繊維又はアラミドフィラメントは、工程ｂ）において抽出溶液とアラミド繊維又はアラミドフィラメントを、８０℃～１４０℃の温度、より好ましくは１２０℃～１４０℃、最も好ましくは１２０℃～１３０℃の温度に調整し、少なくとも２０分間、好ましくは２０～１２０分間、より好ましくは２０～６０分間、この温度を維持し、工程ｃ）において抽出溶液からアラミド繊維又はアラミドフィラメントを取り除くことによって、第１の処理を受ける。

【００５１】

上記の第１の処理に続き、アラミド繊維又はアラミドフィラメントは、工程ｄ）において２～７の範囲のｐＨに調整されていてもよい第１の水性リンス液に導入された後、工程ｅ）において第１のリンス液とアラミド繊維又はアラミドフィラメントを、７０℃～１００℃、より好ましくは８０℃～１００℃の温度に調整し、少なくとも１０分間、好ましくは１０～６０分間、より好ましくは３０～４０分間、この温度を維持し、工程ｆ）において第１のリンス液からアアラミド繊維又はアラミドフィラメントを取り除くことによって、第２の処理を受ける。

【００５２】

本発明の例示的な実施形態においては、第１のリンス液は、ｐＨ５に調整された酢酸水溶液からなることができる。

【００５３】

本発明によるプロセスは、アラミド繊維又はアラミドフィラメントを中性のｐＨに調整した第２の水性リンス液に導入する工程ｇ）と、工程ｈ）において第２のリンス液とアラミド繊維又はアラミドフィラメントを１０℃～７０℃の温度に調整し、少なくとも１０分間、好ましくは１０～６０分間、より好ましくは３０～４０分間、この温度を維持し、工程ｉ）において第２のリンス液からアラミド繊維又はアラミドフィラメントを取り除くことによって、その後、アラミド繊維又はアラミドフィラメントに対して第３の処理を実施する工程と、を更に含んでいてもよい。

【００５４】

場合により、第１及び第２の水性リンス液は、当技術分野において周知の有用な濃度にて、例えば、分散剤、洗剤、又は界面活性剤などの、当技術分野において周知の添加剤を含んでいてもよい。

【００５５】

本発明のプロセスにおける第１及び第２の水性リンス液の目的は、アラミド繊維又はアラミドフィラメントから残留する抽出溶液を除去することである。

【００５６】

「アラミド繊維又はアラミドフィラメントの溶液への導入」とは、アラミド繊維又はアラミドフィラメントが、容器に含有される溶液に能動的に導入され得ること、又は、溶液が、容器に含有されるアラミド繊維又はアラミドフィラメントに加えられ得ることを意味することを理解されたい。同様に、「アラミド繊維又はアラミドフィラメントを溶液から取り除くこと」とは、アラミド繊維又はアラミドフィラメントが、溶液から能動的に取り除かれ得ること、又は、溶液が、アラミド繊維又はアラミドフィラメントと溶液を保持する容器から排水され得ることを意味する。

【００５７】

本発明によるプロセスは、ゆるい、カード掛けされた、カード掛けされない、且つ、細

片状のフィラメント又は繊維、アラミド繊維又はアラミドフィラメントのパルプなどの未固結の形態におけるアラミド繊維又はアラミドフィラメントに対して、又は、アラミド繊維又はアラミドフィラメントを含む織布又は不織布に対して実行されることに適している。

【００５８】

好ましくは、本プロセスにおいて使用されるアラミド繊維又はアラミドフィラメントは、メターアラミド繊維又はメターアラミドフィラメントである。

【００５９】

更に、本発明は、重量パーセントは繊維の総重量に基づく、１重量パーセント未満又は０．０１～１重量パーセント、好ましくは０．２重量パーセント未満又は０．０１～０．２重量パーセント、より好ましくは０．１重量パーセント未満又は０．０１～０．１重量パーセントの、例えば非プロトン性溶媒であるＮ－メチル－２－ピロリドン（ＮＭＰ）、１，３－ジメチル－２－イミダゾリジノン（ＤＭＩ）、又はＮ，Ｎ－ジメチルアセトアミド（ＤＭＡＣ）などの、アラミド繊維又はアラミドフィラメントの製造において使用される溶媒を含む、前述のプロセスによって得られるアラミド繊維又はアラミドフィラメントを提供する。

【００６０】

更に、本発明は、重量パーセントは繊維の総重量に基づく、１重量パーセント未満又は０．０１～１重量パーセント、より好ましくは０．２重量パーセント未満又は０．０１～０．２重量パーセント、より好ましくは０．１重量パーセント未満又は０．０１～０．１重量パーセントの、例えばオルトージクロロベンゼンなどのクロロベンゼン又はその誘導体を含む、前述のプロセスによって得られるアラミド繊維又はアラミドフィラメントを提供する。

【００６１】

更に、本発明は、本発明によるプロセスによって得られるアラミド繊維又はアラミドフィラメントを含む、熱、火炎、及びアークに対して耐性のある布地、並びに、それから作製される衣服を提供する。こうした衣服の例は、消防士ギア、鋳造工場用防護衣料、及びその他のものである。

【００６２】

本発明によるプロセスの重要な利点は、例えば、糸条、トップス、繊維製品材料の糸巻き又はロールなどの小売り形態における実質的にいかなる市販のアラミドにも本プロセスは実行され得ることであり、且つ、従って、アラミドにおける非常に慎重を要する生産又は紡糸プロセスを修正する代わりに、繊維製品コンバーターが容易に利用できる従来の染色機において、１つ以上の残留物が除去可能であることである。しかしながら、本発明によるプロセスは、生産量によってこのような構成が正当である場合、実際の生産又は紡糸プロセス後、直ちに、好ましくはインラインで、実施され得ることを理解するべきである。

【００６３】

本発明によるプロセスの更なる利点は、未処理の繊維又はフィラメントと比較して、処理されたアラミド繊維又はアラミドフィラメントは、結晶化度が増加することになり、これにより、アラミド繊維又はアラミドフィラメントが、熱、火炎、及びアークに対して耐性のある衣服に組み込まれる場合、熱防護効果が改善されたこと、並びに、洗浄された際の耐摩耗性及び寸法安定性などの機械的特性が強化されたことに変わることである。

【００６４】

本発明によるプロセスの更に別の利点は、アラミド繊維又はアラミドフィラメントが、本プロセスを受けた後に、より結晶性になることから、処理されたアラミド繊維又はアラミドフィラメントは、事前に除去された残留物による再汚染に対して、耐性が改善したことになることである。

【００６５】

更に、本発明によるプロセスは、アラミドの布地に利用された場合、毛立ちをより起こ

し難い布地を産生する。

【実施例】

【００６６】

実施例1（Ｎｏｍｅｘ（登録商標））

ＮＯＭＥＸ　Ｎ３０７の商標名にてＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙ（ウィルミントン、デラウエア州、米国）より市販されている、オリーブグリーンの色素着色されたポリ（メタフェニレンイソフタルアミド）短繊維５ｇを、２５０ｍｌのエルレンマイヤーフラスコにおいて分析グレードのメタノール１００ｍｌに混合した。次いで、繊維とメタノールの混合物を、１５０ｒｐｍでの一定撹拌下にて、１２０分間、４２℃で維持した。４２℃にて１２０分後に、メタノール分画をデカントし濾過して保存した。こうして得られたメタノール分画の一部を、試料1としてガスクロマトグラフ（ＧＣ）のバイアルの中に入れて、Ｎ，Ｎ－ジメチルアセトアミドの痕跡を分析した。結果を表1に示す。

【００６７】

実施例2（Ｎｏｍｅｘ（登録商標））

ＮＯＭＥＸ　Ｎ３０７の商標名にてＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙ（ウィルミントン、デラウエア州、米国）より市販されている、オリーブグリーンの色素着色されたポリ（メタフェニレンイソフタルアミド）短繊維３３．３グラムを、リットル当り２０グラムのベンジルアルコール、リットル当り２０グラムの硝酸ナトリウムを含有する、酢酸でｐＨ４．５に調整した水性抽出溶液１０００ｍｌに導入する工程と、実験用染色機（ＡＨＩＢＡ）において、一定の撹拌下にて、４０分間、１３０℃で、繊維と水性抽出溶液の混合物を加熱及び維持することによって、この混合物を１３０℃の温度に調整する工程と、水性抽出溶液から繊維を取り除く工程と、９８℃の温度で繊維を水からなる水性リンス液に導入し、一定の撹拌下にて、３０分間、９８℃で維持する工程と、水性リンス液から繊維を取り除く工程と、その後、乾燥器にて、３０分間、１５０℃で繊維を乾燥させる工程とによって、試験したポリ（メタフェニレンイソフタルアミド）短繊維を事前に処理した違い以外は、試料2としてガスクロマトグラフ（ＧＣ）のバイアルの中に入れたメタノール分画を、実施例1における通りに得て分析した。

【００６８】

表1：本発明のプロセスにおいて処理されなかった試料（試料１）、並びに、本発明のプロセスにおいて処理された試料（試料２）における、重量パーセントでのアラミド繊維におけるＤＭＡＣの濃度を示す。

【表1】

	Ｎ，Ｎ－ジメチルアセトアミド(DMAC) [繊維の総重量に基づいて、重量パーセントにて]
試料１	0.37
試料２	0.07

表1

【００６９】

表1で分かるように、本発明のプロセスに従ってアラミド繊維を処理することによって、約5倍、ＤＭＡＣの含有量が低減することになる。

【００７０】

実施例3（Ｎｏｍｅｘ（登録商標）色素着色）

ＮＯＭＥＸ　Ｎ３０３の商標名にてＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙ（ウィルミントン、デラウエア州、米国）より市販されている、オリーブグリーンの色素着色されたポリ（メタフェニレンイソフタルアミド）短繊維５ｇを、２５０ｍｌのエルレンマイヤーフラスコにおいて分析グレードのメタノール１００ｍｌに混合した。次いで、繊維とメタノールの混合物を、１５０ｒｐｍでの一定撹拌下にて

、１２０分間、４２℃で維持した。４２℃にて１２０分後に、メタノール分画をデカントし濾過して保存した。こうして得られたメタノール分画の一部を、試料３としてガスクロマトグラフ（ＧＣ）のバイアルの中に入れて、オルトージクロロベンゼン（ＯＤＣＢ）の痕跡を分析した。結果を表２に示す。

【００７１】

実施例４（Ｎｏｍｅｘ（登録商標）色素着色、処理実施）

ＮＯＭＥＸ　Ｎ３０３の商標名にてＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙ（ウィルミントン、デラウエア州、米国）より市販されている、グリーンの色素着色されたポリ（メタフェニレンイソフタルアミド）短繊維３３．３グラムを、リットル当り２０グラムのベンジルアルコール、リットル当り４０グラムの硝酸ナトリウムを含有する、酢酸でｐＨ４．５に調整した水性抽出溶液１０００ｍｌに導入する工程と、実験用染色機（ＡＨＩＢＡ）において、一定の撹拌下にて、４０分間、１３０℃で、繊維と水性抽出溶液の混合物を加熱及び維持することによって、この混合物を１３０℃の温度に調整する工程と、水性抽出溶液から繊維を取り除く工程と、１５℃の温度で繊維を水からなる水性リンス液に導入する工程と、水性リンス液から繊維を取り除く工程と、その後、乾燥器にて、３０分間、１５０℃で繊維を乾燥させる工程とによって、試験したポリ（メタフェニレンイソフタルアミド）短繊維を事前に処理した違い以外は、試料４としてガスクロマトグラフ（ＧＣ）のバイアルの中に入れたメタノール分画を、実施例３における通りに得て分析した。

【００７２】

実施例５（Ｎｏｍｅｘ（登録商標）色素着色、処理実施）

ＮＯＭＥＸ　Ｎ３０３の商標名にてＥ．Ｉ．ｄｕ　Ｐｏｎｔ　ｄｅ　Ｎｅｍｏｕｒｓ　ａｎｄ　Ｃｏｍｐａｎｙ（ウィルミントン、デラウエア州、米国）より市販されている、オリーブグリーンの色素着色されたポリ（メタフェニレンイソフタルアミド）短繊維３３．３グラムを、リットル当り４０グラムのベンジルアルコール、リットル当り４０グラムの硝酸ナトリウムを含有する、酢酸でｐＨ４．５に調整した水性抽出溶液１０００ｍｌに導入する工程と、実験用染色機（ＡＨＩＢＡ）において、一定の撹拌下にて、４０分間、１３０℃で、繊維と水性抽出溶液の混合物を加熱及び維持することによって、この混合物を１３０℃の温度に調整する工程と、水性抽出溶液から繊維を取り除く工程と、１５℃の温度で繊維を水からなる水性リンス液に導入する工程と、水性リンス液から繊維を取り除く工程と、その後、乾燥器にて、３０分間、１５０℃で繊維を乾燥させる工程とによって、試験したポリ（メタフェニレンイソフタルアミド）短繊維を事前に処理した違い以外は、試料５としてガスクロマトグラフ（ＧＣ）のバイアルの中に入れたメタノール分画を、実施例３における通りに得て分析した。

【００７３】

表２：本発明のプロセスにおいて処理されなかった試料（試料３）、並びに、本発明のプロセスの２つの条件を用いて処理された２つの試料（試料４及び５）における、重量パーセントでのアラミド繊維におけるオルトージクロロベンゼン（ＯＤＣＢ）の濃度を示す。

【表２】

	オルトージクロロベンゼン(ODCB) ［繊維の総重量に基づいて、重量パーセントにて］
試料３	27,4 ppm
試料４	3,99 ppm
試料５	1,38 ppm

表２

【００７４】

表２から分かるように、本発明のプロセスに従ってアラミド繊維を処理することによって、約１０倍を超えて、オルトージクロロベンゼン（ＯＤＣＢ）の含有量が低減すること

になる。
本発明のまた別の態様は、以下のとおりであってもよい。
〔１〕アラミド繊維又はアラミドフィラメントにおける１つ以上の残留物の含有量を低減する方法であって、
ａ．前記アラミド繊維又は前記アラミドフィラメントを、２～７の範囲のｐＨに調整した抽出溶液に導入する工程と、
ｂ．前記抽出溶液と、前記アラミド繊維又は前記アラミドフィラメントを、８０℃～１４０℃の温度に調整する工程と、
ｃ．前記抽出溶液から前記アラミド繊維又は前記アラミドフィラメントを取り除く工程と、
ｄ．前記アラミド繊維又は前記アラミドフィラメントを、２～７の範囲のｐＨに調整した第１のリンス液に導入する工程と、
ｅ．場合により洗剤を含む工程と、
ｆ．前記第１のリンス液と、前記アラミド繊維及び前記アラミドフィラメントを、７０℃～１００℃の温度に調整する工程と、
ｇ．前記第１のリンス液から前記アラミド繊維又は前記アラミドフィラメントを取り除く工程と
をこの順序にて含み、
前記抽出溶液は０～４０ｇ／ｌの塩成分と、０～４０ｇ／ｌの担体成分とを含む水溶液であり、且つ、
前記塩成分及び前記担体成分の合計は、２０ｇ／ｌ～８０ｇ／ｌである、方法。
〔２〕ｈ．前記アラミド繊維又は前記アラミドフィラメントを、２～７の範囲のｐＨに調整した第２のリンス液に導入する工程であって、場合により洗剤を含んでもよい工程と、
ｉ．前記第２のリンス液と、前記アラミド繊維及び前記アラミドフィラメントを、１０℃～７０℃の温度に調整する工程と、
ｊ．前記第２のリンス液から前記アラミド繊維又は前記アラミドフィラメントを取り除く工程と、
を更に含む、前記〔１〕に記載の方法。
〔３〕アラミド繊維及びアラミドフィラメントの抽出溶液に対する液体比が、１：１～１：１８０である、前記〔１〕又は〔２〕に記載の方法。
〔４〕前記塩成分及び前記担体成分の合計が、２０ｇ／ｌ～６０ｇ／ｌであるという条件で、前記液体比が、１：１～１：２０である場合、前記抽出溶液は、０～２０ｇ／ｌの範囲の量の前記塩成分と、２０～４０ｇ／ｌの範囲の量の前記担体成分とを含む、前記〔１〕又は〔２〕に記載の方法。
〔５〕前記塩成分及び前記担体成分の合計が、２０ｇ／ｌ～６５ｇ／ｌであるという条件で、前記液体比が、１：２０～１：１８０である場合、前記抽出溶液は、２０～４０ｇ／ｌの範囲の量の前記塩成分と、０～２５ｇ／ｌの範囲の量の前記担体成分とを含む、前記〔１〕又は〔２〕に記載の方法。
〔６〕前記抽出溶液は、３～５の範囲のｐＨに調整される、前記〔１〕～〔５〕のいずれか一項に記載の方法。
〔７〕前記アラミド繊維又は前記アラミドフィラメントは、メターアラミド繊維又はメターアラミドフィラメントである、前記〔１〕～〔６〕のいずれか一項に記載の方法。
〔８〕０．１重量パーセント未満のオルトージクロロベンゼンを含み、前記メターアラミド繊維又は前記メターアラミドフィラメントは、乾式紡糸によって得られる乾燥した結晶性メター－アラミド繊維又はメター－アラミドフィラメントである、前記〔７〕に記載の方法によって得られるメターアラミド繊維又はメターアラミドフィラメント。
〔９〕０．１重量パーセント未満のＮ－メチル－２－ピロリドン又はＮ，Ｎ－ジメチルアセトアミドを含み、前記メターアラミド繊維又は前記メターアラミドフィラメントは、乾式紡糸によって得られる乾燥した結晶性メターアラミド繊維又はメターアラミドフィラメントである、前記〔７〕に記載の方法によって得られるメターアラミド繊維又はメターア

ラミドフィラメント。
〔１０〕前記〔８〕又は〔９〕に記載のメター アラミド繊維又はメター アラミドフィラメントと、少なくとも１つの静電気防止繊維とを含む糸条。
〔１１〕前記〔８〕又は〔９〕に記載のアラミド繊維又はアラミドフィラメントを含む、熱、火炎、及びアークに対して耐性のある衣服。
〔１２〕前記〔８〕又は〔９〕に記載のアラミド繊維又はアラミドフィラメントを含む、熱、火炎、及びアークに対して耐性のある布地。

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Selective catalytic reduction system and power apparatus comprising same

Abstract

A selective catalytic reduction system according to an embodiment of the present invention comprises: a reactor installed on a main exhaust flow path in the rear of a turbocharger installed on the main exhaust flow path; a reducing agent injection part, installed on the main exhaust flow path, for injecting a reducing agent to an exhaust gas moving toward the reactor; a decomposition chamber which is supplied with a reducing agent precursor and decomposes the same to generate the reducing agent to be supplied to the reducing agent injection part; a bifurcation channel which is bifurcated from a turbocharger bypass flow path, which is bifurcated from the main exhaust flow path and bypasses the turbocharger and is again merged into the main exhaust flow path, and connected to the decomposition chamber; an external air supply flow path for supplying external air to the decomposition chamber; a blower, installed on the external air supply flow path, for drawing in the external air; and a heating device, installed on the external air supply flow path, for heating the external air drawn in by the blower.

Images (4)



Classifications

- F01N3/2033 Periodically heating or cooling catalytic reactors, e.g. at cold starting or overheating using a fuel burner or introducing fuel into exhaust duct

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Engineering & Computer Science

Chemical & Material Sciences

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Drawings, PDF Machine Translation Translate

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External links: Espacenet, Global Dossier, Patent Scope, Discuss

Claims (13)

Hide Dependent

1. In the selective catalytic reduction system for reducing the nitrogen oxides (NOx) contained in the exhaust gas discharged through the main exhaust passage,

   A reactor installed on the main exhaust flow path behind the supercharger provided on the main exhaust flow path;

   A reducing agent injector installed on the main exhaust passage to inject a reducing agent into the exhaust gas moving to the reactor;

   A decomposition chamber receiving and reducing a reducing precursor to generate a reducing agent to be supplied to the reducing agent injection unit;

   A branch flow passage branched from the main exhaust flow passage, bypassing the supercharger, and branching from the supercharger bypass flow passage that joins the main exhaust flow passage and connected to the decomposition chamber;

   An outside air supply passage for supplying outside air to the decomposition chamber;

   A blower installed on the outside air supply passage to suck outside air; And

   A heating device installed on the outside air supply passage to heat the outside air sucked by the blower;

   Selective catalytic reduction system comprising a.

2. In claim 1,

   And a supercharger bypass valve disposed on the supercharger bypass flow path and the supercharger bypass flow path in front of the branch point of the branch flow path.

3. In claim 1,

And a non-return valve installed on the outside air supply passage to prevent the exhaust gas flowing through the branch passage to the decomposition chamber from flowing back to the outside air supply passage.

4. In claim 1,

And a flow rate control valve for controlling a flow rate of the exhaust gas flowing through the supercharger bypass flow passage and the branch flow passage.

5. In claim 4,

And the flow control valve is a three-way flow control valve installed at a branch point of the supercharger bypass flow passage and the branch flow passage.

6. In claim 4,

The flow rate control valve may include a first flow rate control valve provided between a branch point of the supercharger bypass flow passage and the branch flow passage and a confluence point of the supercharger bypass flow passage and the main exhaust flow passage, and a second flow control valve provided on the branch flow passage. Selective catalytic reduction system comprising a.

7. In claim 4,

A first temperature sensor and a first flow meter installed on the branch flow path;

A second flow meter installed on the outside air supply flow path and measuring a flow rate of the outside air sucked by the blower; And

A second temperature sensor installed on the outside air supply flow path and measuring a temperature of outside air passing through the heating device;

Selective catalytic reduction system further comprising.

8. In claim 7,

And a control unit which receives information from the first temperature sensor, the first flow meter, the second temperature sensor, and the second flow meter to control the opening and closing of the flow control valve and the operation of the blower and the heating device. Catalytic reduction system.

9. In claim 8,

The control unit calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and the calculated amount of heat calculates the amount of heat required to generate a reducing agent in the decomposition chamber. Selective catalytic reduction system for adjusting the opening degree of the flow control valve to follow.

10. In claim 8,

The controller calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and the calculated amount of heat is greater than the amount of heat required to generate a reducing agent in the decomposition chamber. And if it is low, operate the blower and the heating device to supply additional heat to the decomposition chamber through the outside air supply passage.

11. In claim 10,

The control unit calculates the amount of heat supplied to the decomposition chamber through the outside air supply passage from the information obtained from the second temperature sensor and the second flow meter,

The control unit controls the operation degree of the blower and the heating device such that the sum of the amount of heat supplied through the branch flow path and the amount of heat supplied through the outside air supply flow path follows the amount of heat required to generate a reducing agent in the decomposition chamber. Selective catalytic reduction system.

12. In claim 8,

The control unit calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and if the calculated amount of heat exceeds the amount of heat required to generate a reducing agent, the flow rate Selective catalytic reduction system to control the control valve to reduce the flow rate of the exhaust gas flowing to the branch passage.

13. An engine for exhausting exhaust gas containing nitrogen oxides (NOx);

A main exhaust passage through which the exhaust gas discharged by the engine moves;

A supercharger installed on the main exhaust passage;

A supercharger bypass flow path branching from the main exhaust flow path, bypassing the supercharger, and then joining the main exhaust flow path again; And

The selective catalytic reduction system according to any one of claims 1 to 12.

Power device comprising a.

Description

Selective Catalytic Reduction System and Power Plant Including It

The present invention relates to a selective catalytic reduction system for reducing nitrogen oxides contained in exhaust gas by using a selective catalytic reduction reaction and a power unit including the same.

In general, power units used in ships and the like are selective catalytic reduction to reduce the nitrogen oxides contained in diesel engines for generating power, turbochargers for supplying air to the diesel engines, and exhaust gases emitted from diesel engines. selective catalytic reduction (SCR) systems.

In the selective catalytic reduction system, the nitrogen oxide contained in the exhaust gas and the reducing agent react with each other while passing the exhaust gas and the reducing agent together in a reactor in which the catalyst is installed therein, and the reduction process is performed with nitrogen and water vapor.

The selective catalytic reduction system uses urea or ammonia (NH_3) as a reducing agent to reduce nitrogen oxides.

However, when urea is directly injected into an exhaust gas having a temperature of less than 250 degrees Celsius, such as biuret, cyanuric acid, melamine, and ammeline, which are generated as urea decomposes. There is a problem in that the nozzle is clogged by the by-products or obstructs the flow of exhaust gas.

Therefore, in order to improve the decomposition efficiency of urea, the heated fluid is supplied to the decomposition chamber through a separate electric heater or burner to raise the internal temperature of the decomposition chamber to the decomposition reaction temperature, and the urea is stably decomposed in the decomposition chamber and generated. To supply ammonia (NH_3) and isocyanic acid (HNCO) to the reactor.

However, in order to decompose urea, the internal temperature of the decomposition chamber must be raised to the decomposition reaction temperature, which requires a separate heating device such as a burner for supplying thermal energy. And fuel and air are consumed to operate the burner.

As such, the thermal energy consumed for the decomposition of urea is not small, and the fuel and air consumed by the burner occupy a considerable proportion in comparison with the total fuel and air consumed in the selective catalytic reduction system, thereby lowering the overall energy utilization efficiency. There is this

Embodiments of the present invention provide a selective catalytic reduction system and a power unit including the same that maximize the efficiency of the overall energy consumed to produce a reducing agent and reduce the nitrogen oxides contained in the exhaust gas.

According to an embodiment of the present invention, a selective catalytic reduction system for reducing nitrogen oxides (NOx) contained in the exhaust gas discharged through the main exhaust passage is provided on the main exhaust passage behind the supercharger installed on the main exhaust passage. A reactor installed on the main exhaust passage, a reducing agent injecting unit for injecting a reducing agent into the exhaust gas moving to the reactor, a decomposition chamber for receiving and decomposing a reducing precursor and generating a reducing agent to be supplied to the reducing agent injecting unit, A branch flow path branched from the supercharger bypass flow path branched from the main exhaust flow path and bypassing the supercharger and then joined to the main exhaust flow path and connected to the decomposition chamber, and an external air supply flow path supplying outside air to the decomposition chamber; A blower installed on the outside air supply passage to suck outside air, and the it is provided on an external air supply flow path, and includes the heating apparatus which heats the external air which the said blower sucked.

The selective catalytic reduction system may further include a supercharger bypass valve installed on the supercharger bypass flow path and the supercharger bypass flow path in front of the branch point of the branch flow path.

The selective catalytic reduction system may further include a non-return valve installed on the outside air supply flow path to prevent the exhaust gas flowing into the decomposition chamber through the branch flow path to flow back to the outside air supply flow path.

The selective catalytic reduction system may further include a flow control valve for controlling the flow rate of the exhaust gas flowing through the supercharger bypass flow passage and the branch flow passage.

The flow control valve may be a three-way flow control valve installed at a branch point of the supercharger bypass flow passage and the branch flow passage.

The flow rate control valve may include a first flow rate control valve provided between a branch point of the supercharger bypass flow passage and the branch flow passage, and a confluence point of the supercharger bypass flow passage and the main exhaust flow passage, and a second flow rate installed on the branch flow passage. It may include a control valve.

The selective catalytic reduction system includes a first temperature sensor and a first flow meter installed on the branch flow path, a second flow meter installed on the outside air supply flow path and measuring a flow rate of outside air sucked by the blower, and the outside air. The apparatus may further include a second temperature sensor installed on a supply flow path and measuring a temperature of the outside air that has passed through the heating device.

The selective catalytic reduction system receives information from the first temperature sensor, the first flow meter, the second temperature sensor, and the second flow meter to control the opening and closing of the flow control valve and the operation of the blower and the heating device. The control unit may further include a.

The control unit calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and the calculated amount of heat calculates the amount of heat required to generate a reducing agent in the decomposition chamber. The opening degree of the flow control valve can be adjusted to follow.

The controller calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and the calculated amount of heat is greater than the amount of heat required to generate a reducing agent in the decomposition chamber. When low, the blower and the heating device may be operated to supply additional heat to the decomposition chamber through the external air supply passage.

The controller may calculate the amount of heat supplied to the decomposition chamber through the outside air supply flow path from the information obtained from the second temperature sensor and the second flow meter. And the controller controls the operation degree of the blower and the heating device such that the sum of the heat supplied through the branch flow path and the heat supplied through the outside air supply flow path follows the heat required to generate a reducing agent in the decomposition chamber. Can be controlled.

The control unit calculates the amount of heat supplied to the decomposition chamber through the branch flow path from the information obtained from the first temperature sensor and the first flow meter, and if the calculated amount of heat exceeds the amount of heat required to generate a reducing agent, the flow rate The control valve may be controlled to reduce the flow rate of the exhaust gas moving to the branch flow path.

In addition, according to an embodiment of the present invention, the power unit includes an engine for discharging exhaust gas containing nitrogen oxides (NOx), a main exhaust passage through which the exhaust gas discharged by the engine moves, and the main exhaust passage. And an installed supercharger, a supercharger bypass flow path branching from the main exhaust flow path, bypassing the supercharger, and then joining the main exhaust flow path again, and the selective catalytic reduction system described above.

According to the embodiment of the present invention, the selective catalytic reduction system and the power unit including the same can maximize the utilization efficiency of the overall energy consumed to generate the reducing agent and reduce the nitrogen oxide contained in the exhaust gas.

1 is a block diagram of a power unit including a selective catalytic reduction system according to an embodiment of the present invention.

2 and 3 are configuration diagrams showing the operating state of the power unit including the selective catalytic reduction system of FIG.

4 is a block diagram of a power unit including a selective catalytic reduction system according to a modification of an embodiment of the present invention.

Hereinafter, exemplary embodiments of the present invention will be described in detail with reference to the accompanying drawings so that those skilled in the art may easily implement the present invention. As those skilled in the art would realize, the described embodiments may be modified in various different ways, all without departing from the spirit or scope of the present invention.

It is noted that the figures are schematic and not drawn to scale. The relative dimensions and ratios of the parts in the figures have been exaggerated or reduced in size for clarity and convenience in the figures and any dimensions are merely exemplary and not limiting. And the same reference numerals are used to refer to similar features in the same structure, element or part shown in more than one figure.

Embodiments of the invention specifically illustrate ideal embodiments of the invention. As a result, various modifications of the drawings are expected. Thus, the embodiment is not limited to the specific form of the illustrated region, but includes, for example, modification of the form by manufacture.

Hereinafter, a selective catalytic reduction (SCR) system 201 and a power unit 101 including the same will be described with reference to FIGS. 1 to 3.

The selective catalytic reduction system 201 according to an embodiment of the present invention may be manufactured and assembled together with the engine 100 as a component of the power unit 101, but in some cases, an engine that has been installed and used in some cases (in order to reduce the nitrogen oxide (NOx) contained in the exhaust gas discharged from 100) it may be installed after the. Specifically, the selective catalytic reduction system 201 according to an embodiment of the present invention to improve the environmental performance of the existing engine 100 installed during the repair and repair of a vehicle or a land vehicle or a marine or plant, etc. Can be installed additionally.

As shown in Figures 1 to 3, the power unit 101 including a selective catalytic reduction (SCR) system 201 according to an embodiment of the present invention is the engine 100, the main exhaust passage (610, supercharger 150, reactor 300, supercharger bypass flow path 630, reducing agent injector 570, decomposition chamber 500, branch flow path 630, external air supply flow path 640, blower 410), And a heating device 420.

In addition, the power unit 101 including the selective catalytic reduction system 201 according to an embodiment of the present invention is an exhaust receiver 180, a supercharger bypass valve 720, a noreturn valve 770, a flow control valve (710, the first temperature sensor 811, the first flow meter 812, the second flow meter 822, the second temperature sensor 821, and the controller 700 may be further included.

The engine 100 is a main power source for generating power in ships and automobiles. In one embodiment of the present invention, various engines for exhausting exhaust gas containing nitrogen oxides (NOx) may be used as the engine 100

The supercharger 150 is installed on the main exhaust passage, which will be described later. The supercharger 150 rotates the turbine at the pressure of the exhaust gas of the engine 100 to compress and supply new external air to the engine 100, thereby improving the efficiency of the engine 100.

The exhaust receiver 180 evenly relaxes the exhaust gas of the engine 100 discharged with an unbalanced pressure by the cylinder reciprocating motion of the engine 100.

In one embodiment of the present invention, the exhaust gas discharged from the engine 100 has a temperature in the range of 250 degrees Celsius to 500 degrees Celsius, the temperature of the exhaust gas may be lowered through the supercharger 150. For example, the exhaust gas passed through the supercharger 150 may be lowered to a temperature of more than 150 degrees Celsius or less than 250 degrees Celsius.

The main exhaust passage 610 is connected to the exhaust port of the engine 100 to exhaust the exhaust gas of the engine 100. That is, the exhaust gas of the engine 100 moves along the main exhaust flow path 610.

The main exhaust passage 610 sequentially connects the engine 100, the supercharger 150, and the reactor 300 to be described later. As such, the main exhaust flow path 610 supplies the exhaust gas of the engine 100 that has passed through the supercharger 150 to the reactor 300.

The reactor 300 is installed on the main exhaust flow path 610. The reactor 300 includes a catalyst for reducing nitrogen oxides (NOx) contained in the exhaust gas discharged from the engine 100. The catalyst catalyzes the reaction between the nitrogen oxide (NOx) contained in the exhaust gas and the reducing agent to reduce the nitrogen oxide (NOx) to nitrogen and water vapor. At this time, ammonia (NH_3) may be used as the final reducing agent to be reduced by reacting with nitrogen oxide (NOx).

The catalyst may be made of various materials known to those skilled in the art, such as zeolite, vanadium, platinum and the like. In one example, the catalyst may have an active temperature in the range of 250 degrees Celsius to 350 degrees Celsius. Here, the active temperature refers to a temperature at which the catalyst can be stably reduced without poisoning the catalyst. If the catalyst reacts outside the active temperature range, the catalyst is poisoned and the efficiency decreases.

Specifically, the poisoning substance for poisoning the catalyst may include one or more of ammonium sulfate ($(NH_4)_2SO_4$) and ammonium bisulfate (NH_4HSO_4). These catalyst poisoning substances are adsorbed on the catalyst to lower the activity of the catalyst. Since the catalyst poisoning substance decomposes at a relatively high temperature, the catalyst can be regenerated by raising the temperature.

In addition, the housing of the reactor 300, for example, may be made of stainless steel (stainless steel) material.

The decomposition chamber 500 is supplied with a reducing agent precursor urea (urea, $CO(NH_2)_2$) to decompose it to produce ammonia (NH_3) used as a reducing agent to reduce nitrogen oxides (NOx).

Specifically, when the temperature in the decomposition chamber 500 is maintained within the range of 300 degrees Celsius to 500 degrees Celsius, urea (urea, $CO(NH_2)_2$) is easily hydrolyzed or pyrolyzed while ammonia (NH_3) and isocyanate. An isocyanic acid (HNCO) is produced. Isocyanic acid (HNCO) is decomposed into ammonia (NH_3) and carbon dioxide (CO_2) again. That is, when urea is decomposed, ammonia may be finally generated.

The reducing agent injection unit 570 receives ammonia (NH_3) generated in the decomposition chamber 500 and injects the exhaust gas to be introduced into the reactor 300. The injected ammonia is mixed with the exhaust gas to reduce the nitrogen oxide contained in the exhaust gas while passing through the catalyst of the reactor 300.

In detail, the reducing agent injector 570 may inject ammonia NH_3 toward the exhaust gas moving along the main exhaust passage 610 in front of the reactor 300.

In the present specification, the front means an upstream side and the rear means a downstream side based on the flow of exhaust gas.

The urea supply unit 550 supplies urea, a reducing agent precursor, to the decomposition chamber 500. The urea supply unit 550 supplies an appropriate amount of urea to the decomposition chamber 500 in consideration of the required amount of reducing agent that varies according to the load of the engine 100. That is, the urea supply unit 550 may be supplied in accordance with the amount of reducing agent required under the control of the control unit 700 to be described later.

The supercharger bypass flow path 620 branches from the main exhaust flow path 610, bypasses the supercharger 150, and then joins the main exhaust flow path 610 again. That is, since the exhaust gas moving through the supercharger bypass flow path 620 does not go through the supercharger 150, the exhaust gas has a relatively high temperature as compared with the exhaust gas that has passed through the supercharger 150.

The supercharger bypass valve 720 is installed on the supercharger bypass flow path 620.

Specifically, the supercharger bypass valve 720 is installed on the supercharger bypass flow path 620 and the supercharger bypass flow path 620 in front of the branch point of the branch flow path 630 to be described later.

The supercharger bypass valve 720 may be used to regulate combustion pressure and heat load in the combustion chamber of the engine 100.

In addition, the supercharger bypass valve 720 may be used to supply the exhaust gas to the decomposition chamber 500 through the branch passage 630 to be described later.

When the combustion pressure and the heat load in the combustion chamber of the engine 100 increase beyond the allowable values, the supercharger bypass valve 720 is opened to flow a part of the exhaust gas to the supercharger bypass flow path 620 to supply the supercharger 150. Reduce the flow rate of the exhaust gas. Accordingly, the pressure of the compressed air supplied to the engine 100 by the supercharger 150 may be reduced, and thus the combustion pressure in the combustion chamber of the engine 100 may be adjusted.

As such, the supercharger bypass valve 720 may be operated independently from the flow control valve 710 to be described later.

The branch flow path 630 is branched from the supercharger bypass flow path 620 and connected to the decomposition chamber 500. That is, the branch flow path 630 transfers the exhaust gas having a relatively high temperature that moves the supercharger bypass flow path 620 to the decomposition chamber 500 to hydrolyze or pyrolyze urea in the decomposition chamber 500 to obtain ammonia. Supply the heat energy needed to generate.

The flow control valve 710 controls the flow rate of the exhaust gas traveling through the supercharger bypass flow path 620 and the branch flow path 630. For example, the flow control valve 710 may be a three-way flow control valve installed at a branch point of the supercharger bypass flow passage 620 and the branch flow passage 630.

The first temperature sensor 811 and the first flow meter 812 are installed on the branch flow path 630. Thus, in one embodiment of the present invention, the amount of heat supplied to the decomposition chamber 500 through the branch flow path 630 with the temperature information and the flow rate information measured by the first temperature sensor 811 and the first flow meter 812. Can be calculated. The opening rate of the flow control valve 710 may be adjusted so that the calculated amount of heat follows the amount of heat required to generate ammonia as a reducing agent by hydrolyzing or pyrolyzing urea as a reducing agent precursor in the decomposition chamber 500.

In this way, the flow rate control valve 710 according to the calculated amount of heat so that the amount of heat required to generate the reducing agent in the decomposition chamber 500 is supplied to the decomposition chamber 500 through the branch flow path 630. The flow rate of the exhaust gas branched to the branch flow path 630 can be adjusted.

In addition, the amount of heat supplied to the decomposition chamber 500 through the branch flow path 630 is calculated from the information obtained from the first temperature sensor 811 and the first flow meter 812, and the calculated amount of heat is decomposed to generate a reducing agent. When the amount of heat required in the chamber 500 is exceeded, the flow rate control valve 630 may be adjusted to reduce the flow rate of the exhaust gas moving to the branch flow path 630.

That is, when the exhaust gas moving along the supercharger bypass flow path 620 may supply the required heat amount to the decomposition chamber 500 through the branch flow path 630, the remaining exhaust gas corresponding to the remaining heat amount may be the branch flow path (Instead of going to 630, it moves along the supercharger bypass flow path 620 and joins the main exhaust flow path 610 again.

As described above, the exhaust gas joined with the main exhaust passage 610 via the supercharger bypass passage 620 is combined with the exhaust gas whose temperature is lowered while passing through the supercharger 150 to adjust the temperature of the exhaust gas flowing into the reactor 300. It can raise a temperature.

The temperature of the exhaust gas passed through the supercharger 150 may be lowered to 150 degrees Celsius or more and less than 250 degrees Celsius, as described above. When such a relatively low temperature vagas enters the reactor 300, the activity of the catalyst This can be degraded or the catalyst poisoned.

That is, the exhaust gas joined to the main exhaust passage 610 via the supercharger bypass passage 620 may heat up the exhaust gas flowing into the reactor 300 to maintain the activity of the catalyst and suppress the poisoning of the catalyst.

The outside air supply passage 640 supplies the outside air to the decomposition chamber 500. That is, the outdoor air supply flow path 640 branches from the supercharger bypass flow path 620 and supplies air other than the exhaust gas supplied through the branch flow path 630 to the decomposition chamber 500.

The blower 410 and the heating device 420 are installed on the outside air supply passage 640. The blower 410 sucks outside air through the outside air supply passage 640. The heating device 420 heats the outside air sucked by the blower 410. In one example, the heating device 420 may be one of an oil burner, a plasma burner, or an electric heater.

The non-return valve 770 is installed on the outside air supply passage 640 to prevent the exhaust gas flowing into the decomposition chamber 500 through the branch passage 630 from flowing back to the outside air supply passage 640.

According to one embodiment of the present invention, the amount of heat supplied to the decomposition chamber 500 through the branch flow path 630 from the information obtained from the first temperature sensor 811 and the first flow meter 812 is calculated, and the calculated amount of heat If it is lower than the amount of heat required to generate a reducing agent in the decomposition chamber 500, the blower 410 and the heating device 420 may be operated to supply additional heat to the decomposition chamber 500 through the external air supply passage 640. have.

In addition, in one embodiment of the present invention, since a heating device 420 for additionally supplying thermal energy is installed in the outside air supply line 640, when a burner requiring combustion air is used as the heating device 420, the heating device. The supply of oxygen to is easy and effective.

On the other hand, unlike the embodiment of the present invention, if the heating device 420 is installed in the branch flow path 630, the heating device 420 such as a burner because the oxygen concentration of the exhaust gas moving along the branch flow path 630 is thin.) is limited to use.

The second flow meter 822 is installed on the outside air supply flow passage 640. The second flow meter 822 measures the flow rate of the outside air sucked by the blower 410.

The second temperature sensor 821 is provided on the outside air supply passage 640. Specifically, the second temperature sensor 821 may be installed on the outside air supply passage 640 behind the heating device 420. The second temperature sensor 821 measures the temperature of the outside air that has passed through the heating device 420.

Thus, in an embodiment of the present invention, the temperature information and the flow rate information measured by the second temperature sensor 821 and the second flow meter 822 are supplied to the decomposition chamber 500 through the external air supply flow path 640. Calorie can be calculated.

And in one embodiment of the present invention, the sum of the amount of heat supplied through the branch flow path 630 and the amount of heat supplied through the outside air supply flow path 640 follows the amount of heat required to generate a reducing agent in the decomposition chamber 500. The operation of the blower 410 and the heating device 420 may be adjusted.

The control unit 700 receives information from the first temperature sensor 811, the first flow meter 812, the second temperature sensor 821, and the second flow meter 822 to open / close and blow the flow control valve 710 (The operation of the 410 and the heating device 420 may be controlled.

That is, the controller 700 calculates the amount of heat supplied to the decomposition chamber 500 through the branch flow path 630 and the amount of heat supplied to the decomposition chamber 500 through the external air supply flow path 640, and the calculated amount of heat. Control the flow control valve 710 and the blower 410 and the heating device 420 so as to follow the amount of heat required to hydrolyze or pyrolyze the urea as the reducing agent precursor in the decomposition chamber 500 to produce ammonia as the reducing agent. can do.

In addition, the controller 700 may control the urea supply unit 550 for supplying urea to the decomposition chamber 500 according to the amount of the reducing agent required in consideration of the load variation of the engine 100.

By such a configuration, the power unit 101 including the selective catalytic reduction system 201 according to the embodiment of the present invention utilizes the entire energy consumed to generate the reducing agent and reduce the nitrogen oxide contained in the exhaust gas. Efficiency can be maximized.

Specifically, according to an embodiment of the present invention, the thermal energy is discharged from the engine 100 through the supercharger bypass flow path 620 and the branch flow path 630 before passing through the supercharger 150 decomposition chamber It can be utilized to generate a reducing agent at (500).

In addition, since the vessel is used in various climatic regions, the amount of the reducing agent required according to the load variation and environmental change of the engine 100 is changed, and the decomposition chamber (through the supercharger bypass flow path 620 and the branch flow path 630). The amount of heat supplied to 500 is also different.

However, according to an embodiment of the present invention, the heat amount supplied to the decomposition chamber 500 through the supercharger bypass flow path 620 and the branch flow path 630 and the external air supply flow path 640 to the decomposition chamber 500. The amount of heat supplied is calculated, respectively, and the sum of the calculated amounts of heat flow control valve 710 and blower so as to follow the amount of heat required to generate ammonia as a reducing agent by hydrolyzing or pyrolyzing urea as a reducing agent precursor in the decomposition chamber 500. 410 and the heating device 420 can be adjusted. That is, even in the load variation and environmental change of the engine 100, it is possible to maximize the use efficiency of the overall energy consumed to generate a reducing agent and to reduce the nitrogen oxide contained in the exhaust gas.

In addition, as shown in FIG. 4, according to a modification of one embodiment of the present invention, the power unit 102 including the selective catalytic reduction system 202 may include a first flow control valve 711 and a second flow control valve. Use a flow control valve that includes 712.

The first flow control valve 711 is provided between the branch point of the supercharger bypass flow path 620 and the branch flow path 630 and the confluence point of the supercharger bypass flow path 620 and the main exhaust flow path 610.

The second flow control valve 712 is installed on the branch oil 630 passage.

That is, the present modified example uses two flow control valves 711 and 712 instead of one three-way flow control valve, except for this configuration and operation principle are the same as in the embodiment of the present invention.

Hereinafter, the operating principle of the power unit 101 including the selective catalytic reduction system 201 according to an embodiment of the present invention will be described with reference to FIGS. 1 to 3.

As shown in FIG. 1, the control unit 700 has the temperature information and the flow rate information measured by the first temperature sensor 811 and the first flow meter 812 to the decomposition chamber 500 through the branch flow path 630. Calculate the amount of heat supplied.

The controller 700 does not operate the blower 410 and the heating device 420 when the calculated amount of heat satisfies the amount of heat required to generate a reducing agent in the decomposition chamber 500. That is, according to one embodiment of the present invention, it is possible to prevent unnecessary waste of energy.

Next, as shown in FIG. 2, the control unit 700 has the temperature information and the flow rate information measured by the first temperature sensor 811 and the first flow meter 812 and the decomposition chamber 500 through the branch flow path 630.). And the opening rate of the flow control valve 710 is adjusted so that the calculated amount of heat follows the amount of heat required to generate a reducing agent in the decomposition chamber 500.

That is, the controller 700 reduces the flow rate of the exhaust gas moving to the branch flow path 630 by controlling the flow rate control valve 710 when the calculated amount of heat exceeds the amount of heat required to generate the reducing agent.

The remaining exhaust gas corresponding to the amount of heat remaining even after supplying the heat amount required for the decomposition chamber 500 is moved along the supercharger bypass flow path 620 without being directed to the branch flow path 630 and re-loaded to the main exhaust flow path 610. To join.

As described above, the exhaust gas joined with the main exhaust passage 610 via the supercharger bypass passage 620 is combined with the exhaust gas whose temperature is lowered while passing through the supercharger 150 to adjust the temperature of the exhaust gas flowing into the reactor 300. It can raise a temperature.

Next, as shown in FIG. 3, the control unit 700 has the temperature information and the flow rate information measured by the first temperature sensor 811 and the first flow meter 812 and the decomposition chamber 500 through the branch flow path 630. Calculate the amount of heat to be supplied, and if the calculated amount is lower

than the amount of heat required to produce the reducing agent in the decomposition chamber 500, the blower 410 and the heating device 420 are operated to open the outside air supply passage 640. The amount of heat is additionally supplied to the decomposition chamber 500 through.

At this time, the control unit 760 calculates the amount of heat supplied to the decomposition chamber 500 through the external air supply flow path 640 from the information obtained from the second temperature sensor 821 and the second flow meter 822, branch flow path 630 Operation of the blower 410 and the heating device 420 so that the sum of the heat supplied through the air supply channel 640 and the heat supplied through the external air supply passage 640 follows the heat required to generate the reducing agent in the decomposition chamber 500. You can control the degree.

By this operation, the power unit 101 including the selective catalytic reduction system 201 according to the embodiment of the present invention utilizes the entire energy consumed to generate the reducing agent and reduce the nitrogen oxide contained in the exhaust gas. Efficiency can be maximized.

Although the embodiments of the present invention have been described above with reference to the accompanying drawings, those skilled in the art to which the present invention pertains can understand that the present invention can be implemented in other specific forms without changing the technical spirit or essential features. will be.

Therefore, the embodiments described above are to be understood as illustrative and not restrictive in all respects, and the scope of the present invention is represented by the following detailed description, and the meaning and scope of the claims and All changes or modifications derived from the equivalent concept should be interpreted as being included in the scope of the present invention.

The selective catalytic reduction system and the power unit including the same according to the embodiment of the present invention can be used to maximize the utilization efficiency of the overall energy consumed to generate a reducing agent and reduce the nitrogen oxide contained in the exhaust gas.

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Publication number	Priority date	Publication date	Assignee	Title
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JP2007315173A *	2006-05-23	2007-12-06	Nissan Motor Co Ltd	Exhaust system of internal combustion engine
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Family To Family Citations				
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Priority And Related Applications

Priority Applications (2)

Application	Priority date	Filing date	Title
CN201580071498.8A	2014-12-31	2015-12-30	Selective catalytic reduction system and power plant comprising same
JP2017535063A	2014-12-31	2015-12-30	Selective catalytic reduction system and power unit including the same

Applications Claiming Priority (2)

Application	Filing date	Title
KR10-2014-0195192	2014-12-31	
KR102014019519?A	2014-12-31	Selective catalytic reduction system and power plant with the same

Legal Events

Date	Code	Title	Description
2016-08-24	121	Ep: the epo has been informed by wipo that ep was designated in this application	**Ref document number:** 15875710 **Country of ref document:** EP **Kind code of ref document:** A1
2017-06-29	ENP	Entry into the national phase	**Ref document number:** 2017535063 **Country of ref document:** JP

			Kind code of ref document: A
2017-07-31	NENP	Non-entry into the national phase	Ref country code: DE
2018-01-24	122	Ep: pct application non-entry in european phase	Ref document number: 15875710 Country of ref document: EP Kind code of ref document: A1

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(12) 특허협력조약에 의하여 공개된 국제출원

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(30) 우선권정보:
10-2014-0195192 2014 년 12 월 31 일 (31.12.2014) KR

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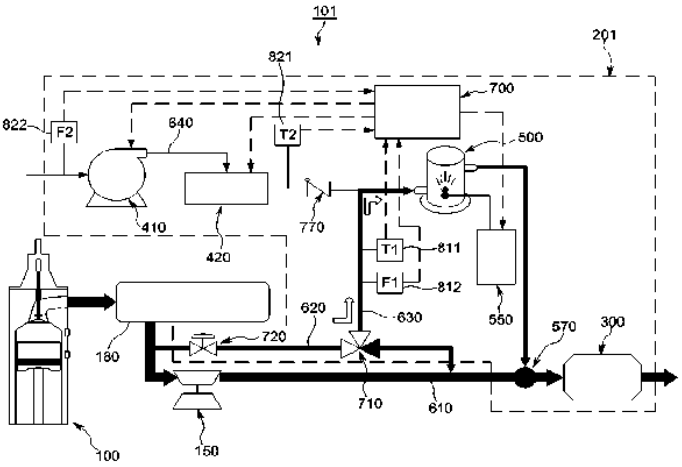
(81) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 국내 권리의 보호를 위하여): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KZ, LA, LC, LK, LR, LS, LU, LY, MA, 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) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 역내 권리의 보호를 위하여): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), 유라시아 (AM, AZ, BY, KG, KZ, RU, TJ, TM), 유럽 (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).

[다음 쪽 계속]

(54) **Title**: SELECTIVE CATALYTIC REDUCTION SYSTEM AND POWER APPARATUS COMPRISING SAME

(54) **발명의 명칭** : 선택적 촉매 환원 시스템 및 이를 포함한 동력 장치



(57) **Abstract**: A selective catalytic reduction system according to an embodiment of the present invention comprises: a reactor installed on a main exhaust flow path in the rear of a turbocharger installed on the main exhaust flow path; a reducing agent injection part, installed on the main exhaust flow path, for injecting a reducing agent to an exhaust gas moving toward the reactor; a decomposition chamber which is supplied with a reducing agent precursor and decomposes the same to generate the reducing agent to be supplied to the reducing agent injection part; a bifurcation channel which is bifurcated from a turbocharger bypass flow path, which is bifurcated from the main exhaust flow path and bypasses the turbocharger and is again merged into the main exhaust flow path, and connected to the decomposition chamber; an external air supply flow path for supplying external air to the decomposition chamber; a blower, installed on the external air supply flow path, for drawing in the external air; and a heating device, installed on the external air supply flow path, for heating the external air drawn in by the blower.

(57) 요약서:

[다음 쪽 계속]

WO 2016/108616 A1

공개:

— 국제조사보고서와 함께 (조약 제 21 조(3))

본 발명의 실시예에 따른 선택적 촉매 환원 시스템은 메인 배기 유로 상에 설치된 과급기 보다 후방의 상기 메인 배기 유로 상에 설치된 반응기와, 상기 메인 배기 유로 상에 설치되어 상기 반응기로 이동하는 배기가스에 환원제를 분사하는 환원제 분사부와, 환원제 전구체를 공급받아 분해하여 상기 환원제 분사부에 공급할 환원제를 생성하는 분해 챔버와, 상기 메인 배기 유로에서 분기하여 상기 과급기를 우회한 후 다시 상기 메인 배기 유로에 합류하는 과급기 바이패스 유로에서 분기되어 상기 분해 챔버와 연결된 분기 유로와, 상기 분해 챔버에 외기를 공급하는 외기 공급 유로와, 상기 외기 공급 유로 상에 설치되어 외기를 흡입하는 블로워, 그리고 상기 외기 공급 유로 상에 설치되어 상기 블로워가 흡입한 외기를 가열하는 가열 장치를 포함한다.

명세서

발명의 명칭: 선택적 촉매 환원 시스템 및 이를 포함한 동력 장치

기술분야

[1] 본 발명은 선택적 촉매 환원 반응을 이용하여 배기가스가 함유한 질소산화물을 저감시키는 선택적 촉매 환원 시스템 및 이를 포함한 동력 장치에 관한 것이다.

배경기술

[2] 일반적으로 선박 등에 사용되는 동력 장치는 동력을 발생시키는 디젤 엔진과, 디젤 엔진에 소기용 공기를 공급하는 과급기(turbocharger), 그리고 디젤 엔진에서 배출된 배기가스가 함유한 질소산화물을 저감시키는 선택적 촉매 환원(selective catalytic reduction, SCR) 시스템 등을 포함한다.

[3] 선택적 촉매 환원 시스템은 촉매가 내부에 설치된 반응기에 배기가스와 환원제를 함께 통과시키면서 배기가스에 함유된 질소산화물과 환원제를 반응시켜 질소와 수증기로 환원 처리한다.

[4] 선택적 촉매 환원 시스템은 질소산화물을 저감시키기 위한 환원제로 우레아(urea)나 암모니아(NH_3)를 사용하고 있다.

[5] 그런데 우레아가 섭씨 250도 미만의 온도를 갖는 배기가스에 직접 분사되면, 우레아가 분해되면서 생성되는 뷰렛(biuret), 시아누르산(cyanuric acid), 멜라민(melamine), 및 암멜린(ammeline) 등과 같은 부산물에 의해 노즐이 막히거나 배기가스의 흐름을 방해하는 문제점이 있다.

[6] 이에, 우레아의 분해 효율을 향상시키기 위해 분해 챔버에 별도의 전기 히터 또는 버너를 통해 가열된 유체를 공급하여 분해 챔버의 내부 온도를 분해 반응 온도까지 상승시키고, 우레아를 분해 챔버에서 안정적으로 분해하여 생성된 암모니아(NH_3)과 이소시안산(HNCO)을 반응기에 공급하는 방법을 사용하고 있다.

[7] 하지만, 우레아를 분해하기 위해서는 분해 챔버의 내부 온도를 분해 반응 온도까지 승온시켜야 하며, 이를 위해서 열에너지를 공급하기 위한 버너와 같은 별도의 가열 장치가 요구된다. 그리고 버너를 가동하기 위한 연료와 공기가 소모된다.

[8] 이와 같이, 우레아의 분해를 위해 소모되는 열에너지가 적지 않으며, 버너가 소모하는 연료와 공기는 선택적 촉매 환원 시스템에 소모되는 전체 연료 및 공기와 대비하여 상당한 비중을 차지하여 전체적인 에너지 이용 효율을 저하시키는 문제점이 있다.

발명의 상세한 설명

기술적 과제

[9] 본 발명의 실시예는 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시킨 선택적

촉매 환원 시스템 및 이를 포함한 동력 장치를 제공한다.

과제 해결 수단

[10] 본 발명의 실시예에 따르면, 메인 배기 유로를 통해 배출되는 배기가스에 함유된 질소산화물(NOx)을 저감시키는 선택적 촉매 환원 시스템은 상기 메인 배기 유로 상에 설치된 과급기 보다 후방의 상기 메인 배기 유로 상에 설치된 반응기와, 상기 메인 배기 유로 상에 설치되어 상기 반응기로 이동하는 배기가스에 환원제를 분사하는 환원제 분사부와, 환원제 전구체를 공급받아 분해하여 상기 환원제 분사부에 공급할 환원제를 생성하는 분해 챔버와, 상기 메인 배기 유로에서 분기하여 상기 과급기를 우회한 후 다시 상기 메인 배기 유로에 합류하는 과급기 바이패스 유로에서 분기되어 상기 분해 챔버와 연결된 분기 유로와, 상기 분해 챔버에 외기를 공급하는 외기 공급 유로와, 상기 외기 공급 유로 상에 설치되어 외기를 흡입하는 블로워, 그리고 상기 외기 공급 유로 상에 설치되어 상기 블로워가 흡입한 외기를 가열하는 가열 장치를 포함한다.

[11] 또한, 상기한 선택적 촉매 환원 시스템은 상기 과급기 바이패스 유로와 상기 분기 유로의 분기점 전방의 상기 과급기 바이패스 유로 상에 설치되는 과급기 바이패스 밸브를 더 포함할 수 있다.

[12] 상기한 선택적 촉매 환원 시스템은 상기 외기 공급 유로 상에 설치되어 상기 분기 유로를 통해 상기 분해 챔버로 이동하는 배기가스가 상기 외기 공급 유로로 역류하는 것을 방지하는 역류 방지 밸브를 더 포함할 수 있다.

[13] 상기한 선택적 촉매 환원 시스템은 상기 과급기 바이패스 유로 및 상기 분기 유로를 이동하는 배기가스의 유량을 제어하는 유량 제어 밸브를 더 포함할 수 있다.

[14] 상기 유량 제어 밸브는 상기 과급기 바이패스 유로와 상기 분기 유로의 분기점에 설치된 3방 유량 제어 밸브일 수 있다.

[15] 또한, 상기 유량 제어 밸브는 상기 과급기 바이패스 유로와 상기 분기 유로의 분기점과 상기 과급기 바이패스 유로와 상기 메인 배기 유로의 합류점 사이에 설치된 제1 유량 제어 밸브와, 상기 분기 유로 상에 설치된 제2 유량 제어 밸브를 포함할 수 있다.

[16] 상기한 선택적 촉매 환원 시스템은 상기 분기 유로 상에 설치된 제1 온도 센서와 제1 유량계와, 상기 외기 공급 유로 상에 설치되며 상기 블로워에 의해 흡입되는 외기의 유량을 측정하는 제2 유량계, 그리고 상기 외기 공급 유로 상에 설치되며 상기 가열 장치를 거친 외기의 온도를 측정하는 제2 온도 센서를 더 포함할 수 있다.

[17] 상기한 선택적 촉매 환원 시스템은 상기 제1 온도 센서, 상기 제1 유량계, 상기 제2 온도 센서, 상기 제2 유량계로부터 정보를 전달받아 상기 유량 제어 밸브의 개폐와 상기 블로워 및 상기 가열 장치의 동작을 제어하는 제어부를 더 포함할 수 있다.

[18] 상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 상기 유량 제어 밸브의 개도율을 조절할 수 있다.

[19] 상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량보다 낮으면 상기 블로워와 상기 가열 장치를 가동하여 상기 외기 공급 유로를 통해 상기 분해 챔버에 열량을 추가적으로 공급할 수 있다.

[20] 상기 제어부는 상기 제2 온도 센서 및 상기 제2 유량계로부터 얻은 정보로부터 상기 외기 공급 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출할 수 있다. 그리고 상기 제어부는 상기 분기 유로를 통해 공급되는 열량과 상기 외기 공급 유로를 통해 공급되는 열량의 합이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 상기 블로워와 상기 가열 장치의 가동 정도를 제어할 수 있다.

[21] 상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 환원제를 생성하기 위해 요구되는 열량을 초과하면 상기 유량 제어 밸브를 제어하여 상기 분기 유로로 이동하는 배기가스의 유량을 감소시킬 수 있다.

[22] 또한, 본 발명의 실시예에 따르면, 동력 장치는 질소산화물(NOx)을 함유한 배기가스를 배출하는 엔진과, 상기 엔진이 배출한 배기가스가 이동하는 메인 배기 유로와, 상기 메인 배기 유로 상에 설치된 과급기와, 상기 메인 배기 유로에서 분기하여 상기 과급기를 우회한 후 다시 상기 메인 배기 유로에 합류하는 과급기 바이패스 유로, 그리고 상기한 선택적 촉매 환원 시스템을 포함한다.

발명의 효과

[23] 본 발명의 실시예에 따르면, 선택적 촉매 환원 시스템 및 이를 포함한 동력 장치는 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시킬 수 있다.

도면의 간단한 설명

[24] 도 1은 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템을 포함한 동력 장치의 구성도이다.

[25] 도 2 및 도 3은 도 1의 선택적 촉매 환원 시스템을 포함한 동력 장치의 동작 상태를 나타낸 구성도들이다.

[26] 도 4는 본 발명의 일 실시예의 변형례에 따른 선택적 촉매 환원 시스템을 포함한 동력 장치의 구성도이다.

발명의 실시를 위한 형태

[27] 이하, 첨부한 도면을 참고로 하여 본 발명의 실시예에 대하여 본 발명이 속하는 기술 분야에서 통상의 지식을 가진 자가 용이하게 실시할 수 있도록 상세히 설명한다. 본 발명은 여러 가지 상이한 형태로 구현될 수 있으며 여기에서 설명하는 실시예에 한정되지 않는다.

[28] 도면들은 개략적이고 축적에 맞게 도시되지 않았다는 것을 일러둔다. 도면에 있는 부분들의 상대적인 치수 및 비율은 도면에서의 명확성 및 편의를 위해 그 크기에 있어 과장되거나 감소되어 도시되었으며 임의의 치수는 단지 예시적인 것이지 한정적인 것은 아니다. 그리고 둘 이상의 도면에 나타나는 동일한 구조물, 요소 또는 부품에는 동일한 참조 부호가 유사한 특징을 나타내기 위해 사용된다.

[29] 본 발명의 실시예는 본 발명의 이상적인 실시예를 구체적으로 나타낸다. 그 결과, 도해의 다양한 변형이 예상된다. 따라서 실시예는 도시한 영역의 특정 형태에 국한되지 않으며, 예를 들면 제조에 의한 형태의 변형도 포함한다.

[30] 이하, 도 1 내지 도 3을 참조하여 본 발명의 일 실시예에 따른 선택적 촉매 환원 반응(selective catalytic reduction, SCR) 시스템(201) 및 이를 포함한 동력 장치(101)를 함께 설명한다.

[31] 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)은 동력 장치(101)의 구성 요소로 엔진(100)과 함께 제작 및 조립될 수 있지만, 경우에 따라서는 기존에 설치되어 사용 중인 엔진(100)에서 배출된 배기가스에 함유된 질소산화물(NOx)을 저감시키기 위하여 사후적으로 설치될 수도 있다. 구체적으로, 선박 또는 차량 등의 운송 수단이나 육상 또는 해상 플랜트의 수리 및 보수 중에 기존에 설치된 엔진(100)의 친환경 성능을 개선하기 위하여 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)이 추가 설치될 수 있다.

[32] 도 1 내지 도 3에 도시한 바와 같이, 본 발명의 일 실시예에 따른 선택적 촉매 환원(selective catalytic reduction, SCR) 시스템(201)을 포함한 동력 장치(101)는 엔진(100), 메인 배기 유로(610), 과급기(150), 반응기(300), 과급기 바이패스 유로(620), 환원제 분사부(570), 분해 챔버(500), 분기 유로(630), 외기 공급 유로(640), 블로워(410), 및 가열 장치(420)를 포함한다.

[33] 또한, 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)을 포함한 동력 장치(101)는 배기 리시버(180), 과급기 바이패스 밸브(720), 역류 방지 밸브(770), 유량 제어 밸브(710), 제1 온도 센서(811), 제1 유량계(812), 제2 유량계(822), 제2 온도 센서(821), 및 제어부(700)를 더 포함할 수 있다.

[34] 엔진(100)은 선박 및 자동차 등에서 동력을 발생시키는 주동력원이다. 본 발명의 일 실시예에서, 엔진(100)으로는 질소산화물(NOx)을 함유한 배기가스를 배출하는 다양한 엔진이 사용될 수 있다.

[35] 과급기(150)는 후술할 메인 배기 유로 상에 설치된다. 과급기(150)는

엔진(100)의 배기가스가 갖는 압력으로 터빈을 돌려 엔진(100)에 새로운 외부 공기를 압축하여 공급함으로써, 엔진(100)의 효율을 향상시킨다.

[36] 배기 리시버(180)는 엔진(100)의 실린더 왕복 운동으로 불균형한 압력을 가지고 배출된 엔진(100)의 배기가스를 고르게 완화시킨다.

[37] 본 발명의 일 실시예에서, 엔진(100)이 배출하는 배기가스는 섭씨 250도 내지 섭씨 500도 범위 내의 온도를 가지며, 배기가스의 온도는 과급기(150)를 거치면 낮아질 수 있다. 일례로, 과급기(150)를 거친 배기가스는 온도가 섭씨 150도 이상 섭씨 250도 미만으로 낮아질 수 있다.

[38] 메인 배기 유로(610)는 엔진(100)의 배기구와 연결되어 엔진(100)의 배기가스를 배출한다. 즉, 엔진(100)의 배기가스는 메인 배기 유로(610)를 따라 이동한다.

[39] 메인 배기 유로(610)는 엔진(100)과 과급기(150) 그리고 후술할 반응기(300)를 순차적으로 연결한다. 이와 같이, 메인 배기 유로(610)는 과급기(150)를 거친 엔진(100)의 배기가스를 반응기(300)에 공급한다.

[40] 반응기(300)는 메인 배기 유로(610) 상에 설치된다. 반응기(300)는 엔진(100)에서 배출된 배기가스가 함유한 질소산화물(NOx)을 저감시키기 위한 촉매를 포함한다. 촉매는 배기가스에 함유된 질소산화물(NOx)과 환원제의 반응을 촉진시켜 질소산화물(NOx)을 질소와 수증기로 환원 처리한다. 이때, 질소산화물(NOx)과 반응하여 환원시킬 최종적인 환원제로 암모니아(NH_3)가 사용될 수 있다.

[41] 촉매는 제올라이트(Zeolite), 바나듐(Vanadium), 및 백금(Platinum) 등과 같이 해당 기술 분야의 종사자에게 공지된 다양한 소재로 만들어질 수 있다. 일례로, 촉매는 섭씨 250도 내지 섭씨 350도 범위 내의 활성 온도를 가질 수 있다. 여기서, 활성 온도는 촉매가 피독되지 않고 안정적으로 질소산화물을 환원시킬 수 있는 온도를 말한다. 촉매가 활성 온도 범위 밖에서 반응하면, 촉매가 피독되면서 효율이 저하된다.

[42] 구체적으로, 촉매를 피독시키는 피독 물질은 황산암모늄(Ammonium sulfate, $(NH_4)_2SO_4$)과 아황산수소암모늄(Ammonium bisulfate, NH_4HSO_4) 중 하나 이상을 포함할 수 있다. 이러한 촉매 피독 물질은 촉매에 흡착되어 촉매의 활성을 저하시킨다. 촉매 피독 물질은 상대적으로 높은 온도에서 분해되므로, 촉매를 승온시키면 피독된 촉매를 재생할 수 있다.

[43] 또한, 반응기(300)의 하우징은, 일례로, 스테인레스 스틸(stainless steel)을 소재로 만들어질 수 있다.

[44] 분해 챔버(500)는 환원제 전구체인 우레아(urea, $CO(NH_2)_2$)를 공급받아 이를 분해하여 질소산화물(NOx)을 환원시킬 환원제로 사용되는 암모니아(NH_3)를 생성한다.

[45] 구체적으로, 분해 챔버(500) 내의 온도가 섭씨 300도 내지 섭씨 500도 범위 내로 유지되면, 우레아(urea, $CO(NH_2)_2$)가 용이하게 가수분해 또는 열분해되면서 암모니아(NH_3)와 이소시안산(Isocyanic acid, HNCO)이 생성된다. 그리고

이소시안산(HNCO)은 다시 암모니아(NH_3)와 이산화탄소(CO_2)로 분해된다. 즉, 우레아가 분해되면 최종적으로 암모니아가 생성될 수 있다.

[46] 환원제 분사부(570)는 분해 챔버(500)에서 생성된 암모니아(NH_3)를 공급받아 반응기(300)에 유입될 배기가스에 분사한다. 분사된 암모니아는 배기가스와 혼합되어 반응기(300)의 촉매를 거치면서 배기가스에 함유된 질소산화물을 환원시킨다.

[47] 구체적으로, 환원제 분사부(570)는 반응기(300) 전방의 메인 배기 유로(610)를 따라 이동하는 배기가스를 향해 암모니아(NH_3)를 분사할 수 있다.

[48] 본 명세서에서 전방은 배기가스의 흐름을 기준으로 상류 측을 의미하며 후방은 하류 측을 의미한다.

[49] 우레아 공급부(550)는 환원제 전구체인 우레아를 분해 챔버(500)에 공급한다. 우레아 공급부(550)는 엔진(100)의 부하에 따라 변동하는 환원제 요구량을 고려하여 적절한 양의 우레아를 분해 챔버(500)에 공급한다. 즉, 우레아 공급부(550)는 후술할 제어부(700)의 제어에 따라 환원제 요구량에 맞춰 공급될 수 있다.

[50] 과급기 바이패스 유로(620)는 메인 배기 유로(610)에서 분기하여 과급기(150)를 우회한 후 다시 메인 배기 유로(610)에 합류한다. 즉, 과급기 바이패스 유로(620)를 이동하는 배기가스는 과급기(150)를 거치지 않으므로, 과급기(150)를 거친 배기가스와 대비하여, 상대적으로 높은 온도를 갖는다.

[51] 과급기 바이패스 밸브(720)는 과급기 바이패스 유로(620) 상에 설치된다.

[52] 구체적으로, 과급기 바이패스 밸브(720)는 과급기 바이패스 유로(620)와 후술할 분기 유로(630)의 분기점 전방의 과급기 바이패스 유로(620) 상에 설치된다.

[53] 과급기 바이패스 밸브(720)는 엔진(100)의 연소실 내 연소 압력 및 열 부하를 조절하기 위해 사용될 수 있다.

[54] 또한, 과급기 바이패스 밸브(720)는 후술할 분기 유로(630)를 통해 분해 챔버(500)에 배기가스를 공급하기 위한 경우에도 사용될 수 있다.

[55] 엔진(100)의 연소실 내 연소 압력 및 열 부하가 허용치 이상으로 증가하면, 과급기 바이패스 밸브(720)가 개방되어 과급기 바이패스 유로(620)로 배기가스의 일부를 흘려 보내 과급기(150)에 공급되는 배기가스의 유량을 감소시킨다. 이에, 과급기(150)가 엔진(100)에 공급하는 압축 공기의 압력이 감소되면서 엔진(100)의 연소실 내 연소 압력을 조절할 수 있다.

[56] 이와 같이, 과급기 바이패스 밸브(720)는 후술할 유량 제어 밸브(710)와 별개로 독립적으로 동작될 수 있다.

[57] 분기 유로(630)는 과급기 바이패스 유로(620)에서 분기되어 분해 챔버(500)와 연결된다. 즉, 분기 유로(630)는 과급기 바이패스 유로(620)를 이동하는 상대적으로 높은 온도를 갖는 배기가스를 분해 챔버(500)에 전달하여 분해 챔버(500)에서 우레아를 가수분해 또는 열분해하여 암모니아를 생성하는데

필요한 열에너지를 공급한다.

[58] 유량 제어 밸브(710)는 과급기 바이패스 유로(620) 및 분기 유로(630)를 이동하는 배기가스의 유량을 제어한다. 일례로, 유량 제어 밸브(710)는 과급기 바이패스 유로(620)와 분기 유로(630)의 분기점에 설치된 3방 유량 제어 밸브일 수 있다.

[59] 제1 온도 센서(811)와 제1 유량계(812)는 분기 유로(630) 상에 설치된다. 이에, 본 발명의 일 실시예에서는, 제1 온도 센서(811)와 제1 유량계(812)가 측정한 온도 정보와 유량 정보를 가지고 분기 유로(630)를 통해 분해 챔버(500)에 공급된 열량을 산출할 수 있다. 그리고 산출된 열량이 분해 챔버(500)에서 환원제 전구체인 우레아를 가수분해 또는 열분해하여 환원제인 암모니아를 생성하는데 요구되는 열량을 추종하도록 유량 제어 밸브(710)의 개도율을 조절할 수 있다.

[60] 이와 같이, 분해 챔버(500)에서 환원제를 생성하는데 필요한 열량이 분기 유로(630)를 통해 분해 챔버(500)에 공급되도록, 유량 제어 밸브(710)는 산출된 열량에 따라 과급기 바이패스 유로(620)에서 분기 유로(630)로 분기되어 흐르는 배기가스의 유량을 조절할 수 있다.

[61] 또한, 제1 온도 센서(811) 및 제1 유량계(812)로부터 얻은 정보로부터 분기 유로(630)를 통해 분해 챔버(500)에 공급되는 열량을 산출하고, 산출된 열량이 환원제를 생성하기 위해 분해 챔버(500)에서 요구되는 열량을 초과하면 유량 제어 밸브(630)를 조절하여 분기 유로(630)로 이동하는 배기가스의 유량을 감소시킬 수 있다.

[62] 즉, 과급기 바이패스 유로(620)를 따라 이동하는 배기가스가 분기 유로(630)를 통해 분해 챔버(500)에 필요한 열량을 공급하고도 남는 경우, 남는 열량에 대응하는 나머지 배기가스는 분기 유로(630)를 향하지 않고 그대로 과급기 바이패스 유로(620)를 따라 이동하여 메인 배기 유로(610)에 다시 합류된다.

[63] 이와 같이, 과급기 바이패스 유로(620)를 거쳐 메인 배기 유로(610)와 합류한 배기가스는 과급기(150)를 기치면서 온도가 내려간 배기가스와 합쳐져 반응기(300)에 유입되는 배기가스의 온도를 승온시킬 수 있다.

[64] 과급기(150)를 거친 배기가스의 온도는, 전술한 바와 같이, 섭씨 150도 이상 섭씨 250도 미만으로 낮아질 수 있는데, 이렇게 상대적으로 낮은 온도의 배기가스가 반응기(300)에 유입되면, 촉매의 활성이 저하되거나 촉매가 피독될 수 있다.

[65] 즉, 과급기 바이패스 유로(620)를 거쳐 메인 배기 유로(610)와 합류한 배기가스는 반응기(300)에 유입되는 배기가스를 승온시켜 촉매의 활성을 유지하고 촉매의 피독을 억제할 수 있다.

[66] 외기 공급 유로(640)는 분해 챔버(500)에 외기를 공급한다. 즉, 외기 공급 유로(640)는 과급기 바이패스 유로(620)에서 분기되어 분기 유로(630)를 통해 공급되는 배기가스 이외의 공기를 분해 챔버(500)에 공급한다.

[67] 블로워(410)와 가열 장치(420)는 외기 공급 유로(640) 상에 설치된다.

블로워(410)는 외기 공급 유로(640)를 통해 외기를 흡입시킨다. 그리고 가열 장치(420)는 블로워(410)가 흡입한 외기를 가열한다. 일례로, 가열 장치(420) 오일 버너(oil burner), 플라스마 버너(plasma burner), 또는 전기 히터 중 하나일 수 있다

[68] 역류 방지 밸브(770)는 외기 공급 유로(640) 상에 설치되어 분기 유로(630)를 통해 분해 챔버(500)로 이동하는 배기가스가 외기 공급 유로(640)로 역류하는 것을 방지한다.

[69] 본 발명의 일 실시예에 따르면, 제1 온도 센서(811) 및 제1 유량계(812)로부터 얻은 정보로부터 분기 유로(630)를 통해 분해 챔버(500)에 공급되는 열량을 산출하고, 산출된 열량이 분해 챔버(500)에서 환원제를 생성하기 위해 요구되는 열량보다 낮으면 블로워(410)와 가열 장치(420)를 가동하여 외기 공급 유로(640)를 통해 분해 챔버(500)에 열량을 추가적으로 공급할 수 있다.

[70] 또한, 본 발명의 일 실시예서는, 열에너지를 추가적으로 공급하는 가열 장치(420)가 외기 공급 라인(640)에 설치되므로, 연소 공기를 필요로 하는 버너가 가열 장치(420)로 사용될 경우, 가열 장치에 대한 산소의 공급이 용이하며 효과적이다.

[71] 반면, 본 발명의 일 실시예와 달리, 가열 장치(420)가 분기 유로(630)에 설치된다면, 분기 유로(630)를 따라 이동하는 배기가스의 산소 농도가 희박하여 버너와 같은 가열 장치(420)를 사용하기에 제한적이다.

[72] 제2 유량계(822)는 외기 공급 유로(640) 상에 설치된다. 제2 유량계(822)는 블로워(410)에 의해 흡입되는 외기의 유량을 측정한다.

[73] 제2 온도 센서(821)는 외기 공급 유로(640) 상에 설치된다. 구체적으로, 제2 온도 센서(821)는 가열 장치(420) 후방의 외기 공급 유로(640) 상에 설치될 수 있다. 제2 온도 센서(821)는 가열 장치(420)를 거친 외기의 온도를 측정한다.

[74] 이에, 본 발명의 일 실시예에서는, 제2 온도 센서(821)와 제2 유량계(822)가 측정한 온도 정보와 유량 정보를 가지고 외기 공급 유로(640)를 통해 분해 챔버(500)에 공급되는 열량을 산출할 수 있다.

[75] 그리고 본 발명의 일 실시예에서는, 분기 유로(630)를 통해 공급되는 열량과 외기 공급 유로(640)를 통해 공급되는 열량의 합이 분해 챔버(500)에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 블로워(410)와 가열 장치(420)의 동작을 조절할 수 있다.

[76] 제어부(700)는 제1 온도 센서(811), 제1 유량계(812), 제2 온도 센서(821), 제2 유량계(822)로부터 정보를 전달받아 유량 제어 밸브(710)의 개폐와 블로워(410) 및 가열 장치(420)의 동작을 제어할 수 있다.

[77] 즉, 제어부(700)는 분기 유로(630)를 통해 분해 챔버(500)에 공급되는 열량과 외기 공급 유로(640)를 통해 분해 챔버(500)에 공급되는 각각의 열량을 산출하고, 산출된 열량의 합이 분해 챔버(500)에서 환원제 전구체인 우레아를 가수분해 또는 열분해하여 환원제인 암모니아를 생성하는데 요구되는 열량을 추종하도록

유량 제어 밸브(710) 및 블로워(410)와 가열 장치(420)를 제어할 수 있다.

[78] 또한, 제어부(700)는 엔진(100)의 부하 변동을 고려하여 요구되는 환원제의 양에 따라 분해 챔버(500)에 우레아를 공급하는 우레아 공급부(550)를 제어할 수 있다.

[79] 이와 같은 구성에 의하여, 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)을 포함한 동력 장치(101)는 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시킬 수 있다.

[80] 구체적으로, 본 발명의 일 실시예에 따르면, 과급기 바이패스 유로(620)와 분기 유로(630)를 통해 엔진(100)에서 배출된 후 과급기(150)를 거치기 전의 배기가스가 갖는 열에너지를 분해 챔버(500)에서 환원제를 생성하는데 활용할 수 있다.

[81] 또한, 선박은 다양한 기후 지역에서 사용되므로, 엔진(100)의 부하 변동 및 환경 변화에 따라 요구되는 환원제의 양이 달라지고, 과급기 바이패스 유로(620)와 분기 유로(630)를 통해 분해 챔버(500)에 공급되는 열량도 달라진다.

[82] 하지만, 본 발명의 일 실시예에 따르면, 과급기 바이패스 유로(620)와 분기 유로(630)를 통해 분해 챔버(500)에 공급되는 열량과 외기 공급 유로(640)를 통해 분해 챔버(500)에 공급되는 열량을 각각 산출하고, 산출된 열량의 합이 분해 챔버(500)에서 환원제 전구체인 우레아를 가수분해 또는 열분해하여 환원제인 암모니아를 생성하는데 요구되는 열량을 추종하도록 유량 제어 밸브(710) 및 블로워(410)와 가열 장치(420)를 조절할 수 있다. 즉, 엔진(100)의 부하 변동 및 환경 변화에도, 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시킬 수 있다.

[83] 또한, 도 4에 도시한 바와 같이, 본 발명의 일 실시예의 변형례에 따르면, 선택적 촉매 환원 시스템(202)을 포함한 동력 장치(102)는 제1 유량 제어 밸브(711)와 제2 유량 제어 밸브(712)를 포함하는 유량 제어 밸브를 사용한다.

[84] 제1 유량 제어 밸브(711)는 과급기 바이패스 유로(620)와 분기 유로(630)의 분기점과 과급기 바이패스 유로(620)와 메인 배기 유로(610)의 합류점 사이에 설치된다.

[85] 제2 유량 제어 밸브(712)는 분기 유(630)로 상에 설치된다.

[86] 즉, 본 변형례는 하나의 3방 유량 제어 밸브 대신 2개의 유량 제어 밸브(711, 712)를 사용한 것으로, 이를 제외하면 본 발명의 일 실시예와 구성 및 동작 원리가 동일하다.

[87] 이하, 도 1 내지 도 3을 참조하여 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)을 포함한 동력 장치(101)의 동작 원리를 설명한다.

[88] 도 1에 도시한 바와 같이, 제어부(700)는 제1 온도 센서(811)와 제1 유량계(812)가 측정한 온도 정보 및 유량 정보를 가지고 분기 유로(630)를 통해 분해 챔버(500)로 공급되는 열량을 산출한다.

[89] 그리고 제어부(700)는 산출된 열량이 분해 챔버(500)에서 환원제 생성에 요구되는 열량을 충족하면, 블로워(410)와 가열 장치(420)를 가동시키지 않는다. 즉, 본 발명의 일 실시예에 따르면, 불필요하게 에너지가 낭비되는 것을 방지할 수 있다.

[90] 다음, 도 2에 도시한 바와 같이, 제어부(700)는 제1 온도 센서(811)와 제1 유량계(812)가 측정한 온도 정보 및 유량 정보를 가지고 분기 유로(630)를 통해 분해 챔버(500)로 공급되는 열량을 산출하고, 산출된 열량이 분해 챔버(500)에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 유량 제어 밸브(710)의 개도율을 조절한다.

[91] 즉, 제어부(700)는 산출된 열량이 환원제를 생성하기 위해 요구되는 열량을 초과하면 유량 제어 밸브(710)를 제어하여 분기 유로(630)로 이동하는 배기가스의 유량을 감소시킨다.

[92] 그리고 분해 챔버(500)에 필요한 열량을 공급하고도 남는 열량에 대응하는 나머지 배기가스는 분기 유로(630)를 향하지 않고 그대로 과급기 바이패스 유로(620)를 따라 이동시켜 메인 배기 유로(610)에 재합류한다.

[93] 이와 같이, 과급기 바이패스 유로(620)를 거쳐 메인 배기 유로(610)와 합류한 배기가스는 과급기(150)를 거치면서 온도가 내려간 배기가스와 합쳐져 반응기(300)에 유입되는 배기가스의 온도를 승온시킬 수 있다.

[94] 다음, 도 3에 도시한 바와 같이, 제어부(700)는 제1 온도 센서(811)와 제1 유량계(812)가 측정한 온도 정보 및 유량 정보를 가지고 분기 유로(630)를 통해 분해 챔버(500)로 공급되는 열량을 산출하고, 산출된 열량이 분해 챔버(500)에서 환원제를 생성하기 위해 요구되는 열량보다 낮으면 블로워(410)와 가열 장치(420)를 가동하여 외기 공급 유로(640)를 통해 분해 챔버(500)에 열량을 추가적으로 공급한다.

[95] 이때, 제어부(700)는 제2 온도 센서(821) 및 제2 유량계(822)로부터 얻은 정보로부터 외기 공급 유로(640)를 통해 분해 챔버(500)에 공급되는 열량을 산출하고, 분기 유로(630)를 통해 공급되는 열량과 외기 공급 유로(640)를 통해 공급되는 열량의 합이 분해 챔버(500)에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 블로워(410)와 가열 장치(420)의 가동 정도를 제어할 수 있다.

[96] 이와 같은 동작에 의하여, 본 발명의 일 실시예에 따른 선택적 촉매 환원 시스템(201)을 포함한 동력 장치(101)는 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시킬 수 있다.

[97] 이상 첨부된 도면을 참조하여 본 발명의 실시예를 설명하였지만, 본 발명이 속하는 기술분야의 당업자는 본 발명이 그 기술적 사상이나 필수적 특징을 변경하지 않고 다른 구체적인 형태로 실시될 수 있다는 것을 이해할 수 있을 것이다.

[98] 그러므로 이상에서 기술한 실시예는 모든 면에서 예시적인 것이며 한정적인

것이 아닌 것으로서 이해되어야 하고, 본 발명의 범위는 상기 상세한 설명은 후술하는 특허청구범위에 의하여 나타내어지며, 특허청구범위의 의미 및 범위 그리고 그 등가개념으로부터 도출되는 모든 변경 또는 변형된 형태가 본 발명의 범위에 포함되는 것으로 해석되어야 한다.

산업상 이용가능성

[99] 본 발명의 실시예에 따른 선택적 촉매 환원 시스템 및 이를 포함한 동력 장치는 환원제를 생성하고 배기가스에 함유된 질소산화물을 저감하기 위해 소모되는 전체적인 에너지의 이용 효율을 극대화시키는데 사용할 수 있다.

청구범위

[청구항 1] 메인 배기 유로를 통해 배출되는 배기가스에 함유된 질소산화물(NOx)을 저감시키는 선택적 촉매 환원 시스템에 있어서,
상기 메인 배기 유로 상에 설치된 과급기 보다 후방의 상기 메인 배기 유로 상에 설치된 반응기;
상기 메인 배기 유로 상에 설치되어 상기 반응기로 이동하는 배기가스에 환원제를 분사하는 환원제 분사부;
환원제 전구체를 공급받아 분해하여 상기 환원제 분사부에 공급할 환원제를 생성하는 분해 챔버;
상기 메인 배기 유로에서 분기하여 상기 과급기를 우회한 후 다시 상기 메인 배기 유로에 합류하는 과급기 바이패스 유로에서 분기되어 상기 분해 챔버와 연결된 분기 유로;
상기 분해 챔버에 외기를 공급하는 외기 공급 유로;
상기 외기 공급 유로 상에 설치되어 외기를 흡입하는 블로워; 및
상기 외기 공급 유로 상에 설치되어 상기 블로워가 흡입한 외기를 가열하는 가열 장치
를 포함하는 선택적 촉매 환원 시스템.

[청구항 2] 제1항에서,
상기 과급기 바이패스 유로와 상기 분기 유로의 분기점 전방의 상기 과급기 바이패스 유로 상에 설치되는 과급기 바이패스 밸브를 더 포함하는 선택적 촉매 환원 시스템.

[청구항 3] 제1항에서,
상기 외기 공급 유로 상에 설치되어 상기 분기 유로를 통해 상기 분해 챔버로 이동하는 배기가스가 상기 외기 공급 유로로 역류하는 것을 방지하는 역류 방지 밸브를 더 포함하는 선택적 촉매 환원 시스템.

[청구항 4] 제1항에서,
상기 과급기 바이패스 유로 및 상기 분기 유로를 이동하는 배기가스의 유량을 제어하는 유량 제어 밸브를 더 포함하는 선택적 촉매 환원 시스템.

[청구항 5] 제4항에서,
상기 유량 제어 밸브는 상기 과급기 바이패스 유로와 상기 분기 유로의 분기점에 설치된 3방 유량 제어 밸브인 선택적 촉매 환원 시스템.

[청구항 6] 제4항에서,
상기 유량 제어 밸브는 상기 과급기 바이패스 유로와 상기 분기 유로의 분기점과 상기 과급기 바이패스 유로와 상기 메인 배기 유로의 합류점 사이에 설치된 제1 유량 제어 밸브와, 상기 분기 유로 상에 설치된 제2 유량 제어 밸브를 포함하는 선택적 촉매 환원 시스템.

[청구항 7] 제4항에서,

상기 분기 유로 상에 설치된 제1 온도 센서와 제1 유량계;
상기 외기 공급 유로 상에 설치되며 상기 블로워에 의해 흡입되는 외기의 유량을 측정하는 제2 유량계; 그리고
상기 외기 공급 유로 상에 설치되며 상기 가열 장치를 거친 외기의 온도를 측정하는 제2 온도 센서
를 더 포함하는 선택적 촉매 환원 시스템.

[청구항 8] 제7항에서,
상기 제1 온도 센서, 상기 제1 유량계, 상기 제2 온도 센서, 상기 제2 유량계로부터 정보를 전달받아 상기 유량 제어 밸브의 개폐와 상기 블로워 및 상기 가열 장치의 동작을 제어하는 제어부를 더 포함하는 선택적 촉매 환원 시스템.

[청구항 9] 제8항에서,
상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 상기 유량 제어 밸브의 개도율을 조절하는 선택적 촉매 환원 시스템.

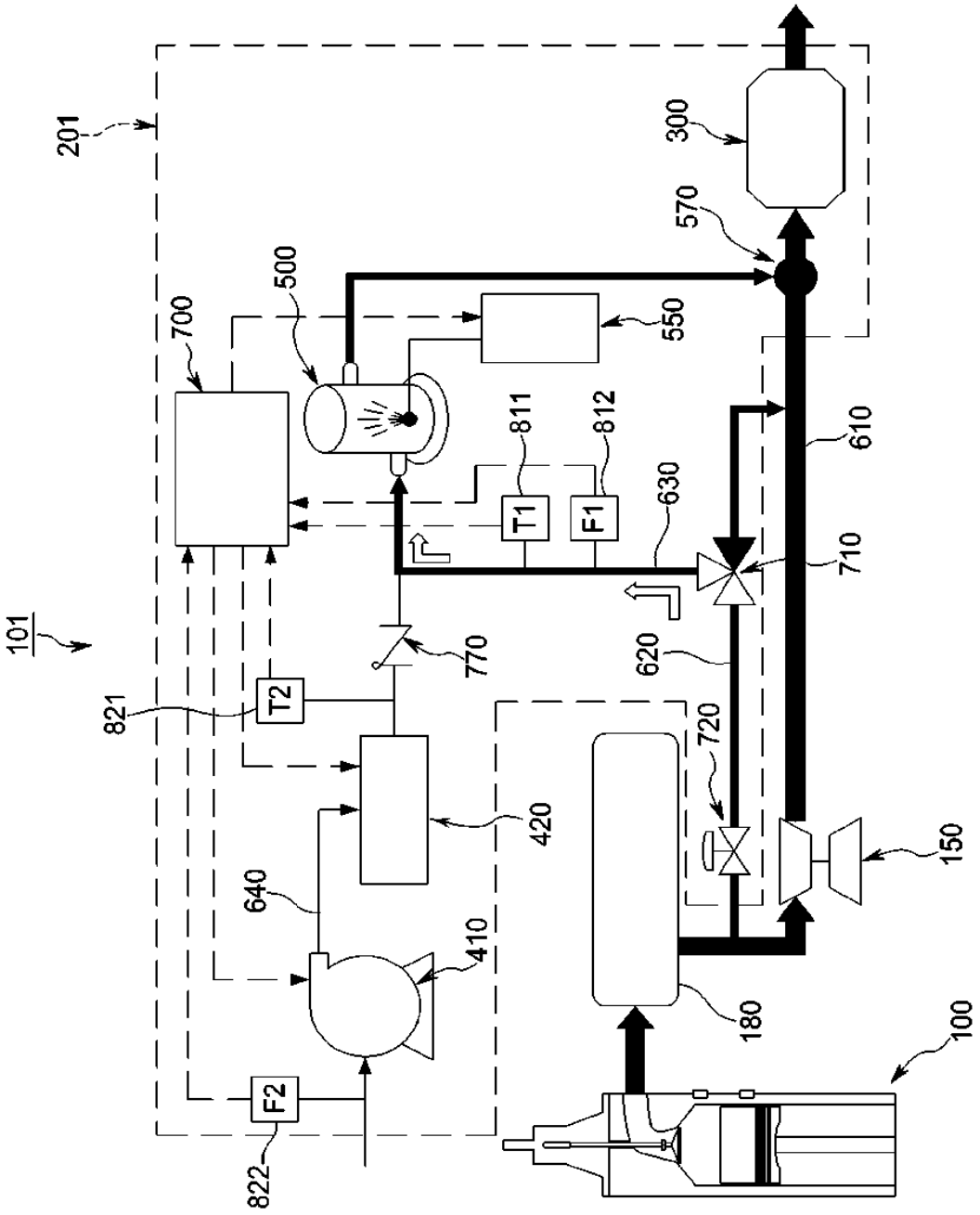
[청구항 10] 제8항에서,
상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량보다 낮으면 상기 블로워와 상기 가열 장치를 가동하여 상기 외기 공급 유로를 통해 상기 분해 챔버에 열량을 추가적으로 공급하는 선택적 촉매 환원 시스템.

[청구항 11] 제10항에서,
상기 제어부는 상기 제2 온도 센서 및 상기 제2 유량계로부터 얻은 정보로부터 상기 외기 공급 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고,
상기 제어부는 상기 분기 유로를 통해 공급되는 열량과 상기 외기 공급 유로를 통해 공급되는 열량의 합이 상기 분해 챔버에서 환원제를 생성하기 위해 요구되는 열량을 추종하도록 상기 블로워와 상기 가열 장치의 가동 정도를 제어하는 선택적 촉매 환원 시스템.

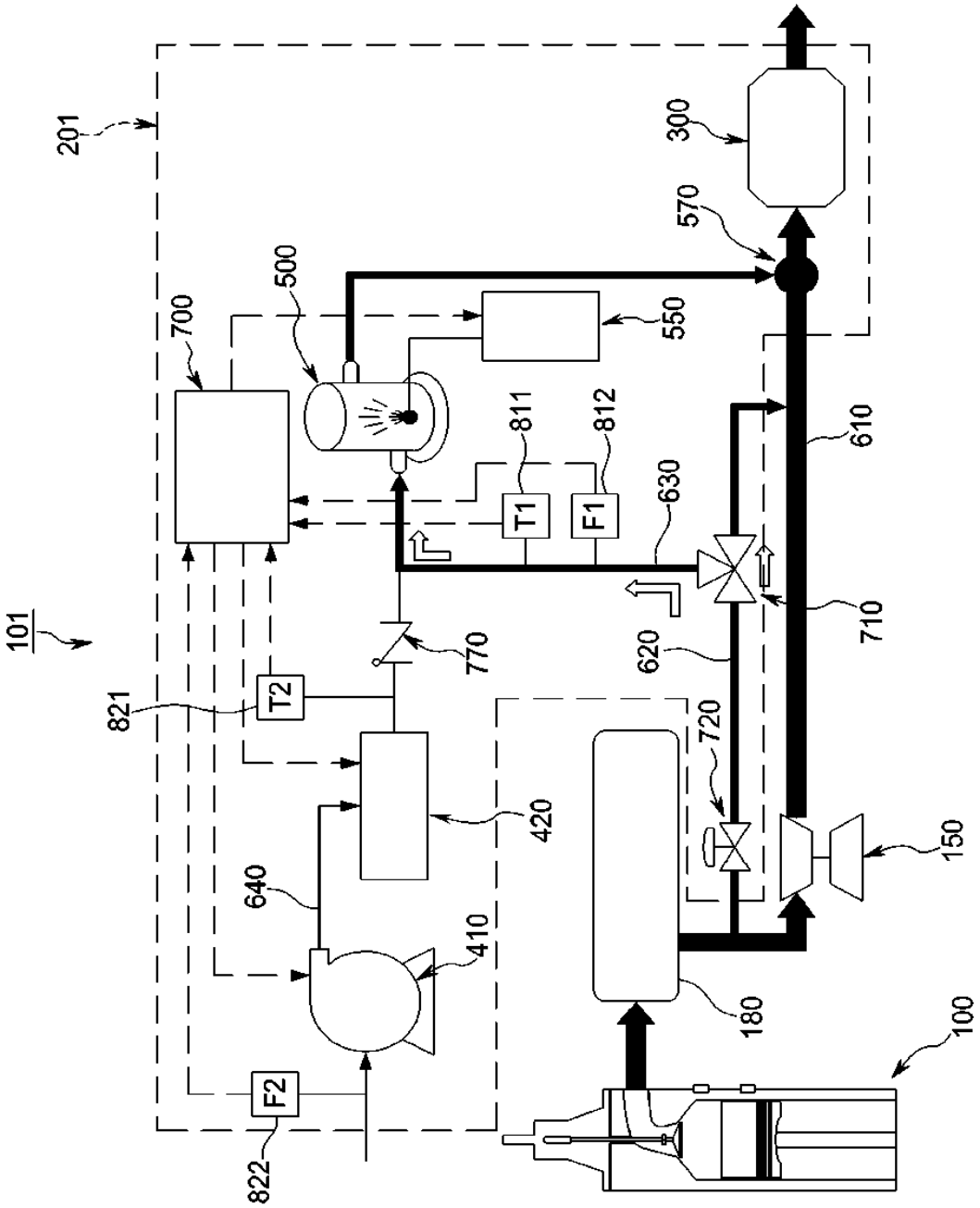
[청구항 12] 제8항에서,
상기 제어부는 상기 제1 온도 센서 및 상기 제1 유량계로부터 얻은 정보로부터 상기 분기 유로를 통해 상기 분해 챔버에 공급되는 열량을 산출하고, 산출된 열량이 환원제를 생성하기 위해 요구되는 열량을 초과하면 상기 유량 제어 밸브를 제어하여 상기 분기 유로로 이동하는 배기가스의 유량을 감소시키는 선택적 촉매 환원 시스템.

[청구항 13] 질소산화물(NOx)을 함유한 배기가스를 배출하는 엔진;
상기 엔진이 배출한 배기가스가 이동하는 메인 배기 유로;
상기 메인 배기 유로 상에 설치된 과급기;
상기 메인 배기 유로에서 분기하여 상기 과급기를 우회한 후 다시 상기 메인 배기 유로에 합류하는 과급기 바이패스 유로; 및
제1항 내지 제12항 중 어느 한 항에 따른 선택적 촉매 환원 시스템
을 포함하는 동력 장치.

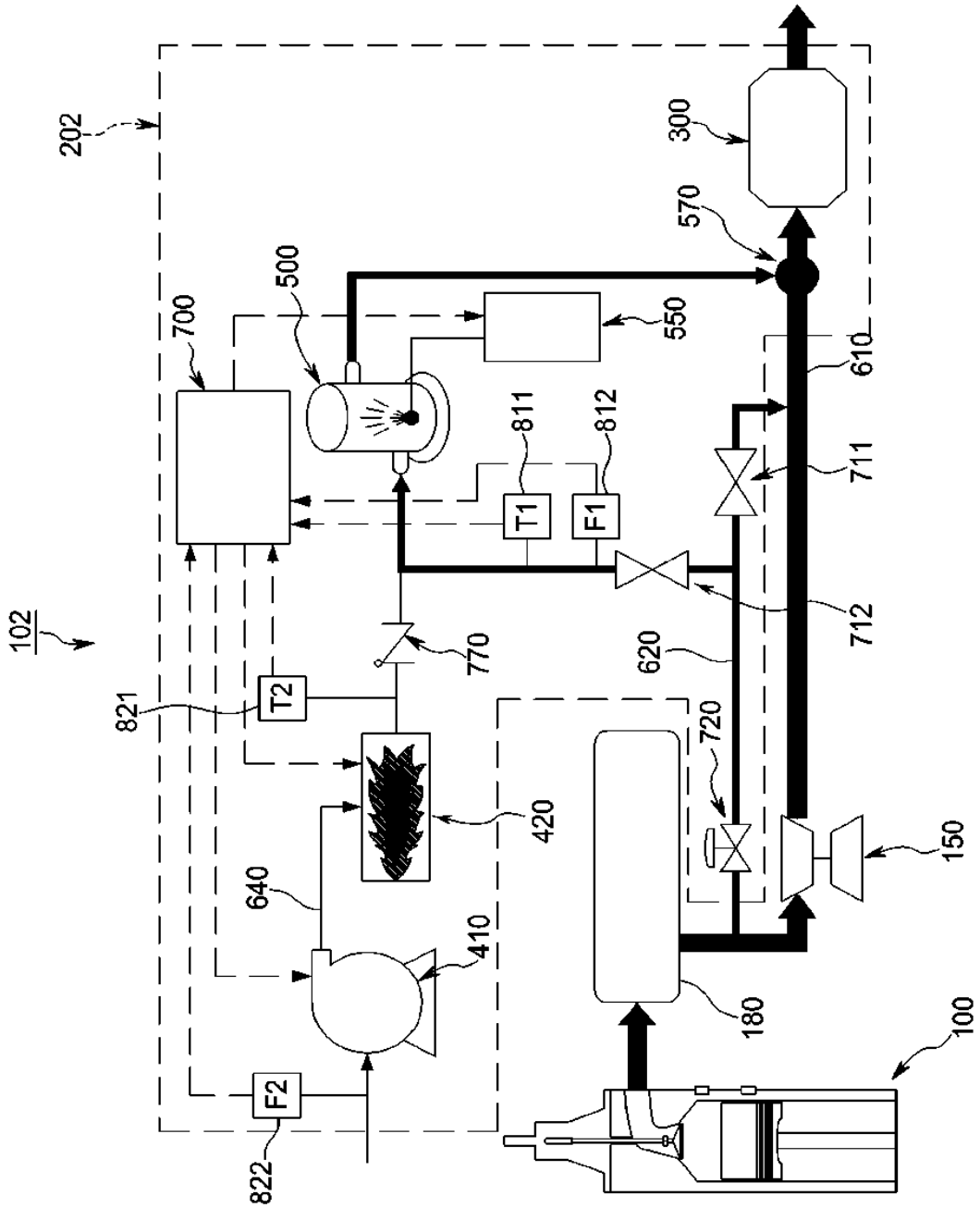
[도1]


201
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T1
F1
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710
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821
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150
640
410
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100
F2
822

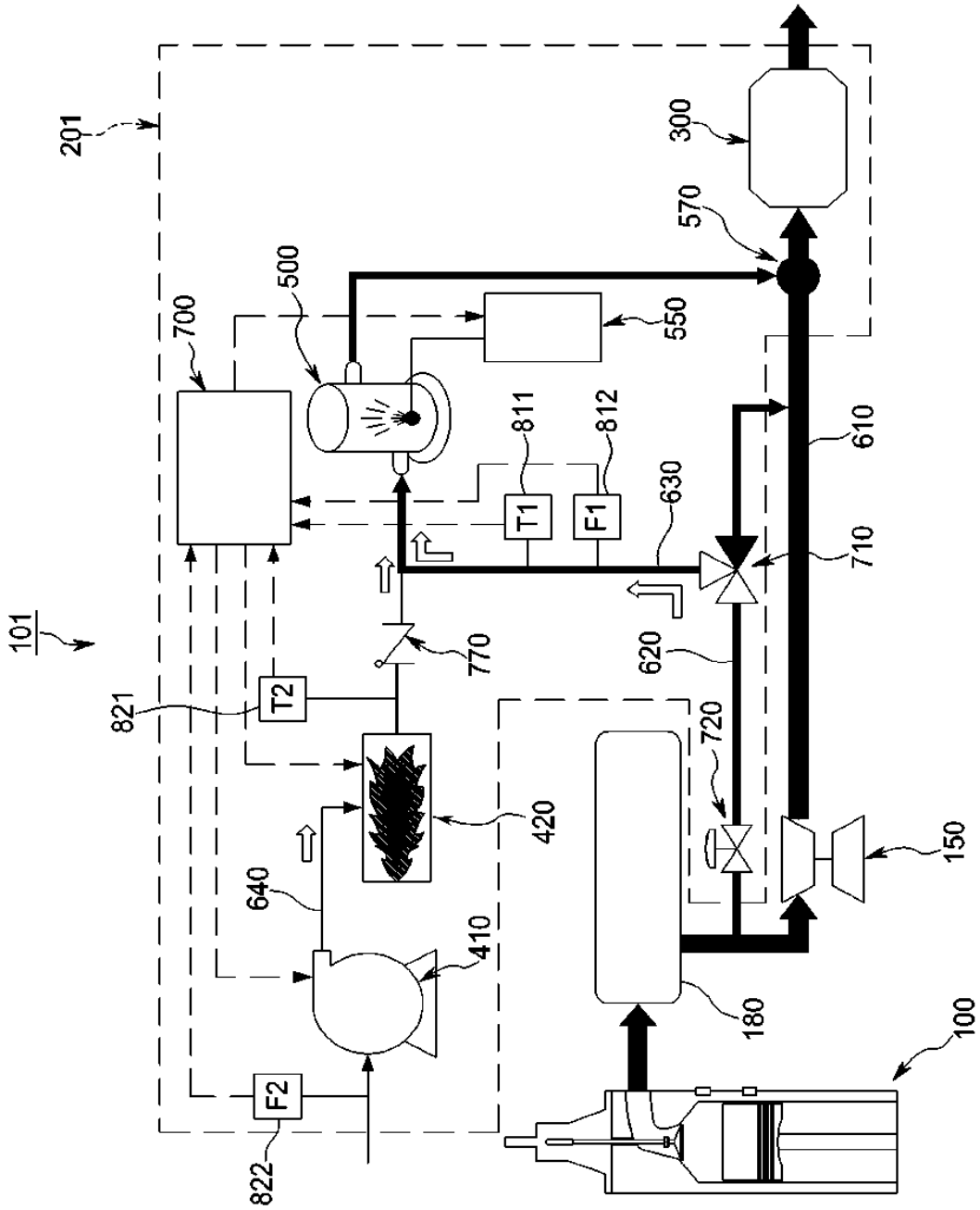
[도2]


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822

[도3]


202
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711
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F1
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770
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821
T2
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F2
822

[도4]


201
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610
T1
F1
630
710
101
770
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821
T2
720
420
150
640
410
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100
F2
822

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2015/014480

A. CLASSIFICATION OF SUBJECT MATTER

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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)

F01N 3/08; H01M 8/04; F01N 3/10; F01N 3/28; B01D 53/94; F01N 7/08; F02D 23/00; F01N 3/02; F01N 3/36; F01N 3/20; F01N 13/08; F01N 9/00; F02B 37/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS (KIPO internal) & Keywords: selective catalytic reduction, SCR, SCR, supercharger, turbo charger, reactor, decomposition chamber, branch, bypass, outer, blower, flow control valve

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KR 10-2014-0000556 A (DOOSAN ENGINE CO., LTD.) 03 January 2014 See paragraphs [0035]-[0068] and figures 1-3.	1-5,13
A		6-12
Y	KR 10-2014-0001633 A (DOOSAN ENGINE CO., LTD.) 07 January 2014 See paragraphs [0035]-[0039] and figure 1	1-5,13
Y	JP 2007-315173 A (NISSAN MOTOR CO., LTD.) 06 December 2007 See abstract, paragraph [0016] and figure 1.	5
A	KR 10-1445038 B1 (DOOSAN ENGINE CO., LTD.) 26 September 2014 See paragraphs [0030]-[0068] and figure 1.	1-13
A	JP 2003-206722 A (MITSUBISHI USO TRUCK & BUS CORP.) 25 July 2003 See paragraphs [0016]-[0023] and figure 1.	1-13

☐ 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 application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 APRIL 2016 (07.04.2016)	**18 APRIL 2016 (18.04.2016)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 189 Seonsa-ro, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/KR2015/014480

Patent document cited in search report	Publication date	Patent family member	Publication date
KR 10-2014-0000556 A	03/01/2014	KR 10-1417296 B1	08/07/2014
KR 10-2014-0001633 A	07/01/2014	KR 10-1367024 B1	24/02/2014
JP 2007-315173 A	06/12/2007	JP 4654973 B2	23/03/2011
KR 10-1445038 B1	26/09/2014	SG 11201510694S A WO 2014-208839 A1	28/01/2016 31/12/2014
JP 2003-206722 A	25/07/2003	JP 4161575 B2	08/10/2008

Form PCT/ISA/210 (patent family annex) (January 2015)

국 제 조 사 보 고 서

국제출원번호
PCT/KR2015/014480

A. 발명이 속하는 기술분류(국제특허분류(IPC))

F01N 3/08(2006.01)i, F01N 3/20(2006.01)i, F01N 3/36(2006.01)i, F01N 13/08(2010.01)i, F01N 9/00(2006.01)i, F02B 37/00(2006.01)i

B. 조사된 분야

조사된 최소문헌(국제특허분류를 기재)
F01N 3/08; H01M 8/04; F01N 3/10; F01N 3/28; B01D 53/94; F01N 7/08; F02D 23/00; F01N 3/02; F01N 3/36; F01N 3/20; F01N 13/08; F01N 9/00; F02B 37/00

조사된 기술분야에 속하는 최소문헌 이외의 문헌
한국등록실용신안공보 및 한국공개실용신안공보: 조사된 최소문헌란에 기재된 IPC
일본등록실용신안공보 및 일본공개실용신안공보: 조사된 최소문헌란에 기재된 IPC

국제조사에 이용된 전산 데이터베이스(데이터베이스의 명칭 및 검색어(해당하는 경우))
eKOMPASS(특허청 내부 검색시스템) & 키워드: 선택적 촉매 환원, 에스씨알, SCR, 과급기, 터보차저, 반응기, 분해챔버, 분기, 바이패스, 외기, 블로워, 유량제어밸브

C. 관련 문헌

카테고리*	인용문헌명 및 관련 구절(해당하는 경우)의 기재	관련 청구항
Y	KR 10-2011-0000556 A (두산엔진주식회사) 2011.01.03 단락 [0035]-[0068] 및 도면 1-3 참조.	1-5,13
A		6 12
Y	KR 10-2014-0001633 A (두산엔진주식회사) 2014.01.07 단락 [0035] [0039] 및 도면 1 참조	1-5,13
Y	JP 2007-315173 A (NISSAN MOTOR CO., LTD.) 2007.12.06 요약, 단락 [0016] 및 도면 1 참조.	5
A	KR 10-1445038 B1 (두산엔진주식회사) 2014.09.26 단락 [0030] [0068] 및 도면 1 참조.	1-13
A	JP 2003-206722 A (MITSUBISHI FUSO TRUCK & BUS CORP.) 2003.07.25 단락 [0016] [0023] 및 도면 1 참조.	1-13

☐ 추가 문헌이 C(계속)에 기재되어 있습니다.

☒ 대응특허에 관한 별지를 참조하십시오.

* 인용된 문헌의 특별 카테고리:

"A" 특별히 관련이 있는 것으로 보이는 일반적인 기술수준을 정의한 문헌

"E" 국제출원일보다 빠른 출원일 또는 우선일을 가지나 국제출원일 이후에 공개된 선출원 또는 특허 문헌

"L" 우선권 주장에 의문을 제기하는 문헌 또는 다른 인용문헌의 공개일 또는 다른 특별한 이유(이유를 명시)를 밝히기 위하여 인용된 문헌

"O" 구두 개시, 사용, 전시 또는 기타 수단을 언급하고 있는 문헌

"P" 우선일 이후에 공개되었으나 국제출원일 이전에 공개된 문헌

"T" 국제출원일 또는 우선일 후에 공개된 문헌으로, 출원과 상충하지 않으며 발명의 기초가 되는 원리나 이론을 이해하기 위해 인용된 문헌

"X" 특별한 관련이 있는 문헌. 해당 문헌 하나만으로 청구된 발명의 신규성 또는 진보성이 없는 것으로 본다.

"Y" 특별한 관련이 있는 문헌. 해당 문헌이 하나 이상의 다른 문헌과 조합하는 경우로 그 조합이 당업자에게 자명한 경우 청구된 발명은 진보성이 없는 것으로 본다.

"&" 동일한 대응특허문헌에 속하는 문헌

국제조사의 실제 완료일	국제조사보고서 발송일
2016년 04월 07일 (07.04.2016)	2016년 04월 18일 (18.04.2016)

ISA/KR의 명칭 및 우편주소
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(35208) 대전광역시 서구 정사로 189,
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서식 PCT/ISA/210 (두 번째 용지) (2015년 1월)

국 제 조 사 보 고 서
대응특허에 관한 정보

국제출원번호
PCT/KR2015/014480

국제조사보고서에서 인용된 특허문헌	공개일	대응특허문헌	공개일
KR 10-2014-0000556 A	2014/01/03	KR 10-1417296 B1	2014/07/08
KR 10-2014-0001633 A	2014/01/07	KR 10-1367024 B1	2014/02/24
JP 2007-315173 A	2007/12/06	JP 4654973 B2	2011/03/23
KR 10-1445038 B1	2014/09/26	SG 11201510694S A WO 2014-208839 A1	2016/01/28 2014/12/31
JP 2003-206722 A	2003/07/25	JP 4161575 B2	2008/10/08

서식 PCT/ISA/210 (대응특허 추가용지) (2015년 1월)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop RCE

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

A concise explanation of the relevance of the non-English language document(s) appears below in accordance with 37 C.F.R. § 1.98(a)(3).

Document **US6** (9580863 B2) is submitted herewith as the English-language counterpart of document **FP6** (JP 6292720 B2).

Copies of documents **FP1-FP10** and **NPL1-NPL12** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patent and patent application publication cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Atty. Dkt. No. 4944.0120006

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: December 3, 2024

1101 K Street, NW
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Washington, D.C. 20005
202-371-2600

Bibliographic data

Title:	Breast pump capable of being used while user lies down without holding
Pub/Pat no:	CN105233355A
Pub/Issue Date:	2016-01-13
Inventor(s):	CHEN JUNBO| CAI YEBIN| LIU SHUIHUA|CHEN JUNBO |CAI YEBIN |LIU SHUIHUA |||
Applicant(s):	CHEN JUNBO
Classification:	A61M1/06AI
Application number:	CN201510647623 2015-10-09
Priority number:	CN201510647623 20151009;

Abstract of CN105233355A

The invention relates to a breast pump capable of being used while a user lies down without holding, and belongs to the field of maternal and child appliances. The breast pump comprises a negative pressure source and a milk sucking device. Different from other milk sucking devices, the milk sucking device comprises a hemispheric cup and a bottom cover; a tapered breast holder fitting breasts of human bodies is arranged in the middle of the bottom cover; a central connection piece and a waterproof ring are embedded in the bottom cover; a connector of the central connection piece is connected with a one-way valve seat, the bottom cover, an air bag and a shell in an embedded manner, wherein the shell provides space needed by airbag deformation; the bottom cover and the central connection piece can be integrated. During use, the one-way valve seat is soaked in milk; the air bag is provided with a plurality of symmetrical grooves at least. The breast bump can be used when the user lies down without holding and is particularly suitable for weak puerperae.

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 105233355 A
(43)申请公布日 2016.01.13

(21)申请号 201510617623.2

(22)申请日 2015.10.09

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(72)发明人 陈俊波 蔡业滨 刘水华

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

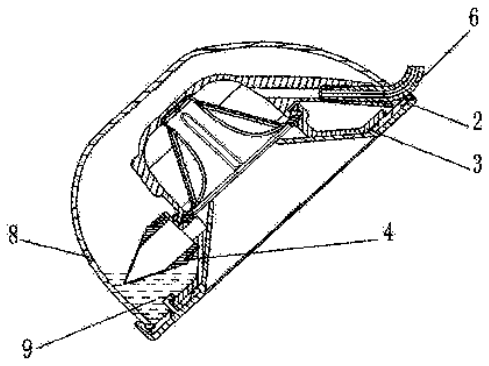
权利要求书1页 说明书3页 附图7页

(54)发明名称

一种适应于躺着使用和免手扶的吸奶器

(57)摘要

本发明涉及到一种适应于躺着使用和免手扶的吸奶器，属于母婴电器领域。该吸奶器包含有负压源和奶液吸取器；与众不同的是，所述奶液吸取器由半球状的罩杯和底盖构成；所述底盖的中间设置有贴合人体乳房的锥形的乳托；中心连接件与防水圈嵌装在底盖上；所述的中心连接件的接口，分别与单向阀座、底盖和气囊以及提供该气囊变形所需空间的壳体相嵌接；底盖与中心连接件也可以做为一整体。使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。该吸奶器可以适用于躺着和免手扶使用，尤其适用于身体虚弱的产妇。



CN 105233355 A

1. 一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；其特征在于，所述奶液吸取器由半球状的罩杯和底盖构成；所述底盖的中间设置有贴合人体乳房的锥形的乳托；中心连接件与防水圈嵌装在底盖上；所述的中心连接件设置有三个接口，一个与单向阀座连接，一个与底盖连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

2. 根据权利要求 1 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

3. 根据权利要求 1 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，罩杯与底盖的连接处设置有密封圈。

4. 根据权利要求 1 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，包含有一个负压源和两个结构相同的奶液吸取器。

5. 根据权利要求 1 或 2 或 3 或 4 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，奶液吸取器安装于相配套的免手扶文胸中。

6. 一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；其特征在于，所述奶液吸取器由半球状的罩杯和连接件基座构成；所述连接件基座的中间设置有贴合人体乳房的锥形的乳托；所述的连接件基座另带有两个接口，一个与单向阀座连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

7. 根据权利要求 6 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，罩杯与连接件基座的连接处设置有密封圈。

8. 根据权利要求 6 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

9. 根据权利要求 6 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，包含有一个负压源和两个结构相同的奶液吸取器。

10. 根据权利要求 6 或 7 或 8 或 9 所述的一种适应于躺着使用和免手扶的吸奶器，其特征在于，奶液吸取器安装于相配套的免手扶文胸中。

一种适应于躺着使用和免手扶的吸奶器

技术领域

[0001] 本发明属于母婴电器领域，具体地说，涉及一种适合于躺着使用和免手扶的吸奶器。

背景技术

[0002] 母乳喂养是目前被证实最科学的喂养婴儿的方法，是配方奶粉和其他辅食无法媲美的。吸奶器作为母乳喂养的辅助工具，能帮助哺乳期女性收集乳汁喂养婴儿。一般来说，吸奶器一般由吸取乳汁的吸乳罩、提供吸力的负压产生装置、用来收集乳汁的收集容器。目前，虽然，奶瓶和奶袋能被用作收集乳汁的收集容器，但是，使用奶瓶或奶袋作为收集容器，使用者的上半身须直立，以保障奶瓶或奶袋的乳液不倒流。

[0003] 在现有技术上，已经出现新结构的吸奶器，基本归纳起来有两种结构：1、集奶容器与同步吸取器是分开的，两者用软管相连接；整机的体积较为庞大，吸奶工作前的安装比较繁琐；2、集奶容器与同步吸取器虽然一同设置于罩杯之中，但是只能上身直立时吸奶使用。

发明内容

[0004] 针对现有吸奶器的不足和缺点，本发明的目的在于提供一种吸奶器。与现有技术相比，该吸奶器能适合于躺着使用且免手扶。

[0005] 本发明是通过以下技术方案来实现。

[0006] 第一技术方案：

本发明所述的一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；与众不同的是，所述奶液吸取器由半球状的罩杯和底盖构成；所述底盖的中间设置有贴合人体乳房的锥形的乳托；中心连接件与防水圈嵌装在底盖上；所述的中心连接件设置有三个接口，一个与单向阀座连接，一个与底盖连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

[0007] 所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

[0008] 罩杯与底盖的连接处设置有密封圈。

[0009] 该吸奶器可以包含有一个负压源和两个结构相同的奶液吸取器。

[0010] 奶液吸取器安装于相配套的免手扶文胸中。

[0011] 第二技术方案：

一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；其特征在于，所述奶液吸取器由半球状的罩杯和连接件基座构成；所述连接件基座的中间设置有贴合人体乳房的锥形的乳托；所述的连接件基座另带有两个接口，一个与单向阀座连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

[0012] 罩杯与连接件基座的连接处设置有密封圈。

[0013] 所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

[0014] 该吸奶器可以包含有一个负压源和两个结构相同的奶液吸取器。

[0015] 奶液吸取器安装于相配套的免手扶文胸中。

[0016] 以上技术方案可以看出，该吸奶器的集奶容器与吸取部件是同一体的，两者不用软管相连接；整机的体积大大缩小，吸奶工作前无需安装。单向阀座虽然浸泡于奶液中，但是在负压的作用下，奶液只进不出；这时单向阀座虽然打开，但奶液不会溢出。可以适用于躺着使用。尤其适用于身体虚弱的产妇。

[0017] 所述的气囊设有多条沟槽，其作用在于：一是扩大变形空间，这对于减少奶液吸取器有限的体积设计是有利的；二是在负压结束后，气囊原状的恢复比较容易，恢复原状的时间也缩短了。

[0018] 使用本发明的吸奶器时，可以把奶液吸取器装入相配套的免手扶文胸中，因而实现了免手扶之目的。

附图说明

[0019] 图 1 是本发明的吸奶器的奶液吸取器分解示意图。

[0020] 图 2 是本发明的吸奶器的组成示意图。

[0021] 图 3 是竖身使用本发明的吸奶器时的奶液吸取器结构剖视示意图。

[0022] 图 4 是躺着使用本发明的吸奶器时的奶液吸取器结构剖视示意图。

[0023] 图 5 是与本发明的吸奶器相配套的免手扶文胸结构示意图。

[0024] 图 6 是本发明的吸奶器的奶液吸取器另一种实施例的分解示意图。

[0025] 图 7 是本发明的吸奶器的奶液吸取器另一种实施例的结构剖视示意图。

[0026] 附图标志意义：1- 底盖，2- 密封圈，3- 中心连接件，4- 单向阀座，5- 气囊，6- 硅胶管，7- 壳体，8- 罩杯，9- 奶液，10- 免手扶文胸，11- 连接件基座，A- 奶液吸取器，B- 负压源。

具体实施方式

[0027] 参照附图，本发明所述的一种适应于躺着使用和免手扶的吸奶器，有两个实施例。

[0028] 第一实施例：

本发明所述的一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；与众不同的是，所述奶液吸取器由半球状的罩杯和底盖构成；所述底盖的中间设置有贴合人体乳房的锥形的乳托；中心连接件与防水圈嵌装在底盖上；所述的中心连接件设置有三个接口，一个与单向阀座连接，一个与底盖连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

[0029] 所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

[0030] 罩杯与底盖的连接处设置有密封圈。

[0031] 该吸奶器可以包含有一个负压源和两个结构相同的奶液吸取器。

[0032] 奶液吸取器安装于相配套的免手扶文胸中。

[0033] 该吸奶器包含有负压源 B 和奶液吸取器 A，所述的奶液吸取器 A 呈半球状，能够贴合人体乳房，可以藏匿于与免手扶文胸之中，或由手扶；所述的奶液吸取器 A 由半球状的罩

杯 8 和底盖 1 构成，所述底盖 1 中间设有贴合人体乳房的锥形的乳托，所述中心连接件 3 与防水圈 2 嵌装在底盖 1 上；所述的中心连接件 3 具备三个接口，一个与单向阀座 4 连接，一个与底盖 1 的连接，另一个与挠性材料的气囊 5 和提供该气囊 5 变形所需空间的壳体 7 相嵌接；所述的壳体 7 有一延伸臂，延伸臂内嵌硅胶管 6；所述的硅胶管 6 与负压源连接；为了使气囊 5 能够快速塌缩与恢复，气囊设有多条沟槽。

[0034] 第二实施例：

图 6 和图 7 是本发明的吸奶器另一种实施例的示意图。

[0035] 一种适应于躺着使用和免手扶的吸奶器，包含有负压源和奶液吸取器；其特征在于，所述奶液吸取器由半球状的罩杯和连接件基座构成；所述连接件基座的中间设置有贴合人体乳房的锥形的乳托；所述的连接件基座另带有两个接口，一个与单向阀座连接，另一个与挠性材料的气囊和提供该气囊变形所需空间的壳体相嵌接；使用时，单向阀座浸泡于奶液中；所述的气囊至少设置有若干条位置相对称的沟槽。

[0036] 罩杯与连接件基座的连接处设置有密封圈。

[0037] 所述的壳体有一延伸臂，延伸臂内嵌硅胶管。

[0038] 该吸奶器可以包含有一个负压源和两个结构相同的奶液吸取器。

[0039] 奶液吸取器安装于相配套的免手扶文胸中。

[0040] 可以看出，第二实施例与第一实施例相比较的区别在于，连接件基座相当于底盖与中心连接件的结合体。

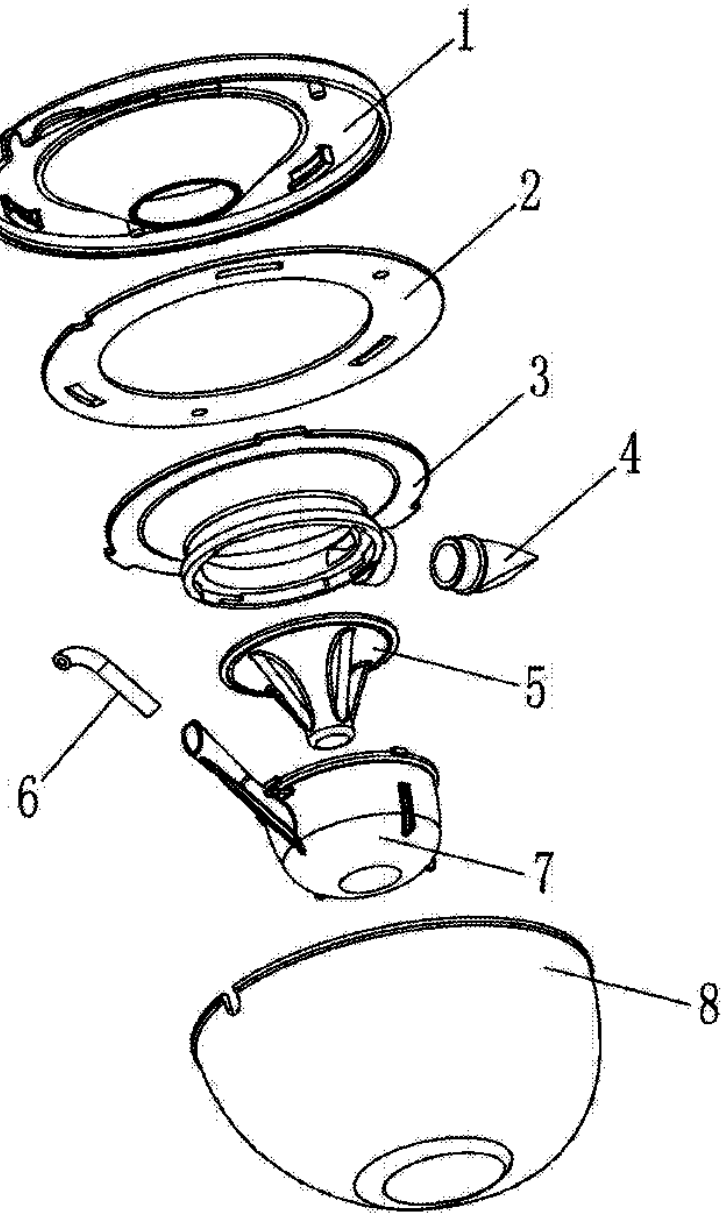


图 1

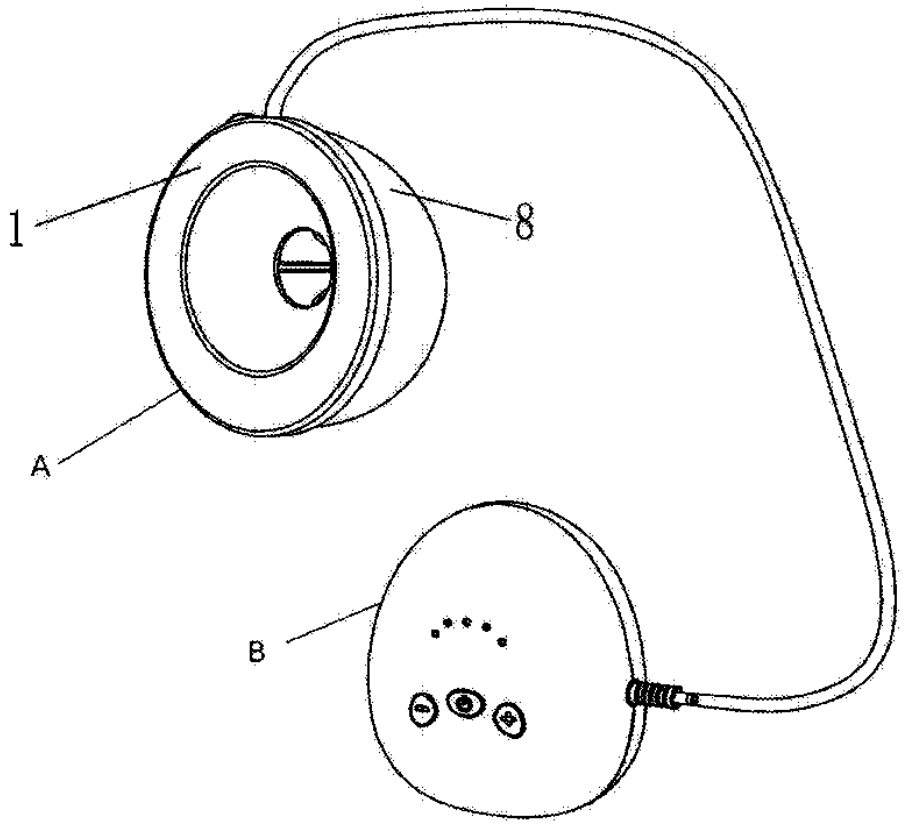


图 2

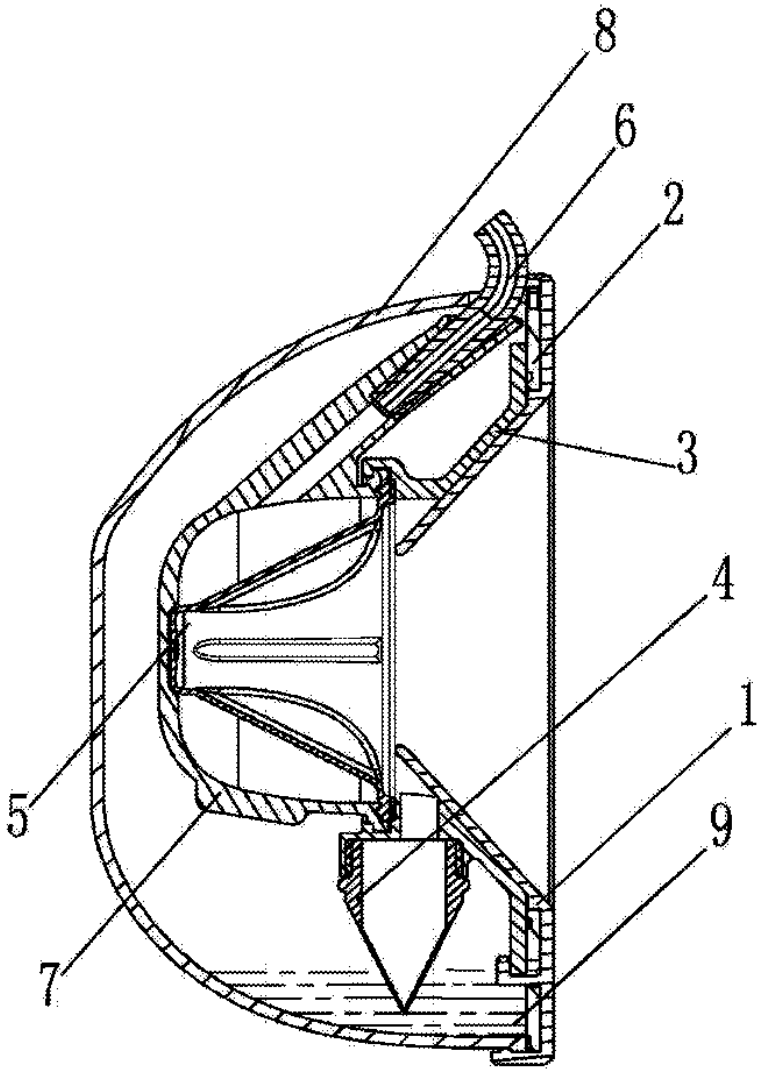


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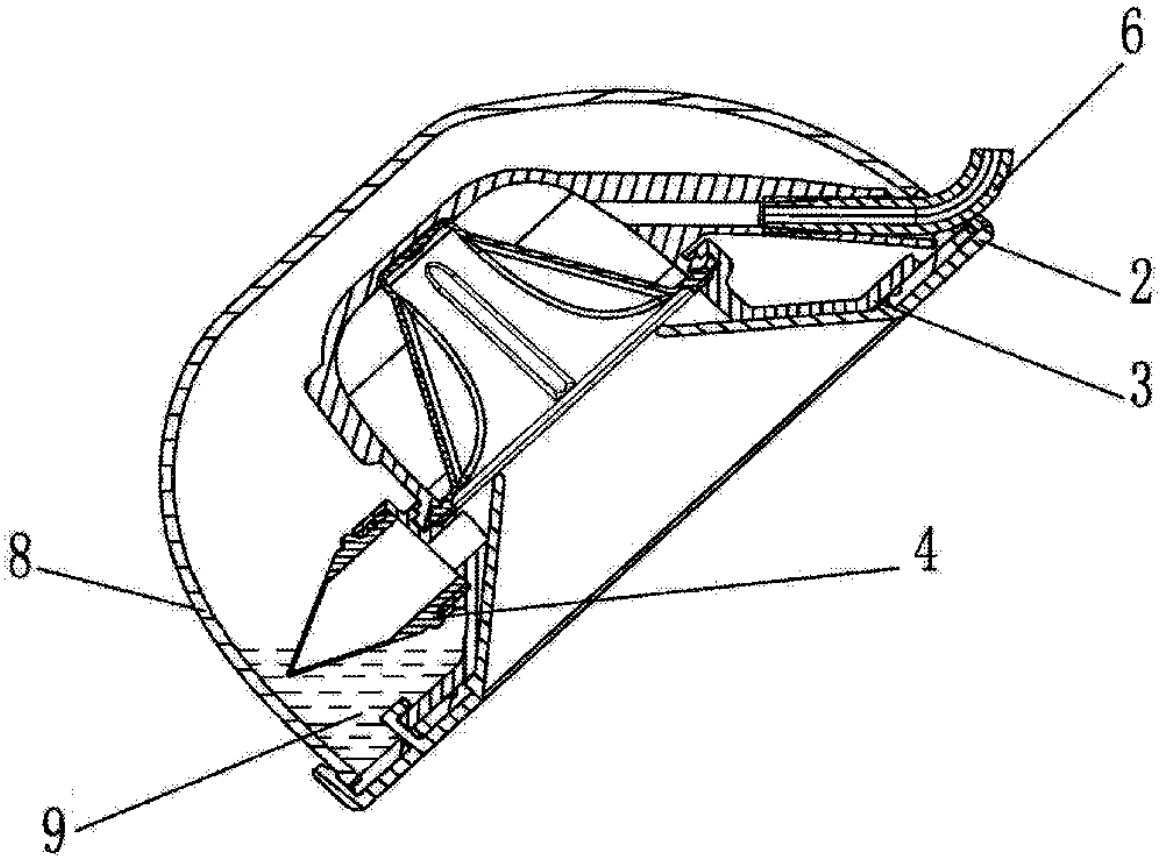


图 4

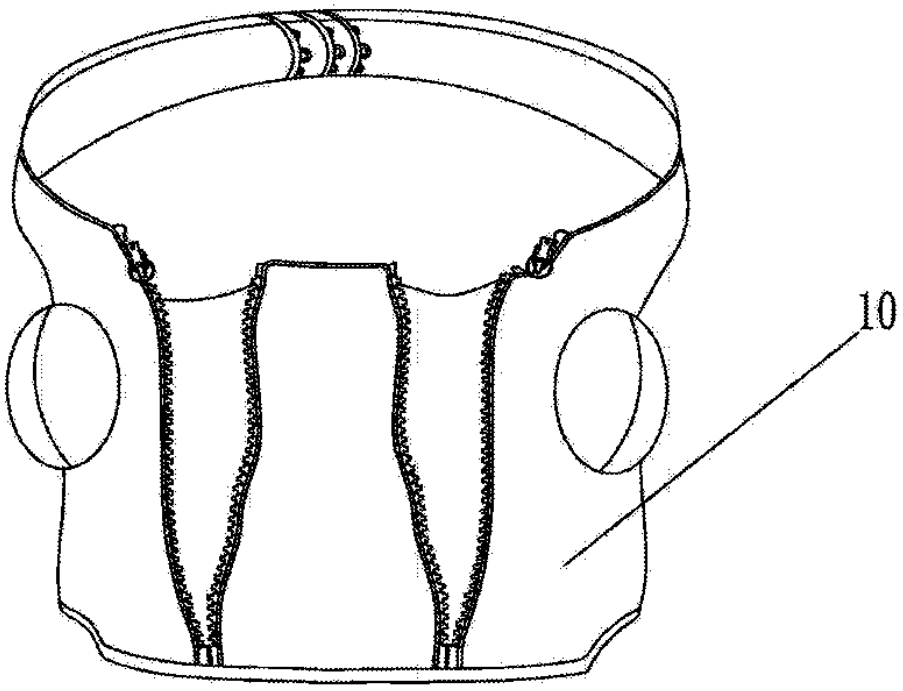


图 5

10

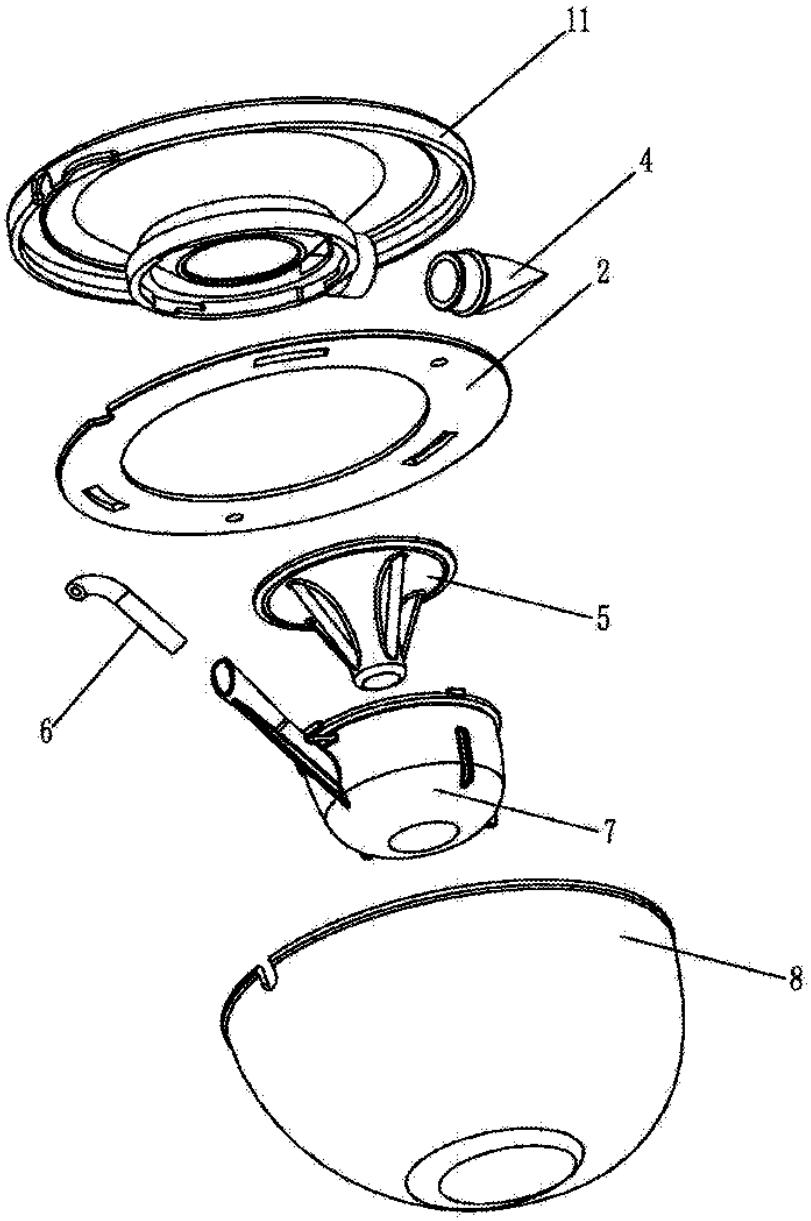


图 6

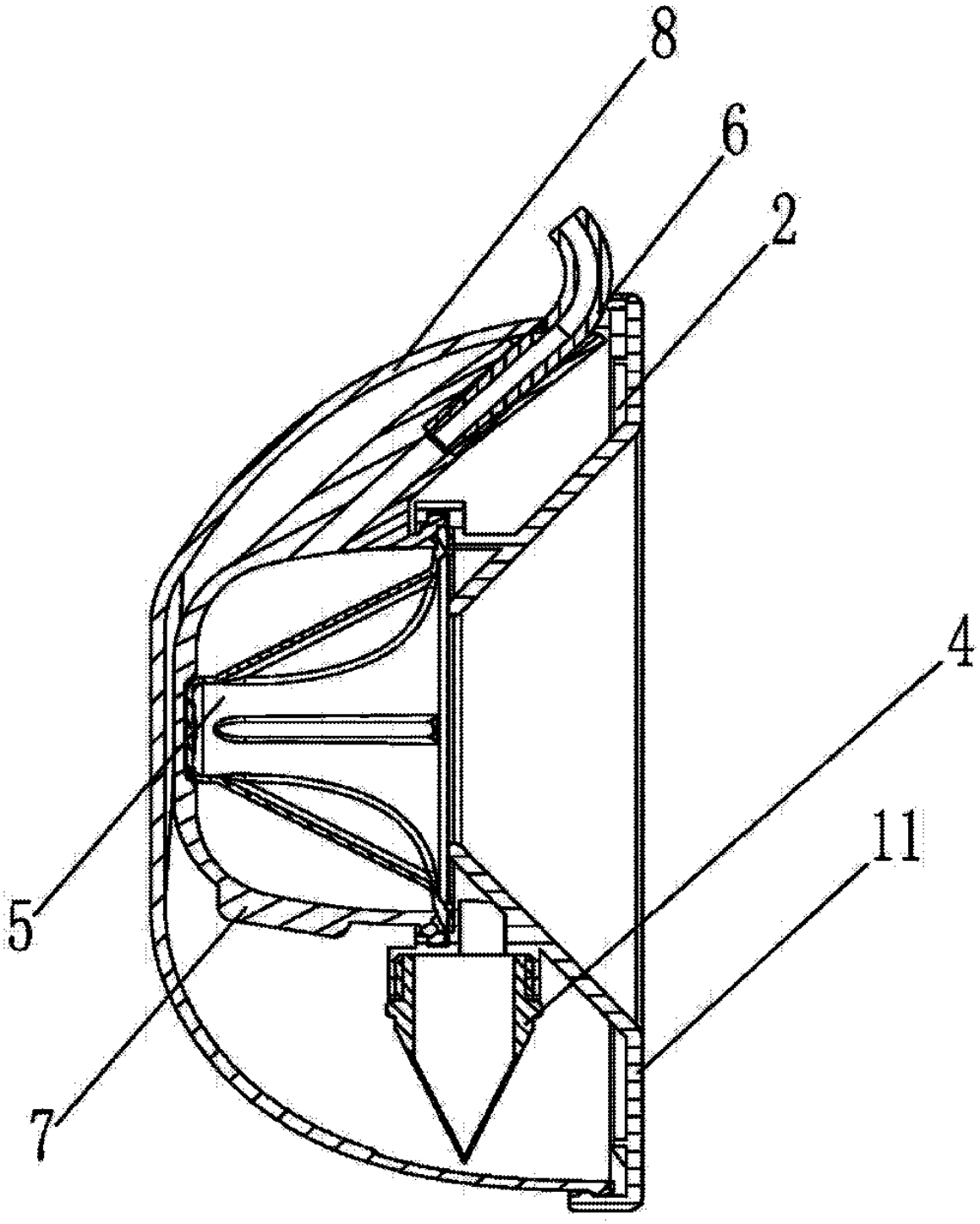


图 7

Bibliographic data

Title:	Hand-free breast pump
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Pub/Issue Date:	2020-02-21
Inventor(s):	CHEN SHAOZHONG|
Applicant(s):	WUXI XINZHONGRUI BABY SUPPLIES CO LTD
Classification:	A61M1/06AI
Application number:	CN201920789895U 2019-05-29
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Abstract of CN210096493U

The utility model discloses a hand-free breast pump, which relates to the field of structural design of breast pumps and comprises a milk sucker and a negative pressure providing device, and the milksucker comprises a flared cover for sucking milk, a three-way part fixed with the flared cover and a milk collecting container for storing milk. The three-way piece comprises a suction air bag used for providing suction and a three-way shell arranged outside the suction air bag in a sleeving mode, the horn mouth cover is communicated with the suction air bag, and the suction air bag is communicated with the milk collecting container. A communicated milk sucking channel is formed between the horn mouth cover and the suction air bag; and the three-way shell, the suction air bag and the negativepressure providing device form a negative pressure air channel for providing negative pressure suction. The hand-free breast pump provided by the utility model is simple in structure, small in size and easy to operate, hands of a mother in a lactation period can be liberated during breast pumping, and other daily or working affairs can be conveniently handled during breast pumping.

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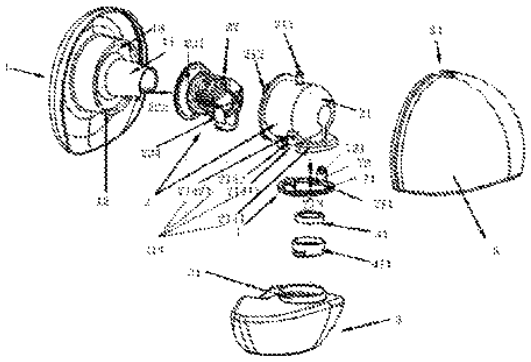
权利要求书1页 说明书7页 附图5页

(54)实用新型名称

免手扶吸奶器

(57)摘要

本实用新型公开了一种免手扶吸奶器，涉及吸奶器结构设计领域，包括乳汁吸取器及负压提供装置，其中，乳汁吸取器包括用于吸乳的喇叭口盖、与喇叭口盖固定的三通件以及用于储存乳汁的乳汁收集容器。三通件包括用于提供吸力的吸力气囊以及套设在吸力气囊外部的三通壳体，喇叭口盖与吸力气囊连通，吸力气囊与乳汁收集容器连通。喇叭口盖、吸力气囊之间形成有连通的吸乳通道；三通壳体、吸力气囊与负压提供装置构成提供负压吸力的负压气路通道。本实用新型提供的免手扶吸奶器结构简单，体量小巧，易操作，能够让哺乳期母亲在吸乳时解放双手，在吸乳的同时方便地处理其它日常或工作事务。



CN 210096493 U

1.一种免手扶吸奶器，其特征在于，包括用于吸乳的乳汁吸取器与用于提供吸力的负压提供装置；所述乳汁吸取器包括喇叭口盖、三通件及乳汁收集容器；所述三通件包括三通壳体及可拆卸嵌套于所述三通壳体内的吸力气囊；所述喇叭口盖与所述三通壳体可拆卸密封固定；所述三通壳体的内侧与所述吸力气囊之间具有用于供所述吸力气囊变形的密闭负压空间；所述负压空间仅与所述负压提供装置管路连通；所述吸力气囊上开设有入奶口，所述吸力气囊通过所述入奶口与所述喇叭口盖连通，形成用于吸乳的吸乳通道；所述吸力气囊上还开设有出奶口，所述吸力气囊通过所述出奶口与所述乳汁收集容器连通。

2.如权利要求1所述的免手扶吸奶器，其特征在于，所述吸力气囊的出奶口向下连续延伸有漏奶通道；所述三通壳体上开设有奶道出口；所述漏奶通道的外壁密封所述奶道出口；所述漏奶通道与所述乳汁收集容器连通。

3.如权利要求2所述的免手扶吸奶器，其特征在于，所述漏奶通道的出口处固定有防逆流机构；所述防逆流机构和/或所述漏奶通道密封所述奶道出口。

4.如权利要求1所述的免手扶吸奶器，其特征在于，所述喇叭口盖包括向后凸设的用于伸入所述吸力气囊中的导流部；所述导流部穿过所述入奶口伸入所述吸力气囊；所述导流部的底部与所述吸力气囊之间形成有用于引导乳汁流向所述出奶口的引流间隙；所述引流间隙的开口朝向所述出奶口。

5.如权利要求1所述的免手扶吸奶器，其特征在于，还包括罩杯外壳；所述罩杯外壳包覆于所述三通件及部分所述喇叭口盖的外侧；所述乳汁收集容器可拆卸固定于所述三通壳体的下方；所述罩杯外壳为四分之一半球状，所述罩杯外壳与所述乳汁收集容器固定后的整体外表面呈半球面状。

6.如权利要求5所述的免手扶吸奶器，其特征在于，所述罩杯外壳分别与所述喇叭口盖、所述乳汁收集容器可拆卸固定连接；所述三通壳体上设置有用于与所述负压提供装置气路连通的吸气孔柱；所述负压提供装置通过硅胶管连通所述吸气孔柱一侧的负压空间；所述罩杯外壳上开设有用于所述硅胶管伸出的罩杯开口。

7.如权利要求1所述的免手扶吸奶器，其特征在于，所述吸力气囊表面具有沟槽纹样。

8.如权利要求1所述的免手扶吸奶器，其特征在于，所述喇叭口盖上设置有沿环状分布的凹槽部，所述三通壳体上设置有沿环状分布的凸起部；或者，所述喇叭口盖上设置有沿环状分布的凸起部，所述三通壳体上设置有沿环状分布的凹槽部，所述凹槽部与所述凸起部以旋转卡槽方式配合固定。

9.如权利要求8所述的免手扶吸奶器，其特征在于，所述吸力气囊的入奶口上设置有环状硅胶翻边；所述喇叭口盖上具有用于容纳所述环状硅胶翻边的凹部；所述三通壳体固定于所述喇叭口盖上时，所述环状硅胶翻边嵌入所述凹部并且所述三通壳体压紧所述环状硅胶翻边。

10.如权利要求1所述的免手扶吸奶器，其特征在于，所述乳汁收集容器与所述三通壳体通过卡扣方式可拆卸固定。

免手扶吸奶器

技术领域

[0001] 本实用新型属于母婴电器领域，具体地说，涉及一种免手扶吸奶器。

背景技术

[0002] 母乳喂养是目前被证实最科学的喂养婴儿的方法，是配方奶粉和其它辅食无法媲美的。吸奶器作为母乳喂养的辅助工具，能帮助哺乳期女性收集乳汁喂养婴儿。一般来说，吸奶器由吸取乳汁的吸乳罩(乳汁吸取器)、提供吸力的负压产生装置、用来收集乳汁的收集容器组成。

[0003] 在现有技术上，吸奶器一般会存在整体部件过多，吸奶工作前的安装较繁琐，且各部件结构复杂的缺点，构成现有的吸奶器组装后的整体体量较大，无法实现免手扶使用，对于快节奏的现代女性来说，造成了极大的不便。

实用新型内容

[0004] 针对上述存在的问题，本实用新型提供一种免手扶吸奶器，具有较为简单的结构和方便地安装方式，来解决现有技术中吸奶器体量大，结构复杂，操作麻烦等缺点。

[0005] 为实现上述目的，本实用新型提供的技术方案为：

[0006] 本实用新型提供的免手扶吸奶器，包括用于吸乳的乳汁吸取器与用于提供吸力的负压提供装置；所述乳汁吸取器包括喇叭口盖、三通件及乳汁收集容器；所述三通件包括三通壳体及可拆卸嵌套于所述三通壳体内的吸力气囊；所述喇叭口盖与所述三通壳体可拆卸密封固定；所述三通壳体的内侧与所述吸力气囊之间具有用于供所述吸力气囊变形的密闭负压空间；所述负压空间仅与所述负压提供装置管路连通；所述吸力气囊上开设有入奶口，所述吸力气囊通过所述入奶口与所述喇叭口盖连通，形成用于吸乳的吸乳通道；所述吸力气囊上还开设有出奶口，所述吸力气囊通过所述出奶口与所述乳汁收集容器连通。

[0007] 本实用新型提供的免手扶吸奶器，优选地，所述吸力气囊的出奶口向下连续延伸有漏奶通道；所述三通壳体上开设有奶道出口；所述漏奶通道的外壁密封所述奶道出口；所述漏奶通道与所述乳汁收集容器连通。

[0008] 本实用新型提供的免手扶吸奶器，优选地，所述漏奶通道的出口处固定有防逆流机构；所述防逆流机构和/或所述漏奶通道密封所述奶道出口。

[0009] 本实用新型提供的免手扶吸奶器，优选地，所述喇叭口盖包括向后凸设的用于伸入所述吸力气囊中的导流部；所述导流部穿过所述入奶口伸入所述吸力气囊；所述导流部的底部与所述吸力气囊之间形成有用于引导乳汁流向所述出奶口的引流间隙；所述引流间隙的开口朝向所述出奶口。

[0010] 本实用新型提供的免手扶吸奶器，优选地，还包括罩杯外壳，还包括罩杯外壳；所述罩杯外壳包覆于所述三通件及部分所述喇叭口盖的外侧；所述乳汁收集容器可拆卸固定于所述三通壳体的下方；所述罩杯外壳为四分之一半球状，所述罩杯外壳与所述乳汁收集容器固定后的整体外表面呈半球面状。

[0011] 本实用新型提供的免手扶吸奶器，优选地，所述罩杯外壳分别与所述喇叭口盖、所述乳汁收集容器可拆卸固定连接；所述三通壳体上设置有用于与所述负压提供装置气路连通的吸气孔柱；所述负压提供装置通过硅胶管连通所述吸气孔柱一侧的负压空间；所述罩杯外壳上开设有用于所述硅胶管伸出的罩杯开口。

[0012] 本实用新型提供的免手扶吸奶器，优选地，所述吸力气囊表面具有沟槽纹样。

[0013] 本实用新型提供的免手扶吸奶器，优选地，所述喇叭口盖上设置有沿环状分布的凹槽部，所述三通壳体上设置有沿环状分布的凸起部；或者，所述喇叭口盖上设置有沿环状分布的凸起部，所述三通壳体上设置有沿环状分布的凹槽部，所述凹槽部与所述凸起部以旋转卡槽方式配合固定。

[0014] 本实用新型提供的免手扶吸奶器，优选地，所述吸力气囊的入奶口上设置有环状硅胶翻边；所述喇叭口盖上具有用于容纳所述环状硅胶翻边的凹部；所述三通壳体固定于所述喇叭口盖上时，所述环状硅胶翻边嵌入所述凹部并且所述三通壳体压紧所述环状硅胶翻边。

[0015] 本实用新型提供的免手扶吸奶器，优选地，所述乳汁收集容器与所述三通壳体通过卡扣方式可拆卸固定。

[0016] 上述技术方案具有如下优点或者有益效果：

[0017] 本实用新型提供的免手扶吸奶器，包括乳汁吸取器及负压提供装置，其中，乳汁吸取器包括用于吸乳的喇叭口盖、与喇叭口盖固定的三通件以及用于储存乳汁的乳汁收集容器。三通件包括用于提供吸力的吸力气囊以及套设在吸力气囊外部的三通壳体，喇叭口盖与吸力气囊连通，吸力气囊与乳汁收集容器连通。喇叭口盖、吸力气囊之间形成有连通的吸乳通道；三通壳体、吸力气囊与负压提供装置构成提供负压吸力的负压气路通道。本实用新型提供的免手扶吸奶器结构简单，体量较小，易操作，能够让哺乳期母亲在吸乳时解放双手，方便地处理其它日常或工作事务。

附图说明

[0018] 通过阅读参照以下附图对非限制性实施例所作的详细描述，本实用新型及其特征、外形和优点将会变得更加明显。在全部附图中相同的标记指示相同的部分。并未刻意按照比例绘制附图，重点在于示出本实用新型的主旨。

[0019] 图1是本实用新型实施例1提供的免手扶吸奶器的乳汁吸取器于一种角度的分解示意图；

[0020] 图2是本实用新型实施例1提供的免手扶吸奶器中乳汁吸取器的另一种角度的分解示意图；

[0021] 图3是本实用新型实施例1提供的免手扶吸奶器的乳汁吸取器一种角度的剖视示意图；

[0022] 图4是本实用新型实施例1提供的免手扶吸奶器的乳汁吸取器另一种角度的剖视示意图；

[0023] 图5是本实用新型实施例1提供的免手扶吸奶器的一种立体角度示意图；

[0024] 图6是本实用新型实施例1提供的免手扶吸奶器的另一种立体角度示意图；

[0025] 附图标志含义：A-乳汁吸取器；B-负压提供装置；1-喇叭口盖；2-三通件；3-乳汁收

集容器；31-瓶口凸起部；11-导流部；12-凹槽部；13-凹部；21-三通壳体；211-吸气孔柱；212-凸起部；213-奶道出口；214-定位件；2141-第一圈状基座；21411-槽口；2142-定位耳；21421-凸柱；22-吸力气囊；221-硅胶翻边；222-入奶口；223-出奶口；224-漏奶通道；23-负压空间；41-硅胶单向阀；411-单向阀固定圈；42-引流间隙；5-罩杯外壳；51-罩杯开口；6-硅胶管；7-奶瓶固定圈；71-第二圈状基座；711-卡接槽；72-卡接耳；721-通孔；8乳汁。

具体实施方式

[0026] 下面结合本实用新型实施例中的附图，对本实用新型实施例中的技术方案进行清楚、完整的说明，显然所描述的实施例仅仅是本实用新型的一部分实施例，而不是全部的实施例。因此，以下对附图中提供的本实用新型实施例中的详细描述并非旨在限制要求保护的本实用新型的范围，而是仅仅表示本实用新型的选定实施例。基于本实用新型的实施例，本领域技术人员在没有作出创造性劳动的前提下所获得的所有其他实施例，都属于本实用新型的保护范围。

[0027] 实施例1：

[0028] 如图5或图6所示，本实用新型实施例1提供一种免手扶吸奶器，包括用于吸乳的乳汁吸取器A与用于提供吸力的负压提供装置B；参照图1～4，所述乳汁吸取器A包括喇叭口盖1、三通件2及乳汁收集容器3；所述三通件2包括三通壳体21及可拆卸嵌套于所述三通壳体21内的吸力气囊22；所述喇叭口盖1与所述三通壳体21可拆卸密封固定；所述三通壳体21的内侧与所述吸力气囊22之间具有用于供所述吸力气囊22变形的密封负压空间23；所述负压空间23仅与所述负压提供装置B管路连接；所述吸力气囊22上开设有入奶口222，所述吸力气囊22通过所述入奶口222与所述喇叭口盖1连通，形成用于吸乳的吸乳通道；所述吸力气囊22上还开设出奶口223，所述吸力气囊22通过所述出奶口223与所述乳汁收集容器3连通。

[0029] 通过将喇叭口盖、三通件及乳汁收集容器进行组合装配，构成免手扶的一体式乳汁吸取器，有效地减小了传统吸奶器的体积。由于吸奶器中涉及的配件较少，免去了复杂的安装流程，且乳汁吸取器结构具有较强的紧凑性，结构的紧凑有利于体量的小型化，便于哺乳期母亲在吸乳时腾出双手，来处理其它事务。在装配时，将喇叭口盖和三通壳体可拆卸固定在一起，将负压提供装置与负压空间管路连通，负压提供装置即可为乳汁吸取器提供工作的吸力。当乳汁吸取器在吸力的作用下工作时，乳汁可顺着喇叭口盖流到吸力气囊的入奶口，并顺着吸力气囊的内表面流至出奶口，最后流至乳汁收集容器中去，吸乳过程简单，具有较高的吸奶效率。

[0030] 为了使得本实用新型实施例1提供的免手扶吸奶器在工作时，通过吸力气囊的收缩和舒张驱动下，乳汁可以更高效地被收集到乳汁收集容器中，如图1或2所示，所述吸力气囊22的出奶口223向下连续延伸有漏奶通道224；所述三通壳体21上开设有奶道出口213；所述漏奶通道224的外壁密封所述奶道出口213；所述漏奶通道224与所述乳汁收集容器3连通。这样一来，从喇叭口盖吸取的乳汁能够通过重力作用更好地流入乳汁收集容器中。同时，漏奶通道224的外壁密封奶道出口213，有利于增强吸力气囊和三通壳体之间负压空间的密封性。

[0031] 目前，市面上大部分的吸奶器，其乳汁吸取器都需要使用者的上半身直立，即只适用于坐姿甚至轻微俯身使用，以防乳汁顺着吸乳罩回流到外面不可收拾，如此对于剖宫产

的女性以及产后腹部不适的女性都是极为不方便的，她们无法长久保持上半身直立坐姿和俯身，多数情况则需要半躺或平躺。

[0032] 考虑到上述问题，在本实用新型提供的免手扶吸奶器中，参照图3或图4，所述漏奶通道的出口处固定有防逆流机构，来阻挡乳汁倒流；并且，所述防逆流机构和/或所述漏奶通道24密封所述奶道出口，在设置防逆流机构时，防逆流机构和漏奶通道共同密封三通壳体的奶道出口或者单独密封三通壳体的奶道出口，均能实现增强负压空间密封性的作用。本实用新型实施例1中，防逆流机构只要能够实现阻挡乳汁倒流，均能够作为防逆流机构使用，在此不予赘述。优选地，所述防逆流机构可以是硅胶单向阀41(如图1~4所示，其可通过一单向阀固定圈411固定于漏奶通道的口部)或鸭嘴阀(未在附图中标示，其实施方式是本领域技术人员能理解的)。通过在漏奶通道224的口部设置硅胶单向阀，被引入乳汁收集容器的乳汁不会发生倒流和逆流，对于哺乳期母亲躺身使用时是方便的。

[0033] 进一步地，为了增强本实用新型实施例1提供的免手扶吸奶器在躺身使用时的舒适性及可靠性，可参照图1，所述喇叭口盖1包括向后凸设的用于伸入所述吸力气囊22中的导流部11；参照图4，所述导流部11穿过所述入奶口222伸入所述吸力气囊22；所述导流部11的底部与所述吸力气囊22之间形成有用于引导乳汁流向所述出奶口223的引流间隙42；所述引流间隙42的开口朝向所述出奶口223。通过在喇叭口盖上设置导流部，使得在吸奶器吸取的过程中，使乳汁能够充分导入吸力气囊，便于使乳汁更加快速地通过出奶口223流入乳汁收集容器3。同时，如图4所示，当哺乳期母亲需要躺身使用本实用新型实施例1提供的免手扶吸奶器时，通过引流间隙42，能够有效地防止吸乳通道中的乳汁顺着喇叭口盖回流，防止哺乳期母亲躺着吸乳时发生洒奶的不良体验，可以更好地适应于躺着使用，对于产后腹部不适、剖宫产的女性来说，提供了极大的方便。

[0034] 通过同时设置上述硅胶单向阀(或鸭嘴阀)和引流间隙、可以多方面地地解决乳汁逆流、回流问题，防止哺乳期母亲躺着吸乳时发生洒奶的不良体验，更好地保障了躺身使用的可靠性。在实施时，可将吸力气囊22嵌套入三通壳体21，将三通壳体21分别与喇叭口盖1以及体积精巧的乳汁收集容器3连通；导流部11伸入吸力气囊22中，且与吸力气囊间形成有引流间隙42；同时，将防逆流机构安装于吸力气囊向下延伸的漏奶通道的口部，将三通壳体21与负压提供装置B气路连通，负压提供装置B为乳汁吸取器A提供模拟婴儿吮吸的吸力，即可构成一个免手扶、多层次防洒奶，易操作的适应于坐与躺着使用的免手扶吸奶器。

[0035] 为了进一步提升哺乳期妈妈的使用体验和吸乳时的优雅性及私密性，本实用新型实施例1提供的免手扶吸奶器，还包括罩杯外壳5，所述罩杯外壳5包覆于所述三通件2及部分所述喇叭口盖1的外侧；所述三通壳体21与所述乳汁收集容器3可拆卸固定连接；所述罩杯外壳5分别与所述喇叭口盖1、所述乳汁收集容器3可拆卸固定连接；所述三通壳体21上设置有用于与所述负压提供装置B气路连通的吸气孔柱211；所述负压提供装置B通过硅胶管6连通所述吸气孔柱211一侧的负压空间23；所述罩杯外壳5上开设有用于所述硅胶管6伸出的罩杯开口51。通过设置罩杯外壳，将其罩于乳汁吸取器外部并与乳汁收集容器固定连接，通过罩杯外壳覆盖三通件及喇叭口盖的透明材料，能够更好地保护哺乳期妈妈吸乳时的优雅性和私密性，还可以增强吸奶器整体结构的刚性和稳定性。在罩杯外壳5上开设用于硅胶管6伸出的罩杯开口51，便于硅胶管路伸出，可将罩杯开口51和三通壳体吸气孔柱211设置于同一轴线上，能够使得硅胶管路气路更加畅通。另一方面，由于罩杯外壳未完全包覆固定

于喇叭口盖上，且与乳汁收集容器固定连接，使得整体的免手扶吸奶器结构更加精巧集成化，十分小巧，便于携带和组装使用。

[0036] 进一步地，考虑到现有技术中，吸奶器连接奶瓶或其它乳汁收集容器体感较大，难以无痕地隐藏于衣物内。因此，在前述免手扶吸奶器结构的基础上，为了在实现部件精简的同时，尽可能减小乳汁吸取器的体积，使吸奶器整体具有更加精巧的体感，优选地，罩杯外壳5为四分之一半球状，所述罩杯外壳5与所述乳汁收集容器3固定后的整体外表面呈半球面状。通过将乳汁收集容器与罩杯外壳进行装配设计，使得乳汁吸取器构成了一个罩杯整体，这样一来，吸奶器的表面能够更好地与孕妇文胸进行贴合，部件精简、体量小巧，以至于便于藏匿于文胸内进行免手扶使用，穿戴及吸乳时隐秘性好、便携性好，可根据需要在多个场合隐蔽使用。虽然市场上也有罩杯状的吸奶器结构，但是其收集的乳汁一般直接存储于罩杯外壳内，没有另外的收集容器，密封稍有不到位乳汁容易从外壳泄漏，且倒奶操作不方便，容易洒出，而本实用新型实施例1提供的乳汁吸取器在可隐蔽使用的同时，乳汁收集容器固定于罩杯外壳的正下方，使得吸奶器操作简单且不易洒出。

[0037] 进一步地，为了缩短吸奶的时间，提高吸奶器的吸奶效率，本实用新型实施例1提供的坐与躺着均适用的免手扶吸奶器中，在所述吸力气囊22的表面设置有沟槽纹样，便于吸力气囊22快速鼓起和快速恢复。在本实用新型实施例1提供的乳汁吸取器A中，喇叭口盖1和三通壳体2只要能够实现可拆卸固定，即可实现装配。优选地，所述喇叭口盖1上设置有沿环状分布的凹槽部12，所述三通壳体21上设置有沿环状分布的凸起部212；或者，所述喇叭口盖上设置有沿环状分布的凸起部，所述三通壳体上设置有沿环状分布的凹槽部（与附图1～2中的实施方式相反，未在附图中示出，但该实施方式是本领域技术人员可以理解的），所述凹槽部与所述凸起部以旋转卡槽方式配合固定。通过旋转卡槽方式定位和固定，既拥有较好的连接紧固性，又能够快速进行定位和拆卸，对于哺乳期妈妈来说，装配拆卸十分方便，相对于例如螺纹装配方式来说，节省了不少吸奶器安装、拆除的时间，使用起来更加得心应手。优选地，所述吸力气囊22的入奶口222上设置有环状硅胶翻边221；所述喇叭口盖1上具有用于容纳所述环状硅胶翻边221的凹部13（参照图1）；所述三通壳体21固定于所述喇叭口盖1上时，所述环状硅胶翻边221嵌入所述凹部13并且所述三通壳体21压紧所述环状硅胶翻边221。通过设置硅胶翻边221，当吸奶器工作时，能够减轻喇叭口盖和三通壳体的振动。同时，增强了喇叭口盖和三通壳体固定连接的强度，在固定时，三通壳体压紧硅胶翻边，还利于为三通壳体和吸力气囊之间的变形空间，起到进一步的密封作用。

[0038] 本实用新型实施例1提供的适应于坐与躺使用的免手扶吸奶器，三通壳体和乳汁收集容器只要能够进行可拆卸固定，即可实现装配。优选地，所述乳汁收集容器3与所述三通壳体21通过卡扣方式可拆卸固定连接，即可以分别在乳汁收集容器3和三通壳体21上分别设置配合固定的卡扣连接件，这样一来，相对于传统的螺纹固定方式来说，通过卡扣配合固定一方面装配和拆卸更快，另一方面，卡扣连接方式更加适合的非标形态的乳汁收集容器（如图1～4所示中的乳汁收集容器3）进行固定，而螺纹方式无法适用于本实施例1中乳汁收集容器无法自由转动装配的场合。乳汁收集容器3只要能够与三通壳体21卡扣固定，即可实现本实用新型快速便捷进行固定的需求，对于具体的卡扣形式，本实用新型不作具体限定。作为一种优选的卡扣实施方式，如图1或2所示，在奶道出口213处的三通壳体21上设置定位件214，在乳汁收集容器3上设置奶瓶固定圈7；将定位件214与奶瓶固定圈7通过卡扣方

式可拆卸配合固定；其中，定位件214包括固定于三通壳体21外壁的第一圈状基座2141以及设置于第一圈状基座2141上的定位耳2142；第一圈状基座2141环绕奶道出口213设置；所述奶瓶固定圈7包括设置于乳汁收集容器3口部的第二圈状基座71以及与所述第二圈状基座71一体成型的卡接耳72，卡接耳72与定位耳2142可拆卸卡扣固定。当乳汁收集容器3固定于三通壳体21上时，第二圈状基座71与第一圈状基座2141密封贴合。这样一来，使得本卡扣固定的方式既实现了快速拆装，还具有较强的密封性，吸奶器在使用的过程中，收集至乳汁收集容器中的乳汁不易从两个圈状基座间的缝隙洒出。定位耳及卡接耳的数量均至少为两个，且优选地，使其均匀分布于第一圈状基座和第二圈状基座上，乳汁收集容器安装于三通壳体后，受力均衡。

[0039] 优选地，所述第一圈状基座2141贯穿有竖直方向开设的槽口21411；所述定位耳2142位于所述槽口21411的正上方；所述卡接耳72竖直延伸至所述第二圈状基座71的上方；所述卡接耳72可贯穿所述槽口21411与所述定位耳2142卡扣连接。通过在第一圈状基座上开设槽口，定位耳、卡接耳均竖直方向设置，便于加工，省去了折弯的成本、可以减小卡扣连接件占用的体积，有利于节省加工成本。

[0040] 对于定位耳2142与卡接耳72通过卡扣方式可形成互锁，可保障连接稳固性。当使用完毕后，可以将卡接耳72脱离定位耳2142来解开卡扣连接，不限于卡接耳上具体的卡扣配合结构，这是本领域技术人员可以理解的。优选地，如图1或2所示，可以在所述卡接耳72上设置通孔721，在所述定位耳2142上设置有凸柱21421；通过凸柱21421与所述通孔7121卡扣配合。由凸柱和通孔配合的卡扣结构简单、易于加工，在实施时，将卡接部的卡接耳的通孔固定于定位耳的凸柱上，在拆卸时，仅需要将卡接耳向外侧弹性变形，即可将其从凸柱上拆卸，拆卸时便于脱离，工作时通过弹性互锁，不易松脱，定位稳固。

[0041] 优选地，如图3或4所示，所述第一圈状基座2141的竖直剖面呈间隔镜像相对的倒“L”状；所述第二圈状基座71可嵌合于所述第一圈状基座2141中。参照图3或图4，当乳汁收集容器固定于三通壳体上，卡接耳穿过槽口与定位耳固定时，第二圈状基座可嵌于第一圈状基座的倒L形空间之内，可以减小奶瓶固定圈与定位件固定后的吸奶器整体体积。更优选地，所述乳汁收集容器3的口部顶端与所述第一圈状基座2141密封贴合，更好地增强了密封性能，防止乳汁溢出乳汁收集容器后渗透于第一圈状基座及第二圈状基座之间，而后流入乳汁收集容器影响乳汁质量。

[0042] 虽然本实用新型实施例1未给出在乳汁收集容器3上一体成型有奶瓶固定圈7的示意图，但是上述实施方式是本领域技术人员所能理解的。考虑到乳汁收集容器3的口部一体成型地设置奶瓶固定圈7的成本较高，若奶瓶固定圈7损坏，则乳汁收集容器3整体将报废，更换代价较大。因此，优选地，本实用新型实施例1提供的免手扶吸奶器中，可采用分体的卡扣固定方式，例如，将乳汁收集容器3的口部外壁与第二圈状基座71内壁可拆卸固定。例如，参照图1或2所示，在所述乳汁收集容器的口部外壁设置多个瓶口凸起部31，在所述第二圈状基座71的内壁上设置有多个与所述瓶口凸起部31对应的卡接槽711；所述瓶口凸起部31可嵌入所述卡接槽711；当所述瓶口凸起部31嵌入所述卡接槽711时，所述乳汁收集容器3的口部紧贴所述第二圈状基座71的内壁固定。在实施时，可以将乳汁收集容器3先与奶瓶固定圈7进行固定，然后，整体上与三通壳体21上的定位件214进行固定。通过分体设计，使得奶瓶固定圈能够单独批量生产，且万一奶瓶固定圈损坏，重新更换即可，相对于更换整体的乳

汁收集容器来说，更换成本降低，便于吸奶器的多次重复使用。当吸乳完成后，将奶瓶固定圈7与乳汁收集容器3整体一起从三通壳体21上脱离，再将乳汁收集容器3从奶瓶固定圈7上脱离，能够便于对奶瓶固定圈7进行清洗，防止细菌滋生。同时由于乳汁收集容器口部具有瓶口凸起部，可以进一步与匹配的凹槽盖体进行配合，便于对吸取的乳汁进行密封保存。

[0043] 考虑到现代哺乳期母亲具有较快的生活节奏，本实用新型实施例1提供的适用于坐与躺着使用的免手扶吸奶器，所述适应于坐与躺着使用的免手扶吸奶器包括两个相同的所述乳汁吸取器A，两个所述乳汁吸取器A均与所述负压提供装置B气路连接，这样一来，通过一个所述负压装置B可同时为两个所述乳汁吸取器A提供负压，以满足哺乳期妇女双边吸奶的需求，提高吸奶效率。

[0044] 本实用新型实施例1提供的适用于坐与躺着使用的免手扶吸奶器在实施时，可将吸力气囊22嵌套于三通壳体21中，在吸力气囊22上延伸的漏奶通道224口部安装防逆流机构(优选实施方式如图5或图6所示，在吸力气囊漏奶通道的口部安装单向阀固定圈411和硅胶单向阀41，也可以是鸭嘴阀)。然后，将三通壳体21与喇叭口盖1通过旋转卡槽旋紧相连，使其压紧吸力气囊22的外圈翻边221。接着，通过硅胶管6嵌入三通壳体21顶部的吸气孔柱211，将罩杯外壳5通过卡槽与喇叭口盖1紧扣相连，硅胶管6从罩杯外壳5顶部的罩杯开口51处伸出。三通壳体21通过奶瓶固定圈7与乳汁收集容器3的口部连接，奶瓶固定圈7靠近三通壳体21奶道出口213的一侧通过卡扣方式由下至上与三通壳体21相连，当吸奶器工作完成后，可实现方便地拆卸脱离，便于操作，且具有良好的连接稳固性。本实用新型实施例1提供的乳汁吸取器体积小巧，便于隐秘地藏匿于文胸中，实现免手扶及便携功能。对于硅胶管6，从罩杯外壳5开口51伸出的另一端连接负压提供装置B，负压提供装置B可以是小型的气泵或吸力控制器，并将其设计成小巧便携的形状，并能够很方便地放在口袋、手提包中等，以满足多种场合下的隐秘哺乳需求，实现即拿即用。使用完毕后，从文胸中取出乳汁吸取器A，直接拔下乳汁收集容器3并倒出乳汁即可，使用完成后只要将喇叭口盖1、吸力气囊22、防逆流机构(例如硅胶单向阀及其固定圈)、乳汁收集容器3进行拆卸并冲洗，即可进入下一次使用流程，十分方便。

[0045] 本领域技术人员应该理解，本领域技术人员结合现有技术以及上述实施例可以实现所述变化例，在此不予赘述。这样的变化例并不影响本实用新型的实质内容，在此不予赘述。

[0046] 以上对本实用新型的较佳实施例进行了描述。需要理解的是，本实用新型并不局限于上述特定实施方式，其中未尽详细描述的设备和结构应该理解为用本领域中的普通方式予以实施；任何熟悉本领域的技术人员，在不脱离本实用新型技术方案作出许多可能的变动和修饰，或修改为等同变化的等效实施例，这并不影响本实用新型的实质内容。因此，凡是未脱离本实用新型技术方案的内容，依据本实用新型的技术实质对以上实施例所做的任何简单修改、等同变化及修饰，均仍属于本实用新型技术方案保护的范围内。

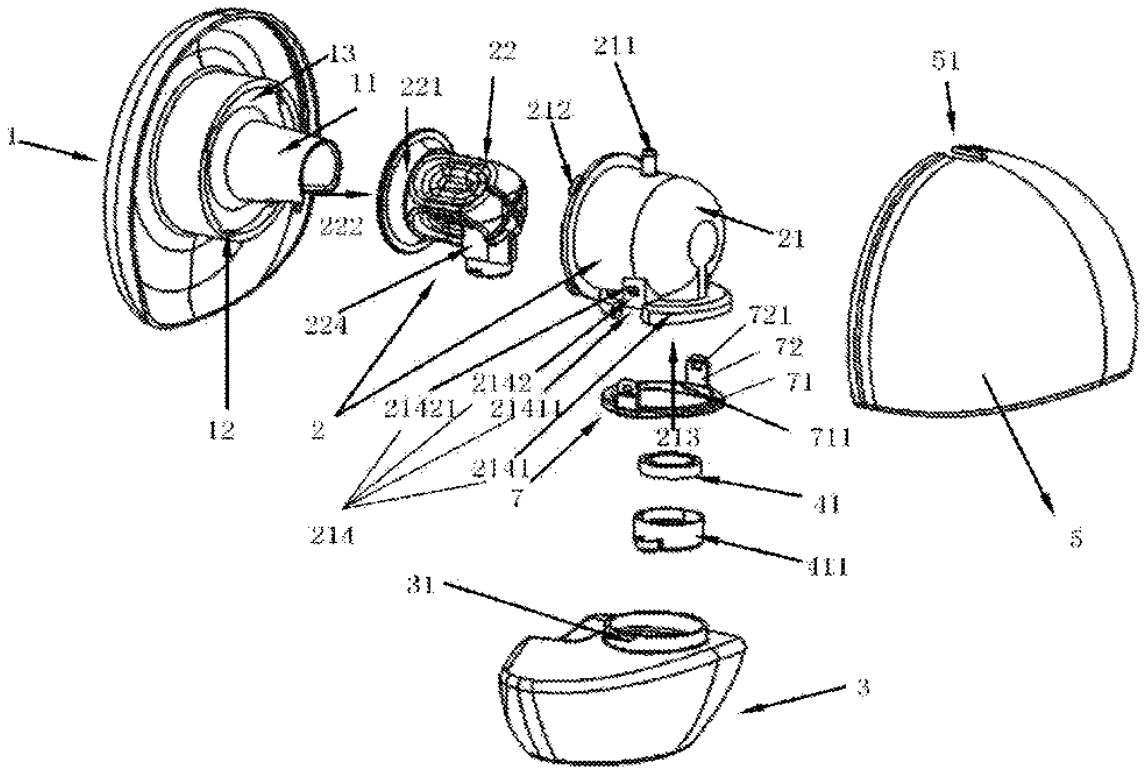

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图1

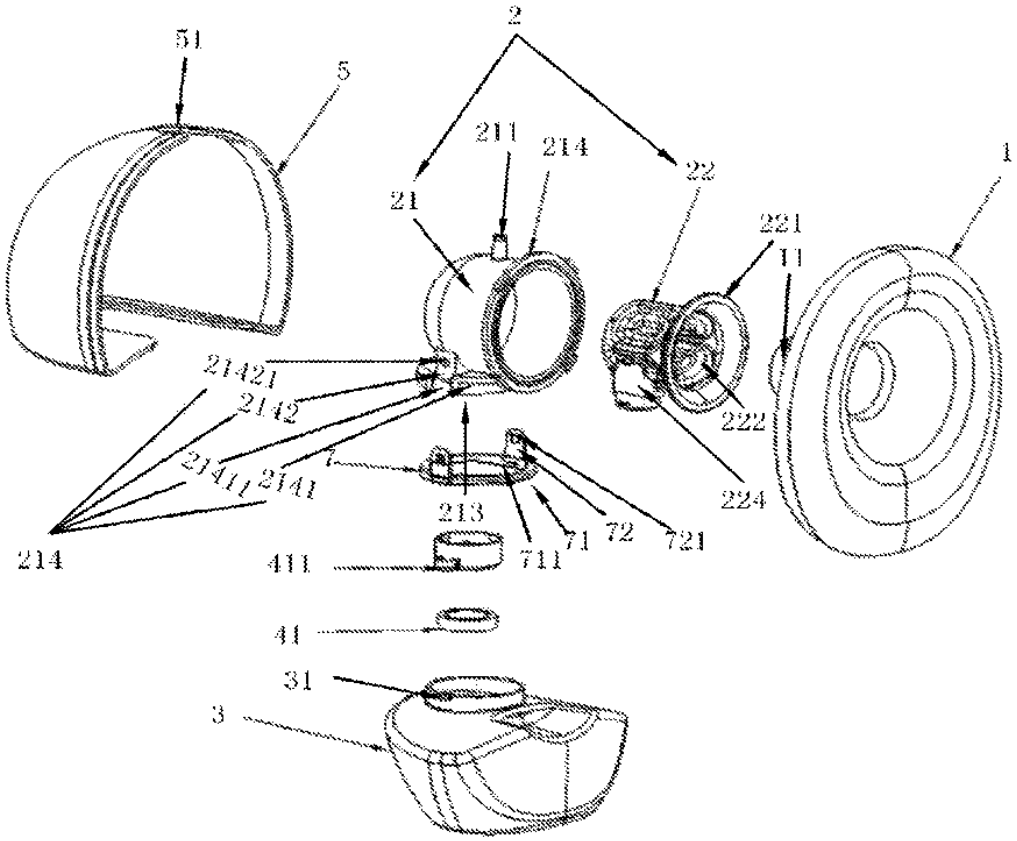

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图2

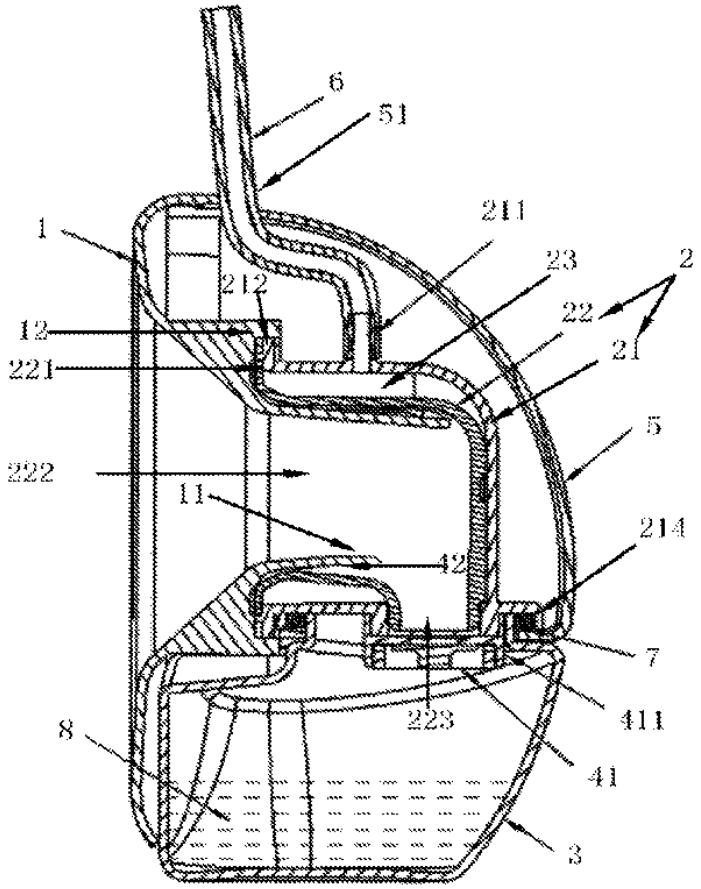


图3

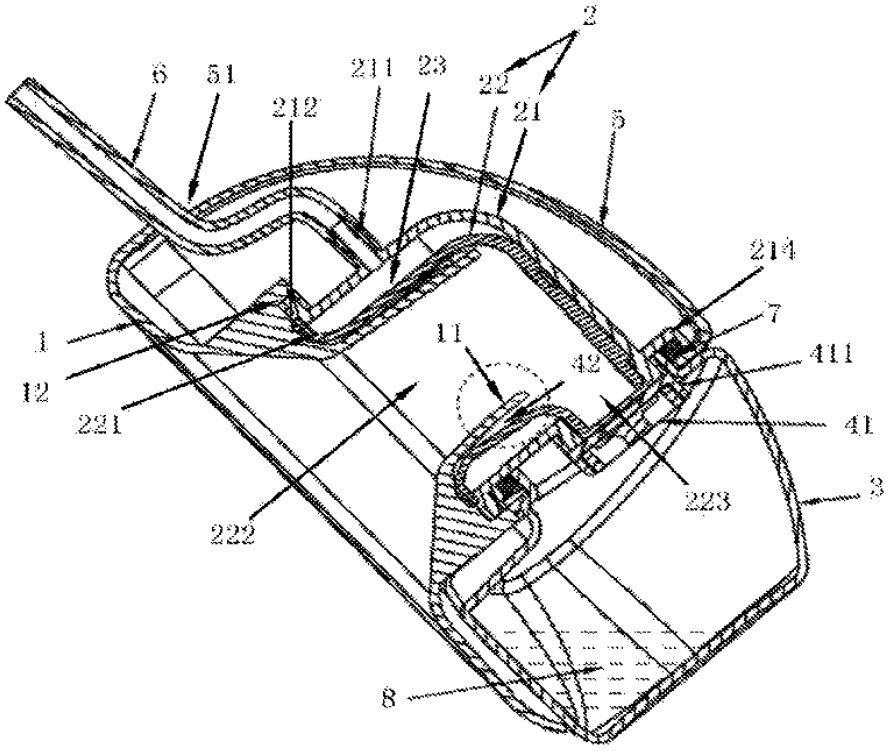


图4

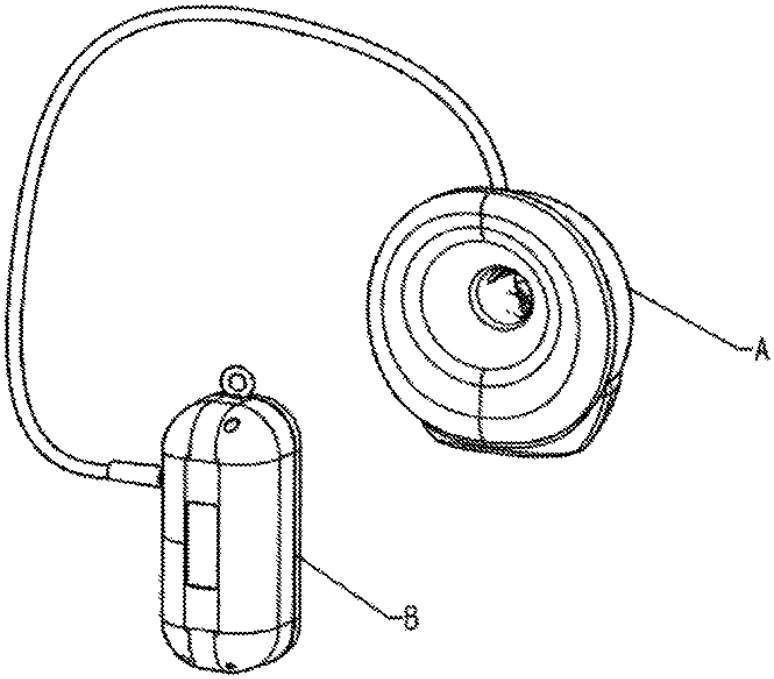


图5

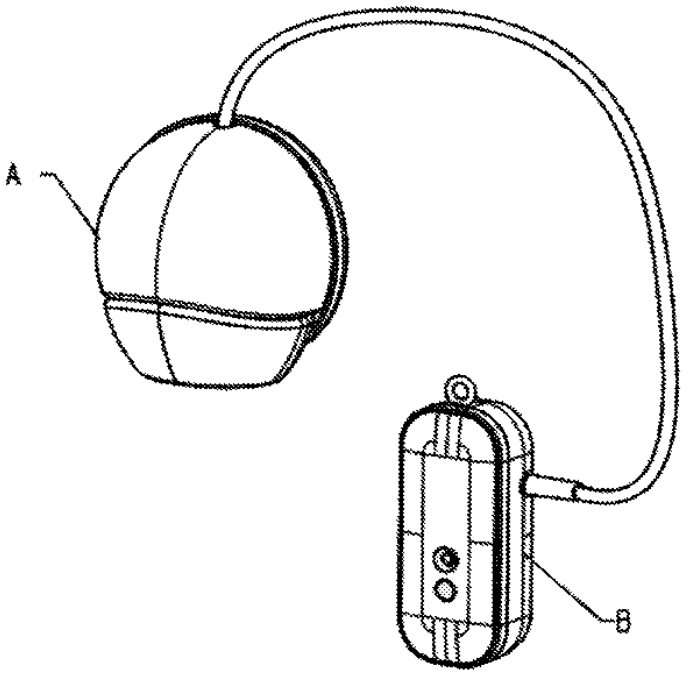


图6

14

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

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Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	002	US-6840918-B1	01-11-2005	BRITTO; James J. et al.	
	003	US-6887210-B2	05-03-2005	QUAY; Steven C.	
	004	US-7875000-B2	01-25-2011	KREBS; Yvonne et al.	
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	007	US-9919084-B2	03-20-2018	POLLEN; Ashia M. et al.	
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	010	US-10660995-B2	05-26-2020	MAKOWER; Joshua et al.	
	011	US-11717599-B2	08-08-2023	MILLER; Jared et al.	
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	019	US-20160213824-A1	07-28-2016	FRIDMAN; Ofer	

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	001	CN-105233355-A	01-13-2016	CHEN JUNBO.		☒

Examiner Signature		Date Considered	

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 4

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
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	003	CN-206473606-U	09-08-2017	SHANTOU HHQ ELECTRON TECH CO LTD.		☒
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	008	WO-2015069095-A1	05-14-2015	SEE JING YEU [MY]		☐
	009	WO-2016108616-A1	07-07-2016	DOOSAN ENGINE CO LTD [KR]		☒
	010	WO-9636298-A1	11-21-1996	SCIMED LIFE SYSTEMS INC [US], et al.		☐

Examiner Signature		Date Considered	

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	Examiner Name	FREDRICKSON, COURTNEY B
Sheet 3 of 4	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	CNET, "Pump on the go with the willow breast pump" 4 pages.	☐
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Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
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Sheet	4	of	4	Attorney Docket Number	4944.0120006

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.

☒ A certification statement is not submitted herewith.

FEE

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-12-03
Name/Print	Yangbeini Wang	Registration Number	800,005

23535945.1

Patents WO 2014/094187 A1

WO2014094187A1 - Breast shield unit having media separation

Breast shield unit having media separation

Abstract

The invention relates to a breast shield unit for use together with a breast pump for expressing human breast milk, comprising a breast shield (2) for receiving a mother's breast (B) and a media separating device (7, 9) for exerting a vacuum in the interior of the breast shield (2). Said breast shield (2) has a receiving area (33) for receiving a nipple of the mother's breast (B). The media separating device (7, 9) has a media separating diaphragm (9) which can be moved to and fro between two positions for the purpose of transmitting the vacuum. The media separating diaphragm (9) is located in the receiving area (33), at least in one of the two aforementioned positions. The breast shield unit according to the invention can be produced extremely compactly, despite integrated media separation, and minimizes the dead volume.

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- A61M1/064 Suction cups

View 4 more classifications

Landscapes

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Application PCT/CH2013/000220 events

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2015-07-09 Publication of WO2014094187A8

Show all events

Info: Patent citations (12), Cited by (26), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, PatentScope, Orbitus

Claims

Hide Dependent

PATENT CLAIMS

Breast shield unit for use with a breast pump for pumping out human breast milk, the breast shield unit having a breast shield (2) for receiving a mother's breast (B) and a media separation device (7, 9) for transmitting a vacuum into the interior of the breast shield (2), wherein the breast shield unit has a receiving area (33) for receiving a nipple of the mother's breast (B) and the media separation device (7, 9) has a media separation membrane (9) which can be moved back and forth between two positions for the purpose of transferring the vacuum, characterized in that that the media separation membrane (9) is located in at least one of the two positions mentioned in the receiving area (33).

Breast shield unit according to claim 1, wherein there is a tubular connector (32) which forms the receiving area (33) and which has an end remote from the breast, the media separation membrane (9) being arranged directly at this end.

Breast shield unit according to one of claims 1 or 2, wherein the breast shield unit has a connector (28) for connection to a milk collection container (5) and wherein the media separation membrane (9) is arranged approximately perpendicular to this connection (28).

Breast shield unit according to claim 1, wherein there is a milk flow path which runs from the collection area (33) to a connection (28) for connection to a milk collection container

(5) leads, and wherein the media separation membrane (9) is arranged in this milk flow path.

Breast shield unit according to claim 4, wherein the media separation membrane (9) interrupts and releases the milk flow path in accordance with a cyclically applied negative pressure.

6. Breast shield unit according to one of claims 1 or 4 to 5, wherein the receiving area (33) has a wall which is provided with openings (35), and wherein the media separation membrane (9) is on an outside of this wall in the area of the openings (35) is arranged.

7. Breast shield unit according to one of claims 1 or 4 to 6, wherein the breast shield unit has a connection (28) for connection to a milk collection container (5) and wherein the media separation membrane (9) is arranged approximately horizontally to this connection (28).

8. Breast shield unit according to one of claims 1 to 7, wherein a check valve (91) is arranged in a milk flow path, and wherein the check valve (91) is formed in one piece with the media separation membrane (9).

9. Breast shield unit according to one of claims 1 to 8, wherein the media separation device (7, 9) as a whole is arranged to be movable relative to the breast shield (2).

10. Breast shield unit according to claim 9, further comprising a breast shield insert (3) which can be fastened in the breast shield (2) and wherein the media separation device (7, 9) is movably suspended in the breast shield (2) by means of this breast shield insert (3). .

11. Breast shield unit according to one of claims 9 or 10, wherein the breast shield (2) has guide slots (24) extending in a longitudinal direction (a) of the breast shield (2), along which the media separation device (7, 9) can be moved as a whole .

12. Breast shield unit according to one of claims 9 to 11, wherein the media separation device (7, 9) has a dimensionally stable housing (70), the media separation membrane (9) being movably held therein.

13. Breast cap unit according to one of claims 9 to 12, wherein the breast cap (2) has a rear opening (23) at an end facing away from the mother's breast (B), whereby the media separation device (7, 9) can be accessed via this rear opening (23) can be moved manually towards the mother's breast (B).

14. Breast shield unit according to one of claims 9 to 13, wherein the breast shield (2) is dimensionally stable and wherein the breast shield unit further has a flexible breast shield insert (3) for insertion into the breast shield (2), the breast shield (2) having a first open one Breast shield end for contact with a mother's breast (B), the breast shield insert (3) having a first and a second insert end (34, 32) which define a longitudinal direction (a), the first open breast shield end having a circumferential edge (22). , to which the breast shield insert (3) can be attached or attached with the first insert end (31), the breast shield insert (3) in the assembled state being located from this first insert end (31) inside the breast shield

(2) extends to the second insert end (32), the breast shield insert (3) extending between the first and second insert ends (31, 32) substantially spaced from the breast shield (2), and the second insert end (32) in the assembled state the breast shield insert (3) can be moved in the longitudinal direction (a) relative to the breast shield (2).

15. Media separation device (7, 9) for use in a roasting hood unit according to one of claims 1 to 14, wherein the media separation device (7, 9) has a dimensionally stable housing (70) and a media separation membrane (9) arranged therein and wherein the housing (70) has a tubular receptacle (74) for receiving a breast shield (2) or a flexible breast shield insert (3) that can be inserted into a breast shield (2), this receptacle (74) having a receiving area (33) for receiving a nipple of a mother's breast (B) defined and wherein the media separation membrane (9) adjoins this receiving area (33) or protrudes into it.

16. Breast shield unit for use with a breast pump for pumping out human breast milk, the breast shield unit being a breast shield (2) Receiving a mother's breast (B) and a media separation device for transmitting a vacuum into the interior of the breast shield (2), the breast shield unit having a receiving area (33) for receiving a nipple of the mother's breast (B) and the media separating device having a media separation membrane (9), which can be moved back and forth between two positions for the purpose of transferring the vacuum, characterized in that the media separation membrane (9) adjoins the receiving area (33) at least in one of the two positions mentioned, the media separation membrane (9) being completely below the Recording area (33) is located.

Description

TITLE

Breast hood unit with media separation

TECHNICAL AREA

The present invention relates to a breast cup unit for use with a breast pump for pumping out human breast milk according to the preamble of patent claims 1 and 16, as well as a media separating device according to the preamble of patent claim 15.

STATE OF THE ART

Breast pumps for pumping human breast milk by means of negative pressure are well known. Manually operated as well as powered breast pumps are available on the market. They are connected either directly or via a vacuum line with a breast shield. The breast cap is applied to the mother's breast to be pumped down, so that at least the nipple, usually also the areola and the surrounding tissue of the mother's breast, are sealed. The breast shield is usually connected either directly or via a milk line with a milk collection container, so that pumped milk can flow directly into this container. Furthermore, media-separation devices for breast pumps are known. They serve to protect the vacuum pump from contamination by milk.

US 2004/0087898 discloses a breast cup unit having a coupling part for connection to a breast pump. In this connection part, a flexible media separation membrane is arranged, which transfers the applied vacuum into the cavity of the breast tube funnel and at the same time separates a milk flow path in the breast shield from a vacuum connection opening. WO 2009/057218 and WO 2011/0387841 also show such media separation membranes, which are arranged in a coupling part.

Although these media retarders offer advantages in terms of protection of the suction line and the breast pump, they nevertheless massively increase the volume of the breast cap. This is particularly in so-called "hands-free" solutions in which the breast cap is worn under clothing in a brassiere, unsuitable

PRESENTATION OF THE INVENTION

It is therefore an object of the invention to provide a breast shield unit with a media separating device, which is formed as compact and small as possible. This object is achieved by a breast shield unit having the features of patent claims 1 and 16 and a media separating device according to the preamble of patent claim 15.

The breast cup unit according to the invention for use with a breast pump for pumping out human breast milk has a breast shield for receiving a mother's breast and a media separating device for transmitting a vacuum into the interior of the breast shield. The breast cup unit has a receiving area for receiving a nipple of the mother's breast. The media separator has a media separation membrane which is reciprocable to transfer the vacuum between two positions. According to the invention, the media separating membrane is located in the receiving area at least in one of the two positions mentioned or, if it is arranged below the receiving area, adjoins it.

Since the medium separating membrane is arranged in the area of the nipple, the breast cup unit can be made extremely compact and small despite the medium separating device. Another significant advantage is that the dead volume, ie the volume to be evacuated during pumping in the breast shield is further minimized. The receiving area of the nipple and the movement space of the medium separating membrane necessary for the transfer of the vacuum partly share the same physical space. Nevertheless, nipple and membrane do not interfere with each other, as the movements occur synchronously. That is, when the membrane moves away from the breast, the nipple moves toward the membrane due to the vacuum transferred in the receiving area and, since the membrane has sufficiently moved away from the receiving area, also has sufficient space to expand. If the membrane subsequently expands again into the receiving area due to the cyclic pumping movement of the vacuum pump, the nipple retracts to its approximately natural length due to the increase in pressure in the receiving area. Therefore, the membrane is not disturbed in its movement and it can expand maximally in the receiving area. There is thus no risk that the media separation membrane is impaired in their mode of action. Also, the risk of the media separation membrane touching or sticking to the nipple and thus suppressing milk flow is virtually non-existent.

In a preferred embodiment, the medium separating membrane is arranged in the extension of the mother's breast at the rear of the breast cup device. Such breast cup units can be produced easily and inexpensively.

In a preferred embodiment, a tubular nozzle is provided which forms the receiving area and which has one end, wherein the media separating membrane is arranged directly at this end. The neck is preferably a part of the breast shield or a breast shield insert.

In a preferred embodiment, the breast cup unit has a connection for connection to a milk collection container, wherein the media separation membrane is arranged approximately perpendicular to this connection. By "approximately perpendicular" is here also understood an angle which differs from 0 ° to 20 °, preferably from 0 ° to 5 ° from the right angle.

In another preferred embodiment, a milk flow path is present which from the receiving area of the breast shield leads to a connection for connection to a milk collection container, wherein the media separating device is arranged in this milk flow path. The medium separating membrane preferably interrupts the milk flow path in accordance with a cyclically applied negative pressure and releases it again. This reduces the dead volume.

In a preferred embodiment, the receiving area, in particular the breast cap or the breast cap insert, has a wall which is provided with openings, wherein the media separating membrane is arranged on an outer side of this wall in the region of the openings. This definitely avoids the risk of the media separation membrane sticking to the nipple.

In a preferred embodiment, the breast cup unit has a connection for connection to a milk collection container, wherein the media separation membrane is arranged approximately horizontally to this connection. By "approximately horizontal" is here also understood an inclination angle, which is 0 ° to 20 °, preferably 0 ° to 5 °.

The three variants above have the advantage that the breast shield unit in the longitudinal direction of the breast shield can be made extremely short and compact. The media separator is located below the receiving area for the nipple and thus does not extend the breast shield. This variant is particularly advantageous in the case of "hands-free" units which are worn under the brassiere, and these variants can also be produced extremely cost-effectively and therefore also sold as disposable products.

In a preferred embodiment, a check valve is provided which separates the receiving area from a port for connection to a milk collection container, the check valve being formed integrally with the media separation membrane. This reduces the manufacturing costs.

In a preferred embodiment, the media separating device is arranged as a whole movable relative to the breast shield in the longitudinal direction. This is an independent one invention in which the medium separating membrane can also be arranged spaced from the receiving area for the nipple.

Preferably, the breast cup unit further comprises a breast cap insert which can be fastened in the brazier hood, wherein the media separating device is suspended movably in the breast cap by means of this breast cup insert.

In a preferred embodiment, the breast cap has guide slots extending in a longitudinal direction of the breast shield, along which the media separating device is movable as a whole. As a result, the movement is guided and limited.

The media separating device preferably has a dimensionally stable housing, wherein the media separating membrane is held movably therein.

In a preferred embodiment, the breast cap has a rear opening at an end facing away from the mother's breast, whereby the media separating device can be manually displaced, in particular pressed, by access via this rear opening in the longitudinal direction to the mother's breast. This facilitates the placement and adjustment of the breast cup unit to the mother's breast, especially when a breast shield or a breast shield insert with a flexible breast pad is used. Preferably, the media separating device is suspended by means of the flexible breast support on the housing. In a preferred embodiment, this suspension takes place in that a circumferential fastening collar of the breast support is slipped over a flange of the breast cap. The breast pad can be pushed forward out of the breast cap. Depending on the shape, it can even be everted. Now, when this breast pad is applied to the breast, it automatically assumes the shape of the breast. Depending on the shape, she folds into this breast adapted form. In a preferred embodiment, the breast shield is dimensionally stable. The breast cup unit further includes a flexible breast cup insert for insertion into the breast cup, the breast cup having a first open end of the breast cup for abutment with a mother's breast, and wherein the breast cup insert has a first and a second one insert end has, which define a longitudinal direction. The first open breast cup end has a peripheral edge to which the breast cup insert is attachable or secured to the first insert end, the breast cup insert extending from the first insert end inside the breast cup to the second insert end when assembled. The breastplate insert extends between the first and second insert ends substantially at a distance from the breastshield, wherein the second insert end is displaceable in the mounted state of the breastplate insert in the longitudinal direction relative to the breastplate. Preferably, the media separator is connected to the second insert end.

This embodiment prevents the nut from exerting too much and / or unevenly distributed pressure on the breast shield and thus on the breast. This would be painful in the long run and prevent optimal milk flow from the breast. In one embodiment, the media separating device according to the invention has a dimensionally stable housing and a media separating membrane arranged therein. The housing has a tubular receptacle for receiving a breast shield or an insertable into a breast cup flexible breast cup insert, said receptacle defining a receiving area for receiving a nipple of a mother's breast and wherein the media separation membrane adjacent to this receptacle or projects into it.

Further embodiments are given in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will be described below with reference to the drawings, which are given by way of illustration only and are not to be interpreted as limiting. In the drawings show.

1 shows a longitudinal section through an inventive breast cup unit mounted on a milk collection container, in a first embodiment; a longitudinal section through an inventive breast cup unit mounted on a milk collection container, in a second embodiment; the breast cup unit according to Figure 2 in an enlarged view; a perspective view of the breast cup unit according to Figure 2 in a first position; the Brashaubeneinheit according to Figure 3 when applied to a mother's breast; a perspective view of the breast cup unit in the position according to Figure 5; the breast cup unit according to Figure 3 when resting on the mother's breast; the breast cup unit according to Figure 3 in an inclined position; a longitudinal section through an inventive Brashaubeneinheit mounted on a milk collection container, in a third embodiment and a longitudinal section through an inventive Brashaubeneinheit mounted on a milk collection container, in a fourth Ausführungsform.

Parts are labeled in the figures with the same reference numerals.

DESCRIPTION OF PREFERRED EMBODIMENTS

1 shows a first embodiment of an inventive Brashaubeneinheit is shown. It has a breast shield 2 and one connected to it Media separator 7 on.

The breast cap 2 has in this embodiment, a dimensionally stable or rigid body 25, preferably made of plastic, on. In this main body 25, a housing 70 of the media separating device 7 is held. The housing 70, as set forth with reference to the following embodiment, be arranged displaceably in the main body 25. However, it can also be firmly and immovably connected to this.

The main body 25 has a milk connection part 28 with a milk outlet opening, which serves for connection to a milk collecting container 5. A valve 8, preferably a check valve, is arranged on the housing 70 of the medium separating device or else on the milk terminal part 28, in order to limit the dead volume during pumping and to prevent backflow of the pumped milk. In this example, a duckbill valve is shown.

The milk connection part 28 and the milk collection container 5 may also have a different shape. The Milchanschlussteil 28 may also be part of the media separator 7 or it may be formed as a lid of the milk collection container. As a milk container, for example, bottles or bags can be used.

In the breast shield 2, a breast shield insert 3 is arranged. It is preferably made of a flexible material, in particular made of silicone. He has a breast pad 30, here in the form of a funnel body, which rests on the base near the end of the body 25 or is releasably secured thereto. The breast pad 30 preferably merges integrally into a socket 32, which in this example is fastened to the housing 70 of the media separating device 7. This type of fastening is particularly advantageous if, as explained below, the media separating device 7 is displaceable relative to the main body 25 of the breast shield 2. The attachment can be done in different ways. In this example, the nozzle 32 on a breast remote flange 329, which held in a corresponding receptacle of the housing 70, in particular snapped, is. The breast pad 30 is preferably at least partially elastic. However, it can also be dimensionally stable and even stiff. The nozzle 32 is preferably formed dimensionally stable, for example, although it is made of the same material as the breast pad 30, but has a greater wall thickness.

The breast pad 30 serves to rest on a mother's breast, with the nipple of the breast protruding into the socket 32. As a result, the nozzle 32 forms with its cavity a receiving area 33 for receiving the nipple. The housing 70 of the Medientrennvorrichtung 7 is preferably rigid or dimensionally stable and in particular made of plastic. On the housing 70 of the media separator 7, a vacuum port 71 is provided for connection to a vacuum pump, not shown. The connection can be made directly or via a suction line. The vacuum pump can be operated manually or by motor. On the housing 70, a milk outlet opening 77 is also provided, which is closed with said valve 8. In embodiments described below, this milk outlet opening is arranged in a Brusthaubenansatz recording 74 of the media separating device. Thus, a milk flow path is formed, through which pumped breast milk from the receiving region 33 through the milk outlet port 77, the valve 8 and the milk outlet 28 of the main body 25 can get into the milk collection container 5

The media separating device 7 has a media separating membrane 9, which is held movably in the housing 70. In this example, it is clamped between a breast distal flange 320 of the nozzle 32 and the housing 70. The media separating membrane 9 forms a wall near the chest and the housing 70 forms the breast-remote wall of a pumping chamber 90. The media separating membrane 9 is preferably made of silicone.

It is used to transmit a cyclically changing negative pressure applied via the vacuum connection 71 into the receiving region 33 of the breast cap insert 3 or the breast cap 2. If a negative pressure is cyclically fed into the pumping chamber 90 via the vacuum port 71, the medium separating membrane 9 moves synchronously thereto and transfers the negative pressure into a cavity, formed by the breast cap insert 3 and the mother's breast B. Milk is pumped off. The media separation membrane 9 prevents that pumped milk can get into the pumping chamber 90 and thus to the vacuum source. Rather, the milk flows through the milk outlet opening 77 upstream of the membrane 9 into the milk collecting container 5. The medium separating membrane 9 therefore moves back and forth between two positions. The first position is not shown in the figures. It is chest away and is reached when a negative pressure is applied. In this first position, the media separation membrane 9 is located in the rear region of the pumping chamber 90, ie at the rear wall of the housing 70. The second position is shown in the figures. She is close to the breast.

The media separation membrane 9 is arranged so that it is located in the receiving area 33 at least in one of these two positions. Usually, it protrudes at least in the second position close to the chest into this receiving region 33 and thus reduces the dead volume in said cavity.

FIGS. 2 to 8 show a further exemplary embodiment. The same parts are provided with the same reference numerals as in the first example.

In this embodiment, the breast shield 2 also has a housing-shaped main body 25. The breast cap 2 is also used for resting on the mother's breast B and at the same time for connection to the milk collection container 5. It also has a Milchanschlussteil 28, with which it can be connected to the milk collection 5. The breast shield 2 is preferably rigid or dimensionally stable and in particular made of plastic. The same applies to the housing 70 of the media separating device, which is arranged in the base body 25.

The milk outlet opening 77, which is provided with the check valve 8, leads through a passage opening 29 of the base body 25 in the milk collection container 5. On the housing 70 of the media separating device 7, a breast cover insert receptacle 74 is formed, which forms a receiving socket for the nozzle 32 of the insert 3. The nozzle 32 is formed in this embodiment as a free end and has no breast remote flange. The nozzle 32 of the insert 3 is immovable in use held in this receptacle 74. For example, it is held in an interference fit and can be removed for cleaning or replacement. However, it can not be non-destructively releasably connected to the media separator 7. An integrally formed on a first insert end 34 of the insert 3 mounting collar 31 is slipped over a flange 22 of the main body 25 of the breast cap 2.

The insert 3 is preferably formed similar to the insert according to the first example. Preferably, the support area 30 is slightly funnel-shaped. It can also be formed approximately or completely as a plane plane. Preferably, the length of the support region 30 is relatively short, i. a multiple shorter than the entire length of the insert 3.

As can be seen in FIG. 5, the media separating membrane 9 already reaches almost or exactly up to the end of the neck 32 of the insert 3 in the undeflected state. FIG. 7 shows that the neck 32 is dimensioned such that it lies within a standard size range Breast and nipple is filled in its entire length by the nipple. However, the media separation membrane 9 preferably does not touch the nipple during pumping, but moves synchronously in the same direction.

The media separating device 7 is preferably movable, in particular displaceably arranged in the base body 25 of the breast shield 2. This can also be the case in the example according to FIG. For this purpose, the main body 25 guide slots 24, in which guide tabs 76 of the housing 70 engage. This can be seen, for example, in FIG. The media separator 7 can be moved along these slots 24. The slots 24 may be rectilinear or curved. In this example, they are straightforward. The valve 8 and the milk outlet opening 77 lead in all positions of the media separator 7 relative to the main body 25 in the milk collection container 5, since the passage opening 29 is formed larger than the valve 8 and the milk outlet 77. Preferably, the passage opening 29 is formed as a slot. The rear end of the main body 25 facing away from the breast is open. The media separation unit 7 can be moved manually via this rear opening 23, here move along the slots 24. In FIGS. 2 to 4, the breast shield unit is shown in the unused or currently unused state. The media separating device 7 protrudes through the rear opening 23 or is located at least in a rear area. The breast pad 30 of the insert 3 is relaxed or not deflected and slightly funnel shaped in this example.

To use the breast cap unit, the media separator 7 is pushed forward by hand, as shown in Figs. The breast pad 30 of the insert 3 is stretched, slipped forward as needed to the mother's breast B out. The nipple can be optimally received in the receiving opening 33. Now, if the manual pressure on the housing 70 is released, the base body 25, however, still held by hand, in a brassiere or other holding device to the chest, so pushes the housing 70 along the slots 24 to the rear and the insert. 3 is tight, but without excessive pressure on the chest B on. This is shown in FIG. The pumping can begin.

The second insert end of the Brusthaubenansatzes 3, i. the nozzle 32 is thus displaceable relative to the breast cap 2, wherein the displacement takes place together with the media separating device 7. Depending on the shape of the guide slots 24, it is also possible to tilt the media separating device 7 relative to the breast cap 2. This is shown in FIG. Preferably, it can be tilted in different directions.

In the two embodiments mentioned above, the medium separating membrane 9 is arranged approximately perpendicular to the connecting part 28, ie approximately perpendicular to the longitudinal direction a of the breast shield 2 and of the breast shield insert 3. In contrast, in the two exemplary embodiments described below, the media separating membrane is approximately horizontal, ie, arranged approximately parallel to the milk connection part or in the milk flow path. FIG. 9 again shows a breast cap 2 according to the invention with a media separating membrane 9 mounted on a milk collecting container 5.

The breast cap 2 in turn has the dimensionally stable, preferably rigid basic body 25 with a milk connection part 28 for attachment to the milk collecting container 5. In the main body 5, in turn, a breast shield insert 3 is arranged, which is preferably designed to be flexible. However, it can also be dimensionally stable, in particular rigid. Likewise, it may be formed integrally with the brake hood 2. The insert 3 defines at its distal, closed end 26 the receiving area 33. A lower wall of the insert 3 or the breast cap 2 is formed as a passage opening 36. The wall is preferably partially formed as a passage opening. Below this opening, the media separation membrane 9 is arranged. It is preferably held clamped between breast shield 2 and insert element 3. The media separation membrane 9 closes the opening 36, wherein it releases depending on the applied negative pressure and thus opens a milk flow path between receiving area 33 and milk collection 5.

Below the passage opening 36 and the media separation membrane 9 is the pumping chamber 90, from which a vacuum channel 250 leads to the outside. The remaining wall of the pumping chamber 90 is formed by the main body 25, or by the Milchanschlussteil 28. The vacuum channel 250 runs in the main body 25 or in the milk terminal part 28. Thus, the breast cap 2 also forms the medium separating device.

The milk flow path or milk channel 251 leads from the passage opening 36 to the milk collection container 5. It is laterally deflected due to the medium separating membrane 9 and extends, preferably in the region close to the chest, laterally to the pumping chamber 90. In this case, it preferably runs through the point of use of the medium separating membrane in use position Milk remains on the membrane. This milk channel 251 is preferably closable by a check valve 91. The Check valve 91 is preferably integrally formed with the media separation membrane 9.

The Ausfuß approximately form according to Figure 10 substantially corresponds to that according to Figure 9. Here, however, the bottom wall of the insert 3 is formed closed except for a few openings 35. As a result, an upper boundary for the medium separating membrane 9 is given and the nipple can not contact this membrane 9.

The inventive Brusthaubeneinheit can be produced extremely compact despite integrated media separation and minimizes Totvolumen.

REFERENCE LIST Breast cap

Flange 5 milk tank rear opening

Guide slot 7 Media separator Base body 70 Housing

Vacuum channel 71 Vacuum connection milk channel 74 Breast cover insert closed end

Milk connection part 76 guide nose

Feedthrough opening 77 Milk outlet opening Breast cover insert 8 Valve

breast pad

Mounting collar 9 Media separating diaphragm Connecting piece 99 Pumping chamber

Flange 91 Check valve intake opening

first deployment end B chest

Breakthroughs T dead volume

Passage opening a longitudinal direction

Patent Citations (12)

Publication number	Priority date	Publication date	Assignee	Title
EP1054697A1 *	1998-03-06	2000-09-13	Ameda AG	Suction bell for breast pump
US20040087898A1	2002-11-01	2004-05-06	Gotthilf Weniger	Breast pump assembly
US20070060873A1 *	2005-09-15	2007-03-15	Katsuyuki Hiraoka	Milking apparatus
WO2008057218A2	2006-11-01	2008-05-15	Medela Holding Ag	Self-returning contamination barrier
WO2011038784A1	2009-09-29	2011-04-07	Nokia Siemens Networks Oy	A method and apparatus
EP2308523A1 *	2001-06-22	2011-04-13	Medela Holding AG	Breastshield
EP2441481A1 *	2010-10-15	2012-04-18	Koninklijke Philips Electronics N.V.	A breast pump
Family To Family Citations				
JP5079364B2 *	2007-03-27	2012-11-21	ピジョン株式会社	Milking machine
CN201431561Y *	2009-06-25	2010-03-31	潘燕卓	Breast pump
EP2324868A1 *	2009-07-28	2011-05-25	Koninklijke Philips Electronics N.V.	Flexible drive for breast pump
WO2011035446A1 *	2009-09-22	2011-03-31	Medela Holding Ag	Breast shield for expressing human breast milk
CN201960093U *	2011-01-26	2011-09-14	上海福爱医疗器械有限公司	Negative pressure adjustable valve membrane device for balancing breast pump

* Cited by examiner, † Cited by third party

Cited By (28)

Publication number	Priority date	Publication date	Assignee	Title
WO2015131677A1	2015-02-20	2015-09-25	Medela Holding Ag	Adapter having a media separation membrane for a breast shield
WO2018041355A1 *	2016-09-02	2018-03-08	Medela Holding Ag	Breast cup
Family To Family Citations				
US8187227B2	2006-11-01	2012-05-29	Medela Holding Ag	Self returning contamination barrier
US9616156B2	2013-03-24	2017-04-11	Naya Health, Inc.	Method, apparatus, and system for expression and quantification of human breast milk
CH708490A1 *	2013-07-15	2015-01-30	Medela Holding Ag	Breastpump unit.
US20160000980A1 *	2014-03-20	2016-01-07	Naya Health, Inc.	Pump apparatus and methods for expression of human breast milk
US10517985B2	2014-03-29	2020-04-14	Exploramed Nc7, Inc.	Fluid measuring reservoir for breast pumps
WO2015007561A1	2014-07-07	2015-01-14	Naya Health, Inc.	Methods and apparatus for transferring pressure during expression of human breast milk
WO2015044802A1	2014-09-19	2015-03-24	Naya Health, Inc.	Quantification and inventory management of expressed human breast milk
EP3058966A1	2015-02-20	2016-08-24	Medela Holding AG	Breast cup
USD788303S1 *	2015-02-20	2017-04-11	Medela Holding Ag	Breastshield connector for breast pump
USD785160S1 *	2015-02-20	2017-04-25	Medela Holding Ag	Membrane for a breastshield of a breast pump
BR112015012602A2	2013-12-02	2019-11-19	Koninklijke Philips Nv	Breast Pump Device and Breast Pump Device Extraction Kit
CN109970806 *	2017-06-15	2023-11-03	安娜贝拉科技有限公司	Breast milk pump
CN113804879A *	2017-10-24	2023-03-17	美德乐控股公司	Breast pump
CN109835393B *	2017-11-27	2021-09-03	贵士株	Invisible milking device
EP3586356A1 *	2018-03-06	2019-09-11	Medela Holding AG	Breast shield
EP3597226A1 *	2018-07-17	2020-01-22	Mam Babyartikel Gesellschaft m.b.H.	Electric breast pump
US11504260B2	2018-10-04	2022-11-22	Lipocosm, Llc	Rigidifying brace
US11040894B2	2018-10-04	2021-06-22	Lipocosm, Llc	Rigidifying brace
CN110025462B *	2019-05-15	2023-12-12	宁波市瑞尔芭比医疗设备有限公司	Scraping instrument
SG10202000832TA *	2020-01-14	2021-08-30	Perfect Nature Pte Ltd	Hand free mobile app operating wearable breast pump with human breast contour ensure air tightness support by nursing bra for expressing milk while continuing work tasks and daily activities.
US12016985B2 *	2020-10-13	2024-06-25	Lansinoh Laboratories, Inc.	Breastmilk collection system
KR20210117159A *	2020-12-07	2021-09-27	엘앤씨	External vacuum tissue expander with non-adhesive rim
US12042458B2	2020-12-07	2024-07-23	Lipocosm, Llc	External vacuum tissue expander with slidable rim
WO2022128899A1 *	2020-12-15	2022-06-23	Medela Holding Ag	Breast shield and breast shield unit
US20230405193A1 *	2022-06-13	2023-12-21	Nooshee Inc.	Breast pump system and components and uses thereof
WO2024082957A1 *	2022-10-17	2024-04-25	陈水云	Integrated breast pump

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
EP2994161B1	2018-10-24	Breast shield unit having media separation
EP3329946B1	2019-12-04	Breastshield unit

EP2460265B1	2015-05-27	Breast shield for expressing human breast milk
EP2911715B1	2016-08-31	Breast shield with media separation
EP2914319B1	2018-01-03	Pumping unit for pumping breast milk
DE10009826C2	2002-03-14	Micro perfusion device with collection container
WO2013010286A1	2013-01-24	Breastshield unit
DE102004039692B3	2005-12-22	Milchabsaugvorrichtung
WO2014177544A1	2014-11-06	Liquid collection container for a device for providing a vacuum for medical applications, and device
WO2013177716A1	2013-12-05	Drainage container device and a suction pouch unit
WO2019080995A1	2019-05-02	Breast pump
DE102011052196A1	2013-01-31	Device for aspirating liquids and / or particles from body orifices
WO2016131681A1	2016-08-25	Breast cup
DE2204893A1	1972-08-24	Valve arrangement on a suction system for medical, hygienic and cosmetic purposes
DE202012008803U1	2013-12-16	Manual breastmilk pump
DE202011051604U1	2011-11-21	Funnel for a breast pump
DE2653832A1	1978-06-29	Medical pump for collecting human milk - has diaphragm raised and lowered by sloping faced cam disc rotated by electric motor
DE202016100154U1	2017-04-20	System for drainage of fluids or wound secretions
DE102005018335A1	2006-11-02	Device for stimulating an udder during a milking process
WO2019038755A1	2019-02-28	Baby mouth simulator
DE202013007660U1	2014-12-01	Breast attachment to a breastmilk pump
DE202004015907U1	2006-02-16	Infusion equipment for supplying infusion liquid to patient body, has plunger is adjustable from insertion position to extraction position for changing volume of dripping chamber to absorb liquid

Priority And Related Applications

Priority Applications (7)

Application	Priority date	Filing date	Title
CN201380066519.3A	2012-12-18	2013-12-12	Breast shield unit having media separation
EP13811344.4A	2012-12-18	2013-12-12	Breast shield unit having media separation
US14/651,505	2012-12-18	2013-12-12	Breast shield unit with media separation
KR1020157017876A	2012-12-18	2013-12-12	Breast shield unit having media separation
AU2013362755A	2012-12-18	2013-12-12	Breast shield unit having media separation
IL239216A	2012-12-18	2015-06-04	Breast shield unit having media separation
HK16101623.5A	2012-12-18	2016-02-15	Breast shield unit having media separation

Applications Claiming Priority (2)

Application	Filing date	Title
CH02839/12A	2012-12-18	Breastshield unit with media separation.
CH2839/12	2012-12-18	

Legal Events

Date	Code	Title	Description
2014-08-20	121	Ep: the epo has been informed by wipo that ep was designated in this application	**Ref document number:** 13811344 **Country of ref document:** EP

			Kind code of ref document: A1
2015-05-28	WWE	Wipo information: entry into national phase	**Ref document number:** 2013811344 **Country of ref document:** EP
2015-06-04	WWE	Wipo information: entry into national phase	**Ref document number:** 239216 **Country of ref document:** IL
2015-06-11	WWE	Wipo information: entry into national phase	**Ref document number:** 14651506 **Country of ref document:** US
2015-06-18	NENP	Non-entry into the national phase	**Ref country code:** DE
2015-07-02	ENP	Entry into the national phase	**Ref document number:** 2013362765 **Country of ref document:** AU **Date of ref document:** 20131212 **Kind code of ref document:** A
2015-07-03	ENP	Entry into the national phase	**Ref document number:** 20157017876 **Country of ref document:** KR **Kind code of ref document:** A

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
breast		title,claims,abstract,description	213	0.000
separation method		title,claims,abstract,description	49	0.000
nipple		claims,abstract,description	23	0.000
human milk		claims,abstract,description	7	0.000
milk		claims,description	69	0.000
milk		claims,description	69	0.000
milk		claims,description	69	0.000
membrane		claims,description	64	0.000
pumping		claims,description	18	0.000
insertion		claims,description	2	0.000
insertion		claims,description	2	0.000

Show all concepts from the description section

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(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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Internationales Büro

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WIPO | PCT

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2839/12 18. Dezember 2012 (18.12.2012) CH

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(81) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare nationale Schutzrechtsart)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Veröffentlicht:

— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

(54) Title: BREAST SHIELD UNIT HAVING MEDIA SEPARATION

(54) Bezeichnung : BRUSTHAUBENEINHEIT MIT MEDIENTRENNUNG

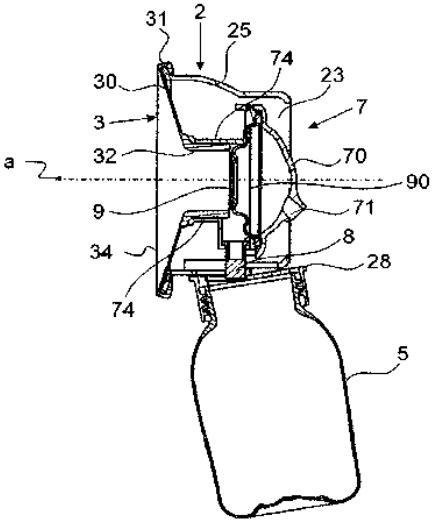


FIG. 2

(57) Abstract: The invention relates to a breast shield unit for use together with a breast pump for expressing human breast milk, comprising a breast shield (2) for receiving a mother's breast (B) and a media separating device (7, 9) for exerting a vacuum in the interior of the breast shield (2). Said breast shield (2) has a receiving area (33) for receiving a nipple of the mother's breast (B). The media separating device (7, 9) has a media separating diaphragm (9) which can be moved to and fro between two positions for the purpose of transmitting the vacuum. The media separating diaphragm (9) is located in the receiving area (33), at least in one of the two aforementioned positions. The breast shield unit according to the invention can be produced extremely compactly, despite integrated media separation, and minimizes the dead volume.

(57) Zusammenfassung: Eine Brusthaubeneinheit zur Verwendung mit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (2) zur Aufnahme einer Mutterbrust (B) und eine Medientrenneinrichtung (7, 9) zur Übertragung eines Vakuums in das Innere der Brusthaube (2) auf. Die Brusthaube (2) weist einen Aufnahmebereich (33) zur Aufnahme einer Brustwarze der Mutterbrust (B) auf. Die Medientrenneinrichtung (7, 9) weist eine Medientrennmembran (9) auf, welche zwecks Übertragung des Vakuums zwischen zwei Positionen hin und her bewegbar ist. Die Medientrennmembran (9) befindet sich mindestens in einer der zwei genannten Positionen im Aufnahmebereich (33). Die erfindungsgemässe Brusthaubeneinheit lässt sich trotz integrierter Medientrennung äusserst kompakt herstellen und minimiert das Totvolumen.

WO 2014/094187 A1

TITEL

Brusthaubeneinheit mit Medientrennung

TECHNISCHES GEBIET

Die vorliegende Erfindung betrifft eine Brusthaubeneinheit zur Verwendung mit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch gemäss Oberbegriff des Patentanspruchs 1 bzw. 16 sowie eine Medientrenneinrichtung gemäss Oberbegriff des Patentanspruchs 15.

STAND DER TECHNIK

Brustpumpen zum Abpumpen von menschlicher Muttermilch mittels Unterdruck sind hinlänglich bekannt. Auf dem Markt sind manuell betriebene wie auch motorisch betriebene Brustpumpen erhältlich. Sie sind entweder direkt oder über eine Vakuumleitung mit einer Brusthaube verbunden. Die Brusthaube wird an die abzupumpende Mutterbrust angelegt, so dass mindestens die Brustwarze, meistens auch die Areola und das umliegende Gewebe der Mutterbrust, dichtend umschlossen sind. Die Brusthaube ist üblicherweise entweder direkt oder über eine Milchleitung mit einem Milchsammelbehälter verbunden, so dass abgepumpte Milch direkt in diesen Behälter fliessen kann.

Ferner sind Medientrenneinrichtungen für Brustpumpen bekannt. Sie dienen dazu, die Vakuumpumpe vor Verschmutzung durch Milch zu schützen.

US 2004/0087898 offenbart eine Brusthaubeneinheit mit einem Kopplungsteil zur Verbindung mit einer Brustpumpe. In diesem Anschlussteil ist eine flexible Medientrennmembran angeordnet, welche das angelegte Vakuum in den Hohlraum des Brusthaubentrichters überträgt und gleichzeitig einen Milchflussweg in der Brusthaube von einer Vakuumanschlussöffnung trennt.

WO 2008/057218 und WO 2011/0387841 zeigen ebenfalls derartige Medientrennmembranen, welche in einem Kopplungsteil angeordnet sind.

Obwohl diese Medientrennvorrichtungen bezüglich Schutz der Saugleitung und der Brustpumpe Vorteile bringen, vergrössern sie das Volumen der Brusthaube doch massiv. Dies ist insbesondere bei sogenannten „Hands-free"-Lösungen, bei welchen die Brusthaube unter der Kleidung in einem Büstenhalter getragen wird, ungeeignet.

DARSTELLUNG DER ERFINDUNG

Es ist deshalb eine Aufgabe der Erfindung, eine Brusthaubeneinheit mit einer Medientrenneinrichtung zu schaffen, welche möglichst kompakt und klein ausgebildet ist.

Diese Aufgabe lösen eine Brusthaubeneinheit mit den Merkmalen des Patentanspruchs 1 bzw. 16 und eine Medientrenneinrichtung gemäss Oberbegriff des Patentanspruchs 15.

Die erfindungsgemässe Brusthaubeneinheit zur Verwendung mit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube zur Aufnahme einer Mutterbrust und eine Medientrenneinrichtung zur Übertragung eines Vakuums in das Innere der Brusthaube auf. Die Brusthaubeneinheit weist einen Aufnahmebereich zur Aufnahme einer Brustwarze der Mutterbrust auf. Die Medientrenneinrichtung weist eine Medientrennmembran auf, welche zwecks Übertragung des Vakuums zwischen zwei Positionen hin und her bewegbar ist. Erfindungsgemäss befindet sich die Medientrennmembran mindestens in einer der zwei genannten Positionen im Aufnahmebereich bzw. sie grenzt, wenn sie unterhalb des Aufnahmebereichs angeordnet ist, an diesen an.

Da die Medientrennmembran im Bereich der Brustwarze angeordnet ist, kann die Brusthaubeneinheit trotz Medientrenneinrichtung äusserst kompakt und klein ausgebildet werden. Ein weiterer wesentlicher Vorteil ist, dass das Totvolumen, d.h. das beim Abpumpen zu evakuierende Volumen in der Brusthaube weiter minimiert ist.

Der Aufnahmebereich der Brustwarze und der für die Übertragung des Vakuums notwendige Bewegungsraum der Medientrennmembran teilen sich teilweise denselben physischen Raum. Trotzdem stören sich Brustwarze und Membran nicht gegenseitig, da die Bewegungen synchron erfolgen. D.h. wenn sich die Membran von der Brust weg bewegt, bewegt sich die Brustwarze, aufgrund des im Aufnahmebereich übertragenen Vakuums zur Membran hin und hat, da sich die Membran aus dem Aufnahmebereich genügend entfernt hat, auch genügend Platz sich auszudehnen. Dehnt sich die Membran anschliessend aufgrund der zyklischen Pumpbewegung der Vakuumpumpe wieder in den Aufnahmebereich hinein aus, so zieht sich die Brustwarze aufgrund des Anstiegs des Drucks im Aufnahmebereich auf ihre annähernd natürliche Länge hin zurück. Deshalb wird die Membran in ihrer Bewegung nicht gestört und sie kann sich maximal in den Aufnahmebereich hin ausdehnen. Es besteht somit keinerlei Gefahr, dass die Medientrennmembran in ihrer Wirkungsweise beeinträchtigt wird. Auch das Risiko, dass die Medientrennmembran die Brustwarze berühren bzw. an ihr anhaften könnte und somit den Milchfluss unterdrücken könnte, ist praktisch inexistent.

In einem bevorzugten Ausführungsbeispiel ist die Medientrennmembran in der Verlängerung der Mutterbrust an der Hinterseite der Brusthaubeneinrichtung angeordnet. Derartige Brusthaubeneinheiten lassen sich einfach und kostengünstig herstellen.

In einer bevorzugten Ausführungsform ist ein rohrförmiger Stutzen vorhanden, welcher den Aufnahmebereich bildet und welcher ein Ende aufweist, wobei die Medientrennmembran unmittelbar an diesem Ende angeordnet ist. Der Stutzen ist vorzugsweise ein Teil der Brusthaube oder eines Brusthaubeneinsatzes.

In einer bevorzugten Ausführungsform weist die Brusthaubeneinheit einen Anschluss zur Verbindung mit einem Milchsammelbehälter auf, wobei die Medientrennmembran annähernd senkrecht zu diesem Anschluss angeordnet ist. Unter „annähernd senkrecht" wird hier auch ein Winkel verstanden, welcher sich von 0° bis 20°, vorzugsweise von 0° bis 5° vom rechten Winkel unterscheidet.

In einer anderen bevorzugten Ausführungsform ist ein Milchflussweg vorhanden, welcher

vom Aufnahmebereich der Brusthaube zu einem Anschluss zur Verbindung mit einem Milchsammelbehälter führt, wobei die Medientrenneinrichtung in diesem Milchflussweg angeordnet ist. Vorzugsweise unterbricht die Medientrennmembran den Milchflussweg nach Massgabe eines zyklisch angelegten Unterdrucks und gibt ihn wieder frei. Dies vermindert das Totvolumen.

In einer bevorzugten Ausführungsform weist der Aufnahmebereich, insbesondere der Brusthaube oder des Brusthaubeneinsatzes, eine Wand auf, welche mit Durchbrüchen versehen ist, wobei die Medientrennmembran auf einer Aussenseite dieser Wand im Bereich der Durchbrüche angeordnet ist. Dadurch wird das Risiko, dass die Medientrennmembran sich an der Brustwarze anhaftet, definitiv vermieden.

In einer bevorzugten Ausführungsform weist die Brusthaubeneinheit einen Anschluss zur Verbindung mit einem Milchsammelbehälter auf, wobei die Medientrennmembran annähernd waagrecht zu diesem Anschluss angeordnet ist. Unter „annähernd waagrecht" wird hier auch ein Neigungswinkel verstanden, welcher 0° bis 20°, vorzugsweise 0° bis 5° beträgt.

Die drei oben stehenden Varianten haben den Vorteil, dass die Brusthaubeneinheit in Längsrichtung der Brusthaube äusserst kurz und kompakt gestaltet werden kann. Die Medientrenneinrichtung befindet sich unterhalb des Aufnahmebereichs für die Brustwarze und verlängert die Brusthaube somit nicht. Diese Variante ist insbesondere bei „hands-free"-Einheiten, welche unter dem Büstenhalter getragen werden, vorteilhaft. Diese Varianten lassen sich zudem äusserst kostengünstig herstellen und deshalb auch als Einwegprodukte vertreiben.

In einer bevorzugten Ausführungsform ist ein Rückschlagventil vorhanden, welches den Aufnahmebereich von einem Anschluss zur Verbindung mit einem Milchsammelbehälter trennt, wobei das Rückschlagventil einstückig mit der Medientrennmembran ausgebildet ist. Dies reduziert die Herstellungskosten.

In einer bevorzugten Ausführungsform ist die Medientrenneinrichtung als Ganzes relativ zur Brusthaube in Längsrichtung bewegbar angeordnet. Dies ist eine eigenständige

Erfindung, bei welcher die Medientrennmembran auch beabstandet zum Aufnahmebereich für die Brustwarze angeordnet sein kann.

Vorzugsweise weist die Brusthaubeneinheit ferner einen Brusthaubeneinsatz auf, welcher in der Brusthaube befestigbar ist, wobei die Medientrenneinrichtung mittels dieses Brusthaubeneinsatzes in der Brusthaube bewegbar aufgehängt ist.

In einer bevorzugten Ausführungsform weist die Brusthaube sich in einer Längsrichtung der Brusthaube erstreckende Führungsschlitze auf, entlang welcher die Medientrenneinrichtung als Ganzes bewegbar ist. Dadurch ist die Bewegung geführt und begrenzt.

Vorzugsweise weist die Medientrenneinrichtung ein formstabiles Gehäuse auf, wobei die Medientrennmembran darin bewegbar gehalten ist.

In einer bevorzugten Ausführungsform weist die Brusthaube an einem der Mutterbrust abgewandten Ende eine rückseitige Öffnung auf, wodurch die Medientrenneinrichtung durch Zugang über diese rückseitige Öffnung in Längsrichtung zur Mutterbrust hin manuell verschiebbar, insbesondere drückbar ist. Dies erleichtert das Aufsetzen und Anpassen der Brusthaubeneinheit an die Mutterbrust, insbesondere wenn eine Brusthaube bzw. ein Brusthaubeneinsatz mit einer flexiblen Brustauflage verwendet wird. Vorzugsweise ist die Medientrennvorrichtung mittels der flexiblen Brustauflage am Gehäuse aufgehängt. In einer bevorzugten Ausführungsform erfolgt diese Aufhängung dadurch, dass ein umlaufender Befestigungskragen der Brustauflage über einen Flansch der Brusthaube gestülpt ist. Die Brustauflage lässt sich nach vorne aus der Brusthaube heraus drücken. Je nach Form lässt sie sich sogar umstülpen. Wird nun diese Brustauflage an die Brust angelegt, so nimmt sie automatisch die Form der Brust an. Je nach Form klappt sie dabei in diese der Brust angepasste Form um.

In einer bevorzugten Ausführungsform ist die Brusthaube formstabil ausgebildet. Die Brusthaubeneinheit weist ferner einen flexiblen Brusthaubeneinsatz zur Einlage in die Brusthaube auf, wobei die Brusthaube ein erstes offenes Brusthaubenende zur Anlage an eine Mutterbrust aufweist und wobei der Brusthaubeneinsatz ein erstes und ein zweites

Einsatzende aufweist, welche eine Längsrichtung definieren. Das erste offene Brusthaubenende weist einen umlaufenden Rand auf, an welchem der Brusthaubeneinsatz mit dem ersten Einsatzende befestigbar oder befestigt ist, wobei sich der Brusthaubeneinsatz im montierten Zustand von diesem ersten Einsatzende im Innern der Brusthaube zum zweiten Einsatzende erstreckt. Der Brusthaubeneinsatz verläuft zwischen dem ersten und dem zweiten Einsatzende im Wesentlichen beabstandet zur Brusthaube, wobei das zweite Einsatzende im montierten Zustand des Brusthaubeneinsatzes in Längsrichtung relativ zur Brusthaube verschiebbar ist. Vorzugsweise ist die Medientrenneinrichtung mit dem zweiten Einsatzende verbunden.

Diese Ausführungsform verhindert, dass die Mutter einen zu starken und/oder einen ungleichmässig verteilten Druck auf die Brusthaube und somit auf die Brust ausübt. Dies wäre auf die Dauer schmerzhaft und verhindert einen optimalen Milchfluss aus der Brust.

Die erfindungsgemässe Medientrenneinrichtung weist in einer Ausführungsform ein formstabiles Gehäuse und eine darin angeordnete Medientrennmembran auf. Das Gehäuse weist eine rohrförmige Aufnahme auf zur Aufnahme einer Brusthaube oder eines in eine Brusthaube einsetzbaren flexiblen Brusthaubeneinsatzes, wobei diese Aufnahme einen Aufnahmebereich zur Aufnahme einer Brustwarze einer Mutterbrust definiert und wobei die Medientrennmembran an diese Aufnahme angrenzt oder in sie hineinragt.

Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

Bevorzugte Ausführungsformen der Erfindung werden im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 einen Längsschnitt durch eine erfindungsgemässe Brusthaubeneinheit, montiert auf einem Milchsammelbehälter, in einer ersten Ausführungsform;

Figur 2 einen Längsschnitt durch eine erfindungsgemässe Brusthaubeneinheit, montiert auf einem Milchsammelbehälter, in einer zweiten Ausführungsform;

Figur 3 die Brusthaubeneinheit gemäss Figur 2 in einer vergrösserten Darstellung;

Figur 4 eine perspektivische Darstellung der Brusthaubeneinheit gemäss Figur 2 in einer ersten Position;

Figur 5 die Brusthaubeneinheit gemäss Figur 3 beim Anlegen auf eine Mutterbrust;

Figur 6 eine perspektivische Darstellung der Brusthaubeneinheit in der Position gemäss Figur 5;

Figur 7 die Brusthaubeneinheit gemäss Figur 3 bei Auflage auf die Mutterbrust;

Figur 8 die Brusthaubeneinheit gemäss Figur 3 in einer geneigten Position;

Figur 9 einen Längsschnitt durch eine erfindungsgemässe Brusthaubeneinheit, montiert auf einem Milchsammelbehälter, in einer dritten Ausführungsform und

Figur 10 einen Längsschnitt durch eine erfindungsgemässe Brusthaubeneinheit, montiert auf einem Milchsammelbehälter, in einer vierten Ausführungsform.

Gleiche Teile sind in den Figuren mit denselben Bezugszeichen beschriftet.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

In Figur 1 ist ein erstes Ausführungsbeispiel einer erfindungsgemässen Brusthaubeneinheit dargestellt. Sie weist eine Brusthaube 2 und eine mit ihr verbundene

Medientrenneinrichtung 7 auf.

Die Brusthaube 2 weist in dieser Ausführungsform einen formstabilen oder steifen Grundkörper 25, vorzugsweise aus Kunststoff, auf. In diesem Grundkörper 25 ist ein Gehäuse 70 der Medientrenneinrichtung 7 gehalten. Das Gehäuse 70 kann, wie anhand des nachfolgenden Ausführungsbeispiels dargelegt ist, verschiebbar im Grundkörper 25 angeordnet sein. Es kann jedoch auch fest und unverschiebbar mit diesem verbunden sein.

Der Grundkörper 25 weist einen Milchanschlussteil 28 mit einer Milchauslassöffnung auf, welcher zur Verbindung mit einem Milchsammelbehälter 5 dient. Am Gehäuse 70 der Medientrenneinrichtung oder auch am Milchanschlussteil 28 ist ein Ventil 8, vorzugsweise ein Rückschlagventil, angeordnet, um das Totvolumen beim Abpumpen zu begrenzen und ein Rückfliessen der abgepumpten Milch zu verhindern. In diesem Beispiel ist ein Entenschnabelventil dargestellt.

Der Milchanschlussteil 28 und der Milchsammelbehälter 5 können auch eine andere Form aufweisen. Das Milchanschlussteil 28 kann auch Bestandteil der Medientrenneinrichtung 7 sein oder er kann als Deckel des Milchsammelbehälters ausgebildet sein. Als Milchsammelbehälter lassen sich beispielsweise Flaschen oder Beutel einsetzen.

In der Brusthaube 2 ist ein Brusthaubeneinsatz 3 angeordnet. Er ist vorzugsweise aus einem flexiblen Material, insbesondere aus Silikon, gefertigt. Er weist eine Brustauflage 30, hier in Form eines Trichterkörpers, auf, welcher am brustnahen Ende am Grundkörper 25 anliegt oder an ihm lösbar befestigt ist. Die Brustauflage 30 geht vorzugsweise einstückig in einen Stutzen 32 über, welcher in diesem Beispiel am Gehäuse 70 der Medientrenneinrichtung 7 befestigt ist. Diese Art der Befestigung ist insbesondere dann vorteilhaft, wenn, wie nachfolgend erläutert ist, die Medientrenneinrichtung 7 relativ zum Grundkörper 25 der Brusthaube 2 verschiebbar ist. Die Befestigung kann auf verschiedene Arten erfolgen. In diesem Beispiel weist der Stutzen 32 einen brustfernen Flansch 320 auf, welcher in einer entsprechenden Aufnahme des Gehäuses 70 gehalten, insbesondere eingeschnappt, ist.

Die Brustauflage 30 ist vorzugsweise mindestens teilweise elastisch ausgebildet. Sie kann jedoch auch formstabil und sogar steif ausgebildet sein. Der Stutzen 32 ist vorzugsweise formstabiler ausgebildet, beispielsweise indem er zwar aus demselben Material wie die Brustauflage 30 gefertigt ist, aber eine grössere Wandstärke aufweist.

Die Brustauflage 30 dient zur Auflage auf eine Mutterbrust, wobei die Brustwarze der Brust bis in den Stutzen 32 hineinragt. Dadurch bildet der Stutzen 32 mit seinem Hohlraum einen Aufnahmebereich 33 zur Aufnahme der Brustwarze.

Das Gehäuse 70 der Medientrennrichtung 7 ist vorzugsweise steif oder formstabil und insbesondere aus Kunststoff ausgebildet. Am Gehäuse 70 der Medientrenneinrichtung 7 ist ein Vakuumanschluss 71 zur Verbindung mit einer nicht dargestellten Vakuumpumpe vorhanden. Die Verbindung kann direkt oder über eine Saugleitung erfolgen. Die Vakuumpumpe kann manuell oder motorisch betrieben sein. Am Gehäuse 70 ist ferner eine Milchauslassöffnung 77 vorhanden, welche mit dem genannten Ventil 8 verschlossen ist. In weiter unten beschriebenen Ausführungsformen ist diese Milchauslassöffnung in einer Brusthaubeneinsatz-Aufnahme 74 der Medientrenneinrichtung angeordnet. Somit ist ein Milchflussweg gebildet, durch welchen abgepumpte Muttermilch vom Aufnahmebereich 33 durch die Milchauslassöffnung 77, das Ventil 8 und den Milchauslass 28 des Grundkörpers 25 in den Milchsammelbehälter 5 gelangen kann.

Die Medientrenneinrichtung 7 weist eine Medientrennmembran 9 auf, welche im Gehäuse 70 bewegbar gehalten ist. In diesem Beispiel ist sie zwischen einem brustfernen Flansch 320 des Stutzens 32 und dem Gehäuse 70 eingeklemmt. Die Medientrennmembran 9 bildet eine brustnahe Wand und das Gehäuse 70 die brustferne Wand einer Pumpkammer 90. Die Medientrennmembran 9 ist vorzugsweise aus Silikon gefertigt.

Sie dient zur Übertragung eines über den Vakuumanschluss 71 angelegten zyklisch sich verändernden Unterdrucks in den Aufnahmebereich 33 des Brusthaubeneinsatzes 3 bzw. der Brusthaube 2. Wird über den Vakuumanschluss 71 zyklisch ein Unterdruck in die Pumpkammer 90 geleitet, so bewegt sich die Medientrennmembran 9 synchron dazu und überträgt den Unterdruck in einen Hohlraum, gebildet durch den Brusthaubeneinsatz 3 und die Mutterbrust B. Milch wird abgepumpt. Die Medientrennmembran 9 verhindert dabei,

dass abgepumpte Milch in die Pumpkammer 90 und somit zur Vakuumquelle gelangen kann. Die Milch fliesst vielmehr durch die der Membran 9 vorgelagerte Milchauslassöffnung 77 in den Milchsammelbehälter 5.

Die Medientrennmembran 9 bewegt sich somit zwischen zwei Positionen hin und her. Die erste Position ist in den Figuren nicht dargestellt. Sie ist brustfern und wird erreicht, wenn ein Unterdruck anliegt. In dieser ersten Position befindet sich die Medientrennmembran 9 im hinteren Bereich der Pumpkammer 90, d.h. bei der hinteren Wandung des Gehäuses 70. Die zweite Position ist in den Figuren dargestellt. Sie ist brustnah.

Die Medientrennmembran 9 ist so angeordnet, dass sie sich mindestens in einer dieser zwei Positionen im Aufnahmebereich 33 befindet. Üblicherweise ragt sie mindestens in der brustnahen zweiten Position in diesen Aufnahmebereich 33 hinein und vermindert so das Totvolumen im genannten Hohlraum.

In den Figuren 2 bis 8 ist ein weiteres Ausführungsbeispiel dargestellt. Gleiche Teile sind mit gleichen Bezugszeichen wie im ersten Beispiel versehen.

In dieser Ausführungsform weist die Brusthaube 2 ebenfalls einen gehäuseförmigen Grundkörper 25 auf. Die Brusthaube 2 dient ebenfalls zur Auflage auf die Mutterbrust B und gleichzeitig zur Verbindung mit dem Milchsammelbehälter 5. Sie weist ebenfalls ein Milchanschlussteil 28 auf, mit welchem sie mit dem Milchsammelbehälter 5 verbunden werden kann. Die Brusthaube 2 ist vorzugsweise steif oder formstabil und insbesondere aus Kunststoff gefertigt. Dasselbe gilt für das Gehäuse 70 der Medientrenneinrichtung, welche im Grundkörper 25 angeordnet ist.

Die Milchauslassöffnung 77, welche mit dem Rückschlagventil 8 versehen ist, führt durch eine Durchführungsöffnung 29 des Grundkörpers 25 in den Milchsammelbehälter 5.

Am Gehäuse 70 der Medientrenneinrichtung 7 ist eine Brusthaubeneinsatz-Aufnahme 74 angeformt, welche einen Aufnahmestutzen für den Stutzen 32 des Einsatzes 3 bildet. Der Stutzen 32 ist in dieser Ausführungsform als freies Ende ausgebildet und weist keinen brustfernen Flansch auf. Der Stutzen 32 des Einsatzes 3 ist bei Gebrauch unverschieblich

in dieser Aufnahme 74 gehalten. Er ist beispielsweise in einem Presssitz gehalten und kann zwecks Reinigung oder Ersatz entfernt werden. Er kann jedoch auch nicht zerstörungsfrei lösbar mit der Medientrenneinrichtung 7 verbunden sein. Ein an einem ersten Einsatzende 34 des Einsatzes 3 angeformter Befestigungskragen 31 ist über einen Flansch 22 des Grundkörpers 25 der Brusthaube 2 gestülpt.

Der Einsatz 3 ist vorzugsweise ähnlich ausgebildet wie der Einsatz gemäss dem ersten Beispiel. Vorzugsweise ist der Auflagebereich 30 leicht trichterförmig ausgebildet. Er kann auch annähernd bzw. ganz als plane Ebene ausgebildet sein. Vorzugsweise ist die Länge des Auflagebereichs 30 relativ kurz, d.h. ein Vielfaches kürzer als die gesamte Länge des Einsatzes 3.

Wie in Figur 5 erkennbar ist, reicht die Medientrennmembran 9 bereits im nicht ausgelenkten Zustand annähernd oder genau bis zum Ende des Stutzens 32 des Einsatzes 3. In Figur 7 ist erkennbar, dass der Stutzen 32 so bemessen ist, dass er bei einer im Normgrössenbereich liegenden Brust und Brustwarze in seiner gesamten Länge von der Brustwarze ausgefüllt ist. Die Medientrennmembran 9 berührt jedoch während des Abpumpens die Brustwarze vorzugsweise nicht, sondern sie bewegen sich synchron in dieselbe Richtung.

Die Medientrenneinrichtung 7 ist vorzugsweise beweglich, insbesondere verschiebbar im Grundkörper 25 der Brusthaube 2 angeordnet. Dies kann auch im Beispiel gemäss Figur 2 der Fall sein.

Hierzu weist der Grundkörper 25 Führungsschlitze 24 auf, in welche Führungsnasen 76 des Gehäuses 70 eingreifen. Dies ist beispielsweise in Figur 4 erkennbar. Die Medientrenneinrichtung 7 lässt sich entlang dieser Schlitze 24 verschieben. Die Schlitze 24 können geradlinig oder gekrümmt verlaufen. In diesem Beispiel sind sie geradlinig. Das Ventil 8 und die Milchauslassöffnung 77 führen in allen Positionen der Medientrenneinrichtung 7 relativ zum Grundkörper 25 in den Milchsammelbehälter 5, da die Durchführöffnung 29 grösser ausgebildet ist als das Ventil 8 und die Milchauslassöffnung 77. Vorzugsweise ist die Durchführungsöffnung 29 als Langloch ausgebildet.

Das hintere, der Brust abgewandte Ende des Grundkörpers 25 ist offen ausgebildet. Die Medientrenneinrichtung 7 lässt sich manuell über diese rückseitige Öffnung 23 bewegen, hier entlang der Schlitze 24 verschieben.

In den Figuren 2 bis 4 ist die Brusthaubeneinheit im unbenützten bzw. aktuell nicht benützten Zustand dargestellt. Die Medientrenneinrichtung 7 ragt durch die rückseitige Öffnung 23 heraus oder befindet sich zumindest in einem hinteren Bereich. Die Brustauflage 30 des Einsatzes 3 ist entspannt bzw. nicht ausgelenkt und in diesem Beispiel leicht trichterförmig.

Um die Brusthaubeneinheit zu verwenden, wird die Medientrenneinrichtung 7 von Hand nach vorne gestossen, wie dies in den Figuren 5 und 6 dargestellt ist. Die Brustauflage 30 des Einsatzes 3 wird gedehnt, je nach Bedarf nach vorne zur Mutterbrust B hin gestülpt. Die Brustwarze kann optimal in der Aufnahmeöffnung 33 aufgenommen werden. Wird nun der manuelle Druck auf das Gehäuse 70 gelöst, der Grundkörper 25 jedoch nach wie vor von Hand, in einem Büstenhalter oder einer anderen Haltevorrichtung an die Brust gehalten, so schiebt sich das Gehäuse 70 entlang der Schlitze 24 nach hinten und der Einsatz 3 liegt dichtend, jedoch ohne übermässigen Druck an der Brust B an. Dies ist in Figur 7 dargestellt. Das Abpumpen kann beginnen.

Das zweite Einsatzende des Brusthaubeneinsatzes 3, d.h. der Stutzen 32, ist somit relativ zur Brusthaube 2 verschiebbar, wobei die Verschiebung gemeinsam mit der Medientrenneinrichtung 7 erfolgt.

Je nach Form der Führungsschlitze 24 ist es auch möglich, die Medientrenneinrichtung 7 relativ zur Brusthaube 2 zu neigen. Dies ist in Figur 8 dargestellt. Vorzugsweise lässt sie sich in verschiedene Richtungen neigen.

In den zwei oben genannten Ausführungsformen ist die Medientrennmembran 9 annähernd senkrecht zum Anschlussteil 28, d.h. annähernd senkrecht zur Längsrichtung a der Brusthaube 2 und des Brusthaubeneinsatzes 3, angeordnet.

In den zwei nachfolgend beschriebenen Ausführungsbeispielen ist die Medientrennmembran hingegen annähernd horizontal, d.h. annähernd parallel zum Milchanschlussteil bzw. im Milchflussweg angeordnet.

In Figur 9 ist wiederum eine erfindungsgemässe Brusthaube 2 mit einer Medientrennmembran 9, montiert auf einem Milchsammelbehälter 5, dargestellt.

Die Brusthaube 2 weist wiederum den formstabilen, vorzugsweise steifen Grundkörper 25 mit einem Milchanschlussteil 28 zur Befestigung auf dem Milchsammelbehälter 5 auf. Im Grundkörper 5 ist wiederum ein Brusthaubeneinsatz 3 angeordnet, welcher vorzugsweise flexibel ausgebildet ist. Er kann jedoch auch formstabil, insbesondere steif ausgebildet sein. Ebenso kann er einstückig mit der Brusthaube 2 ausgebildet sein. Der Einsatz 3 definiert an seinem brustfernen, geschlossenen Ende 26 den Aufnahmebereich 33. Eine untere Wand des Einsatzes 3 bzw. der Brusthaube 2 ist als Durchlassöffnung 36 ausgebildet. Die Wand ist dabei vorzugsweise partial als Durchlassöffnung ausgebildet. Unterhalb dieser Öffnung ist die Medientrennmembran 9 angeordnet. Sie ist vorzugsweise zwischen Brusthaube 2 und Einsatzelement 3 eingeklemmt gehalten. Die Medientrennmembran 9 verschliesst die Öffnung 36, wobei sie je nach angelegtem Unterdruck diese frei gibt und somit einen Milchflussweg zwischen Aufnahmebereich 33 und Milchsammelbehälter 5 öffnet.

Unterhalb der Durchlassöffnung 36 und der Medientrennmembran 9 befindet sich die Pumpkammer 90, von welcher ein Vakuumkanal 250 nach aussen führt. Die übrige Wand der Pumpkammer 90 ist vom Grundkörper 25, bzw. vom Milchanschlussteil 28 gebildet. Der Vakuumkanal 250 verläuft im Grundkörper 25 bzw. im Milchanschlussteil 28. Somit bildet die Brusthaube 2 auch die Medientrenneinrichtung.

Der Milchflussweg oder Milchkanal 251 führt von der Durchlassöffnung 36 zum Milchsammelbehälter 5. Er ist aufgrund der Medientrennmembran 9 seitlich umgelenkt und verläuft, vorzugsweise im brustnahen Bereich, seitlich zur Pumpkammer 90. Dabei verläuft er vorzugsweise durch den in Gebrauchslage tiefsten Punkt der Medientrennmembran, damit keine Milch auf der Membran liegen bleibt. Dieser Milchkanal 251 ist vorzugsweise durch ein Rückschlagventil 91 verschliessbar. Das

Rückschlagventil 91 ist vorzugweise einstückig mit der Medientrennmembran 9 ausgebildet.

Die Ausführungsform gemäss Figur 10 entspricht im Wesentlichen derjenigen gemäss Figur 9. Hier ist die untere Wand des Einsatzes 3 jedoch bis auf einige Durchbrüche 35 geschlossen ausgebildet. Dadurch ist eine obere Begrenzung für die Medientrennmembran 9 gegeben und die Brustwarze kann diese Membran 9 nicht kontaktieren.

Die erfindungsgemässe Brusthaubeneinheit lässt sich trotz integrierter Medientrennung äusserst kompakt herstellen und minimiert das Totvolumen.

BEZUGSZEICHENLISTE

2	Brusthaube		
22	Flansch	5	Milchsammelbehälter
23	rückseitige Öffnung		
24	Führungsschlitz	7	Medientrenneinrichtung
25	Grundkörper	70	Gehäuse
250	Vakuumkanal	71	Vakuumanschluss
251	Milchkanal	74	Brusthaubeneinsatz-Aufnahme
26	geschlossenes Ende		
28	Milchanschlussteil	76	Führungsnase
29	Durchführungsöffnung	77	Milchauslassöffnung
3	Brusthaubeneinsatz	8	Ventil
30	Brustauflage		
31	Befestigungskragen	9	Medientrennmembran
32	Stutzen	90	Pumpkammer
320	Flansch	91	Rückschlagventil
33	Aufnahmeöffnung		
34	erstes Einsatzende	B	Brust
35	Durchbrüche	T	Totvolumen
36	Durchlassöffnung	a	Längsrichtung

PATENTANSPRÜCHE

1. Brusthaubeneinheit zur Verwendung mit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (2) zur Aufnahme einer Mutterbrust (B) und eine Medientrenneinrichtung (7, 9) zur Übertragung eines Vakuums in das Innere der Brusthaube (2) aufweist, wobei die Brusthaubeneinheit einen Aufnahmebereich (33) zur Aufnahme einer Brustwarze der Mutterbrust (B) aufweist und wobei die Medientrenneinrichtung (7, 9) eine Medientrennmembran (9) aufweist, welche zwecks Übertragung des Vakuums zwischen zwei Positionen hin und her bewegbar ist, dadurch gekennzeichnet, dass sich die Medientrennmembran (9) mindestens in einer der zwei genannten Positionen im Aufnahmebereich (33) befindet.

2. Brusthaubeneinheit nach Anspruch 1, wobei ein rohrförmiger Stutzen (32) vorhanden ist, welcher den Aufnahmebereich (33) bildet und welcher ein brustfernes Ende aufweist, wobei die Medientrennmembran (9) unmittelbar an diesem Ende angeordnet ist.

3. Brusthaubeneinheit nach einem der Ansprüche 1 oder 2, wobei die Brusthaubeneinheit einen Anschluss (28) zur Verbindung mit einem Milchsammelbehälter (5) aufweist und wobei die Medientrennmembran (9) annähernd senkrecht zu diesem Anschluss (28) angeordnet ist.

4. Brusthaubeneinheit nach Anspruch 1, wobei ein Milchflussweg vorhanden ist, welcher vom Aufnahmebereich (33) zu einem Anschluss (28) zur Verbindung mit einem Milchsammelbehälter (5) führt, und wobei die Medientrennmembran (9) in diesem Milchflussweg angeordnet ist.

5. Brusthaubeneinheit nach Anspruch 4, wobei die Medientrennmembran (9) nach Massgabe eines zyklisch angelegten Unterdrucks den Milchflussweg unterbricht und wieder freigibt.

6. Brusthaubeneinheit nach einem der Ansprüche 1 oder 4 bis 5, wobei der Aufnahmebereich (33) eine Wand aufweist, welche mit Durchbrüchen (35) versehen ist, und wobei die Medientrennmembran (9) auf einer Aussenseite dieser Wand im Bereich der Durchbrüche (35) angeordnet ist.

7. Brusthaubeneinheit nach einem der Ansprüche 1 oder 4 bis 6, wobei die Brusthaubeneinheit einen Anschluss (28) zur Verbindung mit einem Milchsammelbehälter (5) aufweist und wobei die Medientrennmembran (9) annähernd waagrecht zu diesem Anschluss (28) angeordnet ist.

8. Brusthaubeneinheit nach einem der Ansprüche 1 bis 7, wobei in einem Milchflussweg ein Rückschlagventil (91) angeordnet ist, und wobei das Rückschlagventil (91) einstückig mit der Medientrennmembran (9) ausgebildet ist.

9. Brusthaubeneinheit nach einem der Ansprüche 1 bis 8, wobei die Medientrenneinrichtung (7, 9) als Ganzes relativ zur Brusthaube (2) in dieser bewegbar angeordnet ist.

10. Brusthaubeneinheit nach Anspruch 9, wobei sie ferner einen Brusthaubeneinsatz (3) aufweist, welcher in der Brusthaube (2) befestigbar ist und wobei die Medientrenneinrichtung (7, 9) mittels dieses Brusthaubeneinsatzes (3) in der Brusthaube (2) bewegbar aufgehängt ist.

11. Brusthaubeneinheit nach einem der Ansprüche 9 oder 10, wobei die Brusthaube (2) sich in einer Längsrichtung (a) der Brusthaube (2) erstreckende Führungsschlitze (24) aufweist, entlang welcher die Medientrenneinrichtung (7, 9) als Ganzes bewegbar ist.

12. Brusthaubeneinheit nach einem der Ansprüche 9 bis 11, wobei die Medientrenneinrichtung (7, 9) ein formstabiles Gehäuse (70) aufweist, wobei die Medientrennmembran (9) darin bewegbar gehalten ist.

13. Brusthaubeneinheit nach einem der Ansprüche 9 bis 12, wobei die Brusthaube (2) an einem der Mutterbrust (B) abgewandten Ende eine rückseitige Öffnung (23) aufweist, wodurch die Medientrenneinrichtung (7, 9) durch Zugang über diese rückseitige Öffnung (23) zur Mutterbrust (B) hin manuell verschiebbar ist.

14. Brusthaubeneinheit nach einem der Ansprüche 9 bis 13, wobei die Brusthaube (2) formstabil ausgebildet ist und wobei die Brusthaubeneinheit ferner einen flexiblen Brusthaubeneinsatz (3) zur Einlage in die Brusthaube (2) aufweist, wobei die Brusthaube (2) ein erstes offenes Brusthaubenende zur Anlage an eine Mutterbrust (B) aufweist, wobei der Brusthaubeneinsatz (3) ein erstes und ein zweites Einsatzende (34, 32) aufweist, welche eine Längsrichtung (a) definieren, wobei das erste offene Brusthaubenende einen umlaufenden Rand (22) aufweist, an welchem der Brusthaubeneinsatz (3) mit dem ersten Einsatzende (31) befestigbar oder befestigt ist, wobei sich der Brusthaubeneinsatz (3) im montierten Zustand von diesem ersten Einsatzende (31) im Innern der Brusthaube (2) zum zweiten Einsatzende (32) erstreckt, wobei der Brusthaubeneinsatz (3) zwischen dem ersten und dem zweiten Einsatzende (31, 32) im Wesentlichen beabstandet zur Brusthaube (2) verläuft, und wobei das zweite Einsatzende (32) im montierten Zustand des Brusthaubeneinsatzes (3) in Längsrichtung (a) relativ zur Brusthaube (2) verschiebbar ist.

15. Medientrenneinrichtung (7, 9) zur Verwendung in einer Brusthaubeneinheit gemäss einem der Ansprüche 1 bis 14, wobei die Medientrenneinrichtung (7, 9) ein formstabiles Gehäuse (70) und eine darin angeordnete Medientrennmembran (9) aufweist und wobei das Gehäuse (70) eine rohrförmige Aufnahme (74) aufweist zur Aufnahme einer Brusthaube (2) oder eines in eine Brusthaube (2) einsetzbaren flexiblen Brusthaubeneinsatzes (3), wobei diese Aufnahme (74) einen Aufnahmebereich (33) zur Aufnahme einer Brustwarze einer Mutterbrust (B) definiert und wobei die Medientrennmembran (9) an diesen Aufnahmebereich (33) angrenzt oder in ihn hineinragt.

16. Brusthaubeneinheit zur Verwendung mit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (2) zur

Aufnahme einer Mutterbrust (B) und eine Medientrenneinrichtung zur Übertragung eines Vakuums in das Innere der Brusthaube (2) aufweist, wobei die Brusthaubeneinheit einen Aufnahmebereich (33) zur Aufnahme einer Brustwarze der Mutterbrust (B) aufweist und wobei die Medientrenneinrichtung eine Medientrennmembran (9) aufweist, welche zwecks Übertragung des Vakuums zwischen zwei Positionen hin und her bewegbar ist, dadurch gekennzeichnet, dass die Medientrennmembran (9) mindestens in einer der zwei genannten Positionen an den Aufnahmebereich (33) angrenzt, wobei sich die Medientrennmembran (9) vollständig unterhalb des Aufnahmebereichs (33) befindet.

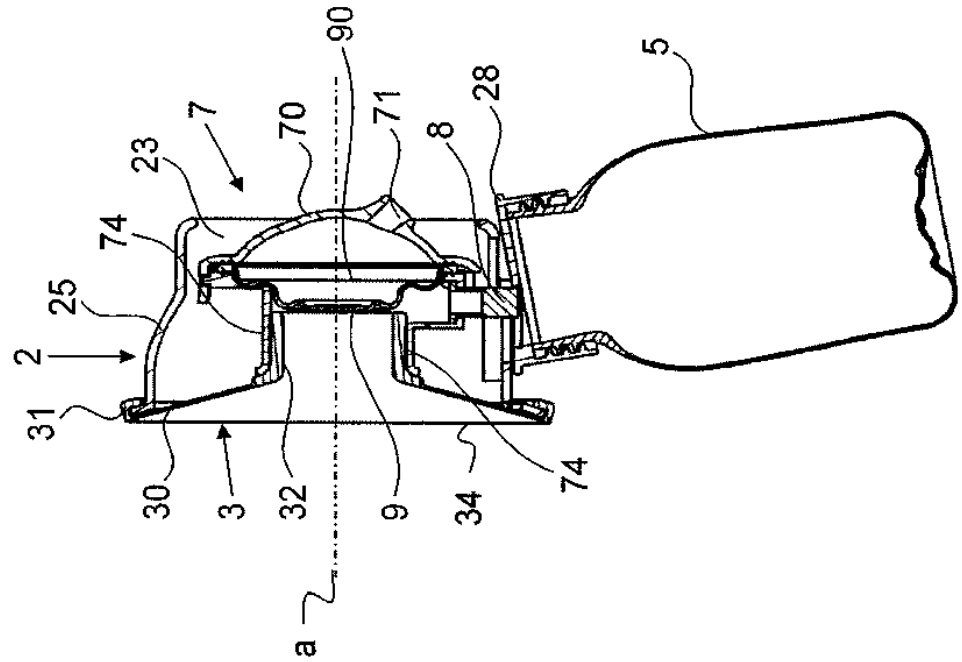

90
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3
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9
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74
a

FIG. 2

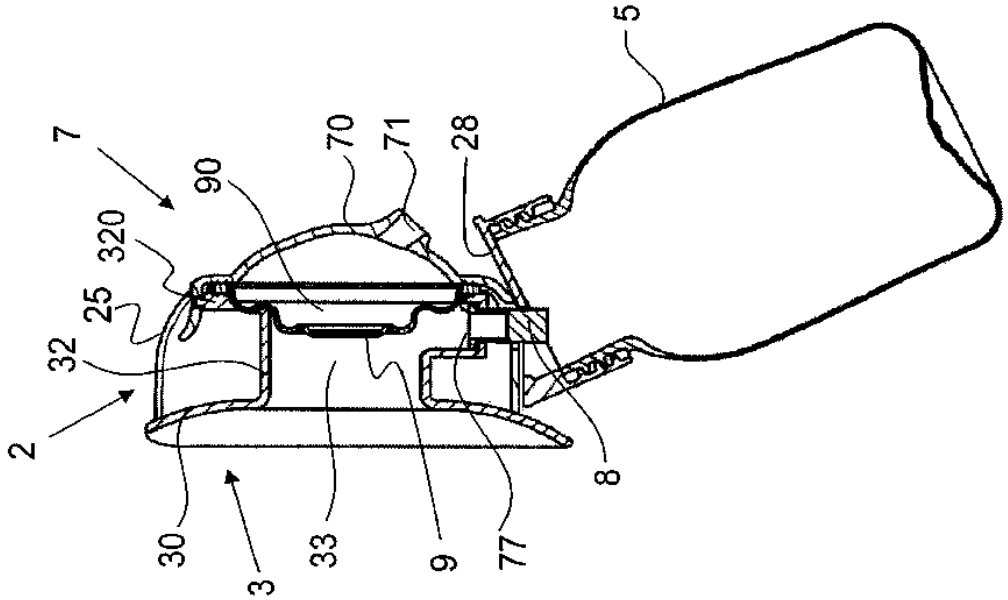

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FIG. 1

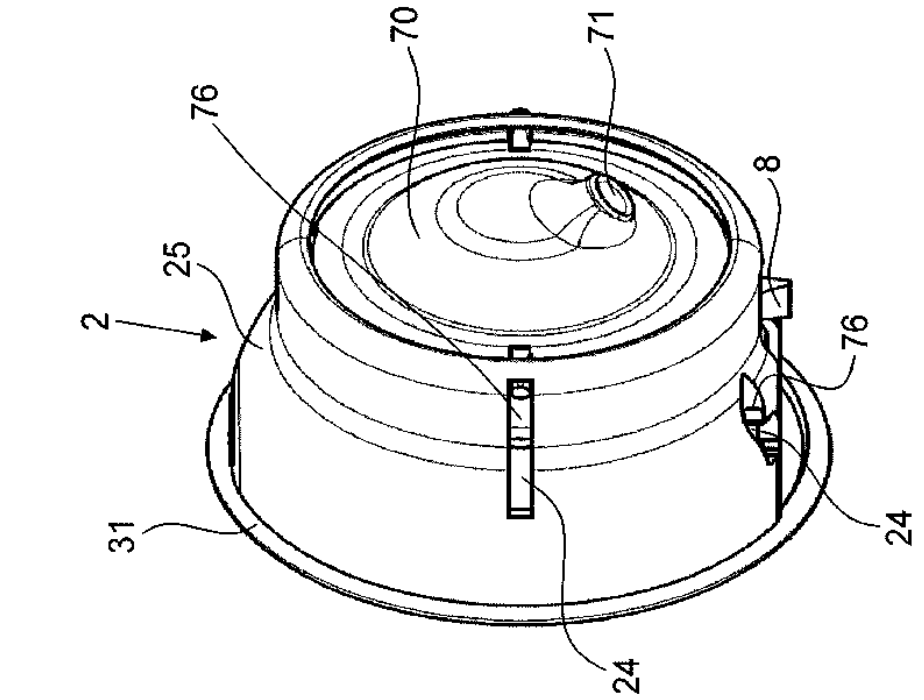

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FIG. 4

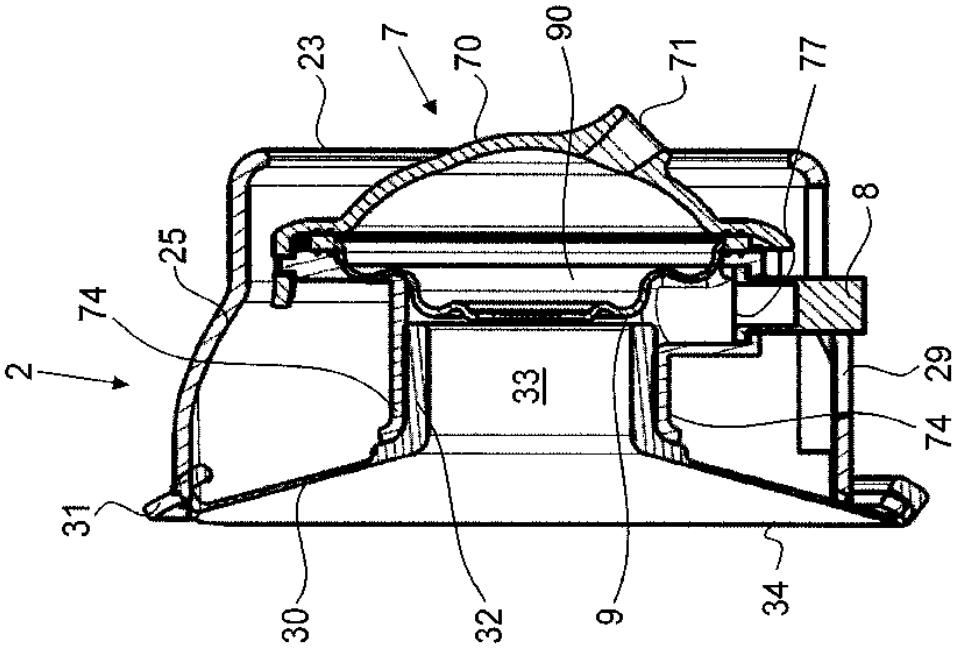

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9
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FIG. 3

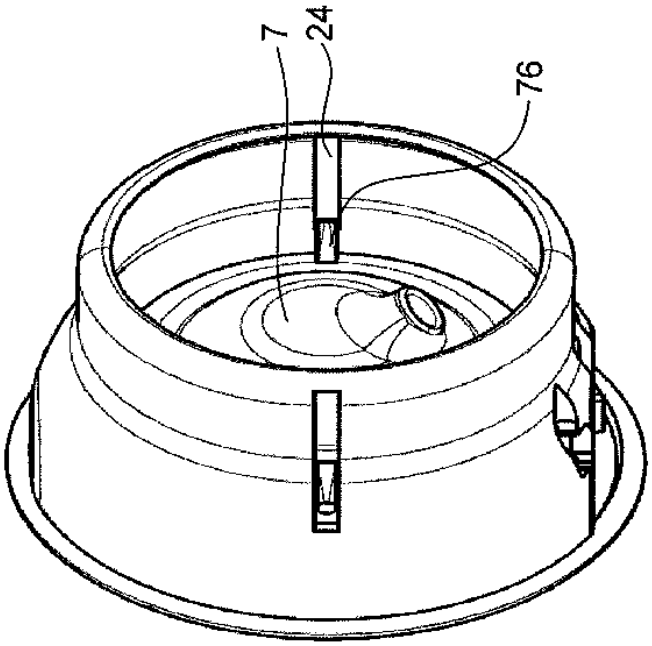


FIG. 6

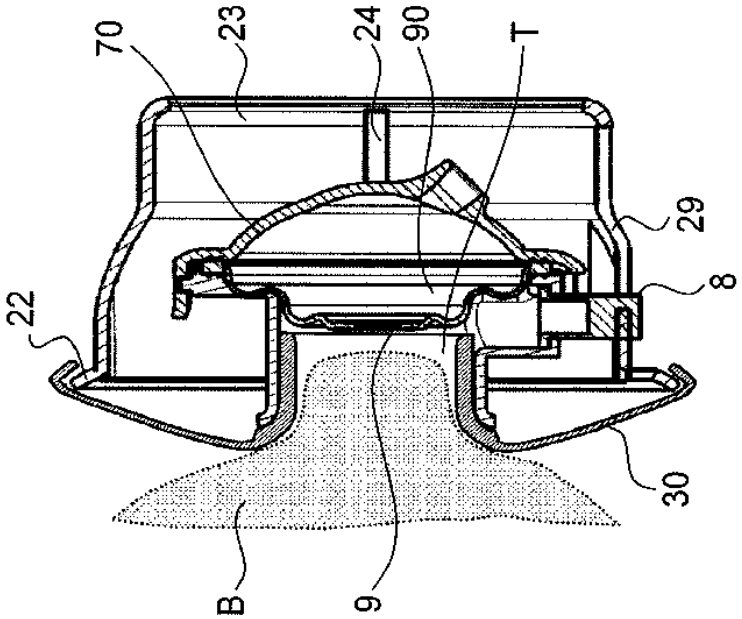


FIG. 5

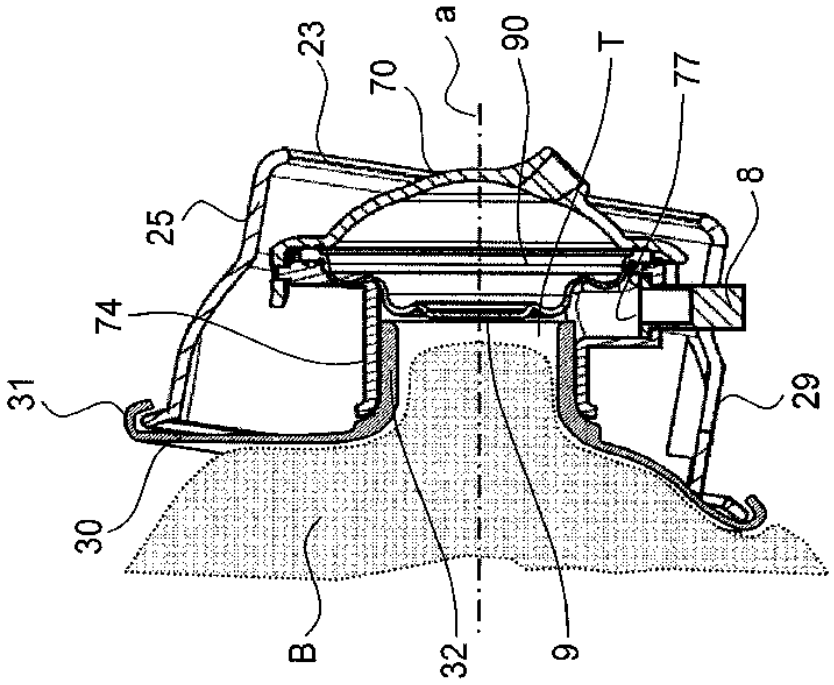


FIG. 8

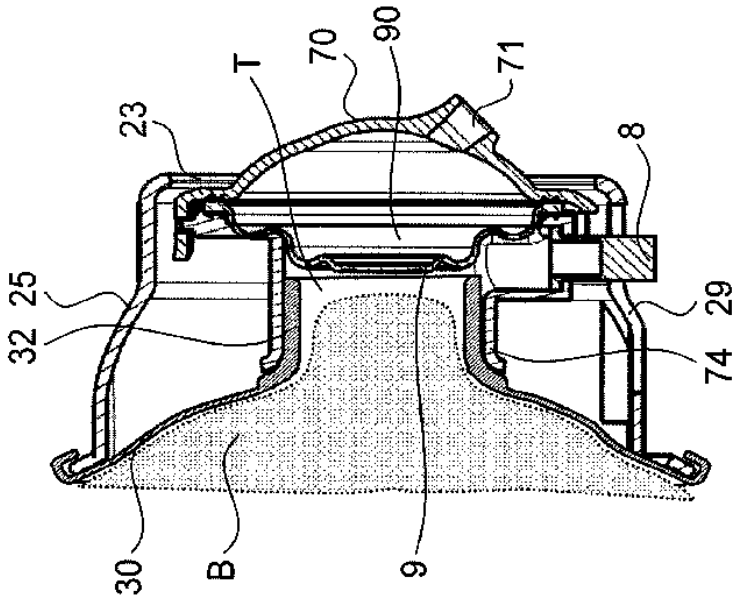


FIG. 7

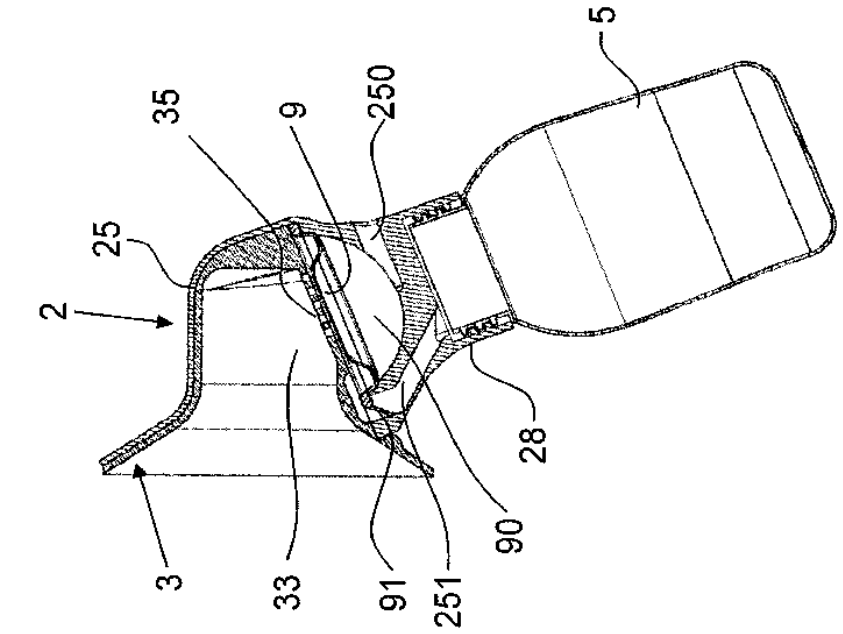


FIG. 10

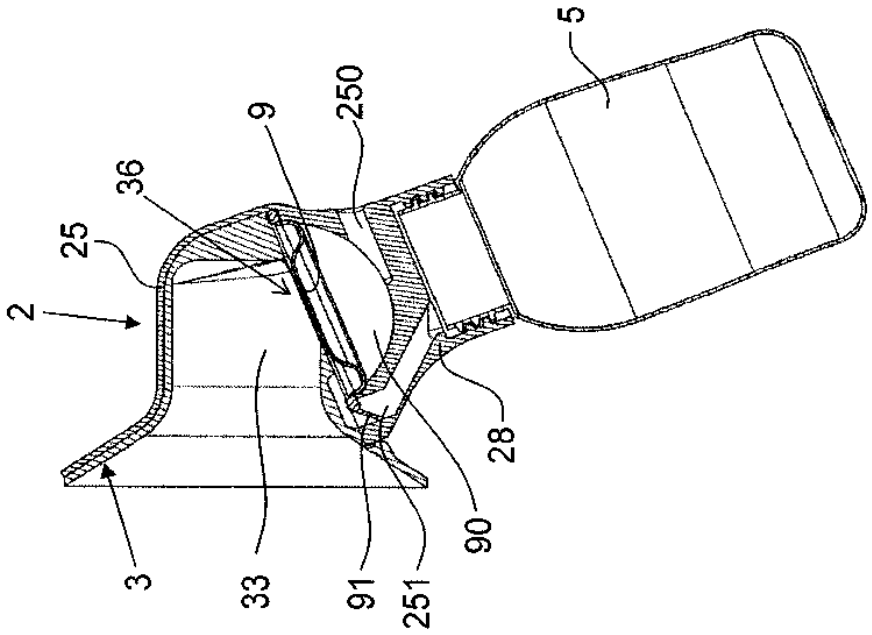


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2013/000220

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 308 523 A1 (MEDELA HOLDING AG [CH]) 13 April 2011 (2011-04-13)	1-5, 7-10,12, 14-16
A	paragraphs [0063] - [0080], [0143] - [0147] figures 9, 10, 11, 23	11

X	EP 2 441 481 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]) 18 April 2012 (2012-04-18)	1-3,6,7, 9,12,13, 15
A	paragraphs [0031] - [0045] figures 3, 4	11

X	EP 1 034 807 A1 (AMEDA AG [CH]) 13 September 2000 (2000-09-13)	1-5, 7-10,12, 13,15
A	paragraphs [0024] - [0033] figure 1	11

	-/--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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"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
5 March 2014	13/03/2014

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2013/000220

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/060873 A1 (HIRAOKA KATSUYUKI [JP] ET AL) 15 March 2007 (2007-03-15) paragraphs [0024] - [0037] figures 1, 2	1,15,16
X	US 2004/087898 A1 (WENIGER GOTTHILF [US]) 6 May 2004 (2004-05-06) cited in the application	16
A	figure 4	1,15

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CH2013/000220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2308523 A1	13-04-2011	AT 522238 T	15-09-2011
		AU 2002322292 B2	17-07-2008
		CA 2451967 A1	03-01-2003
		EP 1404394 A1	07-04-2004
		EP 2298369 A1	23-03-2011
		EP 2308523 A1	13-04-2011
		EP 2316501 A1	04-05-2011
		JP 2005502397 A	27-01-2005
		JP 2009028557 A	12-02-2009
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		NZ 530347 A	25-11-2005
		US 2002198489 A1	26-12-2002
		US 2004015127 A1	22-01-2004
		US 2007088250 A1	19-04-2007
		US 2010121267 A1	13-05-2010
		WO 03000313 A1	03-01-2003
EP 2441481 A1	18-04-2012	EP 2441481 A1	18-04-2012
		EP 2627365 A1	21-08-2013
		JP 2013543409 A	05-12-2013
		US 2013245548 A1	19-09-2013
		WO 2012049606 A1	19-04-2012
EP 1034807 A1	13-09-2000	NONE	
US 2007060873 A1	15-03-2007	NONE	
US 2004087898 A1	06-05-2004	US 2004087898 A1	06-05-2004
		US 2006264816 A1	23-11-2006

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

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2013/000220

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/00 A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	EP 2 308 523 A1 (MEDELA HOLDING AG [CH]) 13. April 2011 (2011-04-13)	1-5, 7-10,12, 14-16
A	Absätze [0063] - [0080], [0143] - [0147] Abbildungen 9, 10, 11, 23	11
X	EP 2 441 481 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]) 18. April 2012 (2012-04-18)	1-3,6,7, 9,12,13, 15
A	Absätze [0031] - [0045] Abbildungen 3, 4	11
X	EP 1 034 807 A1 (AMEDA AG [CH]) 13. September 2000 (2000-09-13)	1-5, 7-10,12, 13,15
A	Absätze [0024] - [0033] Abbildung 1	11

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
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"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
5. März 2014	13/03/2014

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2013/000220

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2007/060873 A1 (HIRAOKA KATSUYUKI [JP] ET AL) 15. März 2007 (2007-03-15) Absätze [0024] - [0037] Abbildungen 1, 2	1,15,16
X	US 2004/087898 A1 (WENIGER GOTTHILF [US]) 6. Mai 2004 (2004-05-06) in der Anmeldung erwähnt	16
A	Abbildung 4	1,15

Formblatt PCT/ISA/210 (Fortsetzung von Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/CH2013/000220

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
EP 2308523 A1	13-04-2011	AT 522238 T	15-09-2011
		AU 2002322292 B2	17-07-2008
		CA 2451967 A1	03-01-2003
		EP 1404394 A1	07-04-2004
		EP 2298369 A1	23-03-2011
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		JP 2009028557 A	12-02-2009
		JP 2012254307 A	27-12-2012
		NZ 530347 A	25-11-2005
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		US 2010121267 A1	13-05-2010
		WO 03000313 A1	03-01-2003
EP 2441481 A1	18-04-2012	EP 2441481 A1	18-04-2012
		EP 2627365 A1	21-08-2013
		JP 2013543409 A	05-12-2013
		US 2013245548 A1	19-09-2013
		WO 2012049606 A1	19-04-2012
EP 1034807 A1	13-09-2000	KEINE	
US 2007060873 A1	15-03-2007	KEINE	
US 2004087898 A1	06-05-2004	US 2004087898 A1	06-05-2004
		US 2006264816 A1	23-11-2006

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

Bibliographic data

Title:	Hidden electric breast pump
Pub/Pat no:	CN209033304U
Pub/Issue Date:	2019-06-28
Inventor(s):	ZHENG GUANGWU|
Applicant(s):	SHANTOU HHQ ELECTRON TECH CO LTD
Classification:	A61M1/06AI
Application number:	CN201820754697U 2018-05-21
Priority number:	CN201820754697U 20180521;

Abstract of CN209033304U

The utility model aims to provide a hidden electric breast pump which can be hidden in underwear or a bra in use, and an exposed connecting pipe is omitted, so that the hidden electric breast pump isconvenient for a user to use. The hidden electric breast pump comprises a funnel-shaped sucking disc part, wing-plate-shaped connecting pieces are connected to the two sides of the tail end of the funnel of the sucker part; an upper cavity used for containing an electric pump and a lower cavity used for containing emulsion are formed in the upper portion and the lower portion of the connecting piece respectively. An upper through opening communicated with the upper cavity is formed in the upper portion of the funnel tail end of the suction cup part, a lower through opening communicated with the lower cavity is formed in the lower portion of the funnel tail end of the suction cup part, a one-way valve is arranged at the lower through opening, and the upper cavity and the lower cavity are buckled above and below the connecting piece respectively and form a bowl-shaped body connected to the back of the suction cup part together.

(19)中华人民共和国国家知识产权局

(12)实用新型专利

(10)授权公告号 CN 209033304 U
(45)授权公告日 2019.06.28

(21)申请号 201820754697.5

(22)申请日 2018.05.21

(73)专利权人 汕头市汇亨洪电子科技有限公司
地址 515000 广东省汕头市龙湖区14A工业区C栋五楼501

(72)发明人 郑光武

(74)专利代理机构 北京科亿知识产权代理事务所(普通合伙) 11350
代理人 汤东凤

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

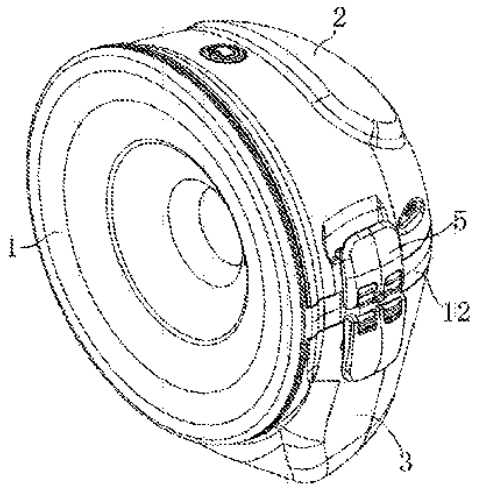
权利要求书1页 说明书3页 附图6页

(54)实用新型名称

一种隐藏式电动吸奶器

(57)摘要

本实用新型的目的是提出一种隐藏式电动吸奶器，使用时可以隐藏在内衣或文胸中，且省去外露的连接管，方便用户使用。该隐藏式电动吸奶器包括漏斗形的吸盘部，所述吸盘部的漏斗尾端向两侧连接有翼板形的连接件，所述连接件的上方和下方分别设有用于容纳电动泵的上腔体和用于盛装乳液的下腔体，所述吸盘部的漏斗尾端上方设有与上腔体连通的上通口，吸盘部的漏斗尾端下方设有与下腔体连通的下通口，所述下通口处设有单向阀，所述上腔体和下腔体分别扣装在连接件的上方和下方且共同形成连接在所述吸盘部背部的碗形体。



CN 209033304 U

1.一种隐藏式电动吸奶器，其特征在于包括漏斗形的吸盘部，所述吸盘部的漏斗尾端向两侧连接有翼板形的连接件，所述连接件的上方和下方分别设有用于容纳电动泵的上腔体和用于盛装乳液的下腔体，所述吸盘部的漏斗尾端上方设有与上腔体连通的上通口，吸盘部的漏斗尾端下方设有与下腔体连通的下通口，所述下通口处设有单向阀，所述上腔体和下腔体分别扣装在连接件的上方和下方且共同形成连接在所述吸盘部背部的碗形体。

2.根据权利要求1所述的隐藏式电动吸奶器，其特征在于所述连接件的侧壁设有锁扣，所述锁扣的一端与连接件的侧壁铰接，另一端设有搭扣，所述上腔体和/或下腔体的外表面设有与所述搭扣配合的扣位。

3.根据权利要求2所述的隐藏式电动吸奶器，其特征在于所述锁扣上下成对设置，所述碗形体的两侧和后部分别设置所述成对设置的锁扣。

4.根据权利要求1或2或3所述的隐藏式电动吸奶器，其特征在于所述连接件位于所述吸盘部的漏斗尾端两侧分别设有左凹腔和右凹腔，所述上通口设有分别连通至所述左凹腔和右凹腔的左气道和右气道，所述连接件上还设有压盖所述左凹腔、右凹腔、左气道和右气道的盖板。

5.根据权利要求4所述的隐藏式电动吸奶器，其特征在于所述连接件的底部位于所述吸盘部的漏斗尾端两侧分别设有左防溢电极和右防溢电极。

6.根据权利要求5所述的隐藏式电动吸奶器，其特征在于所述上腔体内设有陀螺仪。

7.根据权利要求6所述的隐藏式电动吸奶器，其特征在于所述吸盘部的前端设有与所述吸盘部形状适配的软胶体。

8.根据权利要求7所述的隐藏式电动吸奶器，其特征在于所述碗形体的背部设有可拆卸的挂钩部。

一种隐藏式电动吸奶器

技术领域

[0001] 本实用新型属于吸奶器技术领域，具体涉及一种隐藏式电动吸奶器。

背景技术

[0002] 吸奶器作为哺乳期妈妈重要的辅助工具，带来了许多方便。但是，目前市面上的吸奶器，多采用外接奶瓶和负压泵的结构，使用时需要掀开内衣或文胸，让乳房外露，连同同样外露的连接管，会让使用者在公共场合使用时十分的尴尬和麻烦。

实用新型内容

[0003] 本实用新型的目的是提供一种隐藏式电动吸奶器，使用时可以隐藏在内衣或文胸中，且省去外露的连接管，方便用户使用。

[0004] 根据本实用新型提供的隐藏式电动吸奶器，包括漏斗形的吸盘部，所述吸盘部的漏斗尾端向两侧连接有翼板形的连接件，所述连接件的上方和下方分别设有用于容纳电动泵的上腔体和用于盛装乳液的下腔体，所述吸盘部的漏斗尾端上方设有与上腔体连通的上通口，吸盘部的漏斗尾端下方设有与下腔体连通的下通口，所述下通口处设有单向阀，所述上腔体和下腔体分别扣装在连接件的上方和下方且共同形成连接在所述吸盘部背部的碗形体。

[0005] 本实用新型的隐藏式电动吸奶器，将用于产生负压的电动泵和相应的电路元件集成在上腔体中，下腔体则用于盛装乳液，上腔体和下腔体通过连接件扣装，集成为一个连接在吸盘部背部的碗形体，使用时，将整个吸奶器塞入内衣或文胸中，让吸盘部的漏斗进口容纳贴合乳房，即可依靠内衣或文胸的压紧力自动紧固吸奶器，完成吸奶过程，避免了吸奶时外露乳房以及外露连接管的尴尬和麻烦。

[0006] 进一步的，所述连接件的侧壁设有锁扣，所述锁扣的一端与连接件的侧壁铰接，另一端设有搭扣，所述上腔体和/或下腔体的外表面设有与所述搭扣配合的扣位。连接件通过锁扣与上腔体和/或下腔体连接，既可方便吸奶完毕后拆卸下腔体取奶，也可方便拆卸上腔体清洗和维修，提高便利性。当然，仅是上腔体通过锁扣与连接件连接或仅是下腔体通过锁扣与连接件连接，均在本实用新型的保护范围。

[0007] 进一步的，所述锁扣上下成对设置，所述碗形体的两侧和后部分别设置所述成对设置的锁扣，以保证上腔体和下腔体与连接件的紧固连接。

[0008] 进一步的，所述连接件位于所述吸盘部的漏斗尾端两侧分别设有左凹腔和右凹腔，所述上通口设有分别连通至所述左凹腔和右凹腔的左气道和右气道，所述连接件上还设有压盖所述左凹腔、右凹腔、左气道和右气道的盖板。这样可以在左凹腔和右凹腔处分别形成类似人体双肺部的负压腔，提高产生负压的效率。

[0009] 进一步的，所述连接件的底部位于所述吸盘部的漏斗尾端两侧分别设有左防溢电极和右防溢电极。吸奶器工作时，当下腔体内的乳汁液面同时上升漫过左防溢电极和右防溢电极时，防溢电路导通，可通过显示屏或声音或震动提醒使用者，防止乳汁溢漏。

[0010] 进一步的，所述上腔体内设有陀螺仪。通过设置陀螺仪，可以防止使用者倒置或放歪吸奶器，提高便利性。

[0011] 进一步的，所述吸盘部的前端设有与所述吸盘部形状适配的软胶体。该软胶体可选用食品级硅胶，以提高吸奶器与乳房接触部位的卫生安全及舒适度。

[0012] 进一步的，所述碗形体的背部设有可拆卸的挂钩部。由于实际使用时，吸奶器整体具有一定的重量，单靠衣服的压紧力有可能不足支撑吸奶器，造成偏移，因此，设置挂钩部，可以在挂钩部上穿设可以挂在使用者脖子上的绳子，防止吸奶器移位。

附图说明

[0013] 图1为本实用新型的结构示意图。

[0014] 图2为本实用新型的背部结构示意图。

[0015] 图3为本实用新型的分解结构示意图。

[0016] 图4为本实用新型的盖板与单向阀的安装结构示意图。

[0017] 图5为本实用新型装上挂钩部时的结构示意图。

[0018] 图6为本实用新型的挂钩部的安装结构示意图。

[0019] 其中图示：1、吸盘部；11、漏斗尾端；111、上通口；112、下通口；111a、左气道；12、连接件；121、左凹腔；122、右凹腔；13、盖板；141、左防溢电极；15、挂钩部；2、上腔体；21、扣位；3、下腔体；31、扣位；4、单向阀；5、锁扣；51、锁扣；511、搭扣；52、锁扣；521、搭扣；6、软胶体。

具体实施方式

[0020] 下面对照附图，通过对实施实例的描述，对本实用新型的具体实施方式如所涉及的各构件的形状、构造、各部分之间的相互位置及连接关系、各部分的作用及工作原理等作进一步的详细说明。

[0021] 如图1-6，本实用新型的隐藏式电动吸奶器，包括漏斗形的吸盘部1，吸盘部1的漏斗尾端11向两侧连接有翼板形的连接件12，连接件12的上方和下方分别设有用于容纳电动泵(图中未示出)的上腔体2和用于盛装乳液的下腔体3，吸盘部1的漏斗尾端11上方设有与上腔体连通的上通口111，吸盘部1的漏斗尾端11下方设有与下腔体3连通的下通口112，下通口112处设有单向阀4，上腔体2和下腔体3分别扣装在连接件12的上方和下方且共同形成连接在吸盘部1背部的碗形体。

[0022] 本实用新型的隐藏式电动吸奶器，将用于产生负压的电动泵和相应的电路元件集成在上腔体2中，下腔体3则用于盛装乳液，上腔体2和下腔体3通过连接件12扣装，集成为一个连接在吸盘部背部的碗形体，使用时，将整个吸奶器塞入内衣或文胸中，让吸盘部1的漏斗进口容纳贴合乳房，即可依靠内衣或文胸的压紧力自动紧固吸奶器，完成吸奶过程，避免了吸奶时外露乳房以及外露连接管的尴尬和麻烦。由于采用电动泵和相关电路结构产生负压的结构为现有电动吸奶器的较成熟技术，此处不再详细赘述。

[0023] 作为优选的实施方式，连接件12的侧壁设有锁扣5，锁扣5包括上下成对设置的锁扣51和52，锁扣51和锁扣52的一端与连接件12的侧壁铰接，锁扣51的另一端设有搭扣511，上腔体2的外表面设有与搭扣511配合的扣位21，锁扣52的另一端设有搭扣521，下腔体3的

外表面设有与搭扣521配合的扣位31。扣位的结构可以有多种，在本实施例中，扣位21通过凹腔形成，扣位31通过外凸的卡扣形成。该结构既可方便吸奶完毕后拆卸下腔体3取奶，也可方便拆卸上腔体1清洗和维修，提高便利性。

[0024] 优选的，锁扣5上下成对设置，碗形体的两侧和后部分别设置成对设置的锁扣5，以保证上腔体2和下腔体3与连接件12的紧固连接。

[0025] 优选的，连接件12位于吸盘部1的漏斗尾端11两侧分别设有左凹腔121和右凹腔122，上通口111设有分别连通至左凹腔121和右凹腔122的左气道111a和右气道(图中未示出)，连接件12上还设有压盖左凹腔121、右凹腔122、左气道111a和右气道的盖板13。这样可以在左凹腔121和右凹腔122处分别形成类似人体双肺部的负压腔，提高产生负压的效率。

[0026] 优选的，连接件12的底部位于吸盘部1的漏斗尾端11两侧分别设有左防溢电极141和右防溢电极(图中未示出)。吸奶器工作时，当下腔体3内的乳汁液面同时上升漫过左防溢电极和右防溢电极时，防溢电路导通，可通过声音或震动提醒使用者，防止乳汁溢漏。

[0027] 优选的，上腔体2内设有陀螺仪(图中未示出)。通过设置陀螺仪，可以防止使用者倒置或放歪吸奶器，提高便利性。

[0028] 优选的，吸盘部1的前端设有与吸盘部1形状适配的软胶体6。该软胶体6可选用食品级硅胶，以提高吸奶器与乳房接触部位的卫生安全及舒适度。

[0029] 优选的，所述碗形体的背部设有可拆卸的挂钩部15。由于实际使用时，吸奶器整体具有一定的重量，单靠衣服的压紧力有可能不足支撑吸奶器，造成偏移，因此，设置挂钩部15，可以在挂钩部15上穿设可以挂在使用者脖子上的绳子，防止吸奶器移位。

[0030] 以上内容是结合具体的优选实施方式对本实用新型所作的进一步详细说明，不能认定本实用新型的具体实施只局限于这些说明。对于本实用新型所属技术领域的普通技术人员来说，在不脱离本实用新型构思的前提下，还可以做出若干简单推演或替换，都应当视为属于本实用新型的保护范围。

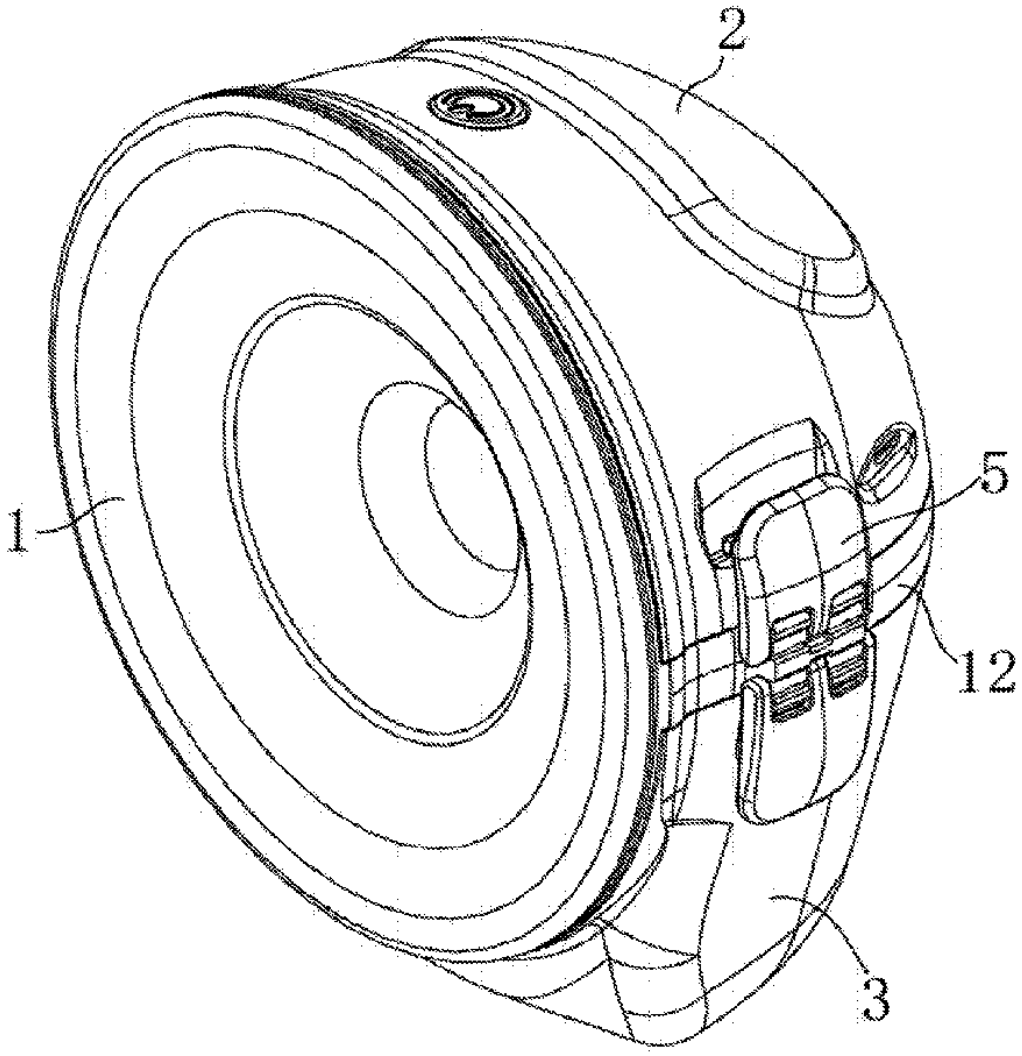


图1

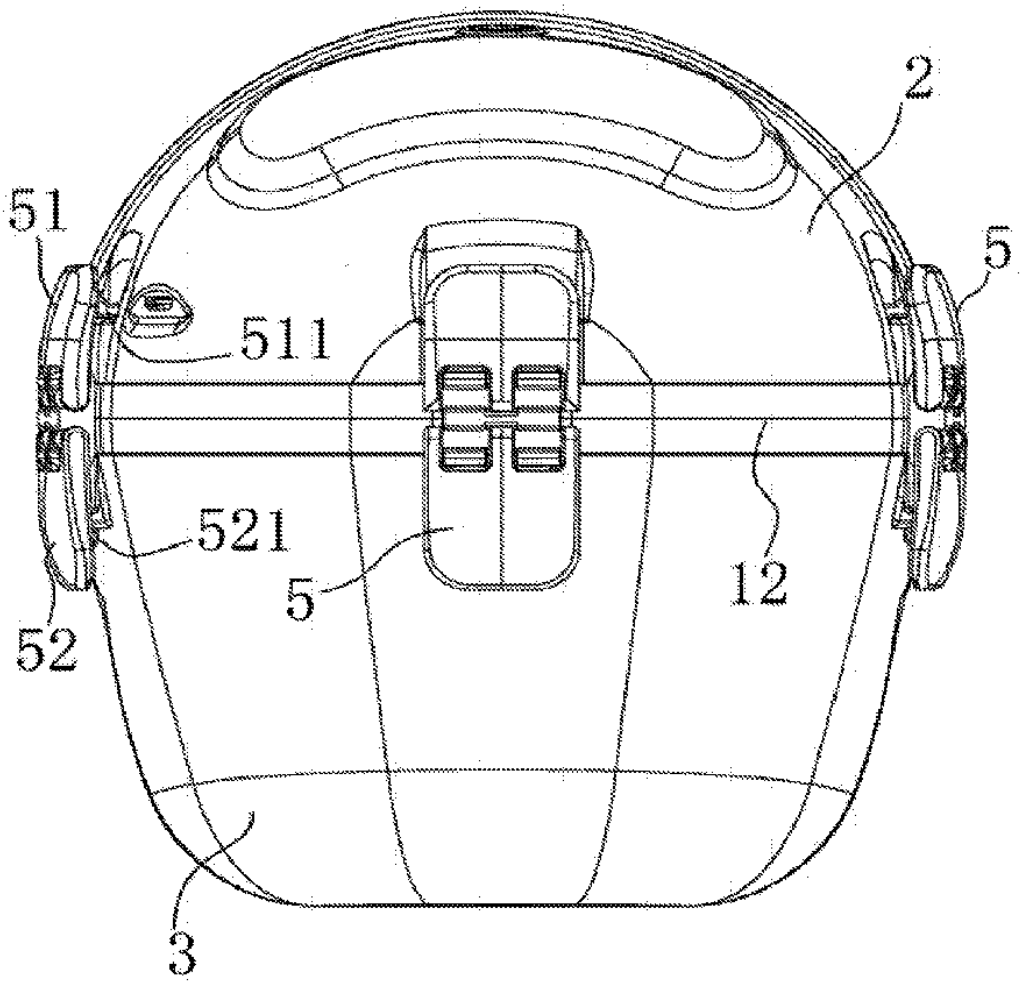


图2

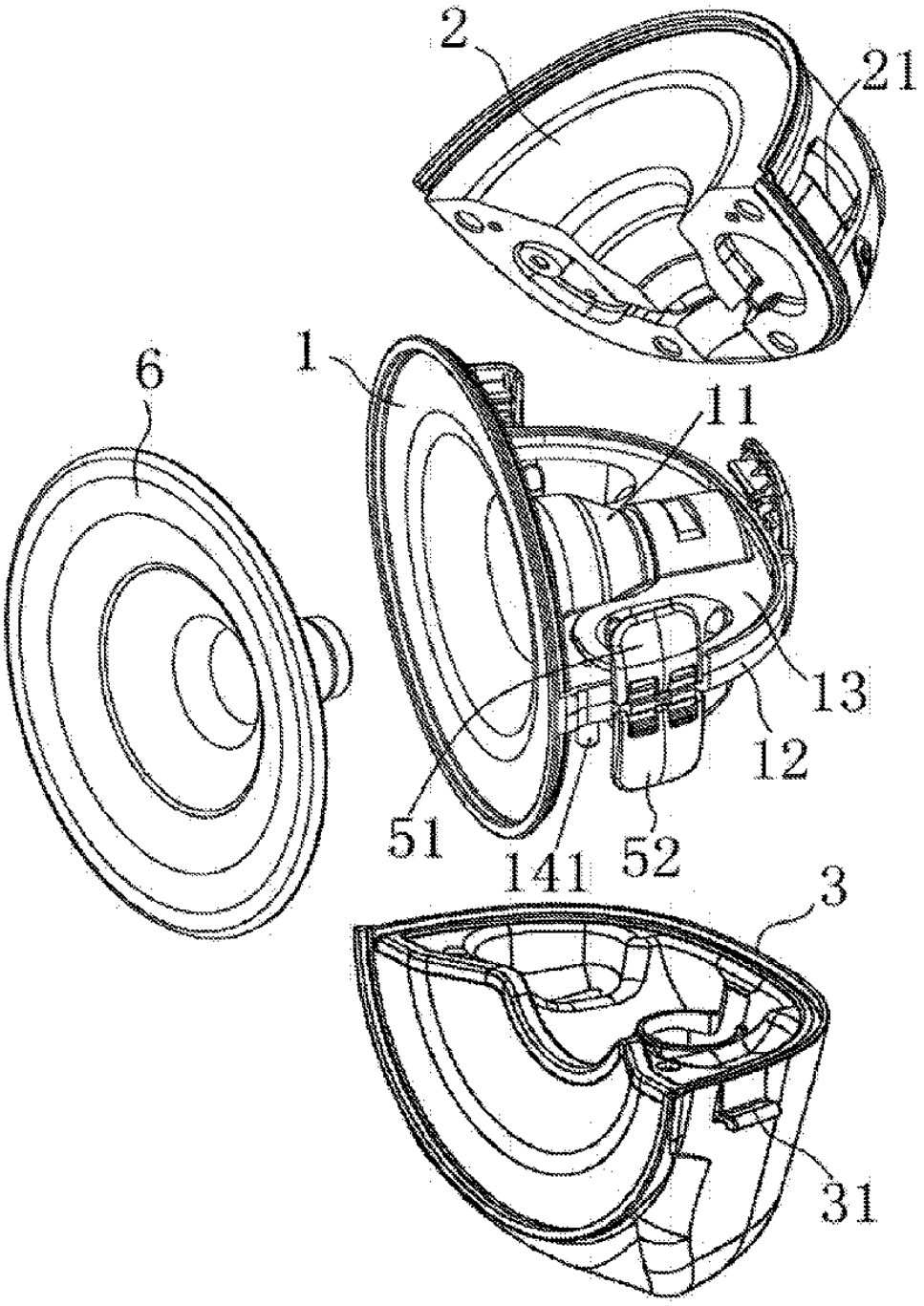


图3

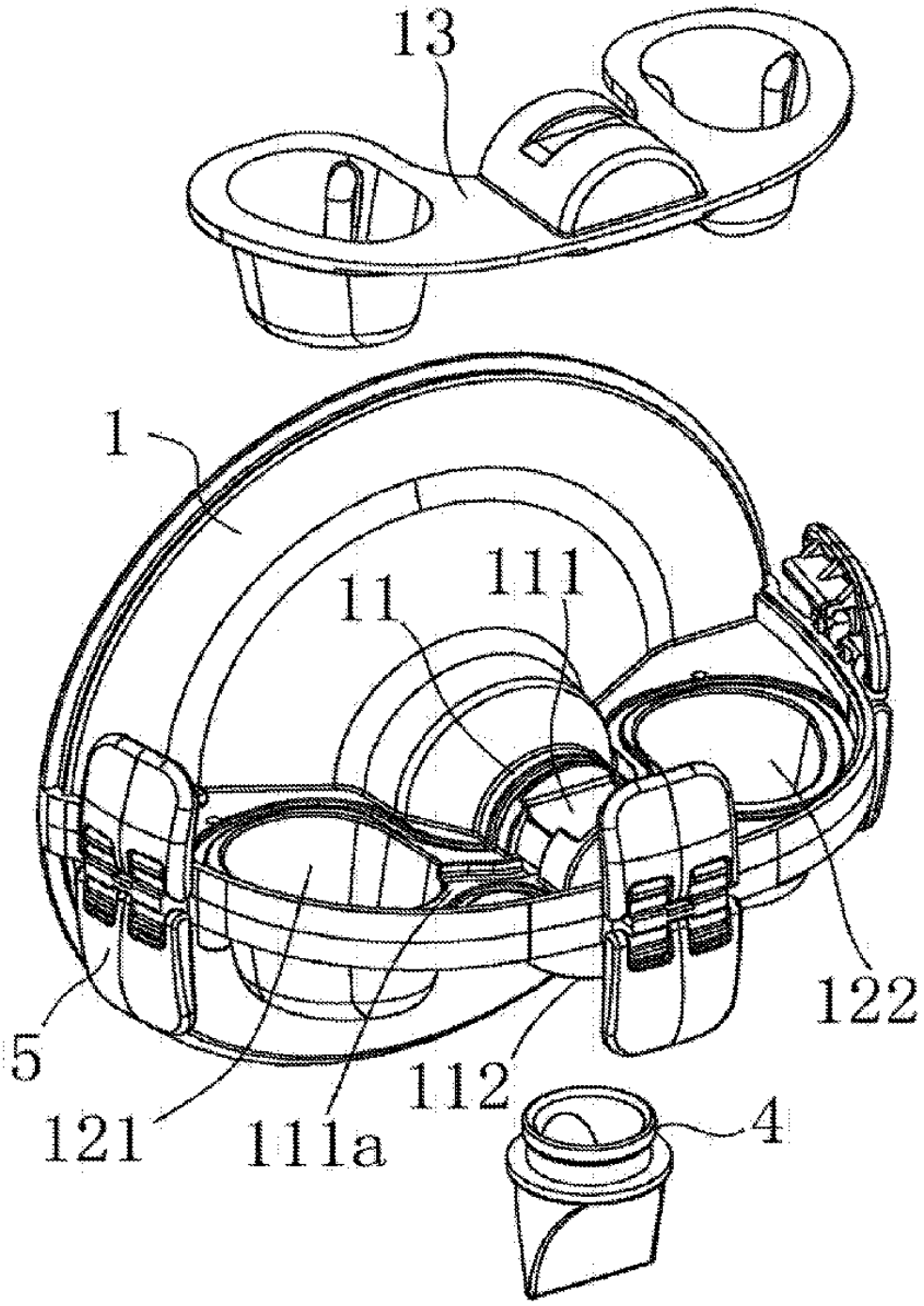


图4

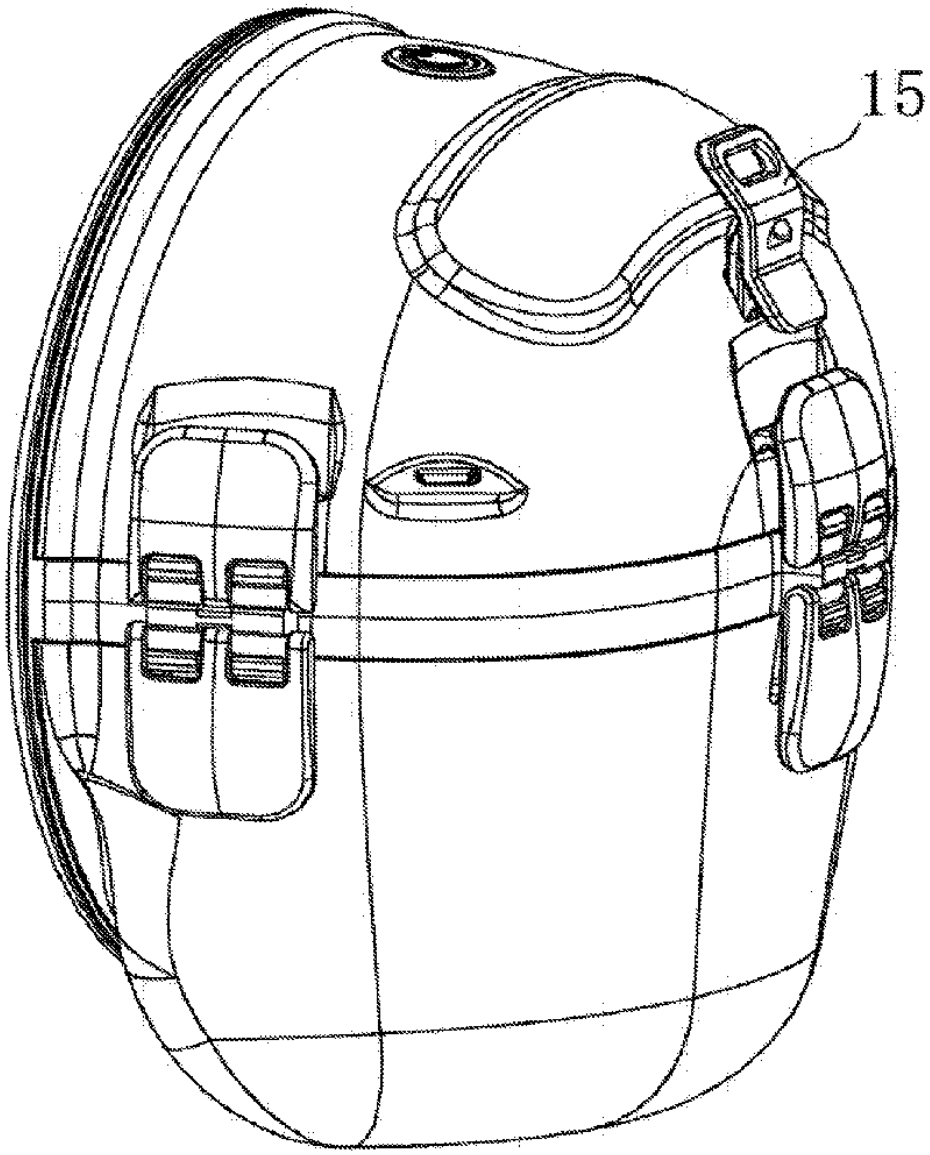


图5

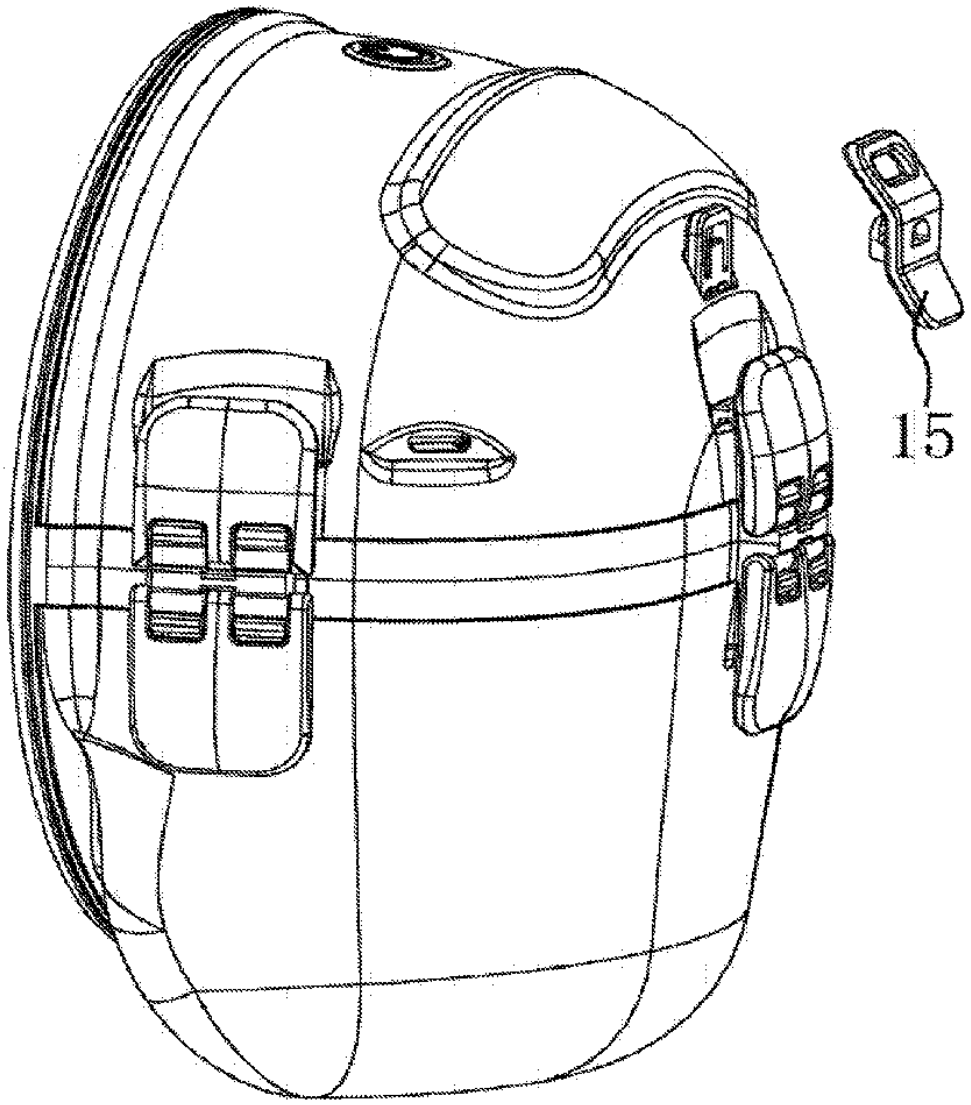


图6

Bibliographic data

Title:	Exempt from hand breast pump
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Pub/Issue Date:	2017-09-08
Inventor(s):	ZHENG GUANGWU|
Applicant(s):	SHANTOU HHQ ELECTRON TECH CO LTD
Classification:	A61M1/06AI
Application number:	CN201620877232U 2016-08-12
Priority number:	CN201620396210U 20160503;

Abstract of CN206473606U

The utility model provides an exempt from hand breast pump, including milking tray, the bowl body, connecting piece, check valve, pressure chamber, it is used for holding the sucking disc of human breast of laminating to be equipped with the funnel type in the middle of the milking tray, the connecting piece is equipped with three opening and connects the less one end of sucking disc bore, pressure chamber and check valve respectively, milking tray cover closes on the bowl body and accomodates connecting piece, check valve and pressure chamber in the internal portion of bowl. Exempt from hand breast pump has 1. Smallly, and the trouble of holding up with the hand rest is removed from in the middle of can wholly putting into the brassiere to the breast pump, simple structure, advantages such as convenient operation.

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(12)实用新型专利

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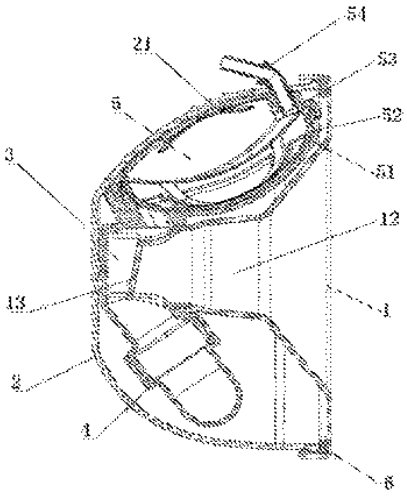
权利要求书1页 说明书2页 附图2页

(54)实用新型名称

免手扶吸奶器

(57)摘要

本实用新型提供的免手扶吸奶器，包括吸乳托盘、碗体、连接件、单向阀、压力舱；所述吸乳托盘中间设有漏斗型用于容纳贴合人体乳房的吸盘；所述连接件设有三个通口分别连接吸盘口径较小的一端、压力舱和单向阀；所述吸乳托盘盖合在碗体上并将连接件、单向阀和压力舱收纳在碗体内部。所述免手扶吸奶器具有1.体积小，吸奶器可整体放入文胸当中，免去用手托扶的麻烦，结构简单，操作方便等优点。



CN 206473606 U

1.免手扶吸奶器，其特征在于，包括吸乳托盘、碗体、连接件、单向阀、压力舱；所述吸乳托盘中间设有漏斗型用于容纳贴合人体乳房的吸盘；所述连接件设有三个通口分别连接吸盘口径较小的一端、压力舱和单向阀；所述吸乳托盘盖合在碗体上并将连接件、单向阀和压力舱收纳在碗体内部。

2.根据权利要求1所述的免手扶吸奶器，其特征在于，所述压力舱包括下腔体、弹性膜片、上腔压盖和导管；所述下腔体与连接器连通；所述上腔压盖与下腔体盖合；所述导管与上腔压盖连通并贯穿碗体伸出外部；所述弹性膜片为碗状置于上腔压盖与下腔体之间，弹性膜片凸出面置于下腔体内部。

3.根据权利要求2所述的免手扶吸奶器，其特征在于，所述弹性膜片设有至少一条加强筋，所述加强筋为圆弧状。

4.根据权利要求1至3任一项所述的免手扶吸奶器，其特征在于，所述吸盘口径较小的一端设有挡板，所述挡板使吸盘通道出口方向偏向单向阀。

5.根据权利要求4所述的免手扶吸奶器，其特征在于，所述吸乳托盘与碗体之间设有密封圈。

6.根据权利要求5所述的免手扶吸奶器，其特征在于，所述碗体外侧设有至少一条凸条。

7.根据权利要求6所述的免手扶吸奶器，其特征在于，所述吸乳托盘上设有把手。

8.根据权利要求2或3所述的免手扶吸奶器，其特征在于，所述上腔压盖与下腔体分别设置公扣与母扣相互扣合固定。

免手扶吸奶器

技术领域

[0001] 本实用新型涉及吸乳器领域，具体是一种免手扶吸奶器。

背景技术

[0002] 随着社会的不断发展，越来越多的人重视母乳的喂养，但由于各种原因，如早产婴儿的吸力不足或者是女性乳头的先天性坍塌等，造成婴儿无法直接吸食到母乳，从而影响婴儿的健康发育，为此，市场上出现了吸奶器，吸奶器可辅助吸出奶水之后供婴儿吸食，该器具带有一吸盘及一可发生负压的部件及一奶瓶，可发生负压的部件有手动或者是电动，现有的吸奶器需要使用者脱下文胸让乳房外露，当负压不够时还需要用手托扶吸奶器，不利于使用者在公共场合使用。

实用新型内容

[0003] 本实用新型旨在提供一种结构简单，可收纳在文胸当中的吸奶器。

[0004] 为了达到上述目的，本实用新型采用以下解决技术方案：

[0005] 免手扶吸奶器，包括吸乳托盘、碗体、连接件、单向阀、压力舱；所述吸乳托盘中间设有漏斗型用于容纳贴合人体乳房的吸盘；所述连接件设有三个通口分别连接吸盘口径较小的一端、压力舱和单向阀；所述吸乳托盘盖合在碗体上并将连接件、单向阀和压力舱收纳在碗体内部。

[0006] 优选的，所述压力舱包括下腔体、弹性膜片、上腔压盖和导管；所述下腔体与连接器连通；所述上腔压盖与下腔体盖合；所述导管与上腔压盖连通并贯穿碗体伸出外部；所述弹性膜片为碗状置于上腔压盖与下腔体之间，弹性膜片凸出面置于下腔体内部。当上腔压盖内部产生负压使弹性膜片变形从而让下腔体产生负压达到吸乳的效果，弹性膜片有效隔绝乳液进入气泵，当气压恢复，弹性膜片回复原来形状。

[0007] 进一步优选的，所述弹性膜片设有至少一条加强筋，所述加强筋为圆弧状。

[0008] 优选的，所述吸盘口径较小的一端设有挡板，所述挡板使吸盘通道出口方向偏向单向阀。挡板可以让雾化的乳汁凝结并流向单向阀，避免过多的乳汁进入压力腔。

[0009] 优选的，所述吸乳托盘与碗体之间设有密封圈，避免乳汁流出。

[0010] 优选的，所述碗体外侧设有至少一条凸条，使吸乳托盘从碗体打开时增加手部与碗体的摩擦，方便打开的同时避免碗体从手部滑落。

[0011] 优选的，所述吸乳托盘上设有把手，方便打开吸乳托盘。

[0012] 优选的，所述上腔压盖与下腔体分别设置公扣与母扣相互扣合固定。

[0013] 本实用新型具有以下有益效果：

[0014] 1．体积小，吸奶器可整体放入文胸当中，免去用手托扶的麻烦；

[0015] 2．结构简单，操作方便，适合大范围推广应用。

附图说明

[0016] 图1为本实用新型的结构示意图；

[0017] 图2为本实用新型的拆分结构示意图。

[0018] 附图标记说明：1-吸乳托盘；11-把手；12-吸盘；13-挡板；2-碗体；21-凸条；3-连接件；4-单向阀；5-压力舱；51-下腔体；52-弹性膜片；521-加强筋；53-上腔压盖；54-导管；6-密封圈。

具体实施方式

[0019] 下面，结合附图以及具体实施方式，对本实用新型做进一步描述：

[0020] 如图1与图2所示，免手扶吸奶器，其包括吸乳托盘1、碗体2、连接件3、单向阀4、压力舱5；所述吸乳托盘1中间设有漏斗型用于容纳贴合人体乳房的吸盘12；所述连接件3设有三个通口分别连接吸盘12口径较小的一端、压力舱5和单向阀4；所述吸乳托盘1盖合在碗体2上并将连接件3、单向阀4和压力舱5收纳在碗体2内部。所述压力舱5包括下腔体51、弹性膜片52、上腔压盖53和导管54；所述下腔体51与连接器3连通；所述上腔压盖53与下腔体51盖合；所述导管54与上腔压盖53连通并贯穿碗体2伸出外部；所述弹性膜片52为碗状置于上腔压盖53与下腔体51之间，弹性膜片52凸出面置于下腔体51内部。当上腔压盖53内部产生负压使弹性膜片52变形从而让下腔体51产生负压达到吸乳的效果，弹性膜片52有效隔绝乳液进入气泵，当气压恢复，弹性膜片52回复原来形状。所述弹性膜片52设有六条加强筋521，所述加强筋52为圆弧状并均匀分布在内表面。所述吸盘12口径较小的一端设有挡板13，所述挡板13使吸盘12通道出口方向偏向单向阀4。挡板13可以让雾化的乳汁凝结并流向单向阀4，避免过多的乳汁进入压力腔5。所述吸乳托盘1与碗体2之间设有密封圈6。所述碗体2外侧设有六条凸条21并以三行两列的形式平行于碗口平面设置。所述吸乳托盘1上设有把手11。所述上腔压盖与下腔体分别设置公扣与母扣相互扣合固定。

[0021] 对于本领域的技术人员来说，可根据以上描述的技术方案以及构思，做出其它各种相应的改变以及变形，而所有的这些改变以及变形都属于本实用新型权利要求的保护范围之内。

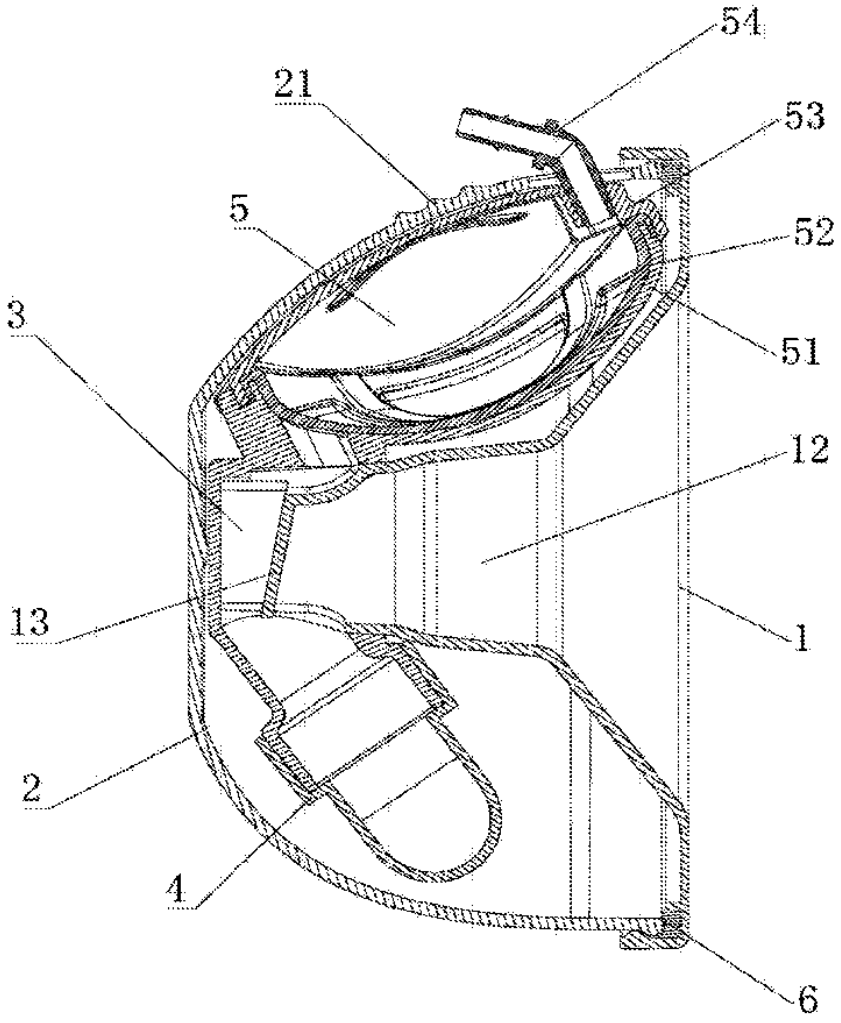


图1

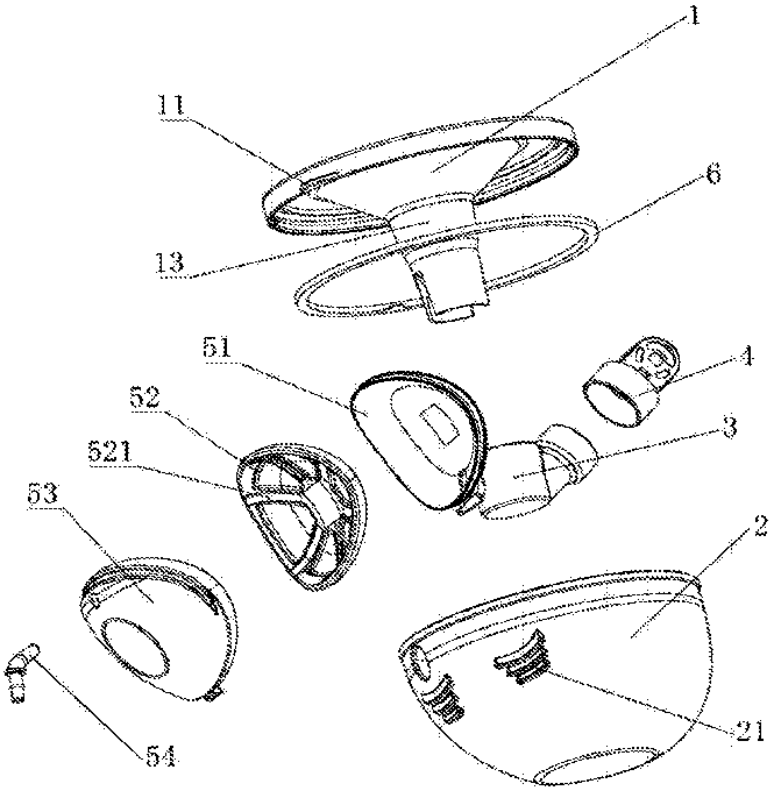


图2

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**12/04/2024 04:13:26 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	68218236	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1005	**E2024B4G14497447**	**Jon Baitlon**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1820	REQUEST FOR CONTINUED EXAMINATION (RCE)- 2ND AND SUBSEQUENT REQUEST (SEE 37 CFR 1.114)	2000.00	1	2000.00
			TOTAL AMOUNT:	**$2,000.00**

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New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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)
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- ☐ Drawing(s)
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- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
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- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
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Request for Continued Examination Transmittal; Copies of FP1-FP10 and NPL1-NPL12.

Remarks

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Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	December 3, 2024	Reg. No.	800,005

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(72) Inventor; and
(71) Applicant : **SEE, Jing Yeu** [MY/MY]; 19, Jln EH 50, Taman Evergreen Heights, 83000, Batu Pahat, Johor (MY).

(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, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

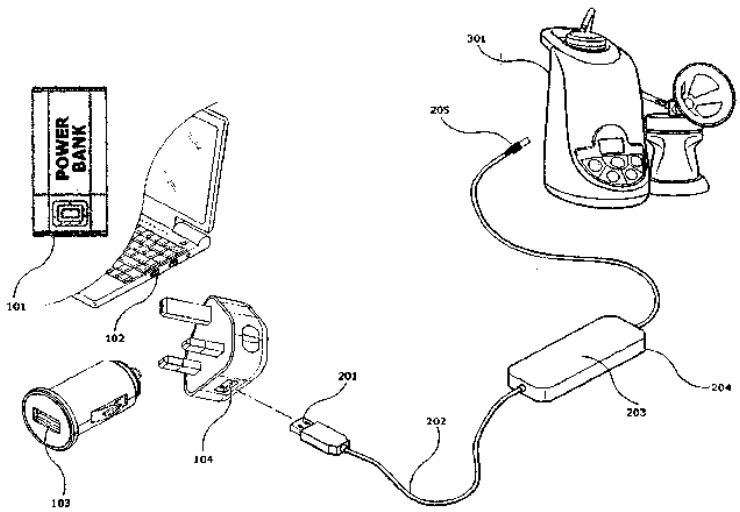
— *of inventorship (Rule 4.17(iv))*

Published:

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

— *with amended claims (Art. 19(1))*

(54) **Title**: A USB (UNIVERSAL SERIAL BUS) POWER CABLE FOR ELECTRIC BREAST PUMP.



(57) **Abstract**: The USB power cable (202) used to operate electric breast pumps (301), can be inserted into a USB port of a computer (102) or power bank (101) or vehicle power source (103) (e.g., a cigarette lighter power source) or be connected with any other USB port (101, 102, 103, 104), so as to meet demands of working and travelling mothers where there is no power supply. Its uniqueness is that it makes the electric breast pump workable even in the car or when there is no direct power supply.

WO 2015/069095 A1

TITLE

A USB (Universal Serial Bus) power cable for electric breast pump.

DESCRIPTION

[0001] This invention relates to general field of electric breast pumps which is a device that extracts milk from the breasts of a lactating woman. The basic objective of this USB cable is that it can be inserted into a USB port of a computer or power bank or vehicle power source (e.g., a cigarette lighter power source) or be connected with any other USB port so as to meet demands of working and travelling mothers.

BACKGROUND OF THE INVENTION

[0002] A breast pump is a which is a device that extracts milk from the breasts of a lactating woman. While previous breast pumps were mechanical, powered by hand or foot devices, later electric breast pumps were invented, powered by mains electricity or batteries. In 1854 the first patent for a breast pump was issued. In later years many improvements upon the original design have been patented and are now sold worldwide. Mechanically, a breast pump is analogous to a milking machine used in commercial dairy production. A misconception is that the breast pump suctions milk out of the breast. A breast pump's job is to trigger the milk ejection response or letdown. Pumps achieve this by using suction to pull the nipple into the tunnel of the breast shield or flange, then release, which counts as one cycle. Thirty to sixty cycles per minute can be expected with better-quality electric breast pumps.

[0003] Women use breast pumps for many reasons. Many women use breast pumps to continue breastfeeding after they return to work. They use the pump to express breast milk, which is later bottle-fed to their child by a caregiver. A breast pump may also be used to stimulate lactation for women with a low milk supply or those who have not just given birth.

[0004] Nowadays, electric breast pumps are preferred as they are quicker in extracting milk and more efficient as they extract almost the whole milk from the breasts.

[0005] The expressed breast milk (EBM) may be stored and later fed to a baby by bottle. Expressed milk may be kept at room temperature for up to six hours, refrigerated for up to 8 days, or frozen for 6 months in a deep freeze separate from a refrigerator maintained at a temperature of 0 degrees Fahrenheit, −18 degrees Celsius. Expressed milk may be donated to milk banks, which provide

human breast milk to premature infants and other high-risk children whose mothers cannot provide for them.

[0006] The invention has taken into account the necessity of electricity without which the functioning of electric breast pump is not possible. That is why the invention provides for a USB cable which can be attached to the pump and which in turn can be inserted into a USB port of a computer or power bank or vehicle power source (e.g., a cigarette lighter power source) or be connected with any other USB port and used effectively.

[0007] Therefore the objective of the invention is to provide mobility to working mothers who are lactating and on the run so that their children are not denied nutrition due to their work schedules.

The existing electric breast pumps power use is 110V-220V AC-DC adaptor or batteries with compatible electric supply range; it will be inoperative without electric supply.

SUMMARY OF THE INVENTION

[0008] The invention is specially designed for lactating women so that they can express milk where there is no power source.

[0009] The purpose of this utility model is aimed at existing technology shortcoming, to propose a USB power cable for electric breast pumps, to take advantage of this low voltage DC to its pumping.

[0010] This utility model compared with the prior art, has a simple structure, safe, & flexibility to mobilize, as well as meeting its energy efficient advantages. It can be operated by:

1) Directly plugging into the computer's USB port; or

2) Connect the phone charger 110V-220V power usage with a USB socket; or

3) Connect to vehicle power source (e.g., a cigarette lighter power) in order to meet the passenger car driving and other needs; or

4) Connect to a power bank.

DESCRIPTION

[0011] 1. A USB power cable (202) for electric breast pumps (301). A USB power cable (202) for electric breast pumps (301) composed of a plastic support unit (204), dc-dc convertor module (203, 206), heat sink (207), USB power connector (201) and dc connector (205).

2. Wherein a USB power cable (202) for electric breast pumps (301) power output of working voltage of 3V - 12V.

3. Wherein an USB power cable (202) for electric breast pumps (301) power output, characterized in that: said between the dc plug (205) and the through hole is changeable.

DETAILED DESCRIPTION

[0012] In the present disclosure, numerous specific details are provided, to provide a thorough understanding of embodiments of the invention. Persons of ordinary skill in the art will recognize, however, that the invention can be practiced without one or more of the specific details.

Figure 1 is a schematic perspective view of the utility model.

SPECIFIC EMBODIMENTS

[00013] Figure 2 is the following examples and the accompanying drawings, the technical scheme of the utility model further specifically described.

[0014] The structure of the utility model: It is mainly made of plastic support unit (204), a dc-dc convertor module (203, 206), a heat sink (207), a USB power connector (201), and a dc connector (205).

[0015] The user attaches the USB power cable to the electric breast pump and connects the other end to a source of power by:

1) Directly plugging into the computer's USB port; or

2) Connect the phone charger 110V-220V power usage with a USB socket; or

3) Connect to vehicle power source (e.g., a cigarette lighter power) in order to meet the passenger car driving and other needs; or

4) Connect to a power bank.

As explained above and by the given diagram, the electric breast pump is ready to use.

TECHNOLOGY

[00016] This utility model relates to electric breast pumps (301), particularly to a USB interface (as provided in the diagram-101, 102, 103, 104) to provide electricity flow to the device.

CLAIMS

[0017] What is claimed is

1. a) A USB power cable which can be attached to an electric breast pump where there is no power source which provides succor to working and travelling mothers who have recently given birth and hence are lactating their children have to be provided with nutrition even if there is no power supply available within reach. The pump derives power by:

a) Directly plugging into the computer's USB port; or

b) Connect the phone charger 110V-220V power usage with a USB socket; or

b) Connect to vehicle power source (e.g., a cigarette lighter power) in order to meet the passenger car driving and other needs; or

d) Connect to a power bank.

This feature of this invention will definitely be a drastic improvement in the currently available pumps which cannot operate without a power source.

2. As claimed in claim 1, wherein a USB power cable (202) for electric breast pumps (301) power output of working voltage of 3V - 12V.

3. As claimed in claim 1, wherein a USB power cable (202) for electric breast pumps (301) power output, characterized in that: said between the dc plug (205) and the through hole is changeable.

AMENDED CLAIMS
received by the International Bureau on 27 May 2014 (27.05.2014)

[0017] What is claimed is

1. A method for using a USB interface to directly power the electric breast pump, comprising a housing, heat sink, dc convertor, USB power cable, characterized in that: said the dc converter will convert USB power to electric breast pump used power.

(2) as claimed in claim 1, wherein the Breast Pump USB power cable, characterized in that: said the cable functions to seek power source from USB and the common problem arising there from is the instability of the power (watt/voltage). The invention with the use of heat sink seeks to treat the problem of overheating resulting in energy inefficiency in powering the electric breast pump.

(3) as claimed in claim 1, wherein the Breast Pump USB power cable, characterized in that: said the invention with the use of dc converter seeks to finalize the purpose of the invention by regulating power sourced from USB in common voltage of 5V, and so convert it to be suitable voltage to power various electric breast pumps ranging from 3V-12V.

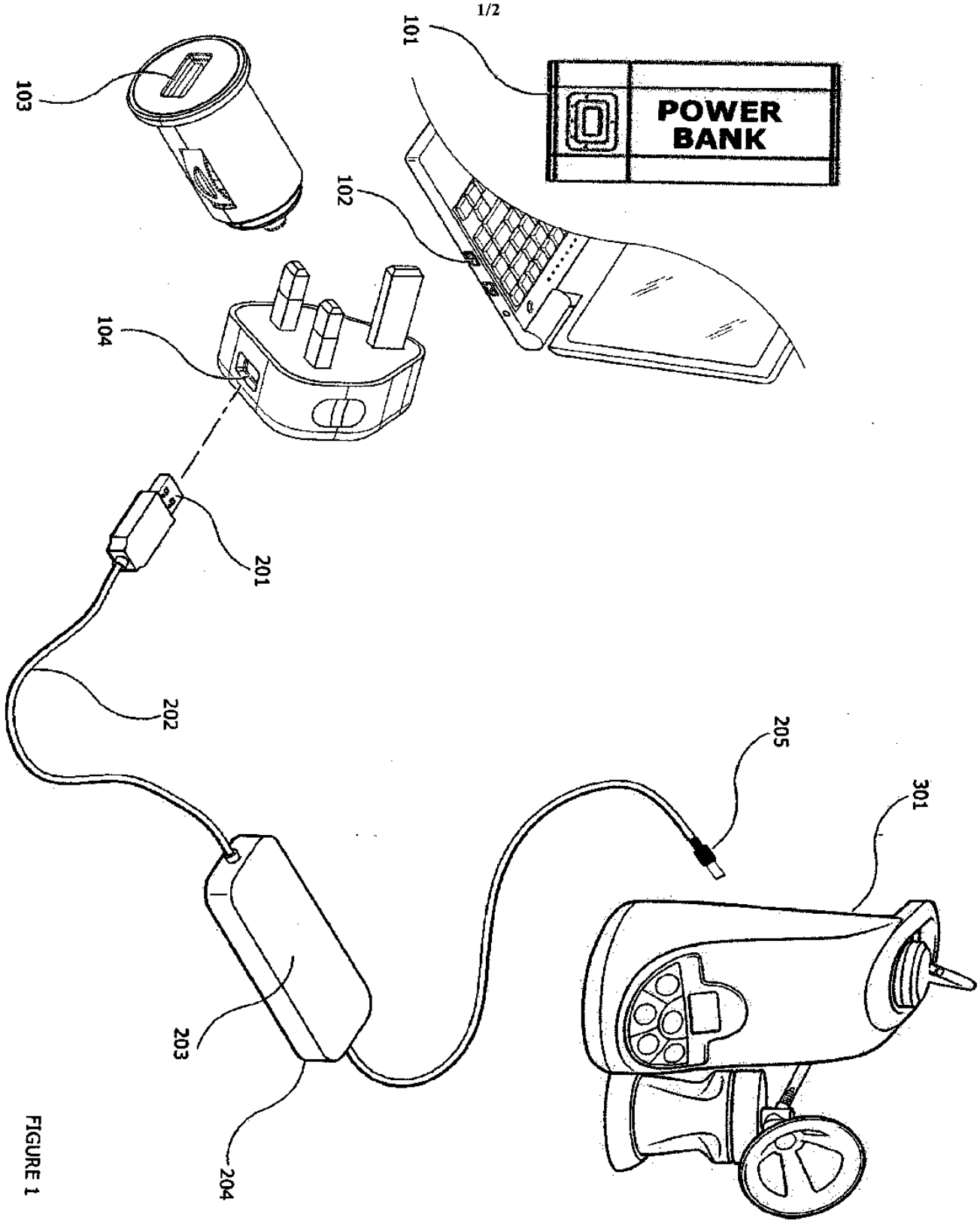


FIGURE 1

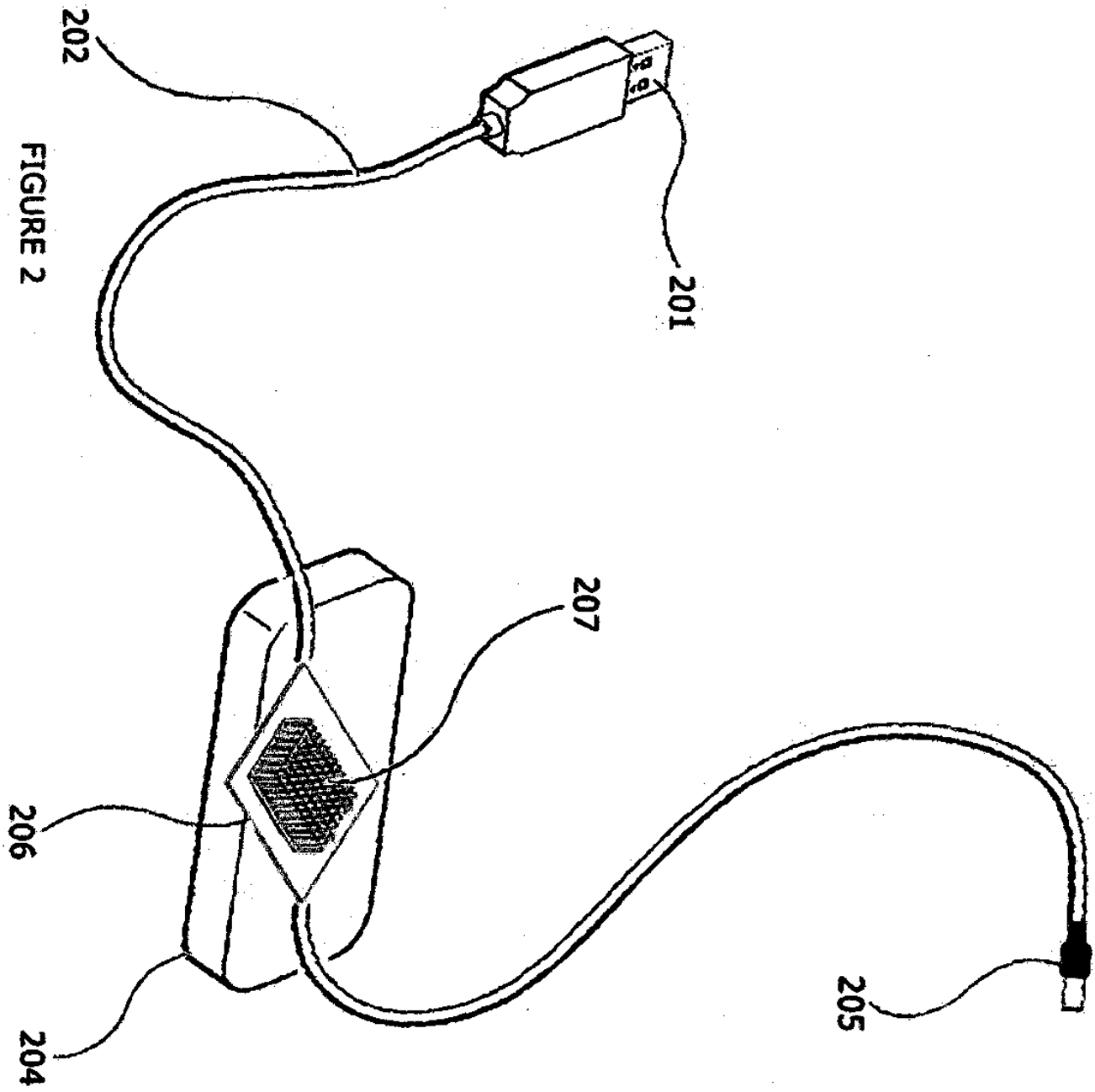


FIGURE 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/MY2013/000195

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl. A61M1/06(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl. A61M1/06

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

Published examined utility model applications of Japan 1922-1996
Published unexamined utility model applications of Japan 1971-2014
Registered utility model specifications of Japan 1996-2014
Published registered utility model applications of Japan 1994-2014

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/117352 A2 (CANNON RUBBER LIMITED) 2006.11.09, column 7, lines 18 to 22, figure 1 & JP 2008-538955 A & US 2010/0174232 A1 & EP 1893254 A2 & CN 101208117 A	1-3
Y	JP 2007-011551 A (SUZUKI Nobuyuki) 2007.01.18, paragraphs [0010] - [0012], figure 1 (Family: none)	1-3
Y	JP 3187092 U (TSUDA Seiji) 2013.11.07, abstract, claim 1, figure 1 (Family: none)	1-3
Y	EP 2211440 A2 (LIU Yunzhao) 2010.07.28, abstract, claim 1, figure 1 & JP 2010-207066 A & US 2010/0225269 A1 & CN 101789612 A	1-3

☑ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10.02.2014	25.02.2014

Name and mailing address of the ISA/JP	Authorized officer
Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Kenji KUMAGAI 3I 3819 Telephone No. +81-3-3581-1101 Ext. 3346

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/MY2013/000195

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0045237 A1 (LIU Jialong) 2010.02.25, abstract, paragraph [0004], figure 1 (Family: none)	1-3

Form PCT/ISA/210 (continuation of second sheet) (July 2009)

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

26111 7590 10/16/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 10/16/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/16/2025

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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 the USPTO patent electronic filing system.

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

26111 7590 10/16/2024
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

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 the USPTO patent electronic filing system 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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/16/2025

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/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 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)

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

☐ Electronic Payment via the USPTO patent electronic filing system ☐ 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

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.

☐ Applicant asserting small entity status. See 37 CFR 1.27

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.

☐ Applicant changing to regular undiscounted fee 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
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 10/16/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 10/16/2024

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) 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));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/181,057	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 RCE and IDSs filed.
   ☐ 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/
Primary Examiner, Art Unit 3783

Continuation of 3. The allowed claim(s) is/are: 1,3-22,24-25 and 28-34

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	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 SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf
Updated search	10/06/2023	cbf
Updated search	06/13/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see SEARCH history	06/13/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					Type	Version
A61M	/	1	/	062	F	2014-02-04
A61M	/	1	/	067	I	2021-05-01
A61M	/	1	/	06935	I	2021-05-01
A61M	/	1	/	0697	I	2021-05-01
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

Use images from artifact folder? (•) Yes ( ) No

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783 (Primary Examiner)	07 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					**Type**	**Version**
A61M	/	2205	/	7536	A	2013-01-01
A61M	/	2205	/	80	A	2013-01-01
A61M	/	2205	/	8206	A	2013-01-01
A61M	/	2209	/	082	A	2013-01-01
A61M	/	2209	/	088	A	2013-01-01

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

Use images from artifact folder? (•) Yes ( ) No

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783 (Primary Examiner) (Date) 07 October 2024	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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)**					

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783 (Primary Examiner) 07 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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		10		19		28								
	2		11		20		29								
	3		12		21		30								
	4		13		22		31								
	5		14		23		32								
	6		15		24		33								
	7		16		25		34								
	8		17		26										
	9		18		27										

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783 (Primary Examiner)	07 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2022/01/01 01:04 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20120277636" OR "20130023821" OR "20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR				

		"8057425" OR "8118772" OR "8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2022/01/14

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				12:42 PM
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"20090281485" "20120165729" "5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2023/03/24

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				05:34 PM
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM
L34	1	1 AND (correct WITH nipple WITH align$6)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/06 02:29 PM
L35	9837	a61m1/06-0697.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:15 PM
L36	23049	breast WITH pump	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:16 PM
L37	61	(35 34) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4 correct$4 appropriat$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:17 PM
L38	69	(35 36) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO;	OR	ON	ON	2024/03/12 05:57 PM

		correct$4 appropriat$4))	JPO; DERWENT; IBM_TDB)				
L39	173	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/13 05:16 PM
L40	76	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:16 PM
L41	42	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:16 PM
L42	0	("16713099").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:20 PM
L43	1	("6328709").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:22 PM
L44	2	("16/713099").app.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:23 PM
L45	1	("20160022477").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:28 PM
L46	376301	breast.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L47	7245334	pump$4.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L48	1027289	shield.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L49	237305	interchang$6.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2024/06/13 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L50	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L51	1017372	spacing.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L52	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L53	4	("20120035559").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 07:07 PM
L54	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:05 PM
L55	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:06 PM
L56	7	(US-10987455-$ | US-20170080135-$ | US-20170136161-$ | US-	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM

		20190275222-$ | US-20210170080-$ | US-20220031918-$ | US-20220409782-$).DID.					
L57	4	("20070060873").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/07 12:07 PM
L58	1	("20070060873").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM
L59	17	53 54 55 56 58	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:07 PM
L60	11	59 AND ((fit$4 siz$4) WITH (shield nipple interface cup flange))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:10 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	76349	breast.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N2	480637	pump$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N3	148822	shield.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N4	57138	interchang$6.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N5	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N6	250019	spacing.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N7	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N8	0	N1 AND N2 AND N3 AND N4 AND N5 AND N6 AND N7	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:35 PM

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-10987455-B2	04-27-2021	AALDERS; Arnold et al.	
	002	US-20170080135-A1	03-23-2017	CHEN; Junbo	
	003	US-20170136161-A1	05-18-2017	ALVAREZ; Jeffery B. et al.	
	004	US-20190275222-A1	09-12-2019	EVANS; Jeremy Patrick et al.	
	005	US-20210170080-A1	06-10-2021	O'TOOLE; Jonathan et al.	
	006	US-20220031918-A1	02-03-2022	QUACKENBUSH; Cam Lane	
	007	US-20220409782-A1	12-29-2022	HÖNER; Sebastian et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-1799436-A	07-12-2006	ZHU YUNYUAN [CN]		☒
	002	CN-205913571-U	02-01-2017	NINGBO YOUHA ELECTRIC TECH CO LTD.		☒
	003	WO-2017190678-A1	11-09-2017	YUEN CHEUK HO [CN]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	Exhibit List for IPR 2024-01296 (DECLARATION OF RYAN BAUER U.S. Patent No. 11,413,380) February 14, 2024, 142 pages.	☐
	002	International Search Report and Written Opinion for Application No. PCT/EP2023/073973, mailed on December 04, 2023, 9 pages.	☐
	003	International Search Report and Written Opinion for Application No. PCT/EP2023/073975, mailed on December 19, 2023, 9 pages.	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/07/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

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.

☒ A certification statement is not submitted herewith.

FEE

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	September 26, 2024
Name/Print	Yangbeini Wang	Registration Number	800,005

23097086.1

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

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2022/01/01 01:04 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20120277636" OR "20130023821" OR "20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR				

		"8057425" OR "8118772" OR "8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2022/01/14

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				12:42 PM
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"20090281485" "20120165729" "5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2023/03/24

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				05:34 PM
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM
L34	1	1 AND (correct WITH nipple WITH align$6)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/06 02:29 PM
L35	9837	a61m1/06-0697.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:15 PM
L36	23049	breast WITH pump	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:16 PM
L37	61	(35 34) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4 correct$4 appropriat$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/12 05:17 PM
L38	69	(35 36) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO;	OR	ON	ON	2024/03/12 05:57 PM

		correct$4 appropriat$4))	JPO; DERWENT; IBM_TDB)				
L39	173	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/13 05:16 PM
L40	76	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:16 PM
L41	42	39 AND (line correct spac$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:16 PM
L42	0	("16713099").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:20 PM
L43	1	("6328709").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:22 PM
L44	2	("16/713099").app.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:23 PM
L45	1	("20160022477").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:28 PM
L46	376301	breast.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L47	7245334	pump$4.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L48	1027289	shield.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:33 PM
L49	237305	interchang$6.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2024/06/13 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L50	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L51	1017372	spacing.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L52	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM
L53	4	("20120035559").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 07:07 PM
L54	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:05 PM
L55	8	("20080255503" OR "20120116299" OR "20120277728" OR "20150217033" OR "20210077673" OR "20230338630" OR "6257070" OR "7347089").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:06 PM
L56	7	(US-10987455-$ | US-20170080135-$ | US-20170136161-$ | US-	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM

		20190275222-$ | US-20210170080-$ | US-20220031918-$ | US-20220409782-$).DID.					
L57	4	("20070060873").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/07 12:07 PM
L58	1	("20070060873").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/07 12:07 PM
L59	17	53 54 55 56 58	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:07 PM
L60	11	59 AND ((fit$4 siz$4) WITH (shield nipple interface cup flange))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:10 PM
L61	1	("4000661").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/07 12:16 PM
L62	15	(("4000661").pn.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/07 12:16 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	76349	breast.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N2	480637	pump$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N3	148822	shield.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N4	57138	interchang$6.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N5	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N6	250019	spacing.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N7	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N8	0	N1 AND N2 AND N3 AND N4 AND N5 AND N6 AND N7	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:35 PM

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-20070060873-A1	03-15-2007	HIRAOKA et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		None				☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	Declaration of Ryan Bauer in Support of Request for Reexamination of U.S. Patent No. 11,357,893 Under 35 U.S.C. § 302 and 37 C.F.R. § 1.510, in the United States Patent and Trademark Office, September 24, 2024; 233 pages.	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/07/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

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.

☒ A certification statement is not submitted herewith.

FEE

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-10-03
Name/Print	Yangbeini Wang	Registration Number	800,005

23269323.1

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

Bibliographic Data

Application No: 17/181,057

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.
02/22/2021	604	3783	4944.0120006
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

This application is a CON of 16009547 06/15/2018 PAT 10926011

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

03/02/2021

STATE OR COUNTRY

UNITED KINGDOM

ADDRESS

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1101 K Street, NW
10th Floor
WASHINGTON, DC 20005
UNITED STATES

FILING FEE RECEIVED

$1,540

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

cU. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6257070-B1	07-10-2001	GIALLORENZO; Mario et al.	
	002	US-7347089-B1	03-25-2008	KELLEY; Anthony R. et al.	
	003	US-20080255503-A1	10-16-2008	QUACKENBUSH; Carr Lane et al.	
	004	US-20120116299 A1	05-10-2012	TACK	
	005	US-20120277728 A1	11-01-2012	WEBER et al.	
	006	US-20150217033 A1	08-06-2015	POLLEN et al.	
	007	US-20210077673-A1	03-18-2021	MASON; Brian et al.	
	008	US-20230338630-A1	10-26-2023	CLAASSEN; Coen Petrus Martinus et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	EP-4000661-A1	05-25-2022	KONINKLIJKE PHILIPS NV [NL]		☐
	002	WO-2005114113-A2	12-01-2005	ACCU GAUGE LTD [GB], et al.		☐
	003	WO-2016186452-A1	11-24-2016	PARK CHO HEE [KR]		☒

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO				Complete if Known	
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				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	FREDRICKSON, COURTNEY B
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	Declaration of Ryan Bauer In Support of Petition for Inter Partes Review of U.S. Patent No. 11,413,380, Exhibit 1005 in IPR2024-00953, May 31, 2024; 137 pages.	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/07/2024

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Attorney Docket Number	4944.0120006

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☐ See attached certification statement.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-06-26
Name/Print	Yangbeini Wang	Registration Number	800,005

22436991.1

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

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(Use as many sheets as necessary)

Sheet | 1 | of | 3

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Attorney Docket Number	4944.0120006

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Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-20070060873-A1	03-15-2007	HIRAOKA et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		None				☐

Examiner Signature		Date Considered	

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Sheet 2 of 3

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	001	Declaration of Ryan Bauer in Support of Request for Reexamination of U.S. Patent No. 11,357,893 Under 35 U.S.C. § 302 and 37 C.F.R. § 1.510, in the United States Patent and Trademark Office, September 24, 2024; 233 pages.	☐

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Sheet 3 of 3

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COPIES

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Signature	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-10-03
Name/Print	Yangbeini Wang	Registration Number	800,005

23269323.1

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**10/03/2024 05:24:14 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	67425032	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-10-03-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	167 KB
2024-10-03-sIDS-Pleading-49440120006.pdf	2	Letter specifying the conditions for filing under 37 CFR 1.97	98 KB
2024-10-03-sIDS-SB08-4944-0120006b.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	110 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_1_Bauer-Decl-Reexam-893.pdf	233	Non Patent Literature	1605 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-10-03-Transmittal-Form-sIDS-4944-0120006.pdf	92710A1CC1212B633A520ED49E9DA4019D30221773483457F8 3CCFB2FF9893380C0116BCD79A1D074681981A1212B0287C9 1462A2BE41141F7C4959EB912FAAE
2024-10-03-sIDS-Pleading-49440120006.pdf	9A0FBDCBDA2A09C9D58F3AEF511AEB19FDB412D4A16E8F6 5AB92767088D9EF99D431A295E416ECFB9F21D86D28ABCEB 08F3F3FAFBC376AF49AFA5CAB2585E81E
2024-10-03-sIDS-SB08-4944-0120006b.pdf	97CDAE5F38992A1C30E096A6E7C07826FE84CFD96E452CF2 AE5BAC26A3BD644DE8A26FB40BD1CC8068B745547FC8B4AF BDF87659E6C726F3EDBB2957BA4E9354
NPL_1_Bauer-Decl-Reexam-893.pdf	C41FA40A2511A7F8CBAE516F2F8F18FDD8A6A0139C79DD17 9428403CDF2C219461FECADCC678F3A0C5025703B7486C65E 673A9987C7CF21CFBDA1E624505A307

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 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 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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):

Copy of NPL1.

Remarks

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any over payment, to our Deposit Account No. 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	October 3, 2024	Reg. No.	800,005

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copy of document **NPL1** is submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copy of the U.S. patent application publication cited on the attached IDS Forms is submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: October 3, 2024

1101 K Street, NW
10th Floor
Washington, D.C. 20005
202-371-2600

23269312.1

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. 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.

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- ☐ 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):

Request for Continued Examination, Copies of FP1-FP3 and NPL1-NPL3.

Remarks

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
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Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	67332601	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 11

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-09-26-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	168 KB
2024-09-26-RCE-Form-4944-0120006.pdf	2	Request for Continued Examination (RCE)	273 KB
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2024-09-26-sIDS-Pleading-4944-0120006.pdf	2	Letter specifying the conditions for filing under 37 CFR 1.97	98 KB
2024-09-26-sIDS-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	112 KB
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FOR_001_CN1799436A_EFS.pdf	14	Foreign Reference	815 KB
FOR_002_CN205913571U_EFS.pdf	26	Foreign Reference	901 KB
FOR_003_WO2017190678A1_EFS.pdf	30	Foreign Reference	1322 KB
NPL_001_Ex1003_IPR2024-01296_US11413380_14Feb2024_142pgs_Part1_EFS.pdf	79	Non Patent Literature	1196 KB
NPL_001_Ex1003_IPR2024-01296_US11413380_14Feb2024_142pgs_Part2_EFS.pdf	63	Non Patent Literature	899 KB
NPL_002_ISR_WO_PCTEP2023073973_04Dec2023_9pgs_EFS.pdf	9	Non Patent Literature	122 KB
NPL_003_ISR_WO_PCTEP2023073975_19Dec2023_9pgs_EFS.pdf	9	Non Patent Literature	120 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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FOR_001_CN1799436A_EFS.pdf	5ABB72968DEDF22C26E982C65FE8A5CB840BB3FCC06A731F0E6505058AFEEFE5DF21933D82B8D5F2B1B591C1BDC956A9F68D16492B41B3D405294E7551AAD2C5
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NPL_001_Ex1003_IPR2024-01296_US11413380_14Feb2024_142pgs_Part1_EFS.pdf	A84B9FBDF20AC4D9B08A46DA8DE7E21A8001E7692B90B16D8607A65B1017E033B162B88E53CC71A3A619928D8FBC14E1B850FDE67D679E3D53CA19573EB42AF7
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NPL_002_ISR_WO_PCTEP2023073973_04Dec2023_9pgs_EFS.pdf	F1C777ADBFB01316D1C22965681820CB8D58B12DF2CC8DD65896BDB014421824B76FB1808A19171893953A66A1118364BC415FD163344B0B1E4FD1F7ABB873B6
NPL_003_ISR_WO_PCTEP2023073975_19Dec2023_9pgs_EFS.pdf	E98B365D67F5B773C7130B67D4F0EA56788B311E300F0D93D48232413B2A22EC541145DFD8CE0916CADDC522F6F24EC9340760AE27CA41B84E4343F07066100B

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Espacenet

Bibliographic data: CN1799436 (A) — 2006-07-12

Air sac squeezing type massaging and breast milk squeezing brassiere

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Classification: - international: *A41C3/00; A61M1/06*
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Abstract of CN1799436 (A)

The invention provides an extrusion massage with air bag and milking brassiere, particularly for nursery-age woman who can not suck in person or possesses excess latex, for which the invention provides a comfortable and clean sucking way. The brassiere comprises three main components: the air bad brassiere body (10); the air help device (20) providing heat for air pressurizing and negative pressure inducing; the drainage accessory for latex (30). The brassiere drops the original sucking with vacuum, replacing the cup with two air bags put in the brassiere, forcing out the latex and inducing to the milk bottle by employing principle that the aerating will makethe air bag expand and pressurized. The brassiere can be mated with far-infrared breast pad and breast vanishing cream to be used as massage brassiere for breast health and beautifying after the nursery-age is over.

[19] 中华人民共和国国家知识产权局

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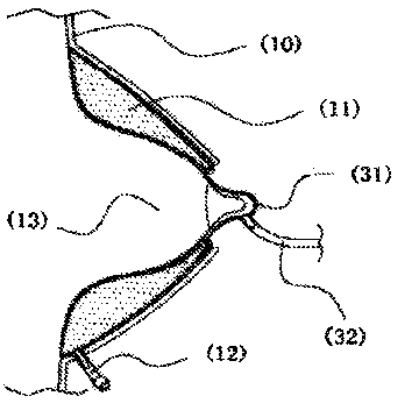
权利要求书 2 页 说明书 5 页 附图 5 页

[54] 发明名称

气囊挤压式按摩及挤乳胸罩

[57] 摘要

本发明气囊挤压式按摩及挤乳胸罩，系针对无法亲自哺乳或乳汁过多的哺乳期妇女，提供一种舒适清洁的挤乳方式。该胸罩由三个主要部件所构成：其一为气囊胸罩本体(10)；其二为提供温热加压空气及引流负压力的空气储浦(20)；其三为乳汁引流配件(30)。该胸罩舍弃以往真空吸引的方式，将两个气囊取代罩杯面置于胸罩内，利用气囊充气膨胀加压原理，将乳汁挤出后再引流至奶瓶中。本发明在妇女哺乳期结束后也可配合其它如远红外线胸垫、美胸乳霜等美胸材料，当作健胸、美胸的按摩胸罩使用。



1. 一种气囊挤压式按摩及挤乳胸罩，其特征在于，包括:

一个置入两个气囊罩杯的胸罩本体，该气囊罩杯的顶端为开口设计，类似于一火山的圆锥形状，以方便乳头露出收集乳汁；气囊罩杯的底部有一通气管延伸至胸罩外侧，借由该通气管可对气囊罩杯充气与放气，使得气囊罩杯得以膨胀与收缩，达到对乳房按摩与全面挤压的目的；

一个可产生正压温热空气及负压吸力的空气泵，经由电子回路与数个电磁阀的控制，该空气泵可产有高低压变化的脉冲温热正压空气，且压力、频率及温度皆可由操作面板设定；当该正压温热空气经导管与气囊罩杯连结后，可使气囊罩杯膨胀与收缩，产生乳房温热按摩与挤乳行程；当负压吸引力经导管与乳汁引流配件连结后，可将乳房挤压出的乳汁引流至一般的婴儿奶瓶中保存；

一组由可耐高温消毒的食用级硅胶(silicon rubber)及碳酸聚酯(poly carbonate resin)材质制成的乳汁引流组件，包含两个吸附于乳头上的集乳吸盘、两条连结集乳吸盘至奶瓶气密结构的乳汁引流导管、与一般婴儿奶瓶奶嘴尺寸相同的奶瓶气密结构、一条连结奶瓶气密结构至空气泵负压空气的吸气接口的导管。

2. 根据权利要求 1 所述的气囊挤压式按摩及挤乳胸罩，其特征在于，该构件之气囊罩杯的特征是气囊的弹性材料采用不同的厚度设计，由圆锥的底部(乳房根部)往顶端开口处(乳头侧)为由薄而渐次变厚的设计，如此当气囊罩杯被充气时，气囊罩杯将由底部先膨胀而渐次膨胀至顶部，产生一由下向上渐次推挤的力量；经由控制气囊罩杯充气与放气的压力及频率，可使气囊罩杯对乳房施予如揉捏般的按摩或由乳房根部往乳头方向的全面挤压作用。

3. 根据权利要求 1 所述的气囊挤压式按摩及挤乳胸罩，其特征在于，该构件之空气泵的特征是内部有一发热体，可输出脉冲温热的正压空气，且透过电子回路与数个电磁阀的控制，该正压空气的压力、频率及温度皆可由操作面板设定；又该空气泵同时具有一提供负压空气的吸气接口，提供乳汁引流时所需要的吸引力，且该负压吸力的强度也可由操作面板上调整。

气囊挤压式按摩及挤乳胸罩

技术领域

本发明属于妇女卫生用品，特别涉及一种哺乳期妇女使用的挤奶器的创新设计，尤其是一种利用温热脉冲正压空气对气囊充放，产生乳房温热按摩效果，以及利用气囊由乳房根部渐次向乳头方向挤压出乳汁，并经由负气压引流方式收集乳汁的设计。

技术背景

众所周知，母乳是自然界最珍贵的婴儿食品，然而由于职业妇女工作的关系，哺乳期职业妇女往往无法亲自哺乳，就算回到家中也因为半夜需起床哺乳而导致精疲力竭。医学证实，清洁未被污染的母乳经冷冻后可保存数周以上，婴儿食用时仅需用温热的水隔水加热即可。针对此需求，市场上出现许多形式的挤乳器，然而传统挤乳器的基本工作原理是将类似吸盘结构的挤乳器局部的罩在乳房的乳头侧，利用手动或电动真空帮浦产生的强力真空吸引方式将母乳吸出，致使哺乳妇女疼痛难耐，使得哺乳期妇女对挤乳视为畏途。甚至于导致乳头外翻、变大、变黑。在使用真空帮浦型式的挤乳器前，仍然需要用热毛巾热敷乳房并施予按摩，使乳腺充分泌乳后才能挤乳。使用时也需双手或单手操作，无法兼做其它如阅读的轻松工作。且目前市场上现存的挤乳器由于吸盘与真空帮浦为一体结构，不利于清洁，在挤乳时有可能造成母乳的污染。

发明内容

本发明的目的是为哺乳期妇女设计一种舒适、方便及容易清洁的母乳收集器——气囊挤压式按摩及挤乳胸罩，舍弃原有用手操作的真空吸引挤乳方式，而改以胸罩穿戴方式的气囊挤压技术手段实行母乳引流收集，同时一举解决上述的各种问题。

本发明的技术方案是这样实现的，该气囊挤压式按摩及挤乳胸罩是由三个主要部件所构成：其一为气囊胸罩本体(10)；其二为提供温热加压空气及引流负压力的空气泵(20)；其三为乳汁引流配件(30)。

气囊胸罩本体(10)的基本设计是将两个罩杯型的气囊置入胸罩内取代原有

的罩杯，惟该胸罩乳头侧为开口设计，以方便乳头穿过露出引流乳汁，开口侧有一组魔术毡(13)用来固定集乳吸盘(31)。该气囊胸罩的两罩杯下方有两个气囊罩杯气管接口(12)供气囊罩杯(11)充气与泄气用，气囊胸罩本体(10)的中央下方有一置放奶瓶的奶瓶袋(14)。该气囊罩杯(11)的气囊壁厚采用不同厚度设计，由底部至顶部的胶壁壁厚由薄渐渐变厚，如此当气囊罩杯(11)被充气时，气囊罩杯(11)将由底部先膨胀而渐次膨胀至顶部，产生一由下向上渐次推挤的力量，其原理就好像吹汽球时，胶壁厚较薄的地方会先凸出一样。当此气囊罩杯(11)罩于乳房上时，对乳房将产生由乳房根部往乳头方向的全面推挤作用，将整个乳房中乳腺分泌的乳汁挤压至乳头，再利用空气泵(20)产生的引流负压力，经由集乳吸盘(31)及乳汁引流导管(32)引流至奶瓶中。气囊罩杯(11)的材质可为橡胶(rubber)、硅胶(silicon rubber)等弹性材料。胸罩本体的外层材质为无伸缩性布料，例如应用于血压计上的尼龙(Nylon)布料即可，如此当气囊罩杯(11)膨胀时，所有的挤压力会集中于乳房上。胸罩本体的内衬材质则使用柔软吸汗的质料即可。

空气泵(20)设计的基本原理类似于一小型活塞往复式空气压缩机，惟该空气压缩机多了一个负压空气的吸气接口以供应乳汁引流所需要的吸引力。该空气泵主要构成部件有两条正压温热空气输出气管(21)、一个负压空气的吸气接口(22)以及一防止乳汁吸入泵的排水阀(221)、产生温热空气的电热器、一个调整正压温热空气压力大小的机械式压力调整阀(23)、一个调整负压空气压力大小的机械式压力调整阀(24)、电子控制回路、电磁阀、操作面板(25)。整体而言，该空气泵(20)的各部件并无特殊的结构，皆为市面上可购得的产品，惟经过电子控制回路与数个电磁阀的控制，可产生气囊挤压式按摩挤乳胸罩所需要的正压温热空气及负压吸引力。本空气泵设计的特色，在于各种正压、负压、充放气周期及温热空气的温度皆可经由电子控制回路的控制，依使用者的需求在操作面板(25)上自行调整。

乳汁引流配件(30)为一组由可耐高温消毒的食用级硅胶(silicon rubber)及碳酸聚酯(poly carbonate resin)材质制成的乳汁引流组件。其中包含两个置放于乳头的集乳吸盘(31)与乳汁引流导管(32)、奶瓶气密结构(33)、连结奶瓶气密结构至空气泵(20)负压空气吸气接口(22)的导管(34)。该配件的奶瓶气密结构(33)设计非常简单，吾人可想象其结构就像一般婴儿奶瓶用的奶嘴变成有3个接口(331)而可连结3条导管的结构。使用时仅需将一般婴儿奶瓶(35)的奶嘴取下，然后换上奶瓶气密结(33)构并锁紧即可。

本发明的有益效果是，先前的挤乳器是以真空吸引的原理设计，使用前仍然需要用热毛巾对乳房施以按摩，使乳腺扩张泌乳后再行真空吸引；本发明气囊挤压式按摩及挤乳胸罩，使用前仅需适当清洁乳房，将气囊胸罩本体(10)依说明书指示穿戴妥当，按下操作面板(25)上的自动挤乳行程，而后电子控制回路会自动执行温热按摩及挤乳的行程。本发明之空气泵设计无论正压、负压、充放气周期及温热空的气温度皆可依使用者的需求自行调整，使用者可轻易找到其最舒适的挤乳模式，而且在气管长度可及的范围内仍然可进行一些轻松的工作。

下面结合附图和实施例对本发明做一详细说明。

附图说明

图 1 为本发明之外观立体组装图；

图 2 为气囊胸罩本体立体透视图；

图 3 为气囊罩杯充气前的剖视图；

图 4 为气囊罩杯充气后对乳房挤压的剖视图；

图 5 为空气泵之外观立体图；

图 6 为乳汁引流配件之外观立体组装图。

具体实施方式

请见图 1-图 6，图中：(10) 气囊胸罩本体，(11) 气囊罩杯，(12) 气囊罩杯气管接口，(13) 乳房，(14) 魔术毡，(15) 奶瓶袋，(20) 空气泵，(21) 正压温热空气输出气管，(22) 负压空气吸气接口，(221) 负压空气吸气接口排水阀，(23) 正压空气机械式压力调整阀，(24) 负压空气机械式压力调整阀，(25) 操作面板，(30) 乳汁引流组件，(31) 集乳吸盘，(32) 乳汁引流导管，(33) 奶瓶气密结构，(331) 奶瓶气密结构导管接口，(34) 负压空气导管，(35) 婴儿奶瓶。

使用气囊挤压式按摩挤及乳胸罩时，首先对乳房做适当的清洁，然后将气囊胸罩本体(10)如一般胸罩一样穿戴于胸部；再将两个气囊罩杯气管接口(12)与空气泵上两条正压温热空气输出气管(21)连结；再将两集乳吸盘(31)置于乳头并用胸罩上的魔术毡(13)固定；取出欲收集乳汁的一般婴儿奶瓶(35)，将奶嘴取下换上奶瓶气密结构(33)并锁紧；再将两乳汁引流导管(32)接到奶瓶气密结

构(33)上的两个接口(331)；再将提供负压吸力的导管(34)由奶瓶气密结构(33)上的第 3 个接口(331)接到空气泵(20)负压空气的吸气接口(22)；而后将奶瓶放入气囊胸罩本体(10)上的奶瓶袋(14)中，即完成挤乳的准备作业。此时将空气泵(20)接上电源，按下操作面板(25)上的自动挤乳行程，就可以轻松的完成舒适卫生的母乳收集。

空气泵(20)作动时，空气泵(20)内的空气压缩机会启动产生需要的正压空气及负压空气。正压空气经气管连结至一可调整正压空气气压的机械式压力调整阀(23)，使用者可依自己的乳房大小调整出舒适的气囊罩杯(11)最大膨胀压力；经过机械式压力调整阀(23)后的正压空气，再经气管连结至一可使正压空气加热的电热器；经电热器加热后的温热正压空气此时被分为两气管通路；每一气管通路上各有一个受电子控制回路控制的三通电磁阀，该三通电磁阀的往复动作相当于气管通路上的一个进气排气口，使得经过该阀后的温热正压空气变成一有高低压变化的脉冲温热正压空气；在三通电磁阀后还有一组与电子控制回路连结的压力及温度感应器，透过该组感应器的监测，电子控制回路会依使用者在操作面板(25)上的设定改变三通电磁阀的往复频率及电热器的功率，进而达到使用者希望的温热脉冲按摩强度、周期及温度；最终该两气管连结到空气泵(20)的两条正压温热空气出气管(21)分别供应给左右气囊罩杯(11)膨胀所需的温热正压空气。负压空气经气管连结至一可调整负压空气气压的机械式压力调整阀(24)，经过机械式压力调整阀(24)后的负压空气，最终经气管连结到空气泵(20)的负压空气吸气接口(22)。

自动挤乳行程执行时，首先空气泵(20)会输出脉冲温热正压空气，此时胸罩内的气囊罩杯(11)会随着脉冲频率快速的膨胀及收缩，对乳房施以如揉捏一般的按摩，由于温热空气的不断进出，气囊罩杯(11)的温度也会随着升高而温热乳房使乳腺泌乳，此为第一阶段的乳房温热按摩行程。透过电子控制回路的控制使用者可在操作面板(25)上设定自己感觉最舒适的按摩强度、周期及温度。待数分钟后乳房温热按摩行程终了，第二阶段挤乳行程开始，此时空气泵(20)会输出依机械式压力调整阀(23)设定的气囊罩杯(11)最大膨胀压力输出温热正压空气，此时气囊罩杯(11)对乳房产生由乳房根部往乳头方向的全面推挤作用，将整个乳房中乳腺分泌的乳汁挤压至乳头侧，被挤压出来的乳汁则经由置于乳头的集乳吸盘(31)及乳汁引流导管(32)引流至奶瓶中。使用者可调整负压空气气压的机械式压力调整阀(24)设定舒适的乳汁引流吸力。透过电子控制回路的控制，在空气泵(20)输出最大膨胀压力持续数秒钟后，三通电磁阀会作动使气

囊罩杯(11)泄气，以免造成使用者的不适。该作动周期会持续反复进行，直到乳房无法再挤出乳汁或胀乳感觉消失时，使用者按下操作面板(25)上的停止键即完成挤乳工作。

由于本发明气囊挤压式按摩及挤乳胸罩的两气囊罩杯(11)分别由两组气管独立供气，再加上电子控制回路及数个气阀的控制，使用者不仅可由操作面板(25)上设定温热脉冲按摩强度、周期、温度及挤乳压力。更可以选择左右乳房同时揉捏按摩和挤压乳汁或交替揉捏按摩和挤压乳汁，也可以单独选择乳房温热按摩行程或挤乳行程。因此本发明气囊挤压式按摩及挤乳胸罩在妇女哺乳期结束后，或是一般爱美的女性，皆可配合其它美胸材料，如远红外线胸垫、美胸乳霜等，当作健胸、美胸的按摩胸罩使用。可说是一集健胸、美胸与挤乳于一身的多功能胸罩。

本发明气囊挤压式按摩及挤乳胸罩的精神，在于利用气囊罩杯的充气(膨胀)与放气(收缩)并控制充放气的温度、压力及频率，使气囊罩杯对乳房施予如揉捏般的温热按摩或由乳房根部往乳头方向的全面挤压作用，进而达到按摩及挤乳的功能。在实施方式中所叙述的实施例为本发明的具体实施方式，但并非用以限制本发明，对于熟知该技艺之人员，也许可利用不同材料、改变或修饰其结构制作出类似的产品，只要不脱离本发明的精神，则均属于本发明的申请专利范围。

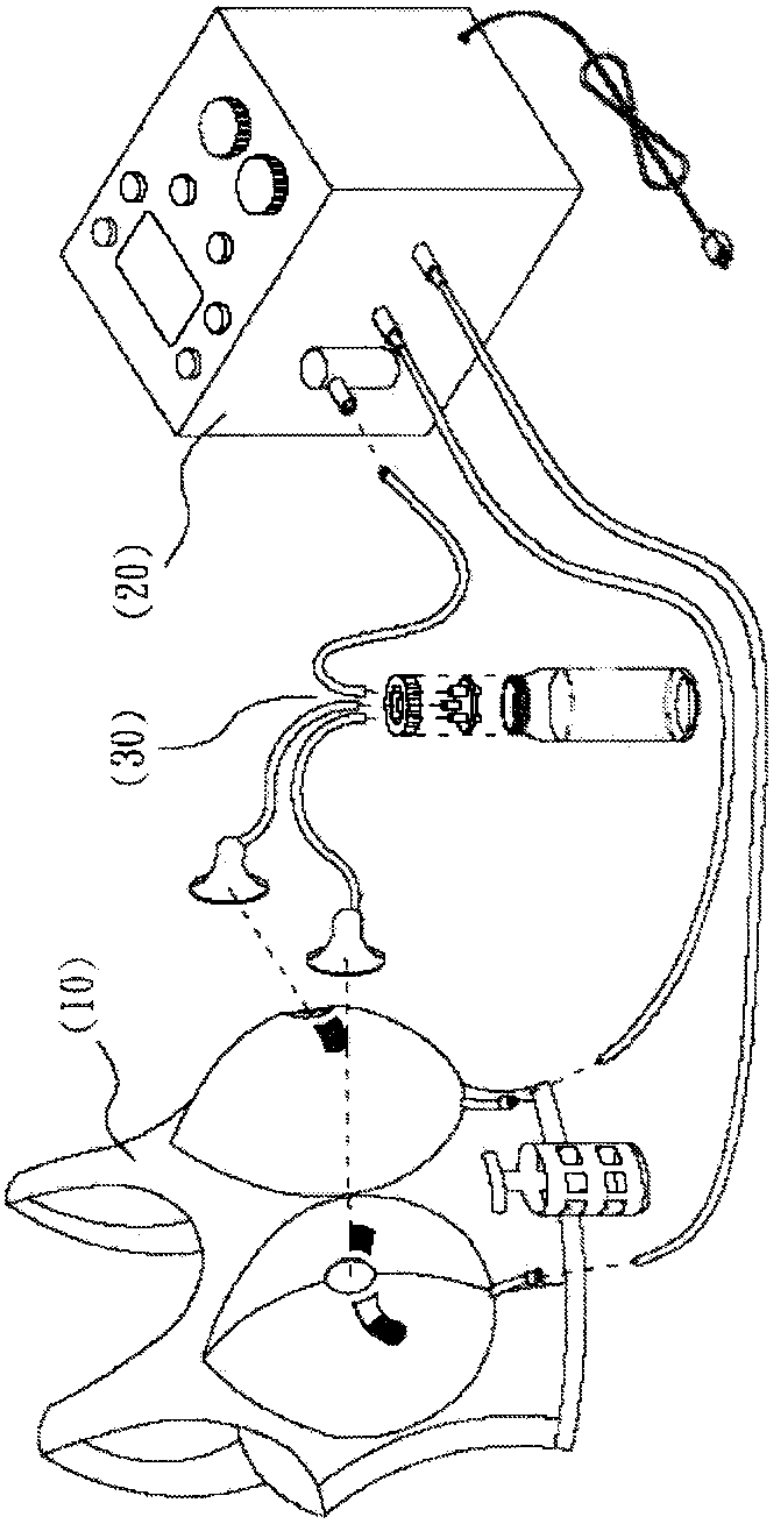


图1

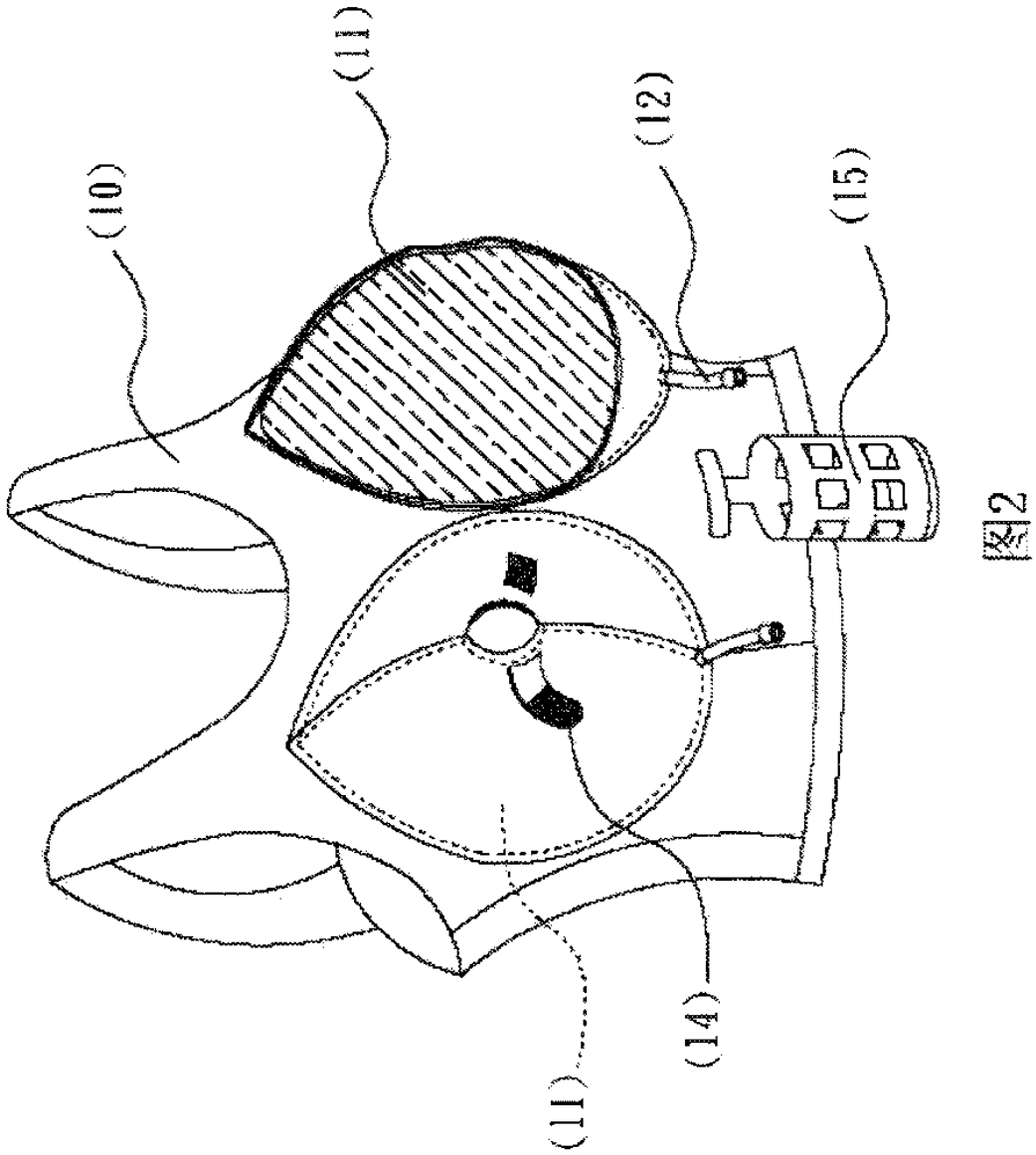


图2

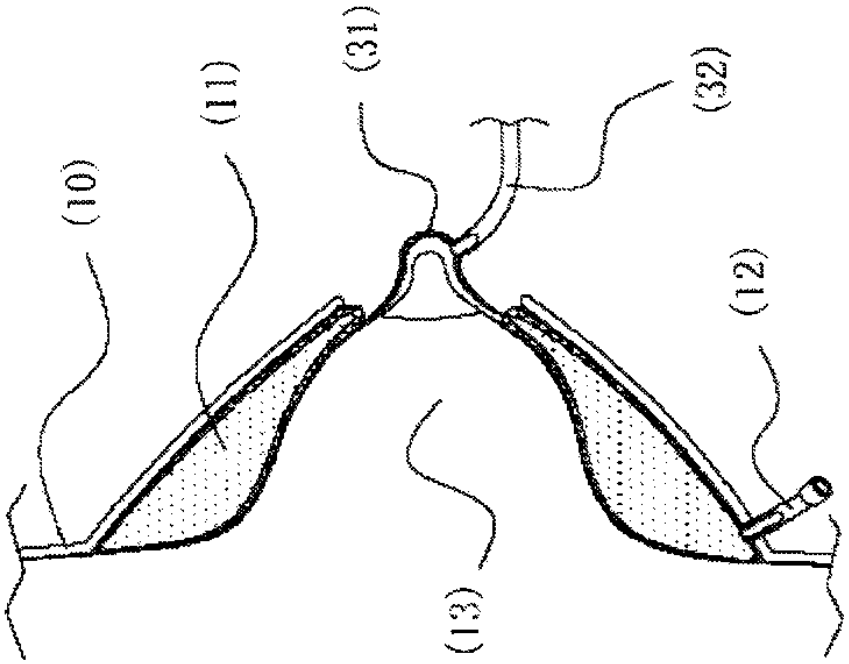


图4

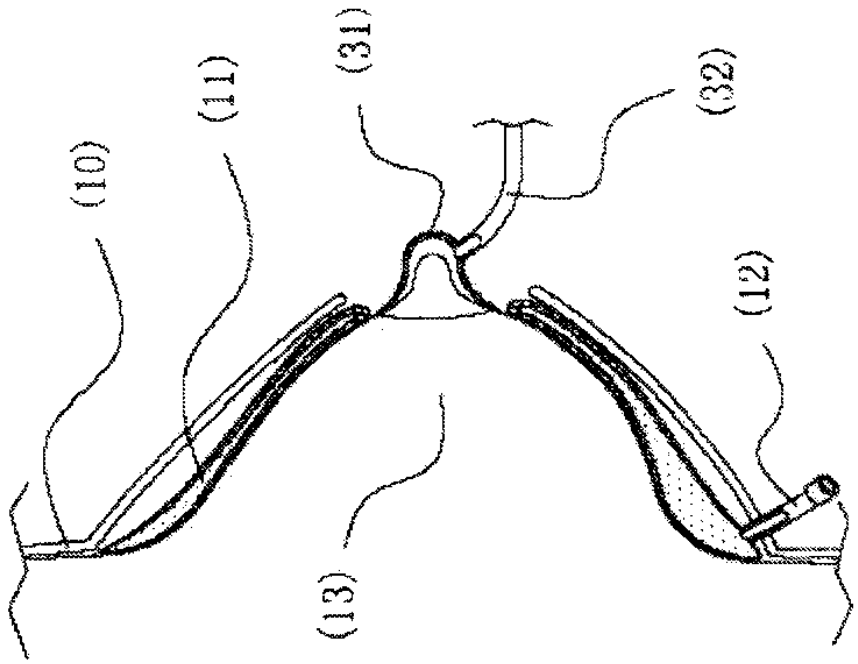


图3

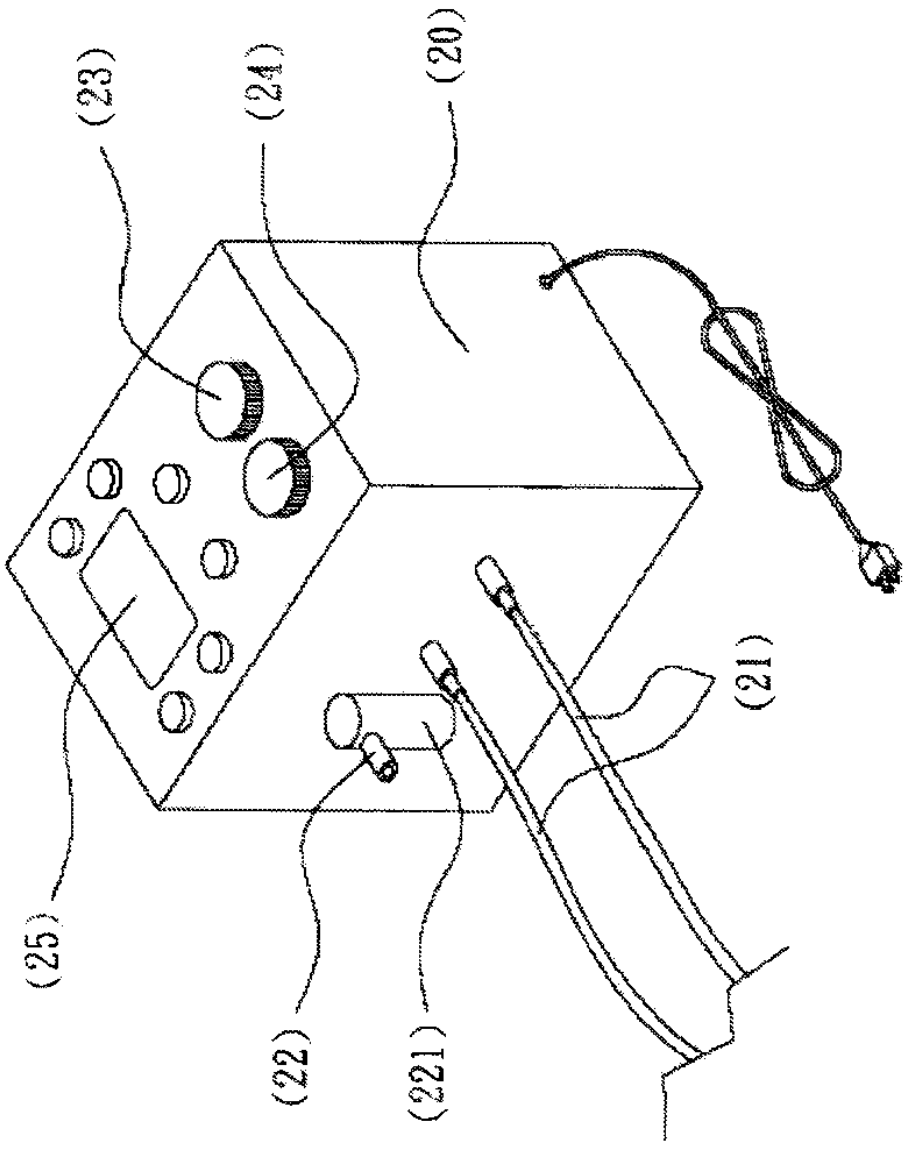


图5

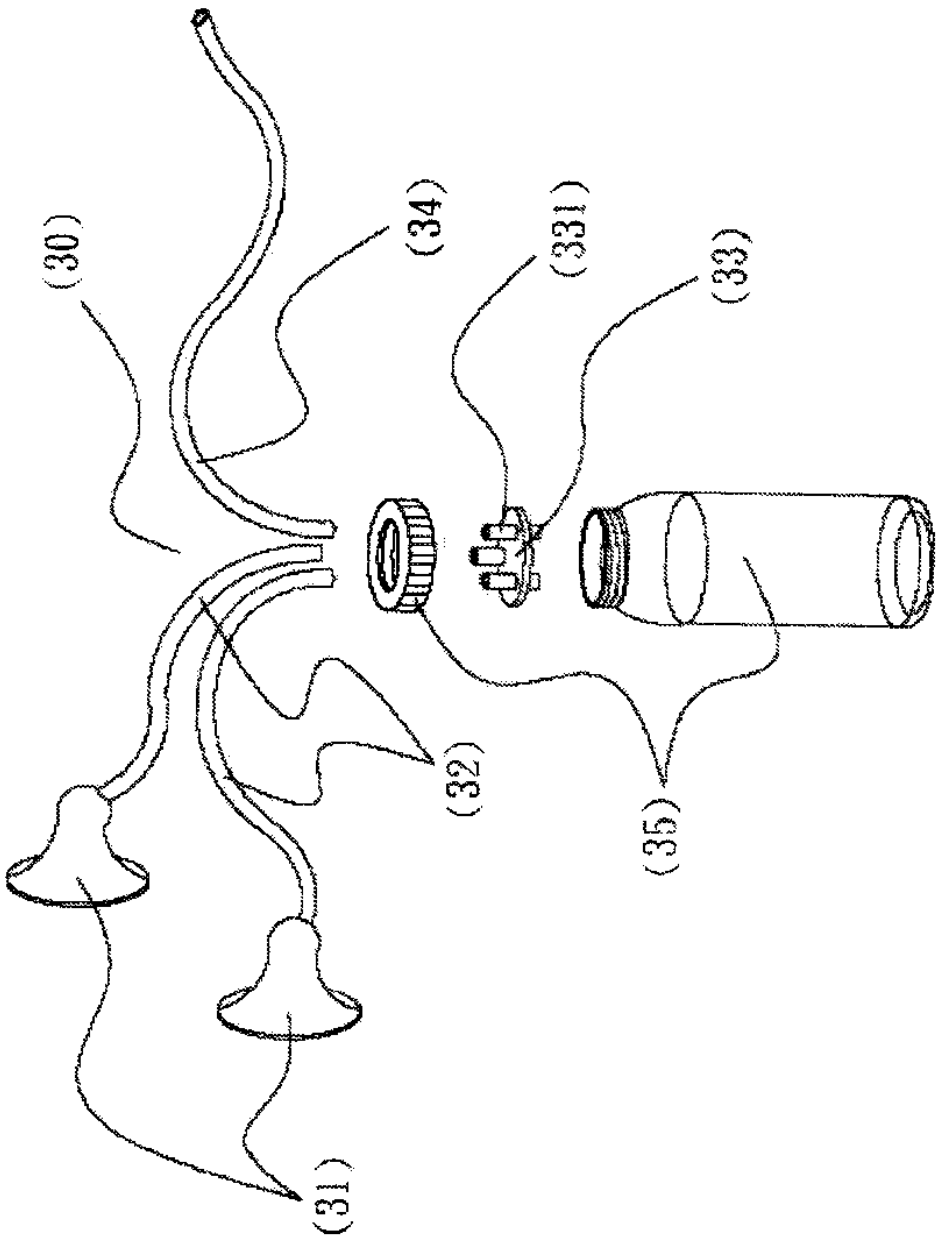


图6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

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PO Box 1450
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Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP3** and **NPL1-NPL3** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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(54) Title: AN APPARATUS FOR RECEIVING A CONTAINER

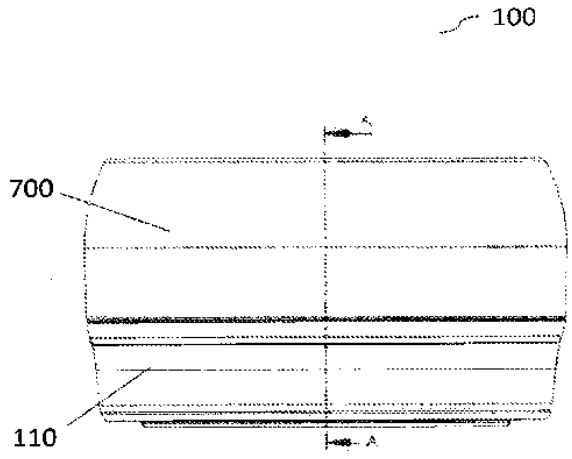


Fig.1A

(57) Abstract: An apparatus for receiving a container, comprising: a weighing unit arranged to measure the mass of the container provided thereon during a predetermined interval; a processor arranged to possess the measured mass during the predetermined interval to provide information relating to the consumption of the content stored in the container.

[Continued on next page]

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AN APPARATUS FOR RECEIVING A CONTAINER

TECHNICAL FIELD

The present invention relates to an apparatus for receiving a container and more particularly, although not exclusively, relates to an apparatus for receiving a container having a weighing unit arranged to measure the mass of the container provided thereon during a predetermined interval.

BACKGROUND

Among numerous ways to monitor a baby's growth, diet pattern has been proven to be an effective reference for infant health analysis. In Hong Kong, the Department of Health advises parents to record their baby weight and milk consumption pattern for 1.5 years. However, the present practice for tracking infant nutrition is performed by manually logging each feed with a baby journal. Although one may track the infant nutrition with mobile applications, such application still requires the manual logging of the infant nutrition while the data presentation of the infant nutrition may not reflect the diet habit of the infant. Thus, the current practice still lacks accuracy to a certain extent and there remains much room for improvement in the field of infant diet tracking.

SUMMARY OF THE INVENTION

To address or reduce at least some of the above problems, examples of the present invention may disclose an apparatus having a weighing unit e.g. a half bridge weight sensor for measuring the mass of the container provided thereon repetitively during a predetermined interval, and a processor with an algorithm for deriving the nutritional uptake by a user from the consumed content of the container based on the measured mass accordingly.

In accordance with a first aspect of the present invention, there is provided an apparatus for receiving a container, comprising: a weighing unit arranged to measure the mass of the container provided thereon during a predetermined interval; a processor arranged to possess the measured mass during the predetermined interval to provide information relating to the consumption of the content stored in the container.

In one embodiment of the first aspect, the weighing unit is isolated from the lower portion of the apparatus underneath.

In one embodiment of the first aspect, the weighing unit is received within a sandwich layer structure having at least an upper layer, a lower layer, and an intermediate layer therebetween.

In one embodiment of the first aspect, the weighing unit is mounted on the intermediate layer and the intermediate layer is mated with the upper layer.

In one embodiment of the first aspect, the lower layer includes a standing structure for stabilising the apparatus.

In one embodiment of the first aspect, the weighing unit includes a half bridge weight sensor.

In one embodiment of the first aspect, the accuracy of the weighing unit is calibrated by a backend comparison.

In one embodiment of the first aspect, further comprising a temperature sensing unit for measuring the temperature of the content stored in the container.

In one embodiment of the first aspect, the temperature of the content is measured by an infrared signal of the temperature sensing unit.

In one embodiment of the first aspect, the temperature sensing unit is provided below the container.

In one embodiment of the first aspect, further comprising an aperture or a transparent window between the container and the temperature sensing unit whereby the infrared signal penetrating therethrough.

In one embodiment of the first aspect, the total consumption of the content stored in one or more containers during the predetermined interval is monitored by a plurality of measured mass.

In one embodiment of the first aspect, each measured mass is obtained at a regular interval.

In one embodiment of the first aspect, each measured mass is obtained from the average of a plurality of successive measurements.

In one embodiment of the first aspect, further comprising an indicator for providing an indication associated with the operation of the apparatus to a user.

In one embodiment of the first aspect, the indication is visually depicted by a plurality of light indications with various wavelengths.

In one embodiment of the first aspect, the indicator is segregated into a plurality of partitions whereby each depicts a light indication with a unique colour.

In one embodiment of the first aspect, the indicator is a ring-shaped indicator.

In one embodiment of the first aspect, the indication is provided on a remote device in communication with the apparatus.

In one embodiment of the first aspect, the indication represents the thermal status of the content relative to a predefined temperature range.

In one embodiment of the first aspect, the indicator provides a first indication when the thermal status of the content exceeds the predefined temperature range.

In one embodiment of the first aspect, the indicator provides a second indication when the thermal status of the content is below the predefined temperature range.

In one embodiment of the first aspect, the operation includes at least one of the power charging, pairing with a remote server or a remote device, and power on/off.

In one embodiment of the first aspect, further comprising a tilt sensing unit for sensing the tilting of the apparatus.

In one embodiment of the first aspect, the weighing unit is activated or temporarily deactivated based on the measured tilt.

In one embodiment of the first aspect, the tilt sensing unit includes an accelerometer.

In one embodiment of the first aspect, the processor includes an algorithm for deriving the nutrition uptake by a user through the consumption of the content stored in the container from the measured mass.

In one embodiment of the first aspect, the processor is in data communication with a database storing the data associated with at least one of the food or beverages and the user info.

In one embodiment of the first aspect, the food or beverages data includes the corresponding nutrition content of various food or beverages.

In one embodiment of the first aspect, the type of food or beverages stored in the container is matched with the food or beverages data prior to the consumption.

In one embodiment of the first aspect, the total nutrition uptake by the user through a plurality of consumptions during the predetermined interval is derived from the accumulated measured mass.

In one embodiment of the first aspect, the food or beverages data includes at least one of the origin, manufacturer info, and market price of the food or beverages.

In one embodiment of the first aspect, the user data includes at least one of the height, mass, head circumferences, age, and diet data of the user.

The height, mass, head circumferences, age, and diet data of the user applies to the user of that is taking the feed, and may be the child, infant or baby.

In one embodiment of the first aspect, further comprising a holder for receiving the container.

In one embodiment of the first aspect, the friction between the holder and the container restrains the movement of the container, thereby improving the accuracy of the measured mass.

In one embodiment of the first aspect, the holder includes a valve-like structure.

In one embodiment of the first aspect, the holder is made of materials with a high friction coefficient.

In one embodiment of the first aspect, the holder is made of silicon.

In one embodiment of the first aspect, the holder is coupled to the apparatus through a magnetic coupling.

In one embodiment of the first aspect, further comprising a pair of magnets of which each provided on the opposing surfaces of the holder and the apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings in which:

Figure 1A shows a front view of the apparatus in accordance with one embodiment of the present invention;

Figure 1B shows a cross sectional view of the apparatus taking along the line A-A in Figure 1A;

Figure 2A shows a perspective view of the weighing device in accordance with one embodiment of the present invention;

Figure 2B shows a front view of the weighing device in accordance with one embodiment of the present invention;

Figure 2C shows a cross sectional view of the weighing device taking along the line A-A in Figure 2B;

Figure 2D shows an explosive view of the weighing device in Figure 2A;

Figure 3A shows a perspective view of the holder in accordance with one embodiment of the present invention;

Figure 3B shows a bottom view of the holder in accordance with one embodiment of the present invention;

Figure 3C shows a cross sectional view of the holder taking along the line A-A in Figure 3B;

Figure 4A shows a front view of the apparatus in accordance with another embodiment of the present invention;

Figure 4B shows a cross sectional view of the apparatus taking along the line A-A in Figure 4A;

Figure 4C shows another cross sectional view of the apparatus taking along the line B-B in Figure 4A;

Figure 5 is a schematic diagram showing the operation flow of the apparatus in accordance with one embodiment of the present invention; and

Figure 6 is a block diagram of the apparatus, illustrating an example of its computer processor and the data in which the processor processes.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to Figures 1A to 4C, there is provided an apparatus 100 for receiving a container comprising: a weighing unit 200 arranged to measure the mass of the container provided thereon during a predetermined interval; a processor 300 arranged to process the measured mass during the predetermined interval to provide information relating to the consumption of the content stored in the container.

In one example embodiment of the apparatus 100, the apparatus 100 is arranged to monitor and measure the consumption of milk, juice, water or any other suitable beverage by a child, toddler or baby by weighing the mass of the contents within a feeding bottle fitted to the apparatus 100 during a feed. Preferably, the bottle may be snuggly fitted to the apparatus 100 by firstly inserting it snugly within a detachable holder 700, and then the holder 700, together with

the bottle may then be engaged to the apparatus 100 via a coupling arrangement that may include the use of a magnetic coupler such that the apparatus 100 may begin its interaction with the bottle to measure its mass and/or temperature or other characteristics to determine consumption of the beverage over a time interval. Thus when the user starts a feed for a child, infant or any other user, the user may alternate between a feeding position (bringing the bottle to the child so as to take the beverage) and placing the bottle onto a surface, such as a table during a feeding break. In turn the apparatus 100 may weigh the mass of the bottle during the feeding break and can determine the weight of any contents that has been consumed over an interval of time as measured from the start of the feed, or when the bottle is in the feeding position. In some alternative embodiments, the holder 700 may also be formed to be part of the apparatus 100 such that the bottle is directly engaged with the apparatus 100 when the bottle is inserted within the holder 700, thus allowing a user to manipulate the bottle with the apparatus 100 as attached to the bottle.

By measuring the consumption of the beverage by a child (calculated based on the amount of beverage that remains in the bottle as determined by the overall mass of the bottle) over a set interval of time, say the feeding time of the child by a parent or caretaker, the information can then be recorded and processed so as to assist the parent or caretaker to track the feeding patterns of the child.

Researches indicate that a baby only needs about 2.5 oz per lb of their weight per 24 hours up until they reach about 10 pounds. Preferably, the apparatus 100 may be used to keep tracking the bottle feeding progress of an infant from time to time. For instance, the apparatus 100 may include a holder arranged to snug fit a bottle with customised size. Initially, the parent or the caretaker may place an empty container horizontally on a flat, stable surface of the holder above the apparatus 100. The user may then pour the milk powder and the preheated water into the bottle, and mix up the content in the bottle vigorously until the milk powder has been fully dissolved. The parent or the caretaker may read the measured mass of the container from the apparatus 100 anytime during milk preparation.

Depending on the feeding habit of the infant, the bottle feeding may not be completed in one go. For example, the infant may not consume the milk continuously and one may even require several breaks in between. Thus, it may be particularly useful to monitor the mass of the bottle throughout a predetermined interval, i.e. the duration of the milk consumption process. Advantageously, the parent or the caretaker may retrieve the data information relevant to the content or the infant, e.g. the remaining mass in the bottle, or the consumption rate of the infant

anytime, for example during each interruption. Such information may be uploaded to the cloud database simultaneously through the apparatus 100 for further data analysis.

Preferably, the size of the holder may be tailor made to snug fit with the bottle. For example, the inner circumference of the holder may tight fit the outer circumference of the bottle, thereby ensuring the bottle is placed on the apparatus 100 securely without any tilting. Alternatively, a bottle with a much smaller outer circumference may also be securely received within the holder through an adaptor or annular ring, preferably made of resilient materials such that the bottle would not be loosened from the apparatus 100 accidentally.

In this embodiment, the apparatus 100 includes a weighing device 110 for measuring the mass of a container (not shown) provided thereon. The weighting device 110 may comprise an upper housing 112 and a lower housing 114, where the two housing portions 112 and 114 and the inner components of the weighing device 110 received therein form a sandwich layer structure 120 having an upper layer, a lower layer and an intermediate layer therebetween.

In this sandwich layer structure 120, a weighing unit 200 is positioned between the upper housing 112 and the lower housing 114 for measuring the mass of a container provided on the upper housing 112. For instance, the weighing unit 200 may be mounted on the intermediate layer, of which mates together with the upper housing 112 or the upper layer of the sandwich layer structure 120. On the other hand, the lower housing 114 may be provided a standing structure 122 underneath as a counterweight against tilting for stabilising the weighing device 110 with respect to the surface where the weighing device 110 is rested thereon. Preferably, the standing structure 122 may further include a pair of pillars 124 made of elastic materials, e.g. rubber for vibration dampening.

Preferably, the weighing unit 200 may be a high sensitivity sensor e.g. a half bridge weight sensor 200 for measuring the volume changed of the container. Advantageously, the weight sensor 200 may be arranged to contact directly only with the upper housing 112, thereby eliminating any errors associated with the weighing of the lower housing 114. For instance, the weight sensor 200 may include a pair of screws 126 for mounting the body of the weight sensor 200 to the upper housing 112 or the upper layer of the sandwich layer structure 120 through a sensor holder 202. The weighing unit 200 is thus isolated from the lower portion of the weighing device 110 underneath, and this may significantly reduce the inaccuracy of the weighing unit 200.

In one embodiment, the weighing unit 200 may measure the total mass of a container and the content stored therein. The mass of the content within each of the plurality of containers are monitored by a plurality of measured mass during the predetermined interval and the differences

between the measured mass of the same container i.e. before and after consumption, is recorded to monitor the total consumption of the content stored in one or more containers. Each measured mass may be obtained at a regular interval. Advantageously, each measured mass may be obtained from the average of a plurality of successive measurements, for example, each record may be averaged from five measurements. The averaged mass may omit the uncertainty of the weighing unit 200 for filtering purpose.

Optionally, the weighing unit 200 may be calibrated by a backend comparison from time to time to maintain its measurement accuracy. For instance, the backend comparison may be conducted with the recent readings, e.g. the six recent readings to ensure that the accuracy of the weighing unit 200 is maintained within its tolerance range throughout the life time.

In one embodiment, the weighing device 110 may include a temperature sensing unit 400 e.g. a noncontact temperature sensor, more preferably an infrared sensor 400 for measuring the temperature of the content stored in the container. Preferably, the infrared sensor 400 may be made of transparent plastic material, thereby allowing the infrared signal to penetrate therethrough. The temperature of the content is measured by the temperature sensing unit 400 based on the infrared signal reflecting from the inner portion of the container, and each temperature measurement is recorded by the temperature sensing unit 400 for further processing.

The temperature sensing unit 400 may be provided adjacent to the container and within a readable range of the infrared radiation. For instance, the temperature sensing unit 400 may be provided within the upper housing 112 below the container. Optionally, there may be provided an opening at the upper housing 112, thereby allowing the infrared signal to be emitted to the container by the temperature sensing unit 400 and the reflecting infrared signal from the container to be received by the temperature sensing unit 400 respectively.

For instance, the upper housing 112 may be provided an aperture or a transparent window 130 between the container and the temperature sensing unit 400 whereby the infrared signal may penetrate therethrough. The temperature sensing unit 400 may record the temperature of the container, and in turn transmit the information associated with the temperature to the processor 300 for further processing.

In one embodiment, the weighing device 110 may include an indicator 500 for providing an indication associated with the operation of the apparatus 100 to a user. For instance, the indication may be visually depicted by a plurality of light indications with various wavelengths to indicate the operation, such as the type of content stored in the container, power charging,

pairing with a remore server or a remore device, or power on/off, active mode or sleep mode of the apparatus 100.

Preferably, the indicator 500 may be a ring-shaped LED indicator 500 and more preferably transparent or at least translucent window disposed about the circumference of the weighing device 110 between the upper housing 112 and the lower housing 114. The indicator 500 may be segregated into a plurality of partitions 502, 504, 506 etc. For instance, the LED indicator 500 may be divided into 120-degree partitions along the ring 500 whereby each partition 502, 504, 506 depicts a light indication with at least one unique colour.

Optionally, each of the indicator 500 or each of the plurality of partitions 502, 504, 506 may be provided a set of multi-colour LEDs group to provide a variety of visual status indicators or visual effects associated with the colour of the LEDs, e.g. a circular movement and colour changes of LED lights which are readily observable by the user through the indicator 500 or each of the plurality of partitions 502, 504, 506.

In one embodiment, the indication of the indicator 500 may represent the thermal status of the content stored in the container relative to a predefined temperature range. For instance, the information associated with the temperature is received from the temperature sensing unit 400 by the processor 300 for further processing. Based on a predefined temperature range, the processor 300 may provide a signal to the indicator 500 for indicating the thermal status of the content relative to the predefined temperature range. For instance, the indicator 500 may provide a first indication when the thermal status of the content exceeds the predefined temperature range, and alternatively, provide a second indication when the thermal status of the content is below the predefined temperature range. Thus in this embodiment, each partition 502, 504, 506 may have a plurality of colours to indicate different information, depending on the partition and the colour as shown. Each partition may represent a unique meaning and in turn allow users to switch partition by pressing the button. For example in one preferred embodiment, the partition may be used to indicate the meal type - partition 1 Breast milk, partition 2 Formula Milk, partition 3 Water. The light indication may also have a unique colour coding system. As an example, the indicators can take the following format:

Status	Color	Patition	Light Status
Charging	Red	All	On
Fully Charged	Green	All	On
Loading	Red	1 of the partitions only indicating meal type	On

Active Mode, connected with mobile App	Blue	1 of the partitions only indicating meal type	On
Active Mode, disconnected with mobile App	White	1 of the partitions only indicating meal type	On
Active Mode, connected with mobile App, finish taking measurement	Blue	1 of the partitions only indicating meal type	Off for 0.5 second
Active Mode, disconnected with mobile App, finish taking measurement	White	1 of the partitions only indicating meal type	Off for 0.5 second

In one example application, the temperature sensing unit 400 and the indicator 500 may function together to monitor the temperature of hot content e.g. milk, thereby ensuring that the content is suitable for consumption by an infant. For instance, the temperature of the content in the container may be measured by the temperature sensing unit 400. The indicator 500 may provide a red light i.e. a first indication to indicate that the milk is too hot for the baby to consume, and on the other hand, provide a blue light i.e. a second indication to indicate that the milk is too cold for the baby to consume. Optionally, the indicator 500 may provide a green light or a colour different from the first and second indications as a third indication to indicate that the temperature of the milk is suitable for consumption.

Preferably, the indication may be depicted by the ring-shaped LED indicator 500. Alternatively, a LED indicator 410 may be located inside the temperature sensing unit 400 and underneath the upper housing 112 such that the indication may be observed by the user through the aperture or the transparent window 130, or alternatively the indication may be visible by the user through the housing 112 and 114. Optionally, the indication may also be provided in an application of a remote device (not shown) in communication with the apparatus 100.

The inventors have discovered that the mass measurement operation by the weighing unit 200 may be highly battery demanding. If the weighing unit 200 is operated continuously throughout the consumption of the content by the user, the battery of the apparatus 100 may be drained too fast and would not be able to last until the operation is completed.

In one embodiment, the weighing device 110 may include a tilt sensing unit 600, preferably an accelerometer 600 for sensing the tilting of the weighing device 110 and thus selectively activate or temporarily deactivate the apparatus 100 or at least some of the components e.g. the weighing unit 200 and the temperature sensing unit 400 or features of the apparatus 100 based on the measured tilt for power saving. For instance, when the weighing device 110 is idled (at a resting position) i.e. no tilting is detected over a predetermined interval by

the tilt sensing unit 600, the apparatus 100 would enter a sleep mode 1500. The operation of the device 100 with respect to one example method of minimizing its power consumption based on its present detected usage state is outlined in the flow diagram of Figure 5.

As shown in this example, when a slight tilting of the weighing device 110 is detected by the tilt sensing unit 600, the tilt sensing unit 600 may provide an Inertial Measurement Unit (IMU) signal 1502 to the apparatus 100 and the apparatus 100 would switch from the sleep mode 1500 to a standby mode (active) 1504 for further operations, including recording of measured data 1506 or the communication with a smartphone or computer 1508 to exchange data or upload of data to a central cloud server or system 1510 as shown in the operation flow of Figure 5. For example, the weighing unit 200 may be activated to measure the mass of the container.

Advantageously, the tilt sensing unit 600 may provide a power saving function to reduce the battery consumption of the weighing device 110 and prolong the battery life of the weighing device 110. Furthermore, the weighing unit 200 may be activated only if a tilting act has been performed by the user, such that the mass would be measured intentionally at a desirable time. Thus, this may also improve the accuracy of the measured mass and avoid any undesirable measurements when the consumption process is still in progress.

As shown with reference to Figure 6, in one embodiment, the processor 300 of the weighing device 110 may include an algorithm 310 for possessing the measured mass during the predetermined interval to provide information relating to the consumption of the content stored in the container. Preferably, the apparatus 100 may include a database 320 for storing the data associated with food or beverages. For instance, the food or beverages data may include the corresponding nutrition content, origin, manufacturer info, and expected market price of the food or beverages. The nutrition uptake by a user through the consumption of the content stored in the container may be computed by the processor 300 based on the measured mass and the data stored in the database 320. Advantageously, the total nutrition uptake by the user through a plurality of consumptions during the predetermined interval may be derived by the algorithm 310 based on the accumulated measured mass.

Preferably, the nutrition uptake by a user may be derived by the processor 300 through a nutrient consumption computation. Initially, the type of food or beverages stored in the container may be matched with the food or beverages data on the database 320 prior to the consumption and the mass measurement by the weighing unit 200. Upon the matching is completed, the processor 300 may obtain the corresponding nutrition content, e.g. the suggested milk concentration ratio from the database 320 and the algorithm 310 may then convert the

measured mass into the milk consumption by multiplying the measured mass with the obtained concentration ratio. Advantageously, the individual consumption of each nutrient from the content stored in the container such as carbohydrates, proteins, fat, and minerals may also be derived by multiplying the measured mass with the nutrition information.

In one example application, the database 320 may be a local database 320 for storing food and beverage information or tracking information for a specific brand of milk formula. The database 320 may be retrieved by a smart device through a barcode-reading mechanism with an imaging device, e.g. the camera of a smartphone. When the user need to input new types of food and beverage consumed or the milk formula consumed by an infant, one may input the information associated with the nutrition, for example scanning the barcode on the product or milk formula packaging by the imaging device.

In the event of any missing data, the application may prompt the user to scan the barcode on the product or milk formula packaging and capture the nutrition information. Such information would be uploaded to a cloud database 330 and any missing information e.g. missing item or missing brand of the formula milk would be completed by the cloud database 330. The completed information would finally be stored on the local database 320.

Optionally, the database 320 may also include the data associated with the user info, for example the social network account of the user, the infant growth data including the height, mass, head circumferences, age, and diet data of the user including the milk formula brand, breastfeeding situation, feeding frequency, duration, time and volume.

Preferably, the database 320 may also include additional information obtained from the internet. Initially, the data may be obtained from online sources e.g. World Health Organisation (WHO) and the information may be possessed and presented to the user with a more accessible format in an application on a smart device. Advantageously, the data may be further possessed to provide some guidance on the diet habit to the user, for example the recommended consumption volume of milk of the infant.

In one embodiment, the apparatus 100 may include a holder 700 between the container and the upper housing 112 for receiving the container thereon. Preferably, the holder 700 may be made of materials with a high friction coefficient, e.g. silicon and more preferably, in the form of a ring-shaped holder 700 with a central opening 702 for the infrared signal of the temperature sensing unit 400 passing therethrough.

In this arrangement, the surface of the holder 700 may contact with the container extensively. Advantageously, the friction between the holder 700 and the container on the

contacting surface may restrain the movement of the container, thereby reducing the resulting horizontal force due to the undesirable orientation of the container and thus improve the accuracy of the measured mass.

In one embodiment, the holder 700 may further include a valve-like structure 710 at the lower portion thereof for contacting with the upper housing 112 without contacting the lower housing 114 or the outer housing 116 below the upper housing 112, as shown in Figure 4B. Advantageously, the mass of the container and the holder 700 may only be exerted on the upper housing 112 and the lower housing 114, and in turn moves the upper housing 112 and the lower housing 114 downwards. The outer housing 116 remain stationary throughout the operation.

In one embodiment, the apparatus 100 may include a magnetic coupling for coupling the holder 700 to the upper housing 112. For instance, there may be provided a pair of magnets 802 and 804, of which each being provided on the opposing contacting surfaces of the holder 700 and the upper housing 112 of the weighing device 110. Each pair of magnets 802 and 804 may be mounted with opposite polarity for providing a coupling force between the holder 700 and the adjacent upper housing 112, thereby achieving a snap-fit coupling. Optionally, the upper housing 112 may further include a press-fit locking structure for mounting the magnet 804.

Preferably, the holder 700 may be detachably mounted on and removed from the upper housing 112 through rotation, such that a unique and instant alignment of the holder 700 and upper housing 112 may be completed. Advantageously, the holder 700 and the container may be coupled to the upper housing 112 and detached therefrom readily for frequent replacement and cleaning of the container.

Alternatively, the coupling between the holder 700 and the upper housing 112 may be implemented by a screw-cap mechanism 810, as shown in Figure 4B. The outer housing 116 may be provided a screw-like outer surface 820 along the outer circumference for mounting the holder 700 thereon.

In one embodiment, the apparatus 100 may include a circuitry arrangement 900 having a circular and double-partition structure for dividing the hardware components into two compartments 910 and 920 based on the functionality to maximise the space utility. The first compartment 910 may receive the weighing unit 200, the temperature sensing unit 400 and a data processing amplifier 302. The second compartment 920 may receive the processor 300 and a Bluetooth module 930 for broadcasting its Universally Unique Identifier (UUID) and transmitting data to a paired smart device, and the tilt sensing unit 600.

Optionally, the weighing device 110 may include a home button 1000 preferably at the central bottom of the lower housing 114 positioned within an overmolded plastic 1010. For instance, the overmolded plastic 1010 may firmly attach the home button 1000 to the lower housing 114 for providing a water proof and dust proof function to the housings 112 and 114. Preferably, the home button 1000 may be received within a button holder 1020, and mated to the weighing unit 200, the circuitry 900 within the upper housing 112. For instance, the home button 1000 may also be held together with the weighing unit 200, the circuitry 900 and the upper housing 112 by the pair of screws 126.

In one example arrangement, the home button 1000 may be pressed by the user and the press motion may be detected by a microcontroller 940 of the circuitry 900. Advantageously, the user may activate the apparatus 100 or input different parameters e.g. the type of food or beverages to the processor 300 by pressing the home button 1000 for a predefined duration or force magnitude in various scenario.

Optionally, the apparatus 100 may be powered by a rechargeable battery 1100. The battery 1100 may be charged by a power supply through a charging port 1110 e.g. a micro USB port located on the upper housing 112. The charging port 1110 may be covered by a plastic lid 1120 to offer water resistance to the apparatus 100 during normal operations. Preferably, the circuitry 900 may monitor the charging current and the overall progress. For instance, the circuitry 900 may provide a signal associated with the charging status of the apparatus 100 to the indicator 500 for presenting a visual indication to the user.

In one example application, the weighing device 110 may receive a container, e.g. a baby bottle or a baby trainer cup available in the market through the holder 700. The user may select the liquid type, such as breast milk, formula milk or water by pressing the home button 1000. The weighing unit 200 may measure the mass and deliver the baby consumption information to the baby logging mobile application to record the baby diet patterns.

Optionally, the baby logging mobile application may allow the manual entry of other necessary metrics such as infant height, weight, and potentially milk formula brand. The mobile application may synched with a cloud database 330, which is managed by the manufacturer and includes an algorithm for providing tailor made recommendations e.g. suggested nutritional uptake for each infant user.

In yet another example application, the weighing device 110 may receive an ingredient plate 701 mounted with magnets 802. When the apparatus 100 is paired with the recipes mobile application via Bluetooth module 930, the user may measure and send the measured mass of each

gradient listed in the recipes. In practice, the user first needs to select the ingredient being measured on the mobile application, thereby matching the type of ingredient to be measured with the data on the database 320. When the LED indicator 500 indicates a successful pairing, the user may put the ingredient on the ingredient plate 701. Upon successful measurement, the user may repeat the same process until all the ingredients are measured. Advantageously, the mobile application may generate real-time nutrition facts of each meal. The recipes mobile application may also customise the recipe based on the user preference such as avoidance of particular food ingredients, goals on calories or other specific nutrient intake criteria.

In yet another example application, the weighing device 110 may receive directly a bottle or a bowl mounted with magnets 802. The apparatus 100 may be customised for users to select their pre-set drink types by pressing the home button 1000. The beverage logging mobile application may allow the users to record a certain types of drinks and their corresponding nutrition fact. When the apparatus 100 is paired with the diet logging mobile application, the user may select the food type from the database 320, creating a new food type with the barcode mechanism or beverage prepared with known ingredients. The apparatus 100 may measure the mass of the beverage and sends the consumption information to the beverage logging mobile application to record beverage consumption patterns, and to the diet logging mobile application to record diet patterns respectively.

Optionally, the apparatus 100 may provide a growth monitoring function to the user. For instance, the comprehensive data on baby's growth factors on weight, length and head circumferences, infant growth trend may be plotted onto the WHO Growth Curve to determine the percentile the baby falls into, thereby monitoring the growth of the infant with respect to the overall population in the world.

Optionally, the apparatus 100 may also provide a nutrition management function to the user. For instance, the apparatus 100 may correlate the infant health condition with growth and diet pattern. With a comprehensive nutrition breakdown obtained from the measured mass, the apparatus 100 may review if the infant has reached the Adequate Intake (AI) requirement or have exceeded the Upper Limit (UL). The apparatus 100 may recommend a balance diet for an infant so as to ensure the infant is under a healthy development and supplied with sufficient macro- and micro-nutrients.

Optionally, the apparatus 100 may further provide an allergy prediction function to the user. For instance, the apparatus 100 may determine if the baby is potentially allergic to particular

nutrition on dairy products e.g. proteins by providing checkboxes for user to record infant allergy symptoms and referencing to the infant nutrient consumption trends.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Any reference to prior art contained herein is not to be taken as an admission that the information is common general knowledge, unless otherwise indicated.

CLAIMS

1. An apparatus for receiving a container, comprising:

a weighing unit arranged to measure the mass of the container provided thereon during a predetermined interval;

a processor arranged to possess the measured mass during the predetermined interval to provide information relating to the consumption of the content stored in the container.

2. The apparatus according to claim 1, wherein the weighing unit is isolated from the lower portion of the apparatus underneath.

3. The apparatus according to claim 1, wherein the weighing unit is received within a sandwich layer structure having at least an upper layer, a lower layer, and an intermediate layer therebetween.

4. The apparatus according to claim 3, wherein the weighing unit is mounted on the intermediate layer and the intermediate layer is mated with the upper layer.

5. The apparatus according to claim 3, wherein the lower layer includes a standing structure for stabilising the apparatus.

6. The apparatus according to claim 1, wherein the weighing unit includes a half bridge weight sensor.

7. The apparatus according to claim 1, wherein the accuracy of the weighing unit is calibrated by a backend comparison.

8. The apparatus according to claim 1, further comprising a temperature sensing unit for measuring the temperature of the content stored in the container.

9. The apparatus according to claim 8, wherein the temperature of the content is measured by an infrared signal of the temperature sensing unit.

10. The apparatus according to claim 8, wherein the temperature sensing unit is provided below the container.

11. The apparatus according to claim 8, further comprising an aperture or a transparent window between the container and the temperature sensing unit whereby the infrared signal penetrating therethrough.

12. The apparatus according to claim 1, wherein the total consumption of the content stored in one or more containers during the predetermined interval is monitored by a plurality of measured mass.

13. The apparatus according to claim 12, wherein each measured mass is obtained at a regular interval.

14. The apparatus according to claim 12, wherein each measured mass is obtained from the average of a plurality of successive measurements.

15 The apparatus according to claim 1, further comprising an indicator for providing an indication associated with the operation of the apparatus to a user.

16. The apparatus according to claim 15, wherein the indication is visually depicted by a plurality of light indications with various wavelengths.

17. The apparatus according to claim 15, wherein the indicator is segregated into a plurality of partitions whereby each depicts a light indication with a unique colour.

18. The apparatus according to claim 15, wherein the indicator is a ring-shaped indicator.

19. The apparatus according to claim 15, wherein the indication is provided on a remote device in communication with the apparatus.

20. The apparatus according to claim 15, wherein the indication represents the thermal status of the content relative to a predefined temperature range.

21. The apparatus according to claim 20, wherein the indicator provides a first indication when the thermal status of the content exceeds the predefined temperature range.

22. The apparatus according to claim 20, wherein the indicator provides a second indication when the thermal status of the content is below the predefined temperature range.

23. The apparatus according to claim 15, wherein the operation includes at least one of the power charging, pairing with a remote server or a remote device, and power on/off.

24. The apparatus according to claim 1, further comprising a tilt sensing unit for sensing the tilting of the apparatus.

25. The apparatus according to claim 24, wherein the weighing unit is activated or temporarily deactivated based on the measured tilt.

26. The apparatus according to claim 24, wherein the tilt sensing unit includes an accelerometer.

27. The apparatus according to claim 1, wherein the processor includes an algorithm for deriving the nutrition uptake by a user through the consumption of the content stored in the container from the measured mass.

28. The apparatus according to claim 27, wherein the processor is in data communication with a database storing the data associated with at least one of the food or beverages and the user info.

29. The apparatus according to claim 28, wherein the food or beverages data includes the corresponding nutrition content of various food or beverages.

30. The apparatus according to claim 29, wherein the type of food or beverages stored in the container is matched with the food or beverages data prior to the consumption.

31. The apparatus according to claim 30, wherein the total nutrition uptake by the user through a plurality of consumptions during the predetermined interval is derived from the accumulated measured mass.

32. The apparatus according to claim 28, wherein the food or beverages data includes at least one of the origin, manufacturer info, and market price of the food or beverages.

33. The apparatus according to claim 28, wherein the user data includes at least one of the height, mass, head circumferences, age, and diet data of the user.

34. The apparatus according to claim 1, further comprising a holder for receiving the container.

35. The apparatus according to claim 34, wherein the friction between the holder and the container restrains the movement of the container, thereby improving the accuracy of the measured mass.

36. The apparatus according to claim 34, wherein the holder includes a valve-like structure.

37. The apparatus according to claim 34, wherein the holder is made of materials with a high friction coefficient.

38. The apparatus according to claim 34, wherein the holder is made of silicon.

39. The apparatus according to claim 34, wherein the holder is coupled to the apparatus through a magnetic coupling.

40. The apparatus according to claim 39, further comprising a pair of magnets of which each provided on the opposing surfaces of the holder and the apparatus.

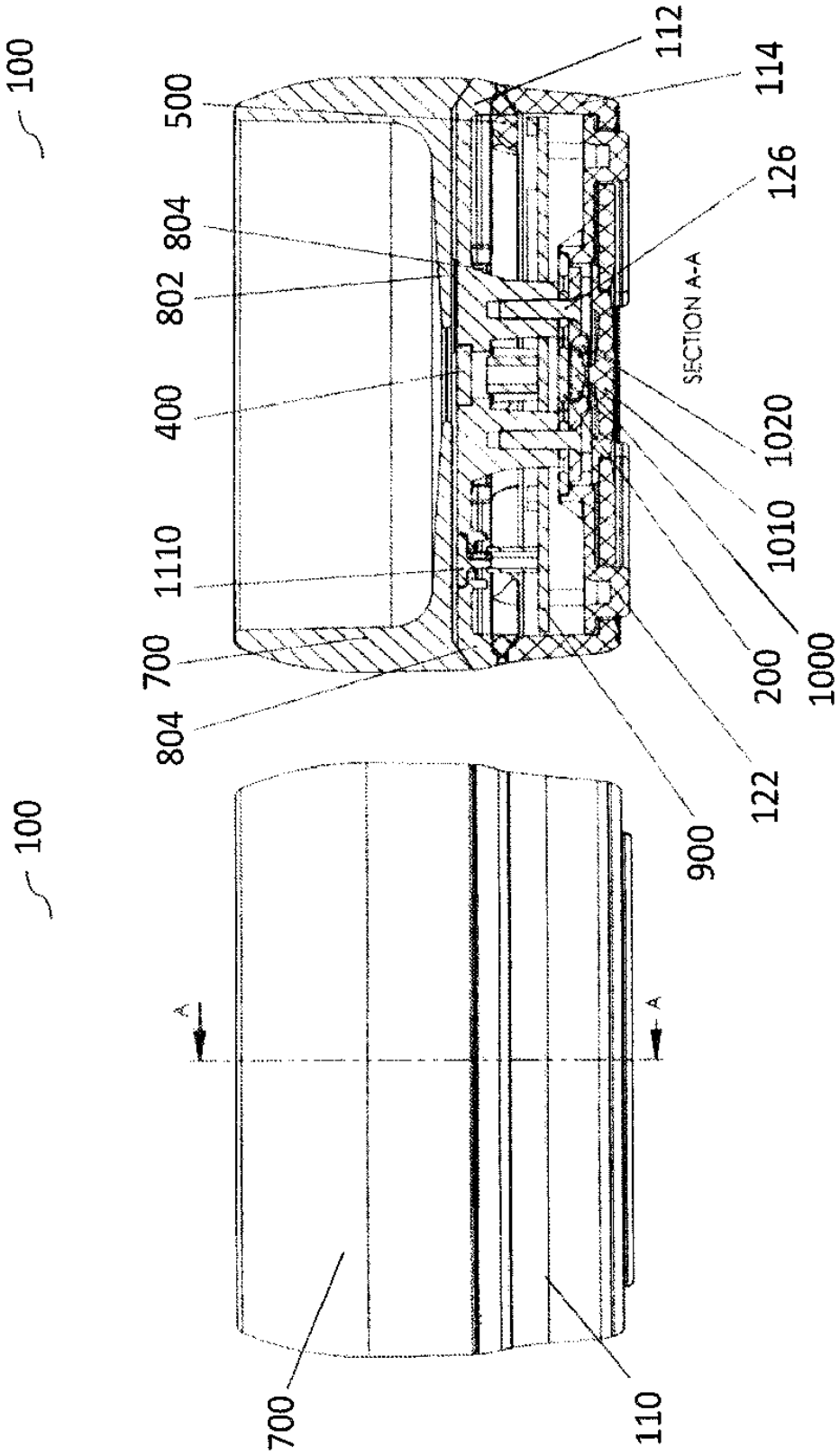

100
500
804
802
400
1110
700
804
112
114
126
SECTION A-A
1020
1010
200
1000
122
900
A
A
700
110

Fig.1B

Fig.1A

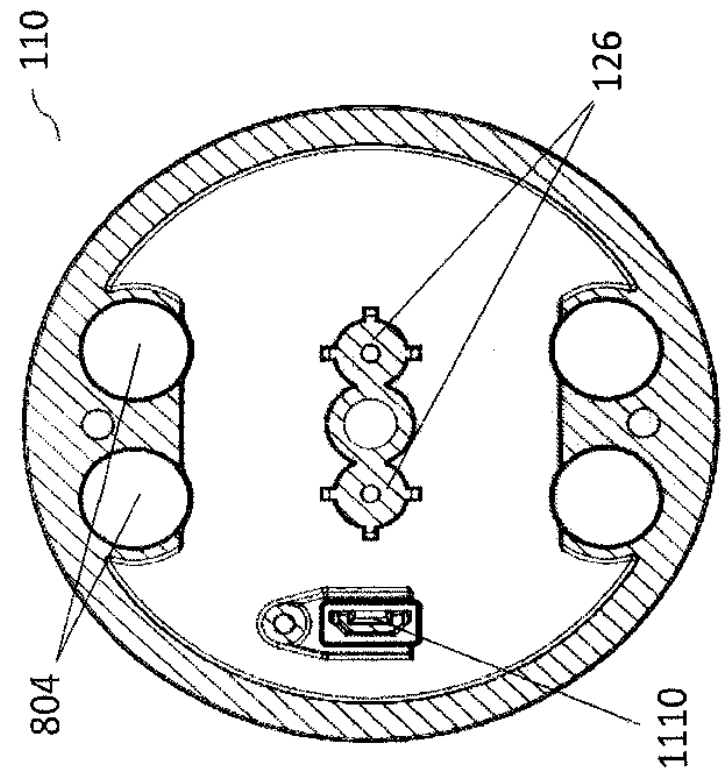


Fig.2C

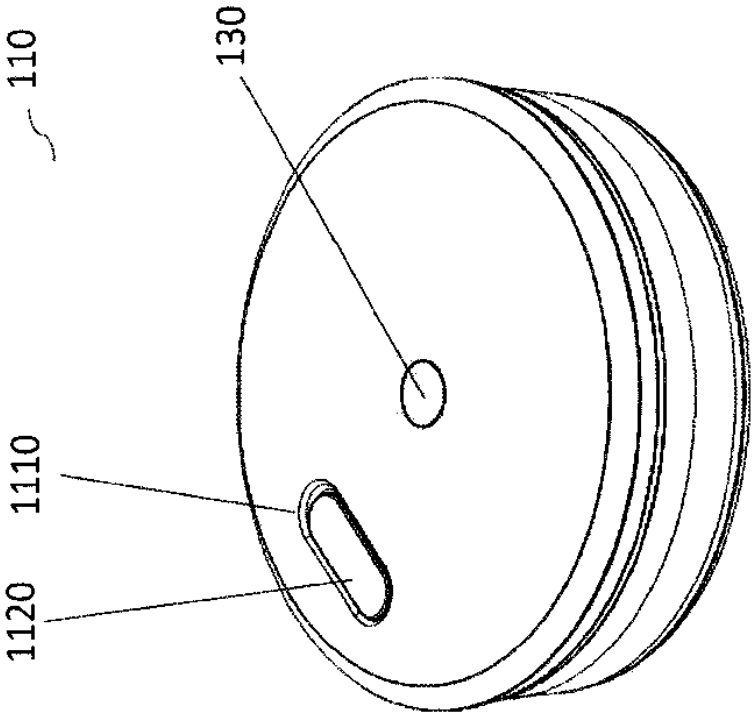


Fig.2A

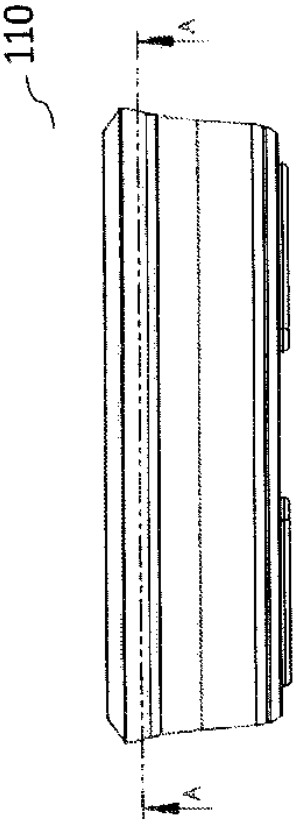


Fig.2B

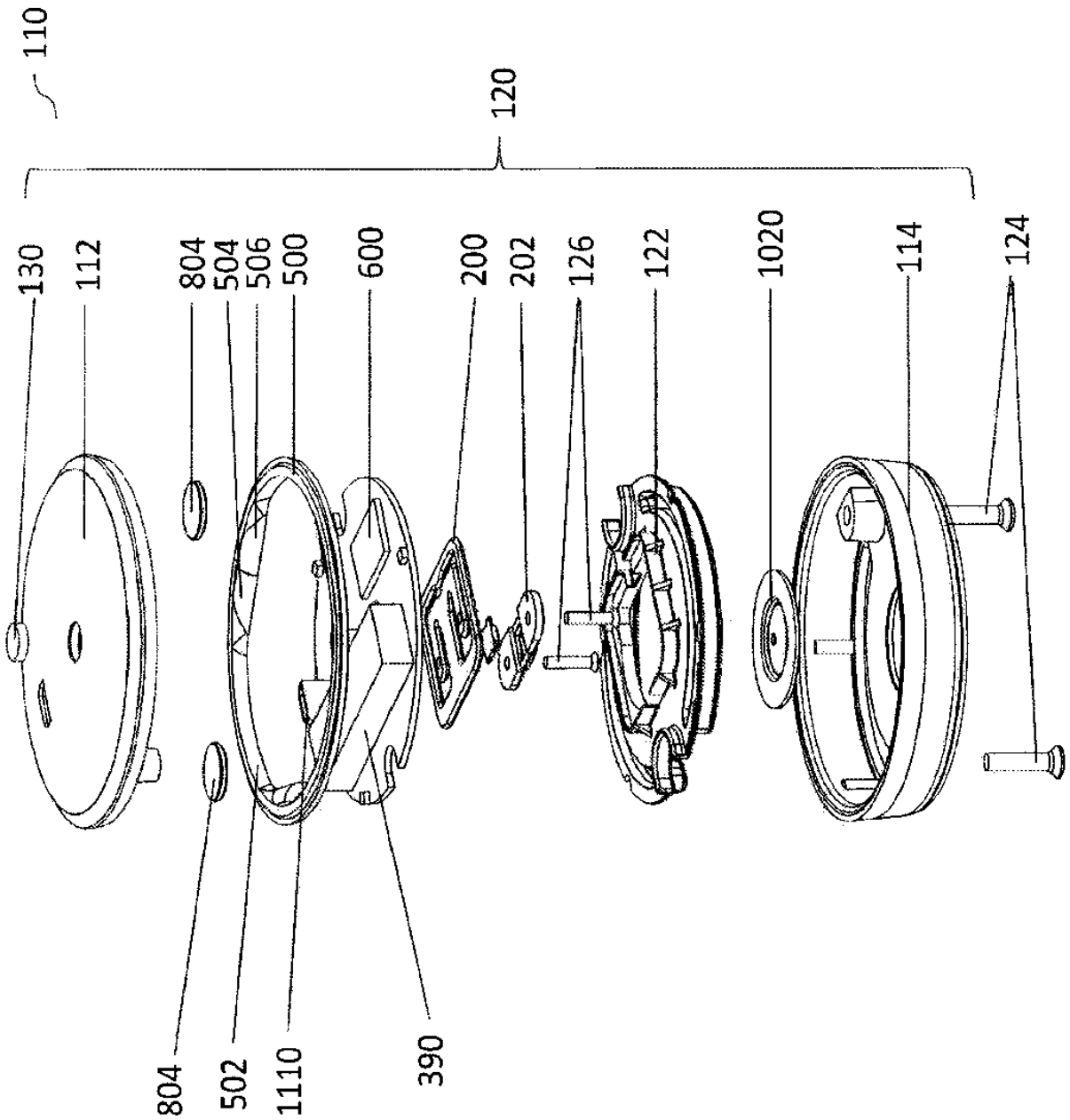

110
120
130
112
804
504
506
500
600
200
202
126
122
1020
114
124
804
502
1110
390

Fig.2D

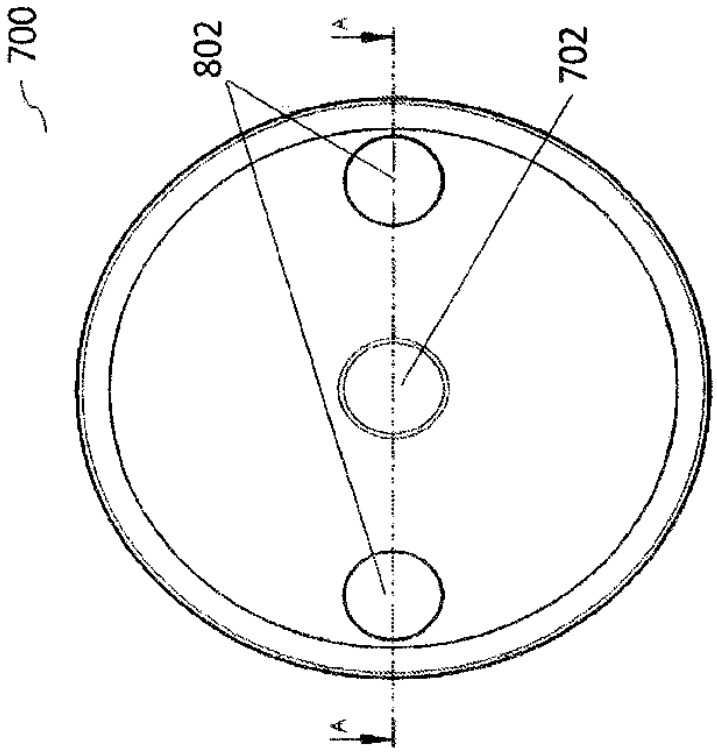


Fig.3B

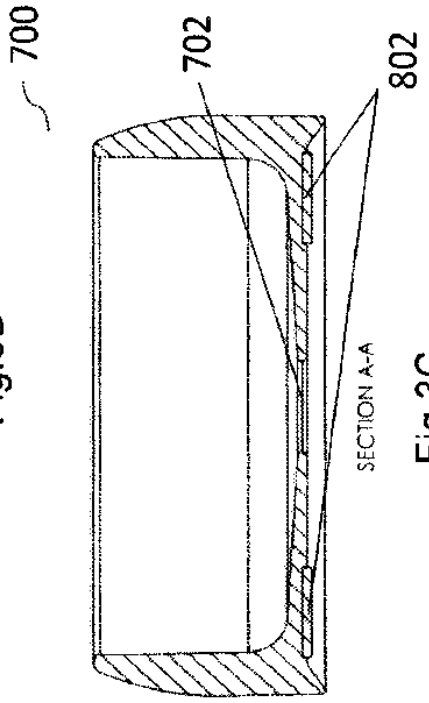


Fig.3C

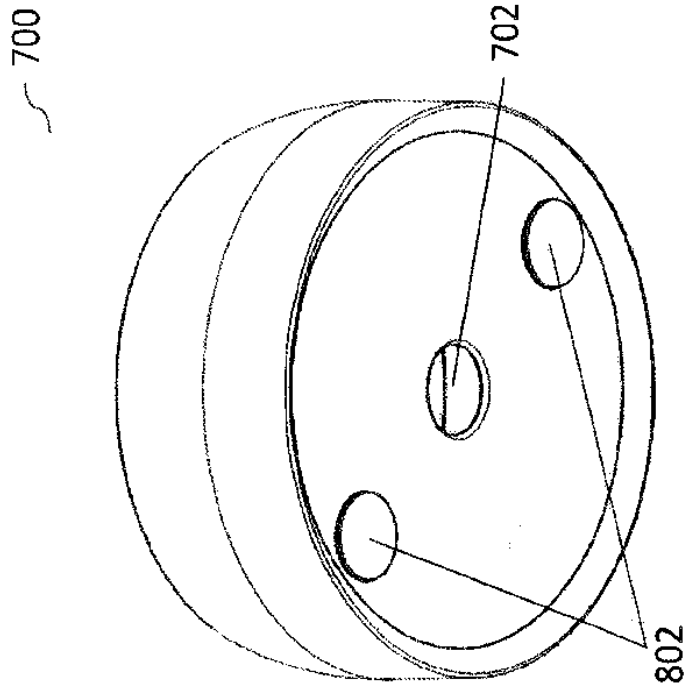


Fig.3A

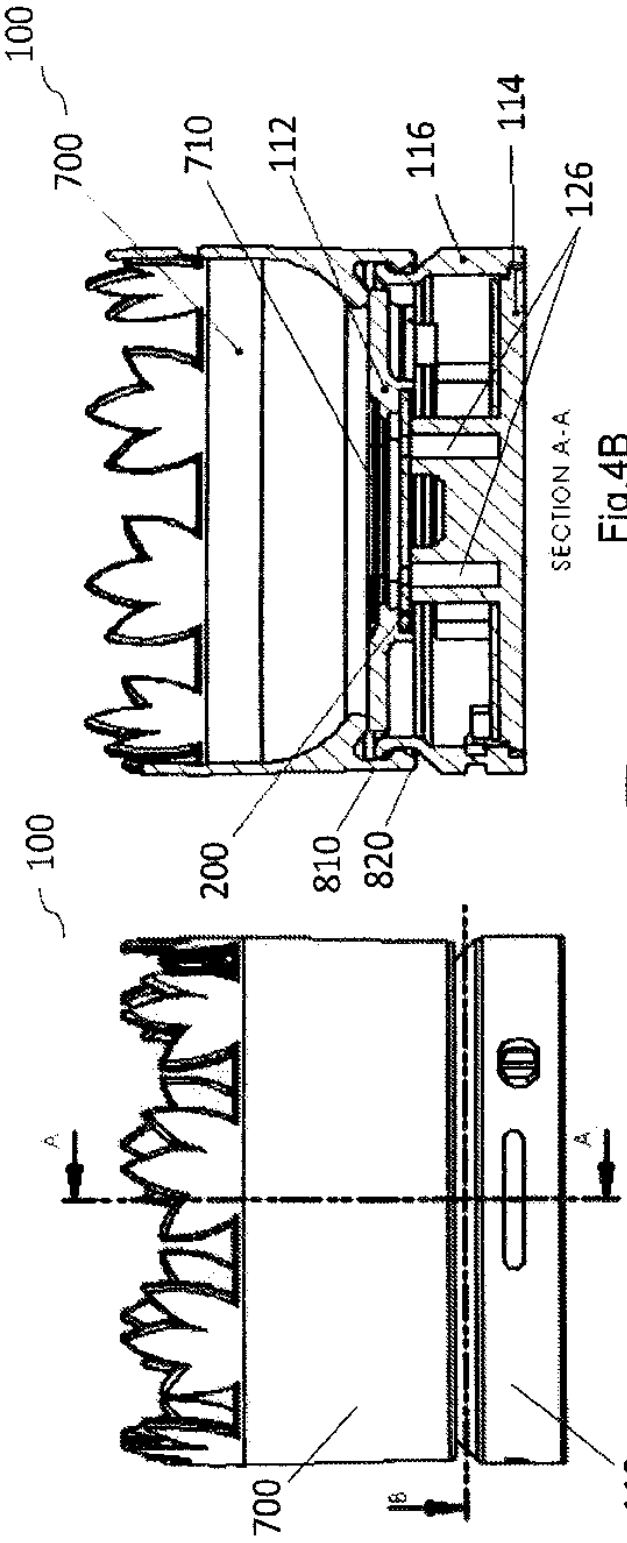


Fig.4B

Fig.4A

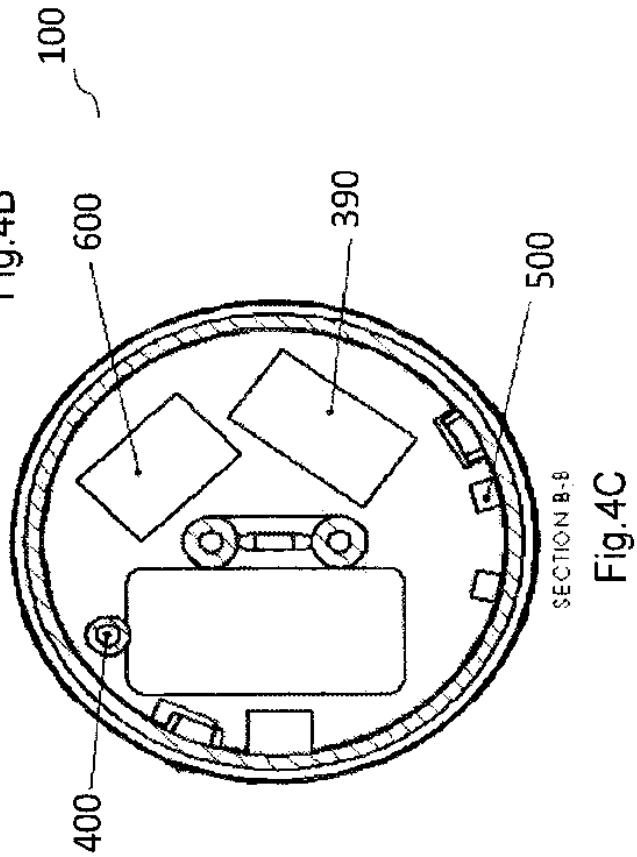


Fig.4C

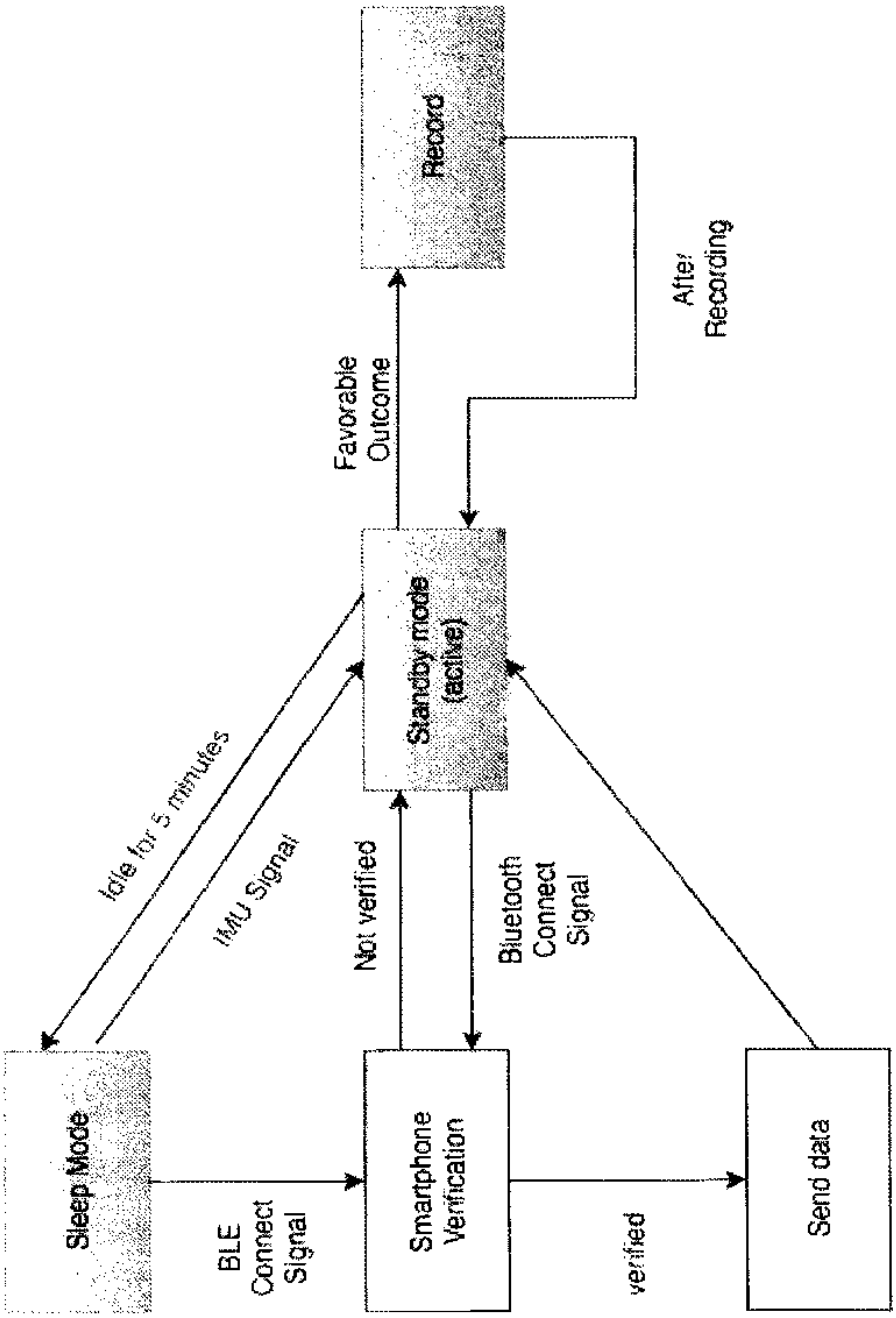

Record
After Recording
Favorable Outcome
Standby mode (active)
Idle for 5 minutes
IMU Signal
Not verified
Bluetooth Connect Signal
Sleep Mode
BLE Connect Signal
Smartphone Verification
verified
Send data

Fig.5

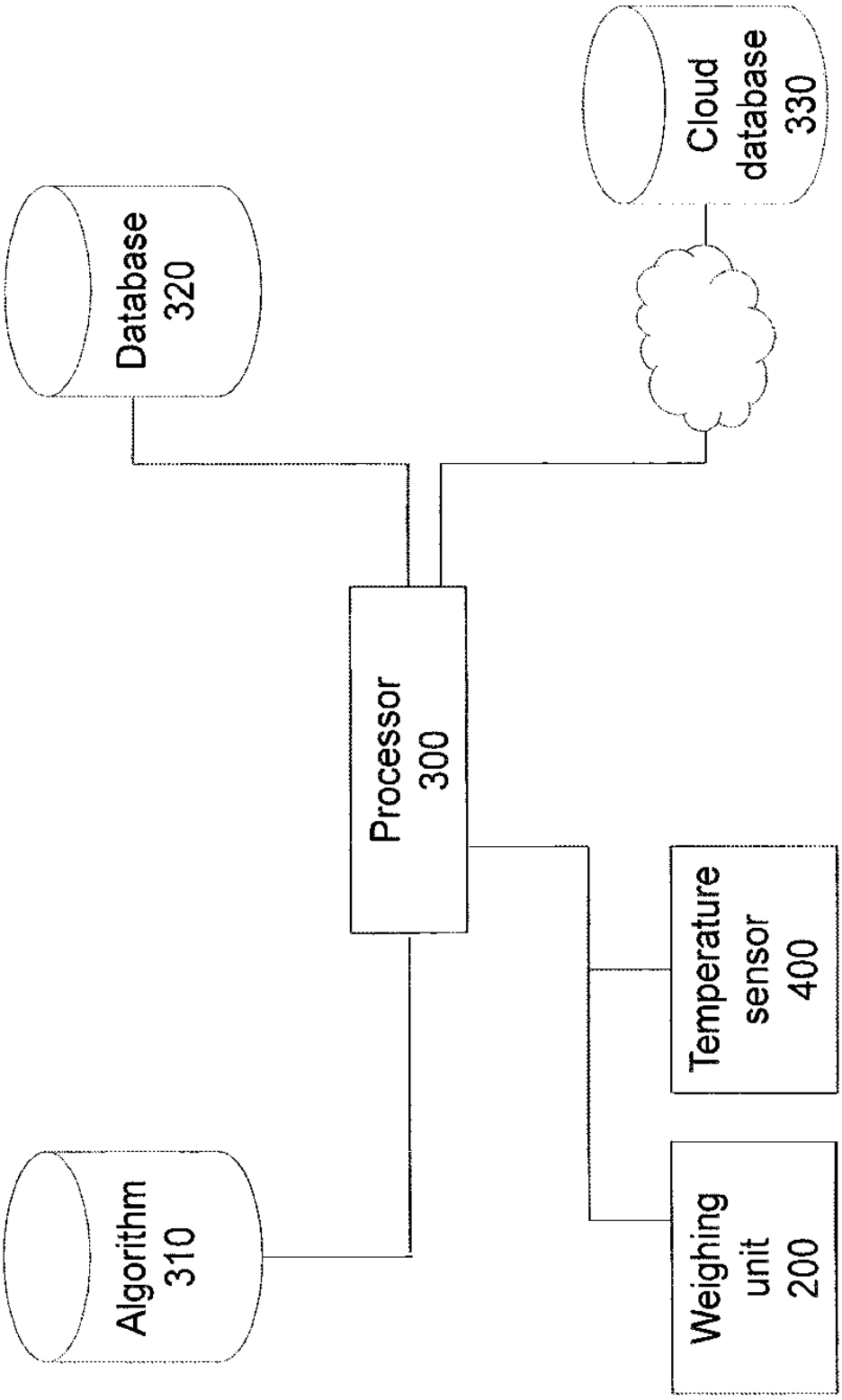

Cloud database 330
Database 320
Processor 300
Temperature sensor 400
Algorithm 310
Weighing unit 200

Fig.6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2017/083146

A. CLASSIFICATION OF SUBJECT MATTER

G01G 19/40(2006.01)i; G01G 23/38(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01G

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CNABS;SIPOABS;HKABS;VEN: WEIGH, MEASURE, MASS,PROCESSOR, CONSUMPTION, CONTAINER, TRACK, DIET, HEALTH, ANALYSIS, NUTRIENT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015168207 A1 (SURGITRAC CORP) 18 June 2015 (2015-06-18) description, paragraphs [0029]-[0060], figures 1-12	1-7, 12-23, 34-40
Y	US 2015168207 A1 (SURGITRAC CORP) 18 June 2015 (2015-06-18) description, paragraphs [0029]-[0060], figures 1-12	27-33
Y	WO 2016031246 A1 (HAIER ASIA CO LTD) 03 March 2016 (2016-03-03) abstract	27-33
X	US 2014262553 A1 (SURGITRAC CORP) 18 September 2014 (2014-09-18) figures 1-12 and their explanations	1-7, 12-23, 34-40
A	US 5629498 A (POLLOCK RICHARD A) 13 May 1997 (1997-05-13) the whole document	1-40
A	KR 101507118 B1 (TECH INTERNAT CO LTD G) 30 March 2015 (2015-03-30) the whole document	1-40

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2017	**12 July 2017**
Name and mailing address of the ISA/CN **STATE INTELLECTUAL PROPERTY OFFICE OF THE P.R.CHINA** **6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088** **China**	Authorized officer **LI,Weiwei**
Facsimile No. **(86-10)62019451**	Telephone No. **(86-10)62085325**

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2017/083146

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
US	2015168207	A1	18 June 2015	US	9347817	B2	24 May 2016
WO	2016031246	A1	03 March 2016	None			
US	2014262553	A1	18 September 2014	US	8963025	B2	24 February 2015
US	5629498	A	13 May 1997	AU	4917196	A	07 August 1996
				EP	0804718	A4	16 June 1999
				WO	9622510	A1	25 July 1996
				CA	2213504	A1	25 July 1996
				EP	0804718	A1	05 November 1997
KR	101507118	B1	30 March 2015	None			

Form PCT/ISA/210 (patent family annex) (July 2009)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP2023/073975	31 August 2023 (31-08-2023)	31 August 2022 (31-08-2022)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[ ] the text is approved as submitted by the applicant

[X] the text has been established by this Authority to read as follows:

MILK-VOLUME MEASUREMENT SYSTEM

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/073975

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2018/361040 A1 (O'TOOLE JONATHAN [GB] ET AL) 20 December 2018 (2018-12-20) paragraph [0166] - paragraph [0170]; claim 20	1-30
A	US 10 987 455 B2 (KONINKLIJKE PHILIPS NV [NL]) 27 April 2021 (2021-04-27) claim 12 column 2, line 8 - line 10 column 2, line 27 - line 51 column 2, line 60 - line 64 column 4, line 43 - line 64	1-30

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 2023	19/12/2023

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	Mata Vicente, Teresa

1

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2023/073975

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018361040 A1	20-12-2018	AU 2018283715 A1	16-01-2020
		CA 3066971 A1	20-12-2018
		CN 213964594 U	17-08-2021
		CN 216798371 U	24-06-2022
		DE 202018006774 U1	13-12-2022
		DE 202018006776 U1	14-12-2022
		DE 202018006777 U1	14-12-2022
		DE 202018006778 U1	14-12-2022
		DE 202018006806 U1	30-01-2023
		EP 3638334 A1	22-04-2020
		EP 4066870 A2	05-10-2022
		EP 4176909 A1	10-05-2023
		ES 2951176 T3	18-10-2023
		JP 7335234 B2	29-08-2023
		JP 2020523179 A	06-08-2020
		JP 2023109823 A	08-08-2023
		SG 11201912135S A	30-01-2020
		US 2018361040 A1	20-12-2018
		US 2020139026 A1	07-05-2020
		US 2021170080 A1	10-06-2021
		US 2021196873 A1	01-07-2021
		US 2021196874 A1	01-07-2021
		US 2021196875 A1	01-07-2021
		US 2021196876 A1	01-07-2021
		US 2021205511 A1	08-07-2021
		US 2021205512 A1	08-07-2021
		US 2021205513 A1	08-07-2021
		US 2021205514 A1	08-07-2021
		US 2021205515 A1	08-07-2021
		US 2021205516 A1	08-07-2021
		US 2021205517 A1	08-07-2021
		US 2021205518 A1	08-07-2021
		US 2021228789 A1	29-07-2021
		US 2021268158 A1	02-09-2021
		US 2023143842 A1	11-05-2023
		WO 2018229504 A1	20-12-2018
US 10987455 B2	27-04-2021	BR 112018012671 A2	04-12-2018
		CN 108430530 A	21-08-2018
		EP 3393540 A1	31-10-2018
		JP 2018538105 A	27-12-2018
		RU 2018126785 A	27-01-2020
		US 2018369464 A1	27-12-2018
		WO 2017108555 A1	29-06-2017

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2023/073975	31.08.2023	31.08.2022

International Patent Classification (IPC) or both national classification and IPC
INV. A61M1/06

Applicant
CHIARO TECHNOLOGY LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Mata Vicente, Teresa Telephone No. -0

Form PCT/ISA/237 (Cover Sheet) (July 2022)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed.

   b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)).

      ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-30
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-30
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 US 2018/361040 A1 (O'TOOLE JONATHAN [GB] ET AL) 20 December 2018 (2018-12-20)

D2 US 10 987 455 B2 (KONINKLIJKE PHILIPS NV [NL]) 27 April 2021 (2021-04-27)

1 D1 discloses (see paragraphs 0166-0170 and claim 20) a method for measuring the volume of milk in a milk container of a breast pump, the method comprising: applying positive pressure which is conveyed to the milk container, monitoring the pressure increase with a pressure sensor, determining the rate of pressure increase and, subsequently, calculate the volume of milk expressed based on the fact that the rate at which the pump can increase the pressure in the system is a function of the volume of aire that remains in the milk collection container. D1 does not disclose a first and second parameters of the gas (the parameter changed and the one measured are one and the same) and, therefore, all claims are novel over D1.

1.1 D2 discloses (see col. 2, lines 8-10 and 27-51; col. 4, lines 43-64; and cl. 12) a method for measuring the volume of milk in a collection container of a breast pump, the method comprising: measuring the vacuum pressure in order to determine the air volume in the system and, based thereon, calculate the volume of milk that has entered the system. Given that D2 does not disclose a step of changing a first parameter (of the gas), it does not prejudice the novelty of the claims.

1.2 In view of the prior art, all claims (1-30) are compliant with Art. 33(2) PCT.

2 D1 is regarded as the closest prior art. The difference between D1 and the present application lies in the fact that D1 does not disclose a first and second parameters of the gas (both the parameter changed and the parameter measured are the gas pressure).

2.1 The technical problem can be defined as the provision of an improved method for measuring the volume of milk in the collection container of a breast pump.

2.2 The solution herein proposed is as described in claim 1.

2.3 The skilled person would have found no hint in either D1 alone or combined with D2 to introduce the missing steps and/or modify the existing ones in the method of D1 in order to arrive at the subject-matter herein described and claimed.

2.4 In consequence, claims 1-30 fulfil the requirements of Art. 33(3) PCT.

2.5 The subject-matter of claims 1-30 is industrially applicable and, therefore, the requirements of Art. 33(4) PCT are satisfied.

Re Item VII

Certain defects in the international application

3 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Re Item VIII

Certain observations on the international application

4 The fact that claim 2 states that the first and second parameters of claim 1 are different throw doubt on the meaning of claim 1, thus rendering it unclear (Art. 6 PCT). The mere fact that claim 1 refers to a first and a second parameter makes the skilled reader understand that the parameters are different, and this is how the claim has been interpreted for the purposes of the search and the opinion on patentability. For the sake of completeness it must be added that, regardless of the objection just raised, the application does not provide sufficient disclosure (Art. 5 EPC) and/or support (Art. 6 PCT) for methods wherein the first and second parameter are the same which, moreover, are known in the prior art (for ex. in D1).

4.1 The type of parameters (see claim 2) is regarded as an essential technical feature. The independent claims do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

4.2 The vague and imprecise statements and claim-like "clauses" in paragraph 318, imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them.

4.3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.

(19) The National Intellectual Property Administration of the People's Republic of China

(12) Utility Model Patent

(10) Publication No.: CN 205913571 U
(45) Publication Date: Feb 1, 2017

(21) Appl. No.: 201620663091.1

(22) Filed on: June 29, 2016

(73) Patentee: NINGBO YOUHA ELECTRIC TECH CO LTD

Address: No. 65, Xiamaojia Road, Shuangqingpu Village, Xinpu Town, Cixi, Ningbo, Zhejiang Province 315322

(72) Inventor(s): FANG Guofeng

(51) Int. Cl.

A61M 1/06 (2006.01)

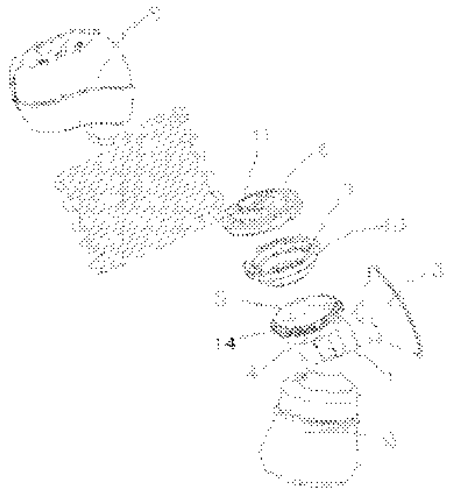
Claims: 2 pages, Description: 4 pages, Drawings: 7 pages

(54) Title of Utility Model

ELECTRIC BREAST PUMP CONVENIENT FOR BOTH SEPARATE AND COMBINED CONFIGURATIONS

(57) Abstract

An electric breast pump convenient for both separate and combined configurations includes a three-way connector, a first end of the three-way connector is connected to a suction head, and a second end of the three-way connector is connected to a container. A third end of the three-way connector is provided with an expansion opening, the expansion opening is connected to an annular edge, a connection cover is detachably provided on the annular edge, and an elastic diaphragm that separates the third end of the three-way connector into an inner cavity and an outer cavity is provided within the annular edge. The electric breast pump further includes an air pump main unit, an end face of the air pump main unit is provided with a circular protruding edge that matches the annular edge, and an upper airflow opening of the air pump main unit is located inside the protruding edge. The connection cover is provided with a lower airflow opening, and further includes a detachable air pipe. The beneficial effects of the utility model lie in that installation of the air pump main unit can be implemented in two ways, allowing the air pump main unit to be installed by selecting one of them, thereby respecting the usage habits of customers.



Shenzhen Root 1009

ELECTRIC BREAST PUMP CONVENIENT FOR BOTH SEPARATE AND COMBINED CONFIGURATIONS

TECHNICAL FIELD

[0001] The present utility model relates to a breast pump used for breastfeeding assistance.

BACKGROUND ART

[0002] A common electric breast pump in the prior art is formed by connecting a suction head to an air pump main unit and a milk bottle by a three-way connector. There are usually two ways to connect the air pump main unit to the three-way connector. The first is to use an air pipe to connect to the three-way connector. The advantage is that there are fewer handheld parts and the equipment is relatively light, while the disadvantage is that a platform is required to place the air pump main unit. The other way is to fix the air pump main unit directly onto the three-way connector. The disadvantage thereof is that the equipment is relatively heavy.

SUMMARY OF THE UTILITY MODEL

[0003] In order to overcome the deficiency of existing electric breast pumps in which the installation manner of an air pump main unit cannot be freely determined to suit different usage habits, the present utility model provides an electric breast pump convenient for both separate and combined configurations.

[0004] The technical solution of the present utility model to solve the technical problem thereof is as follows: an electric breast pump convenient for both separate and combined configurations, comprising a three-way connector, a first end of the three-way connector being connected to a suction head, and a second end of the three-way connector being connected to a container, wherein a third end of the three-way connector is provided with an expansion opening, the expansion opening is connected to an annular edge, a connection cover is detachably provided on the annular edge, and an elastic diaphragm that separates the third end of the three-way connector into an inner cavity and an outer cavity is provided within the annular edge; the electric breast pump further comprises an air pump main unit, an end face of the air pump main unit is provided with a circular protruding edge that matches the annular edge, the air pump main unit is configured to be detachably mounted on the annular edge by means of connecting the protruding edge to the annular

edge, and an upper airflow opening of the air pump main unit is located inside the protruding edge; the connection cover is provided with a lower airflow opening, and further comprises a detachable air pipe, and the air pipe connects the upper airflow opening and the lower airflow opening. The elastic diaphragm is used to prevent milk from flowing into the air pump main unit.

[0005] Further, the elastic diaphragm has a circular wrapping edge, the wrapping edge is sleeved on the annular edge, and the connection cover presses the wrapping edge against the annular edge; when the air pump main unit is installed on the three-way connector, the protruding edge presses the wrapping edge of the elastic diaphragm against the annular edge. Such an elastic diaphragm can be installed more securely.

[0006] Further, an annular groove is recessed on an outer annular surface of the annular edge, an outermost end of the wrapping edge of the elastic diaphragm is inwardly provided with an insert element, and the insert element is inserted into the annular groove.

[0007] Further, a lower end of the connection cover is divided into an inner ring and an outer ring, a clamping groove is provided between the inner ring and the outer ring, and the clamping groove clamps the wrapping edge of the elastic diaphragm against the annular edge.

[0008] Further, the outer annular surface of the annular edge is provided with a circle of barbs and an annular top edge, and the annular groove is located between the barbs and the top edge.

[0009] In the present utility model, when in use, the air pump main unit can be installed in two different ways. The first way is to install the connection cover on the annular edge, and then use the air pipe to connect the upper airflow opening and the lower airflow opening. The second way is to directly remove the connection cover and the air pipe, and connect the air pump main unit by engaging the protruding edge with the annular edge.

[0010] The present utility model has the following beneficial effects: 1. the installation of the air pump main unit can be implemented in two different ways, so that one of them can be selected to connect and install the air pump main unit, thereby respecting the usage habits of customers. 2. the elastic diaphragm is installed on the annular edge of the three-way connector by means of the wrapping edge and the insert element, thereby achieving secure installation.

BRIEF DESCRIPTION OF DRAWINGS

[0011] FIG. 1 is a schematic diagram of an embodiment of the present utility model.

[0012] FIG. 2 is a bottom-up schematic diagram of an embodiment of the present utility model.

[0013] FIG. 3 is a partial cross-sectional schematic diagram of an embodiment of the present utility model.

[0014] FIG. 4 is an enlarged schematic diagram of area A in FIG. 3.

[0015] FIG. 5 is an exploded schematic diagram of an embodiment of the present utility model.

[0016] FIG. 6 is a schematic diagram showing an air pump main unit directly connected to a three-way connector.

[0017] FIG. 7 is a cross-sectional schematic diagram of an air pump main unit directly connected to a three-way connector.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0018] The present utility model will be further described in detail below in conjunction with the accompanying drawings and specific implementations.

[0019] With reference to FIG. 1 to 7, an electric breast pump convenient for both separate and combined configurations is provided, comprising a three-way connector 1, a first end of the three-way connector 1 is connected to a suction head 2, and a second end of the three-way connector 1 is connected to a container 3. A third end of the three-way connector 1 is provided with an expansion opening 4, the expansion opening 4 is connected to an annular edge 5, a connection cover 6 is detachably provided on the annular edge 5, and an elastic diaphragm 7 that separates the third end of the three-way connector 1 into an inner cavity and an outer cavity is provided within the annular edge 5. The electric breast pump further comprises an air pump main unit 8, an end face of the air pump main unit 8 is provided with a circular protruding edge 9 that matches the annular edge 5, the air pump main unit 8 is configured to be detachably mounted on the annular edge 5 by means of connecting the protruding edge 9 to the annular edge 5, and an upper airflow opening 10 of the air pump main unit 8 is located inside the protruding edge 9. The connection cover 6 is provided with a lower airflow opening 11, and further comprises a detachable air pipe 12, and the air pipe 12 connects the upper airflow opening 10 and the lower airflow opening 11. The elastic diaphragm 7 is used to prevent milk from flowing into the air pump main unit 8.

[0020] Further, the elastic diaphragm 7 has a circular wrapping edge 13, the wrapping edge 13 is sleeved on the annular edge 5, and the connection cover 6 presses the wrapping edge 13 against

the annular edge 5. When the air pump main unit 8 is installed on the three-way connector 1, the protruding edge 9 presses the wrapping edge 12 of the elastic diaphragm 7 against the annular edge 5. Such an elastic diaphragm 7 can be installed more securely.

[0021] Further, an annular groove 14 is recessed on an outer annular surface 17 of the annular edge 5, an outermost end of the wrapping edge 13 of the elastic diaphragm 7 is inwardly provided with an insert element 15, and the insert element 15 is inserted into the annular groove 14.

[0022] Further, a lower end of the connection cover 6 is divided into an inner ring 16 and an outer ring 17, a clamping groove is provided between the inner ring 16 and the outer ring 17, and the clamping groove clamps the wrapping edge 13 of the elastic diaphragm against the annular edge 5.

[0023] Further, an outer ring 15 surface of the annular edge 5 is provided with a circle of barbs 18 and an annular top edge 19, and the annular groove 14 is located between the barbs 18 and the top edge 19.

[0024] In the present utility model, when in use, the air pump main unit 8 can be installed in two different ways. The first way is to install the connection cover 6 on the annular edge 5, and then use the air pipe 12 to connect the upper airflow opening 10 and the lower airflow opening 11. The second way is to directly remove the connection cover 6 and the air pipe 12, and connect the air pump main unit 8 by engaging the protruding edge 9 with the annular edge 5.

[0025] The present utility model has the following beneficial effects: 1. the installation of the air pump main unit can be implemented in two different ways, so that one of them can be selected to connect and install the air pump main unit, thereby respecting the usage habits of customers. 2. the elastic diaphragm is installed on the annular edge of the three-way connector by means of the wrapping edge and the insert element, thereby achieving secure installation.

CLAIMS

1. An electric breast pump convenient for both separate and combined configurations, comprising a three-way connector, a first end of the three-way connector being connected to a suction head, and a second end of the three-way connector being connected to a container, characterized in that: a third end of the three-way connector is provided with an expansion opening, the expansion opening is connected to an annular edge, a connection cover is detachably provided on the annular edge, and an elastic diaphragm that separates the third end of the three-way connector into an inner cavity and an outer cavity is provided within the annular edge; the electric breast pump further comprises an air pump main unit, an end face of the air pump main unit is provided with a circular protruding edge that matches the annular edge, the air pump main unit is configured to be detachably mounted on the annular edge by means of connecting the protruding edge to the annular edge, and an upper airflow opening of the air pump main unit is located inside the protruding edge; the connection cover is provided with a lower airflow opening, and further comprises a detachable air pipe, and the air pipe connects the upper airflow opening and the lower airflow opening.

2. The electric breast pump convenient for both separate and combined configurations according to claim 1, wherein the elastic diaphragm has a circular wrapping edge, the wrapping edge is sleeved on the annular edge, and the connection cover presses the wrapping edge against the annular edge; when the air pump main unit is installed on the three-way connector, the protruding edge presses the wrapping edge of the elastic diaphragm against the annular edge.

3. The electric breast pump convenient for both separate and combined configurations according to claim 2, wherein an annular groove is recessed on an outer annular surface of the annular edge, an outermost end of the wrapping edge of the elastic diaphragm is inwardly provided with an insert element, and the insert element is inserted into the annular groove.

4. The electric breast pump convenient for both separate and combined configurations according to claim 3, wherein a lower end of the connection cover is divided into an inner ring and

an outer ring, a clamping groove is provided between the inner ring and the outer ring, and the clamping groove clamps the wrapping edge of the elastic diaphragm against the annular edge.

5. The electric breast pump convenient for both separate and combined configurations according to claim 3 or 4, wherein the outer annular surface of the annular edge is provided with a circle of barbs and an annular top edge, and the annular groove is located between the barbs and the top edge.

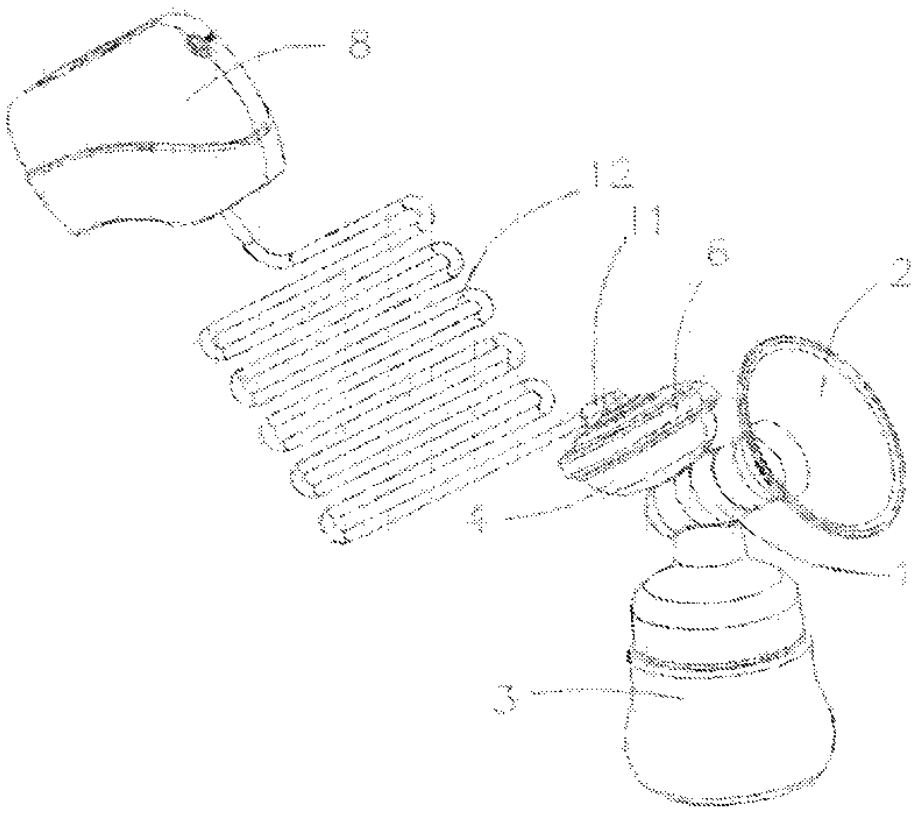


FIG. 1

7
8

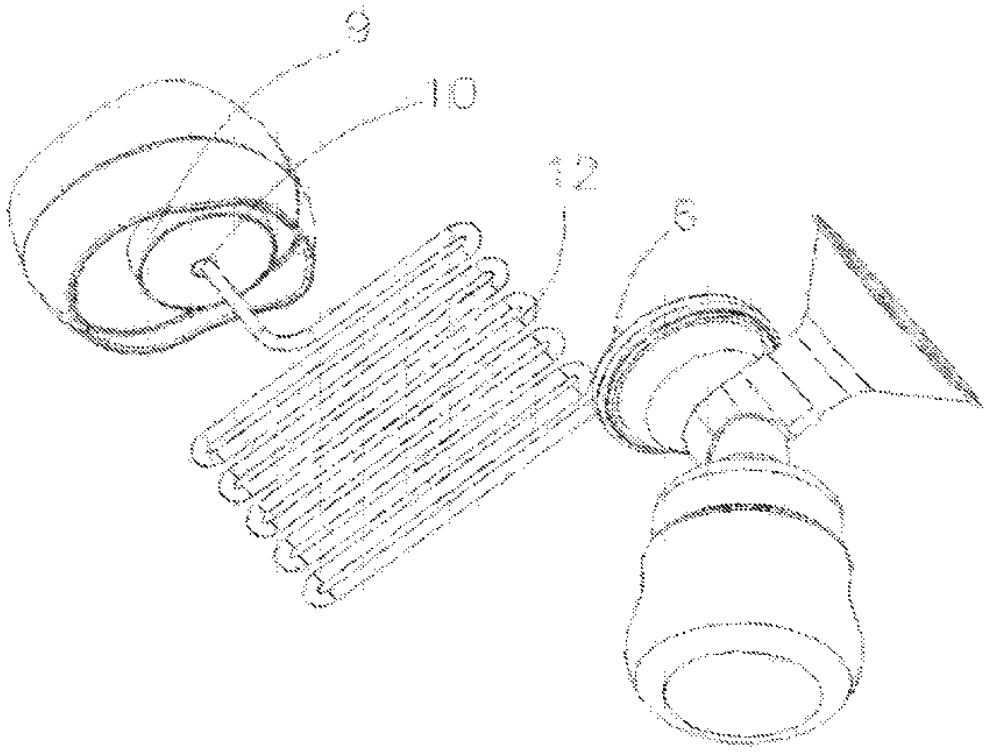


FIG. 2

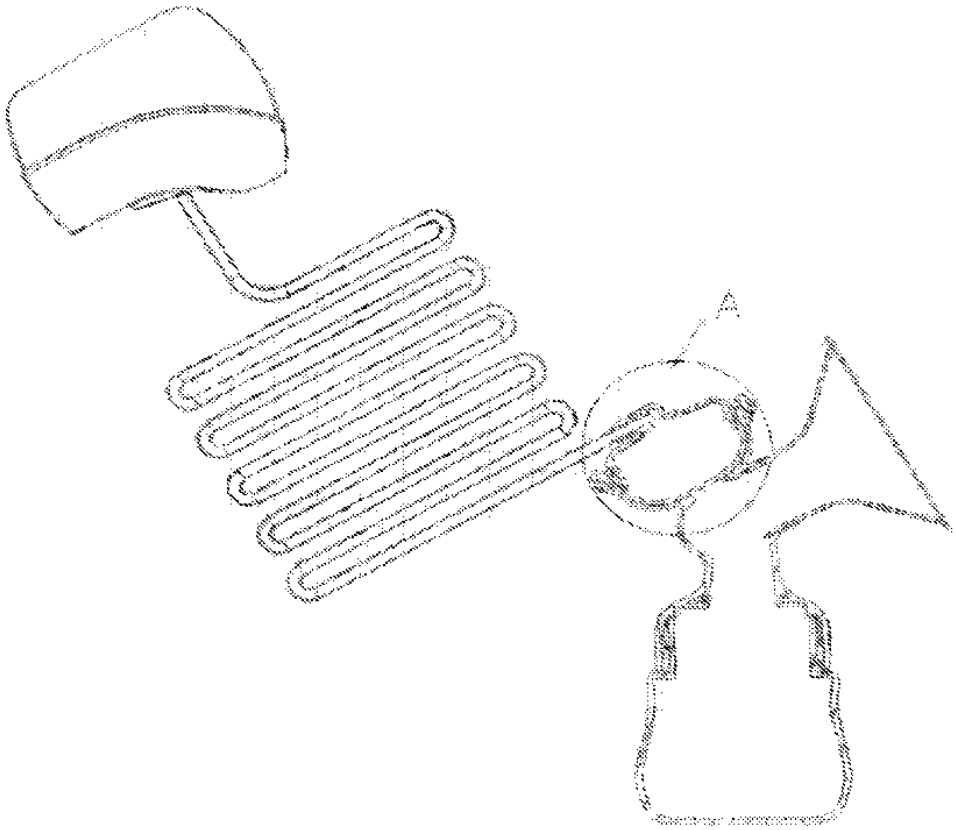


FIG. 3

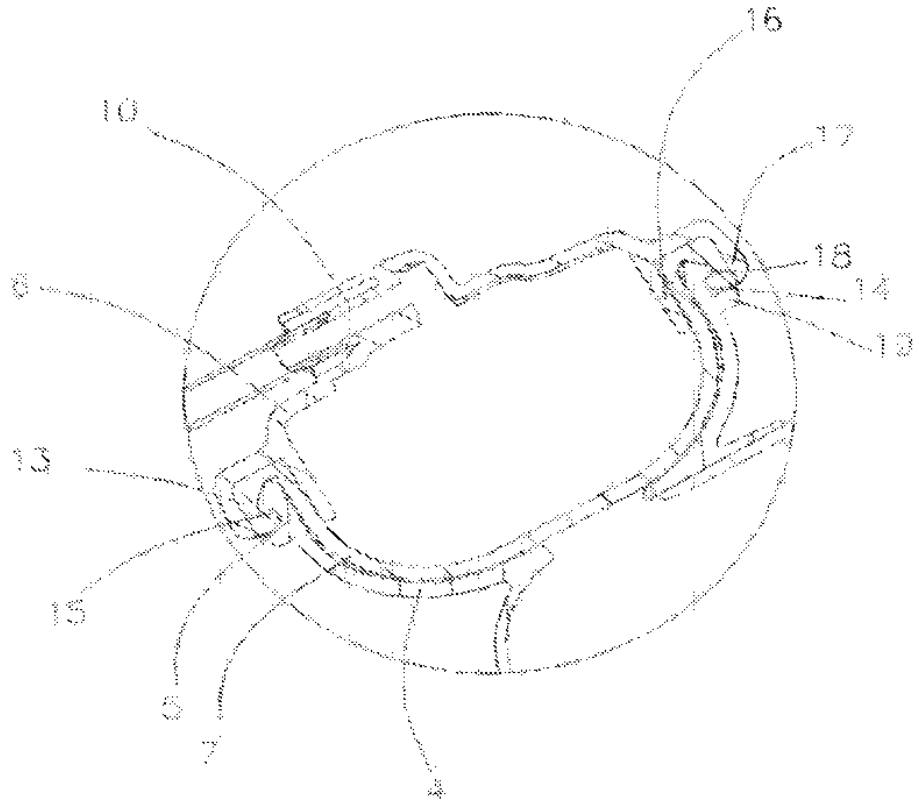


FIG. 4

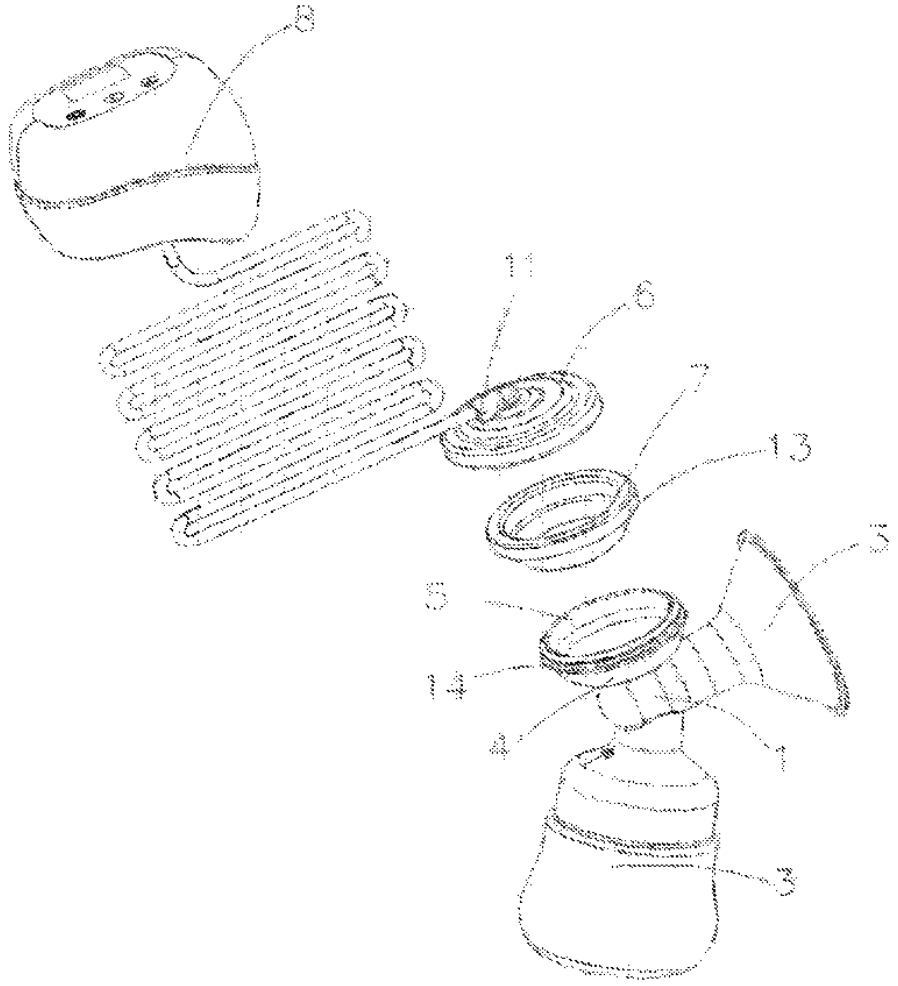


FIG. 5

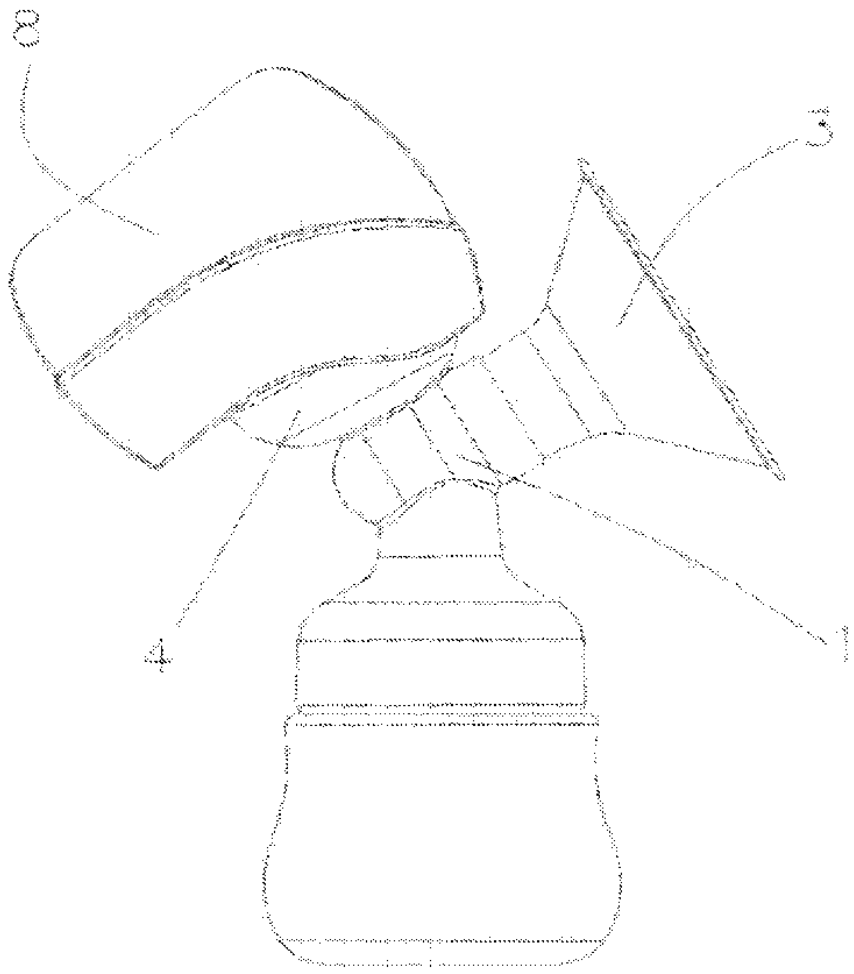


FIG. 6

12
13

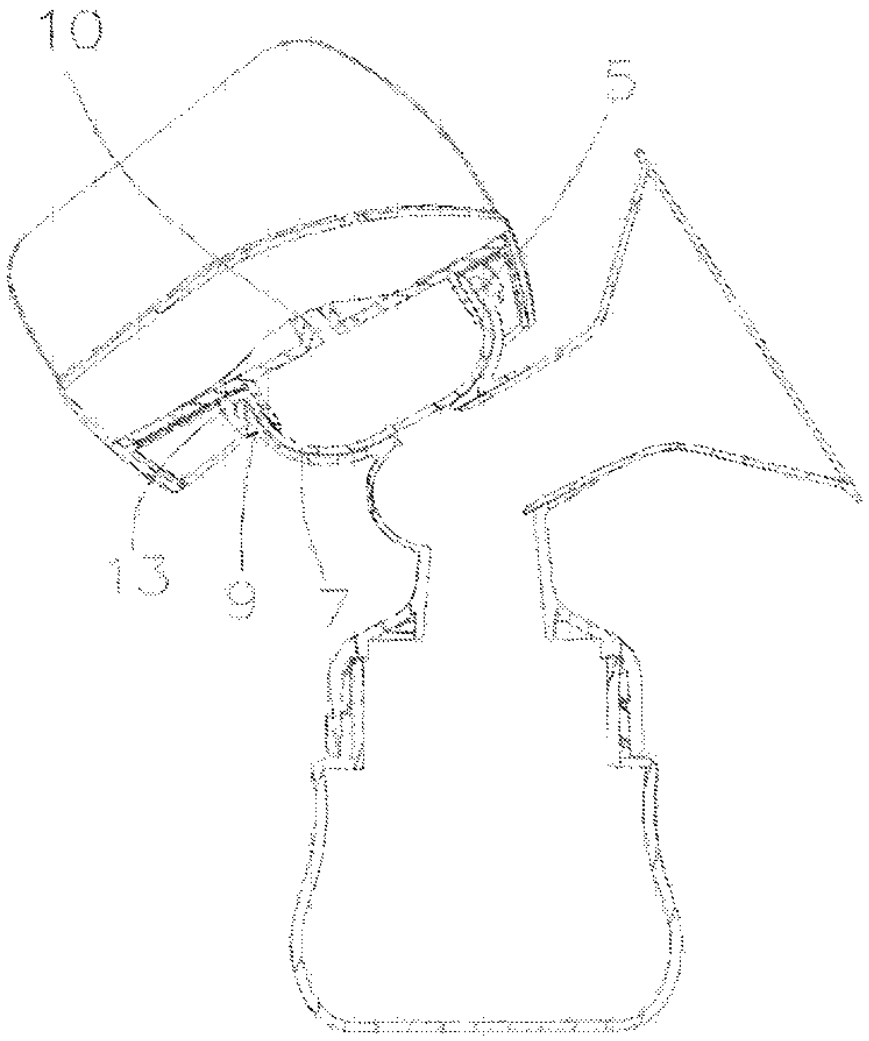


FIG. 7

13
14

Questel

TRANSLATOR'S CERTIFICATE OF TRANSLATION

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Date: August 9, 2024

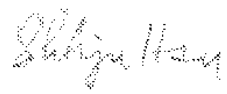
To whom it may concern:

I, Shih-szu Hsu, a translator fluent in the Chinese and English languages, on behalf of Questel, do solemnly and sincerely declare that the following is, to the best of my knowledge and belief, a true and correct translation of the document(s) listed below in a form that best reflects the intention and meaning of the original text.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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Signed this 9th day of August, 2024



Signature

Shih-szu Hsu

Name

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权利要求书1页 说明书2页 附图7页

(54)实用新型名称

一种分合两便的电动吸奶器

(57)摘要

一种分合两便的电动吸奶器，包括一个三通，所述三通第一端连接一个吸奶头，所述三通第二端连接一个容器，所述三通的第三端设有一个扩口，所述扩口连接一圈环边，所述的环边上可拆卸的有一个连接盖，所述的环边内设有一个把三通的第三端隔成里外两能室的弹性膜片；还包括一个气泵主机，所述的气泵主机一端面设有一圈与所述环边相配合的凸边，气泵主机开设的上通气开口位于凸边内；所述连接盖上设有下通气开口，还包括一个可拆卸的气管，本实用新型的有益效果在于：实现了在两种方式安装气泵主机，可择一连接安装气泵主机，尊重客户的使用习惯。



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1.一种分合两便的电动吸奶器，包括一个三通，所述三通第一端连接一个吸奶头，所述三通第二端连接一个容器，其特征在于：所述三通的第三端设有一个扩口，所述扩口连接一圈环边，所述的环边上可拆卸的有一个连接盖，所述的环边内设有一个把三通的第三端隔成里外两腔室的弹性膜片；还包括一个气泵主机，所述的气泵主机一端面设有一圈与所述环边相配合的凸边，所述的气泵主机能通过凸边连接在环边上的形式可拆卸的安装在环边上，气泵主机开设的上通气开口位于凸边内；所述连接盖上设有下通气开口，还包括一个可拆卸的气管，所述气管连接所述上通气开口和下通气开口。

2.根据权利要求1所述分合两便的电动吸奶器，其特征在于：所述的弹性膜片有一圈包边，所述的包边套在所述环边上，且所述连接盖把包边压在环边上；所述气泵主机安装在三通上时，所述凸边把弹性膜片的包边压在环边上。

3.根据权利要求2所述分合两便的电动吸奶器，其特征在于：所述的环边上外环面上凹设有一圈环槽，所述弹性膜片的包边上最外端向内设有内嵌，所述内嵌卡进所述环槽中。

4.根据权利要求3所述分合两便的电动吸奶器，其特征在于：所述的连接盖下端分为内环和外环，所述内环与外环之间设有夹槽，所述夹槽夹住弹性膜片的包边抵在环边上。

5.根据权利要求3或4所述分合两便的电动吸奶器，其特征在于：所述环边的外环面上设有一圈倒钩和一圈顶边，所述环槽位于倒钩与顶边之间。

一种分合两便的电动吸奶器

技术领域

[0001] 本实用新型涉及一种吸奶器，用于辅助哺乳。

背景技术

[0002] 现有技术的电动吸奶器常见的就是一个吸奶头通过一个三通连接到一个气泵主机和一个奶瓶，气泵主机通常有两种方法连接三通，第一种是采用气管连接到三通，好处是手持的部件少，比较轻，坏处是需要一个平台放置气泵主机，另一种是气泵主机直接固定在三通上，缺点就是比较重。

发明内容

[0003] 为了克服现有的电动吸奶器无法自主确定气泵主机的安装方式来适应不同使用习惯不足，本实用新型提供一种分合两便的电动吸奶器。

[0004] 本实用新型解决其技术问题的技术方案是：一种分合两便的电动吸奶器，包括一个三通，所述三通第一端连接一个吸奶头，所述三通第二端连接一个容器，所述三通的第三端设有一个扩口，所述扩口连接一圈环边，所述的环边上可拆卸的有一个连接盖，所述的环边内设有一个把三通的第三端隔成里外两腔室的弹性膜片；还包括一个气泵主机，所述的气泵主机一端面设有一圈与所述环边相配合的凸边，所述的气泵主机能通过凸边连接在环边上的形式可拆卸的安装在环边上，气泵主机开设的上通气开口位于凸边内；所述连接盖上设有下通气开口，还包括一个可拆卸的气管，所述气管连接所述上通气开口和下通气开口。所述的弹性膜片用以防止奶水流进气泵主机。

[0005] 进一步，所述的弹性膜片有一圈包边，所述的包边套在所述环边上，且所述连接盖把包边压在环边上；所述气泵主机安装在三通上时，所述凸边把弹性膜片的包边压在环边上。这样的弹性膜片安装比较牢靠。

[0006] 进一步，所述的环边上外环面上固设有一圈环槽，所述弹性膜片的包边上最外端向内设有内嵌，所述内嵌卡进所述环槽中。

[0007] 进一步，所述的连接盖下端分为内环和外环，所述内环与外环之间设有夹槽，所述夹槽夹住弹性膜套的包边抵在环边上。

[0008] 进一步，所述环边的外环面上设有一圈倒钩和一圈顶边，所述环槽位于倒钩与顶边之间。

[0009] 本实用新型在使用时，可以采用两种不同的方式安装气泵主机，第一种是在环边上安装好连接盖，然后拿气管连接上通气开口和下通气开口。第二种方式是直接去掉连接盖和气管，将气泵主机通过凸边卡在环边上的方式连接。

[0010] 本实用新型的有益效果在于：1、实现了在两种方式安装气泵主机，可择一连接安装气泵主机，尊重客户的使用习惯。2、弹性膜片采用包边内嵌安装在三通的环边上，安装牢靠。

附图说明

[0011] 图1是本实用新型一个实施例的示意图。

[0012] 图2是本实用新型一个实施例的下往上示意图。

[0013] 图3是本实用新型一个实施例的局部剖视示意图。

[0014] 图4是图3中的A处的放大示意图。

[0015] 图5是本实用新型一个实施例的爆炸示意图。

[0016] 图6是气泵主机直接连接在三通上的示意图。

[0017] 图7是气泵主机直接连接在三通上的剖视示意图。

具体实施方式

[0018] 下面结合附图和具体实施方式对本实用新型作进一步详细说明。

[0019] 结合附图1至7，一种分合两便的电动吸奶器，包括一个三通1，所述三通1第一端连接一个吸奶头2，所述三通1第二端连接一个容器3，所述三通1的第三端设有一个扩口4，所述扩口4连接一圈环边5，所述的环边5上可拆卸的有一个连接盖6，所述的环边5内设有一个把三通1的第三端隔成里外两腔室的弹性膜片7；还包括一个气泵主机8，所述的气泵主机8一端面设有一圈与所述环边5相配合的凸边9，所述的气泵主机8能通过凸边9连接在环边5上的形式可拆卸的安装在环边5上，气泵主机8开设的上通气开口10位于凸边9内；所述连接盖6上设有下通气开口11，还包括一个可拆卸的气管12，所述气管12连接所述上通气开口10和下通气开口11。所述的弹性膜片7用以防止奶水流进气泵主机8。

[0020] 进一步，所述的弹性膜片7有一圈包边13，所述的包边13套在所述环边5上，且所述连接盖6把包边13压在环边5上；所述气泵主机8安装在三通1上时，所述凸边9把弹性膜片7的包边13压在环边5上。这样的弹性膜片7安装比较牢靠，

[0021] 进一步，所述的环边5上外环17面上凹设有一圈环槽14，所述弹性膜片7的包边13上最外端向内设有内嵌15，所述内嵌15卡进所述环槽14中。

[0022] 进一步，所述的连接盖6下端分为内环16和外环17，所述内环16与外环17之间设有夹槽，所述夹槽夹住弹性膜套的包边13抵在环边5上。

[0023] 进一步，所述环边5的外环17面上设有一圈倒钩18和一圈顶边19，所述环槽14位于倒钩18与顶边19之间。

[0024] 本实用新型在使用时，可以采用两种不同的方式安装气泵主机8，第一种是在环边5上安装好连接盖6，然后拿气管12连接上通气开口10和下通气开口11。第二种方式是直接去掉连接盖6和气管12，将气泵主机8通过凸边9卡在环边5上的方式连接。

[0025] 本实用新型的有益效果在于：1、实现了在两种方式安装气泵主机，可择一连接安装气泵主机，尊重客户的使用习惯。2、弹性膜片采用包边内嵌安装在三通的环边上，安装牢靠。

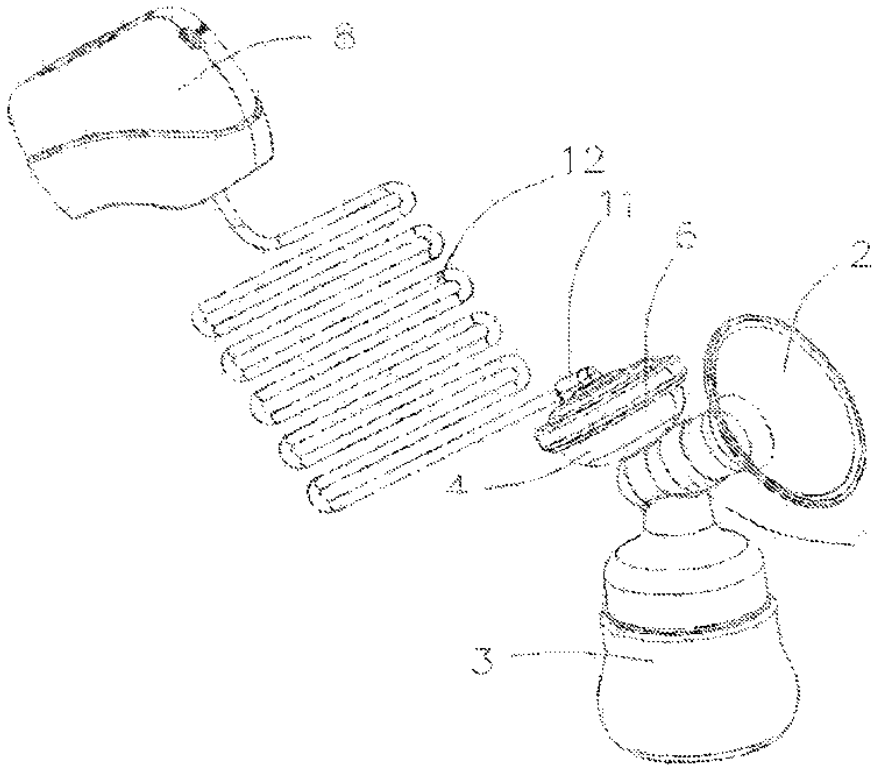


图1

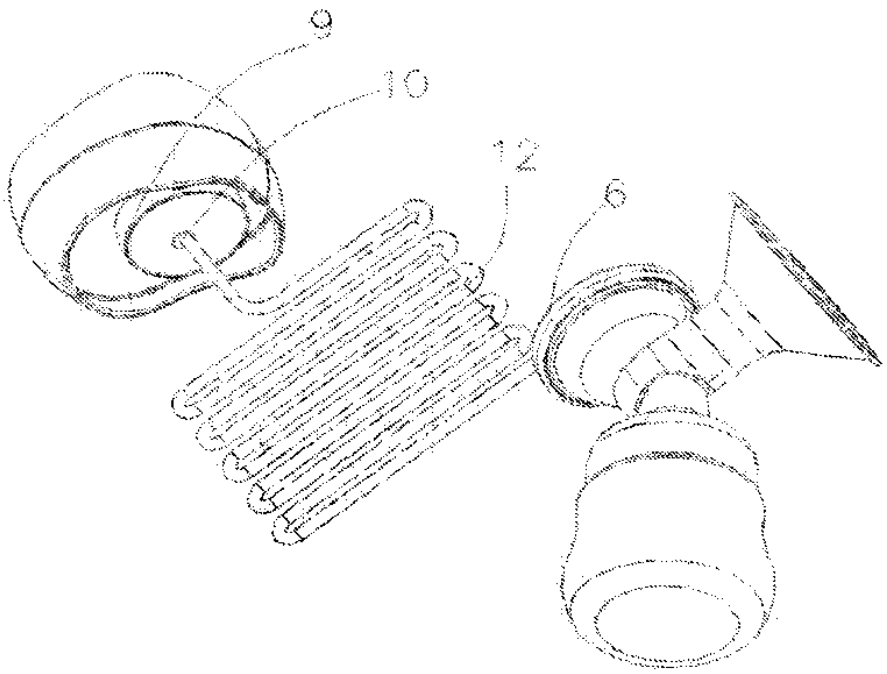


图2

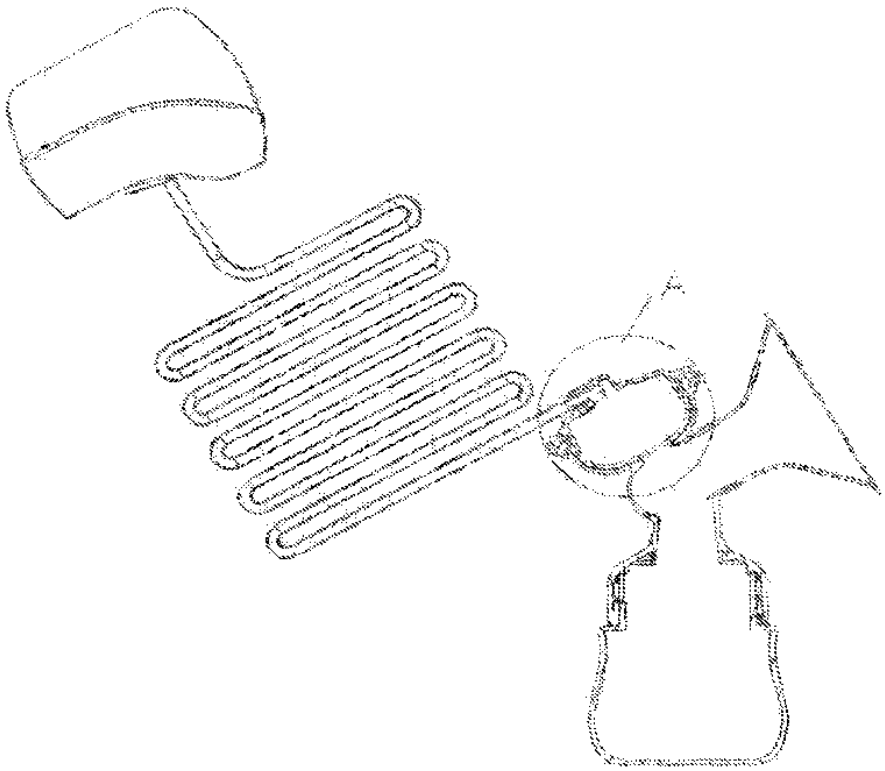


图3

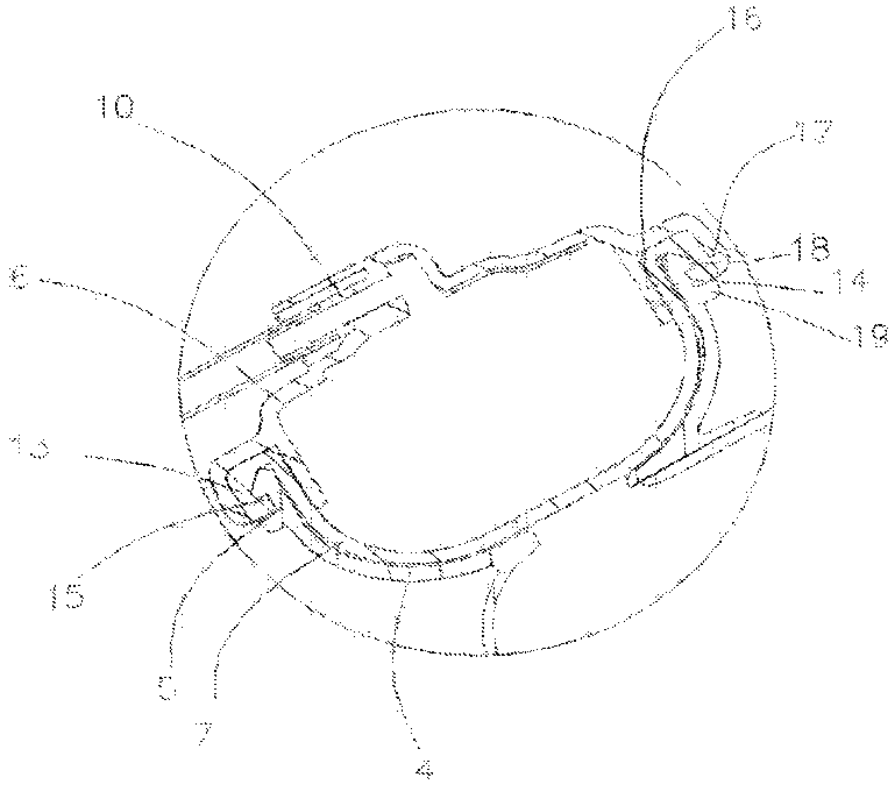


图1

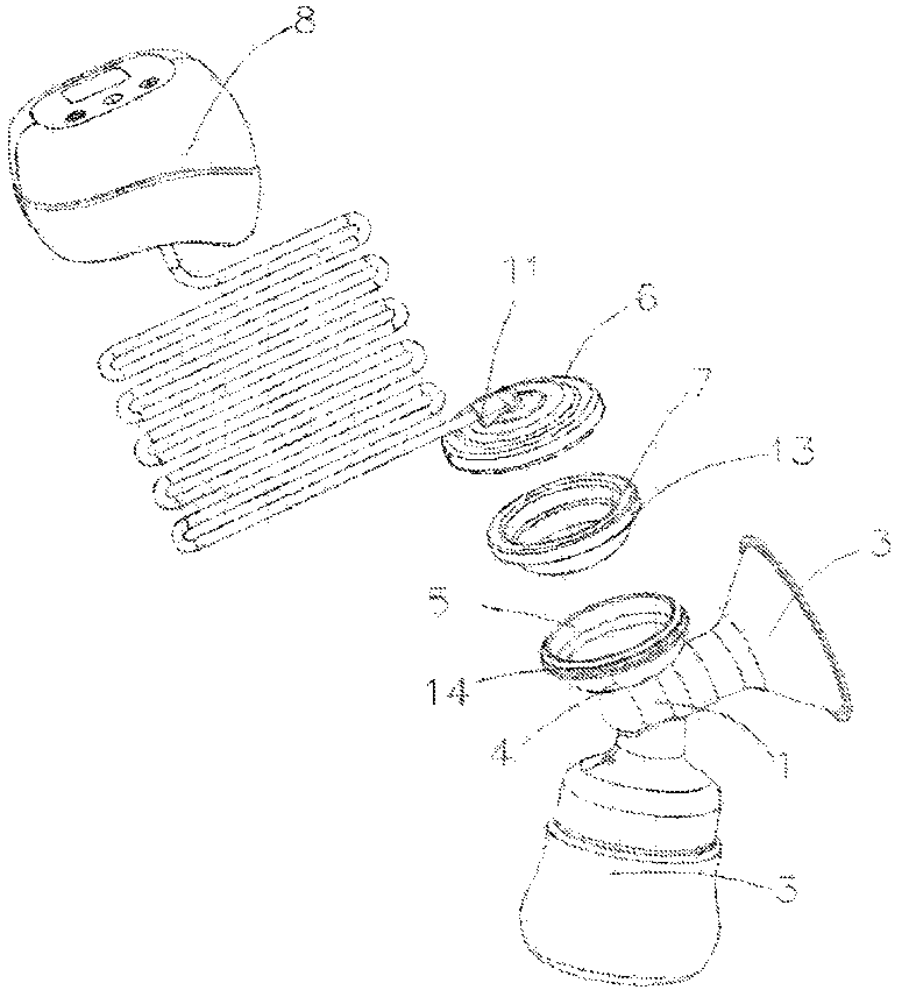


图5

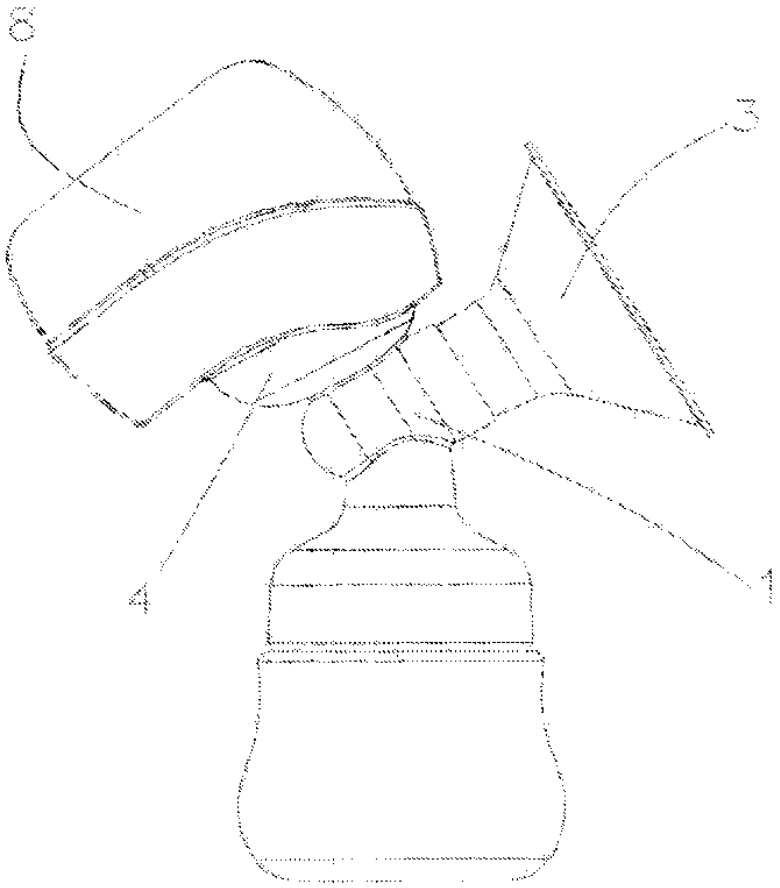


图6

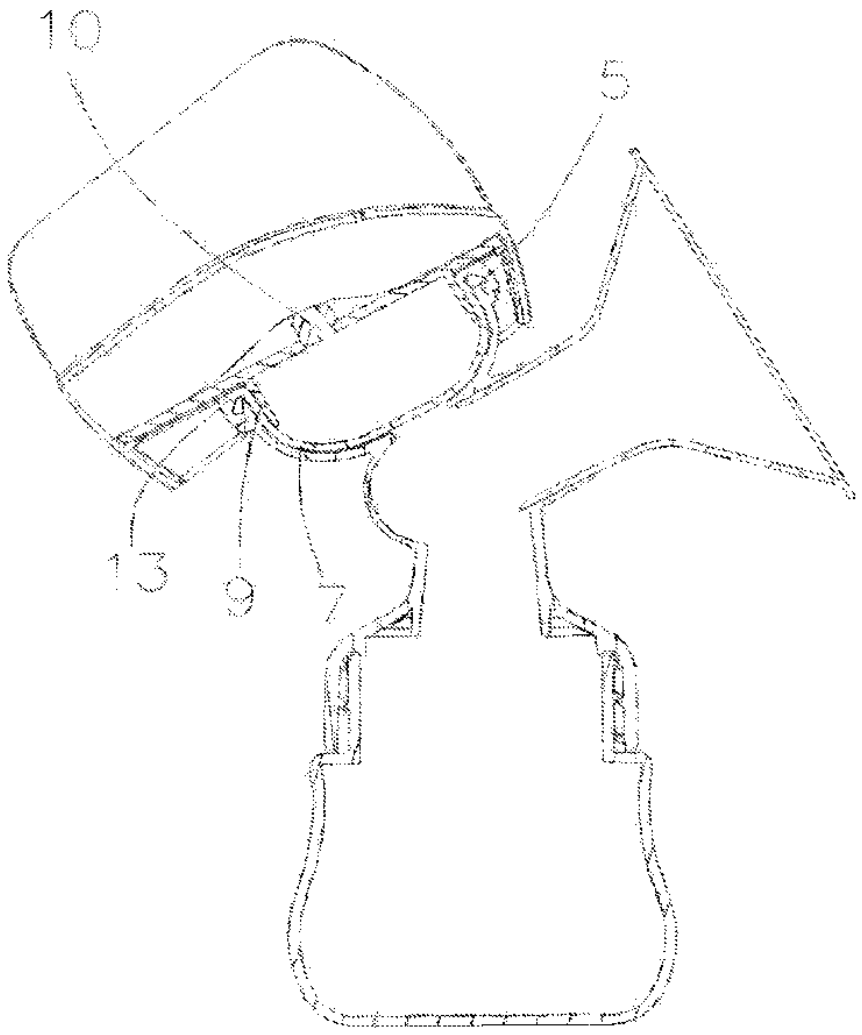


图7

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
P209758WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP2023/073973	31 August 2023 (31-08-2023)	31 August 2022 (31-08-2022)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/073973

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/058928 A1 (NOWROOZI BRYAN NEEMA [US] ET AL) 3 March 2016 (2016-03-03) paragraph [0087] - paragraph [0088] figure 1B paragraph [0104]; figure 13	1-27
X	EP 4 000 661 A1 (KONINKLIJKE PHILIPS NV [NL]) 25 May 2022 (2022-05-25) claim 1 figure 2 paragraph [0008] - paragraph [0012] paragraph [0060] - paragraph [0062] paragraph [0048]	1-27
X	US 2008/255503 A1 (QUACKENBUSH CARR LANE [US] ET AL) 16 October 2008 (2008-10-16) paragraph [0082]; figure 18 paragraph [0085] - paragraph [0086]; figure 515	1-27

[ ] 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" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 November 2023	04/12/2023

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	Mata Vicente, Teresa

2

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2023/073973

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016058928 A1	03-03-2016	US 2016058928 A1	03-03-2016
		US 2017065753 A1	09-03-2017
		WO 2016033107 A1	03-03-2016
EP 4000661 A1	25-05-2022	CN 116457037 A	18-07-2023
		EP 4000661 A1	25-05-2022
		EP 4247448 A1	27-09-2023
		WO 2022106252 A1	27-05-2022
US 2008255503 A1	16-10-2008	AU 2008240295 A1	23-10-2008
		BR PI0809908 A2	07-10-2014
		CA 2682491 A1	23-10-2008
		CN 101730554 A	09-06-2010
		EP 2142232 A1	13-01-2010
		EP 3138590 A1	08-03-2017
		EP 3485923 A1	22-05-2019
		ES 2689722 T3	15-11-2018
		JP 2010523283 A	15-07-2010
		JP 2013039445 A	28-02-2013
		KR 20090128497 A	15-12-2009
		PL 2142232 T3	31-01-2019
		RU 2009141381 A	20-05-2011
		US 2008255503 A1	16-10-2008
		WO 2008127991 A1	23-10-2008

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2023/073973	31.08.2023	31.08.2022

International Patent Classification (IPC) or both national classification and IPC
INV. A61M1/06

Applicant
CHIARO TECHNOLOGY LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Mata Vicente, Teresa Telephone No. -0

Form PCT/ISA/237 (Cover Sheet) (July 2022)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed.

   b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)).

      ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6, 12-15, 24, 26, 27
	No:	Claims	1-5, 7-11, 16-23, 25
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-27
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 US 2016/058928 A1 (NOWROOZI BRYAN NEEMA [US] ET AL) 3 March 2016 (2016-03-03)

D2 EP 4 000 661 A1 (KONINKLIJKE PHILIPS NV [NL]) 25 May 2022 (2022-05-25)

D3 US 2008/255503 A1 (QUACKENBUSH CARR LANE [US] ET AL) 16 October 2008 (2008-10-16)

1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 is not new in the sense of Article 33(2) PCT.

1.1 D1 discloses (see fig. 1B and fig. 13) an in-bra wearable (see para. 0087) breast pump, comprising:
an air pump system for generating a base level vacuum and a pumping vacuum;
a breast shield for receiving a user's breast and comprising a first side and a second side;
a first channel for drawing the base level vacuum on the first side of the breast shield;
a second channel for drawing the pumping vacuum on the second side of the breast shield.

1.2 Furthermore, as in the present application, the pump of D1 is configured to draw a baseline vacuum longitudinally in one side of the shield (to ensure that the shield remains attached to the breast) and to draw milk-expression vacuum radially in the other side. Furthermore, it can do it using one or two vacuum sources (see fig. 13). Claims 1-5, 7-11, 18-23 and 25 lack novelty over D1.

1.3 D2 discloses (see claim 1 and fig. 2) an in-bra wearable (see paras. 0028 and 0008-0012) breast-pump comprising an air-pump system and a breast shield with an inner and an outer side, wherein the pump is configured to draw a baseline vacuum radially in the outer side (to ensure that the shield remains attached to the breast) and to draw milk-expression vacuum longitudinally in the inner side. In consequence, it prejudices the novelty of claims 1, 5, 7-11, 16-20,

22, 23 and 25. In D2 the pump is not configured to draw a baseline vacuum longitudinally in one side of the shield and a "pumping vacuum" radially in the other side.

1.4 D3 discloses breast-pump comprising an air-pump system and a breast shield with two sides, wherein the pump is configured to draw a baseline vacuum radially in the one side through the suction channels (to ensure that the shield remains attached to the breast) and to draw milk-expression vacuum longitudinally in the other side. Given that D3 does not mention whether the breast-pump therein disclosed can be worn in a bra, it does not prejudice the novelty of claims 1-27.

1.5 In view of the prior art, claims 6, 12-15, 24, 26 and 27 fulfil the novelty requirements of Art. 33(2) PCT.

2 Nevertheless, the dependent claims 6, 12-15, 24, 26 and 27 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, because in view of the closest prior art document D1 it would have been obvious for the skilled person to arrive at the subject-matter thereof with the routinary skills and knowledge expected from someone skilled in the art.

2.1 In consequence, claims 1-27 are regarded as not involving an inventive step in the sense of Art. 33(3) PCT.

3 The subject-matter claims 1-27 are industrially applicable. Therefore the requirements of Article 33(4) PCT are met.

Re Item VII

Certain defects in the international application

4 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

4.1 In the present case the features of the claims should have been provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

5 The technical features recited in dependent claims 2, 4 and 5 are regarded as essential technical features. The independent claims do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

5.1 Further to the objection raised in the previous paragraph, the reference to the method of claims 22-25 is not sufficient to clearly define the product of claim 26, which therefore lacks essential technical features in order to satisfy the requirements of Art. 6 PCT. If the claim had mentioned that the method was performed by the breast pump (a non-transitory computer readable medium comprising computer executable instructions which, when executed by a processor, cause a breast pump as defined in claim 1 to perform the method of claims 22 to 25), it would have been regarded as clearly defined in the sense of Art. 6 PCT.

5.2 The statement "herein incorporated by reference" and similar ones (for example in para. 006) indicate that the patent specification is not self-contained regarding the essential features of the invention.

5.3 The vague and imprecise statements and the claim-like "clauses" in paragraph 235, imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them.

5.4 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.

PTO/SB/30 (11-17)
Approved for use through 05/31/2024. 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

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B
Attorney Docket Number	4944.0120006

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. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. 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).

   a. ☐ 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.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ 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)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 19-0036 .

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

   d. ■ Payment by EFS-Web

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Yangbeini Wang #800,005/	Date	September 26, 2024
Name (Print/Type)	Yangbeini Wang	Registration No.	800,005

CERTIFICATE OF MAILING OR TRANSMISSION

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

Signature			
Name (Print/Type)		Date	

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **If filing this completed form by mail, 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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013). https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to: 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law; 2) a Federal, state, local, or international agency, in response to its request; 3) a contractor of the USPTO having need for the information in order to perform a contract; 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record; 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record; 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations; 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals; 8) 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)); 9) the Office of Personnel Management (OPM) for personnel research purposes; and 9) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Additional Uses

Additional USPTO uses of the information in this record may include disclosure to: 1) the International Bureau of the World Intellectual Property Organization, if the record is related to an international application filed under the Patent Cooperation Treaty; 2) the public i) after publication of the application pursuant to 35 U.S.C. 122(b), ii) after issuance of a patent pursuant to 35 U.S.C. 151, iii) 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, or iv) without publication of the application or patent under the specific circumstances provided for by 37 CFR 1.14(a)(1)(v)-(vii); and/or 3) the National Archives and Records Administration, for inspection of records.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-10987455-B2	04-27-2021	AALDERS; Arnold et al.	
	002	US-20170080135-A1	03-23-2017	CHEN; Junbo	
	003	US-20170136161-A1	05-18-2017	ALVAREZ; Jeffery B. et al.	
	004	US-20190275222-A1	09-12-2019	EVANS; Jeremy Patrick et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
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Examiner Signature		Date Considered	

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	Exhibit List for IPR 2024-01296 (DECLARATION OF RYAN BAUER U.S. Patent No. 11,413,380) February 14, 2024, 142 pages.	☐
	002	International Search Report and Written Opinion for Application No. PCT/EP2023/073973, mailed on December 04, 2023, 9 pages.	☐
	003	International Search Report and Written Opinion for Application No. PCT/EP2023/073975, mailed on December 19, 2023, 9 pages.	☐

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				Art Unit	3783
				Examiner Name	FREDRICKSON, COURTNEY B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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.

☒ A certification statement is not submitted herewith.

FEE

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	September 26, 2024
Name/Print	Yangbeini Wang	Registration Number	800,005

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
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Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
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			TOTAL AMOUNT:	**$2,000.00**

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.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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(54) BREAST SHIELD FOR A BREAST PUMP

(57) A breast shield for a breast pump comprises a first (inner) cavity for placing over the nipple and having a first pressure control port for controlling milk expression. A second (outer) cavity is radially outward of the first cavity and is coupled to a second pressure control port for providing a sealing or positioning and then holding function. Thus, a positioning/holding function and a milk expression function may be optimized independently.

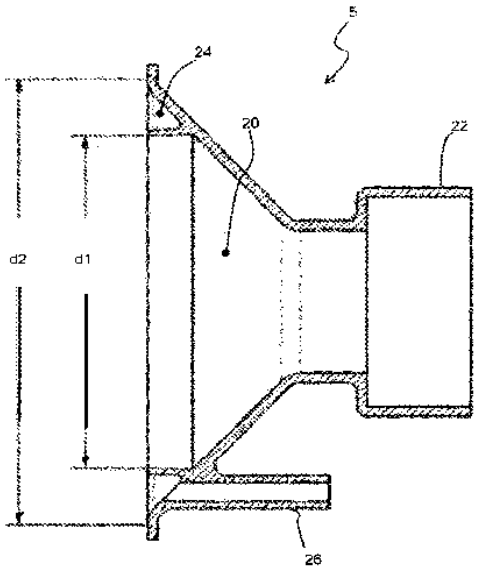


FIG. 2

EP 4 000 661 A1

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a breast shield for a breast pump to receive the breast of a user. The invention also relates to a breast pump comprising the shield of the invention.

BACKGROUND OF THE INVENTION

[0002] Breast pumps are well known devices for extracting milk from a breast of a user. A breast pump may be used if the baby or infant is not itself able to extract milk from the breast, or if the mother is separated from the baby or infant and is to be fed with breast milk by someone else.

[0003] Breast pumps allow the nursing mother to express milk and provide collection of the breastmilk for later use. For some mothers, breast pumps may be a necessity, as when a child has suckling problems, or if the mother has problems with excessive or deficient milk production, or soreness, deformation or injury of the mammilla, or like conditions that are not conducive to suckling at the breast.

[0004] Breast pumps typically comprise a rigid, funnel-shaped shield connected to a vacuum pump having a container for collecting the milk. The funnel shaped shield is known as the breast shield. It is the interface between the user's breast and nipple with the pump and so its design is critical to maintaining the user's comfort whilst using the device. It is also important to ensure that the vacuum seal between the breast and the shield is maintained for optimal pumping.

[0005] The breast pump typically has two operating modes, namely a stimulation mode and an extraction mode. During the stimulation mode, the milk ejection reflex is stimulated. When the breast pump is activated, a pressure source such as a vacuum pump inside the breast pump generates an under-pressure and the stimulation mode can be started. The vacuum pump is typically driven by an electric motor. For portable breast pumps, these motors are driven by battery power.

[0006] Typical pressure profiles oscillate between a maximum negative pressure and then return to atmospheric pressure at the end of each cycle. By generating a pressure cycle, particularly a cycle using under-pressure levels below atmospheric pressure, a simulation of a feeding action is obtained, which triggers the necessary let-down reflex for lactating. However, a return to ambient pressure within the breast shield chamber may not be required, and benefits may be achieved by maintaining a certain level of under-pressure, i.e. a baseline vacuum, on the breast throughout at least a portion of the pumping session.

[0007] During placement of the breast shield, the mother has to correctly place the expression kit while at the same time having to turn on the vacuum pump (with the other hand). The nipple should be aligned as well as possible in the center of the breast shield. If the mother then turns on the vacuum pump, the breast shield often moves out of place. This problem becomes even more apparent if two expression kits are used at the same time, one for each breast.

[0008] While expressing milk, the breast shield or shields also need to be held in place during the entire duration of the session. Some dedicated bras are commercially available for hand-free use of the breast pumps. Besides increasing the cost of the expression set, an expression bra might not be as comfortable as a normal bra when needed to be worn for the whole day and women might need to undress before expressing milk.

[0009] Incorrect placement results in a number of disadvantages such as leakage and pain and trauma. If the breast shield is not correctly sealed against the breast, leakage can occur which can result in milk spilling over clothes or breastmilk waste. Pain and trauma may be caused by bruising to the nipple and areola.

[0010] To address this issue, breast pumps may also include an attachment mode before the breast pumping session, during which a low under-pressure level (i.e. a pressure close to atmospheric pressure) is applied to assist the user in positioning the breast shield. The use of an attachment mode is for example described in EP 3 151 876.

[0011] The pumping profile, baseline pressure and attachment pressure are usually controlled within a breast shield by acting on the same breast area (nipple and areola). This hampers comfort and the possibility of independently optimizing the different functions.

[0012] There is therefore a need for an improved design of breast shield to improve the ease of alignment.

SUMMARY OF THE INVENTION

[0013] The invention is defined by the claims.

[0014] According to examples in accordance with an aspect of the invention, there is provided a breast shield for a breast pump, comprising:

a first cavity for placing over a first portion of the breast surface including the nipple of a breast, the first cavity coupled to a first pressure control port for controlling milk expression; and

a second cavity positioned radially outwardly from the first cavity, the second cavity coupled to a second pressure control port for providing a sealing, or positioning function, wherein the second cavity is for applying a pressure to a second portion of the breast surface radially outward from the first portion.

[0015] The first cavity is intended to cover the nipple, whereas the second cavity covers an area of the breast surface further radially outwardly spaced from the nipple. It is positioned radially outwardly, with reference to radial direction of the first cavity. This radial direction is perpen-

dicular to the projection direction of the nipple, and perpendicular to a corresponding length axis of the first cavity.

[0016] The second cavity may have a closed shape (such as a circle or ellipse) surrounding the first cavity or it may have a shape which does not fully surround the first cavity. The use of separate pressure control ports means that different under-pressure levels and/or profiles may be applied to the different areas of the breast. For example, the pressure applied to the second portion of the breast may be a baseline under-pressure aimed at providing improved and easy placement whereas the pressure applied to the first portion is for the most efficient milk expression.

[0017] The breast shield thus has two separate compartments to enable this use of independent pressure profiles. The second cavity may be formed outside the normal size of a breast shield. In this case, the breast shield provides a larger surface of contact. Alternatively, the first cavity may have a reduced sized compared to a conventional breast shield so that the overall size remains approximately the same.

[0018] When the second has a closed shape around the first cavity, the breast shield has one circular (or oval) first cavity for providing an expression pressure profile and a concentric second cavity in the shape of a corresponding closed shape.

[0019] The second cavity may comprise an open shape which may be only partially around the first cavity. Thus, a full closed shape is not needed. The size of the second cavity only needs to be sufficient to perform the intended function, which is for example a holding function. It may be simply to one side of the first cavity, e.g. above the first cavity.

[0020] The first cavity may have a milk output channel and the second cavity is a shape with an interruption located at the milk output channel. Thus, the second cavity does not complicate the connections to the first cavity.

[0021] The second cavity may have a covering membrane. This is used to protect the vacuum pump system from dirt and debris and makes the breast shield easier to clean. The membrane forms an interface between the second cavity and the breast. This may also give more comfort to the user.

[0022] There may be one or more further cavities, so that there is a set of cavities radially outside the first cavity, for example a set of two or more concentric outer cavities. A pressure may be switched between the multiple chambers defined by these outer cavities to maintain a constantly applied under-pressure to hold the breast pump while not having a constant under-pressure on any particular area of the breast tissue. This avoids bruises that can occur when an under-pressure is constantly applied to a same position. In this way, the breast shield further comprises at least one further cavity positioned radially outwardly of the second cavity.

[0023] The second cavity may be divided into segments, wherein each segment has its own pressure control port. Some of these pressure control ports may be coupled together so that the segments are grouped, or they may be independent.

[0024] The use of multiple segments, to which independent and adaptive pressure profiles may be applied, gives the option of massaging the breast during milk expression. Massaging the breast during milk expression has been demonstrated to increase the quality of breast milk. The combination of suckling and massaging also assists in emptying the milk ducts as well encouraging the production of more milk.

[0025] The second cavity maybe rigidly mounted to the first cavity. They may for example be formed as a single molded unit.

[0026] Alternatively, the second cavity may be elastically non-rigidly mounted to the first cavity. There may for example be an elastic ring between them. This improves user comfort by enabling the breast shield to adapt at least partly to the shape of the breast.

[0027] A ridge between the inner and outer cavity is preferably designed to maximize comfort, by avoiding high friction surfaces, hard materials or sharp edges. This ridge functions as the main seal for preventing leakage of milk from the first cavity into the second cavity. The second cavity is not intended to function as a milk collection chamber.

[0028] The second cavity may be non-circular with a greater height than width. The height is the axis which is intended to be aligned with the height axis of the user, i. e. intended to be vertical in normal use. It may for example be oval. This means that more of the suction force is acting against the momentum resulting from the weight of the wearable part multiplied by the distance to the center of gravity, so providing a more effective holding of the breast shield. This results in improved fitting.

[0029] The invention also provides a breast pump comprising:

a vacuum pump system;
an expression kit which comprises the breast shield as defined above coupled to the vacuum pump system; and
a controller for controlling the vacuum pump system.

[0030] The vacuum pump system may comprise a vacuum pump, and a pressure regulator system for delivering a pressure to the first cavity and the second cavity. Thus, a single vacuum pump may be used, and the output is regulated by a regulator system (e.g. separate pressure regulators) to create at least two different pressure profiles.

[0031] The vacuum pump system may instead comprise a first vacuum pump for the first cavity (for the expression function) and a second vacuum pump for the second cavity (e.g. for creating a baseline pressure).

[0032] The controller may be adapted to apply a holding vacuum to the second cavity which adapts over time from an intermittent application of under-pressure to a

constant application of under-pressure when the breast shield is first positioned.

[0033] Alternatively, a constant but low initial holding under-pressure may be used when the breast shield is first positioned.

[0034] The intermittent application of under-pressure and/or the use of a low under-pressure enables a user to reposition the breast shield initially, and the breast shield is then held more constantly when the constant or higher under-pressure is applied.

[0035] The controller may be adapted to apply a massage pressure profile to the second cavity during milk expression using the first cavity. This may for example make use of a segmented second cavity as discussed above.

[0036] The breast pump system may comprise a user interface to allow a user to select pressure characteristics for the first and second cavities. Thus, the user may prefer to have the attachment performed by the expression pressure (as in a conventional breast pump) and may thus choose to disable the pressure applied to the second cavity. Thus, the system can be configured to operate in different ways, including operating in the same way as conventional breast pumps.

[0037] These and other aspects of the invention will be apparent from and elucidated with reference to the embodiment(s) described hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] For a better understanding of the invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example only, to the accompanying drawings, in which:

Figure 1 shows a known breast pump system;
Figure 2 shows a first example of a breast shield;
Figure 3 shows a first implementation of the example of Figure 2;
Figure 4 shows a second implementation of the example of Figure 2;
Figure 5 shows a second example of a breast shield;
Figure 6 shows a third example of a breast shield;
Figure 7 shows a fourth example of a breast shield;
Figure 8 shows two designs with additional outer cavities;
Figure 9 shows a fifth example of a breast shield;
Figure 10 shows an example of an intermittent application of under-pressure; and
Figure 11 shows a design for the seal provided between the first and second cavities.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0039] The invention will be described with reference to the Figures.

[0040] It should be understood that the detailed description and specific examples, while indicating exemplary embodiments of the apparatus, systems and methods, are intended for purposes of illustration only and are not intended to limit the scope of the invention. These and other features, aspects, and advantages of the apparatus, systems and methods of the present invention will become better understood from the following description, appended claims, and accompanying drawings. It should be understood that the Figures are merely schematic and are not drawn to scale. It should also be understood that the same reference numerals are used throughout the Figures to indicate the same or similar parts.

[0041] The invention provides a breast shield for a breast pump, which comprises a first cavity for placing over the nipple and having a first pressure control port for controlling milk expression. A second cavity is radially outwardly positioned relative to first cavity (e.g. around or partially around the first cavity) and is coupled to a second pressure control port for providing a sealing or positioning function. Thus, a positioning/holding function and a milk expression function may be optimized independently.

[0042] Figure 1 shows a known breast pump system 1, comprising an expression unit 2 and a pump arrangement 3 which are connected via a tube 4. The pump arrangement includes various components in addition to the pump, so may be considered to be a general operating unit.

[0043] The expression unit 2 is formed with a main body 7, a funnel 5 for receiving a breast of a user and a receptacle 6 for collecting the expressed milk. The funnel 5 is commonly known as a breast shield. The breast shield 5 and the receptacle 6 are connected to the main body 7. The main body 7 comprises a vacuum chamber, i.e. a chamber to which any desired under-pressure may be applied. A flexible membrane or diaphragm is located in the vacuum chamber, and this membrane prevents expressed milk from flowing into the tube 4 leading to the pump arrangement unit 3.

[0044] The pump arrangement 3 may instead be directly mounted and connected to the main body 7. In this case, the membrane prevents expressed milk from flowing directly into the pump arrangement 3.

[0045] The pump arrangement 3 comprises a controller 10, a power source 12, a motor 14 and a vacuum pump 16. The controller controls 10 the operation of the power source 12, motor 14 and vacuum pump 16. The vacuum pump delivers an under-pressure at one side and an over-pressure at an opposite side (relative to a middle reference pressure, which may be the atmospheric pressure). The pump arrangement 3 further comprises a solenoid valve 18.

[0046] In use, the vacuum pump applies an under-pressure to the membrane located in the main body 7 so that it deforms. The membrane deforms to create an under-pressure in the breast shield 5 which in turns applies an under-pressure to the breast which enables milk to be expressed.

[0047] Although the breast pump system 1 is described as comprising a membrane such that the under-pressure is applied indirectly to the breast, it should be understood that in an alternative embodiment, the under-pressure is applied directly to the breast of a user. In this case, the breast pump system does not comprise a membrane and the under-pressure created by the vacuum pump is applied directly to the breast.

[0048] The under-pressure is applied to the breast at intervals. That is, a pressure differential is applied on a cyclic basis. After an under-pressure has been established, the pressure from the vacuum pump is released by the use of the solenoid valve which is temporarily opened. The solenoid valve is an electromechanically operated valve configured to open and close an air passage that connects to the vacuum side of the vacuum pump to ambient air such that when the solenoid valve is closed, the vacuum pump generates an under-pressure in the expression unit which enables milk to be expressed from the breast of a user. When the solenoid valve is opened, the under-pressure generated by the vacuum pump is released as ambient air flows towards the vacuum or negative pressure created by the vacuum pump such that the pressure exerted on the breast of a user is partially or completely reduced.

[0049] This is a basic description of the known operation of a standard breast pump system.

[0050] The invention relates in particular to the breast shield 5. The breast shield needs to be correctly aligned on the breast and it also needs to remain in place during milk expression. In conventional systems, these functions all have to be achieved by the pressure profile applied to the single area of the breast within the breast shield.

[0051] Figure 2 shows a first example of a breast shield 5 in accordance with the invention. The breast shield 5 has a first cavity 20 for placing over the nipple. This will be termed a "first portion" of the breast surface. It has a closed shape such as circle around the nipple. It will be described as an inner cavity in the following description. The inner cavity 20 is coupled to a first pressure control port 22 for applying a first pressure profile to the first cavity, in particular for controlling the milk expression. This first pressure profile is thus applied to the nipple.

[0052] A second cavity 24 extends at least partially around the outside of the inner cavity 20. It will be described as an outer cavity in the following description. The outer cavity is coupled to a second pressure control port 26 for applying a second pressure profile to the outer cavity, in particular for providing a sealing, or positioning function. The outer cavity interfaces with a second portion of the breast surface which extends at least partially around the first portion. This second portion is typically a ring of breast tissue outside the area of the areole.

[0053] The first pressure profile may be considered to implement the basic functionality of the breast pump and the second pressure profile may be considered to implement supporting functions. The two functions may be operated independently, in space and time. Inside the breast shield, the basic functionality focuses on efficient milk extraction e.g. the pumping profile and baseline under-pressure. The supporting functions are for example ensuring a good seal to provide leakage prevention, and to provide attachment of the breast shield and optionally a separate hold and assist function during initial placement of the breast shield.

[0054] In one example, the inner cavity has an inner diameter d1 such as to fit an average range of nipple/teat sizes while the outer diameter d2 is similar to the existing diameters of the breast shield.

[0055] The inner diameter d1 for example may range from 20mm to 35mm and the outer diameter 2d may range from 10cm to 15cm.

[0056] The surface area between d1 and d2 is proportional to the force exerted by the cup due to the applied under-pressure.

[0057] Alternatively, the inner diameter may be the same as the existing diameter of a breast shield, and the second cavity results in an increased size.

[0058] The diameter ratio and pressure ratio between the cavities can differ in relation to the amount of desired under-pressure.

[0059] While the physical separation into two compartments mainly concerns the basic and support functions for the under-pressure, atmospheric pressure and over pressure, a separation in time enables additional user interface and user experience (UI/UX) functionality.

[0060] For example, the independent control of the two pressure profiles enables personalization and adjustability based on user preferences but also allows adjusting the pressure profiles independently of each other. For example, there may be the option to have direct attachment using the second cavity without applying a baseline vacuum to the nipple and areola. Alternatively, the holding function may, as in conventional breast pump, be implemented by the inner cavity.

[0061] The attachment force for holding the breast shield on the breast is achieved using a minimum baseline under-pressure in the second cavity, intended to mimic the baseline vacuum naturally created by the baby's mouth between the tongue and palate for attachment.

[0062] The contact area and level of negative pressure determine the force required to balance the weight of the breast shield and any connected components, and hold it in place. Ideally, the second cavity is able to support the full weight of the device alone and/or in combination with the first, internal cavity. This may be achieved with different vacuum levels in the two compartments.

[0063] As mentioned above, the user may choose not to use the option of direct attachment using the second cavity.

[0064] Figure 3 shows a first implementation of the example of Figure 2 in which the outer cavity 24 comprises a closed shape around the inner cavity.

[0065] Figure 4 shows a second implementation of the

example of Figure 2 in which the outer cavity 24 comprises a shape only partially around the inner cavity.

[0066] The second cavity is thus open, having a C-shape. This enables connections to the first cavity bypassing the direct attachment of the outer compartment. For example, a milk transport passage may extend from the first cavity towards the bottle through the interruption 30. The inner cavity 22 then has a milk output channel 32 and the outer cavity has an interruption 30 located at the milk output channel.

[0067] The outer cavity may be smaller and hence located at one location around the outer periphery of the inner cavity, e.g. at the top

[0068] Figure 5 shows an example in which the outer cavity has a covering membrane 40.

[0069] The example of Figures 2 to 4 are open systems, meaning the under-pressure or other pressure is in direct contact with the skin. This might be undesirable when there is a rapid application of under-pressure or if there is a risk of milk being sucked into the vacuum system. The membrane 40 functions as an active suction cup to create an attachment on the breast.

[0070] Figure 6 shows an example in which the outer cavity is separated into segments 50, wherein each segment has its own pressure control port (not shown). The segments may be controlled individually or in groups. Thus, each segment has a pressure control port so that a pressure may be applied to the chamber formed by the segment.

[0071] A single covering membrane as shown in Figure 5 may cover the set of separated segments of the design of Figure 6.

[0072] Having multiple segments for example enables the use of over pressure in one or more segments while the other segments secure the breast shield by an applied under-pressure. By having a balance between the under-pressure of some segments and the over pressure of other segments, a number of over pressure profiles can provide massaging, by circular motion or within a specific target area, to improve the milk extraction while the remaining segments still hold the breast shield secure to the breast.

[0073] A massage function for example requires a difference in pressure between different points, which varies over time. The massage function may use an over-pressure or an under-pressure or a combination.

[0074] By changing the actuation of the segments, the over pressure and massage function can move around the outer diameter of the breast. There may again be a membrane between the applied pressure and the skin.

[0075] The examples above all form the two cavities using a single integrated molded component so that the outer cavity is rigidly mounted to the inner cavity.

[0076] Figure 7 shows an example in which the outer cavity 24 is elastically non-rigidly mounted to the inner cavity 22 by means of an elastic ring 60. This elastic ring may form part of the tubing of the breast shield. This reduces the attachment to the remainder of the breast shield and provides a suspension. This makes the outer cavity at least partially mechanically independent from the central body of the breast shield, so that movement can be supported between the two cavities to allow a best fit to the breast.

[0077] The examples above have a single inner cavity and a single outer cavity. There may instead be multiple outer cavities.

[0078] Figure 8 shows in the top image two concentric outer cavities 24a, 24b around the inner cavity. Figure 8 shows in the bottom image three concentric outer cavities 24a, 24b, 24c around the inner cavity.

[0079] By switching the application of under-pressure between the multiple outer cavities, it can be ensured that there is a constantly present under-pressure to hold the breast pump while there is no constant under-pressure all of the tissue. This avoid bruises that can occur when an under-pressure is constantly applied to one location of the skin. The pressures could for example follow a sinusoidal pattern, with opposite phase between the two outer cavities 24a,24b, or a three phase approach for three outer cavities.

[0080] The positioning of the breast shield needs to overcome the force of gravity.

[0081] Figure 9 shows an example in which at least the outer cavity is non-circular with a greater height than width. This means that the force component exerted by the second cavity in the vertical direction (parallel to gravity) is stronger than the horizontal component. An oval or rectangular shape may be used. This gives the advantage that in the vertical direction more force is available, avoiding unintended movement, while horizontal movements, which are less influenced by gravity, are facilitated for improved comfort and fit.

[0082] The sum of the forces resulting from the under-pressure levels applied to the first and second cavities preferably remains at least at a level sufficient to hold the expression kit to the breast, thereby counteracting gravity.

[0083] The oval design may be combined with any of the previous examples. When the inner and outer cavities are concentric, they will both have the same non-circular shape.

[0084] In order to provide different under-pressure levels and/or profiles to the two cavities (or indeed the multiple segments for a segmented second cavity), a single vacuum pump may be used but with a regulator system which controls the pressure applied to first cavity and the second cavity. A buffer and valve system may be used to regulate the pressures in the cavities from a share vacuum pump. For example, EP 2 598 183 discloses a vacuum pump and a variable volume buffer volume, in which the buffer volume may be used to control a negative pressure generated. This type of system may be used for each of the cavities.

[0085] Alternatively, there may be a first vacuum pump for the first cavity and a second vacuum pump for second cavity.

[0086] As explained above, the second cavity may have the function of providing a holding force. A holding vacuum may be applied to the outer cavity which adapts over time from an intermittent application of under-pressure to a constant application of under-pressure when the breast shield is first positioned.

[0087] Placing a breast shield with a fixed pre-established constant vacuum results in a quick positioning of the device on the breast. However, a constant baseline vacuum is not optimal for repositioning, as the user needs to break the vacuum seal before repositioning into the desired position. The use of an intermittent short holding (vacuum) and a release pressure (a lower vacuum, or atmospheric pressure or even an over pressure) means the user can reposition gradually until she feels that the positon is optimal. The rhythm or pace of the intermitting pressure and release changes to a full vacuum suitable for holding and operating the device hands-free.

[0088] Figure 10 shows the intermittent application of under-pressure as pressure (relative to atmospheric pressure) versus time. The intermittent pressure enables repositioning by the user until the correct alignment is found.

[0089] The switch to a constant vacuum may be after a fixed time, or user specified time, or when an input command is received from the user, the pressure can convert to a fixed baseline pressure.

[0090] The controller may also apply a massage pressure profile to the outer cavity during milk expression using the first cavity.

[0091] A user interface may allow a user to select pressure characteristics for the first and second cavities as mentioned above. This provides personalization and adjustment to user preferences. Direct attachment using the second cavity means that the pumping vacuum profile does not need the conventional baseline vacuum on the nipple and areola.

[0092] In the examples above, there is an annular ridge between the cavities, and this ridge is held against the skin by the under-pressure in one or both of the cavities on each side. This ridge may be adapted to ensure the best possible comfort for the wearer. For example, instead of a flat surface with a sharp edges leading into the cavities on each side, a curved shape may be formed, with a soft low friction surface where there will be contact with the skin. By providing a curved shape for the wall between the cavities, sharp edges can be avoided.

[0093] Figure 11 shows an example of a design of the interface between the inner and outer cavities. The ridge 70 has a smooth curved surface. In addition, it can deflect as represented by the arrow so that it can move in response to movement of the skin surface 72 for example induced by the different pressures applied to the cavities. In this way, the ridge can remain in contact with the same area of skin and does not need to slide relative to the skin surface when there are small movements in the skin surface. The ridge can move with the skin.

[0094] A curved shape may be formed by an integrated molded shape feature, but it may instead be an externally applied pad which is mounted over the front face of the breast shield.

[0095] The curved shape between the cavities may be formed by a flexible wall portion which defines the transition between adjacent cavities. It may then define a soft sealing ring which separates a first cavity from a second cavity.

[0096] The invention has been described above with reference to a conventional vacuum pump (motor and impeller) and solenoid. However, there are other options for creating the desired under-pressure, such as hydraulic-driven systems, ultrasonic motors, and peristaltic pumps. Any of these different ways of producing an under-pressure may be used for the inner and/or outer cavities.

[0097] 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.

[0098] 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.

[0099] If the term "adapted to" is used in the claims or description, it is noted the term "adapted to" is intended to be equivalent to the term "configured to".

[0100] Any reference signs in the claims should not be construed as limiting the scope.

Claims

1. A breast shield (5) for a breast pump, comprising:

   a first cavity (20) for placing over a first portion of the breast surface including the nipple of a breast, the first cavity coupled to a first pressure control port (20) for controlling milk expression; and

   a second cavity (24) positioned radially outwardly from the first cavity, the second cavity coupled to a second pressure control port (26) for providing a sealing, or positioning function, wherein the second cavity is for applying a pressure to a second portion of the breast surface radially outward from the first portion.

2. The breast shield of claim 1, wherein the second cavity extends at least partially around the outside of the first cavity.

3. The breast shield of claim 1, wherein the second cavity (24) comprises:

a closed shape around the first cavity; or
an open shape extending partially around the first cavity.

4. The breast shield of claim 3, wherein the first cavity (20) has a milk output channel (32) and the ring has an interruption (30) located at the milk output channel.

5. The breast shield of any one of claims 1 to 4, wherein the second cavity (24) has a covering membrane (40).

6. The breast shield of any one of claims 1 to 5, wherein the second cavity (24) is separated into segments, wherein each segment has its own pressure control port.

7. The breast shield of any one of claims 1 to 6, wherein:

the second cavity (24) is rigidly mounted to the first cavity (20); or
the second cavity (24) is elastically non-rigidly mounted to the first cavity (20).

8. The breast shield of any one of claims 1 to 7, further comprising at least one further cavity (24a, 24b) positioned radially outwardly of the second cavity (24c).

9. The breast shield of any one of claims 1 to 8, wherein the second cavity (24) is non-circular with a greater height than width.

10. A breast pump comprising.

a vacuum pump system (14,16);
an expression kit (2) which comprises the breast shield of any one of claims 1 to 9 coupled to the vacuum pump system (14,16); and
a controller (10) for controlling the vacuum pump system.

11. The breast pump system of claim 10, wherein the vacuum pump system comprises a vacuum pump (16), and a regulator system for controlling the pressure applied from the vacuum pump to the first and second cavities.

12. The breast pump system of claim 10, wherein the vacuum pump system comprises a first vacuum pump for the first cavity and a second vacuum pump for the second cavity.

13. The breast pump system of any one of claims 10 to 12, wherein the controller (10) is adapted to apply a holding under-pressure to the second cavity which adapts over time from an intermittent application of a particular under-pressure level to a constant application of under-pressure when the breast shield is first positioned.

14. The breast pump system of any one of claims 10 to 13, wherein the controller (10) is adapted to apply a massage pressure profile to the second cavity during milk expression using the first cavity.

15. The breast pump system of any one of claims 10 to 14, comprising a user interface to allow a user to select pressure characteristics for the first and second cavities.

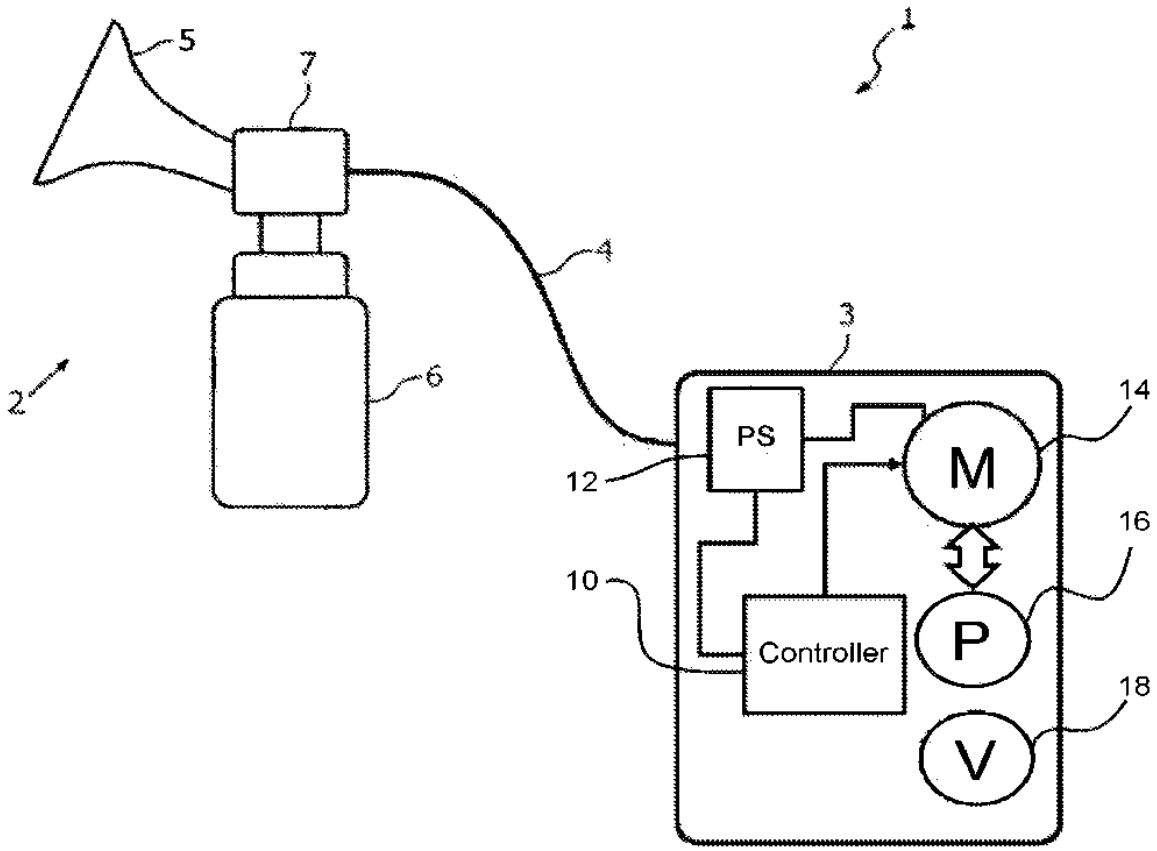


FIG. 1

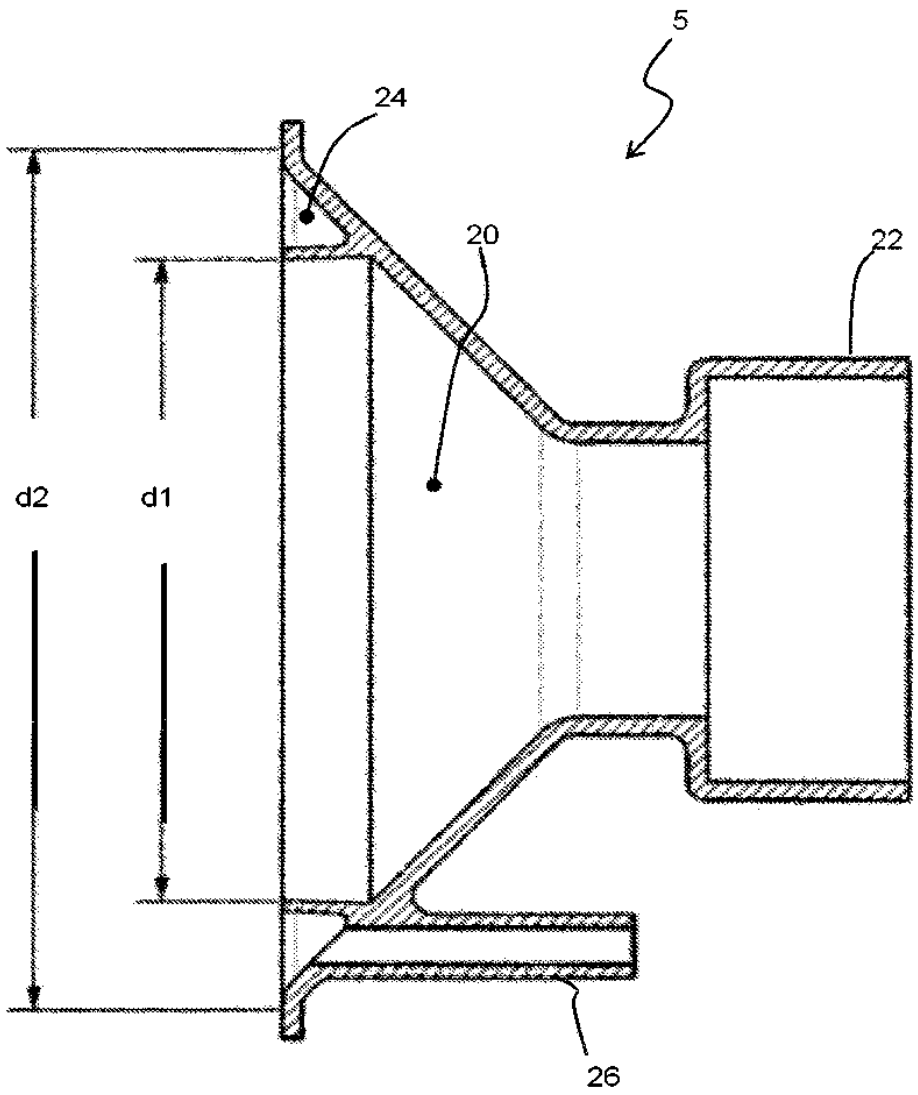


FIG. 2

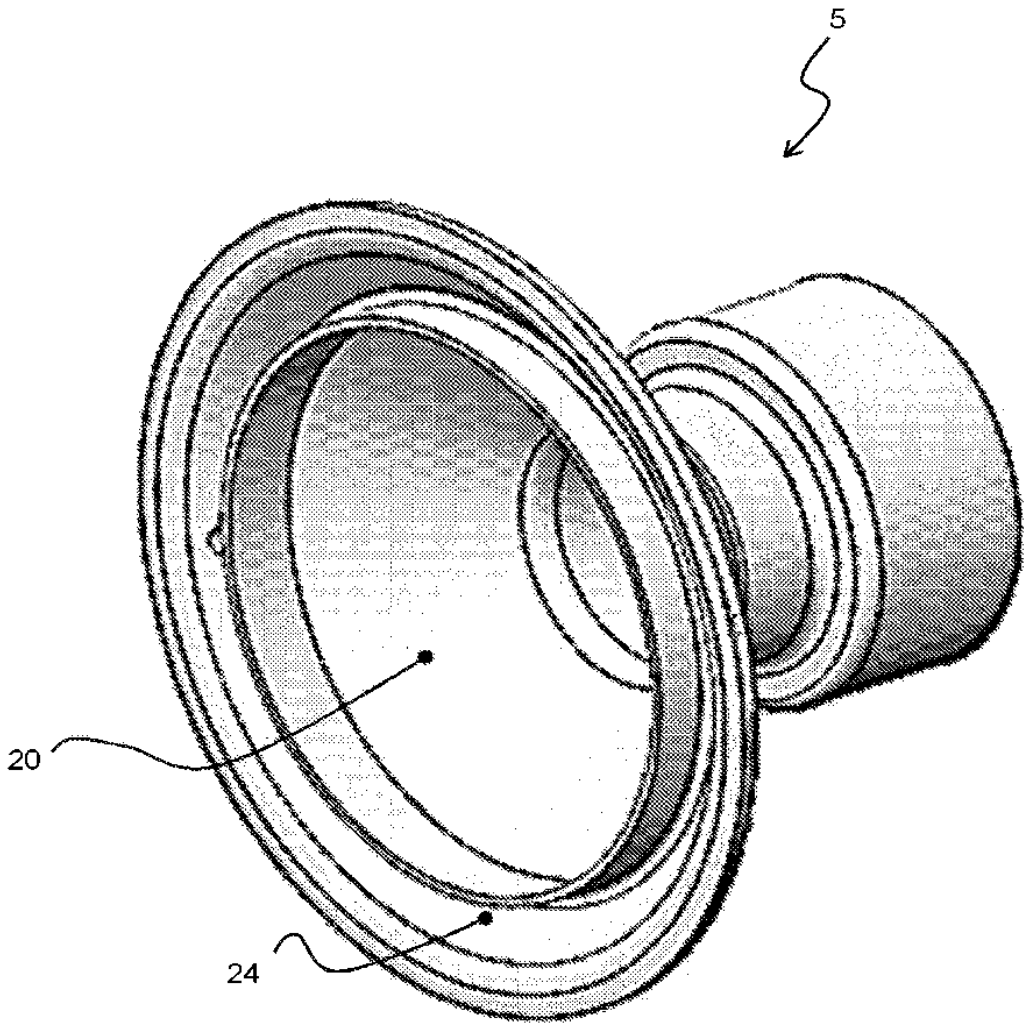


FIG. 3

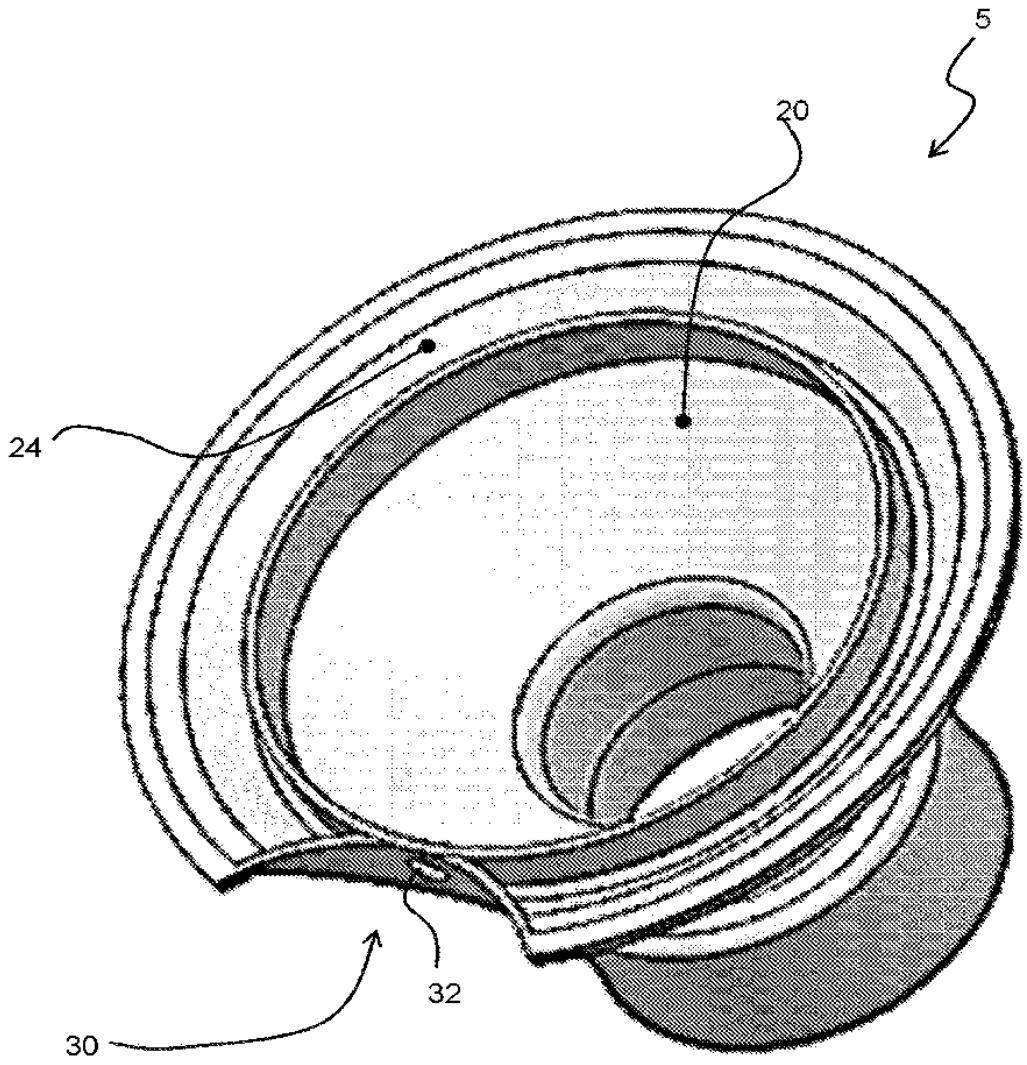


FIG. 4

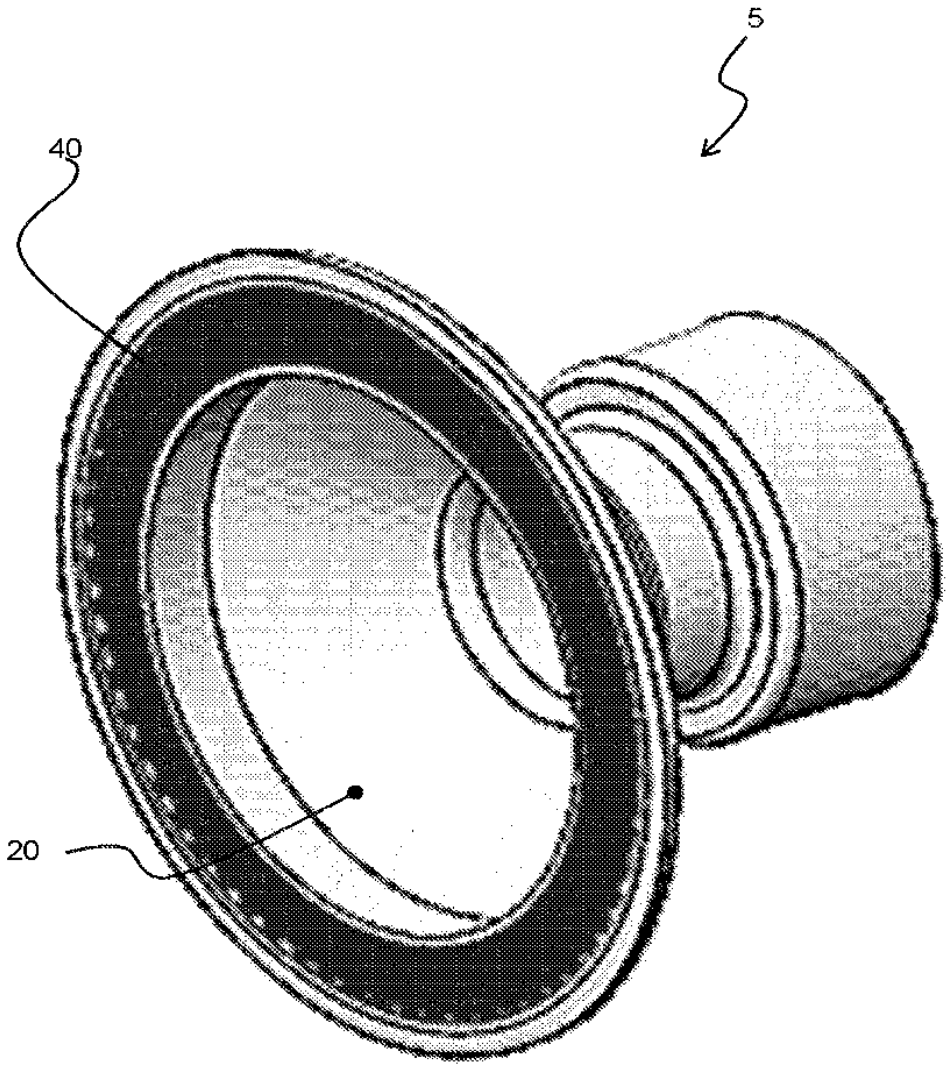


FIG. 5

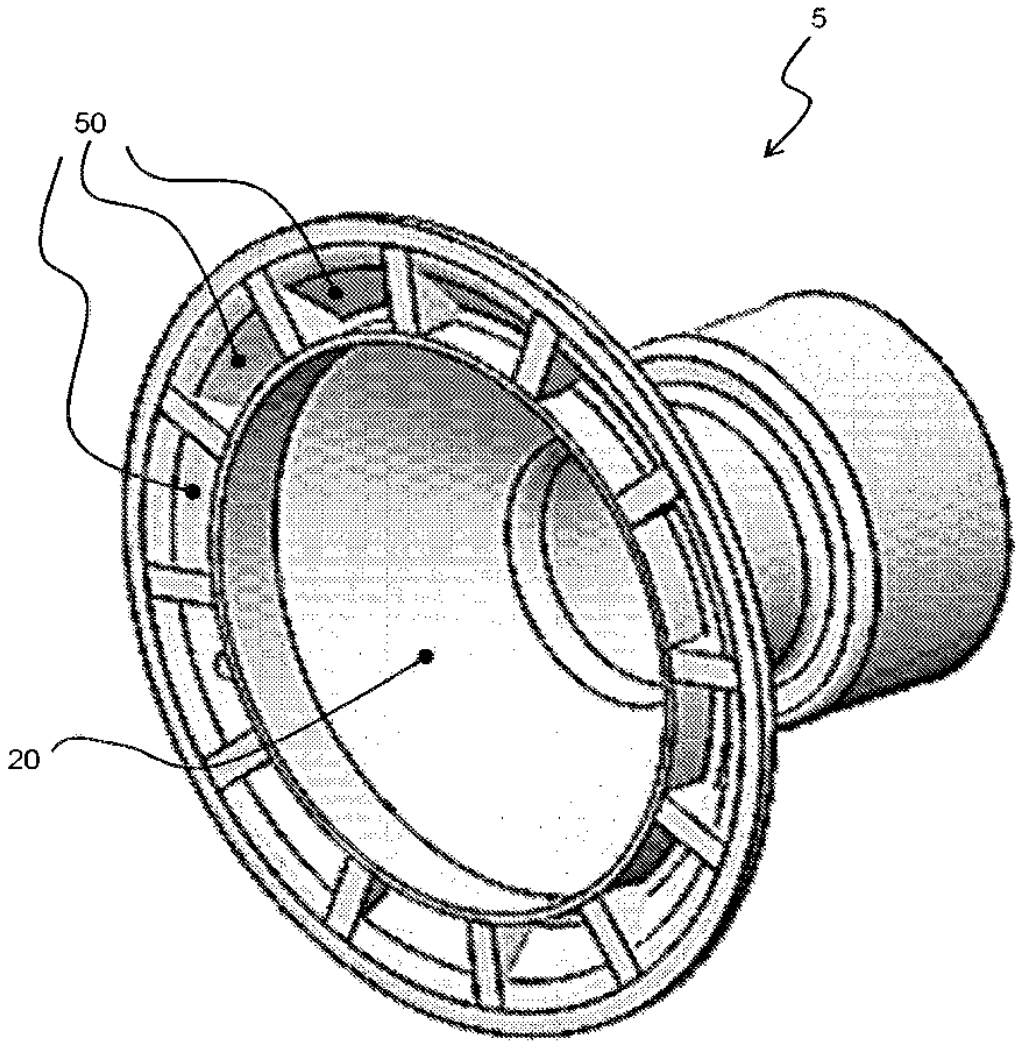


FIG. 6

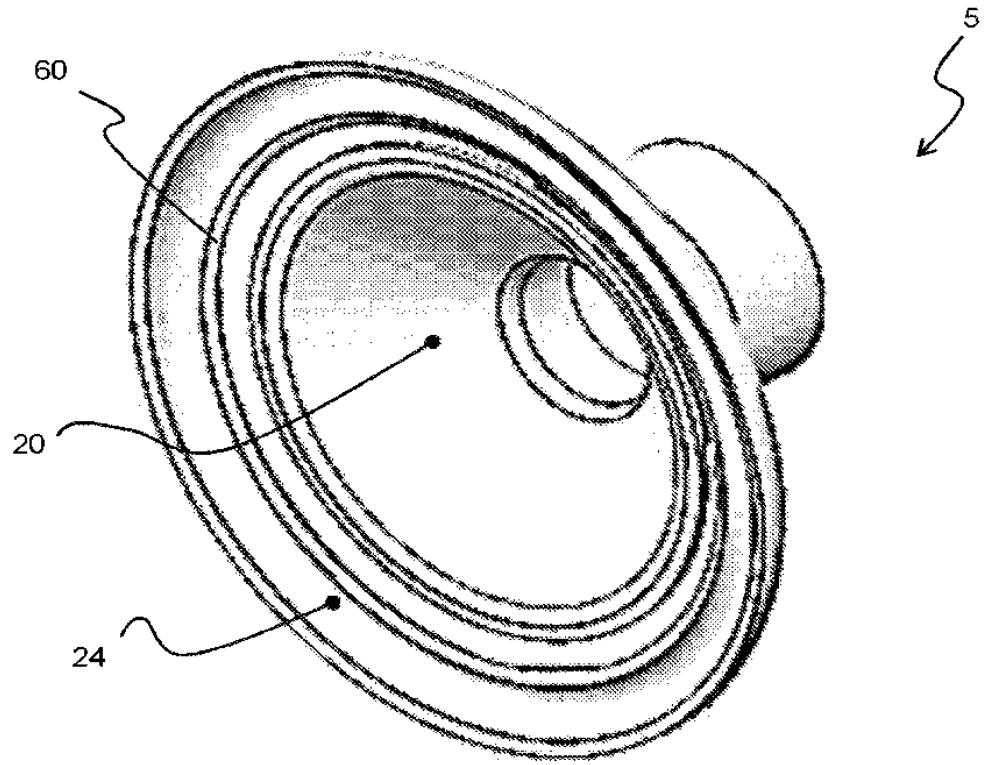


FIG. 7

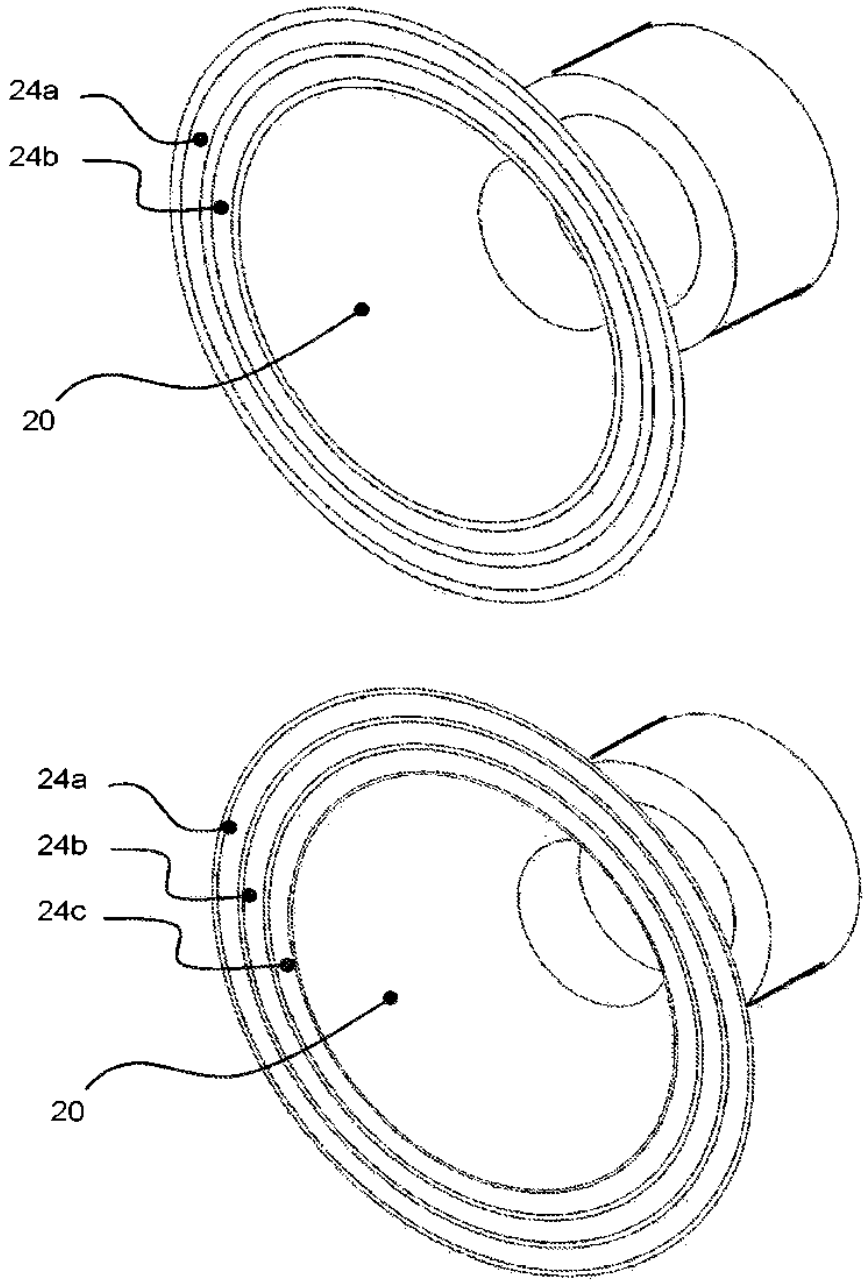


FIG. 8

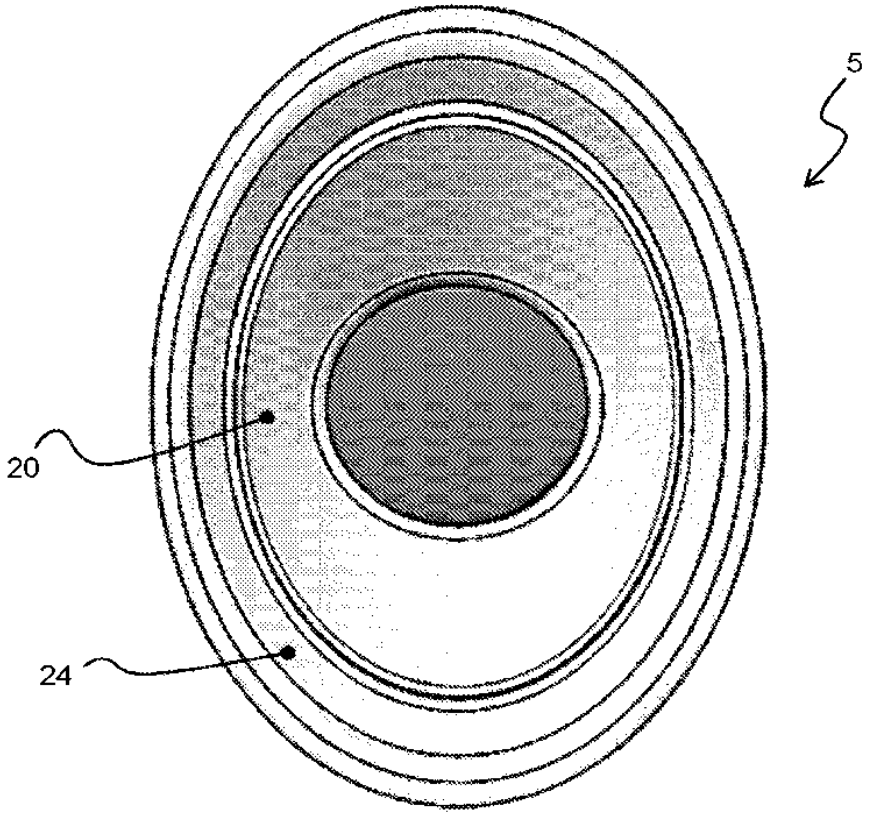


FIG. 9

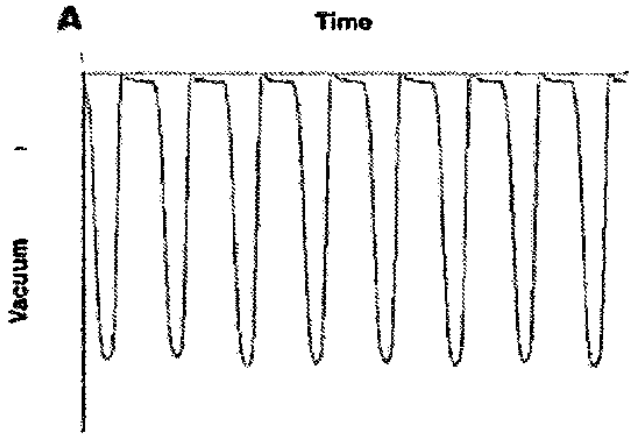


FIG. 10

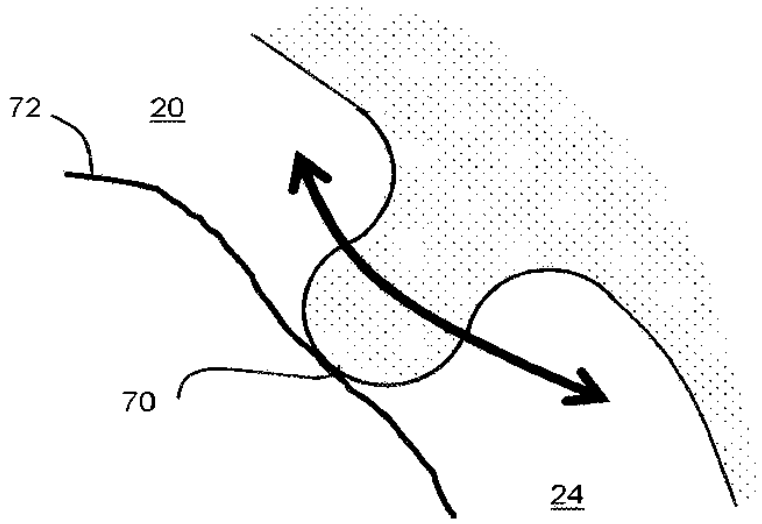


FIG. 11

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EUROPEAN SEARCH REPORT

Application Number
EP 20 20 8087

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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TECHNICAL FIELDS SEARCHED (IPC)
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	30 April 2021	Chevtchik, Natalia

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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L : document cited for other reasons

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 20 20 8087

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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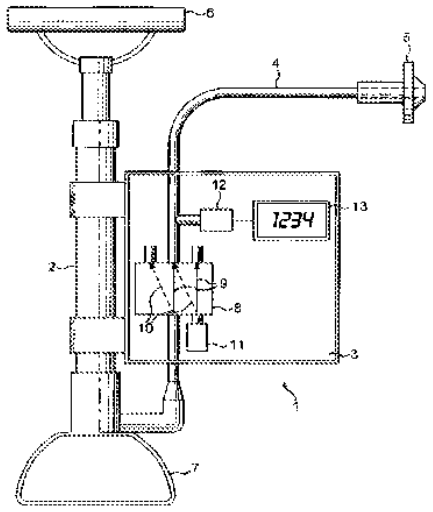
(74) Agent: **HINDLE, Alistair, Andrew**; Hindle Lowther, 28 Rutland Square, Edinburgh EH1 2BW (GB).

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[Continued on next page]

(54) Title: VOLUME METER



(57) Abstract: There is provided a device and methods for determining the volume of air space within a container, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means. A particular application is determining a change in the amount of fuel in a fuel tank between the beginning and end of a vehicle rental.

WO 2005/114113 A2

FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

VOLUME METER

The present invention relates to a device to determine a volume of fluid present in a tank or other container. More particularly, but not exclusively, it relates to a device to determine a volume of fuel present in a vehicle fuel tank, for example so as to compare volumes present before and after use, and to a method of use of such a device.

When a car, van or other vehicle is hired out, it is common for a hire agreement to specify that the vehicle should be returned with the same volume of fuel in its fuel tank as was present when it was driven away. Should there be a deficit, the hirer is liable to pay for the vehicle to be refuelled to the initial level.

However, in practice, it is difficult to assess exactly how much fuel is present in a vehicle fuel tank, using only the vehicle's dashboard fuel gauge, which is usually connected to a float sensor within the tank. The gauge can normally be read to no better than the nearest eighth of a tank-full, which will typically represent five to ten litres of fuel. It is thus possible to return a vehicle with significantly less fuel in its tank, without this being clearly indicated by its fuel gauge. Furthermore, in borderline situations, considerations such as good customer relations will often militate against arguing with a customer over whether a fuel gauge needle is nearer to three-eighths of a tank or a quarter of a tank, for example.

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It is estimated that such shortfall causes loss to vehicle hirers of around £250,000 per year in the United Kingdom alone. This could be extrapolated to an annual loss for the entire vehicle hire market of approximately £80 million. There is hence a need for a precise and unequivocal means of measuring how much fuel is present in a vehicle's tank, before and after use.

Such means should, however, preferably not involve modification to the vehicles themselves, on grounds of cost and inconvenience. It should be quick and easy to use, and must be safe for use in the presence of highly inflammable fuel vapours.

Conventional liquid level sensors would not be appropriate, since they would be significantly affected by the exact attitude of the vehicle to the horizontal when the measurements are taken. In any case, it is difficult to access the fuel itself from outside the tank. However, an approach that appears to have received little attention is to measure the volume of the air above the fuel in the tank. In practice, the volume of air above the fuel will include the volume of a filler pipe leading from a filler cap or the like to the fuel tank, so the term "tank" hereinafter should be understood also to comprise such piping. Within this application, the term "air space" is used to refer to the volume within a container (which may include liquid) which is not occupied by the liquid, and is not intended to be limited to a volume occupied by atmospheric air.

Vehicle fuel tanks will be produced to a standard size for any given model. Thus, the volume of fuel in the tank plus the volume of air above it will be constant (strictly speaking, only true at a constant temperature, but such considerations can be allowed for mathematically, or by calibrating at a range of temperatures). In principle, a change of air volume in the tank will indicate a change in fuel volume, and measuring air volume has the advantage that a direct connection with this volume can be established through an existing, unmodified filler cap.

While a particular problem to be addressed is the measurement of fuel volumes within vehicle fuel tanks, as discussed above, there will be many other applications in which quick and accurate measurements of liquid volumes within substantially rigid containers will be required. A device suitable for measuring fuel volumes may well also be applicable to other such measurement needs. For example, such a device would be useful in the brewing industry for determining the amount of liquid in a tank or still.

It is hence an object of some embodiments of the present invention to produce a device to determine the volume of liquid present in a container by measuring the volume of gas in the container, and to provide a method for determining such volumes and changes in such volumes, using said apparatus.

However, some embodiments of the present invention are relevant to applications where it is not necessary to determine the absolute volume of the liquid present in the container. For example, for the purposes of determining whether a customer has brought a rental car back with same amount of fuel as when they rented the vehicle, it will be sufficient only to determine whether there has been a change in the volume of the liquid. By determining the amount of the change in the volume of air space, it is possible to determine the amount by which the volume of fuel has changed and issue a bill accordingly. As changes in the volume of liquid within a container of substantially fixed volume will result in corresponding and opposite changes in the volume of the air space within the container, measuring the change in the air space within the container is sufficient to determine whether the volume of liquid within the container has changed and/or the amount of the change, if appropriate.

According to a first aspect of the present invention, there is provided a device for determining the volume of air space within a container, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means,

valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

The volume of air space within the container can be calculated from the determined rate of pressure change. Where the volume of the container is known, it is possible to determine the volume of liquid within a container by subtracting the air space from the volume of the container. Preferably, the device includes computing means (such as a computer) to calculate the volume of liquid in a container by subtracting the air space from the volume of the container.

There is also provided a device for determining whether the volume of air space within a container has changed between two readings, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

The device is also suitable for determining whether the volume of liquid within a container has changed between two readings as, provided that the container is of substantially fixed volume, if the volume of air space has not changed between two readings, then the volume of liquid should not have changed. Again, the volume of air space within the container can be calculated from the determined rate of pressure change.

There is also provided a device for determining the change in volume of air space within a container between two readings, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to

measure pressure within the container, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

The device is also suitable for determining the change in volume of liquid within a container as this will be the opposite of the change in the volume of air space between two readings provided that the volume of the container is substantially fixed. Again, the volume of air space within the container can be calculated from the determined rate of pressure change.

The means to determine the rate of pressure change within the container while the container is connected to the restrictor means preferably includes means to measure pressure within the container (such as a pressure transducer) although it would be possible in principle to use a device which measures the rate of change of pressure, or the flow rate (such as the molecular or volumetric flow rate) of gas through the restrictor means. In these cases it would remain preferable for the device to comprise a means to measure the pressure within the container as the rate of pressure change will in general depend on the pressure within the container.

The means to measure pressure may measure absolute pressure, but preferably measures the pressure difference across the restrictor means. If the restrictor means opens out into ambient air, the pressure difference across the restrictor means will be the pressure difference between the inside of the container and ambient air. It is preferable to measure the pressure difference across the restrictor means because the pressure difference is the predominant factor determining the rate at which gas flows through the restrictor means and so the rate at which pressure tends to ambient pressure within the container. Preferably, therefore, the means to measure pressure within the container comprises a pressure transducer which measures the pressure difference across the restrictor means. The pressure difference across the restrictor means is generally the pressure difference between the interior of the container and ambient air.

Preferably, absolute pressure is taken into account when calculating the volume of the air space (and thus the volume of the liquid, or change in volume of the liquid). This can improve the accuracy of the resulting measurements because the rate of pressure change depends in practice not just on the pressure difference across the restrictor means, but also the absolute pressure difference. Gases of different pressures, and thus different densities, can be expected to flow differently through the restrictor means. One skilled in the art will recognise that the absolute pressure which is taken into account could be the pressure within the container or the ambient pressure.

Thus, in a preferred embodiment, the device further includes means to measure absolute pressure, such as a pressure transducer. This pressure transducer may be a different pressure transducer to that used to measure the pressure within the container, or it might be the same pressure transducer. If it is the same pressure transducer, a valve may be engageable to connect the pressure transducer to the atmosphere. This valve may also constitute or be part of the valve means to connect the container either to the pressure altering means or to the restrictor means. For example, the valve may have three positions, one which connects the pressure transducer to the container, another which connects the pressure transducer to the gas flow restrictor means, and a third which connects the pressure transducer to the atmosphere.

The temperature of the gas within the container or ambient temperature (measured by a temperature transducer such as a thermometer or other temperature gauge) may also be taken into account when calculating the volume of the air space in the container from the rate of change of pressure within the container. However, the effect of temperature is less important than the effect of absolute pressure.

The device (or a separate computing device, if appropriate) may comprise means to determine the effect of absolute pressure (and optionally absolute temperature) on the rate of pressure change while the container is connected to the restrictor means. For example, the device may

comprise calibration data (such as a calibration table) or an implementation of a computing algorithm which enables the data measured while the container is connected to the restrictor means (such as the rate of pressure change within the container, or the period taken for the pressure within the container to change from a first value to a second value, or the change in pressure within the container during a period of time) to be analysed taking into account the atmospheric pressure (and optionally the ambient temperature).

In a preferred embodiment, there is provided a memory storing a calibration table for the restrictor means which allow an estimate of instantaneous molecular flow rate to be computed from the pressure difference across the restrictor means, the ambient pressure (and optionally the ambient temperature).

The means to determine the rate of pressure change within the container may time a period taken for the pressure within the container to change from a first value to a second value while the container is connected to the restrictor means. The first and second values could be predetermined. However, the first and second values could be calculated by calculating means (such as a computer); for example, the first and second values could be calculated by analysing the change in pressure with time while the means to alter the gas pressure within the container alters the gas pressure within the container.

Alternatively, the means to determine the rate of pressure change within the container may determine the change in the pressure within the container during a period of time. The time period may start when the pressure within the container reaches a predetermined value. Again, the pressure may be absolute pressure but is preferably pressure relative to ambient pressure. The period of time may be calculated by analysing the change in pressure with time while the means to alter the gas pressure within the container alters the gas pressure within the container.

The means to determine the rate of pressure change within the container may measure pressure within the container at a plurality of times and analyse the successive pressure values, preferably using calculating means, such as a computer.

The volume of air space within the container can be calculated from the rate of pressure change, the time period or pressure change, as appropriate. If the volume of the container is known, then the volume of liquid within the container can be calculated by subtracting the volume of the air space from the volume of the container. If two successive reading are taken, the change in volume of air space can be determined by storing data from the first reading and comparing it with data from the second reading.

One skilled in the art will recognise that it is not necessary for the device to actually calculate the volume of air space within the container. It is sufficient to determine a parameter which can be related to the volume of air space within the container: for example, the rate of pressure change, the period taken for the pressure within the container to change from the first value to the second value, and/or the pressure difference during a period of time. Such parameters can be related to the volume of air space within the container as and when required. It is possible to determine whether the amount of liquid within the container has changed, or the amount by which it has changed, between two readings without having to actually calculate the respective volumes of air space.

The device preferably comprises one or more of a display to display the determined volume or change in volume or parameter, a memory to store the determined volume, change in volume or parameter, or an interface to transmit the volume, change in volume or parameter to an external computer or storage device. Preferably, the device includes a computer to carry out any necessary calculations. The invention also extends to a system comprising one or more computers and a plurality of devices according to the present invention. Such a system would enable readings carried out at one location (such as a car rental depot from which a car

is rented) to be compared with readings carried out at another location (such as a car rental deport to which a car is returned).

Further preferred features and options correspond to those described below.

According to a second aspect of the present invention, there is provided a method of measuring the volume of a liquid in a container of known volume comprising the steps of altering the pressure of gas within the interior of a container and allowing the pressure within the container to start equilibrating with air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of pressure within the container, thereby calculating the volume of the container which is not occupied by the liquid and thereby calculating the volume of the liquid.

There is also provided a method of determining whether the volume of a liquid in a container of substantially fixed volume has changed between first and second readings, comprising the steps of, for each reading, altering the pressure of gas within the interior of the container and allowing the pressure within the container to start equilibrating with air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of pressure within the container, thereby calculating the volume of the air space within the container, and then comparing the calculated air space volumes. (Air space refers to the volume of the container not occupied by liquid).

There is also provided a method of determining a change in the volume of a liquid in a container of substantially fixed volume between first and second readings, comprising the steps of, for each reading, altering the pressure gas within the interior of the container and allowing the pressure within the container to start equilibrating air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of

pressure within the container, thereby calculating the air space volume, and then calculating the difference in the air space volumes between readings.

Air of another pressure is preferably ambient air.

The provided methods preferably include the step of measuring either or both of absolute pressure (typically absolute ambient pressure) and ambient temperature and taking these measurements into account when calculating one or more of the volume of the air space, whether there has been a change in the volume of the air space, the amount of change in the volume of the air space, the volume of liquid in the container, whether there has been a change in the volume of liquid in the container or whether there has been a change in the volume of liquid in the container.

Values of air space volume or a parameter related thereto (e.g. the rate of pressure change, the period taken for the pressure to change from one value to another, or the pressure change in a particular period) may be stored between the first and second readings.

The step of measuring the rate of change of pressure within the container may comprise measuring the period taken for the pressure within the container to change from a first value to a second value while the container is connected to the restrictor means. The first and second values could be predetermined. However, the first and second values could be calculated; for example, the first and second values could be calculated by analysing the change in pressure with time while the means to alter the gas pressure within the container alters the gas pressure within the container.

Alternatively, the step of measuring the rate of change of pressure within the container may comprise determining the change in the pressure within the container during a period of time. The time period may start when the pressure within the container reaches a predetermined

value. Again, the pressure may be absolute pressure but is preferably pressure relative to ambient pressure. The period of time may be calculated by analysing the change in pressure with time while the means to alter the gas pressure within the container alters the gas pressure within the container.

The step of measuring the rate of change of pressure within the container may comprise measuring the pressure within the container at a plurality of times and analysing the successive pressure values.

Analysis is preferably carried out using calculating means, such as a computer.

According to a third aspect of the present invention, there is provided a method of calculating a charge to be issued in relation to the rental of a vehicle having a fuel tank for containing fuel, the method comprising the steps of, on at least two occasions, determining the volume of air space in the fuel tank, or a parameter related thereto, thereby calculating the change in the amount of fuel between the occasions, and issuing a bill dependant on the calculated change in the amount of fuel.

The volume of air space, or a parameter related thereto, may be calculated using a device according to the first aspect or the fourth aspect. A different device may be used on each occasion.

The volume of air space, or a parameter related thereto, may be calculated according to a method of the second aspect or the fifth aspect.

According to a fourth aspect of the present invention, there is provided a device to measure a volume of liquid held within a container of known volume, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow

restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to time a period taken for the pressure within the container to change from a first predetermined value to a second predetermined value while the container is connected to the restrictor means.

There is further provided means to measure the absolute value of pressure (either or both of ambient pressure or pressure within the container) and the device takes this measured value into account when determining the measured volume of liquid.

Preferably, the device is provided with display means to indicate said period.

Alternatively or additionally, the device may be provided with memory means adapted to record said period for future reference, or for subsequent transmission to a separate computing device.

Advantageously, said display means may comprise numeric or alphanumeric display means.

Optionally, said display means comprises a liquid crystal display.

Preferably, the device is provided with electronic control means.

Advantageously, said electronic control means is adapted to operate the valve means.

The electronic control means may be adapted to operate the valve means so as to connect the container to the restrictor means when the pressure in the container has been altered to a third preselected value, further than said first and second values from ambient pressure.

The gas flow restrictor means preferably comprises calibrated orifice means through which gas may flow at a substantially constant rate.

The device may be provided with means to convert said period to a liquid volume within a particular container.

Said conversion means may comprise a set of graphs or tables of said periods against gas volume and/or liquid volume for particular preselected containers.

Alternatively or additionally, the device may be provided with memory means containing data to enable conversion of said periods to gas volumes and/or liquid volumes for particular preselected containers, and the electronic control means is adapted to perform said conversion.

The device may then be provided with display means adapted to indicate a calculated volume.

The pressure-altering means preferably comprises pump means.

Advantageously, the pump means is manually- or pedally-operable.

The pump means may be adapted to raise the pressure within the container above ambient pressure.

Alternatively, the pump means may be adapted to reduce the pressure within the container below ambient pressure.

The pressure-altering means may alternatively comprise a source of gas under pressure, such as a compressed-air line or reservoir vessel containing gas under pressure.

The device may be provided with pressure release means adapted to operate at a pressure differential within the container below that which might damage the container.

The connecting means may be adapted to form a gas-tight connection with a range of different container apertures, for example fuel tank filler pipe openings of different models of vehicle.

Further features or alternative features may correspond to those discussed in relation to the first and second aspects above.

According to a fifth aspect of the present invention, there is provided a method for measuring a volume of liquid held within a container of fixed volume, comprising the steps of providing a device as described in the fourth aspect above, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, timing the period taken for the pressure within the container to fall from said first predetermined value to a second predetermined value, and calculating from said period a gas volume and hence a liquid volume within the container.

Preferably, the method further comprises the steps of subsequently measuring an altered liquid volume within the container as described above and calculating a change in liquid volume between said measurements.

Further or alternative steps may correspond to those discussed in relation to the second aspect above.

According to a sixth aspect of the present invention there is provided a device to measure a volume of liquid held within a container of known volume, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and measure the change in pressure within the container to change during a period while the container is connected to the restrictor means.

Further preferred features correspond to those discussed in relation to the fourth aspect above.

According to a seventh aspect of the present invention, there is provided a method for measuring a volume of liquid held within a container of fixed volume, comprising the steps of providing a device as described in the sixth aspect above, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, determining the pressure change within the container during a period and calculating from said pressure change a gas volume and hence a liquid volume within the container.

Further preferred features correspond to those discussed in relation to the fifth aspect above.

An embodiment of the present invention will now be more particularly described by way of example and with reference to the accompanying drawing, in which:

Figure 1 is a frontal elevation of a fuel volume meter embodying the present invention;

Figure 2 is a frontal elevation of a fuel volume meter according to a second embodiment of the present invention; and

Figure 3 is a frontal elevation of a fuel volume meter according to a third embodiment of the present invention.

Referring now to Figure 1, a fuel volume meter 1 comprises a pressuring pump 2 connected to a measurement unit 3, which is in turn linked by means of a flexible pressure hose 4 to a tank connector fitting 5. The tank connector fitting 5 is shaped to form a gas-tight seal with an external opening of a fuel filler pipe leading to a fuel tank of a vehicle. (Where a wide range of different sizes of and/or shapes of openings may be encountered, it may be necessary to provide alternative, exchangeable fittings 5).

The pressuring pump 2 is here a manually-operable stirrup pump, with a reciprocally vertically-moveable pump handle 6 and a stirrup base 7 into which a user may insert a foot in order to stabilize the meter 1 during pumping. Other embodiments may use foot-operated pumps, or even (at the expense of portability) an existing or dedicated compressed-air supply, via a suitable regulator. It would even be possible to use a regulated compressed gas cylinder, for example to provide a source of inert gas for use in connection with extremely flammable fuels or other liquids.

The measuring unit 3 contains a two-position valve 8. In a first position, represented by solid arrows 9, the valve 8 connects the pressurising pump 2 to the pressure hose 4, and hence to the fuel tank. In a second position, represented by broken arrows 10, the pressurising pump 2 is connected to open air, while the pressure hose 4 and fuel tank are connected to a restrictor 11 comprising a calibrated orifice through which air may exit the meter 1. A (first) pressure transducer 12 measures the air pressure within the pressure hose 4 (and hence within the fuel

tank). The measuring unit 3 also contains electronic control apparatus (including a timing circuit), which is adapted to control the valve 8 and to receive data from the pressure transducer 12. The measuring unit 3 is also provided with a display 13, most conveniently a liquid crystal numeric or alphanumeric display, although light emitting diode or analogue displays may also be used. The electronic components are all encapsulated for safety in the presence of highly flammable fuel vapours. The portable meter 1 shown uses a low-voltage dry cell battery as power supply, which is also located within a gas-tight chamber.

To use the meter 1, a filler cap is removed from a fuel filler pipe of a vehicle, and the fitting 5 is securely and sealingly connected to its external opening. The meter 1 is turned on, the valve 8 being it its first position 9. The user pumps the handle 6 of the pressurising pump 2, transferring air through the hose 4 to an interior of the fuel tank.

When the pressure within the fuel tank, the filler pipe and the hose 4 reaches 250 millibars above atmospheric pressure, as indicated by the pressure transducer 12, the electronic control apparatus switches the valve 8 from its first position 9 to its second position 10. The pressurising pump 2 is now connected to the atmosphere, so no more air can be pumped into the fuel tank, which is now linked, via the hose 4, to the restrictor 11. The slightly pressurised air within the fuel tank is now free to bleed out via the calibrated orifice of the restrictor 11, so that the pressure in the fuel tank, etc, begins to fall.

When the pressure transducer 12 registers a first pre-set pressure, for example 200 millibars, the timing circuit begins to run. Air continues to bleed out through the restrictor 11 until a second pre-set pressure is reached, for example 100 millibars, at which point the timing circuit stops. The display 13 indicates an elapsed time between reaching the first and second pre-set pressures, which the user may record. The pressure within the tank is then allowed to return to atmospheric pressure, and the fitting 5 is removed.

In principle, the behaviour of a gas under pressure is governed by the ideal equation:

$$PV = nRT$$

where P is pressure, V is volume, T is temperature, R is the ideal gas constant, and n is the number of moles of gas present. In the course of the above pressurisation and depressurisation sequence, V is the free volume of the fuel tank above the fuel (which includes, as defined, the volume of the filler pipe and the hose 4), which will be substantially constant. Over the range of pressure changes envisaged, it may be assumed that the temperatures T will not vary appreciably, and R is an universal constant. Thus, the pressure is in effect directly related to n, the amount of gas present, and a change in pressure, ΔP, is directly related to a change in the amount of gas present, Δn:

$$\Delta P = \Delta n.RT/V$$

Hence, the larger the value of V, the greater the value of Δn to give a particular value of ΔP.

The calibrated orifice in the restrictor 11 allows gas to escape at a relatively constant rate (for the overpressure ranges in question), i.e. it allows n to change at a substantially constant rate over time. That being said, the number of molecules flowing through the restrictor means and so the rate of pressure change will be a function of the pressure difference across the restrictor means, the absolute pressure, the temperature of the gas, the composition of the gas and so forth. Absolute pressure can be a significant factor. Temperature is less of a factor. Composition of the gas can also be a factor but if air is used, the variation in its composition will usually be minimal, unless perhaps the device is used with a particularly volatile liquid.

Thus, the time t, measured for a specific pressure drop to occur through the restrictor 11 is a measure of the amount of gas that has escaped to produce that pressure drop:

$$\Delta n = k.t, \text{ where } k \text{ is a constant}$$

$$\therefore \Delta P = k.t.RT/V$$

$$\text{or } V = k.t.RT/\Delta P$$

Since k and R are constant, and T is effectively constant and ΔP is predetermined, the free volume V above the fuel in the tank is directly proportional to the time t.

In reality, gas behaviour tends to diverge from ideal gas behaviour, but in a repeatable fashion. Thus, a graph of V versus t may not be a straight line, but it is possible to produce a reliable calibration curve for any given standard fuel tank by part-filling it with a range of known volumes of liquid, and measuring t in each case.

Thus, one may use the meter 1 on a tank of known type containing an unknown volume of fuel, to obtain an accurate assessment of the free volume within the tank, and hence the volume of fuel.

This procedure may be carried out when a vehicle is hired out, repeated when the vehicle is returned, and any difference calculated. If there is a deficit, the hire company may charge the person who has hired the vehicle for the exact shortfall.

In its basic form, the meter 1 indicates only the time taken for the pressure to drop from a first to a second preset value, leaving the user to read off a fuel volume from a calibration curve for the particular vehicle model being used. However, it is envisaged that the meter could be provided with a memory chip or the like containing the calibration curves for a range of vehicles, and a touch-pad or the like allowing the user to select a particular model. The meter display 13 would then show a calculated fuel volume.

Alternatively, the meter could record the time in its memory, and then be connected to a computer, over a standard RS232 connection or the like, in order to transfer this time data. In this case, the computer could hold the calibration curves in its memory and use them to calculate the fuel volume present. It would store the "as hired" fuel volume of each vehicle, compare it with the "as returned" fuel volume of that vehicle, and calculate any refuelling charges automatically.

The meter described will be safe in use, as its electrical components are isolated from any fuel vapour mixed with the air above the fuel in the vehicle's tank. Also, the overpressures used, approximately one-quarter of atmospheric pressure at most, will be well within the range of what a vehicle fuel tank is designed to withstand. If safety regulations require, a pressure relief valve, bursting disc, or the like can be provided to release excess pressure if the valve fails to operate at 250mbar as described above.

It should also be noted that while operation of the meter 1 is described above with the fuel tank, etc, being pressurised to a slight overpressure, it is equally possible to evacuate the tank partially, creating an underpressure that sucks air into the tank through the restrictor 11.

A second embodiment is illustrated in Figure 2. In this embodiment, the meter includes a second pressure transducer 14 which measures ambient pressure, and a memory 15 which stores a calibration table. The calibration table includes data relating the rate at which gas flows through the restrictor 11 to the pressure difference across the restrictor (i.e. the difference in pressure between the inside of the container and ambient pressure), the ambient pressure (and optionally the ambient temperature measured by a temperature transducer). A computer 16 calculates the volume of the fuel tank which is not occupied by liquid taking into account the data stored in the calibration data and the pressure values measured by first pressure transducer 12 and second pressure transducer 14. The computer uses the data in the calibration table to estimate the instantaneous molecular flow rate from the pressure

difference across the restrictor and ambient pressure. (In a further embodiment not shown, the meter also includes a temperature transducer and the computer uses the measured temperature in its calculations). The instantaneous molecular flow rate is evaluated periodically during the measurement process and numerically integrated over time to give an estimate of Δn and thus V.

We have found that the instantaneous molecular flow rate through the restrictor 11 (and hence the rate of change of pressure within the container with time) does not depend only on the pressure measured by the first pressure transducer 12, but also on the absolute value of ambient pressure measured by the second transducer 14. Accordingly, the second embodiment should provide more accurate results than the first embodiment. The second pressure transducer 14 should measure absolute pressure. The first pressure transducer 12 could measure either absolute pressure or the pressure difference between the inside of the container and the ambient air.

A third embodiment is illustrated in Figure 3. In this embodiment, the valve 10 has three positions. The first two positions correspond to the two positions of the first embodiment. The third position connects the first pressure transducer 12 to the surrounding atmosphere. Calculations are carried out as with the second embodiment. An advantage of the third embodiment is that one less pressure transducer is required. This embodiment requires that the pressure transducer measures absolute pressure as it must be able to measure the pressure of ambient air.

Claims

1. A device for determining the volume of air space within a container, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

2. A device for determining the volume of liquid within a container comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

3. A device for determining whether the volume of air space within a container has changed between two readings, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

4. A device for determining whether the volume of liquid within a container has changed between two readings comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or

to the restrictor means, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

5. A device for determining the change in volume of air space within a container between two readings, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

6. A device for determining the change in volume of liquid within a container between two readings, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to determine the rate of pressure change within the container while the container is connected to the restrictor means.

7. A device according to any one of claims 1 to 6, wherein the means to determine the rate of pressure change comprises a pressure transducer.

8. A device according to claim 7, wherein the pressure transducer measures the pressure difference across the restrictor means.

9. A device according to any one of the preceding claims, further comprising means to measure absolute pressure.

10. A device according to any one of the preceding claims, comprising a pressure transducer for measuring absolute pressure, wherein the valve means is operable to connect the pressure transducer either to the interior of the container or to ambient air.

11. A device according to claim 9 or claim 10, wherein the device or a separate computing device comprises means to determine the effect of absolute pressure (and optionally absolute temperature) on the rate of pressure change while the container is connected to the restrictor means.

12. A device according to any one of the preceding claims, comprising a temperature gauge.

13. A device according to any one of the preceding claims, wherein the means to determine the rate of pressure change within the container determines the period taken for the pressure within the container to change from a first value to a second value while the container is connected to the restrictor means.

14. A device according to claim 13, wherein the first and second values are calculated by calculating means.

15. A device according to any one of claims 1 to 12, wherein the means to determine the rate of pressure change within the container determines the change in the pressure within the container during a period of time.

16. A device according to any one of claims 1 to 12, wherein the means to determine the rate of pressure change within the container measures pressure within the container at a plurality of times and analyses the successive pressure values.

17. A device according to any one of the preceding claims, comprising a display to display at least one determined parameter related to the volume of air space or liquid within the container.

18. A device according to any one preceding claim, comprising a memory to store at least one determined parameter related to the volume of air space or liquid within the container.

19. A device according to any one preceding claim, comprising an interface to interface with an external computer system for storing and processing at least one determined parameter related to the volume of air space or liquid within the container.

20. A device according to any one preceding claim comprising a computer to calculate at least one parameter related to the volume of air space or liquid within the container.

21. A system comprising at least one computer and a plurality of devices according to any one of the preceding claims.

22. A method of measuring the volume of a liquid in a container of known volume comprising the steps of altering the pressure of gas within the interior of a container and allowing the pressure within the container to start equilibrating with air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of pressure within the container, thereby calculating the volume of the container which is not occupied by the liquid and thereby calculating the volume of the liquid.

23. A method of determining whether the volume of a liquid in a container of substantially fixed volume has changed between first and second readings,

comprising the steps of, for each reading, altering the pressure of gas within the interior of the container and allowing the pressure within the container to start equilibrating with air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of pressure within the container, thereby calculating the volume of the air space within the container, and then comparing the calculated air space volumes.

24. A method of determining a change in the volume of a liquid in a container of substantially fixed volume between first and second readings, comprising the steps of, for each reading, altering the pressure gas within the interior of the container and allowing the pressure within the container to start equilibrating air of another pressure through gas flow restrictor means whilst carrying out at least one measurement of the rate of change of pressure within the container, thereby calculating the air space volume, and then calculating the difference in the air space volumes between readings.

25. A method according to any one of claims 22 to 24 wherein air of another pressure is ambient air.

26. A method according to any one of claims 22 to 25 including the step of measuring absolute pressure and taking this measurement into account in calculating the value to be determined.

27. A method according to any one of claims 22 to 26, wherein the step of measuring the rate of change of pressure within the container comprises measuring the period taken for the pressure within the container to change from a first value to a second value while the container is connected to the restrictor means..

28. A method according to any one of claims 22 to 27, wherein the step of measuring the rate of change of pressure within the container comprises determining the change in the pressure within the container during a period of time.

29. A method according to any one of claims 22 to 28, wherein the step of measuring the rate of change of pressure within the container comprises measuring the pressure within the container at a plurality of times and analysing the successive pressure values.

30. A method of calculating a charge to be issued in relation to the rental of a vehicle having a fuel tank for containing fuel, the method comprising the steps of, on at least two occasions, determining the volume of air space in the fuel tank, or a parameter related thereto, thereby calculating the change in the amount of fuel between the occasions, and issuing a bill dependant on the calculated change in the amount of fuel.

31. A device to measure a volume of liquid held within a container of known volume, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to measure pressure within the container, and means to time a period taken for the pressure within the container to change from a first predetermined value to a second predetermined value while the container is connected to the restrictor means.

32. A device to measure a volume of liquid held within a container of known volume, comprising means to connect the device to the container, means to alter the gas pressure within the container, gas flow restrictor means, valve means to connect the container either to the pressure altering means or to the restrictor means, means to

measure pressure within the container, and measure the change in pressure within the container to change during a period while the container is connected to the restrictor means.

33. A device according to claim 31 or 32 comprising means to measure absolute pressure, wherein absolute pressure is taken into account in determining the volume of liquid.

34. A method for measuring a volume of liquid held within a container of fixed volume, comprising the steps of providing a device according to claim 31 or claim 33 when dependent on claim 31, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, timing the period taken for the pressure within the container to fall from said first predetermined value to a second predetermined value, and calculating from said period a gas volume and hence a liquid volume within the container.

35. A method for measuring a volume of liquid held within a container of fixed volume, comprising the steps of providing a device according to claim 32 or claims 33 when dependent on claim 32, connecting it to an aperture of the container, connecting the pressurising means to the container and raising the pressure therein to above a first predetermined value, connecting the container to the gas flow restrictor means so as to allow gas from the container to exit therethrough, measuring the change in pressure within the container during a period and calculating from said change in pressure a gas volume and hence a liquid volume within the container.

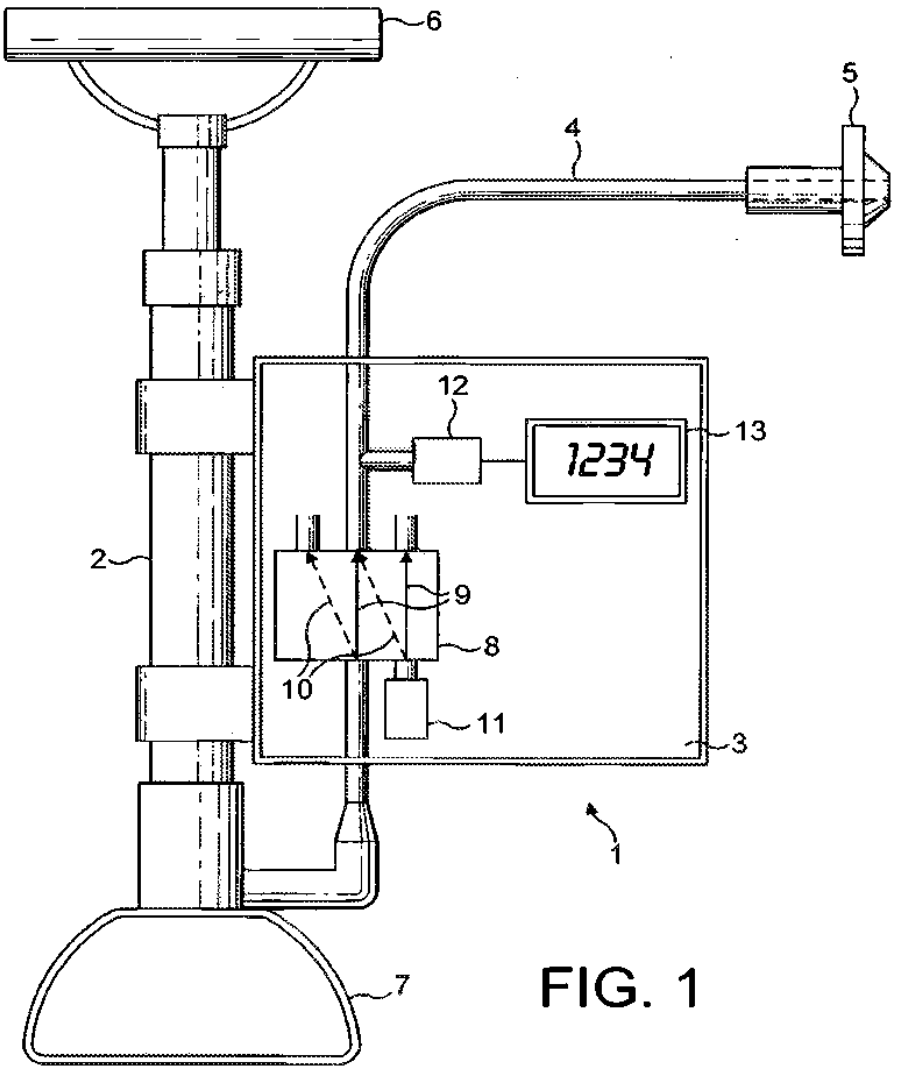


FIG. 1

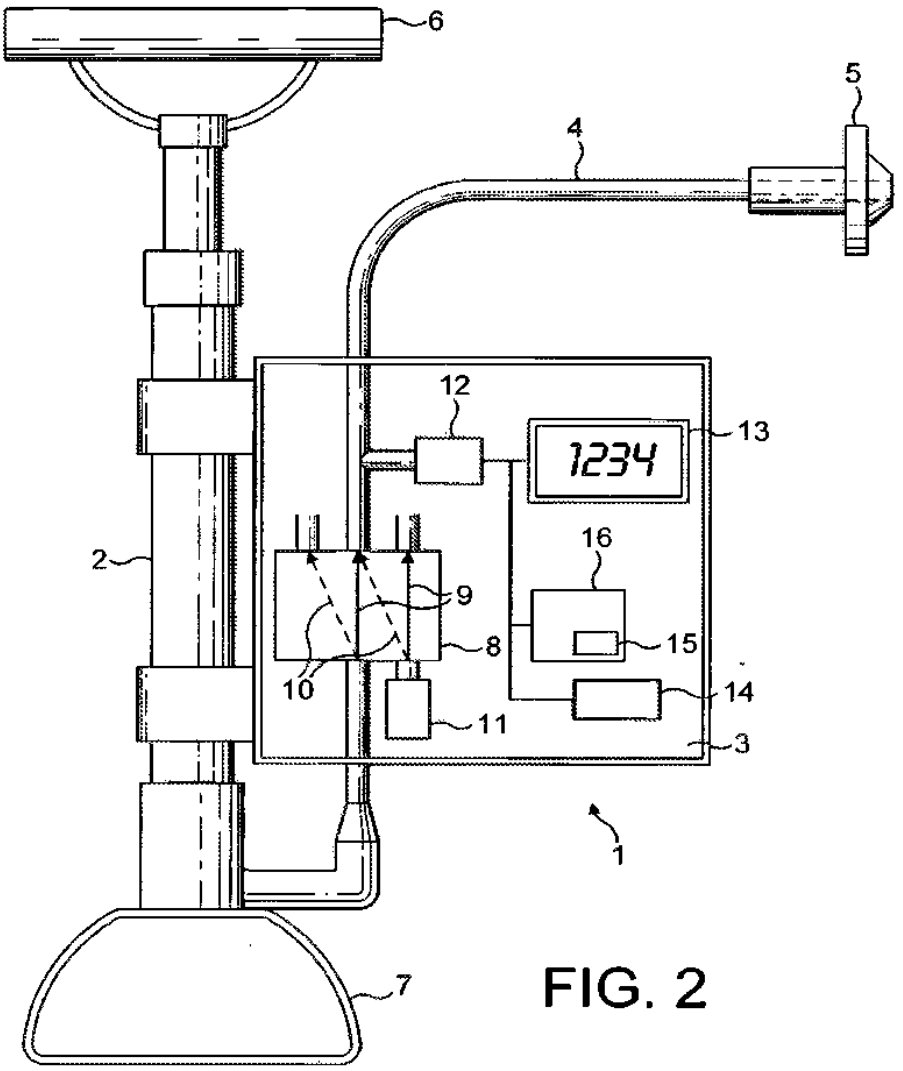


FIG. 2

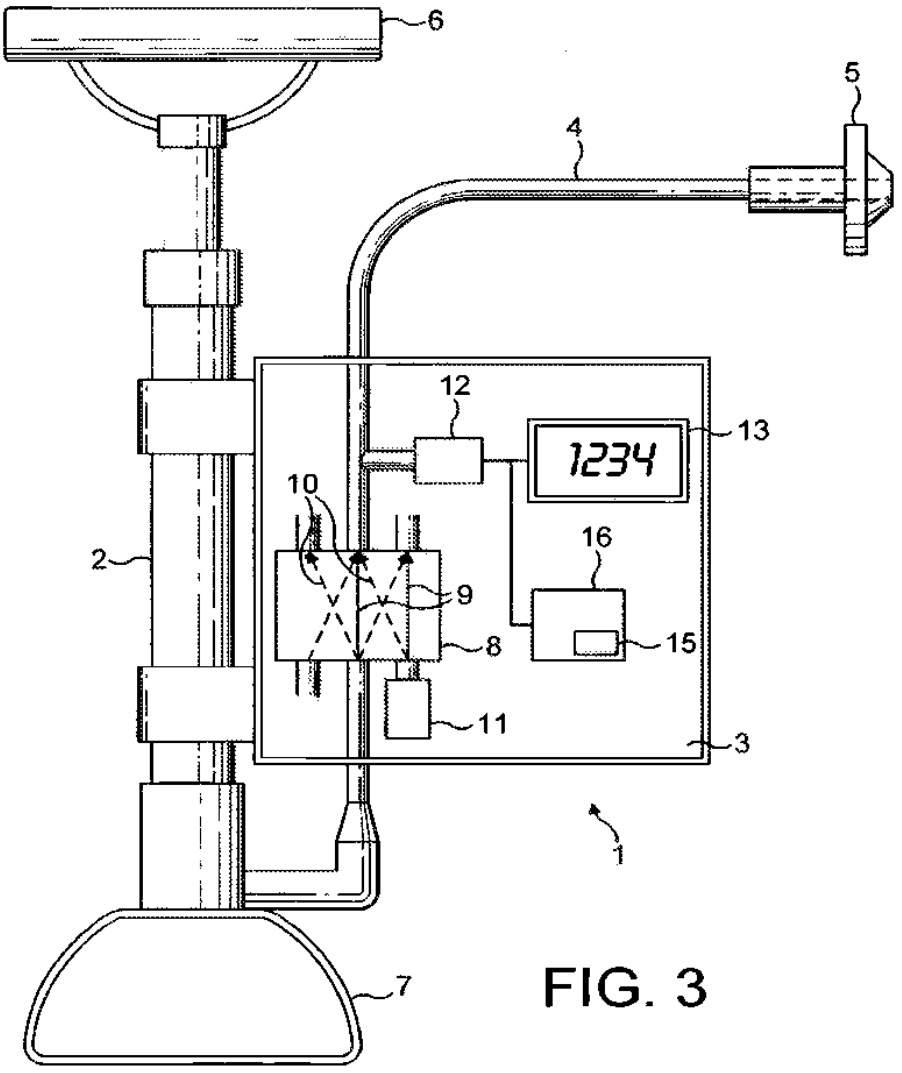


FIG. 3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP3** and **NPL1** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

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Attorney for Applicant
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Atty. Dkt. No. 4944.0120006

Doc Code: TRAN.LET

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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
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- ☐ Extension of Time Request
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- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
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- ☐ Drawing(s)
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- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):

Copies of FP1-FP3 and NPL1.

Remarks

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any over payment, to our Deposit Account No. 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	June 26, 2024	Reg. No.	800,005

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	FREDRICKSON, COURTNEY B
Attorney Docket Number	4944.0120006

cU. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6257070-B1	07-10-2001	GIALLORENZO; Mario et al.	
	002	US-7347089-B1	03-25-2008	KELLEY; Anthony R. et al.	
	003	US-20080255503-A1	10-16-2008	QUACKENBUSH; Carr Lane et al.	
	004	US-20120116299 A1	05-10-2012	TACK	
	005	US-20120277728 A1	11-01-2012	WEBER et al.	
	006	US-20150217033 A1	08-06-2015	POLLEN et al.	
	007	US-20210077673-A1	03-18-2021	MASON; Brian et al.	
	008	US-20230338630-A1	10-26-2023	CLAASSEN; Coen Petrus Martinus et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	EP-4000661-A1	05-25-2022	KONINKLIJKE PHILIPS NV [NL]		☐
	002	WO-2005114113-A2	12-01-2005	ACCU GAUGE LTD [GB], et al.		☐
	003	WO-2016186452-A1	11-24-2016	PARK CHO HEE [KR]		☒

Examiner Signature		Date Considered	

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				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	FREDRICKSON, COURTNEY B
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
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	001	Declaration of Ryan Bauer In Support of Petition for Inter Partes Review of U.S. Patent No. 11,413,380, Exhibit 1005 in IPR2024-00953, May 31, 2024; 137 pages.	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	17/181,057
				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	FREDRICKSON, COURTNEY B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-06-26
Name/Print	Yangbeini Wang	Registration Number	800,005

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(12) 특허협력조약에 의하여 공개된 국제출원

(19) 세계지식재산권기구
국제사무국

(43) 국제공개일
2016 년 11 월 24 일 (24.11.2016)

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(10) 국제공개번호
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A61M 1/06 (2006.01)

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(22) 국제출원일: 2016 년 5 월 18 일 (18.05.2016)

(25) 출원언어: 한국어

(26) 공개언어: 한국어

(30) 우선권정보:
10-2015-0069851 2015 년 5 월 19 일 (19.05.2015) KR

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(71) 출원인 : 박초희 (PARK, Cho Hee) [KR/KR]; 17571 경기도 안성시 고수 2 로 20, 203 동 501 호 (당왕동, 대우경남아파트), Gyeonggi-do (KR).

(74) 대리인: 특허법인 메이저 (MAJOR PATENT AND LAW FIRM); 06235 서울시 강남구 테헤란로 20 길 10, 3 층 (역삼동, 쓰리엠타워), Seoul (KR).

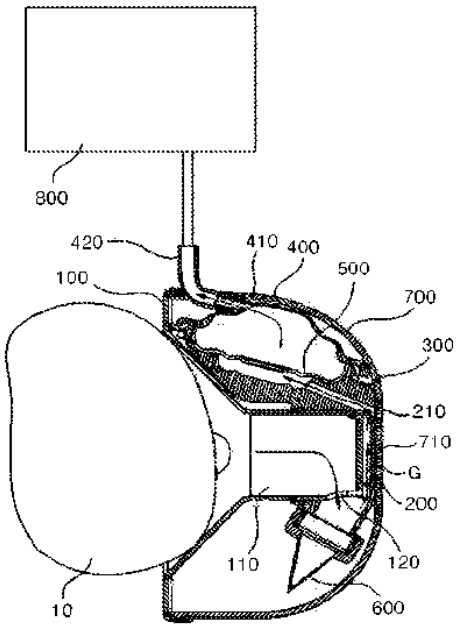
(81) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 국내 권리의 보호를 위하여): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KZ, LA, LC, LK, LR, LS, LU, LY, MA, 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) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 역내 권리의 보호를 위하여): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), 유라시아 (AM, AZ, BY, KG, KZ, RU, TJ, TM), 유럽 (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).

공개:
---- 국제조사보고서와 함께 (조약 제 21 조(3))

(54) Title: BREAST PUMP

(54) 발명의 명칭 : 착유기



(57) Abstract: A breast pump according to the present invention comprises: a fastening housing, which is fastened to a breast of a lactating woman, which has a protrusion formed in a part corresponding to a nipple of the lactating woman so as to extend forwards, and which has a milk discharge hole formed on the bottom surface of the protrusion near the end thereof; a cap connector coupled in such a structure that the end side of the protrusion is covered, a spacing space being provided between the same and the end surface of the protrusion, and the cap connector having a milk outflow tube extending downwards from the lower end of the milk discharge hole so as to communicate with the spacing space; a funnel connector provided on the upper side of the cap connector so as to have a concavely formed upper surface, thereby having an inner space, the funnel connector having a communication channel via which the inner space and the spacing space communicate with each other; a cover coupled so as to cover the inner space of the funnel connector; a flow isolation membrane for isolating the space between the funnel connector and the cover into upper and lower spaces; and an air tube via which air flows into/out of the space between the cover and the flow isolation membrane.

(57) 요약서: 본 발명에 의한 착유기는, 산모의 유방에 밀착되며, 전방을 향해 연장되는 돌출부가 산모의 유두와 대응되는 부위에 형성되되 상기 돌출부의 끝단측 바닥면에 모유배출공이 형성된 밀착하우징; 상기 돌출부의 끝단측을 덮는 구조로 결합되며, 상기 돌출부 끝단면과의 사이에 이격공간이 마련되고, 상기 모유배출공의

[다음 쪽 계속]

WO 2016/186452 A1

하단으로부터 하향 연장되되 상기 이격공간과 연통되는 모유유출관을 구비하는 캡커넥터; 내측공간을 갖도록 상면이 오목하게 형성되어 상기 캡커넥터의 상측에 구비되며, 상기 내측공간과 상기 이격공간을 연통시키는 연통유로를 구비하는 깔때기커넥터; 상기 깔때기커넥터의 내측공간을 덮도록 결합되는 덮개; 상기 깔때기커넥터와 덮개 사이의 공간을 상하로 격리시키는 유동격리막; 상기 덮개와 유동격리막 사이의 공간으로 공기를 유출입시키는 에어관;을 포함하여 구성된다.

명세서

발명의 명칭: 착유기

기술분야

[1] 본 발명은 착유기에 관한 것으로, 더 상세하게는 유축 과정동안 산모가 양손을 자유롭게 사용할 수 있고 모유의 역류가 방지되도록 구성되는 착유기에 관한 것이다.

[2]

배경기술

[3] 일반적으로 모유 착유기(일명 '유축기'라고도 함)는, 유아에게 모유를 먹이는 유방에 젖이 남거나 유아가 젖을 먹지 않을 경우, 산모는 유방에 젖이 과다하게 남아서 심한 고통(유방울혈)을 느끼게 되므로, 과다하게 남은 모유를 유방으로부터 강제로 짜내기 위해 사용된다.

[4] 이러한 모유 착유기는 현재 여러 형태로 시중에 시판되고 있는데, 동력원의 형태에 따라 수동식과 전동식으로 대별된다. 수동식 착유기는 유방에 씌워지는 깔때기 형태의 흡입기와, 상기 흡입기에 공기압을 발생시키기 위한 고무공 형태의 진공 펌프 및 흡착기로 유입된 모유가 저장되는 젖병으로 이루어져 있다. 상기와 같은 구성으로 이루어진 수동식 착유기는 산모 또는 보조자가 한 손으로 흡착기를 유방에 밀착시키고 다른 한 손으로는 진공 펌프를 눌렀다 폈다하는 동작을 반복하여 모유를 유방으로부터 강제로 빼내게 된다. 그러나, 이러한 수동식 착유기는 사용자의 손의 힘에 의해 공기압이 발생되기 때문에, 강한 공기압을 발생시킬 수가 없었으므로 유축 효율이 매우 낮고, 사용자의 힘이 많이 소요되어 사용이 매우 불편한 점이 있다.

[5] 반면에, 전동식 착유기는 모터와 에어 실린더를 갖는 공압 발생 펌프와, 상기 공압 발생 펌프에 연결되며 산모의 유방에 씌워지는 깔때기 형태의 흡입기 및, 상기 흡입기를 통해 유입된 모유가 저장되는 젖병으로 구성되어, 상기 공압 발생 펌프에 의해 발생하는 흡인력에 의해 모유를 강제로 짜낸다. 이와 같은 전동식 착유기를 이용하면 사용자의 힘이 많이 소요되지 아니하고 유축 효율이 높아진다는 장점이 있다.

[6] 그러나 종래의 착유기를 사용하는 경우 산모가 젖병을 지속적으로 들고 있어야 하는바, 유축에 많은 불편함이 있다는 단점이 있다. 또한, 흡입기를 통해 모유가 흡입되는 과정에서 모유가 역류하는 문제가 종종 발생하였고, 이러한 역류로 인해 관로가 막히거나 펌프가 오염되어 작동 불량이 유발되는 문제가 있었다. 즉, 모유 착유기를 이용하여 모유를 흡착할 때, 펌프의 작동에 의해 흡착기 내부의 압력이 급격히 저하되면서 유방으로부터 모유가 짜내어지게 되는데, 이 때 흡착기와 펌프를 연결하는 관로 상에도 강한 음압이 걸리게 되므로 흡입기 내로 흡입된 모유의 일부가 관로 상으로 역류하는 경우가 종종 발생하였다.

[7]

발명의 상세한 설명

기술적 과제

[8] 본 발명은 상기와 같은 문제점을 해결하기 위하여 제안된 것으로, 산모가 양손을 자유롭게 사용할 수 있고, 모유가 역류되는 현상을 방지할 수 있으며, 세척 및 유지 보수가 용이한 착유기를 제공하는데 목적이 있다.

[9]

과제 해결 수단

[10] 상기와 같은 목적을 달성하기 위한 본 발명에 의한 착유기는, 산모의 유방에 밀착되며, 전방을 향해 연장되는 돌출부가 산모의 유두와 대응되는 부위에 형성되되 상기 돌출부의 끝단측 바닥면에 모유배출공이 형성된 밀착하우징; 상기 돌출부의 끝단측을 덮는 구조로 결합되며, 상기 돌출부 끝단면과의 사이에 이격공간이 마련되고, 상기 모유배출공의 하단으로부터 하향 연장되되 상기 이격공간과 연통되는 모유유출관을 구비하는 캡커넥터; 내측공간을 갖도록 상단이 오목하게 형성되어 상기 캡커넥터의 상측에 구비되며, 상기 내측공간과 상기 이격공간을 연통시키는 연통유로를 구비하는 깔때기커넥터; 상기 깔때기커넥터의 내측공간을 덮도록 결합되는 덮개; 상기 깔때기커넥터와 덮개 사이의 공간을 상하로 격리시키는 유동격리막; 상기 덮개와 유동격리막 사이의 공간으로 공기를 유출입시키는 에어관;을 포함하여 구성된다.

[11]

[12] 상기 캡커넥터와 깔때기커넥터와 덮개와 유동격리막과 실리콘밸브가 내부에 인입되도록 상기 밀착하우징에 착탈 가능한 구조로 결합되며, 상기 모유유출관을 통해 배출된 모유가 저장되는 공간을 구비하는 저장하우징을 더 포함한다.

[13]

[14] 상기 캡커넥터의 외측단에는 상기 연통유로와 연통되는 세척공이 형성되고,

[15] 상기 저장하우징은 상기 밀착하우징과 결합되었을 때 상기 세척공에 압착되는 밀폐패킹을 구비한다.

[16]

[17] 상기 캡커넥터는 상기 모유유출관이 형성된 측에 젖병커넥터를 구비한다.

[18]

[19] 일측이 상기 모유유출관의 출구측에 결합되며, 뾰족하게 형성된 타단에 절개선이 구비된 실리콘밸브를 더 포함한다.

[20]

[21] 상기 에어관을 통해 공기를 흡입시키는 전동펌프를 더 포함한다.

[22]

발명의 효과

[23] 본 발명에 의한 착유기는, 산모가 양손을 자유롭게 사용할 수 있어 활용성이 우수하고, 모유가 역류되는 현상을 방지할 수 있어 위생적이며, 세척 및 유지 보수가 용이하여 사용이 편리하다는 장점이 있다.

[24]

도면의 간단한 설명

[25] 도 1은 본 발명에 의한 착유기의 사시도이다.

[26] 도 2 내지 도 4는 본 발명에 의한 착유기의 각 방향별 분해사시도이다.

[27] 도 5는 본 발명에 의한 착유기의 분해단면도이다.

[28] 도 6은 본 발명에 의한 착유기의 사용상태 정면도이다.

[29] 도 7 및 도 8은 본 발명에 의한 착유기의 사용상태 단면도이다.

[30] 도 9는 본 발명에 의한 착유기 제2 실시예의 분해단면도이다.

[31] 도 10은 본 발명에 의한 착유기 제2 실시예의 분해사시도이다.

[32] 도 11은 본 발명에 의한 착유기 제2 실시예의 사시도이다.

[33]

발명의 실시를 위한 최선의 형태

[34] 이하 첨부된 도면을 참조하여 본 발명에 의한 착유기의 실시예를 상세히 설명한다.

[35] 도 1은 본 발명에 의한 착유기의 사시도이고, 도 2 내지 도 4는 본 발명에 의한 착유기의 각 방향별 분해사시도이며, 도 5는 본 발명에 의한 착유기의 분해단면도이다.

[36] 본 발명에 의한 착유기는 산모의 유방(10) 측으로 진공압을 인가하여 모유를 유축하기 위한 장치로서, 진공압이 인가되는 유로를 통해 모유가 역류하는 현상을 방지할 수 있도록 구성된다는 점에 특징이 있다.

[37] 즉, 본 발명에 의한 착유기는, 전방을 향해 연장되는 돌출부(110)가 산모의 유두와 대응되는 부위에 형성되되 상기 돌출부(110)의 끝단측 바닥면에 모유배출공(120)이 형성되는 밀착하우징(100)과, 상기 돌출부(110)의 끝단측을 덮는 구조로 결합되는 캡커넥터(200)와, 내측공간을 갖도록 상면이 오목하게 형성되어 상기 캡커넥터(200)의 상측에 장착되는 깔때기커넥터(300)와, 상기 깔때기커넥터(300)의 내측공간을 덮도록 결합되는 덮개(400)와, 상기 깔때기커넥터(300)와 덮개(400) 사이의 공간을 상하로 격리시키는 유동격리막(500)과, 상기 덮개(400)와 유동격리막(500) 사이의 공간으로 공기를 유출입시키는 에어관(420)과, 상기 에어관(420)을 통해 공기를 흡입시키는 전동펌프(800)를 포함하여 구성된다.

[38] 상기 캡커넥터(200)는 상기 돌출부(110) 끝단면과 대응되는 부위가 상기 돌출부(110)의 끝단에 밀착되는 것이 아니라 일정거리 이격되는바, 돌출부(110) 끝단면과 캡커넥터(200) 사이에는 이격공간(G)이 마련되고, 상기 모유배출공(120)의 하단으로부터 하향 연장되되 상기 이격공간(G)과 연통되는

모유유출관(210)을 구비한다. 또한 깔때기커넥터(300)의 내측공간과 이격공간(G)을 연통시키는 연통유로(310)가 구비되는바, 상기 깔때기커넥터(300)의 내측공간은 연통유로(310)와 이격공간(G)과 모유유출관(210)을 통해 돌출부(110) 내측부와 연통된다.

[39] 상기 유동격리막(500)은 외력에 의해 쉽게 휘어질 수 있도록 연성을 갖는 재료로 제작되는바, 공기노즐(410)을 통해 덮개(400)와 유동격리막(500) 사이의 공기가 외부로 흡입되면, 상기 유동격리막(500)은 상향으로 이동된다. 이와 같이 유동격리막(500)이 상향으로 이동되면 유동격리막(500)과 깔때기커넥터(300) 사이의 공간이 확장되어 진공압이 형성되는데, 상기 진공압은 연통유로(310)와 이격공간(G)과 모유유출관(210)과 돌출부(110) 내부를 통해 산모의 유방(10)까지 전달되는바, 산모의 유방(10)으로부터 모유가 유축된다.

[40] 이때, 산모의 모유가 진공압에 의해 이격공간(G) 및 연통유로(310)를 통해 깔때기커넥터(300)의 내부까지 빨려 들어가는 경우가 있을 수 있지만, 상기 깔때기커넥터(300)의 내측공간은 유동격리막(500)에 의해 밀폐되는바, 상기 모유가 공기노즐(410)까지는 역류되지 못하게 된다. 즉, 본 발명에 의한 축유기는 모유가 역류되어 외부로 유출되지 아니하는바, 전동펌프(800)가 모유에 의해 오염되거나 손상되는 현상이 발생되지 아니한다는 장점이 있다. 또한, 모유가 외부로 유출되지 아니하므로, 위생상태 역시 개선된다는 효과를 얻을 수 있다.

[41]

[42] 한편, 본 발명에 의한 축유기는, 별도의 젖병을 사용하지 아니하더라도 유축된 모유를 모을 수 있도록, 상기 캡커넥터(200)와 깔때기커넥터(300)와 덮개(400)와 유동격리막(500)과 실리콘밸브(600)가 내부에 인입되는 구조로 밀착하우징(100)에 결합되는 저장하우징(700)을 구비할 수 있다. 이와 같이 저장하우징(700)이 밀착하우징(100)에 장착되면, 산모는 별도의 젖병을 들고 있지 아니하더라도 유축을 할 수 있으므로, 자신의 양손을 모두 사용할 수 있다는 장점이 있다. 물론, 상기 저장하우징(700)은 착탈 가능한 구조로 밀착하우징(100)에 결합되는바, 사용자는 저장하우징(700) 내부에 일정량의 모유가 담겨진 이후 상기 저장하우징(700)을 밀착하우징(100)으로부터 분리시켜 모유를 포집할 수 있다.

[43] 물론, 저장하우징(700)을 밀착하우징(100)으로부터 분리시키지 아니하더라도 저장하우징(700) 내의 모유를 외부로 유출시켜 포집할 수 있도록, 상기 저장하우징(700)에는 별도의 모유 유출구가 마련될 수도 있다. 이때 상기 모유 유출구에는, 사용자의 선택에 따라 밀폐 및 개방 가능한 마개가 구비되어야 하는데, 이와 같은 마개는 본 발명이 해당하는 기술분야에서 다양한 형태로 널리 적용되고 있는바, 상기 마개의 구조 및 동작에 관한 상세한 설명은 생략한다.

[44] 또한, 저장하우징(700) 내부에 채워진 모유가 모유유출관(210)을 통해 역류되는 현상을 방지할 수 있도록, 상기 모유유출관(210)의 출구측에는 체크밸브 기능을 갖는 실리콘밸브(600)가 장착됨이 바람직하다. 상기

실리콘밸브(600)는, 일측(본 실시예에서는 상측)이 모유유출관(210)에 결합되고 타단(본 실시예에서는 하단)이 뾰족하게 형성되되, 타단에 절개선(미도시)이 형성되도록 구성된다. 따라서 모유유출관(210)을 통해 유출된 모유는 실리콘밸브(600) 내부로 유입된 후 절개선을 통해 저장하우징(700) 내부에 채워진다. 그러나 저장하우징(700) 내부의 모유는 절개선을 통해 실리콘밸브(600) 내부로 유입되기 어려우므로, 저장하우징(700) 내부의 모유가 산모의 유방(10)으로 역류되는 현상이 방지될 수 있다.

[45] 한편, 상기 언급한 바와 같이 돌출부(110) 내부의 모유가 진공압에 의해 연통유로(310)까지는 유입될 수 있는데, 상기 연통유로(310)가 캡커넥터(200) 외측으로 노출되지 못하면 상기 연통유로(310)를 세척하는데 어려움이 있고, 이에 따라 오염 및 세균번식의 우려가 있다. 따라서 상기 캡커넥터(200)의 외측단에는 연통유로(310)와 연통되는 세척공(220)이 형성될 수 있다.

[46] 이때, 상기 세척공(220)이 항시 개방되어 있으면 연통유로(310)에 형성된 진공압이 세척공(220)을 통해 해제될 우려가 있는바, 상기 저장하우징(700)은 상기 밀착하우징(100)과 결합되었을 때 상기 세척공(220)에 압착됨으로써 상기 세척공(220)을 밀폐시키는 밀폐패킹(710)을 구비함이 바람직하다. 상기 밀폐패킹(710)은 고무 등과 같이 밀폐력이 있는 재료로 제작되어야 할 것이다. 한편, 상기 저장하우징(700) 중 밀폐패킹(710) 이외의 나머지 부위가 기준치 이상의 강도를 가질 수 있도록 플라스틱으로 제작됨이 바람직하므로, 상기 저장하우징(700)은 이중사출 공정을 통해 제작됨이 바람직하다.

[47] 또한, 돌출부(110)와 캡커넥터(200) 간의 결합방향이 일정하게 한정될 수 있도록, 돌출부(110)의 끝단에는 안착홈(130)이 형성되고, 상기 캡커넥터(200)의 내측에는 상기 안착홈(130)에 끼워맞춤 방식으로 체결되는 안착돌기(230)가 형성된다. 이와 같이 안착홈(130)과 안착돌기(230)가 형성되면, 캡커넥터(200)가 돌출부(110)에 대해 헛도는 현상이 발생되지 아니하는바, 보다 안정적인 착유가 가능해진다는 이점이 있다.

[48] 또한, 상기 밀착하우징(100)과 저장하우징(700)은 상호 간의 결합각도가 일정하게 유지될 수 있고, 사용자가 밀착하우징(100) 및 저장하우징(700)을 보다 견고하게 움켜쥐고 돌릴 수 있도록 횡단면이 비원형으로 형성됨이 바람직하다. 그러나 상기 밀착하우징(100)과 저장하우징(700)의 형상은 본 실시예에 도시된 형상 이외에 다양한 형상으로 변경될 수 있다.

[49] 한편, 본 실시예에서는 전동펌프(800)에 의해 에어관(420)을 통해 공기가 흡입되는 구조 즉, 전동펌프(800)에 의해 진공압이 발생되는 자동식 착유기만이 도시되어 있으나, 상기 전동펌프(800) 대신 사용자가 손으로 눌러 진공압을 형성할 수 있도록 튜브펌프가 장착된 수동식 착유기로 구성될 수도 있다.

[50]

[51] 도 6은 본 발명에 의한 착유기의 사용상태 정면도이고, 도 7 및 도 8은 본 발명에 의한 착유기의 사용상태 단면도이다.

[52] 본 발명에 의한 착유기는 도 6에 도시된 바와 같이 산모의 왼쪽 유방과 오른쪽 유방에 각각 독립적으로 장착되는바, 본 발명에 의한 착유기를 사용하는 경우 좌우측 유방의 착유를 동시에 수행할 수 있어 착유시간을 절반으로 단축시킬 수 있고, 착유를 하는 동안 산모가 착유기를 손으로 잡고 있을 필요가 없으므로 산모의 양손이 자유로워진다는 장점이 있다.

[53] 한편 본 발명에 의한 착유기는, 진동펌프(800)가 작동하지 아니하는 초기 즉, 연통유로(310)부터 돌출부(110) 내부에 진공압이 형성되지 아니하는 초기에는, 도 7에 도시된 바와 같이 유동격리막(500)이 깔때기커넥터의 바닥면에 안착된 상태를 유지한다.

[54] 도 7에 도시된 상태에서 진동펌프(800)가 작동하여 에어관(420) 및 공기노즐(410)을 통해 덮개(400)와 유동격리막(500) 사이의 공기가 배출되면, 상기 유동격리막(500)은 도 8에 도시된 바와 같이 덮개(400)를 향해 당겨지는바, 유동격리막(500)과 깔때기커넥터(300) 사이에 공간이 형성되고, 이에 따라 연통유로(310)에 진공압이 발생된다. 연통유로(310)에 발생된 진공압은 이격공간(G) 및 모유배출공(120)을 통해 돌출부(110) 내부로 인가되는바, 밀착하우징(100)에 밀착된 유방(10)에 자극이 전달되고, 이에 따라 착유가 가능해진다.

[55] 한편, 모유유출관(210)을 통해 유출되던 모유가 진공압에 의해 이격공간(G) 및 연통유로(310)를 통해 깔때기커넥터(300)의 내부까지 빨려 들어갈 수 있지만, 상기 깔때기커넥터(300)와 덮개(400)는 유동격리막(500)에 의해 완벽하게 격리되는바, 깔때기커넥터(300) 내부로 유입된 모유가 공기노즐(410)을 통해 에어관(420)으로 빨려 들어가는 현상은 발생되지 아니하게 된다.

[56] 또한, 진동펌프(800)의 작동이 중단되어 덮개(400)와 유동격리막(500) 사이에 형성되었던 진공압이 해제되면, 상기 유동격리막(500)은 자체 탄성복원력에 의해 깔때기커넥터(300)의 바닥면에 밀착되는 원상태 즉, 도 8에 도시된 상태로 되돌아간다. 이와 같이 외력이 인가되었을 때 변형되고, 인가된 외력이 해제될 때 원상태로 되돌아가는 유동격리막(500)은 유압분야에서 다양한 용도로 활용되고 있는바, 상기 유동격리막(500)의 재질 및 복원원리에 대한 상세한 설명은 생략한다.

[57]

[58] 도 9는 본 발명에 의한 착유기 제2 실시예의 분해단면도이고, 도 10은 본 발명에 의한 착유기 제2 실시예의 분해사시도이며, 도 11은 본 발명에 의한 착유기 제2 실시예의 사시도이다.

[59] 본 발명에 의한 착유기는 유축된 모유가 저장하우징(700)에 저장되지 아니하고 젖병(20)에 직접 저장되도록 구성될 수도 있다. 즉, 본 발명에 의한 착유기는, 도 9 내지 도 11에 도시된 바와 같이 젖병(20)의 입구측에 나사결합되는 젖병커넥터(240)가 캡커넥터(200) 중 모유유출관(210)이 형성된 측에 형성될 수 있다.

[60] 이와 같이 모유유출관(210)을 둘러싸도록 젖병커넥터(240)가 형성되면, 도 11에 도시된 바와 같이 상기 젖병커넥터(240)를 젖병(20) 입구에 결합시켰을 때 상기 모유유출관(210) 및 이에 결합된 실리콘밸브(600)가 젖병(20) 내부를 향하게 되는바, 모유유출관(210) 및 실리콘밸브(600)를 통해 유출되는 모유는 젖병(20) 내부에 곧바로 채워질 수 있게 된다.

[61] 이때, 상기 젖병커넥터(240)를 제외한 나머지 구성은 도 1 내지 도 8에 도시된 착유기와 동일하므로, 모유 축유 과정 및 각 구성요소의 동작에 대한 상세한 설명은 생략한다.

[62] 이상, 본 발명을 바람직한 실시예를 사용하여 상세히 설명하였으나, 본 발명의 범위는 특정 실시예에 한정되는 것은 아니며, 첨부된 특허청구범위에 의하여 해석되어야 할 것이다. 또한, 이 기술분야에서 통상의 지식을 습득한 자라면, 본 발명의 범위에서 벗어나지 않으면서도 많은 수정과 변형이 가능함을 이해하여야 할 것이다.

청구범위

[청구항 1] 산모의 유방(10)에 밀착되며, 전방을 향해 연장되는 돌출부(110)가 산모의 유두와 대응되는 부위에 형성되되 상기 돌출부(110)의 끝단측 바닥면에 모유배출공(120)이 형성된 밀착하우징(100);
상기 돌출부(110)의 끝단측을 덮는 구조로 결합되며, 상기 돌출부(110) 끝단면과의 사이에 이격공간(G)이 마련되고, 상기 모유배출공(120)의 하단으로부터 하향 연장되되 상기 이격공간(G)과 연통되는 모유유출관(210)을 구비하는 캡커넥터(200);
내측공간을 갖도록 상면이 오목하게 형성되어 상기 캡커넥터(200)의 상측에 구비되며, 상기 내측공간과 상기 이격공간(G)을 연통시키는 연통유로(310)를 구비하는 깔때기커넥터(300);
상기 깔때기커넥터(300)의 내측공간을 덮도록 결합되는 덮개(400);
상기 깔때기커넥터(300)와 덮개(400) 사이의 공간을 상하로 격리시키는 유동격리막(500);
상기 덮개(400)와 유동격리막(500) 사이의 공간으로 공기를 유출입시키는 에어관(420);
을 포함하여 구성되는 것을 특징으로 하는 착유기.

[청구항 2] 청구항 1에 있어서,
상기 캡커넥터(200)와 깔때기커넥터(300)와 덮개(400)와 유동격리막(500)과 실리콘밸브(600)가 내부에 인입되도록 상기 밀착하우징(100)에 착탈 가능한 구조로 결합되며, 상기 모유유출관(210)을 통해 배출된 모유가 저장되는 공간을 구비하는 저장하우징(700)을 더 포함하는 것을 특징으로 하는 착유기.

[청구항 3] 청구항 2에 있어서,
상기 캡커넥터(200)의 외측단에는 상기 연통유로(310)와 연통되는 세척공(220)이 형성되고,
상기 저장하우징(700)은 상기 밀착하우징(100)과 결합되었을 때 상기 세척공(220)에 압착되는 밀폐패킹(710)을 구비하는 것을 특징으로 하는 착유기.

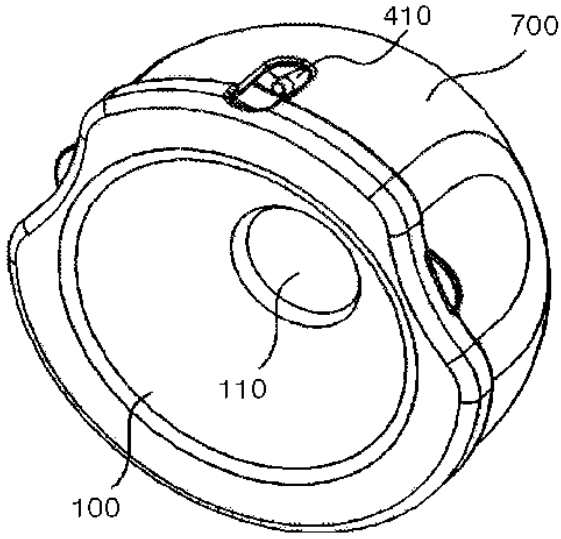
[청구항 4] 청구항 1에 있어서,
상기 캡커넥터(200)는 상기 모유유출관(210)이 형성된 측에 젖병커넥터(240)를 구비하는 것을 특징으로 하는 착유기.

[청구항 5] 청구항 1 내지 청구항 4 중 어느 하나의 청구항에 있어서,
입측이 상기 모유유출관(210)의 출구측에 결합되며, 뾰족하게 형성된 타단에 절개선이 구비된 실리콘밸브(600)를 더 포함하는 것을 특징으로 하는 착유기.

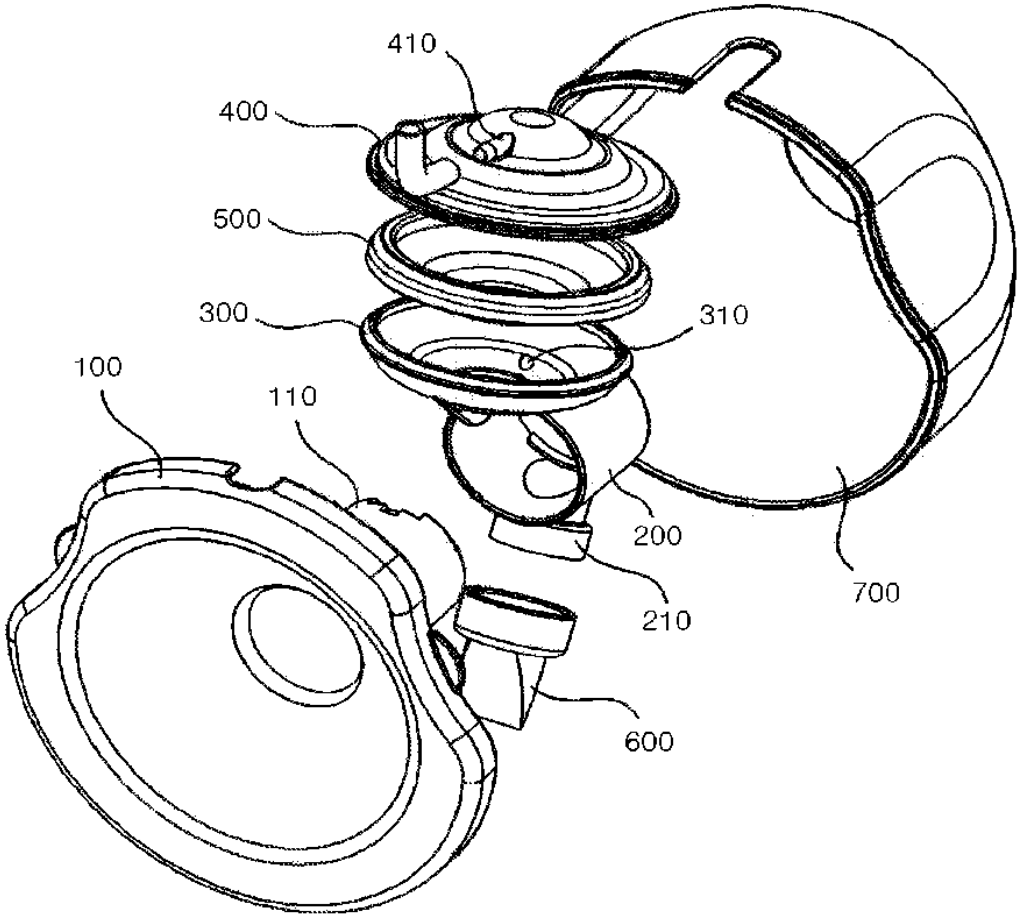
[청구항 6] 청구항 1 내지 청구항 4 중 어느 하나의 청구항에 있어서,

상기 에어관(420)을 통해 공기를 흡입시키는 전동펌프(800)를 더 포함하는 것을 특징으로 하는 착유기.

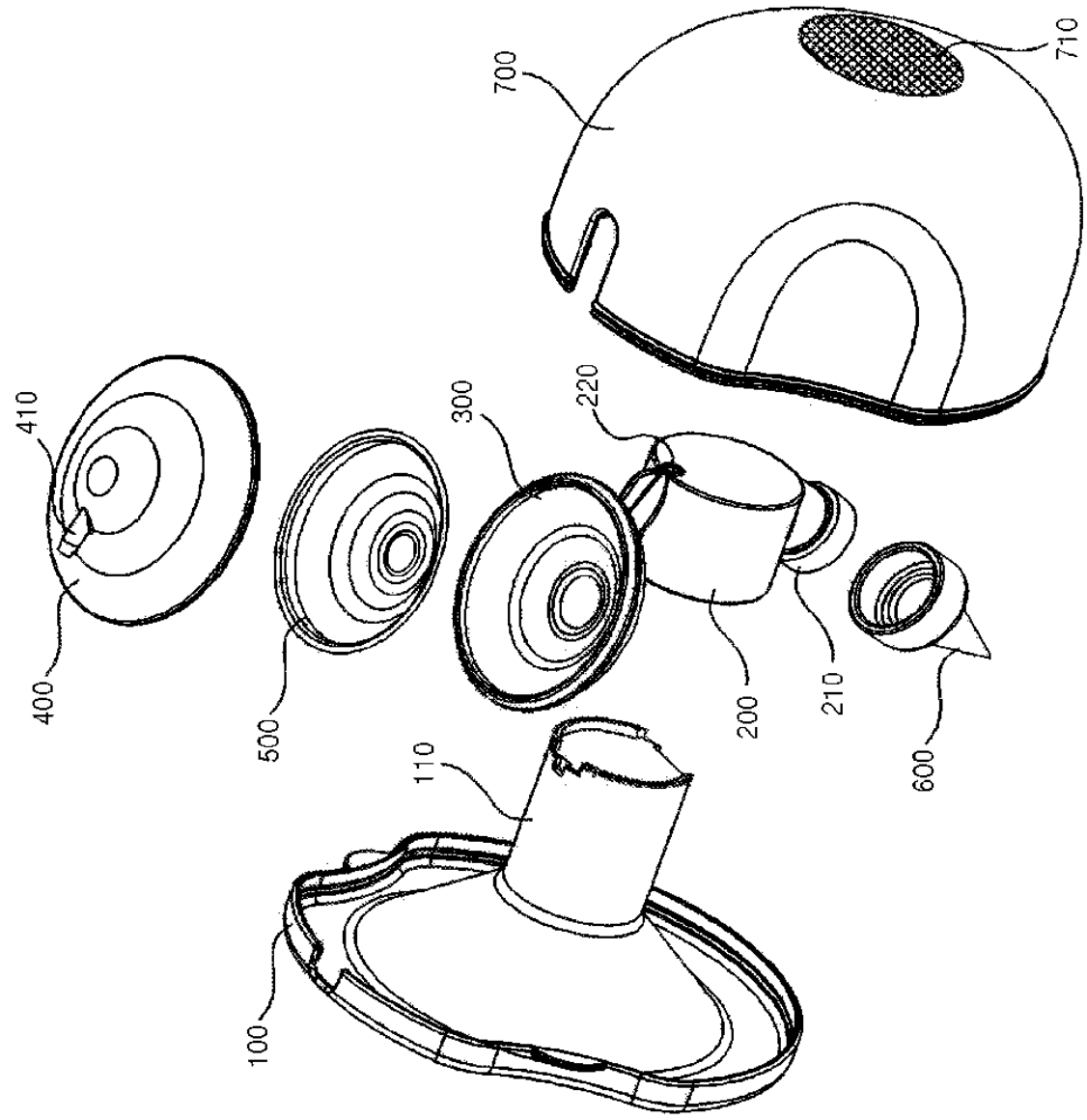
[도1]



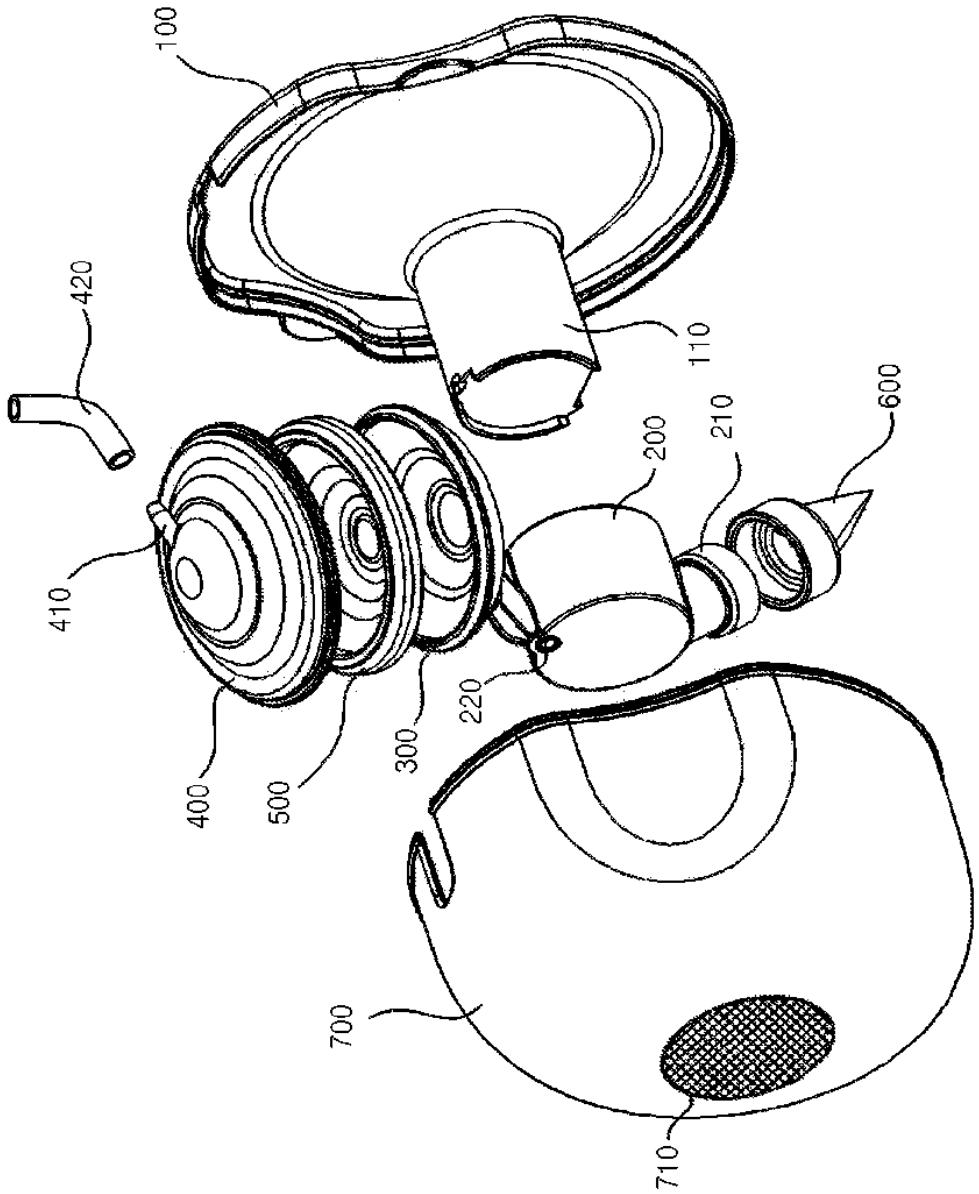
[도2]



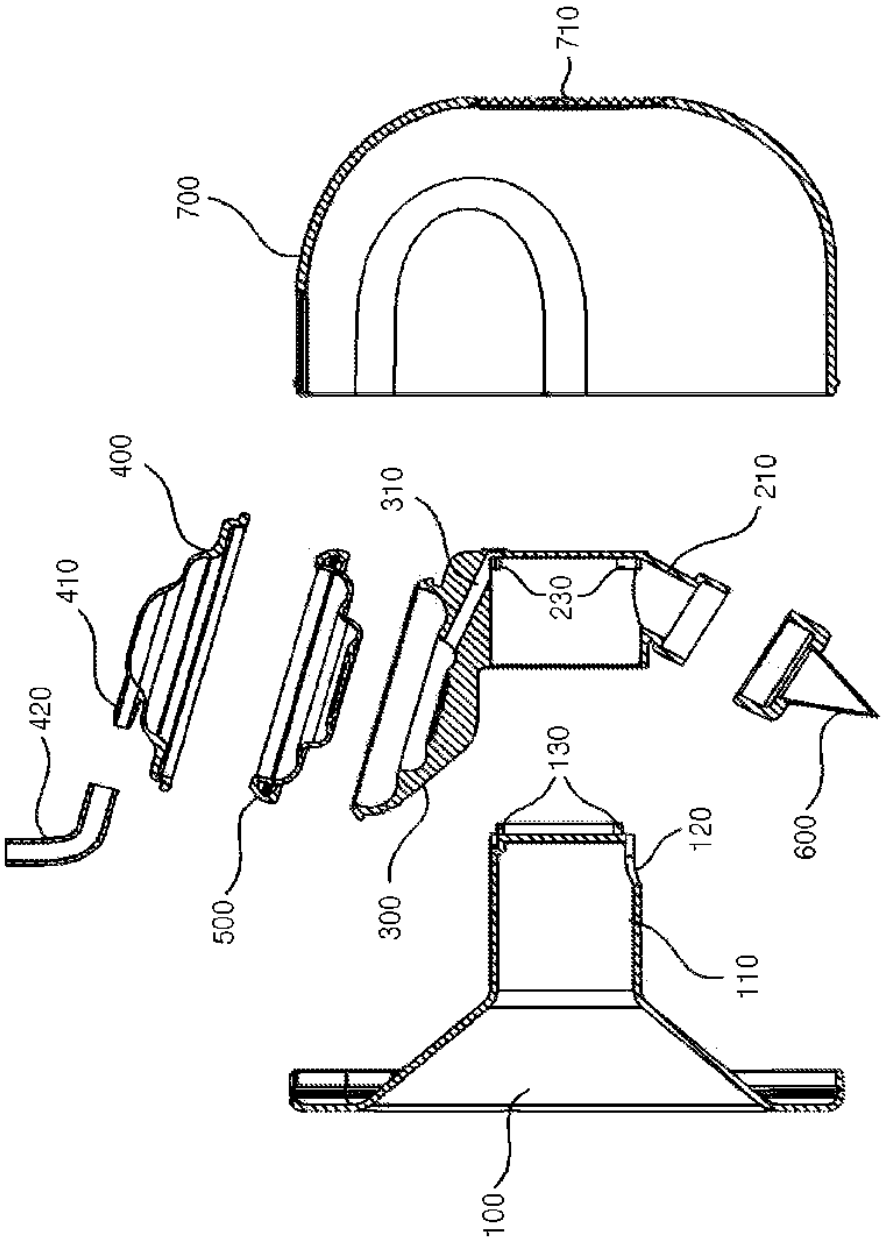
[도3]



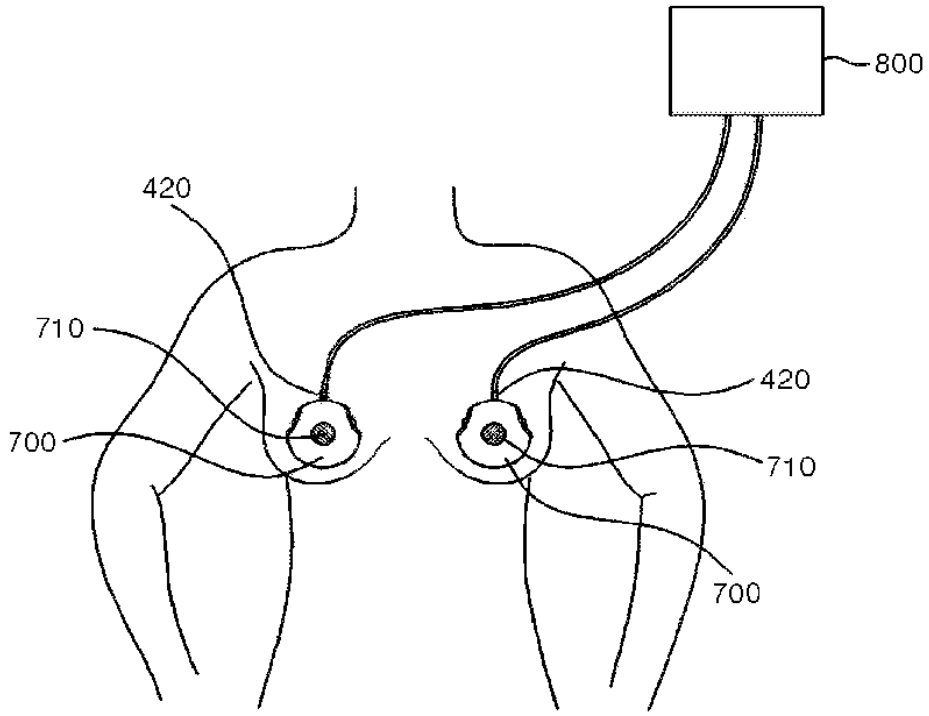
[도4]



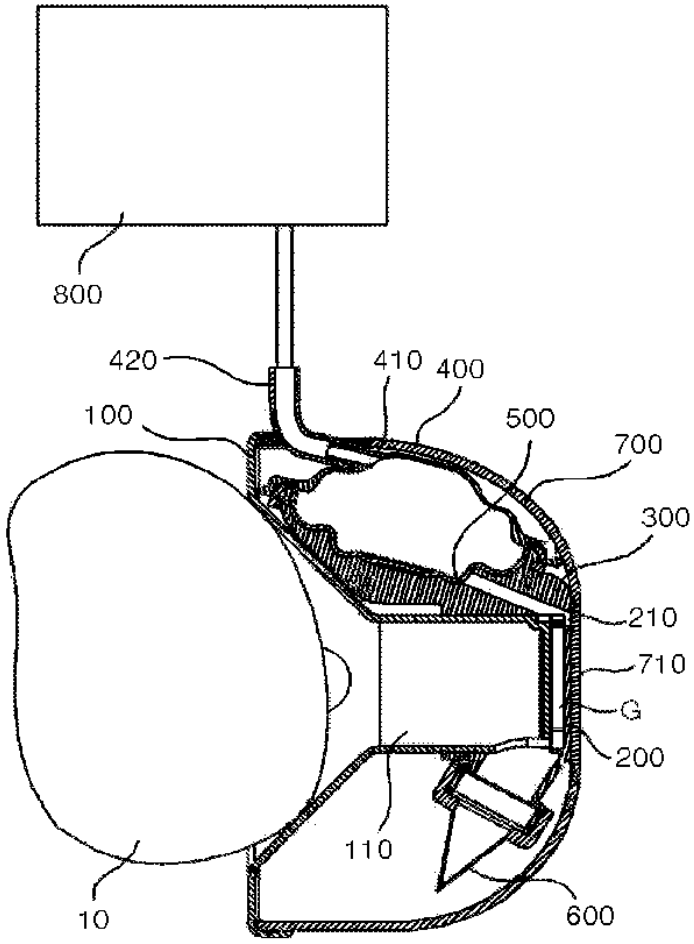
[도5]



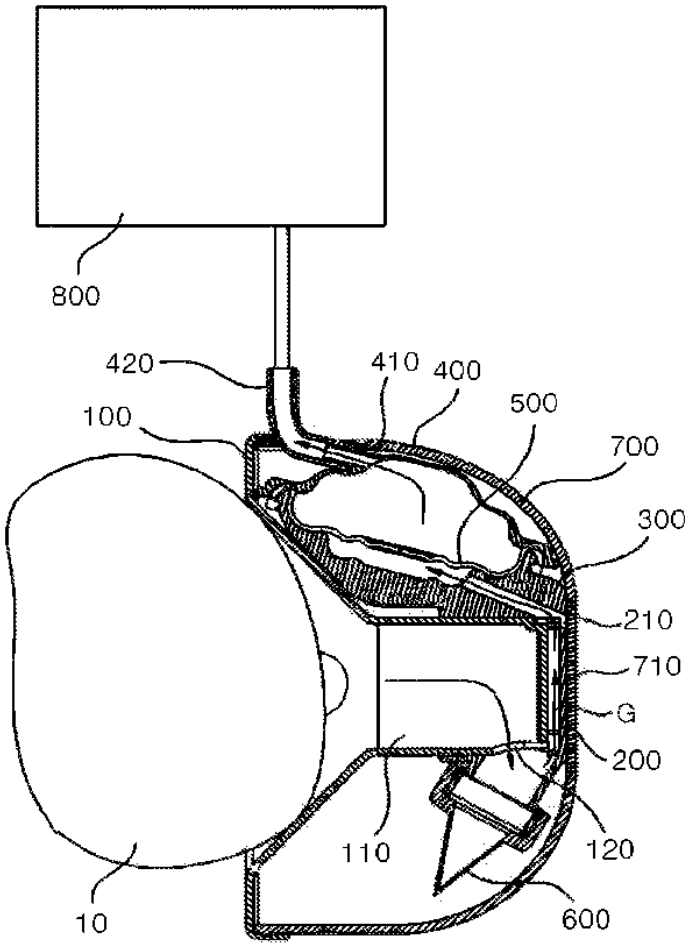
[도6]



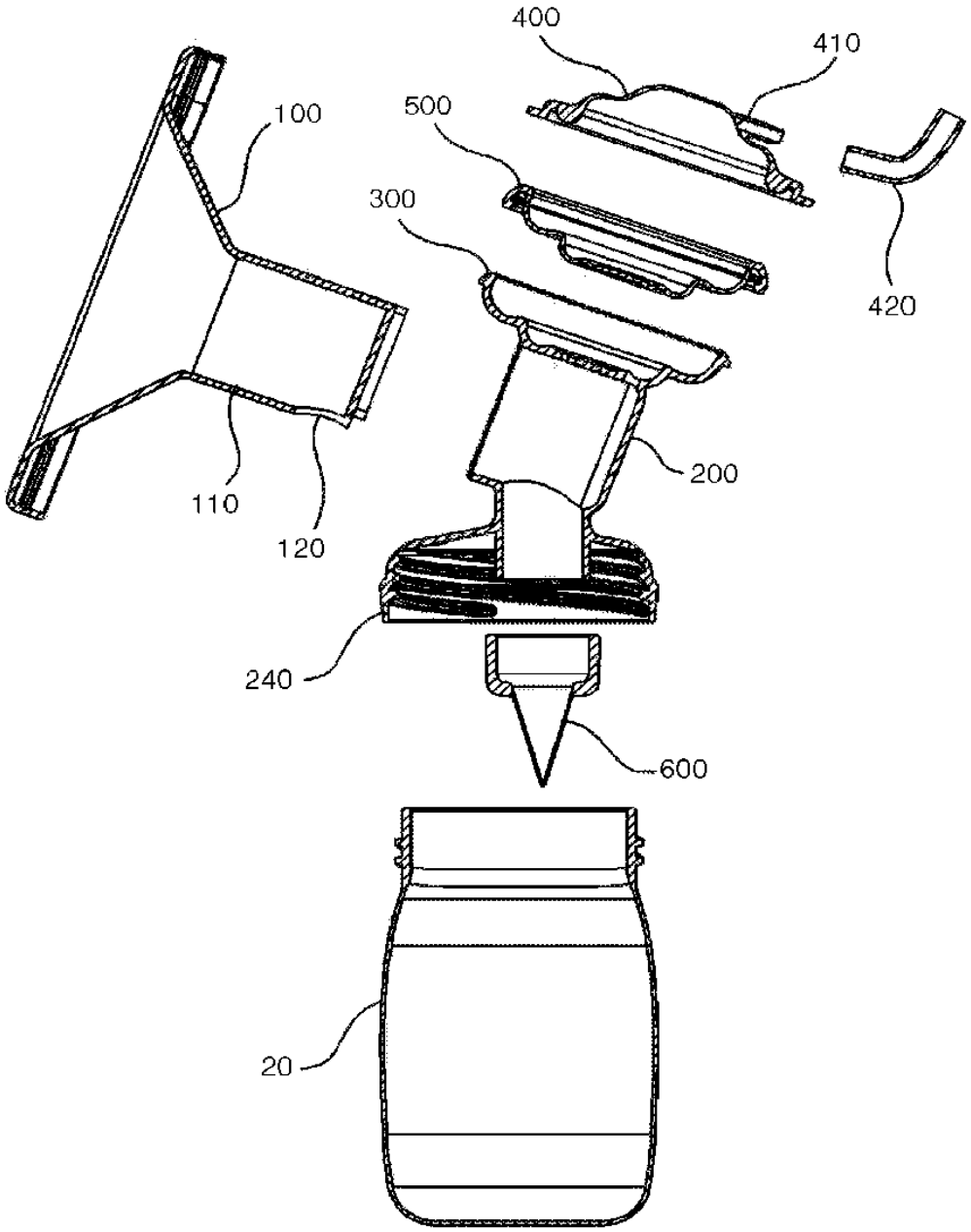
[도7]



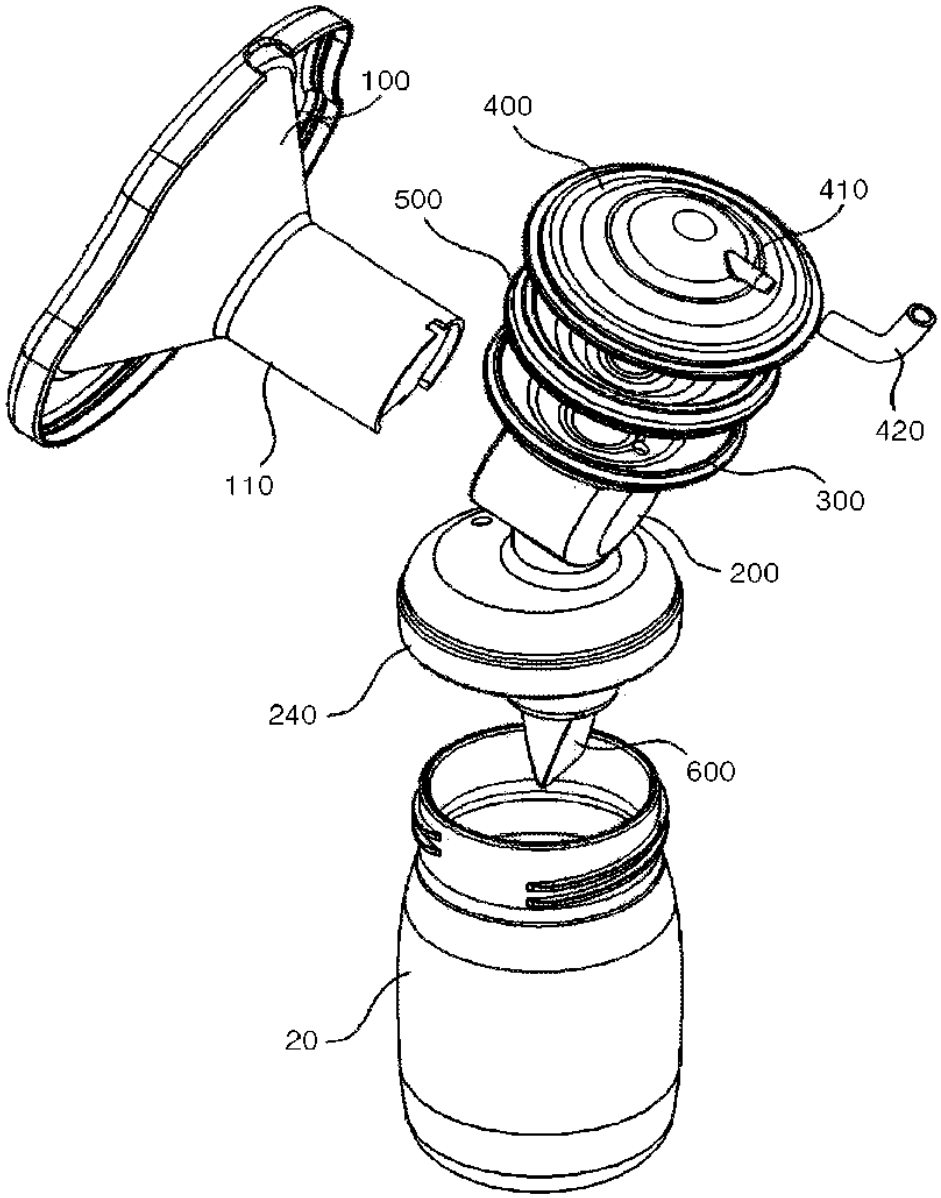
[도8]



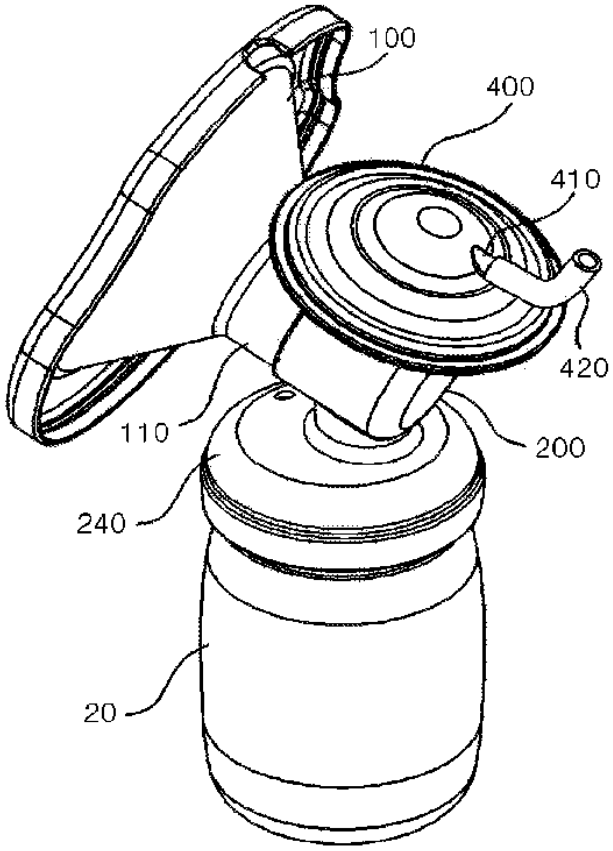
[도9]



[도10]



[도11]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2016/005271

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 1/06; A61J 9/00; A61M 31/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS (KIPO internal) & Keywords: breast pump, breast pump, contact housing, cap connector, funnel connector, flow separation film, air pipe, air, valve, washing

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2014-0052056 A1 (GARBEZ, D. et al.) 20 February 2014 See abstract; claim 6; paragraphs [0018]-[0022]; and figures 1-4.	1,2,4-6
A		3
Y	KR 20-2013-0000616 U (SUH, Jin Hyouk) 28 January 2013 See abstract; claims 1-3; paragraphs [0009]-[0018]; and figures 1-5.	1,2,4-6
A	JP 2014-057777 A (JEX INC.) 03 April 2014 See abstract; claims 1-6; and figures 1-5.	1-6
A	KR 10-2009-0089850 A (MEDELA HOLDING AG.) 24 August 2009 See abstract; claims 1-10; and figures 1-9.	1-6
A	US 2008-0262420 A1 (DAO, S. et al.) 23 October 2008 See abstract; claims 1, 10; and figures 1-14.	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 JULY 2016 (11.07.2016)	**12 JULY 2016 (12.07.2016)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 189 Sconsa-ro, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/KR2016/005271

Patent document cited in search report	Publication date	Patent family member	Publication date
US 2014-0052056 A1	20/02/2014	US 8702646 B2	22/04/2014
KR 20-2013-0000616 U	28/01/2013	KR 20-0466652 Y1	06/05/2013
JP 2014-057777 A	03/04/2014	NONE	
KR 10-2009-0089850 A	24/08/2009	AU 2007-318174 A1	15/05/2008
		AU 2007-318174 B2	14/07/2011
		CA 2667089 A1	15/05/2008
		CA 2667089 C	10/07/2012
		CN 101553264 A	07/10/2009
		CN 101553264 B	06/08/2014
		EP 2077868 A2	15/07/2009
		JP 2010-508117 A	18/03/2010
		JP 2013-013793 A	24/01/2013
		JP 5121840 B2	16/01/2013
		US 2008-0171970 A1	17/07/2008
		US 8187227 B2	29/05/2012
		WO 2008-057218 A2	15/05/2008
		WO 2008-057218 A3	15/05/2008
US 2008-0262420 A1	23/10/2008	US 7559915 B2	14/07/2009

Form PCT/ISA/210 (patent family annex) (January 2015)

국제조사보고서

국제출원번호
PCT/KR2016/005271

A. 발명이 속하는 기술분류(국제특허분류(IPC))

A61M 1/06(2006.01)i

B. 조사된 분야

조사된 최소문헌(국제특허분류를 기재)
A61M 1/06; A61J 9/00; A61M 31/00

조사된 기술분야에 속하는 최소문헌 이외의 문헌
한국등록실용신안공보 및 한국공개실용신안공보: 조사된 최소문헌란에 기재된 IPC
일본등록실용신안공보 및 일본공개실용신안공보: 조사된 최소문헌란에 기재된 IPC

국제조사에 이용된 전산 데이터베이스(데이터베이스의 명칭 및 검색어(해당하는 경우))
eKOMPASS(특허청 내부 검색시스템) & 키워드:착유기, breast pump, 밀착허우징, 캡커넥터, 꼭때기 커넥터, 유동격리막, 에어관, 공기, 밸브, 세척

C. 관련 문헌

카테고리*	인용문헌명 및 관련 구절(해당하는 경우)의 기재	관련 청구항
Y	US 2014-0052056 A1 (GARBEZ, D. 등) 2014.02.20 요약; 청구항 6; 단락 [0018]-[0022]; 및 도면 1-4 참조.	1,2,4-6
A		3
Y	KR 20-2013-0000616 U (서신혁) 2013.01.28 요약; 청구항 1-3; 단락 [0009]-[0018]; 및 도면 1-5 참조.	1,2,4-6
A	JP 2014-057777 A (JEX INC.) 2014.04.03 요약; 청구항 1-6; 및 도면 1-5 참조.	1-6
A	KR 10-2009-0089850 A (메델라 홀딩 아게) 2009.08.24 요약; 청구항 1-10; 및 도면 1-9 참조.	1-6
A	US 2008-0262420 A1 (DAO, S. 등) 2008.10.23 요약; 청구항 1, 10; 및 도면 1-14 참조.	1-6

☐ 추가 문헌이 C(계속)에 기재되어 있습니다.

☒ 대응특허에 관한 별지를 참조하십시오.

* 인용된 문헌의 특별 카테고리:

"A" 특별히 관련이 없는 것으로 보이는 일반적인 기술수준을 정의한 문헌

"E" 국제출원일보다 빠른 출원일 또는 우선일을 가지나 국제출원일 이후에 공개된 선출원 또는 특허 문헌

"L" 우선권 주장에 의문을 제기하는 문헌 또는 다른 인용문헌의 공개일 또는 다른 특별한 이유(이유를 명시)를 밝히기 위하여 인용된 문헌

"O" 구두 개시, 사용, 전시 또는 기타 수단을 언급하고 있는 문헌

"P" 우선일 이후에 공개되었으나 국제출원일 이전에 공개된 문헌

"T" 국제출원일 또는 우선일 후에 공개된 문헌으로, 출원과 상충하지 않으며 발명의 기초가 되는 원리나 이론을 이해하기 위해 인용된 문헌

"X" 특별한 관련이 있는 문헌. 해당 문헌 하나만으로 청구된 발명의 신규성 또는 진보성이 없는 것으로 본다.

"Y" 특별한 관련이 있는 문헌. 해당 문헌이 하나 이상의 다른 문헌과 조합하는 경우로 그 조합이 당업자에게 자명한 경우 청구된 발명은 진보성이 없는 것으로 본다.

"&" 동일한 대응특허문헌에 속하는 문헌

국제조사의 실제 완료일	국제조사보고서 발송일
2016년 07월 11일 (11.07.2016)	2016년 07월 12일 (12.07.2016)

ISA/KR의 명칭 및 우편주소
대한민국 특허청
(35208) 대전광역시 서구 청사로 189, 4동 (둔산동, 정부대전청사)
팩스 번호 +82-42-481-8578

심사관
장봉호
전화번호 +82-42-481-3353

서식 PCT/ISA/210 (두 번째 용지) (2015년 1월)

국제조사보고서
대응특허에 관한 정보

국제출원번호
PCT/KR2016/005271

국제조사보고서에서 인용된 특허문헌	공개일	대응특허문헌	공개일
US 2014-0052056 A1	2014/02/20	US 8702646 B2	2014/04/22
KR 20-2013-0000616 U	2013/01/28	KR 20-0466652 Y1	2013/05/06
JP 2014-057777 A	2014/04/03	없음	
KR 10-2009-0089850 A	2009/08/24	AU 2007-318174 A1	2008/05/15
		AU 2007-318174 B2	2011/07/14
		CA 2667089 A1	2008/05/15
		CA 2667089 C	2012/07/10
		CN 101553264 A	2009/10/07
		CN 101553264 B	2014/08/06
		EP 2077868 A2	2009/07/15
		JP 2010-508117 A	2010/03/18
		JP 2013-013793 A	2013/01/24
		JP 5121840 B2	2013/01/16
		US 2008-0171970 A1	2008/07/17
		US 8187227 B2	2012/05/29
		WO 2008-057218 A2	2008/05/15
		WO 2008-057218 A3	2008/05/15
US 2008-0262420 A1	2008/10/23	US 7559915 B2	2009/07/14

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/26/2024 02:44:37 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	66125999	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-06-26-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	167 KB
2024-06-26-sIDS-Pleading-4944-0120006.pdf	2	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-06-26-sIDS-SB08-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	137 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_EP4000661A1_EFS.pdf	21	Foreign Reference	725 KB

FOR_3_WO2016186452A1_EFS.pdf	25	Foreign Reference	725 KB
NPL_1_Decl.-R.-Bauer.pdf	137	Non Patent Literature	1938 KB
FOR_2_WO2005114113A2.pdf	33	Foreign Reference	299 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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2024-06-26-sIDS-SB08-0120006.pdf	4A0E3DD3D795AF0A6431008A28514B2AF128D5EAA94C959413EA7B75A6545364187AC8A41B10C64B789AF83DCFADCCD4F58F0DE2CF0ACA1022FE2745F6C5BB39
FOR_1_EP4000661A1_EFS.pdf	B745B9F554D2E2E27DE340DCB116E54F3661D28AC0F2C6453EEACAE3AC4B20A2FF9E0857E0F4AD730632F6305E116651A5C1DB51DE0797692329CE432D59FF1A
FOR_3_WO2016186452A1_EFS.pdf	FA6A932E81BCE2A9BBD7DC914A2F9433AD61F68CB41DEC00F693E9A8C7CF1407BF7CE23A779753154C593FDCFFA822BAA84170DE2E3CC2B0A36031B87B023CB0
NPL_1_Decl.-R.-Bauer.pdf	1B07AD03FC623E2491245882C471749BC4B34C9FEDFEB985C0875DC79B8BEE486FE74810D52685837C31FD765F0DB624F7FF7409F5379467C4AD244C1E0ADBA5
FOR_2_WO2005114113A2.pdf	F205E8F44F90C29BB101F74C751CA75830F9AA503BF167F8310C04CD172A50EA7258EFAD29EDF240C9814C3F4AB22A1D7D

EE477860D19030713BB2364011456C

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 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

26111 7590 06/26/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 06/26/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	09/26/2024

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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 the USPTO patent electronic filing system.

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

26111 7590 06/26/2024
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

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 the USPTO patent electronic filing system 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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	09/26/2024

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/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 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)

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

☐ Electronic Payment via the USPTO patent electronic filing system ☐ 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

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.

☐ Applicant asserting small entity status. See 37 CFR 1.27

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.

☐ Applicant changing to regular undiscounted fee 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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 06/26/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 06/26/2024

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) 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));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/181,057	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 12February2024.
   ☐ 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/
Primary Examiner, Art Unit 3783

Continuation of 3. The allowed claim(s) is/are: 1,3-22,24-25 and 28-34

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.

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.

The application has been amended as follows:

Amend **claim 6** as follows:

wherein the breast shield is configured to rotate smoothly around [[a]] the nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto [[a]] the breast.

Amend **claim 7** as follows:

wherein the breast shield is configured to present, in use, a single continuous surface to [[a]] the nipple and [[a]] the breast.

Amend **claim 22** as follows:

wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of [[a]] the bra.

Amend **claim 32** as follows:

the guide lines are configured to enable a user to visually inspect whether that breast shield is sized for [[a]] the nipple of the user when the nipple is placed in the nipple tunnel.

Allowable Subject Matter

Claims 1, 3-22, 24, 25, and 28-34 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 device.

The closest prior art of record is Silver (20020198489).

Regarding independent claim 1, Silver fails to teach among all the limitations or render obvious guide lines that are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved and to visually define a correct spacing of the nipple from the side wall of the nipple tunnel, in combination with the total structure and function as claimed. Instead, Silver teaches longitudinal stiffening ribs (ribs 1160, 1164, 1166 in fig. 28) serve to reduce the tendency of the shield to expand or contract along its length (paragraph 202). There is no indication in Silver whether or not these ribs would be configured to visually define a correct spacing between the nipple and the sidewall of the nipple tunnel.

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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Primary Examiner, Art Unit 3783

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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	01/12/2022	10/17/2022	03/24/2023	10/06/2023	06/13/2024				
	1	✓	✓	✓	✓	=				
	2	✓	-	-	-	-				
	3	✓	✓	✓	✓	=				
	4	✓	✓	✓	✓	=				
	5	✓	✓	✓	✓	=				
	6	✓	✓	✓	✓	=				
	7	✓	✓	✓	✓	=				
	8	✓	✓	✓	✓	=				
	9	✓	✓	✓	✓	=				
	10	✓	✓	✓	✓	=				
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	17	✓	✓	✓	✓	=				
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	25	✓	✓	✓	✓	=				
	26	-	-	-	-	-				
	27	-	-	-	-	-				
	28	✓	✓	✓	✓	=				
	29	✓	✓	✓	✓	=				
	30	✓	✓	✓	✓	=				
	31	✓	✓	✓	✓	=				
	32	✓	✓	✓	✓	=				
	33	✓	✓	✓	✓	=				
	34		✓	✓	✓	=				

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					**Type**	**Version**
A61M	/	1	/	062	F	2014-02-04
A61M	/	1	/	067	I	2021-05-01
A61M	/	1	/	06935	I	2021-05-01
A61M	/	1	/	0697	I	2021-05-01
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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	13 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20240613

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

CPC						
Symbol					**Type**	**Version**
A61M	/	2205	/	7536	A	2013-01-01
A61M	/	2205	/	80	A	2013-01-01
A61M	/	2205	/	8206	A	2013-01-01
A61M	/	2209	/	082	A	2013-01-01
A61M	/	2209	/	088	A	2013-01-01

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	13 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20240613

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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)**					

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783 (Primary Examiner) 13 June 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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		10		19		28								
	2		11		20		29								
	3		12		21		30								
	4		13		22		31								
	5		14		23		32								
	6		15		24		33								
	7		16		25		34								
	8		17		26										
	9		18		27										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	13 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20240613

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	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 SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf
Updated search	10/06/2023	cbf
Updated search	06/13/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see SEARCH history	06/13/2024	cbf

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	11,135 A	06-20-1854	Needham	
	US2	949,414 A	02-15-1910	Cunningham	
	US3	3,840,012 A	10-08-1974	Rushton, Jr.	
	US4	4,263,912 A	04-28-1981	Adams	
	US5	4,270,538 A	06-02-1981	Murphy	
	US6	4,772,262 A	09-20-1988	Grant et al.	
	US7	4,857,051 A	08-15-1989	Larsson	
	US8	4,929,229 A	05-29-1990	Larsson	
	US9	5,514,166 A	05-07-1996	Silver et al.	
	US10	5,571,084 A	11-05-1996	Palmer	
	US11	5,954,690 A	09-21-1999	Larsson	
	US12	6,379,327 B2	04-30-2002	Lundy	
	US13	2003/0191433 A1	10-09-2003	Prentiss	
	US14	6,652,484 B1	11-25-2003	Hunckler et al.	
	US15	2005/0154349 A1	07-14-2005	Renz et al.	
	US16	2006/0111664 A1	05-25-2006	Samson et al.	
	US17	7,223,255 B2	05-29-2007	Myers et al.	
	US18	7,559,915 B2	07-14-2009	Dao et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	CN 2452494 Y	10-10-2001	XU JIANHUA		X
	FP2	EP 3299043 A1	03-28-2018	MEDELA HOLDING AG		X
	FP3	WO 1990000413 A1	01-25-1990	MEDELA INC		
	FP4	WO 2002102437 A2	12-27-2002	WHISPER WEAR INC		
	FP5	WO 2008137678 A1	11-13-2008	WHISPER WEAR INC		
	FP6	WO 2016014494 A1	01-28-2016	EXPLORAMED NC7 LLC		
	FP7	WO 2017139437 A1	08-17-2017	EXPLORAMED NC7 LLC		

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

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO	Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17/181,057
	Filing Date	02/22/2021
	First Named Inventor	Jonathan O'TOOLE
	Art Unit	3783
	Examiner Name	FREDERICKSON, Courtney B
Sheet 2 of 4	Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP8	WO 2018054758 A1	03-29-2018	MEDELA HOLDING AG		
	FP9	WO 2019080995 A1	05-02-2019	MEDELA HOLDING AG		X

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Amended Claims in Response to Rule 71(3) (clean) regarding European Patent Application No. 18741597.1 to Positec Power Tools (Suzhou) Co. Ltd; dated February 20, 2024; 4 pages.	
	NPL2	Breastfeeding and the Use of Human Milk, American Academy of Pediatrics, Pediatrics, Vol. 100, No. 6, December 6, 1997; pp. 1035-1039.	
	NPL3	Courage, Katherine, "The Sucky History of the Breast Pump," Innovation, Smithsonian Magazine, September 12, 2022; 17 pages. Available at: https://www.smithsonianmag.com/innovation/sucky-history-of-the-breast-pump-180980653/	
	NPL4	GB 201709566.2 entitled 'Breast Pump' filed June 15, 2017; 44 pages (Priority Document 1).	
	NPL5	GB201709564.7 entitled' A Liquid Level Measurement System' filed June 15, 2017; 24 pages (Priority Document 2).	
	NPL6	GB 201709561.3 entitled 'Bra Clip' filed June 15, 2017; 24 pages (Priority Document 3).	
	NPL7	GB 201809036.5 entitled 'Breast Pump System' filed June 1, 2018; 169 pages (Priority Document 4).	
	NPL8	Illinois Nursing Mothers in the Workplace Act, Illinois General Assembly, July 12, 2001; 2 pages. Available at: https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2429	
	NPL9	Omnexus, "Silicone Rubber: Complete Guide on Highly Durable Elastomer" 28.02.2024, [cited 28.02.2024] Available from: [https://omnexus.specialchem.com/selection-guide/silicone-rubber-elasto]	
	NPL10	Reply to communication under Rule 71(3) regarding European Patent Application No. 18741597.1 to Positec Power Tools (Suzhou) Co. Ltd, dated February 20, 2024; 1 page.	

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

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	4	Attorney Docket Number	4944.0120006

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL11	Sex Descrimination- Breastfeeding and Expressing Milk, British Columbia Human Righs Commission Policy and Procedure Manual, August 1, 2000; 2 pages. Available at: http://www.infactcanada.ca/br_bc_humanrights.htm	
	NPL12	Women's Health Today, "How to Choose a Breast Pump" 08.11.2017, 8 pages; Available from: [https://womenshealthtoday.blog/2017 /11 /08/how-to-choose-a-breast-pump/] original file name: D2 How to Choose a Breast Pump_Womens Health Today.pdf	
	NPL13	Wyatt, Stephanie, MSN, APN, "Challenges of the Working Breastfeeding Mother, Workplace Solutions," AAOHN Journal, Vol. 50, No. 2, February 2022; pp. 61-66,	

/COURTNEY B FREDRICKSON/ 06/13/2024

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

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	4	of	4	Attorney Docket Number	4944.0120006

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.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-04-17
Name/Print	Yangbeini Wang	Registration Number	800,005

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 CFR1.14. 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.**

22122310.1

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

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-10195321-B2	02-05-2019	TATTERFIELD et al.	
	002	US-10335525-B2	07-02-2019	FELBER; Armin et al.	
	003	US-11806454-B2	11-07-2023	DE BECDELIEVRE; Thibault et al.	
	004	US-20060106334-A1	05-18-2006	JORDAN; Alan, et al.	
	005	US-20080171970-A1	07-17-2008	LUZBETAK; Mark A. et al.	
	006	US-20120136325-A1	05-31-2012	ALLEN; Julie et al.	
	007	US-20160174728-A1	06-23-2016	KARP et al.	
	008	US-20160304004-A1	10-20-2016	SANDBOTHE et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-109621041-A	04-16-2019	BINHAI CHANGZHENG ENTERPRISE MAN CO LTD [CN]		☐
	002	JP-2016508804-A	03-24-2016	KONINKLIJKE PHILIPS N.V. [NL]		☐
	003	WO-2018229504-A1	12-20-2018	CHIARO TECH LIMITED [GB]		☐
	004	WO-9625187-A1	08-22-1996	MEDELA INC [US]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	17/181,057
				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
		None	

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	06/13/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

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

OR

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

☐ See attached certification statement.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-03-26
Name/Print	Yangbeini Wang	Registration Number	800,005

21575616.1

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

Bibliographic Data

Application No: 17/181,057

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.
02/22/2021	604	3783	4944.0120006
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

This application is a CON of 16009547 06/15/2018 PAT 10926011

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

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03/02/2021

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
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L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20120277636" OR "20130023821" OR "20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR				

		"8057425" OR "8118772" OR "8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
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L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT;	OR	ON	ON	2022/01/14

			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				12:42 PM
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"20090281485" "20120165729" "5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
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			USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				05:34 PM
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L38	69	(35 36) AND ((line indicat$4 indicia icon signal signif$6) WITH nipple WITH (placement align$4 width siz$4) WITH (proper$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO;	OR	ON	ON	2024/03/12 05:57 PM

		correct$4 appropriat$4))	JPO; DERWENT; IBM_TDB)				
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			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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L52	14008312	line.clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/06/13 05:34 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	76349	breast.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N2	480637	pump$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N3	148822	shield.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N4	57138	interchang$6.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N5	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N6	250019	spacing.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N7	1665436	line.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:34 PM
N8	0	N1 AND N2 AND N3 AND N4 AND N5 AND N6 AND N7	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/13 05:35 PM

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DESCRIPTION WO2019080995A1

[0001]

13 TITLE

[0002]

17 BREAST PUMP

[0003]

21 TECHNICAL FIELD

[0004]

25 The present invention relates to a breast pump for pumping out human breast milk as well as a breast cap, a milk collection container and a method for operating a breast pump.

[0005]

30 STATE OF THE ART Devices for pumping out human breast milk are well known.

31 Basically there are two different types: the first are operated manually, i.e. the negative pressure required for pumping out is generated by manually operating the vacuum pump.

33 In the second types, the vacuum pump is electrically operated.

34 These vacuum pumps are connected to a breast shield either directly or via a vacuum line.

35 The breast shield has an interior to accommodate the mother's breast or her nipple. The negative pressure is transferred to the interior via a first line, the pumped milk flows via a second line into a milk collection container.

[0006]

41 WO 2016/014494 AI and WO 2016/014469 AI describe a compact breast pump in which pumped milk is transported into a milk collection container under positive pressure.

43 For this purpose, for example, a milk pipe is cyclically squeezed. WO 201 1/035447 AI discloses a breast pump in which the vacuum line simultaneously forms the milk line. The pumping chamber, in which the negative pressure is generated, fills with milk during pumping, so that the pumping system changes from a pneumatic system to a hydraulic system and the milk that has already been pumped out becomes the working fluid. So that the pump chamber can fill with milk, a valve is arranged at the outlet of the pump chamber, which leads to the milk collecting container. This valve only opens at a certain pressure within the pump chamber, i.e. when the pump chamber is sufficiently filled with milk.

[0007]

54 This combined pneumatic and hydraulic pump has several advantages.

55 The system has no or almost no dead volume. The pumping unit can be minimized because once the system has been filled with milk, only a low pumping power is required to pump out more milk. In particular, batteries with a lower capacity can be used than with pneumatic vacuum pumps. The vacuum pump can therefore be made more cost-effective and smaller. The breast pump is particularly suitable for so-called “hands-free” applications in which the breast pump is worn on the body and no hands are needed to hold the breast shield. Due to the minimized dead volume, the applied pressure is also easier to control. This means that individually optimized pumping parameters can be selected for each mother.

[0008]

66 A breast pump is also described in WO 2013/049944 A2, which changes from a pneumatic to a hydraulic pump system.

68 There is a pressure sensor in the pump chamber, which includes a flag attached to a flexible membrane.

[0009]

73 PRESENTATION OF THE INVENTION

[0010]

77 It is therefore an object of the invention to optimize the breast pump mentioned above.

[0011]

81 This task is solved by a breast pump according to claims 1, 8, 35, 36, 39 and 42, a milk collection container according to claim 41, a breast shield according to claim 43 and a method with the features of claim 44.

[0012]

87 In a preferred embodiment, the breast pump according to the invention for pumping out human breast milk has a housing with a drive unit, a pump chamber with a flexible pump membrane driven by the drive unit to generate a vacuum and a breast shield with an interior for receiving a mother's breast.

91 The interior can be subjected to a cyclically changing negative pressure by means of the pump chamber, with a milk channel leading from the interior through a first inlet opening into the pump chamber, with pumped milk flowing from the interior of the breast shield through the milk channel into the pump chamber, and with the pump chamber having an outlet opening , through which the pumped milk flows from the pump chamber into a milk collecting container.

96 A multi-part hygiene module is present, the hygiene module having a first part with a flow opening for connection to the interior, a valve body with at least one valve and a second part with a rigid shell to form the pump chamber, the valve body between the first and second parts is arranged and wherein the hygiene module as a whole can be sealingly and releasably connected to the housing of the breast pump.

[0013]

104 This hygiene module has a compact design.

105 It is easy to assemble and disassemble, making it easy to clean the relevant parts of the breast pump.

107 The use of a valve body in the hygiene module makes manufacturing, assembly and cleaning even easier.

[0014]

112 The rigid shell preferably has a milk path which extends from the pump chamber into a milk collecting container and which runs at least over a partial area perpendicular to a drive axis of the pump membrane.

115 The milk path preferably runs in a plane perpendicular to the drive axis, the milk path in this plane extending over at least half of the height of the pump chamber, preferably over the entire height of the pump chamber.

118 The course of this milk path makes it possible to at least partially, preferably completely fill the pumping chamber with pumped milk, so that during pumping there is a change from a pneumatic pumping system to a mixed or even completely hydraulic pumping system.

[0015]

124 Preferably, the valve body has at least one flow valve and one ventilation valve.

125 Preferably, the valve body is formed in one piece from a flexible material. This makes manufacturing, assembly and cleaning easier.

[0016]

130 Preferably the first part is a component of the breast shield.

131 This means that the breast pump can be made compact and the hygiene module can be easily attached to the breast pump without the breast shield also having to be installed.

[0017]

136 The breast shield preferably has a flange for a detachable connection to the housing.

[0018]

140 The connection to the housing can be established in a particularly simple manner if it is positive and non-positive, preferably a bayonet lock.

142 In a further preferred embodiment, the breast pump according to the invention for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, the interior being able to be subjected to a cyclically changing negative pressure by means of the pump chamber.

146 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. When the breast pump is in the vertical position of use, the outlet opening is arranged in an upper region of the pumping chamber and/or above the inlet opening, at least at the beginning of a pumping process.

[0019]

155 This means that the pump chamber can be almost completely filled with milk and the system can be converted from a pneumatic to a hydraulic or mixed pneumatic/hydraulic system within a very short time.

158 The same drive power for the pumping means, e.g. B. the pump membrane, leads to a greater pump performance, i.e. to a higher negative pressure in the pump chamber and thus in the interior of the breast shield. Batteries with a lower capacity can be used. This reduces manufacturing costs, increases the overall service life of the pump and minimizes the size of the drive unit.

[0020]

166 The milk channel preferably forms a vacuum channel for applying the cyclically changing negative pressure to the interior of the breast shield.

168 This means that the vacuum is first applied via the same line or channel and the milk is then sucked out. The same line or channel is used for both working fluids, i.e. Air and milk, used.

[0021]

173 Depending on the embodiment, the pump is a piston pump, a diaphragm pump or another type of vacuum pump.

175 Preferably, however, the pump chamber has a rigid first shell and a flexible pump membrane, wherein the pump membrane lies sealingly against the first shell and wherein the pump membrane is driven and by its movement relative to the first shell a negative pressure can be generated in the pump chamber. A flexible media separation membrane is preferably arranged between the rigid shell and the flexible pump membrane, so that the pump membrane is protected from contact with pumped milk. Milk and air that are present in the breast shield only reach the media separation membrane. The pump membrane and the other parts of the breast pump are therefore protected from contamination.

[0022]

186 The media separation membrane can be easily separated from the pump membrane.

187 It is preferably part of the hygiene module already mentioned. The media separation membrane can preferably be separated from the remaining parts of the hygiene module and thus cleaned in a simple manner. The remaining parts of the hygiene module can also be separated from one another as necessary so that they can be cleaned and then put back together in a simple manner and preferably without tools and used again.

[0023]

195 The first shell preferably has an outlet channel which extends from the outlet opening of the pump chamber to an outlet, the outlet channel extending at least over a partial area in a direction perpendicular to the direction of movement of the pump membrane.

198 It preferably runs in a plane perpendicular to this direction of movement, with the channel preferably extending over at least half the height of the pump chamber, preferably over the entire pump chamber.

[0024]

204 In other embodiments, the channel is partially or completely designed as a closed channel.

205 Preferably, however, the pump membrane or, if present, the media separation membrane

closes the outlet channel of the rigid first shell to form a channel that is closed except for the release opening and the outlet.

[0025]

211 The trough preferably extends adjacent to the pump chamber and not within it.

[0026]

215 In a preferred embodiment, the breast shield has a first passage opening, which forms part of the milk canal, the passage opening being arranged in an upper region of the interior when the breast shield is in the position of use, at least at the beginning of the pumping process, so that the interior below the first passage opening with pumped milk Milk can be filled.

[0027]

222 This allows the breast shield to be partially or completely filled with milk at the start of the pumping process.

224 This massively shortens the time until switching to the hydraulic pump system.

225 Usually, the interior of the breast shield is filled first and then the pump chamber before the milk reaches the milk collection container for the first time.

[0028]

230 Preferably, the milk channel can be closed by means of a first valve in order to remove the pumped milk from the pumping chamber at the end of the pumping process.

232 This valve is preferably the same valve that opens and closes automatically when the milk is pumped out.

234 It is now permanently closed for emptying. Depending on the embodiment, the closure takes place manually or automatically, e.g. B. using the electronic control of the breast pump. If a valve is arranged subsequently, the first valve can always be open during the pumping process.

[0029]

241 Preferably, there is an emptying channel between the interior of the breast shield and the pump chamber, which runs separately from the milk canal, the emptying channel being closable by means of a second valve.

244 The emptying channel is closed during the pumping process and is open at the end of the pumping process. Depending on the embodiment, this is also done manually or automatically. The second valve preferably functions in the same or similar way as the first valve. It is preferably designed identically. It opens and closes during the pumping process when

emptying the breast shield in the same way as the first valve when pumping breast milk from the mother's breast. If a valve is arranged subsequently, the second valve can always be open during the emptying process.

[0030]

254 Preferably there is also a ventilation valve for ventilating the interior of the breast shield.

255 This is also preferably always closed during the pumping process and is opened manually or automatically to make emptying the breast shield easier.

[0031]

260 Preferably, the ventilation valve can be closed together with the second valve and can be opened together with it.

[0032]

265 In a preferred embodiment, a third valve is present which maintains a basic negative pressure when the cyclically changing negative pressure in the interior of the breast shield increases.

267 The pressure in the interior of the breast shield is therefore below atmospheric pressure throughout the entire pumping process and preferably also during emptying.

269 This reduces the strain on the nipple and has a positive effect on the flow of milk from the mother's breast.

[0033]

274 There is preferably a fourth valve in the milk channel, which opens and closes in accordance with the negative pressure applied.

276 This fourth valve is arranged downstream of the first valve in the direction of pumping out the milk. However, the fourth valve can also be formed by the first valve, as already described above. However, if it is downstream, it can be designed, for example, as a flutter valve in the valve body.

[0034]

283 Preferably, there is a fifth valve in the emptying channel, which opens and closes in accordance with the negative pressure applied.

285 This fifth valve is arranged downstream of the second valve in the direction of emptying the milk. The fifth valve can be formed by the second valve as described above. If it is downstream, it can be, for example, a flutter valve in the valve body.

[0035]

291 Preferably at least one part, preferably all of the valves mentioned are arranged in a common valve body.

293 This makes manufacturing easier and minimizes costs.

[0036]

297 The valve body is preferably designed in one piece and flexible.

298 It is preferably made of silicone.

[0037]

302 The breast pump preferably has a pump housing with a drive for the pump membrane, the rigid first shell being detachably connected to the pump housing.

304 This makes assembly easier, even after cleaning by the mother.

[0038]

308 Preferably, the first rigid shell is part of a multi-part module which can be connected together to the pump housing, the module further having at least the valves mentioned.

310 This module is preferably the hygiene module mentioned above.

[0039]

314 Preferably, the first rigid shell is part of an adapter part, with the valve body being held in a receptacle of the adapter part.

316 This makes assembly easier and, in particular, enables a modular structure and the use of a hygiene module.

[0040]

321 Preferably, the module further comprises a manual actuation means for simultaneously actuating the first and second valves.

323 Manually operating the two valves is a cost-effective and reliable solution. Preferably, the adapter part and the actuating part cannot be detached from one another in a non-destructive manner. This ensures that the module is always put together correctly and can only be used together with all elements. Preferably, the breast pump has a pump housing, wherein the breast shield can be releasably attached to the pump housing and by attaching the breast shield to the pump housing, parts which lie between the breast shield and the pump housing are sealingly connected to one another, so that a tight connection between the pump chamber and the interior of the breast shield arises. The breast shield is easy to hold by hand, making it easier to assemble the pump. Since the remaining parts also fit tightly due to the attachment of

the breast shield to the pump housing, the breast pump is ready for use with a single movement, namely the attachment of the breast shield to the pump housing.

334 The individual parts can be removed just as easily for cleaning. Preferably the breast shield and the valve body are part of the module.

[0041]

339 The breast pump preferably has a pump housing to which the breast shield can be releasably attached, the breast pump further having a milk collecting container which can be attached to the pump housing by means of a snap lock.

342 Fastening the milk collection container using a snap lock is unconventional. Twist locks are usually used. Thanks to the snap closure, the container can be designed differently and, in particular, can be attached and removed more quickly.

[0042]

348 The milk collecting container preferably has a base body and a lid, the lid being at least partially air-permeable and liquid-impermeable.

350 This lid thus forms a valve which is used for ventilation, but which also allows the container to be turned upside down without loss of liquid. The lid preferably has an air-permeable and liquid-impermeable membrane. Preferably, the lid is clamped between the milk collection container and the pump and can be positioned using spacer pins. In addition, the lid is preferably provided with a one-way valve, which leads from the pump chamber into the milk collecting container.

[0043]

359 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, wherein the interior can be subjected to a cyclically changing negative pressure by means of the pump chamber.

362 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. An emptying channel is present between the interior of the breast shield and the pumping chamber, which runs separately from the milk canal, the emptying channel being closable by means of a valve, the emptying channel being closed during the pumping process and being open at the end of the pumping process. This makes it easy to remove milk from the breast shield at the end of the pumping process. The emptying channel is preferably subjected to a negative pressure by means of the pump chamber in order to actively pump out the milk and force it into the milk collecting container.

[0044]

375 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, wherein the interior can be subjected to a cyclically changing negative pressure by means of the pump chamber.

378 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. The breast pump has a pump housing, a pump membrane and a module, the module having at least one rigid shell to form the pump chamber and the breast shield. The module can be attached as a unit to the pump housing, creating a tight connection between the pump chamber and the interior of the breast shield and the pump membrane being held sealingly between the module and the pump housing. This makes it easier for the mother to clean the relevant parts of the breast pump and to assemble it after such cleaning.

[0045]

391 The module preferably also has a valve body which is arranged between the breast shield and the rigid shell.

393 The valve body and the corresponding areas of the first and second parts, which preferably have sealing seats for the valves of the valve body, form a common valve unit, also called a valve construct.

[0046]

399 Preferably, the module further has a manual actuation means for actuating at least one valve of the valve construct.

[0047]

404 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield for receiving a mother's breast, a pump housing and a milk collecting container, the pump housing being detachably connectable to the breast shield on the one hand and detachably connected to the milk collecting container on the other hand.

408 The milk collection container can be attached to the pump housing using a snap lock.

[0048]

412 This breast pump preferably has a pump chamber and a milk channel through which pumped milk flows from an interior of the breast shield into the pump chamber, the pump chamber having an outlet which is connected to the milk collecting container and through which the pumped milk flows into the milk collecting container.

[0049]

419 In a preferred embodiment, there is a milk collecting container according to the invention for connection to a pump housing of a breast pump for pumping out human breast milk, the milk collecting container having a lid which faces the pump housing and which is permeable to air and impermeable to liquids at least in one area.

[0050]

426 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield for receiving a mother's breast and a pump housing, the breast shield being detachably connectable to the pump housing.

429 The breast shield can be connected to the pump housing using a bayonet lock.

430 In a preferred embodiment, a breast shield according to the invention is present, which is used to attach to a pump housing of a breast pump.

432 The breast shield has an interior for receiving the mother's breast and a connector for attachment to the pump housing, the connector being provided with a bayonet lock.

[0051]

437 In a preferred variant of a method according to the invention for operating a breast pump for pumping out human breast milk, the breast pump has a breast shield with an interior for receiving a mother's breast and a pump chamber, the interior being subjected to a cyclically changing negative pressure by means of the pump chamber.

441 In a first pumping phase, the interior is subjected to the cyclically changing negative pressure in order to pump milk from the mother's breast, the interior being filled with pumped milk without any pumped milk flowing out of the interior.

444 In a second pumping phase, pumped milk flows from the interior into the pumping chamber and the pumping chamber is filled with pumped milk. In a third pumping phase, the pumped milk flows from the pump chamber into a milk collecting container, with the interior and the pump chamber remaining filled with pumped milk. The change from the second pumping phase to the third pumping phase occurs when a level of the pumped milk reaches an outlet opening which leads from the pumping chamber to the milk collecting container, whereby milk flows through the outlet opening from the pumping chamber into the milk collecting container.

[0052]

454 Thanks to this process, the pumping system switches relatively quickly from a pneumatic to a hydraulic or predominantly hydraulic pumping system.

456 This means that smaller drives and less powerful motors can be used.

[0053]

460 Preferably, the first pumping phase is a completely or predominantly pneumatic pumping phase and the second pumping phase is a completely or predominantly hydraulic pumping phase.

[0054]

465 In a preferred variant of the method, the interior space is almost completely filled in the first pumping phase.

467 In a preferred variant, the interior and/or the pumping chamber are almost completely filled with pumped milk in the second and/or third pumping phase.

[0055]

472 Preferably, the change from the first pumping phase to the second pumping phase takes place in that a filling level of the pumped milk reaches a first through-opening, which leads from the interior to the pumping chamber, whereby milk flows through the first through-opening from the interior into the pumping chamber.

[0056]

479 In the third pumping phase, the pumped milk preferably flows through the first through opening into the pump chamber and through the outlet opening into the milk collecting container.

[0057]

484 Preferably, in a fourth pumping phase, the interior is emptied and the milk that has already been pumped out is guided from the interior to the milk collecting container through a second through opening.

[0058]

490 Preferably, the first through opening can be closed with a first valve and the second through opening can be closed with a second valve, the second through opening being always closed during the first to third pumping phases.

493 Preferably, the first through opening is always closed during the fourth pumping phase.

[0059]

497 Preferably, the second through opening leads from the interior into the pump chamber and is in fluid communication with the outlet opening via the pump chamber.

[0060]

502 Preferably, a base negative pressure is maintained during at least part of the pumping phases, preferably during the first, second and third pumping phases.

504 Preferably, a third valve is present, which first opens and then closes when the pressure of the cyclically changing negative pressure increases towards atmospheric pressure, thereby maintaining the basic negative pressure.

507 Further embodiments and variants of the method are specified in the dependent claims.

[0061]

511 The individual elements listed in the claims can also be combined to form other combinations without having to adopt all the features of the claims.

513 In particular, individual elements can also be used in purely pneumatic breast pumps, especially in pneumatic membrane breast pumps.

[0062]

518 BRIEF DESCRIPTION OF THE DRAWINGS

[0063]

522 Preferred embodiments of the invention are described below with reference to the drawings, which serve only for explanation and are not to be interpreted in a restrictive manner.

524 Shown in the drawings:

[0064]

528 Figure 1 is a perspective view of a breast pump according to the invention,

[0065]

532 Figure 2 is an exploded view of the breast pump according to Figure 1 in a perspective view;

[0066]

536 Figure 3 is an exploded view of the breast pump according to Figure 1 in a further perspective view; Figure 4 shows a partial section through the breast pump according to Figure 1 in a first perspective view;

[0067]

542 Figure 5 shows a partial section through the breast pump according to Figure 1 in a second perspective view;

[0068]

547 Figure 6 shows a longitudinal section through a hygiene module, attached to a

[0069]

551 Carrier module of the breast pump according to Figure 1 in an exploded view; Figure 7 is a perspective view of the assembled hygiene module according to Figure 6;

[0070]

556 Figure 8a is a perspective view of a breast shield of the breast pump according to

[0071]

560 Figure 1;

[0072]

564 Figure 8b shows a partial section through the breast shield according to Figure 8a;

[0073]

568 Figure 9a is a perspective view through a valve body of the breast pump according to Figure 1;

[0074]

572 Figure 9b shows a partial section through the valve body according to Figure 9a;

[0075]

576 Figure 9c shows a longitudinal section through the valve body according to Figure 9a;

[0076]

580 Figure 9d is a view of the valve body according to Figure 9a;

[0077]

584 Figure 10a is a perspective view of an adjusting ring of the breast pump according to

[0078]
588 Figure 1;

[0079]
592 Figure 10b is a view of the adjusting ring according to Figure 10a;

[0080]
596 Figure I Ia is a perspective view of an adapter part of the breast pump according to

[0081]
600 Figure 1 from a first page;

[0082]
604 Figure 1Ib shows a partial section through the adapter part according to Figure I1a;

[0083]
608 Figure 11c is a perspective view of the adapter part according to Figure I1a from a second side;

[0084]
612 Figure 12a is a perspective view of a media separation membrane

[0085]
616 Breast pump according to Figure 1 from a first side;

[0086]
620 Figure 12b is a perspective view of the media separation membrane according to Figure

[0087]
624 12a from a second page;

[0088]

628 Figure 12c shows a longitudinal section through the media separation membrane according to Figure 12a; Figure 13a is a perspective view of a pump membrane of the breast pump according to Figure 1 from a first side;

[0089]

634 Figure 13b is a perspective view of the pump membrane according to Figure 13a from a second side; Figure 13c shows a longitudinal section through the pump membrane according to Figure 13a;

[0090]

640 Figure 14 is a perspective view of a carrier module of the breast pump according to Figure 1;

[0091]

644 Figure 15 is a perspective view of an upper frame part

[0092]

648 Milk collection container of the breast pump according to Figure 1;

[0093]

652 Figure 16 shows a longitudinal section through the upper frame part according to Figure 15 with a

[0094]

657 container valve;

[0095]

661 Figure 17 is a perspective view of a vessel in the milk collection container of the breast pump according to Figure 1; Figure 18 shows a schematic representation of the pump system according to the invention

[0096]

667 applying negative pressure;

[0097]
671 Figure 19a shows the pump system shown schematically according to Figure 1 in the

[0098]
675 Activation of the mother's breast in a first lifting position;

[0099]
679 Figure 19b shows the pump system according to Figure 19a in a second lifting position;

[0100]
683 Figure 19c is a graphical representation of the pressure within a breast shield

[0101]
687 Change from the first lifting position to the second lifting position according to Figures 19a and 19b; Figure 20a shows the pump system according to Figure 19a at the beginning of the milk flow from the

[0102]
693 chest in a first lifting position;

[0103]
697 Figure 20b shows the pump system according to Figure 20a in a second lifting position;

[0104]
701 Figure 20c is a graphical representation of the pressure within a breast shield

[0105]
705 Change from the first lifting position to the second lifting position according to Figures 20a and 20b;

[0106]

710 Figure 21a shows the pump system according to Figure 19a during the continuous

[0107]

714 milk flow from the breast in a first lifting position; Figure 21b shows the pump system according to Figure 21a in a second lifting position;

[0108]

719 Figure 21c is a graphical representation of the pressure within a breast shield

[0109]

723 Change from the first lifting position to the second lifting position according to

[0110]

727 Figures 21a and 21b;

[0111]

731 Figure 22a shows the pump system according to Figure 19a when the milk flow ends in a first stroke position;

[0112]

736 Figure 22b shows the pump system according to Figure 22a in a second lifting position;

[0113]

740 Figure 22c is a graphical representation of the pressure within a breast shield

[0114]

744 Change from the first lifting position to the second lifting position according to

[0115]

748 Figures 22a and 22b;

[0116]

752 Figure 23a shows the pump system according to Figure 19a when emptying in a first

[0117]
756 lifting position;

[0118]
760 Figure 23b shows the pump system according to Figure 23a in a second lifting position and Figure 23c shows a graphic representation of the pressure within a breast shield

[0119]
765 Change from the first lifting position to the second lifting position according to

[0120]
769 Figures 23a and 23b.

[0121]
773 DESCRIPTION OF PREFERRED EMBODIMENTS

[0122]
777 A preferred embodiment of the breast pump according to the invention is shown in FIGS. 1 to 17.

[0123]
782 The overview of the individual components

[0124]
786 As can be seen in Figure 1, the breast pump has a compact structure.
787 It has a pump housing 8 with a breast shield 2 attached to it and a milk collecting container 9 also attached to the pump housing 8.
789 A motor with a force transmission element, for example a spindle, is arranged in the pump housing 8.
791 The pump housing 8 also contains at least one electronic control for controlling the motor, actuation switch 86 for actuating the pump and an energy storage device.
793 Figures 2 and 3 show an exploded view of this breast pump.

794 It includes the mentioned breast shield 2 for receiving the mother's breast, a valve body 3 made of a flexible material, in particular silicone, an adapter part 4, a two-part adjusting ring 5, a media separation membrane 6, a pump membrane 7, a carrier module 8 ', which is part of the pump housing 8 as well as the already mentioned milk collection container 9.

[0125]

801 The milk collection container

[0126]

805 The milk collecting container 9 can preferably be latched onto the underside of the pump housing 8, preferably it can be releasably attached in a pivoting manner.

807 Corresponding latching elements 901, 902 can be seen in FIG. 17.

808 The pump housing 8 has matching latching elements, but not shown here.

[0127]

812 The milk collecting container 9 has a vessel 90 with an interior 900 for receiving the pumped milk (see Figure 17).

814 This vessel 90 is open at the top and can be closed with a lid.

815 The lid includes a rigid lower frame member 91, a rigid, semi-rigid or flexible cover 92 and a rigid upper frame member 93.

817 The lower frame part 91 corresponds to the shape of the circumference of the opening of the vessel 90 and lies sealingly on it.

819 The rigid upper frame part 93 clamps the cover between the lower and upper frame parts 91, 93.

821 Preferably, the two frame parts 91, 93 are glued together, welded or cannot be separated from one another in a non-destructive manner.

823 The cover 92 is a film or other membrane-like part which is permeable to air but impermeable to liquids.

825 Air can therefore escape from the vessel 90, but no liquid can escape.

[0128]

829 The upper frame part 93 preferably also corresponds in shape to the shape of the vessel 90, in particular its frame 930 corresponds to the shape of the lower frame part 91.

831 It is shown in detail in Figures 15 and 16.

832 In the frame 930 there are 92 struts 931 to reinforce and protect the cover.

833 A handle 933 makes lifting the lid easier.

834 Spacer pins 934, which are arranged on the frame 930 and protrude beyond it, ensure a distance from the pump housing 8 when the milk collecting container 9 is mounted, so that air

can escape from the container interior 900 into the environment.

837 A valve receptacle 932 is formed on the upper frame part 93 and forms the only liquid access into the interior of the vessel 90.

[0129]

842 A container valve 94, which is designed as a one-way valve, is arranged in this valve receptacle 932.

844 This means that when the lid is closed, liquid can only get into the milk collecting container 9, but not out.

846 The container valve 94 is preferably a duckbill valve as shown here.

[0130]

850 The hygiene module

[0131]

854 A hygiene module according to the invention is shown in Figures 6 and 7.

855 It includes at least the connector 23 of the chest tube 2, the valve body 3, the adapter part 4 and the adjusting ring 5.

857 As shown here, it can also include a flexible media separation membrane 6.

858 If the breast shield is made in one piece, it is part of the hygiene module as a whole.

859 The parts mentioned can, as shown in Figures 6 and 7, be put together to form a common assembly and releasably fastened together in the carrier module 8 '.

861 For this purpose, the connector 23 of the breast shield 2 can preferably be fastened in a positive and non-positive manner in corresponding receptacles, here two opposite side arms 80, of the carrier module 8 '.

864 The connection is preferably made via a bayonet lock, as shown here.

865 The connector 23 has a corresponding flange 22, the side arms 80 of the carrier module 8' have corresponding receptacles for the flange and the other elements of the bayonet lock.

[0132]

870 Thanks to the attachment of the breast shield to the carrier module 8 'and thus to the pump housing 8, the parts in between, i.e. the valve body 3, the adapter part 4 and the media separation membrane 6 of the hygiene module as well as the pump membrane 7, are also tightly connected to one another.

[0133]

877 The adjusting ring 5 is preferably not detachably attached to the adapter part 4 in a non-

destructive manner, and can be pivoted relative to the adapter part 4 about the longitudinal central axis of the hygiene module.

880 The individual parts of the device and their interaction are described below.

[0134]

884 The breast shield

[0135]

888 The breast shield 2 is shown in Figures 8a and 8b.

889 It is used to hold the mother's breast.

890 It has a funnel 20 for resting on the mother's breast and an interior 200, which can be subjected to a cyclically changing negative pressure and in which the mother's breast or at least the nipple is received.

893 The breast shield is preferably made in one piece and preferably from a rigid or semi-rigid plastic.

895 However, it can also be made in several parts.

896 It can also be used with a soft liner, e.g.

897 B. with a breast shield insert made of soft silicone.

898 The funnel 20 is followed by a connector 23 with an at least partially circumferential flange 22, which forms part of the bayonet lock mentioned.

900 The interior 200 merges into a through opening 21 on the side of the nozzle 23 facing away from the chest, which forms a channel running in the central longitudinal axis.

902 On the connector 23, on the side of the flange 22 facing away from the chest, there is a recess on two diametrically opposite sides.

[0136]

907 A first outlet opening 24 and an angular first flow opening 25 are present in the first recess.

908 The first outlet opening 24 leads from the interior 200 to the outside of the nozzle 23, more precisely into the first recess.

910 The first flow opening 25 leads from this first recess in a preferably rectangular channel to the free end face of the nozzle 23 facing away from the chest.

912 On the circumference of the nozzle 23 there is a ventilation opening 26 next to the first outlet opening 24, but outside the first recess.

914 This leads from the interior 200 to the outside.

[0137]

918 On the diametrically opposite side of the nozzle 23 there is an analogous second recess with a second outlet opening 27 and a second passage opening 28, which are designed in the same

way as the first openings.

921 Furthermore, a second ventilation opening 29 is also present outside the second recess and next to the second outlet opening 27.

923 This second ventilation opening 29 actually has no function but is closed when the device is used as intended.

925 However, so that the breast shield 2 can also be mounted on the carrier module 8 'in a position rotated by 180 °, all openings are arranged symmetrically.

[0138]

930 The valve body

[0139]

934 Figures 9a to 9d show the valve body 3.

935 The valve body 3 is made of a flexible material, preferably silicone.

936 It is preferably formed in one piece.

937 It has a hollow cylindrical base body 30 with a rear wall 31.

938 There is a through opening 32 centrally in the rear wall.

939 On the side facing away from the chest, the rear wall 31 has a groove 312 which runs annularly around the through opening 32 and forms a sealing surface 310 on the opposite side near the chest.

942 The circumferential edge of the through opening 32 is provided with a circumferential sealing lip 311 on the side facing away from the chest (see Figures 9b and 9c).

944 The area of the rear wall 31 within the circumferential sealing surface 310 thus forms a valve, which, as explained further below, serves as a base vacuum valve.

[0140]

949 The base body 30 has a radially projecting positioning lug 33 on the side facing the chest.

950 A first knob 34 and a ventilation knob 35 are present on the jacket of the base body 3.

951 There is a second knob 36 diametrically opposite.

952 The three knobs protrude radially outwards.

953 The first knob 34 and the second knob 36 are solid, i.e. not hollow.

954 The ventilation knob 35 has a through opening from the interior of the base body 30 to the outside.

[0141]

959 In the annular area of the rear wall 31 between the sealing surface 310 and the jacket of the base body 30, diametrically opposed valve flaps are also present.

961 A first of these valve flaps is provided with the reference number 37, and a second of these

valve flaps is provided with the reference number 38.
963 They are preferably located on the same diagonal as the first and second knobs 34, 36.

[0142]
967 The adjusting ring

[0143]
971 Figures 10a and 10b show the adjusting ring 5.
972 It is preferably stiff and preferably made of plastic.
973 The adjusting ring 5 preferably consists of two parts.
974 A first part 50 has the shape of a half ring and is provided with a first plug part 51 at both free ends.
976 The second part 52 also has the shape of a half ring and is provided with a second plug part 53 at each of its free ends.
978 The first and two parts 50, 52 form a common ring and the two pairs of plug parts 51, 53 are provided with latching elements 54 in order to preferably be permanently connected to one another.
981 On the inner circumference of the ring there is a partially circumferential stop 55 which projects radially inwards and which prevents the adjusting ring 5 from being removed again after assembly on the adapter part 4.
984 A first and a second pressing element 56, 57 are formed on the inner wall of the adjusting ring.
985 These are preferably elevations projecting radially inwards, which merge via an inclined surface, also called a ramp, into a surface running parallel to the inner surface of the ring.
987 An actuating lever 58 which projects towards the outside is formed on the first part 50.

[0144]
991 The adapter part

[0145]
995 Figures I1a to 11c show the adapter part 4.
996 It preferably consists of a rigid material, preferably plastic.
997 It has a hollow cylindrical base body 40 with a substantially closed, flange-like wall 41 on the pump side.
999 The base body 40 has a first window 400 and a diametrically opposite second window 401 in its jacket.
1001 On the end face of the base body 40 near the breast cap there is a positioning aid 402, which forms the counterpart to the positioning base 33 of the valve body 3 and which, together with the positioning nose 33, serves to position the valve body 3 in a rotation-proof manner.

[0146]

1007 The pump-side wall 40 extends in a direction, which is referred to here as downward, into a channel wall 410.

1009 The pump-side wall also has a raised central wall part 42, which projects into the area near the breast shield.

1011 On the opposite side of the wall part 42, i.e. facing the pump housing, a concave surface is formed, which forms the already mentioned rigid shell and is part of the pump chamber 47.

[0147]

1016 A first through opening 43 and a second through opening 44 are present in the pump-side wall 41 between the raised wall part 42 and the jacket of the base body 40.

1018 The two through openings 43, 44 are diametrically opposed to one another.

1019 In this example they are circular.

1020 In the edge area of the raised wall part 42, but already on its elevation, a first backwash opening 45 and a second backwash opening 46 are present.

1022 These are preferably elongated.

1023 These openings all lead into the pump chamber 47.

[0148]

1027 As can be seen in Figure 11c, the concave shell of the pump chamber 47 is surrounded by a circumferential flat edge, which serves as a sealing surface.

1029 A channel 48 runs in this edge, which preferably begins at an uppermost point of the pump chamber 47 and is in fluid-communicating connection with it via an outlet opening 480.

1031 The channel 48 runs along the circumference of the pump chamber 47, here in a part circle, downwards to an outlet 49.

1033 The outlet 49 is located in the channel wall 410.

[0149]

1037 The media separation membrane

[0150]

1041 The media separation membrane 6 is shown in FIGS. 12a to 12c.

1042 It is designed to be flexible, is preferably made in one piece and is preferably made of silicone.

1043 It has a membrane surface 60, which is preferably provided in a known manner with at least one annular groove.

1045 A central region 61 of the membrane surface is preferably raised and faces the adapter part 4.

1046 The edge of the membrane surface 60 is designed as a sealing surface 62 and lies sealingly against the edge of the adapter part 4, whereby the pump chamber 47 is formed.

1048 A channel 63 runs within the sealing surface 62 along the circumference of the media separation membrane 6 and forms the sealing closure of the channel 48 of the adapter part 4.

1051 A recess 64 in the lower region of the media separation membrane 6 facing the pump housing serves as a free space for a pressure sensor, which is described below.

[0151]

1056 The media separation membrane 6 preferably has, as shown in the figures, stiffeners in the form of ribs, which ensure the functionality of the media separation membrane.

1058 This means that the ribs ensure that the membrane moves in the desired manner and still always fits tightly against its neighboring parts.

1060 The pump membrane

[0152]

1064 The pump membrane 7 is shown in FIGS. 13a to 13c.

1065 It also has a membrane surface 70 and a central area 71.

1066 In contrast to the full-surface media separation membrane 6, the central region 71 of the pump membrane 7 is provided with a through opening 72, the edge region of which preferably has a reinforcement 73, here in the form of ribs.

1069 There is again a circumferential sealing surface 74 which, in the assembled state of the device, rests sealingly on the corresponding surface of the carrier module 8 '.

1071 Outside the sealing surface 74 there are side wings 77. When assembled, the side wings 77, together with the circumferential flat sealing surface 74 (FIG. 13b), form a tight barrier against liquids acting from the outside and thus protect the electronics.

[0153]

1077 The lower area of the pump membrane 7, which is still located within the closed circumferential sealing surface 74, is designed as a pressure sensor.

1079 The pressure sensor comprises a sensor surface 75 in the form of a membrane, which is connected to the membrane surface 70 via a connecting web, and a flag 76, which projects vertically from the sensor surface in the direction of the pump housing. This type of pressure sensor is described in WO 2013/049944 Al.

[0154]

1086 As can be seen in the figures, the media separation membrane 6 and the pump membrane 7 have similar shapes, in particular with regard to their movable areas to generate the negative

pressure.

1089 The carrier module

[0155]

1093 The carrier module 8' is shown in Figure 14.

1094 It is held in an outer housing of the pump housing. The outer housing is visible in Figure 1. Preferably, the carrier module 8' is screwed into this outer housing. The corresponding fastening holes are provided with the reference number 84. The carrier module can be made in one piece from plastic. However, it can also be made in several parts and/or from a different material. The carrier module 8 'has two protruding side arms 10 with a bayonet lock for receiving the breast shield 2. The side arms are arranged laterally on a spindle holder 82. The spindle receptacle 82 has a through opening and a circumferential edge 85, which forms the counterpart to the sealing surface 74 of the pump membrane 7. On the spindle holder 82, a motor holder 81 is formed in the form of a shell. The motor holder 81 serves to hold an electric motor, which is connected to a spindle 83 (see Figure 4).

[0156]

1107 How the assembled assembly works

[0157]

1111 Based on Figure 6 you can see how the individual openings and valves interact.

1112 The valve body 3 can be inserted into the hollow cylindrical base body 40 of the adapter part 4 in a rotational position.

1114 The adjusting ring 5 is already permanently connected to the adapter part 4, with the first pressing element 56 protruding inwards through the first window 400 and the second pressing element 57 protruding inwards through the second window 401. The first knob 34 of the valve body 3 is located below the first window 400 and the second knob 36 is above the first window 401. The valve flaps 37, 38 of the valve body 3 are each located above the first and second through openings 43, 44 of the adapter part. The sealing lip 31 1 lies sealingly on the raised wall part 42, with the first and second backwash openings being arranged in a tight annular area between the groove 312 and the sealing lip 31 1.

[0158]

1125 If the breast shield 2 is now inserted, the first knob 34 lies above the first outlet opening 24 and the ventilation knob 35 lies above the first ventilation opening 26.

1127 The second knob 36 lies above the second outlet opening 27. The second ventilation opening 29 is covered by the jacket of the valve body 4 and is therefore closed.

[0159]

1132 If the breast shield 2 is now connected to the carrier module 8 ', the individual connections between the channels and openings described are created and sealed from the outside.

[0160]

1137 In Figures 4 and 5 the breast pump according to the invention is shown in the assembled state.

1139 As can be clearly seen, this system has virtually no dead space.

1140 In Figure 4 the spindle 83 can be seen, which drives the pump membrane 7. The media separation membrane 6 has a shape which hugs the pump membrane 7, so that both membranes 6, 7 move together and no losses occur here either. The pump housing 8, more precisely the carrier module 8', has a rear wall 85, against which the pump membrane 7 lies sealingly when the hygiene module is attached to the carrier module 8'. This can be clearly seen in Figures 4 and 5. The adjusting ring 5 is pivotally arranged within the side arms 80, with the actuating lever 58 also serving as a display element. It moves along a display 87, which is attached to the pump housing 8 and which thus provides the user with information about the position of individual valves and thus indicates the operating status of the pump. This means that it is displayed whether the pump is ready for pumping or is in the emptying state. This is explained below. By turning the adjusting ring 5, individual valves can be opened and closed manually.

1152 More specifically, the first outlet opening 24 can be opened and closed manually together with the first flow opening 25 as an alternative to the second outlet opening 27 together with the second flow opening 28. The first ventilation opening 26 is opened and closed together with the second outlet opening 27 and the second flow opening 28. The second ventilation opening 29 always remains closed due to its position within the valve body 3.

[0161]

1160 If the breast shield 2 is positioned relative to the valve body 3 in such a way that the second openings are at the position of the first openings, the second ventilation opening is of course opened and closed instead of the first.

[0162]

1166 In a first position, which is selected at the beginning of the pumping process and throughout the entire pumping process, the second knob 36 of the valve body 3 is pressed down by the second pressing element 57 of the adjusting ring and lies on the recess and thus the second outlet opening 27 and the second Flow opening 28 of the breast shield 2.

1170 In addition, the ventilation knob 35 is pressed onto the first ventilation opening 26 by the first pressing element 56 and closes it.

1172 The first knob 34 of the valve body 3, on the other hand, is released, so that the first outlet opening 24 and the first flow opening 25 form a fluid-communicating channel from the interior 200 of the breast shield into the base body 30 of the valve body 3. This is best seen in Figures 2, 3 and 6. In a second position, the adjusting ring 5 is rotated. The first pressing element 56 releases the ventilation knob 35 and thus the first ventilation opening 26, but presses the first knob 34 onto the recess and thus closes the first outlet opening 24 and the first flow opening 25. The second pressing element 57 also releases the second knob 36, so that the second outlet opening 27 and the second flow opening 28 now form an open, continuous channel from the interior 200 of the breast shield 2 into the valve body 3. The second outlet opening 27 and the second flow opening 28 form an emptying channel, which will be described in more detail below. The mutual opening and closing preferably takes place at the same time.

1184 However, it is also possible to arrange the pressing elements offset so that all openings are closed in an intermediate state.

[0163]

1189 Pumping breast milk and emptying process

[0164]

1193 So that milk can be pumped out of the mother's breast, the actuating lever 58 and thus the adjusting ring 5 are brought into the first position mentioned.

1195 By means of the drive, the pump membrane 7 is moved back and forth together with the media separation membrane 6 to the adapter part 4, so that a negative pressure is created in the pump chamber 47 and in the interior 200 of the breast shield 2.

1198 The vacuum line from the pump chamber 47 into the interior space 200 of the breast shield 2 is formed by the first through opening 43 in the adapter part 4, the opening in the valve body 3 covered by the first valve flap 37 and the channel formed by the first flow opening 25 and the first outlet opening 24 in the breast shield. The base vacuum valve, formed, among other things, by the sealing lip 31 1 of the valve body 3, enables a base negative pressure to be maintained in the interior 200 of the breast shield 2 when the pump stroke runs towards atmospheric pressure. The basic vacuum valve opens towards atmospheric pressure during the pump stroke and only closes when a predetermined minimum pressure in the interior 200 is reached. The mode of operation is explained in more detail below using a diagram. The air flows back into the breast shield 2 via the first and second backwash openings 45, 46 of the adapter part 4, the through opening 32 of the valve body 3 and the through opening 21 of the breast shield 2.

[0165]

1213 By applying this vacuum to the mother's breast, it is stimulated and milk flows from the breast

into the interior 200 of the breast shield 2.

1215 The interior 200 fills until the milk level reaches the first outlet opening 24. The breast shield 2 is preferably held in such a way that this first outlet opening 24 is located in an upper region of the breast shield 2.

[0166]

1221 The pumped milk then flows through the channel, formed by the first outlet opening 24 and the first passage opening 25, and through the opening covered by the first valve flap 37 into the adapter part 4, where it passes through the first through opening 43 into the pump chamber 47.

[0167]

1228 The pump chamber 47 also fills with milk until the outlet opening 480 located at the top is reached.

1230 The milk then flows through the channel, formed by the channel 48 of the adapter part 4 and the channel 63 or the cover of the media separation membrane 6, through the outlet 49 out of the hygiene module and through the container valve 94 into the milk collecting container 9.

[0168]

1236 If the pump stroke creates a negative pressure towards atmospheric pressure, the base vacuum valve opens first and allows a partial backflow of the air or milk in the interior 200.

1238 This partial backflow occurs through the first and second backwash openings 45, 46, the open base vacuum valve, the through opening 32 and the through opening 21.

1240 The valve closes at a certain vacuum value in the interior so that the pressure cannot rise further towards atmospheric pressure.

[0169]

1245 When the mother wants to stop pumping out the milk or when no more milk flows from the breast, she pivots the adjusting ring 5 into the second position.

1247 The previously used vacuum and milk channel is closed by closing the first outlet opening 24 and the first passage opening 25. However, the second outlet opening 27, the second passage opening 28 and the first ventilation opening 26 open. This changeover can take place while the pump is running, i.e. with the pump membrane 7 still being driven. The pump can also be switched off and then put back into operation. Since the pump now continues to suck, the milk that is still in the interior 200 of the breast shield 2 and has already been pumped out of the mother's breast is passed through the second release opening 27, the second passage opening 28, the opening of the valve body 3 covered by the second valve flap 37 and the second Through opening 44 of the adapter part 4 is pumped into the pump

chamber 47. From there it is displaced from the pump chamber 47 towards the outlet opening 480 by the movement of the pump membrane 7 and the media separation membrane 6. It therefore also flows through the channel 48 and the outlet 49 into the milk collecting container 9.

1260 In this way, both the interior 200 of the breast shield 2 and the pump chamber 47 can be almost completely emptied. The device can also be placed in an inclined position in order to empty all of the milk from the system into the milk collecting container 9.

[0170]

1266 It should be noted that at the beginning of the pumping process, the breast pump is preferably held in such a way that the first outlet opening 24 of the breast shield and the outlet opening 480 of the pumping chamber 47 are located in an upper region of the respective cavity.

1269 This allows air to escape from the system and the two hollow chambers are filled with milk relatively quickly. This enables a change as quickly as possible from a purely pneumatic pump system with air as the working fluid to a purely or predominantly hydraulic pump system in which milk forms the working fluid or at least forms a large proportion of the working fluid. However, it is not absolutely necessary that the openings are arranged in this way at the beginning of the pumping process. Changing from one pump system to the other simply takes a long time and/or cannot be completed completely.

[0171]

1279 As soon as the milk has partially flooded the interior 200 and the pump chamber 47, preferably up to the openings mentioned, the breast pump can be moved into any position.

1281 This applies not only to the breast shield 2 and the pump chamber 47, but in particular also to the milk collecting container 9. Thanks to the container valve 94 designed as a check valve and thanks to the liquid-impermeable cover 92, the milk collecting container 9 can even be turned upside down without affecting the operation of the breast pump.

[0172]

1288 In preferred embodiments, the breast shield and also the adjusting ring are illuminated so that the mother can carry out a visual check while pumping at night.

[0173]

1293 The breast pump described above is merely an exemplary embodiment in which the principle according to the invention can be implemented and the method according to the invention can be applied.

1296 Figures 18 to 23c therefore show again schematically what the core of the ideas according to the invention lies.

[0174]

1301 Basic principle

[0175]

1305 The breast shield 2 with the interior 200 is shown schematically in FIG.

1306 The breast shield 2 is placed sealingly on a mother's breast, the nipple W protrudes into the interior 200.

1308 The interior 200 is connected to a pump chamber 47 via an outlet opening 16.

1309 An additional emptying opening 19 also leads from the interior 200 to the pump chamber 47. The outlet opening 16 is provided with a pump valve 12, the emptying opening with a drain valve 14. A base vacuum valve 13 closes a third opening 17 between the vacuum chamber 47 and the interior 200 of the breast shield 2. A ventilation opening 15, which can be closed with a ventilation valve 11, also leads from the interior 200 of the breast shield 2 to the outside.

[0176]

1318 The volume of the pump chamber 47 can be changed by means of a pump means 10, for example a pump membrane or a piston.

1320 The pumping means 10 is driven, for example by means of a spindle 100.

[0177]

1324 An outlet opening 480 leads from the pump chamber 47 into a milk collecting container 9.

1325 The inlet into the milk collecting container 9 is preferably provided with a check valve, here called container valve 94. The milk collecting container 9 is ventilated; an inlet 95 with an inlet valve 96 is preferably present for this purpose.

[0178]

1331 The comparison with the exemplary embodiment described in detail above shows that the ventilation opening 15 and the ventilation valve 11 correspond to the first ventilation opening 26, the ventilation knob 35 and the first pressing element 56.

[0179]

1337 The outlet opening 16 and the base vacuum valve 12 of the schematic representation correspond to the first outlet opening 24, the first flow opening 25, the first knob 34, the first pressing element 56 and the first valve flap 37 of the specific exemplary embodiment.

[0180]

1343 The emptying opening 19 and the emptying valve 14 of the schematic representation correspond to the second outlet opening 27, the second flow opening 28, the second knob 36, the second pressing element 57 and the second valve flap 38 of the specific exemplary embodiment.

[0181]

1350 The base vacuum valve 13 and the third opening 17 of the schematic representation correspond to the sealing lip 311, the first and second backwash openings 45, 46 and the through opening 32 in the valve body 3 of the specific exemplary embodiment.

[0182]

1356 The container valve 94 in the schematic representation corresponds to the container valve in the specific exemplary embodiment.

[0183]

1361 The inlet 95 and the inlet valve 96 of the schematic representation are formed in the specific exemplary embodiment described above by the air-permeable and liquid-impermeable cover, i.e. by a correspondingly selected cover film.

[0184]

1367 These valves can also be implemented in other ways.

1368 The valve openings can also be accommodated in an additional module part, which is detachably connected to the breast shield.

1370 In addition, the outlet opening 16 and/or the emptying opening 19 can be designed as a channel which runs in a line, in particular a flexible line.

1372 Depending on the design of this line, the pump chamber can be arranged at a distance from the breast shield and, depending on the embodiment, also at a distance from a valve module.

1374 The valves can preferably be accommodated in a module which is arranged between the pump chamber and the breast shield funnel.

1376 If the pump chamber is arranged at a distance from the breast shield, the valve module can be arranged adjacent to the pump chamber or adjacent to the breast shield or can be a component of the breast shield.

[0185]

1382 The following explains how it works:

[0186]

1386 In the illustration according to Figure 18, the pump is not yet switched on.

1387 The valves are closed except for the inlet valve 96 of the milk collecting container 9.

1388 Atmospheric pressure prevails in all areas, i.e. p=0.

[0187]

1392 In the illustration according to Figures 19a to 19c, the pumping process begins and the mother's breast is stimulated by the negative pressure applied.

1394 The pump valve 12 can open and close.

1395 In the specific exemplary embodiment, the first outlet opening 24 and the first flow opening 25 are released and the first valve flap 37 opens and closes the valve.

1397 The drain valve 14 is tightly closed. In the specific exemplary embodiment, this is done by bringing the adjusting ring 5 into the corresponding position and tightly closing the second outlet opening 27 and the second flow opening 28. Likewise, the ventilation valve 11 remains tightly closed. In the specific exemplary embodiment, this is achieved by the first knob 34 closing the first ventilation opening 26 by means of the adjusting ring 5. The pumping means 10, preferably a pump membrane or a piston, is pulled outwards in order to generate a negative pressure in the pump chamber 47 (here e.g. B. - 150 mmHg). The pump valve 12 opens and the negative pressure is transferred into the interior 200 of the breast shield 2, or Air flows from this interior into the pump chamber 47. There is also a negative pressure in the interior, ideally the same pressure of -150 mmHg, for example. The pressure curve in the line space 200 is shown in Figure 19c. The pressure according to reference number a) corresponds to the pressure in the interior 200 according to FIG. 19a.

1409 The container valve 94 remains closed. The pressure in the milk collecting container 9 is still atmospheric pressure, i.e. p=0. If the pumping means 10 is now pushed back and the volume of the pumping chamber 47 is reduced, the pumping valve 12 closes and the pressure in the pumping chamber 47 increases to atmospheric pressure p-0. The pressure in the interior 200 also increases due to the base vacuum valve 13 now being opened. However, since the base vacuum valve 13 closes at a certain negative pressure, a base vacuum is maintained in the interior 200. This is, for example, -20 mmHg. This situation is shown in Figure 19b and the pressure curve is labeled b) in Figure 19c. Comparing Figures 19a and 19b also shows how the nipple W expands and contracts again in the interior 200.

[0188]

1421 In Figures 20a to 20c the flow of milk from the mother's breast has begun.

1422 The milk is given the reference symbol M in the figures. The interior 200 of the breast shield 2 fills with pumped milk. A lake of milk is created below the pump valve 12. Thanks to the milk

now available, the pump power increases while the drive power remains the same, for example to -170 mmHg in the pump chamber 47 and the interior 200. As before, the pump valve 12 and the base vacuum valve 13 open and close with each pump stroke, with the emptying valve 14 and the ventilation valve 11 remaining closed. Figure 20a shows the situation at maximum negative pressure (absolute value), which is also marked with a) in Figure 20c. Figure 20b shows the situation while maintaining the basic negative pressure in the interior 200 and atmospheric pressure in the pump chamber 47, which is marked with b) in Figure 20c. As soon as the interior 200 has filled with milk M up to the outlet openings 16, milk M flows through the pump valve 12 into the vacuum chamber 47. The pumped milk M now also fills the vacuum chamber 47 until its level reaches the outlet opening 480 to the milk collecting container 9.

1435 Now the container valve 94 opens, preferably due to the pressure of the accumulated milk M, and milk M flows into the milk collecting container 9.

[0189]

1440 Figures 21a to 21c show the situation in which, optimally, there is no longer any air in the system and the original pneumatic system has completely changed to a hydraulic system.

1442 In practice, a mixed system is often present, with the pumped milk preferably filling a significant portion of the volumes and thus forming the main working fluid. As already explained with reference to Figures 19a to 19c, the pump valve 12 and the base vacuum valve 13 open and close in accordance with the pump stroke, so that a negative pressure is generated in the interior 200 and a basic negative pressure can be maintained. The pressure in the vacuum chamber 47 changes, for example, between -250 mmHg and 0 mmHg, the pressure in the interior between -250 mmHg and -20 mmHg. The pressure in the milk collecting container 9 remains at atmospheric pressure, i.e. at 0 mmHg.

[0190]

1453 Figures 22a to 22c show the situation when milk no longer flows from the breast.

1454 The system initially continues to pump, and the pump pressure is no longer sufficient to open the container valve 94 to the milk collecting container 9. This is the point in time at which the pump valve 12 is completely closed and the emptying valve 14 is activated so that it can now open and close automatically. In the specific exemplary embodiment, the adjusting ring 5 is adjusted manually for this purpose. However, other ways of activating or deactivating these two valves are possible. For example, they can be controlled with appropriate electronics.

[0191]

1463 In Figures 23a to 23c, the pump valve 12 is now firmly closed and the emptying channel and the emptying valve 14 are opened.

1465 The pumping means 10 continues to move and continues to generate a pressure in the

pumping chamber 47 that varies from a maximum negative pressure to atmospheric pressure. In accordance with this movement, the emptying valve 14 also opens and closes, like the pump valve 12 before, and thus pumps the milk M from the interior 200 into the pump chamber 47. From there it is conveyed into the milk collecting container 9, preferably first by means of negative pressure and then by means of displacement by the pumping means 10. In this pumping situation, the emptying valve 14 is preferably located at a low point on the breast shield, preferably relatively far down. The sinking lake of milk in the interior can be clearly seen in Figures 23a and 23b. Figures 23a and 23b again show the two extreme situations of a pump stroke. The pressure curve is shown in Figure 23c. The pressure curve in the interior 200 is relatively unspecific. The pump will therefore continue to be operated during emptying. If there is still milk in the vacuum chamber 47 at the end, it can easily be directed into the milk collecting container 9 by tilting or turning the pump upside down.

[0192]

1481 The breast pump according to the invention and the method according to the invention thus enable the use of pumped milk in a hydraulic pump system, whereby the drive of the pump can be minimized.

[0193]

1487 REFERENCE SYMBOL LIST

[0194]

1491 32 Through opening pump means 33 positioning nose

[0195]

1495 Spindle 34 first stud

[0196]

1499 Ventilation valve 35 ventilation knob

[0197]

1503 Pump valve 36 second knob

[0198]

1507 Basic vacuum valve 37 first valve flap

[0199]
1511 Drain valve 38 second valve flap ventilation opening

[0200]
1515 Outlet opening 4 adapter part

[0201]
1519 third opening 40 base body

[0202]
1523 Drain opening 400 first window

[0203]
1527 401 second window

[0204]
1531 Breast shield 402 positioning aid

[0205]
1535 Funnel 41 pump-side wall interior 410 channel wall

[0206]
1539 Through opening 42 raised wall part flange 43 first through opening nozzle 44 second through opening first outlet opening 45 first backwash opening first flow opening 46 second backwash opening first ventilation opening 47 pump chamber

[0207]
1545 second outlet opening 48 gutter

[0208]
1549 second flow opening 480 outlet opening second ventilation opening 49 outlet valve body 5

adjusting ring

[0209]
1554 Basic body 50 first part

[0210]
1558 Rear wall 51 first connector part

[0211]
1562 Sealing surface 52 second part

[0212]
1566 Sealing lip 53 second plug part groove 54 latching element stop 83 spindle

[0213]
1570 first pressing element 84 mounting holes second pressing element 85 edge

[0214]
1574 Operating lever 86 operating switch

[0215]
1578 87 Advertisement

[0216]
1582 Media separation membrane

[0217]
1586 Membrane surface

[0218]
1590 Central area 9 milk collection container sealing surface 90 vessel

[0219]
1594 Gutter 900 interior

[0220]
1598 Recess 901 first latching element["]

[0221]
1602 902 second latching element pump membrane 91 lower frame part membrane surface 92 cover

[0222]
1607 Central area 93 upper frame part passage opening 930 frame

[0223]
1611 Reinforcement 931 struts

[0224]
1615 Sealing surface 932 Valve holder Sensor surface 933 Handle

[0225]
1619 Flag 934 spacer pins

[0226]
1623 Side wing 94 container valve

[0227]
1627 95 inlet

[0228]
1631 Pump housing 96 inlet valve

[0229]
1635 Carrier module

[0230]
1639 Side arm W nipple

[0231]
1643 Motor mount M milk

[0232]
1647 Spindle mount

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(54) **Title:** BREAST PUMP

(54) **Bezeichnung:** BRUSTPUMPE

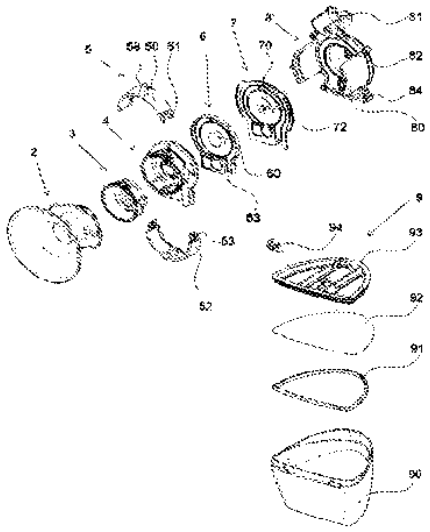


FIG. 2

(57) **Abstract:** A breast pump for expressing human breast milk has a housing (8), a pumping chamber (47) with a driven pump membrane (7) for generating a vacuum, and also has a breastshield (2) with an interior (200) in which to position a breast. Expressed milk flows from the interior (200), through a milk channel, into the pumping chamber (47), which has an outlet opening (480) through which expressed milk flows from the pumping chamber (47) into a milk-collecting container (9). The breast pump has a multi-part hygiene module (2, 3, 4, 5) having a first part (2) with a throughflow opening (24, 25) for connection to the interior (200), having a valve body (3) with at least one valve (34, 37), and having a second part (4) with a rigid shell for forming the pumping chamber (47). The valve body (3) is arranged between the first and second parts (2, 4) and the hygiene module (2, 3, 4, 5) can be connected, as a whole, to the housing (8) of the breast pump in a sealing and releasable manner.

(57) **Zusammenfassung:** Eine Brustpumpe zum Abpumpen von menschlicher Muttermilch weist ein Gehäuse (8), eine Pumpkammer (47) mit einer angetriebenen Pumpmembran (7) zur Erzeugung eines Vakuums und eine Brusthaube (2) mit einem Innenraum (200) zur Aufnahme einer Mutterbrust auf. Abgepumpte Milch fliesst vom Innenraum (200) durch einen Milchkanal in die Pumpkammer (47), welche eine Auslassöffnung (480) aufweist, durch die abgepumpte Milch von der Pumpkammer (47) in einen Milchsammelbehälter (9) fliesst. Die Brustpumpe weist ein mehrteiliges Hygienemodul (2, 3, 4, 5) auf mit einem ersten Teil (2) mit einer Durchflussöffnung (24, 25) zur Verbindung mit dem Innenraum (200), einem Ventilkörper (3) mit mindestens einem Ventil (34, 37) und einem zweiten Teil (4) mit einer steifen Schale zur Bildung der Pumpkammer (47). Der Ventilkörper (3) ist zwischen dem ersten und zweiten Teil (2, 4) angeordnet und das Hygienemodul (2, 3, 4, 5) ist als Ganzes mit dem Gehäuse (8) der Brustpumpe dichtend und lösbar verbindbar.

[Fortsetzung auf der nächsten Seite]

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).

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— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

TITEL

BRUSTPUMPE

TECHNISCHES GEBIET

Die vorliegende Erfindung betrifft eine Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie eine Brusthaube, einen Milchsammelbehälter und ein Verfahren zum Betreiben einer Brustpumpe.

STAND DER TECHNIK

Vorrichtungen zum Abpumpen von menschlicher Muttermilch sind hinlänglich bekannt. Grundsätzlich gibt es zwei verschiedene Typen: die ersten werden manuell bedient, d.h. der für das Abpumpen notwendige Unterdruck wird durch manuelle Betätigung der Vakuumpumpe erzeugt. Bei den zweiten Typen ist die Vakuumpumpe elektrisch betrieben.

Diese Vakuumpumpen sind entweder direkt oder über eine Vakuumleitung mit einer Brusthaube verbunden. Die Brusthaube weist einen Innenraum zur Aufnahme der Mutterbrust bzw. deren Brustwarze auf. Der Unterdruck wird über eine erste Leitung in den Innenraum übertragen, die abgepumpte Milch fliesst über eine zweite Leitung in einen Milchsammelbehälter.

WO 2016/014494 A1 und WO 2016/014469 A1 beschreiben eine kompakte Brustpumpe, bei welcher abgepumpte Milch unter positivem Druck in einen Milchsammelbehälter transportiert wird. Hierfür wird beispielsweise eine Milchleitung zyklisch gequetscht.

WO 2011/035447 A1 offenbart eine Brustpumpe, bei welcher die Vakuumleitung gleichzeitig die Milchleitung bildet. Die Pumpkammer, in welcher der Unterdruck erzeugt wird, füllt sich während des Abpumpens mit Milch, so dass das Pumpsystem von einem pneumatischen System in ein hydraulisches System wechselt und die bereits abgepumpte

Milch zum Arbeitsfluid wird. Damit sich die Pumpkammer mit Milch füllen kann, ist am Ausgang der Pumpkammer, welcher zum Milchsammelbehälter führt, ein Ventil angeordnet. Dieses Ventil öffnet sich erst bei einem bestimmten Druck innerhalb der Pumpkammer, d.h. wenn die Pumpkammer ausreichend mit Milch gefüllt ist.

Diese kombinierte pneumatische und hydraulische Pumpe weist mehrere Vorteile auf. Das System weist kein oder fast kein Totvolumen auf. Das Pumpaggregat kann minimiert werden, da nach Füllung des Systems mit Milch nur mehr eine geringe Pumpleistung notwendig ist, um weitere Milch abzupumpen. Insbesondere lassen sich Batterien mit geringerer Kapazität verwenden als bei pneumatischen Vakuumpumpen. Die Vakuumpumpe lässt sich somit kostengünstiger und kleiner ausbilden. Die Brustpumpe eignet sich insbesondere für sogenannte „hands-free" Anwendungen, bei welchen die Brustpumpe am Körper getragen und keine Hände zum Festhalten der Brusthaube benötigt werden. Aufgrund des minimierten Totvolumens lässt sich zudem der angelegte Druck leichter kontrollieren. Dadurch lassen sich für jede Mutter individuell optimierte Pumpparameter wählen.

In WO 2013/049944 A2 ist ebenfalls eine Brustpumpe beschrieben, welche von einem pneumatischen in ein hydraulisches Pumpsystem wechselt. In der Pumpkammer ist ein Drucksensor vorhanden, welcher eine an einer flexiblen Membran angebrachte Fahne umfasst.

DARSTELLUNG DER ERFINDUNG

Es ist deshalb eine Aufgabe der Erfindung, die oben genannte Brustpumpe zu optimieren.

Diese Aufgabe löst eine Brustpumpe gemäss den Ansprüchen 1, 8, 35, 36, 39 und 42, ein Milchsammelbehälter gemäss Anspruch 41, eine Brusthaube gemäss Anspruch 43 sowie ein Verfahren mit den Merkmalen des Anspruchs 44.

In einer bevorzugten Ausführungsform weist die erfindungsgemässe Brustpumpe zum Abpumpen von menschlicher Muttermilch ein Gehäuse mit einer Antriebseinheit, eine

Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust auf. Der Innenraum ist mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, wobei abgepumpte Milch vom Innenraum der Brusthaube durch den Milchkanal in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Ein mehrteiliges Hygienemodul ist vorhanden, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

Dieses Hygienemodul ist kompakt aufgebaut. Es lässt sich einfach montieren und auseinander nehmen, so dass sich die relevanten Teile der Brustpumpe einfach reinigen lassen. Die Verwendung eines Ventilkörpers im Hygienemodul erleichtert die Herstellung, den Zusammenbau und die Reinigung zusätzlich.

Vorzugsweise weist die steife Schale einen Milchpfad auf, welcher von der Pumpkammer in einen Milchsammelbehälter führt und welcher mindestens über einen Teilbereich senkrecht zu einer Antriebsachse der Pumpmembran verläuft. Vorzugsweise verläuft der Milchpfad in einer Ebene senkrecht zur Antriebsachse, wobei sich der Milchpfad in dieser Ebene über mindestens die Hälfte der Höhe der Pumpkammer, vorzugsweise über die gesamte Höhe der Pumpkammer erstreckt. Der Verlauf dieses Milchpfades ermöglicht es, die Pumpkammer mit abgepumpter Milch mindestens teilweise, vorzugsweise vollständig zu füllen, so dass während des Abpumpens von einem pneumatischen Pumpsystem auf ein gemischtes oder sogar vollständig hydraulisch funktionierendes Pumpsystem gewechselt wird.

Vorzugsweise weist der Ventilkörper mindestens ein Durchflussventil und ein Belüftungsventil auf. Vorzugsweise ist der Ventilkörper einstückig aus einem flexiblen

Material gebildet. Dies erleichtert sowohl die Herstellung, wie auch den Zusammenbau und die Reinigung.

Vorzugsweise ist der erste Teil ein Bestandteil der Brusthaube. Dadurch lässt sich die Brustpumpe kompakt ausbilden und das Hygienemodul lässt sich auf einfache Art und Weise an der Brustpumpe befestigen, ohne dass zusätzlich noch die Brusthaube montiert werden muss.

Vorzugsweise weist die Brusthaube einen Flansch zur lösbaren Verbindung mit dem Gehäuse auf.

Die Verbindung mit dem Gehäuse lässt sich auf besonders einfache Art und Weise herstellen, wenn sie form- und kraftschlüssig, vorzugsweise ein Bajonettverschluss, ist.

In einer weiteren bevorzugten Ausführungsform weist die erfindungsgemässe Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Die Auslassöffnung ist in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet.

Dadurch lässt sich die Pumpkammer annähernd vollständig mit Milch füllen und das System kann innerhalb kürzester Zeit von einem pneumatischen in ein hydraulisches oder gemischt pneumatisch/hydraulisches System übergeführt werden. Dieselbe Antriebsleistung für die Pumpmittel, z.B. der Pumpmembran, führt zu einer grösseren Pumpleistung, d.h. zu einem betragsmässig höheren Unterdruck in der Pumpkammer und somit im Innenraum der Brusthaube. Es lassen sich Batterien mit geringerer Kapazität verwenden. Dies vermindert die Herstellungskosten, erhöht die Lebensdauer der Pumpe

insgesamt und minimiert die Grösse der Antriebseinheit.

Vorzugsweise bildet der Milchkanal einen Vakuumkanal zur Beaufschlagung des Innenraums der Brusthaube mit dem sich zyklisch ändernden Unterdruck. D.h. es wird über dieselbe Leitung bzw. über denselben Kanal zuerst das Vakuum angelegt und anschliessend die Milch abgesaugt. Dieselbe Leitung bzw. derselbe Kanal wird für beide Arbeitsfluide, d.h. Luft und Milch, verwendet.

Je nach Ausführungsform ist die Pumpe eine Kolbenpumpe, eine Membranpumpe oder eine andere Art Vakuumpumpe. Vorzugsweise weist die Pumpkammer jedoch eine steife erste Schale und eine flexible Pumpmembran auf, wobei die Pumpmembran dichtend an der ersten Schale anliegt und wobei die Pumpmembran angetrieben ist und durch deren Bewegung relativ zur ersten Schale ein Unterdruck in der Pumpkammer erzeugbar ist.

Vorzugsweise ist zwischen der steifen Schale und der flexiblen Pumpmembran eine flexible Medientrennmembran angeordnet, so dass die Pumpmembran vor einem Kontakt mit abgepumpter Milch geschützt ist. Milch und Luft, welche in der Brusthaube vorliegen, gelangen nur bis zur Medientrennmembran. Die Pumpmembran und die übrigen Teile der Brustpumpe sind somit vor einer Kontamination geschützt.

Die Medientrennmembran lässt sich auf einfache Art und Weise von der Pumpmembran trennen. Sie ist vorzugsweise Teil des bereits erwähnten Hygienemoduls. Die Medientrennmembran lässt sich vorzugsweise von den übrigen Teilen des Hygienemoduls trennen und so auf einfache Art und Weise reinigen. Auch die übrigen Teile des Hygienemoduls lassen sich soweit notwendig voneinander trennen, so dass sie gereinigt und anschliessend auf einfache Art und Weise und vorzugsweise ohne Werkzeuge wieder zusammen gesetzt und erneut verwendet werden können.

Vorzugsweise weist die erste Schale eine Auslassrinne auf, welche sich von der Auslassöffnung der Pumpkammer zu einem Ausgang erstreckt, wobei die Auslassrinne mindestens über einen Teilbereich in einer Richtung senkrecht zur Bewegungsrichtung der Pumpmembran verläuft. Vorzugsweise verläuft sie in einer Ebene senkrecht zu dieser Bewegungsrichtung, wobei sich die Rinne vorzugsweise über mindestens die Hälfte der

Höhe der Pumpkammer, vorzugsweise über die gesamte Pumpkammer erstreckt.

In anderen Ausführungsformen ist die Rinne teilweise oder ganz als geschlossener Kanal ausgebildet. Vorzugsweise verschliesst jedoch die Pumpmembran, oder, falls vorhanden, die Medientrennmembran die Auslassrinne der steifen ersten Schale zu einem bis auf die Auslössöffnung und den Ausgang geschlossenen Kanal.

Die Rinne erstreckt sich vorzugsweise neben der Pumpkammer und nicht innerhalb derselben.

In einer bevorzugten Ausführungsform weist die Brusthaube eine erste Durchlassöffnung auf, welche Teil des Milchkanals bildet, wobei die Durchlassöffnung in Gebrauchslage der Brusthaube mindestens zu Beginn des Abpumpvorgangs in einem oberen Bereich des Innenraums angeordnet ist, so dass der Innenraum unterhalb der ersten Durchlassöffnung mit abgepumpter Milch befüllbar ist.

Dadurch lässt sich die Brusthaube zu Beginn des Abpumpvorgangs mit Milch teilweise oder ganz füllen. Dies verkürzt die Zeit bis zum Wechsel auf das hydraulische Pumpsystem nochmals massiv. Üblicherweise wird zuerst der Innenraum der Brusthaube gefüllt und anschliessend die Pumpkammer, bevor die Milch erstmals in den Milchsammelbehälter gelangt.

Vorzugsweise ist der Milchkanal mittels eines ersten Ventils verschliessbar, um am Ende des Abpumpvorgangs die abgepumpte Milch aus der Pumpkammer zu entfernen. Dieses Ventil ist vorzugsweise dasselbe Ventil, welches sich beim Abpumpen der Milch selbsttätig öffnet und schliesst. Für die Entleerung wird es nun permanent geschlossen. Die Schliessung erfolgt je nach Ausführungsform manuell oder automatisch, z.B. mittels der elektronischen Steuerung der Brustpumpe. Ist nachfolgend ein Ventil angeordnet, so kann das erste Ventil während des Abpumpvorgangs auch stets geöffnet sein.

Vorzugsweise ist ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden, welcher getrennt vom Milchkanal verläuft, wobei der Entleerungskanal mittels eines zweiten Ventils verschliessbar ist. Der Entleerungskanal ist

während des Abpumpvorgangs geschlossen und ist am Ende des Abpumpvorgangs geöffnet. Auch dies erfolgt je nach Ausführungsform manuell oder automatisch. Das zweite Ventil funktioniert vorzugsweise gleich oder ähnlich wie das erste Ventil. Es ist vorzugsweise identisch ausgebildet. Es öffnet und schliesst sich während des Pumpvorgangs beim Entleeren der Brusthaube gleich wie das erste Ventil während des Abpumpens der Muttermilch aus der Mutterbrust. Ist nachfolgend ein Ventil angeordnet, so kann das zweite Ventil während des Entleerungsvorgangs auch stets geöffnet sein.

Vorzugsweise ist zudem ein Belüftungsventil zur Belüftung des Innenraums der Brusthaube vorhanden. Dieses ist ebenfalls vorzugsweise während des Abpumpvorgangs stets geschlossen und wird manuell oder automatisch geöffnet, um das Entleeren der Brusthaube zu erleichtern.

Vorzugsweise ist das Belüftungsventil gemeinsam mit dem zweiten Ventil verschliessbar und es lässt sich gemeinsam mit diesem öffnen.

In einer bevorzugten Ausführungsform ist ein drittes Ventil vorhanden, welches bei Druckanstieg des sich zyklisch ändernden Unterdrucks im Innenraum der Brusthaube einen Basisunterdruck beibehält. Der Druck im Innenraum der Brusthaube liegt somit während des gesamten Abpumpvorgangs und vorzugsweise auch während der Entleerung unter dem Atmosphärendruck. Dies vermindert die Belastung der Brustwarze und wirkt sich positiv auf den Milchfluss aus der Mutterbrust aus.

Vorzugsweise ist im Milchkanal ein viertes Ventil vorhanden, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst. Dieses vierte Ventil ist in Abpumprichtung der Milch dem ersten Ventil nachfolgend angeordnet. Das vierte Ventil kann jedoch auch, wie oben bereits beschrieben, durch das erste Ventil gebildet sein. Ist es jedoch nachgeordnet, kann es beispielsweise als Flatterventil im Ventilkörper ausgebildet sein.

Vorzugsweise ist im Entleerungskanal ein fünftes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst. Diese fünfte Ventil ist in Entleerungsrichtung der Milch dem zweiten Ventil nachfolgend angeordnet. Das fünfte

Ventil kann wie oben beschrieben durch das zweite Ventil gebildet sein. Ist es nachgeordnet, kann es beispielsweise ein Flatterventil im Ventilkörper sein.

Vorzugsweise ist mindestens ein Teil, vorzugsweise sind alle der genannten Ventile in einem gemeinsamen Ventilkörper angeordnet. Dies erleichtert die Herstellung und minimiert die Kosten.

Vorzugsweise ist der Ventilkörper einstückig und flexibel ausgebildet. Vorzugsweise besteht er aus Silikon.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse mit einem Antrieb für die Pumpmembran auf, wobei die steife erste Schale lösbar mit dem Pumpengehäuse verbunden ist. Dies erleichtert den Zusammenbau, auch nach einer Reinigung durch die Mutter.

Vorzugsweise ist die erste steife Schale Bestandteil eines mehrteiligen Moduls, welches gemeinsam mit dem Pumpengehäuse verbindbar ist, wobei das Modul des Weiteren mindestens die genannten Ventile aufweist. Dieses Modul ist vorzugsweise das oben genannte Hygienemodul.

Vorzugsweise ist die erste steife Schale Bestandteil eines Adapterteils, wobei der Ventilkörper in einer Aufnahme des Adapterteils gehalten ist. Dies erleichtert die Montage und ermöglicht insbesondere einen modulartigen Aufbau sowie die Verwendung eines Hygienemoduls.

Vorzugsweise umfasst das Modul ferner ein manuelles Betätigungsmittel zum zeitgleichen Betätigen des ersten und zweiten Ventils. Die manuelle Betätigung der zwei Ventile ist eine kostengünstige und betriebssichere Lösung.

Vorzugsweise sind das Adapterteil und das Betätigungsteil nicht zerstörungsfrei voneinander lösbar. Dadurch ist sichergestellt, dass das Modul stets korrekt zusammengestellt und nur mit sämtlichen Elementen gemeinsam verwendet werden kann.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse auf, wobei die Brusthaube lösbar am Pumpengehäuse befestigbar ist und wobei durch die Befestigung der Brusthaube am Pumpengehäuse Teile, welche zwischen Brusthaube und Pumpengehäuse liegen, dichtend miteinander verbunden werden, so dass eine dichte Verbindung zwischen Pumpkammer und Innenraum der Brusthaube entsteht. Die Brusthaube lässt sich einfach mit der Hand halten, was den Zusammenbau der Pumpe erleichtert. Da die übrigen Teile durch die Befestigung der Brusthaube am Pumpengehäuse ebenfalls dicht anliegen, ist die Brustpumpe somit mit einem einzigen Handgriff, nämlich der Befestigung der Brusthaube am Pumpengehäuse, einsatzbereit. Ebenso einfach lassen sich die einzelnen Teile entfernen, um gereinigt zu werden. Vorzugsweise sind die Brusthaube und der Ventilkörper Teil des Moduls.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse auf, an welchem die Brusthaube lösbar befestigbar ist, wobei die Brustpumpe ferner einen Milchsammelbehälter aufweist, welcher am Pumpengehäuse mittels eines Schnappverschlusses befestigbar ist. Die Befestigung des Milchsammelbehälters mittels eines Schnappverschlusses ist unkonventionell. Üblicherweise werden Drehverschlüsse verwendet. Dank des Schnappverschlusses lässt sich der Behälter anders ausbilden und insbesondere schneller befestigen und entfernen.

Vorzugsweise weist der Milchsammelbehälter einen Grundkörper und einen Deckel auf, wobei der Deckel mindestens teilweise luftdurchlässig und flüssigkeitsundurchlässig ausgebildet ist. Dieser Deckel bildet somit ein Ventil, welches der Belüftung dient, welches aber auch ermöglicht, dass der Behälter ohne Flüssigkeitsverlust auf den Kopf gestellt werden kann. Vorzugsweise weist der Deckel eine luftdurchlässige und flüssigkeitsundurchlässige Membran auf. Vorzugsweise ist der Deckel zwischen dem Milchsammelbehälter und der Pumpe eingeklemmt und mittels Distanzstiften positionierbar.

Zudem ist der Deckel vorzugsweise mit einem Einwegventil versehen, welches von der Pumpkammer in den Milchsammelbehälter führt.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von

menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Ein Entleerungskanal ist zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden, welcher getrennt vom Milchkanal verläuft, wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist. Dadurch lässt sich Milch am Ende des Abpumpvorgangs auf einfache Art und Weise aus der Brusthaube entfernen. Der Entleerungskanal wird vorzugsweise mittels der Pumpkammer mit einem Unterdruck beaufschlagt, um die Milch aktiv abzupumpen und in den Milchsammelbehälter zu drängen.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Die Brustpumpe weist ein Pumpengehäuse, eine Pumpmembran und ein Modul auf, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist. Das Modul ist als Einheit am Pumpengehäuse befestigbar, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist. Dies erleichtert die Reinigung der relevanten Teile der Brustpumpe durch die Mutter und den Zusammenbau nach einer derartigen Reinigung.

Vorzugsweise weist das Modul ferner einen Ventilkörper auf, welcher zwischen

Brusthaube und steifer Schale angeordnet ist. Der Ventilkörper sowie die entsprechenden Bereiche des ersten und zweiten Teils, welche vorzugsweise Dichtsitze für die Ventile des Ventilkörpers aufweisen, bilden eine gemeinsame Ventileinheit, auch Ventilkonstrukt genannt.

Vorzugsweise weist das Modul ferner ein manuelles Betätigungsmittel zur Betätigung mindestens eines Ventils des Ventilkonstrukts auf.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter auf, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist. Der Milchsammelbehälter ist mittels eines Schnappverschlusses am Pumpengehäuse befestigbar.

Vorzugsweise weist diese Brustpumpe eine Pumpkammer und einen Milchkanal auf, durch welchen abgepumpte Milch von einem Innenraum der Brusthaube in die Pumpkammer fliesst, wobei die Pumpkammer einen Ausgang aufweist, welcher mit dem Milchsammelbehälter verbunden ist und durch welchen die abgepumpte Milch in den Milchsammelbehälter fliesst.

In einer bevorzugten Ausführungsform ist ein erfindungsgemässer Milchsammelbehälter zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, vorhanden, wobei der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse auf, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist. Die Brusthaube ist mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar.

In einer bevorzugten Ausführungsform ist eine erfindungsgemässe Brusthaube vorhanden, welche zur Befestigung an einem Pumpengehäuse einer Brustpumpe dient. Die Brusthaube weist einen Innenraum zur Aufnahme der Mutterbrust und einen Stutzen zur Befestigung am Pumpengehäuse auf, wobei der Stutzen mit einem Bajonettverschluss versehen ist.

In einer bevorzugten Variante eines erfindungsgemässen Verfahren zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird. In einer ersten Pumpphase wird der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst. In einer zweiten Pumpphase fliesst abgepumpte Milch aus dem Innenraum in die Pumpkammer und die Pumpkammer wird mit abgepumpter Milch gefüllt. In einer dritten Pumpphase fliesst die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt bleiben. Der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

Dank dieses Verfahrens stellt das Pumpsystem relativ schnell von einem pneumatischen auf ein hydraulisches oder vorwiegend hydraulisches Pumpsystem um. Dadurch lassen sich kleinere Antriebe und leistungsschwächere Motoren verwenden.

Vorzugsweise ist die erste Pumpphase eine vollständig oder vorwiegend pneumatische Pumpphase und die zweite Pumpphase eine vollständig oder vorwiegende hydraulische Pumpphase.

In einer bevorzugten Variante des Verfahrens wird der Innenraum in der ersten Pumpphase annähernd vollständig gefüllt. In einer bevorzugten Variante werden der Innenraum und/oder die Pumpkammer in der zweiten und/oder dritten Pumpphase annähernd

vollständig mit abgepumpter Milch gefüllt.

Vorzugsweise erfolgt der Wechsel von der ersten Pumpphase zur zweiten Pumpphase, indem ein Füllstand der abgepumpten Milch eine erste Durchgangsöffnung erreicht, welche vom Innenraum zur Pumpkammer führt, wodurch Milch durch die erste Durchgangsöffnung vom Innenraum in die Pumpkammer fliesst.

Vorzugsweise fliesst in der dritten Pumpphase die abgepumpte Milch durch die erste Durchgangsöffnung in die Pumpkammer und durch die Auslassöffnung in den Milchsammelbehälter.

Vorzugsweise wird in einer vierten Pumpphase der Innenraum entleert und die darin befindliche, bereits abgepumpte Milch wird durch eine zweite Durchgangsöffnung aus dem Innenraum zum Milchsammelbehälter geführt.

Vorzugsweise ist die erste Durchgangsöffnung mit einem ersten Ventil verschliessbar und die zweite Durchgangsöffnung mit einem zweiten Ventil verschliessbar, wobei die zweite Durchgangsöffnung während der ersten bis dritten Pumpphase stets geschlossen ist.

Vorzugsweise ist die erste Durchgangsöffnung während der vierten Pumpphase stets geschlossen.

Vorzugweise führt die zweite Durchgangsöffnung vom Innenraum in die Pumpkammer und steht über die Pumpkammer in fluidkommunizierender Verbindung mit der Auslassöffnung.

Vorzugsweise wird während mindestens einem Teil der Pumpphasen, vorzugsweise während der ersten, zweiten und dritten Pumpphase ein Basisunterdruck beibehalten.

Vorzugsweise ist ein drittes Ventil vorhanden, welches bei Druckanstieg des sich zyklisch ändernden Unterdrucks in Richtung Atmosphärendruck zuerst öffnet und dann schliesst und dadurch den Basisunterdruck beibehält.

Weitere Ausführungsformen und Varianten des Verfahrens sind in den abhängigen Ansprüchen angegeben.

Die einzelnen in den Ansprüchen aufgeführten Elemente lassen sich auch zu anderen Kombinationen zusammenfügen, ohne dass sämtliche Merkmale der Ansprüche übernommen werden müssen. Insbesondere lassen sich einzelne Elemente auch in reinen pneumatischen Brustpumpen verwenden, insbesondere in pneumatischen Membran-Brustpumpen.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

Bevorzugte Ausführungsformen der Erfindung werden im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine perspektivische Darstellung einer erfindungsgemässen Brustpumpe,

Figur 2 eine Explosionsdarstellung der Brustpumpe gemäss Figur 1 in einer perspektivischen Ansicht;

Figur 3 eine Explosionsdarstellung der Brustpumpe gemäss Figur 1 in einer weiteren perspektivischen Ansicht;

Figur 4 einen Teilschnitt durch die Brustpumpe gemäss Figur 1 in einer ersten perspektivischen Ansicht;

Figur 5 einen Teilschnitt durch die Brustpumpe gemäss Figur 1 in einer zweiten perspektivischen Ansicht;

Figur 6 einen Längsschnitt durch ein Hygienemodul, befestigt an einem Trägermodul der Brustpumpe gemäss Figur 1 in Explosionsdarstellung;

Figur 7 eine perspektivische Darstellung des zusammengesetzten Hygienemodul gemäss Figur 6;

Figur 8a eine perspektivische Darstellung einer Brusthaube der Brustpumpe gemäss Figur 1;

Figur 8b einen Teilschnitt durch die Brusthaube gemäss Figur 8a;

Figur 9a eine perspektivische Darstellung durch einen Ventilkörper der Brustpumpe gemäss Figur 1;

Figur 9b einen Teilschnitt durch den Ventilkörper gemäss Figur 9a;

Figur 9c einen Längsschnitt durch den Ventilkörper gemäss Figur 9a;

Figur 9d eine Ansicht des Ventilkörpers gemäss Figur 9a;

Figur 10a eine perspektivische Darstellung eines Stellrings der Brustpumpe gemäss Figur 1;

Figur 10b eine Ansicht des Stellrings gemäss Figur 10a;

Figur 11a eine perspektivische Darstellung eines Adapterteils der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 11b einen Teilschnitt durch das Adapterteil gemäss Figur 11a;

Figur 11c eine perspektivische Darstellung des Adapterteils gemäss Figur 11a von einer zweiten Seite;

Figur 12a eine perspektivische Darstellung einer Medientrennmembran der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 12b eine perspektivische Darstellung der Medientrennmembran gemäss Figur 12a von einer zweiten Seite;

Figur 12c einen Längsschnitt durch die Medientrennmembran gemäss Figur 12a;

Figur 13a eine perspektivische Darstellung einer Pumpmembran der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 13b eine perspektivische Darstellung der Pumpmembran gemäss Figur 13a von einer zweiten Seite;

Figur 13c einen Längsschnitt durch die Pumpmembran gemäss Figur 13a;

Figur 14 eine perspektivische Darstellung eines Trägermoduls der Brustpumpe gemäss Figur 1;

Figur 15 eine perspektivische Darstellung eines oberen Rahmenteils eines Milchsammelbehälters der Brustpumpe gemäss Figur 1;

Figur 16 einen Längsschnitt durch das obere Rahmenteil gemäss Figur 15 mit einem Behälterventil;

Figur 17 eine perspektivische Darstellung eines Gefässes des Milchsammelbehälters der Brustpumpe gemäss Figur 1;

Figur 18 eine schematische Darstellung des erfindungsgemässen Pumpsystems vor Anlegen eines Unterdrucks;

Figur 19a das schematisch dargestellte Pumpsystem gemäss Figur 1 bei der Aktivierung der Mutterbrust in einer ersten Hubposition;

Figur 19b das Pumpsystem gemäss Figur 19a in einer zweiten Hubposition;

Figur 19c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 19a und 19b;

Figur 20a das Pumpsystem gemäss Figur 19a zu Beginn des Milchflusses aus der Brust in einer ersten Hubposition;

Figur 20b das Pumpsystem gemäss Figur 20a in einer zweiten Hubposition;

Figur 20c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 20a und 20b;

Figur 21a das Pumpsystem gemäss Figur 19a während des kontinuierlichen Milchflusses aus der Brust in einer ersten Hubposition;

Figur 21b das Pumpsystem gemäss Figur 21a in einer zweiten Hubposition;

Figur 21c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 21a und 21b;

Figur 22a das Pumpsystem gemäss Figur 19a bei Beendigung des Milchflusses in einer ersten Hubposition;

Figur 22b das Pumpsystem gemäss Figur 22a in einer zweiten Hubposition;

Figur 22c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 22a und 22b;

Figur 23a das Pumpsystem gemäss Figur 19a beim Entleeren in einer ersten Hubposition;

Figur 23b das Pumpsystem gemäss Figur 23a in einer zweiten Hubposition und

Figur 23c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 23a und 23b.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

In den Figuren 1 bis 17 ist ein bevorzugtes Ausführungsbeispiel der erfindungsgemässen Brustpumpe dargestellt.

Die Zusammenschau der einzelnen Bauteile

Wie in Figur 1 erkennbar ist, ist die Brustpumpe kompakt aufgebaut. Sie weist ein Pumpengehäuse 8 mit einer daran befestigten Brusthaube 2 und einem ebenfalls am Pumpengehäuse 8 befestigten Milchsammelbehälter 9 auf. Im Pumpengehäuse 8 ist ein Motor mit einem Kraftübertragungselement, beispielsweise eine Spindel, angeordnet. Im Pumpengehäuse 8 sind ferner mindestens eine elektronische Steuerung zur Steuerung des Motors, Betätigungsschalter 86 zur Betätigung der Pumpe und ein Energiespeicher vorhanden.

Die Figuren 2 und 3 zeigen eine Explosionsdarstellung dieser Brustpumpe. Sie umfasst die erwähnte Brusthaube 2 zur Aufnahme der Mutterbrust, einen Ventilkörper 3 aus einem flexiblen Material, insbesondere Silikon, ein Adapterteil 4, einen zweiteiligen Stellring 5, eine Medientrennmembran 6, eine Pumpmembran 7, ein Trägermodul 8', welches Teil des Pumpengehäuses 8 ist sowie den bereits erwähnten Milchsammelbehälter 9.

Der Milchsammelbehälter

Der Milchsammelbehälter 9 ist vorzugsweise auf der Unterseite des Pumpengehäuses 8 an dieses einklinkbar, vorzugsweise lässt es einschwenkbar lösbar befestigen. Entsprechende Einrastelement 901, 902 sind in Figur 17 erkennbar. Das Pumpengehäuse 8 weist dazu passende, jedoch hier nicht dargestellte Einrastelemente auf.

Der Milchsammelbehälter 9 weist ein Gefäss 90 mit einem Innenraum 900 zur Aufnahme der abgepumpten Milch auf (siehe Figur 17). Dieses Gefäss 90 ist oben offen ausgebildet und mit einem Deckel verschliessbar. Der Deckel umfasst ein steifes unteres Rahmenteil 91, eine steife, halbsteife oder flexible Abdeckung 92 und ein steifes oberes Rahmenteil 93. Das untere Rahmenteil 91 entspricht der Form des Umfangs der Öffnung des Gefässes 90 und liegt dichtend auf diesem auf. Das steife obere Rahmenteil 93 klemmt die Abdeckung zwischen unterem und oberen Rahmenteil 91, 93 ein. Vorzugsweise sind die zwei Rahmenteile 91, 93 miteinander verleimt, verschweisst oder auf andere Art und Weise nicht zerstörungsfrei voneinander lösbar. Die Abdeckung 92 ist eine Folie oder ein anderes membranähnliches Teil, welche luftdurchlässig aber flüssigkeitsundurchlässig ist. Somit kann Luft aus dem Gefäss 90 entweichen, jedoch keine Flüssigkeit austreten.

Das obere Rahmenteil 93 entspricht vorzugsweise ebenfalls in seiner Form der Form des Gefässes 90, insbesondere entspricht sein Rahmen 930 der Form des unteren Rahmenteils 91. Es ist in den Figuren 15 und 16 detailliert dargestellt. Im Rahmen 930 sind zur Verstärkung und als Schutz der Abdeckung 92 Streben 931 vorhanden. Ein Griff 933 erleichtert das Anheben des Deckels. Distanzstifte 934, welche auf dem Rahmen 930 angeordnet sind und diesen überragen, gewährleisten bei montiertem Milchsammelbehälter 9 einen Abstand zum Pumpengehäuse 8, so dass Luft aus dem Behälterinnenraum 900 in die Umgebung entweichen kann. Eine Ventilaufnahme 932 ist am oberen Rahmenteil 93

angeformt und bildet den einzigen Flüssigkeitszugang in den Innenraum des Gefässes 90.

In dieser Ventilaufnahme 932 ist ein Behälterventil 94 angeordnet, welches als Einwegventil ausgebildet ist. Somit kann bei geschlossenem Deckel Flüssigkeit nur in den Milchsammelbehälter 9 hinein gelangen, nicht jedoch hinaus. Das Behälterventil 94 ist vorzugsweise, wie hier dargestellt, ein Entenschnabelventil.

Das Hygienemodul

In den Figuren 6 und 7 ist ein erfindungsgemässes Hygienemodul dargestellt. Es umfasst mindestens den Stutzen 23 der Brusthabe 2, den Ventilkörper 3, das Adapterteil 4 sowie den Stellring 5. Es kann zudem, wie hier dargestellt ist, auch eine flexible Medientrennmembran 6 umfassen. Ist die Brusthaube einstückig ausgeführt, so ist sie gesamthaft Teil des Hygienemoduls.

Die genannten Teile lassen sich, wie in den Figuren 6 und 7 dargestellt, zu einer gemeinsamen Baugruppe zusammenfügen und gemeinsam im Trägermodul 8' lösbar befestigen. Hierfür ist der Stutzen 23 der Brusthaube 2 vorzugsweise form- und kraftschlüssig in entsprechende Aufnahmen, hier zwei einander gegenüberliegende Seitenarme 80, des Trägermoduls 8' befestigbar. Vorzugsweise erfolgt die Verbindung über einen Bajonettverschluss, wie hier dargestellt ist. Der Stutzen 23 weist einen entsprechenden Flansch 22 auf, die Seitenarme 80 des Trägermoduls 8' entsprechende Aufnahmen für den Flansch und die übrigen Elemente des Bajonettverschlusses.

Dank der Befestigung der Brusthaube am Trägermodul 8' und somit am Pumpengehäuse 8 sind auch die dazwischenliegenden Teile, d.h. der Ventilkörper 3, das Adapterteil 4 und die Medientrennmembran 6 des Hygienemoduls sowie die Pumpmembran 7 miteinander dicht verbunden.

Der Stellring 5 ist vorzugsweise nicht zerstörungsfrei lösbar auf dem Adapterteil 4 befestigt, wobei er relativ zu diesem um die Längsmittelachse des Hygienemoduls schwenkbar ist.

Im Folgenden werden die einzelnen Teile der Vorrichtung und deren Zusammenwirken beschrieben.

Die Brusthaube

In den Figuren 8a und 8b ist die Brusthaube 2 dargestellt. Sie dient zur Aufnahme der Mutterbrust. Sie weist einen Trichter 20 zur Auflage auf die Mutterbrust und einen Innenraum 200 auf, welcher mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist und in welchem die Mutterbrust oder zumindest die Brustwarze aufgenommen wird.

Die Brusthaube ist vorzugsweise einstückig und vorzugsweise aus einem steifen oder halbsteifen Kunststoff gefertigt. Sie kann jedoch auch mehrteilig ausgeführt sein. Sie kann zudem mit einem weichen Liner verwendet werden, z.B. mit einem Brusthaubeneinsatz aus einem weichen Silikon.

Der Trichter 20 folgt ein Stutzen 23 mit einem mindestens teilweise umlaufenden Flansch 22, welcher einen Teil des genannten Bajonettverschlusses bildet. Der Innenraum 200 geht auf der brustabgewandten Seite des Stutzens 23 in eine Durchgangsöffnung 21 über, welche einen in der Mittellängsachse verlaufenden Kanal bildet. Am Stutzen 23, auf der brustabgewandten Seite des Flansches 22 ist, ist auf zwei diametral gegenüberliegenden Seiten je eine Vertiefung vorhanden.

In der ersten Vertiefung ist eine erste Auslassöffnung 24 sowie eine winkelförmige erste Durchflussöffnung 25 vorhanden. Die erste Auslassöffnung 24 führt vom Innenraum 200 zur Aussenseite des Stutzens 23, genauer in die erste Vertiefung. Die erste Durchflussöffnung 25 führt von dieser ersten Vertiefung in einem vorzugsweise rechtwinkligen Kanal zur brustabgewandten freien Stirnfläche des Stutzens 23. Auf dem Umfang des Stutzens 23 ist neben der ersten Auslassöffnung 24, aber jedoch ausserhalb der ersten Vertiefung, eine Belüftungsöffnung 26 vorhanden. Diese führt vom Innenraum 200 nach aussen.

Auf der diametral gegenüberliegenden Seite des Stutzens 23 ist eine analoge zweite Vertiefung mit einer zweiten Auslassöffnung 27 und einer zweiten Durchlassöffnung 28 vorhanden, welche gleich ausgebildet sind wie die ersten Öffnungen. Des Weiteren ist

ebenfalls ausserhalb der zweiten Vertiefung und neben der zweiten Auslassöffnung 27 eine zweite Belüftungsöffnung 29 vorhanden. Diese zweite Lüftungsöffnung 29 hat eigentlich keine Funktion sondern ist bei bestimmungsgemässen Gebrauch der Vorrichtung verschlossen. Damit die Brusthaube 2 jedoch in um 180° gedrehter Position ebenfalls am Trägermodul 8' montiert werden kann, sind alle Öffnungen symmetrisch angeordnet.

Der Ventilkörper

Die Figuren 9a bis 9d zeigen den Ventilkörper 3. Der Ventilkörper 3 ist aus einem flexiblen Material, vorzugsweise aus Silikon, gefertigt. Er ist vorzugsweise einstückig ausgebildet. Er weist einen hohlzylinderförmigen Grundkörper 30 mit einer Rückwand 31 auf. In der Rückwand befindet sich zentral eine Durchgangsöffnung 32. Die Rückwand 31 weist auf der brustabgewandten Seite eine die Durchgangsöffnung 32 ringförmig umlaufende Rille 312 auf, welche auf der gegenüberliegenden, brustnahen Seite eine Dichtfläche 310 bildet. Der umlaufende Rand der Durchgangsöffnung 32 ist auf der brustabgewandten Seite mit einer umlaufenden Dichtlippe 311 versehen (siehe Figuren 9b und 9c). Der Bereich der Rückwand 31 innerhalb der umlaufenden Dichtfläche 310 bildet somit ein Ventil, welches wie weiter unten erläutert ist, als Basisvakuum-Ventil dient.

Der Grundkörper 30 weist auf der brustzugewandten Seite eine radial abstehende Positioniernase 33 auf. Am Mantel des Grundkörpers 3 ist eine erste Noppe 34 sowie eine Belüftungsnoppe 35 vorhanden. Diametral gegenüberliegend befindet sich eine zweite Noppe 36. Die drei Noppen stehen radial nach aussen vor. Die erste Noppe 34 und die zweite Noppe 36 sind massiv, d.h. nicht hohl, ausgebildet. Die Belüftungsnoppe 35 weist eine Durchgangsöffnung vom Innenraum des Grundkörpers 30 nach aussen auf.

Im Ringbereich der Rückwand 31 zwischen Dichtungsfläche 310 und Mantel des Grundkörpers 30 sind einander ebenfalls diametral gegenüber liegende Ventilklappen vorhanden. Eine erste dieser Ventilklappen ist mit dem Bezugszeichen 37 versehen, eine zweite dieser Ventilklappen mit dem Bezugszeichen 38. Sie befinden sich vorzugsweise auf derselben Diagonalen wie die erste und der zweite Noppe 34, 36.

Der Stellring

Die Figuren 10a und 10b zeigen den Stellring 5. Er ist vorzugsweise steif und

vorzugsweise aus Kunststoff ausgebildet. Der Stellring 5 besteht vorzugsweise aus zwei Teilen. Ein erstes Teil 50 weist die Form eines halben Ringes auf und ist an beiden freien Enden mit einem ersten Steckerteil 51 versehen. Der zweite Teil 52 weist ebenfalls die Form eines halben Ringes auf und ist an seinen freien Enden mit je einem zweiten Steckerteil 53 versehen. Der erste und zwei Teil 50, 52 bilden einen gemeinsamen Ring und die zwei Steckerteil-Paare 51, 53 sind mit Einrastelementen 54 versehen, um sich vorzugsweise unlösbar miteinander zu verbinden. Am inneren Umfang des Rings ist ein teilweise umlaufender, nach innen radial vorstehender Anschlag 55 vorhanden, welcher nach erfolgter Montage auf dem Adapterteil 4 ein erneutes Entfernen des Stellrings 5 verhindert. An der innere Wandung des Stellrings ist ein erstes und ein zweites Anpresselement 56, 57 angeformt. Diese sind vorzugsweise radial nach innen vorstehende Erhöhungen, welche über eine Schrägfläche, auch Rampe genannt, in einen parallel zur Ringinnenfläche verlaufende Fläche übergehen. Am ersten Teil 50 ist ein nach assen vorstehender Betätigungshebel 58 angeformt.

Das Adapterteil

Die Figuren 11a bis 11c zeigen das Adapterteil 4. Es besteht vorzugsweise aus einem steifen Material, vorzugsweise aus Kunststoff. Es weist einen hohlzylinderförmigen Grundkörper 40 mit einer im Wesentlichen geschlossenen, flanschartigen pumpenseitigen Wand 41 auf. Der Grundkörper 40 weist in seinem Mantel ein erstes Fenster 400 und ein diametral gegenüberliegendes zweites Fenster 401 auf. An der brusthaubennahen Stirnfläche des Grundkörpers 40 ist eine Positionierhilfe 402 vorhanden, welche das Gegenstück zur Positioniernase 33 des Ventilkörpers 3 bildet und welche gemeinsam mit der Positioniernase 33 der drehsicheren Positionierung des Ventilkörpers 3 dient.

Die pumpenseitige Wand 40 verlängert sich in einer Richtung, welche hier als unten bezeichnet wird, in eine Kanalwand 410. Die pumpenseitige Wand weist ferner einen erhöhten zentralen Wandteil 42 auf, welcher in den brusthaubennahen Bereich ragt. Auf der gegenüberliegenden Seite des Wandteils 42, also dem Pumpengehäuse zugewandt, ist somit eine konkave Fläche ausgebildet, welche die bereits genannte steife Schale bildet und einen Teil der Pumpkammer 47 ist.

Zwischen dem erhöhten Wandteil 42 und Mantel des Grundkörpers 40 ist in der

pumpenseitigen Wand 41 eine erste Durchgangsöffnung 43 und eine zweite Durchgangsöffnung 44 vorhanden. Die zwei Durchgangsöffnungen 43, 44 liegen einander diametral gegenüber. Sie sind in diesem Beispiel kreisförmig ausgebildet. Im Randbereich des erhöhten Wandteils 42, jedoch bereits auf seiner Erhöhung, sind eine erste Rückspülöffnung 45 und eine zweite Rückspülöffnung 46 vorhanden. Diese sind vorzugsweise länglich ausgebildet. Diese Öffnungen führen alle in die Pumpkammer 47.

Wie in Figur 11c zu erkennen ist, ist die konkave Schale der Pumpkammer 47 von einem umlaufenden planen Rand umgeben, welche als Dichtfläche dient. In diesem Rand verläuft eine Rinne 48, welcher vorzugsweise an einem obersten Punkt der Pumpkammer 47 beginnt und mit dieser über eine Auslassöffnung 480 in fluidkommunizierender Verbindung steht. Der Kanal 48 verläuft entlang des Umfangs der Pumpkammer 47, hier teilkreisförmig, nach unten zu einem Auslass 49 hin. Der Auslass 49 befindet sich in der Kanalwand 410.

Die Medientrennmembran

In den Figuren 12a bis 12c ist die Medientrennmembran 6 dargestellt. Sie ist flexibel ausgebildet, ist vorzugsweise einstückig und vorzugsweise aus Silikon gefertigt. Sie weist eine Membranfläche 60 auf, welche vorzugsweise in bekannter Weise mit mindestens einer ringförmigen Rille versehen ist. Ein Zentralbereich 61 der Membranfläche ist vorzugsweise erhöht ausgebildet und dem Adapterteil 4 zugewandt. Der Rand der Membranfläche 60 ist als Dichtfläche 62 ausgebildet und liegt dichtend am Rand des Adapterteils 4 an, wodurch die Pumpkammer 47 gebildet wird. Eine Rinne 63 verläuft innerhalb der Dichtfläche 62 entlang des Umfangs der Medientrennmembran 6 und bildet den dichtenden Verschluss der Rinne 48 des Adapterteils 4. Eine dem Pumpengehäuse zugewandte Vertiefung 64 im unteren Bereich der Medientrennmembran 6 dient als Freiraum für einen Drucksensor, welcher nachfolgend noch beschrieben ist.

Die Medientrennmembran 6 weist vorzugsweise, wie in den Figuren dargestellt ist, Versteifungen in Form von Rippen auf, welche die Funktionsweise der Medientrennmembran sicherstellen. D.h. die Rippen gewährleisten, dass sich die Membran in gewünschter Art und Weise bewegt und trotzdem stets dichtend an ihren benachbarten Teilen anliegt.

Die Pumpmembran

In den Figuren 13a bis 13c ist die Pumpmembran 7 dargestellt. Auch sie weist eine Membranfläche 70 sowie einen Zentralbereich 71 auf. Im Gegensatz zur vollflächigen Medientrennmembran 6 ist der Zentralbereich 71 der Pumpmembran 7 mit einer Durchgangsöffnung72 versehen, deren Randbereich vorzugsweise eine Verstärkung 73, hier in Form von Rippen, aufweist. Es ist wiederum eine umlaufende Dichtfläche 74 vorhanden, welche im zusammengesetzten Zustand der Vorrichtung dichtend auf der entsprechenden Fläche des Trägermoduls 8' anliegt. Ausserhalb der Dichtfläche 74 befinden sich Seitenflügel 77. Die Seitenflügel 77 bilden zusammen mit der umlaufenden planen Dichtfläche 74 (Figur 13b) im zusammengebauten Zustand eine dichte Barriere gegenüber von aussen einwirkenden Flüssigkeiten und schützen somit die Elektronik.

Der untere Bereich der Pumpmembran 7, welcher sich jedoch noch innerhalb der geschlossenen umlaufenden Dichtfläche 74 befindet, ist als Drucksensor ausgebildet. Der Drucksensor umfasst eine Sensorfläche 75 in Form einer Membran, welche über einen Verbindungssteg mit der Membranfläche 70 verbunden ist, und einer Fahne 76, welche der Sensorfläche senkrecht in Richtung Pumpengehäuse vorsteht. Diese Art Drucksensor ist in WO 2013/049944 A1 beschrieben.

Wie in den Figuren erkennbar ist, weisen die Medientrennmembran 6 und die Pumpmembran 7 ähnliche Formen auf, insbesondere bezüglich ihrer zur Erzeugung des Unterdrucks bewegbaren Bereiche.

Das Trägermodul

Das Trägermodul 8' ist in Figur 14 dargestellt. Es ist in einem Aussengehäuse des Pumpengehäuses gehalten. Das Aussengehäuse ist in Figur 1 sichtbar. Vorzugsweise ist das Trägermodul 8' in diesem Aussengehäuse verschraubt. Die entsprechenden Befestigungslöcher sind mit dem Bezugszeichen 84 versehen. Das Trägermodul lässt sich einstückig aus Kunststoff herstellen. Es kann jedoch auch mehrteilig und/oder aus einem anderen Material gefertigt sein. Das Trägermodul 8' weist zwei vorstehende Seitenarme 10 mit einem Bajonettverschluss zur Aufnahme der Brusthaube 2 auf. Die Seitenarme sind seitlich an einer Spindelaufnahme 82 angeordnet. Die Spindelaufnahme 82 weist ein

Durchgangsöffnung auf sowie einen umlaufenden Rand 85, welcher das Gegenstück zur Dichtfläche 74 der Pumpmembran 7 bildet. Auf der Spindelaufnahme 82 ist eine Motoraufnahme 81 in Form einer Schale ausgebildet. Die Motoraufnahme 81 dient der Halterung eines Elektromotors, welcher mit einer Spindel 83 (siehe Figur 4) verbunden ist.

Wirkungsweise der zusammengesetzten Baugruppe

Anhand der Figur 6 lässt sich erkennen, wie die einzelnen Öffnungen und Ventile zusammenwirken.

Der Ventilkörper 3 lässt sich in den hohlzylindrischen Grundkörper 40 des Adapterteils 4 drehpositioniert einführen. Der Stellring 5 ist dabei bereits unlösbar mit dem Adapterteil 4 verbunden, wobei das erste Anpresselement 56 durch das erste Fenster 400 nach innen ragt und das zweite Anpresselement 57 durch das zweite Fenster 401 nach innen ragt. Die erste Noppe 34 des Ventilkörpers 3 befindet sich dabei unterhalb des ersten Fensters 400 und die zweite Noppe 36 oberhalb des ersten Fensters 401. Die Ventilklappen 37, 38 des Ventilkörpers 3 befinden sich jeweils über der ersten bzw. der zweiten Durchgangsöffnung 43, 44 des Adapterteils. Die Dichtlippe 311 liegt dichtend auf dem erhöhten Wandteil 42 auf, wobei die erste und zweite Rückspülöffnung in einem dichten Ringbereich zwischen Rille 312 und Dichtlippe 311 angeordnet sind.

Wird nun die Brusthaube 2 eingesetzt, so liegt die erste Noppe 34 über der ersten Auslassöffnung 24 und die Belüftungsnoppe 35 liegt über der ersten Belüftungsöffnung 26. Die zweite Noppe 36 liegt über der zweiten Auslassöffnung 27. Die zweite Belüftungsöffnung 29 ist vom Mantel des Ventilkörpers 4 überdeckt und somit verschlossen.

Wird nun die Brusthaube 2 mit dem Trägermodul 8' verbunden, so werden die einzelnen Verbindungen zwischen den beschriebenen Kanälen und Öffnungen erstellt und gegenüber aussen gedichtet.

In den Figuren 4 und 5 ist die erfindungsgemässe Brustpumpe im zusammen gesetzten Zustand dargestellt. Wie gut erkennbar ist, weist dieses System praktisch keinen Totraum auf.

In Figur 4 ist die Spindel 83 erkennbar, welche die Pumpmembran 7 antreibt. Die Medientrennmembran 6 hat eine Form, welche sich der Pumpmembran 7 anschmiegt, so dass sich beide Membrane 6, 7 gemeinsam bewegen und auch hier keine Verluste auftreten. Das Pumpengehäuse 8, genauer das Trägermodul 8' weist eine Rückwand 85 auf, an welcher die Pumpmembran 7 dichtend anliegt, wenn das Hygienemodul am Trägermodul 8' befestigt ist. Dies ist in den Figuren 4 und 5 gut erkennbar. Der Stellring 5 ist schwenkbar innerhalb der Seitenarme 80 angeordnet, wobei der Betätigungshebel 58 auch als Anzeigeelement dient. Er bewegt sich entlang einer Anzeige 87, welche am Pumpengehäuse 8 angebracht ist und welche dem Benutzer somit Auskunft über die Stellung einzelner Ventile gibt und somit den Betriebszustand der Pumpe gibt. D.h. es wird angezeigt, ob die Pumpe betriebsbereit zum Abpumpen ist oder sich im Entleerungszustand befindet. Dies wird nachfolgend erläutert.

Durch Drehen des Stellrings 5 lassen sich einzelne Ventile manuell öffnen und schliessen. Genauer lassen sich die erste Auslassöffnung 24 gemeinsam mit der ersten Durchflussöffnung 25 alternativ zur zweiten Auslassöffnung 27 gemeinsam mit der zweiten Durchflussöffnung 28 manuell öffnen und schliessen. Die erste Belüftungsöffnung 26 wird gemeinsam mit der zweiten Auslassöffnung 27 und der zweiten Durchflussöffnung 28 geöffnet und geschlossen. Die zweite Belüftungsöffnung 29 bleibt aufgrund ihrer Position innerhalb des Ventilkörpers 3 stets geschlossen.

Ist die Brusthaube 2 derart relativ zum Ventilkörper 3 positioniert, dass die zweiten Öffnungen an der Position der ersten Öffnungen liegen, wird selbstverständlich die zweite anstelle der ersten Belüftungsöffnung geöffnet und geschlossen.

In einer ersten Stellung, die zu Beginn des Abpumpvorgangs und während des gesamten Abpumpvorgangs gewählt ist, wird die zweite Noppe 36 des Ventilkörpers 3 durch das zweite Anpresselement 57 des Stellrings nach unten gedrückt und liegt auf der Vertiefung und somit der zweiten Auslassöffnung 27 und der zweiten Durchflussöffnung 28 der Brusthaube 2 auf. Zudem wird die Belüftungsnoppe 35 durch das erste Anpresselement 56 auf die erste Belüftungsöffnung 26 gedrückt und verschliesst diese. Die erste Noppe 34 des Ventilkörpers 3 ist hingegen freigeben, so dass die erste Auslassöffnung 24 und die erste

Durchflussöffnung 25 einen fluidkommunizierenden Kanal vom Innenraum 200 der Brusthaube in den Grundkörper 30 des Ventilkörpers 3 bilden. Dies ist am besten in den Figuren 2, 3 und 6 erkennbar.

In einer zweiten Stellung wird der Stellring 5 gedreht. Das erste Anpresselement 56 gibt die Belüftungsnoppe 35 und somit die erste Belüftungsöffnung 26 frei, presst hingegen die erste Noppe 34 auf die Vertiefung und verschliesst somit die erste Auslassöffnung 24 und die erste Durchflussöffnung 25. Das zweite Anpresselement 57 gibt zudem die zweite Noppe 36 frei, so dass nun die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 einen offenen, durchgehenden Kanal vom Innenraum 200 der Brusthaube 2 in den Ventilkörper 3 bilden. Die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 bilden einen Entleerungskanal, welcher weiter unten noch genauer beschrieben wird.

Das gegenseitige Öffnen und Schliessen erfolgt vorzugsweise gleichzeitig. Es ist jedoch auch möglich, die Anpresselemente so versetzt anzuordnen, dass in einem Zwischenzustand alle Öffnungen verschlossen sind.

Abpumpen der Muttermilch und Entleerungsvorgang

Damit Milch von der Mutterbrust abgepumpt werden kann, wird der Betätigungshebel 58 und somit der Stellring 5 in die erwähnte erste Stellung gebracht. Mittels des Antriebs wird die Pumpmembran 7 gemeinsam mit der Medientrennmembran 6 zum Adapterteil 4 hin und zurückbewegt, so dass in der Pumpkammer 47 und im Innenraum 200 der Brusthaube 2 ein Unterdruck entsteht. Die Vakuumleitung von der Pumpkammer 47 in den Innentraum 200 der Brusthaube 2 ist dabei gebildet durch die erste Durchgangsöffnung 43 im Adapterteil 4, die Öffnung im Ventilkörper 3 bedeckt durch die erste Ventilklappe 37 sowie den Kanal gebildet durch die erste Durchflussöffnung 25 und die erste Auslassöffnung 24 in der Brusthaube.

Das Basisvakuumventil, unter anderem gebildet durch die Dichtlippe 311 des Ventilkörpers 3, ermöglicht die Erhaltung eines Basisunterdrucks im Innenraum 200 der Brusthaube 2, wenn der Pumphub in Richtung Atmosphärendruck verläuft. Das Basisvakuumventil öffnet sich beim Pumphub in Richtung Atmosphärendruck und

schliesst erst bei Erreichen eines vorgegebenen Minimaldrucks im Innenraum 200. Die Wirkungsweise wird weiter unten anhand eines Schemas nochmals genauer erläutert. Der Rückfluss der Luft in die Brusthaube 2 erfolgt über die erste und zweite Rückspülöffnung 45, 46, des Adapterteils 4, die Durchgangsöffnung 32 des Ventilkörpers 3 und die Durchgangsöffnung 21 der Brusthaube 2.

Durch Anlegen dieses Vakuums an die Mutterbrust wird diese stimuliert und Milch fliesst aus der Brust in den Innenraum 200 der Brusthaube 2. Der Innenraum 200 füllt sich, bis der Füllstand der Milch die erste Auslassöffnung 24 erreicht. Die Brusthaube 2 wird dabei vorzugsweise so gehalten, dass sich diese erste Auslassöffnung 24 in einem oberen Bereich der Brusthaube 2 befindet.

Die abgepumpte Milch fliesst dann durch den Kanal, gebildet durch die erste Auslassöffnung 24 und die erste Durchlassöffnung 25, und durch die von der ersten Ventilklappe 37 bedeckten Öffnung in das Adapterteil 4, wo sie durch die erste Durchgangsöffnung 43 in die Pumpammer 47 gelangt.

Die Pumpkammer 47 füllt sich ebenfalls mit Milch, bis die oben angeordnete Auslassöffnung 480 erreicht ist. Die Milch fliesst anschliessend durch den Kanal, gebildet durch die Rinne 48 des Adapterteils 4 und der Rinne 63 bzw. der Abdeckung der Medientrennmembran 6 durch den Auslass 49 aus dem Hygienemodul heraus und durch das Behälterventil 94 in den Milchsammelbehälter 9.

Wenn der Pumphub jeweils von Erzeugung eines Unterdrucks in Richtung Atmosphärendruck, so öffnet sich zuerst das Basisvakuum-Ventil und ermöglicht einen Teilrückfluss der Luft bzw. der Milch Innenraum 200. Dieser Teilrückfluss erfolgt durch die erste und zweite Rückspülöffnung 45, 46, das offene Basisvakuumventil, die Durchgangsöffnung 32 und die Durchgangsöffnung 21. Das Ventil schliesst sich bei einem bestimmten Vakuumwert im Innenraum, so dass der Druck nicht weiter Richtung Atmosphärendruck ansteigen kann.

Wenn die Mutter das Abpumpen der Milch beenden will bzw. wenn keine Milch mehr aus der Brust fliesst, so schwenkt sie den Stellring 5 in die zweite Stellung. Der bisher benützte

Vakuum- und Milchkanal wird verschlossen, indem die erste Auslassöffnung 24 und die erste Durchlassöffnung 25 verschlossen werden. Dabei öffnen sich jedoch die zweite Auslassöffnung 27, die zweite Durchlassöffnung 28 und die erste Belüftungsöffnung 26. Diese Umstellung kann bei laufender Pumpe, d.h. bei nach wie vor angetriebener Pumpmembran 7, erfolgen. Die Pumpe kann hierfür auch abgestellt und anschliessend wieder in Betrieb genommen werden. Da die Pumpe nun weiter saugt, wird die sich noch im Innenraum 200 der Brusthaube 2 befindliche, bereits aus der Mutterbrust abgepumpte Milch durch die zweite Auslössöffnung 27, die zweite Durchlassöffnung 28, die durch die zweite Ventilklappe 37 verdeckte Öffnung des Ventilkörpers 3 und die zweite Durchgangsöffnung 44 des Adapterteils 4 in die Pumpkammer 47 gepumpt. Von dort wird sie durch die Bewegung der Pumpmembran 7 und der Medientrennmembran 6 aus der Pumpkammer 47 in Richtung Auslassöffnung 480 verdrängt. Sie fliesst somit ebenfalls durch die Rinne 48 und den Auslass 49 in den Milchsammelbehälter 9. Auf diese Weise lassen sich sowohl der Innenraum 200 der Brusthaube 2 wie auch die Pumpkammer 47 annähernd vollständig entleeren. Die Vorrichtung lässt sich zudem in eine Schräglage bringen, um die gesamte Milch aus dem System in den Milchsammelbehälter 9 zu entleeren.

Zu beachten ist, dass zu Beginn des Abpumpvorgangs die Brustpumpe vorzugsweise so gehalten wird, dass sich die erste Auslassöffnung 24 der Brusthaube und die Auslassöffnung 480 der Pumpkammer 47 in einem oberen Bereich des jeweiligen Hohlraums befinden. Dadurch kann Luft aus dem System entweichen und die zwei Hohlkammern werden relativ schnell mit Milch gefüllt. Dies ermöglicht ein möglichst rasches Wechseln von einem rein pneumatischen Pumpsystem mit Luft als Arbeitsfluid in ein reines oder mehrheitliches hydraulisches Pumpsystem, in welchem Milch das Arbeitsfluid bildet oder zumindest einen grossen Anteil des Arbeitsfluids bildet. Es ist jedoch nicht zwingend notwendig, dass die Öffnungen zu Beginn des Abpumpvorgangs derart angeordnet sind. Der Wechsel von einem Pumpsystem in das andere benötigt einfach längere Zeit und/oder kann nicht vollständig vollzogen werden.

Sobald die Milch den Innenraum 200 und die Pumpkammer 47 teilweise geflutet hat, vorzugsweise bis zu den genannten Öffnungen, kann die Brustpumpe in eine beliebige Position gebracht werden. Dies gilt nicht nur für die Brusthaube 2 und die Pumpkammer

47, sondern insbesondere auch für den Milchsammelbehälter 9. Dank des als Rückschlagventil ausgebildeten Behälterventils 94 und dank der flüssigkeitsundurchlässigen Abdeckung 92 kann der Milchsammelbehälter 9 sogar auf den Kopf gestellt werden, ohne den Betrieb der Brustpumpe zu beeinträchtigen.

In bevorzugten Ausführungsformen ist die Brusthaube und auch der Stellring beleuchtet, damit die Mutter auch in der Nacht während des Abpumpens eine Sichtkontrolle durchführen kann.

Die oben beschriebene Brustpumpe ist lediglich ein Ausführungsbeispiel, in welcher das erfindungsgemässe Prinzip umgesetzt und das erfindungsgemässe Verfahren angewendet werden kann. In den Figuren 18 bis 23c ist deshalb nochmals schematisch dargestellt, worin der Kern der erfindungsgemässen Ideen liegt.

Grundprinzip

In Figur 1 ist schematisch die Brusthaube 2 mit dem Innenraum 200 dargestellt. Die Brusthaube 2 ist dichtend auf eine Mutterbrust angelegt, die Brustwarze W ragt den Innenraum 200 hinein. Der Innenraum 200 ist über eine Auslassöffnung 16 mit einer Pumpkammer 47 verbunden. Eine zusätzliche Entleerungsöffnung19 führt ebenfalls vom Innenraum 200 zur Pumpkammer 47. Die Auslassöffnung 16 ist mit einem Pumpventil 12 versehen, die Entleerungsöffnung mit einem Entleerungsventil 14. Ein Basisvakuumventil 13 schliesst eine dritte Öffnung 17 zwischen Vakuumkammer 47 und Innenraum 200 der Brusthaube 2. Eine mit einem Belüftungsventil 11 verschliessbare Belüftungsöffnung 15 führt zudem vom Innenraum 200 der Brusthaube 2 nach aussen.

Das Volumen der Pumpkammer 47 ist mittels eines Pumpmittels 10, beispielsweise einer Pumpmembran oder einem Kolben, veränderbar. Das Pumpmittel 10 ist angetrieben, beispielsweise mittels einer Spindel 100.

Von der Pumpkammer 47 führt eine Auslassöffnung 480 in einen Milchsammelbehälter 9. Der Einlass in den Milchsammelbehälter 9 ist vorzugsweise mit einem Rückschlagventil, hier Behälterventil 94 genannt, versehen. Der Milchsammelbehälter 9 ist belüftet,

vorzugsweise ist hierfür ein Einlass 95 mit einem Einlassventil 96 vorhanden.

Der Vergleich mit dem oben ausführlich beschriebenen Ausführungsbeispiel zeigt, dass die Belüftungsöffnung 15 und das Belüftungsventil 11 der ersten Belüftungsöffnung 26, der Belüftungsnoppe 35 und dem ersten Anpresselement 56 entsprechen.

Die Auslassöffnung 16 und das Basisvakuumventil 12 der schematischen Darstellung entsprechen der ersten Auslassöffnung 24, der ersten Durchflussöffnung 25, der erste Noppe 34, dem ersten Anpresselement 56 sowie der ersten Ventilklappe 37 des konkreten Ausführungsbeispiels.

Die Entleerungsöffnung 19 und das Entleerungsventil 14 der schematischen Darstellung entsprechen der zweiten Auslassöffnung 27, der zweiten Durchflussöffnung 28, der zweiten Noppe 36, dem zweiten Anpresselement 57 sowie der zweiten Ventilklappe 38 des konkreten Ausführungsbeispiels.

Die Basisvakuumventil 13 sowie die dritte Öffnung 17 der schematischen Darstellung entsprechen der Dichtlippe 311, der ersten und zweiten Rückspülöffnung 45, 46 sowie der Durchgangsöffnung 32 im Ventilkörper 3 des konkreten Ausführungsbeispiels.

Das Behälterventil 94 der schematischen Darstellung entspricht dem Behälterventil des konkreten Ausführungsbeispiels.

Der Einlass 95 und das Einlassventil 96 der schematischen Darstellung sind in dem oben beschriebenen konkreten Ausführungsbeispiel durch die luftdurchlässige und flüssigkeitsundurchlässige Abdeckung, d.h. durch eine entsprechend gewählte Abdeckfolie, gebildet.

Diese Ventile lassen sich auch auf andere Art und Weise verwirklichen. Die Ventilöffnungen können auch in einem zusätzlichen Modulteil untergebracht sein, welches mit der Brusthaube lösbar verbunden ist. Zudem können die Auslassöffnung 16 und/oder die Entleerungsöffnung 19 als Kanal ausgebildet sein, welcher in einer Leitung, insbesondere einer flexiblen Leitung verläuft. Je nach Ausbildung dieser Leitung kann die

Pumpkammer beabstandet zur Brusthaube und je nach Ausführungsform auch beabstandet zu einem Ventilmodul angeordnet sein. Die Ventile lassen sich vorzugsweise in einem Modul unterbringen, welches zwischen Pumpkammer und Brusthaubentrichter angeordnet ist. Ist die Pumpkammer beabstandet zur Brusthaube angeordnet, so kann das Ventilmodul benachbart zur Pumpkammer oder benachbart zur Brusthaube angeordnet sein bzw. ein Bestandteil der Brusthaube sein.

Im Folgenden wird die Funktionsweise erläutert:

In der Darstellung gemäss Figur 18 ist die Pumpe noch nicht eingeschaltet. Die Ventile sind bis auf das Einlassventil 96 des Milchsammelbehälters 9 geschlossen. In allen Bereichen herrscht Atmosphärendruck, d.h. p=0.

In der Darstellung gemäss den Figuren 19a bis 19c beginnt der Pumpvorgang und die Mutterbrust wird durch den angelegten Unterdruck stimuliert. Das Pumpventil 12 kann sich öffnen und schliessen. Im konkreten Ausführungsbeispiel ist hierfür die erste Auslassöffnung 24 und die erste Durchflussöffnung 25 freigegeben und die erste Ventilklappe 37 öffnet und schliesst das Ventil. Das Entleerungsventil 14 ist fest verschlossen. Im konkreten Ausführungsbeispiel erfolgt dies, indem der Stellring 5 in die entsprechende Position gebracht wird und die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 fest verschliesst. Ebenso bleibt das Belüftungsventil 11 fest verschlossen. Im konkreten Ausführungsbeispiel wird dies erreicht, indem mittels des Stellrings 5 die erste Noppe 34 die erste Belüftungsöffnung 26 verschliesst.

Das Pumpmittel 10, vorzugsweise eine Pumpmembran oder ein Kolben, wird nach aussen gezogen, um einen Unterdruck in der Pumpkammer 47 zu erzeugen (hier z.B. -150 mmHg). Das Pumpventil 12 öffnet sich und der Unterdruck wird in den Innenraum 200 der Brusthaube 2 übertragen, bzw. Luft strömt aus diesem Innenraum in die Pumpkammer 47. Auch im Innenraum herrscht somit ein Unterdruck, optimalerweise derselbe Druck von beispielsweise -150 mmHg. Der Druckverlauf im Innenraum 200 ist in Figur 19c dargestellt. Der Druck gemäss Bezugszeichen a) entspricht dem Druck im Innenraum 200 gemäss Figur 19a. Das Behälterventil 94 bleibt geschlossen. Der Druck im Milchsammelbehälter 9 beträgt nach wie vor Atmosphärendruck, d.h. p=0.

Wird das Pumpmittel 10 nun zurückgeschoben und die Pumpkammer 47 im Volumen verkleinert, so schliesst sich das Pumpventil 12 und der Druck in der Pumpkammer 47 erhöht sich bis zum Atmosphärendruck p=0. Der Druck im Innenraum 200 steigt aufgrund des nun geöffneten Basisvakuumventils 13 ebenfalls an. Da sich das Basisvakuumventil 13 jedoch bei einem bestimmten Unterdruck schliesst, wird ein Basisvakuum im Innenraum 200 beibehalten. Dieser liegt beispielsweise bei -20 mmHg. Diese Situation ist in Figur 19b gezeigt und der Druckverlauf in Figur 19c mit b) bezeichnet.

Durch Vergleich der Figuren 19a und 19b zeigt sich auch, wie sich die Brustwarze W im Innenraum 200 dehnt und wieder zusammenzieht.

In den Figuren 20a bis 20c hat der Milchfluss aus der Mutterbrust begonnen. Die Milch ist in den Figuren mit dem Bezugszeichen M versehen. Der Innenraum 200 der Brusthaube 2 füllt sich mit abgepumpter Milch. Es entsteht ein Milchsee unterhalb des Pumpventils 12. Dank der nun vorhandenen Milch erhöht sich die Pumpleistung bei gleichbleibender Antriebsleistung, beispielsweise auf -170 mmHg in der Pumpkammer 47 und dem Innenraum 200. Nach wie vor öffnet und schliessen sich bei jedem Pumphub das Pumpventil 12 und das Basisvakuumventil 13, wobei das Entleerungsventil 14 und das Belüftungsventil 11 geschlossen bleiben. Figur 20a zeigt die Situation bei maximalem Unterdruck (absoluter Wert), welcher auch mit a) in Figur 20c gekennzeichnet ist. Figur 20b zeigt die Situation bei Beibehaltung des Basisunterdrucks im Innenraum 200 und Atmosphärendruck in der Pumpkammer 47, was in Figur 20c mit b) gekennzeichnet ist.

Sobald sich der Innenraum 200 mit Milch M bis zur Auslassöffnungen 16 gefüllt hat, fliesst Milch M durch das Pumpventil 12 in die Vakuumkammer 47. Die abgepumpte Milch M füllt nun auch die Vakuumkammer 47 bis ihr Füllstand die Auslassöffnung 480 zum Milchsammelbehälter 9 erreicht. Nun öffnet sich das Behälterventil 94, vorzugsweise auf Grund des Drucks der angesammelten Milch M und Milch M fliesst in den Milchsammelbehälter 9.

Die Figuren 21a bis 21c zeigen die Situation, in welcher sich optimalerweise keine Luft mehr im System befindet und das ursprüngliche pneumatische System vollständig auf ein

hydraulisches System gewechselt hat. In der Praxis ist oft ein gemischtes System vorhanden, wobei die abgepumpte Milch vorzugsweise einen wesentlichen Teil der Volumina füllt und somit das Hauptarbeitsfluid bildet.

Wie bereits anhand der Figuren 19a bis 19c erläutert, öffnen und schliessen sich das Pumpventil 12 und das Basisvakuumventil 13 nach Massgabe des Pumphubs, so dass ein Unterdruck im Innenraum 200 erzeugt und eine Basisunterdruck beibehalten werden kann. Der Druck in der Vakuumkammer 47 wechselt dabei beispielsweise zwischen -250 mmHg und 0 mmHg, der Druck im Innenraum zwischen -250 mmHg und -20 mmHg. Der Druck im Milchsammelbehälter 9 bleibt bei Atmosphärendruck, also bei 0 mmHg.

In den Figuren 22a bis 22c ist die Situation dargestellt, wenn keine Milch mehr aus der Brust fliesst. Das System pumpt zuerst noch weiter, wobei der Pumpdruck nicht mehr ausreicht, um das Behälterventil 94 zum Milchsammelbehälter 9 zu öffnen. Dies ist der Zeitpunkt, an welchem das Pumpventil 12 vollständig geschlossen und dafür das Entleerungsventil 14 aktiviert wird, so dass sich dieses nun selbsttätig öffnen und schliessen lässt. Im konkreten Ausführungsbeispiel wird hierfür der Stellring 5 manuell verstellt. Andere Arten, diese zwei Ventile zu aktivieren bzw. deaktivieren sind jedoch möglich. Beispielsweise lassen sie sich mit einer entsprechenden Elektronik steuern.

In den Figuren 23a bis 23c ist nun das Pumpventil 12 fest verschlossen und dafür der Entleerungskanal und das Entleerungsventil 14 geöffnet. Das Pumpmittel 10 bewegt sich weiter und erzeugt nach wie vom in der Pumpkammer 47 einen sich von einem maximalen Unterdruck zur Atmosphärendruck wechselnden Druck. Nach Massgabe dieser Bewegung öffnet und schliesst sich, wie vorher das Pumpventil 12, auch das Entleerungsventil 14 und pumpt somit die Milch M aus dem Innenraum 200 in die Pumpkammer 47. Von dort wird sie in den Milchsammelbehälter 9 gefördert, vorzugsweise zuerst mittels Unterdruck und anschliessend mittels Verdrängung durch das Pumpmittel 10. Das Entleerungsventil 14 befindet sich in dieser Pumpsituation vorzugsweise an einer tiefen Stelle der Brusthaube, vorzugsweise relativ weit unten. Der sinkende Milchsee im Innenraum ist in den Figuren 23a und 23b gut erkennbar. Die Figuren 23a und 23b zeigen wiederum die zwei Extremsituationen eines Pumphubs. Der Druckverlauf ist in Figur 23c dargestellt. Der Druckverlauf im Innenraum 200 ist relativ unspezifisch.

Die Pumpe wird somit während des Entleerens weiterhin betätigt. Sollte sich zum Schluss noch Milch in der Vakuumkammer 47 befinden, lässt sie sich durch Kippen oder „auf den Kopf stellen" der Pumpe einfach in den Milchsammelbehälter 9 leiten.

Die erfindungsgemässe Brustpumpe und das erfindungsgemässe Verfahren ermöglichen somit die Verwendung von abgepumpter Milch in einem hydraulischen Pumpsystem, wodurch der Antrieb der Pumpe minimiert werden kann.

BEZUGSZEICHENLISTE

		32	Durchgangsöffnung
10	Pumpmittel	33	Positioniernase
100	Spindel	34	erste Noppe
11	Belüftungsventil	35	Belüftungsnoppe
12	Pumpventil	36	zweite Noppe
13	Basisvakuumventil	37	erste Ventilklappe
14	Entleerungsventil	38	zweite Ventilklappe
15	Belüftungsöffnung		
16	Auslassöffnung	4	Adapterteil
17	dritte Öffnung	40	Grundkörper
19	Entleerungsöffnung	400	erstes Fenster
		401	zweites Fenster
2	Brusthaube	402	Positionierhilfe
20	Trichter	41	pumpenseitige Wand
200	Innenraum	410	Kanalwand
21	Durchgangsöffnung	42	erhöhter Wandteil
22	Flansch	43	erste Durchgangsöffnung
23	Stutzen	44	zweite Durchgangsöffnung
24	erste Auslassöffnung	45	erste Rückspülöffnung
25	erste Durchflussöffnung	46	zweite Rückspülöffnung
26	erste Belüftungsöffnung	47	Pumpkammer
27	zweite Auslassöffnung	48	Rinne
28	zweite Durchflussöffnung	480	Auslassöffnung
29	zweite Belüftungsöffnung	49	Auslass
3	Ventilkörper	5	Stellring
30	Grundkörper	50	erster Teil
31	Rückwand	51	erstes Steckerteil
310	Dichtungsfläche	52	zweiter Teil
311	Dichtlippe	53	zweites Steckerteil
312	Rille	54	Einrastelement

55	Anschlag
56	erstes Anpresselement
57	zweites Anpresselement
58	Betätigungshebel
6	Medientrennmembran
60	Membranfläche
61	Zentralbereich
62	Dichtfläche
63	Rinne
64	Vertiefung
7	Pumpmembran
70	Membranfläche
71	Zentralbereich
72	Durchgangsöffnung
73	Verstärkung
74	Dichtfläche
75	Sensorfläche
76	Fahne
77	Seitenflügel
8	Pumpengehäuse
8‘	Trägermodul
80	Seitenarm
81	Motoraufnahme
82	Spindelaufnahme
83	Spindel
84	Befestigungslöcher
85	Rand
86	Betätigungsschalter
87	Anzeige
9	Milchsammelbehälter
90	Gefäss
900	Innenraum
901	erstes Einrastelement"
902	zweites Einrastelement
91	unterer Rahmenteil
92	Abdeckung
93	oberer Rahmenteil
930	Rahmen
931	Streben
932	Ventilaufnahme
933	Griff
934	Distanzstifte
94	Behälterventil
95	Einlass
96	Einlassventil
W	Brustwarze
M	Milch

PATENTANSPRÜCHE

1. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe ein Gehäuse mit einer Antriebseinheit, eine Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust aufweist,
   wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist,
   wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, wobei abgepumpte Milch vom Innenraum der Brusthaube durch den Milchkanal in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst,
   dadurch gekennzeichnet,
   dass ein mehrteiliges Hygienemodul vorhanden ist, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

2. Brustpumpe nach Anspruch 1, die steife Schale einen Milchpfad aufweist, welcher von der Pumpkammer in einen Milchsammelbehälter führt und welcher mindestens über einen Teilbereich senkrecht zu einer Antriebsachse der Pumpmembran verläuft.

3. Brustpumpe nach einem der Ansprüche 1 oder 2, wobei der Ventilkörper mindestens ein Durchflussventil und ein Belüftungsventil aufweist.

4. Brustpumpe nach einem der Ansprüche 1 bis 3, wobei der Ventilkörper einstückig aus einem flexiblen Material gebildet ist.

5. Brustpumpe nach einem der Ansprüche 1 bis 4, wobei der erste Teil Bestandteil der Brusthaube ist.

6. Brustpumpe nach einem der Ansprüche 1 bis 5, die Brusthaube einen Flansch zur lösbaren Verbindung mit dem Gehäuse aufweist.

7. Brustpumpe nach Anspruch 6, wobei die Verbindung form- und kraftschlüssig, vorzugsweise ein Bajonettverschluss, ist.

8. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass die Auslassöffnung in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet ist.

9. Brustpumpe nach Anspruch 1, wobei der Milchkanal einen Vakuumkanal zur Beaufschlagung des Innenraums der Brusthaube mit dem sich zyklisch ändernden Unterdruck bildet.

10. Brustpumpe nach einem der Ansprüche 8 oder 9, wobei die Pumpkammer eine steife erste Schale und eine flexible Pumpmembran aufweist, wobei die Pumpmembran dichtend an der ersten Schale anliegt und wobei die Pumpmembran angetrieben ist und durch deren Bewegung relativ zur ersten Schale ein Unterdruck in der Pumpkammer erzeugbar ist.

11. Brustpumpe nach Anspruch 10, wobei zwischen der steifen Schale und der flexiblen Pumpmembran eine flexible Medientrennmembran angeordnet ist, so dass die

Pumpmembran vor einem Kontakt mit abgepumpter Milch geschützt ist.

12. Brustpumpe nach einem der Ansprüche 10 oder 11, wobei die erste Schale eine Auslassrinne aufweist, welche sich von der Auslassöffnung der Pumpkammer zu einem Ausgang erstreckt, wobei die Auslassrinne sich mindestens über einen Teilbereich in einer Richtung senkrecht zur Bewegungsrichtung der Pumpmembran verläuft.

13. Brustpumpe nach einem der Ansprüche 11 oder 12, wobei die Pumpmembran, oder, falls vorhanden, die Medientrennmembran die Auslassrinne der steifen ersten Schale zu einem bis auf die Auslössöffnung und den Ausgang geschlossenen Kanal verschliesst.

14. Brustpumpe nach einem der Ansprüche 1 bis 13, wobei die Brusthaube eine erste Durchlassöffnung aufweist, welche Teil des Milchkanals bildet, wobei die Durchlassöffnung in Gebrauchslage der Brusthaube mindestens zu Beginn des Abpumpvorgangs in einem oberen Bereich des Innenraums angeordnet ist, so dass der Innenraum unterhalb der ersten Durchlassöffnung mit abgepumpter Milch befüllbar ist.

15. Brustpumpe nach einem der Ansprüche 1 bis 14, wobei der Milchkanal mittels eines ersten Ventils verschliessbar ist, um am Ende des Abpumpvorgangs die abgepumpte Milch aus der Pumpkammer zu entfernen.

16. Brustpumpe nach einem der Ansprüche 1 bis 15, wobei ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines zweiten Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist.

17. Brustpumpe nach einem der Ansprüche 1 bis 16, wobei ein Belüftungsventil zur Belüftung des Innenraums der Brusthaube vorhanden ist.

18. Brustpumpe nach den Ansprüchen 16 und 17, wobei das Belüftungsventil gemeinsam mit dem zweiten Ventil verschliessbar ist und sich gemeinsam mit diesem öffnen lässt.

19. Brustpumpe nach einem der Ansprüche 1 bis 18, wobei ein drittes Ventil vorhanden ist, welches bei Druckanstieg des zyklisch sich ändernden Unterdrucks im Innenraum der Brusthaube einen Basisunterdruck beibehält.

20. Brustpumpe nach einem der Ansprüche 1 bis 19, wobei im Milchkanal ein viertes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst.

21. Brustpumpe nach einem der Ansprüche 1 bis 20, wobei im Entleerungskanal ein fünftes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst.

22. Brustpumpe nach einem der Ansprüche 1 bis 21, wobei mindestens ein Teil, vorzugsweise alle, der genannten Ventile in einem gemeinsamen Ventilkörper angeordnet sind.

23. Brustpumpe nach Anspruch 22, wobei der Ventilkörper einstückig und flexibel ausgebildet ist.

24. Brustpumpe nach einem der Ansprüche 10 bis 23, sofern rückbezogen auf Anspruch 10, wobei die Brustpumpe ein Pumpengehäuse mit einem Antrieb für die Pumpmembran aufweist und wobei die steife erste Schale lösbar mit dem Pumpengehäuse verbunden ist.

25. Brustpumpe nach Anspruch 24, wobei die erste steife Schale Bestandteil eines mehrteiligen Moduls ist, welches gemeinsam mit dem Pumpengehäuse verbindbar ist, wobei das Modul des Weiteren mindestens die genannten Ventile aufweist.

26. Brustpumpe nach den Ansprüchen 23 und 25, wobei die erste steife Schale

Bestandteil eines Adapterteils ist und wobei der Ventilkörper in einer Aufnahme des Adapterteils gehalten ist.

27. Brustpumpe nach Anspruch 26, wobei das Modul ferner ein manuelles Betätigungsmittel umfasst zum zeitgleichen Betätigen des ersten und zweiten Ventils.

28. Brustpumpe nach Anspruch 27, wobei das Adapterteil und das Betätigungsteil nicht zerstörungsfrei voneinander lösbar sind.

29. Brustpumpe nach einem der Ansprüche 1 bis 28, wobei die Brustpumpe ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar am Pumpengehäuse befestigbar ist und wobei durch die Befestigung der Brusthaube am Pumpengehäuse Teile, welche zwischen Brusthaube und Pumpengehäuse liegen, dichtend miteinander verbunden werden, so dass eine dichte Verbindung zwischen Pumpkammer und Innenraum der Brusthaube entsteht.

30. Brustpumpe nach den Ansprüchen 25 und Anspruch 29, wobei die Brusthaube und der Ventilkörper Teil des Moduls sind.

31. Brustpumpe nach einem der Ansprüche 1 bis 30, wobei die Brustpumpe ein Pumpengehäuse aufweist, an welchem die Brusthaube lösbar befestigbar ist, und wobei die Brustpumpe ferner einen Milchsammelbehälter aufweist, welcher am Pumpengehäuse mittels eines Schnappverschlusses befestigbar ist.

32. Brustpumpe nach Anspruch 31, wobei der Milchsammelbehälter einen Grundkörper und einen Deckel aufweist, wobei der Deckel mindestens teilweise luftdurchlässig und flüssigkeitsundurchlässig ausgebildet ist.

33. Brustpumpe nach Anspruch 32, wobei der Deckel eine luftdurchlässige und flüssigkeitsundurchlässige Membran aufweist.

34. Brustpumpe nach einem der Ansprüche 31 bis 33, wobei der Deckel mit einem

Einwegventil versehen ist.

35. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist. .

36. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass die Brustpumpe ein Pumpengehäuse, eine Pumpmembran und ein Modul aufweist, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist, wobei das Modul als Einheit am Pumpengehäuse befestigbar ist, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist.

37. Brustpumpe nach Anspruch 36, wobei das Modul ferner einen Ventilkörper aufweist,

welcher zwischen Brusthaube und steifer Schale angeordnet ist.

38. Brustpumpe gemäss Anspruch 37, wobei das Modul ferner ein manuelles Betätigungsmittel zur Betätigung mindestens eines Ventils des Ventilkörpers aufweist.

39. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter aufweist, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist, dadurch gekennzeichnet, dass der Milchsammelbehälter mittels eines Schnappverschlusses am Pumpengehäuse befestigbar ist.

40. Brustpumpe nach Anspruch 39, wobei sie eine Pumpkammer und einen Milchkanal aufweist, durch welchen abgepumpte Milch von einem Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer einen Ausgang aufweist, welcher mit dem Milchsammelbehälter verbunden ist und durch welchen die abgepumpte Milch in den Milchsammelbehälter fliesst.

41. **Milchsammelbehälter** zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, dadurch gekennzeichnet, dass der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.

42. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist, dadurch gekennzeichnet, dass die Brusthaube mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar ist.

43. **Brusthaube** zur Befestigung an einem Pumpengehäuse einer Brustpumpe gemäss Anspruch 42, wobei die Brusthaube einen Innenraum zur Aufnahme der Mutterbrust

und einen Stutzen zur Befestigung am Pumpengehäuse aufweist, dadurch gekennzeichnet, dass der Stutzen mit einem Bajonettverschluss versehen ist.

44. **Verfahren** zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird,
wobei in einer ersten Pumpphase der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt wird, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst,
wobei in einer zweiten Pumpphase abgepumpte Milch aus dem Innenraum in die Pumpkammer fliesst und die Pumpkammer mit abgepumpter Milch gefüllt wird und
wobei in einer dritten Pumpphase die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt bleiben,
wobei der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

45. Verfahren nach Anspruch 44, wobei die Brustpumpe während des Abpumpens von einem pneumatischen Pumpsystem auf ein hydraulisches Pumpsystem wechselt, wobei die erste Pumpphase eine pneumatische Pumpphase ist und die zweite Pumpphase eine hydraulische Pumpphase ist.

46. Verfahren nach einem der Ansprüche 44 oder 45, wobei der Innenraum in der ersten Pumpphase annähernd vollständig gefüllt wird.

47. Verfahren nach einem der Ansprüche 44 bis 46, wobei der Innenraum und/oder die Pumpkammer in der zweiten und/oder dritten Pumpphase annähernd vollständig mit abgepumpter Milch gefüllt sind.

48. Verfahren nach der Ansprüche 44 bis 47, wobei der Wechsel von der ersten Pumpphase zur zweiten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine erste Durchgangsöffnung erreicht, welche vom Innenraum zur Pumpkammer führt, wodurch Milch durch die erste Durchgangsöffnung vom Innenraum in die Pumpkammer fliesst.

49. Verfahren nach Anspruch 48, wobei in der dritten Pumpphase die abgepumpte Milch durch die erste Durchgangsöffnung in die Pumpkammer fliesst und durch die Auslassöffnung in den Milchsammelbehälter fliesst.

50. Verfahren nach einem der Ansprüche 44 bis 49, wobei in einer vierten Pumpphase der Innenraum entleert wird und die darin befindliche, bereits abgepumpte Milch durch eine zweite Durchgangsöffnung aus dem Innenraum zum Milchsammelbehälter geführt wird.

51. Verfahren nach den Ansprüchen 48 und 50, wobei die erste Durchgangsöffnung mit einem ersten Ventil verschliessbar ist und wobei die zweite Durchgangsöffnung mit einem zweiten Ventil verschliessbar ist, wobei die zweite Durchgangsöffnung während der ersten bis dritten Pumpphase stets geschlossen ist.

52. Verfahren nach Anspruch 51, wobei die erste Durchgangsöffnung während der vierten Pumpphase stets geschlossen ist.

53. Verfahren nach Anspruch 52, wobei die zweite Durchgangsöffnung vom Innenraum in die Pumpkammer führt und über die Pumpkammer in fluidkommunizierender Verbindung mit der Auslassöffnung steht.

54. Verfahren nach einem der Ansprüche 44 bis 53, wobei während mindestens einem Teil der Pumpphasen, vorzugsweise während der ersten, zweiten und dritten Pumpphase ein Basisunterdruck beibehalten wird.

55. Verfahren nach Anspruch 54, wobei ein drittes Ventil vorhanden ist, welches bei

Druckanstieg des zyklisch sich ändernden Unterdrucks in Richtung Atmosphärendruck zuerst öffnet und dann schliesst und dadurch den Basisunterdruck beibehält.

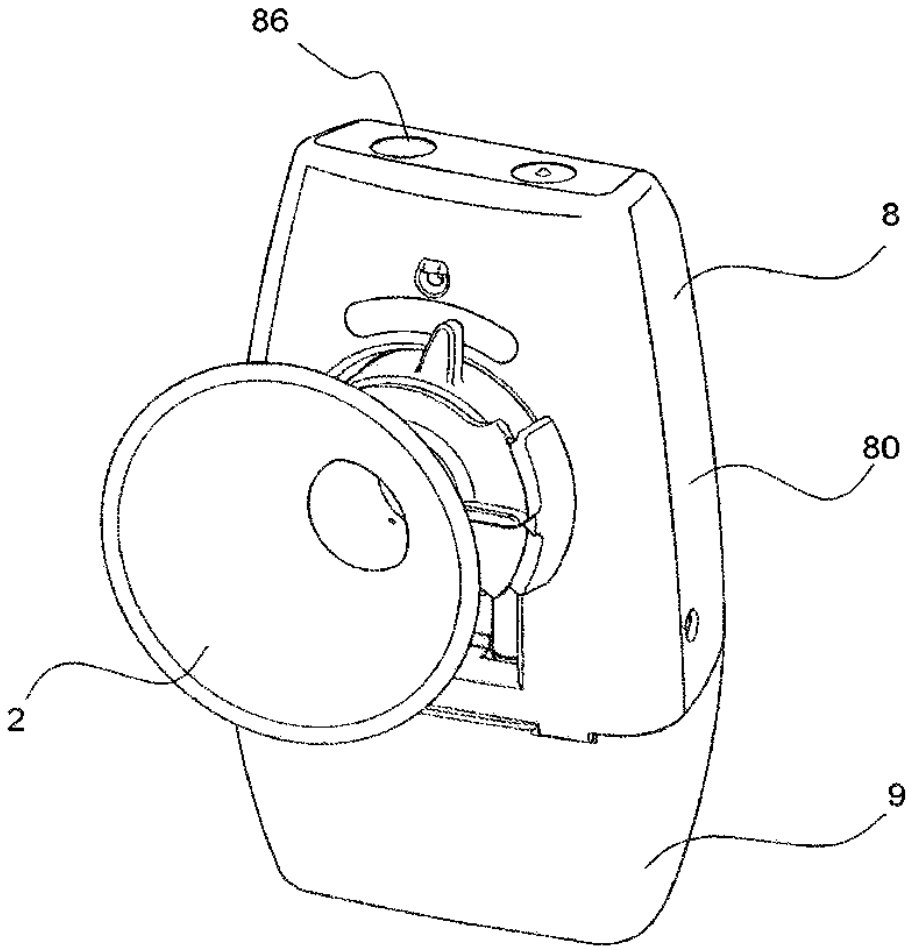


FIG. 1

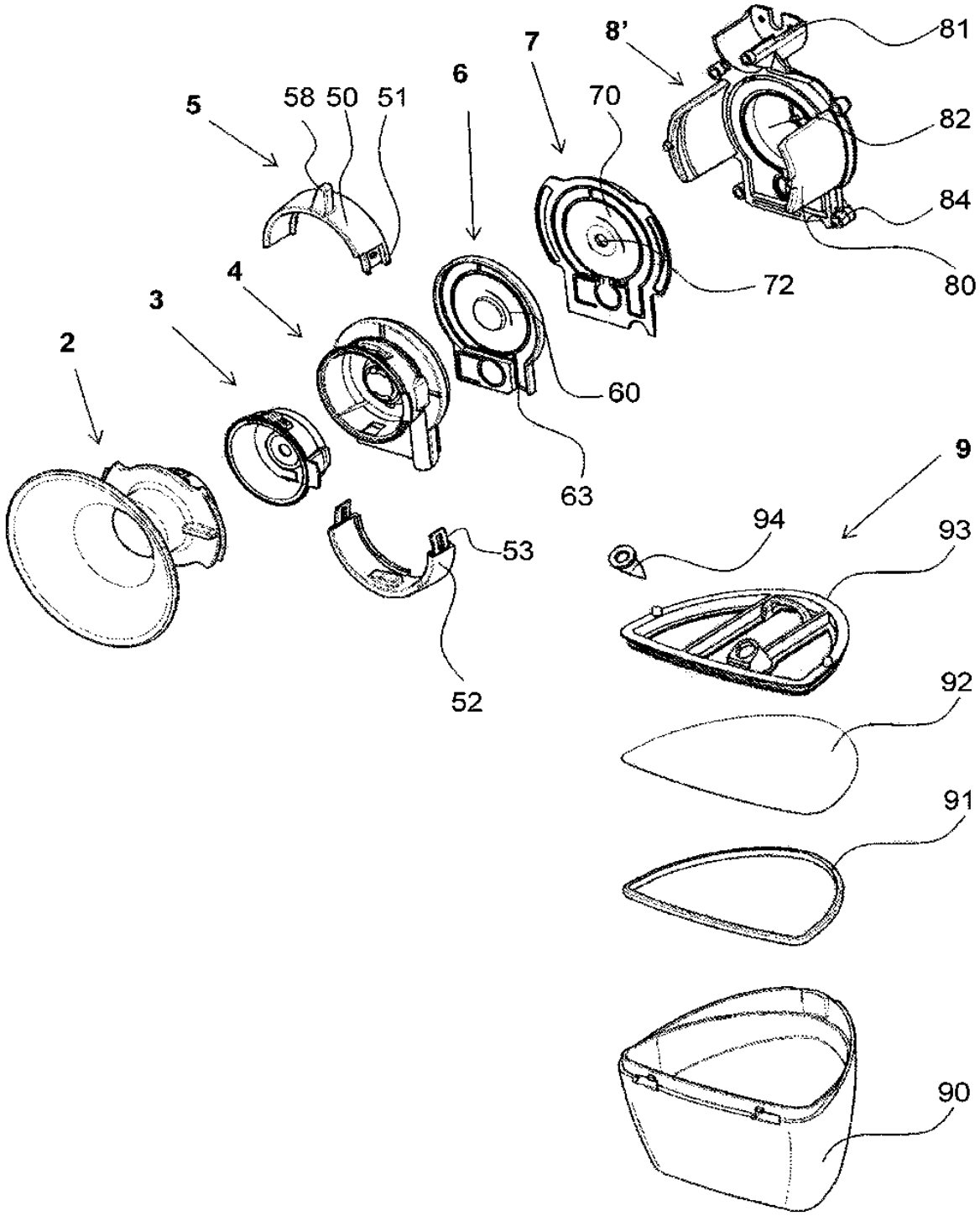


FIG. 2

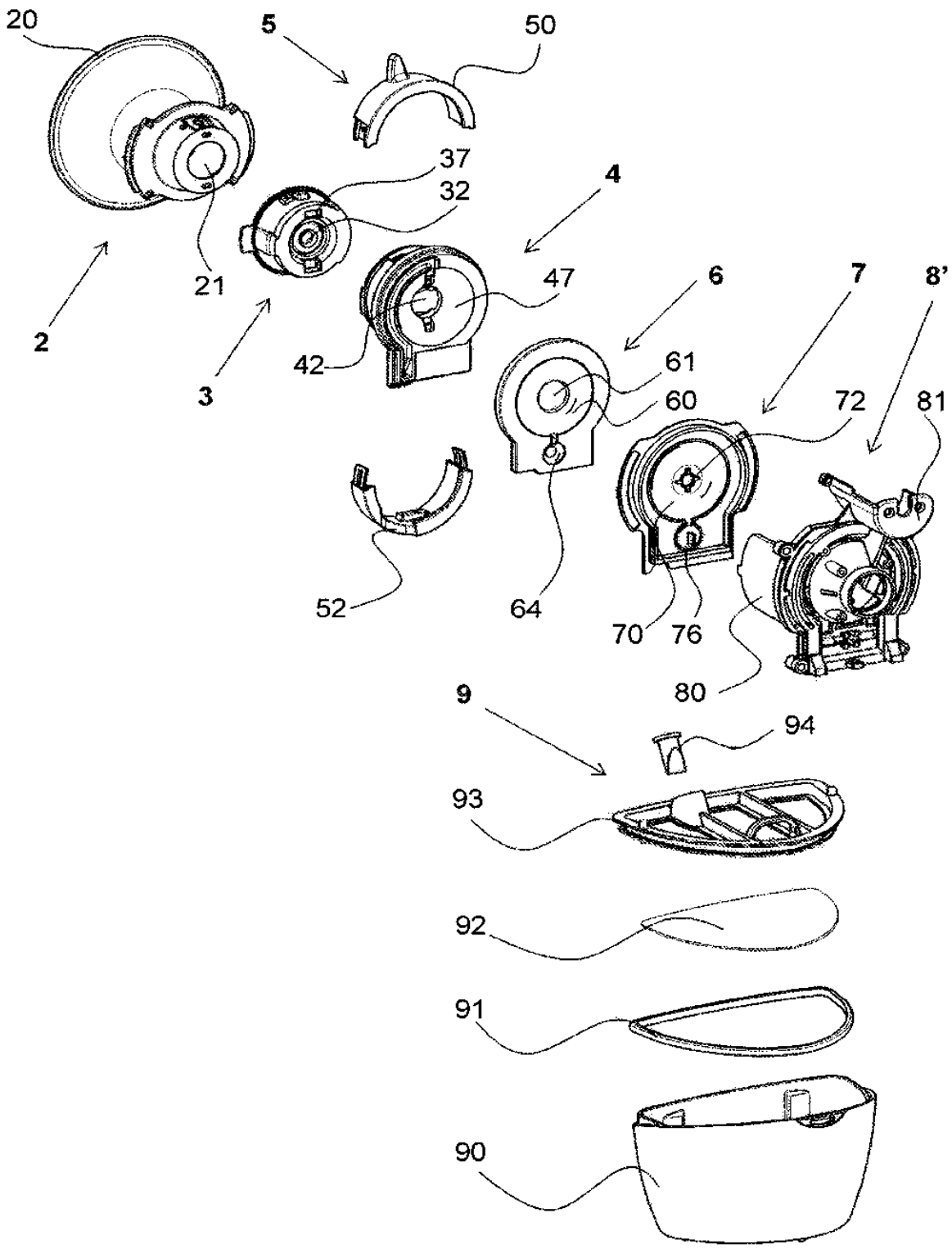

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FIG. 3

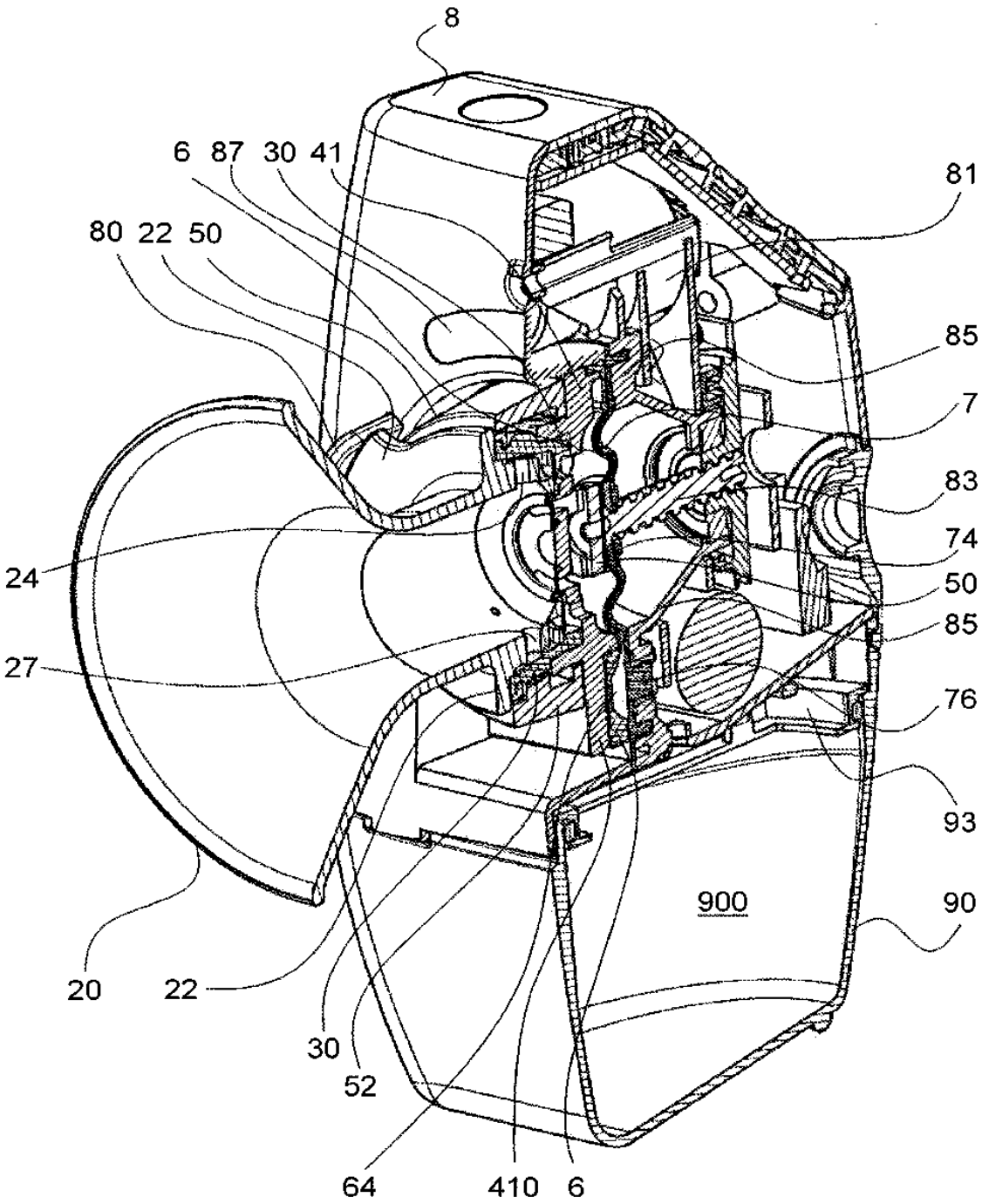

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FIG. 4

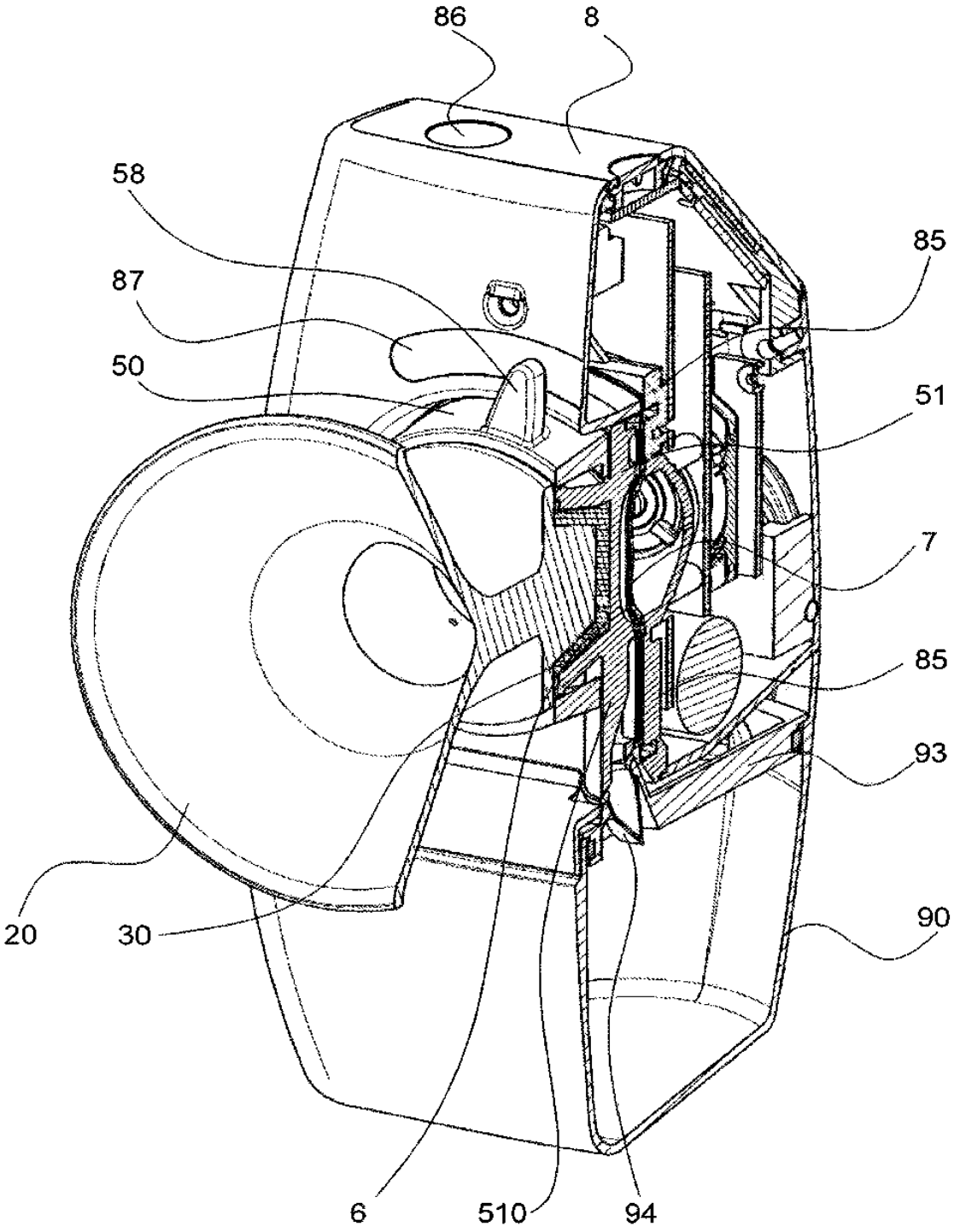


FIG. 5

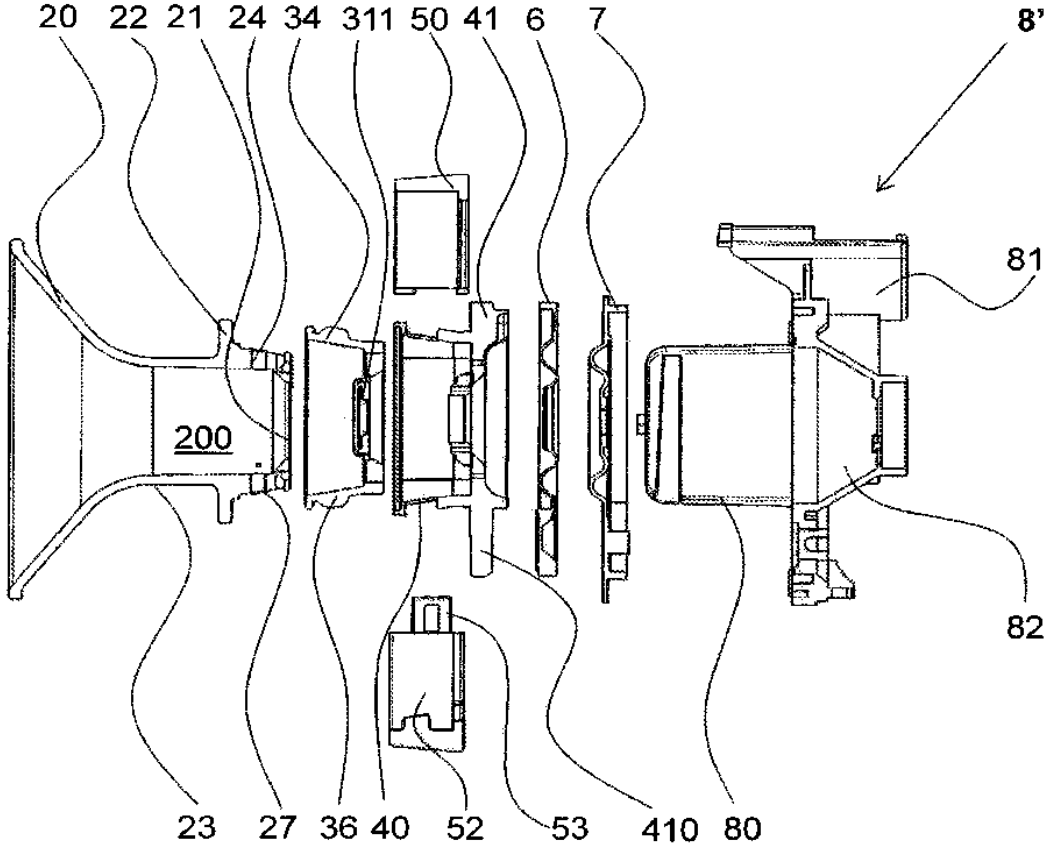

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FIG. 6

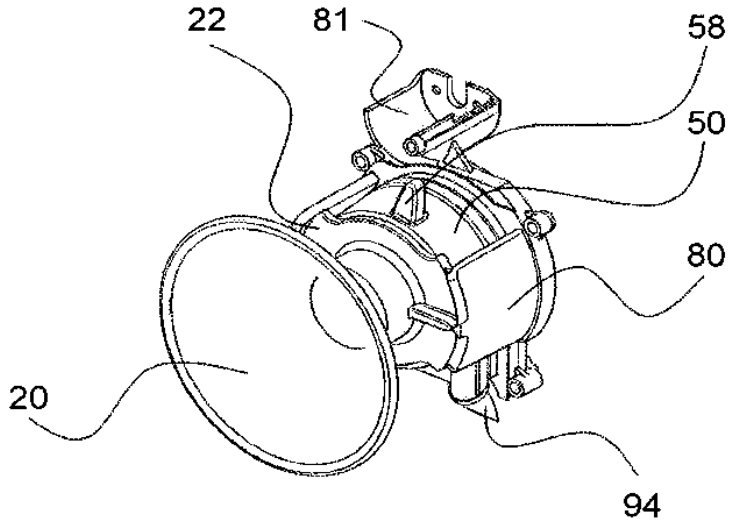

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FIG. 7

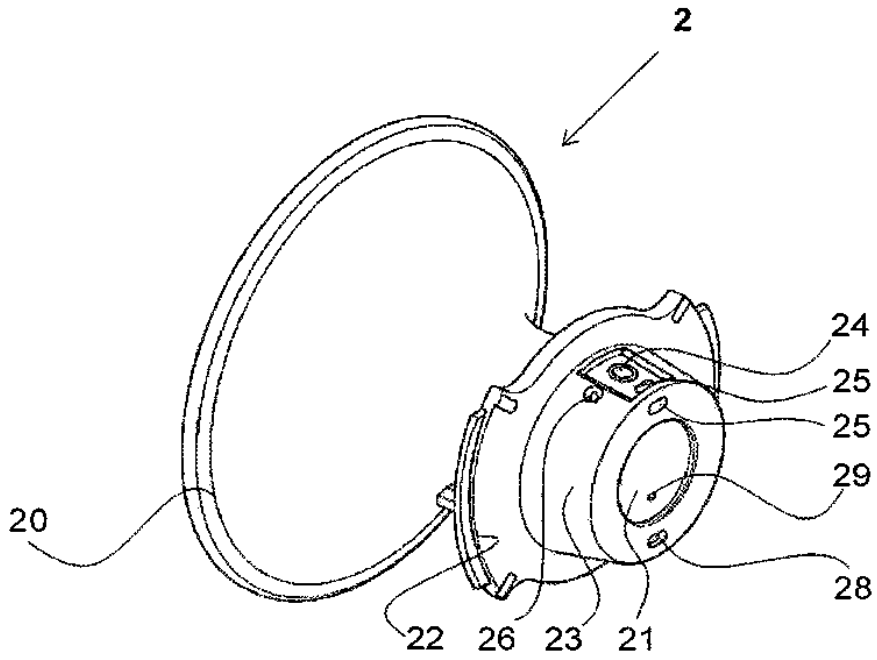


FIG. 8a

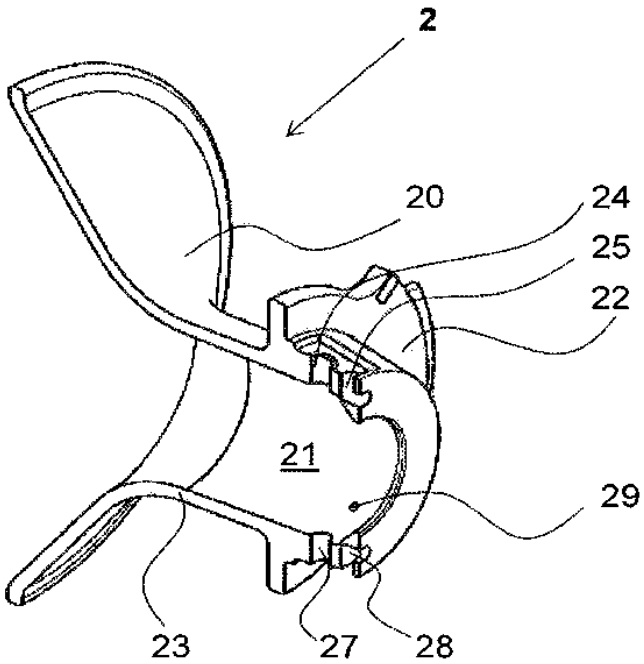


FIG. 8b

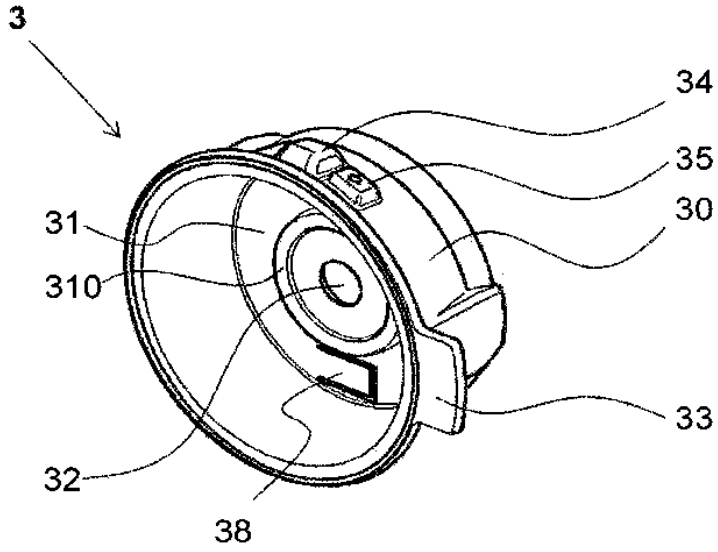


FIG. 9a

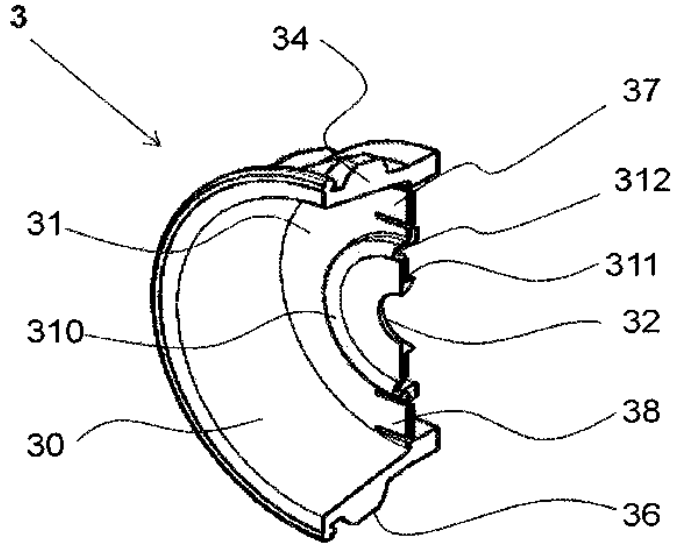


FIG. 9b

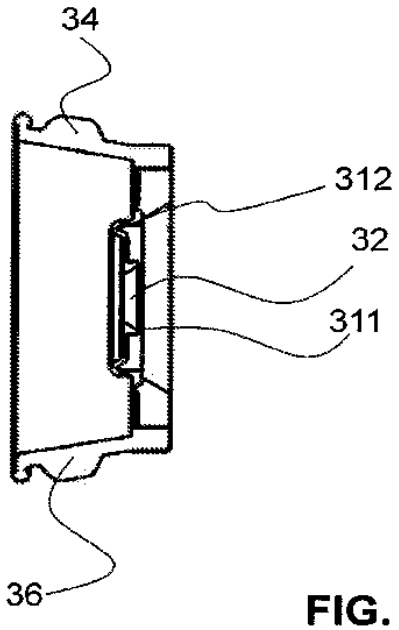


FIG. 9c

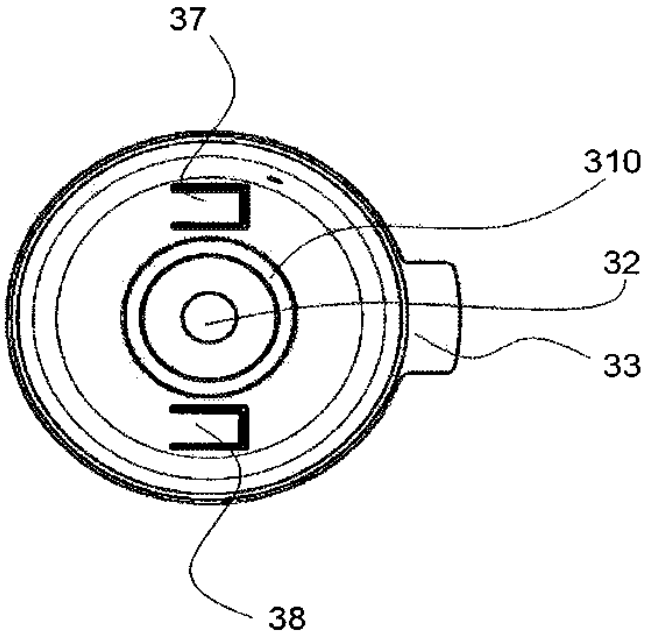


FIG. 9d

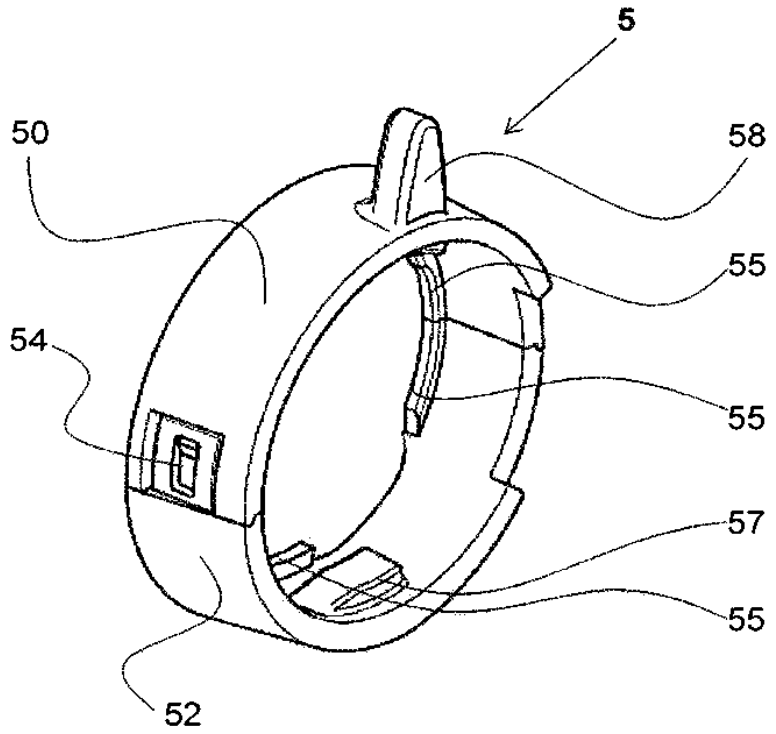


FIG. 10a

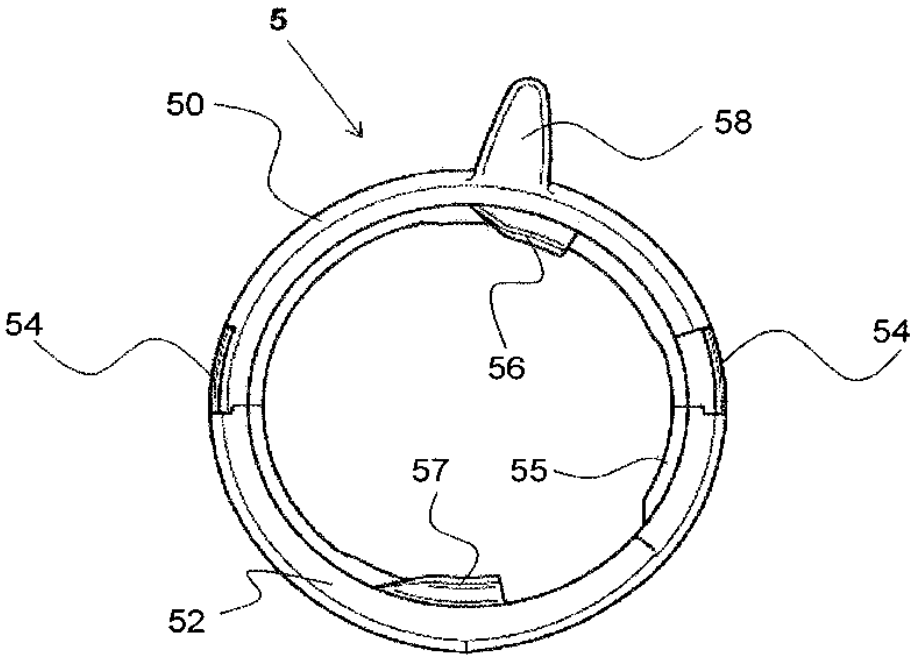


FIG. 10b

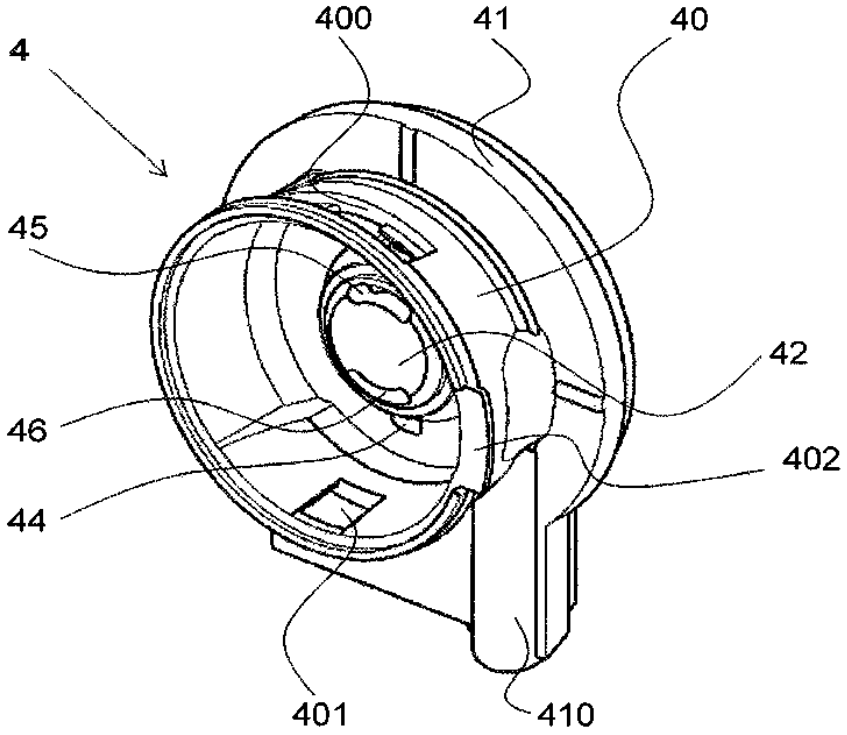


FIG. 11a

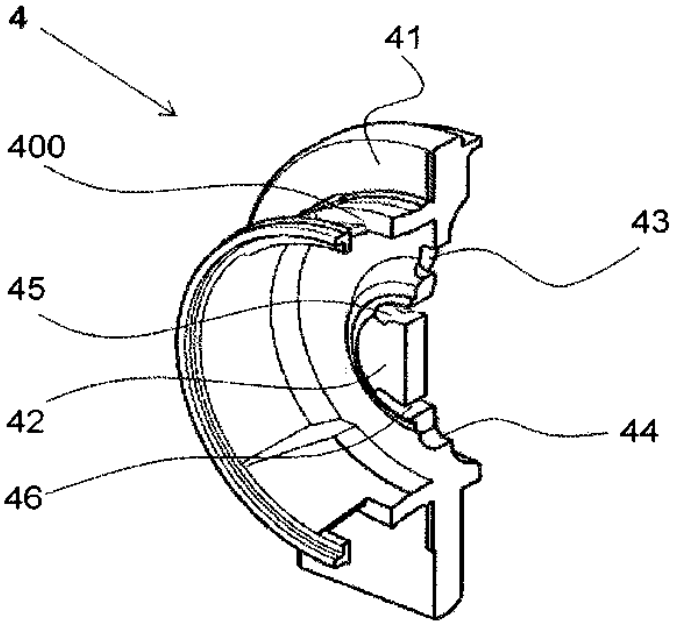


FIG. 11b

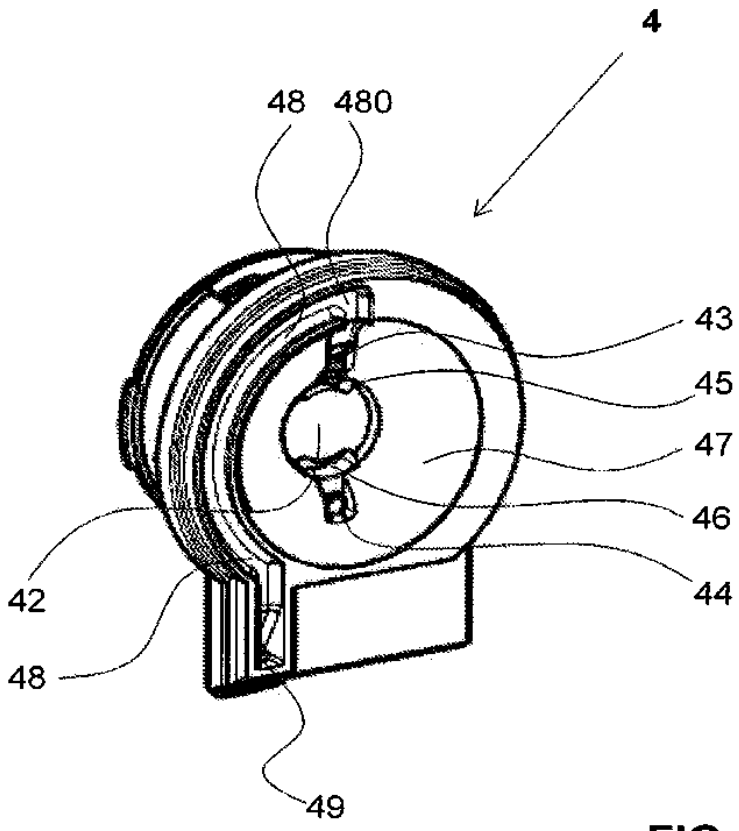


FIG. 11c

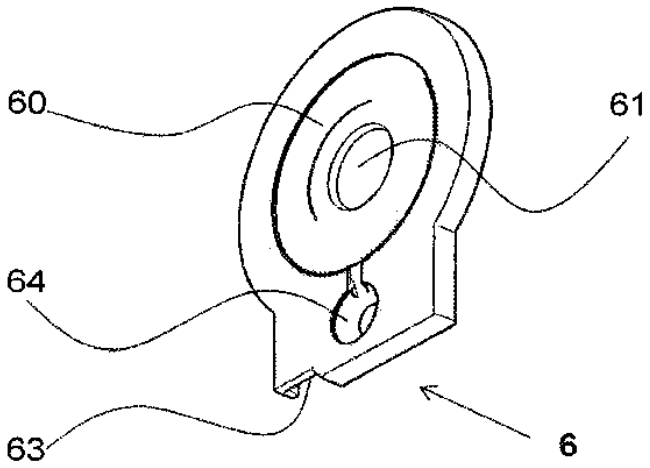


FIG. 12a

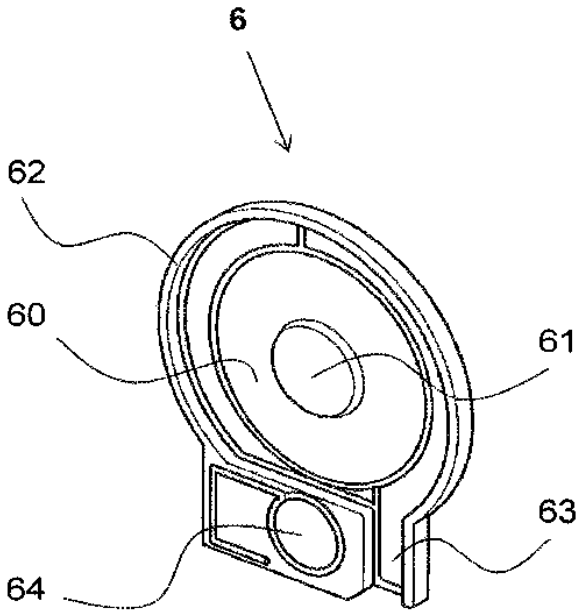


FIG. 12b

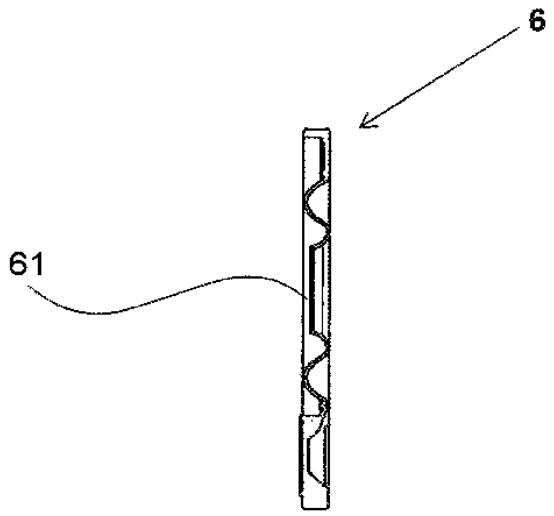


FIG. 12c

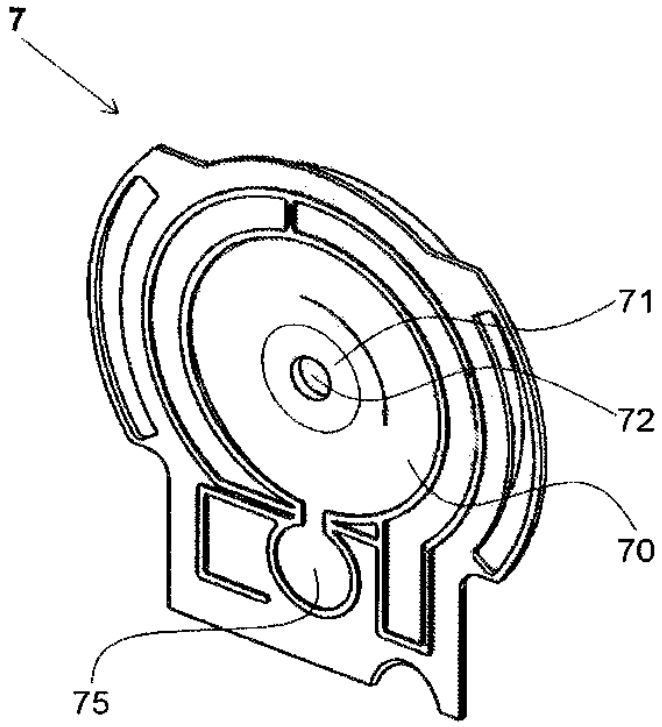


FIG. 13a

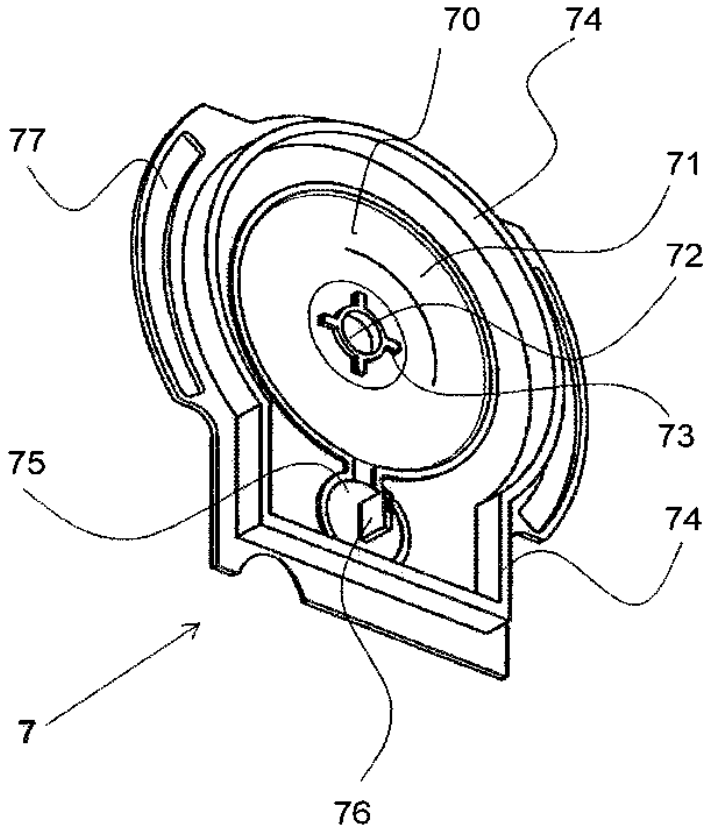


FIG. 13b

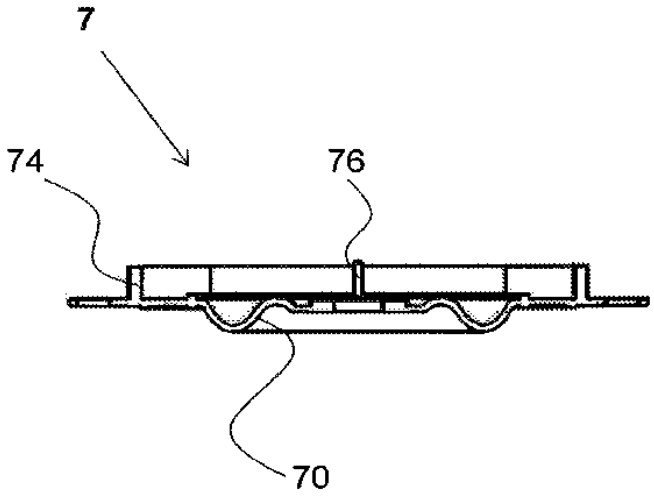


FIG. 13c

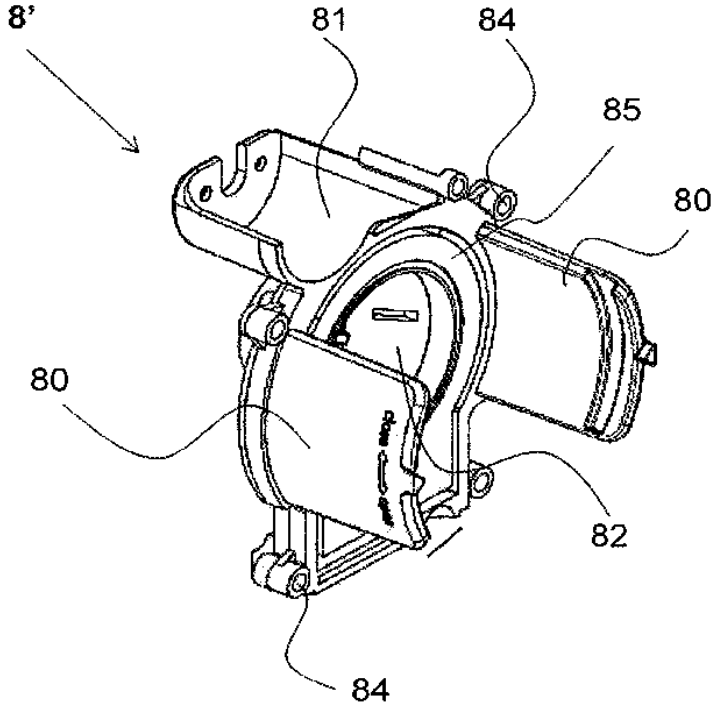


FIG. 14

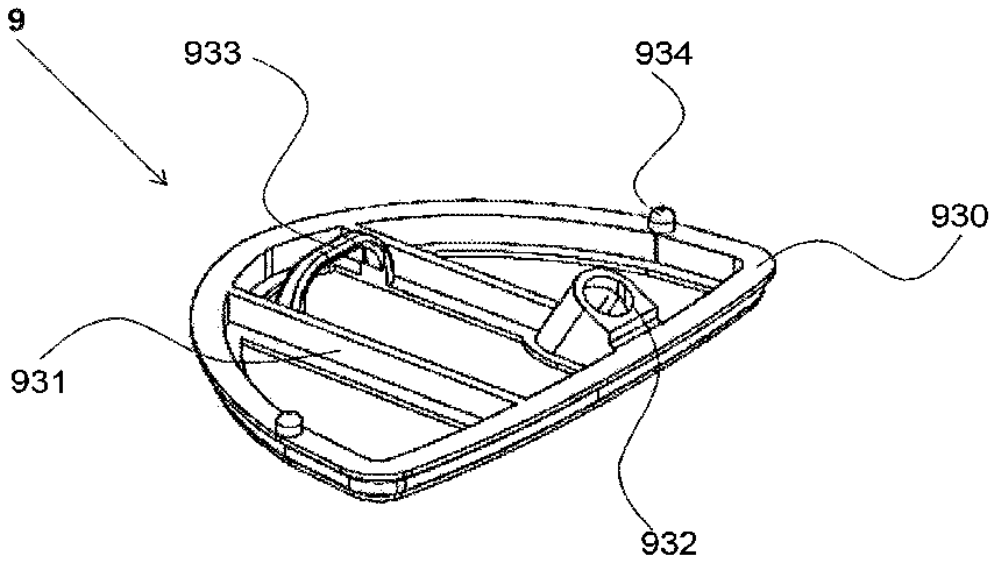


FIG. 15

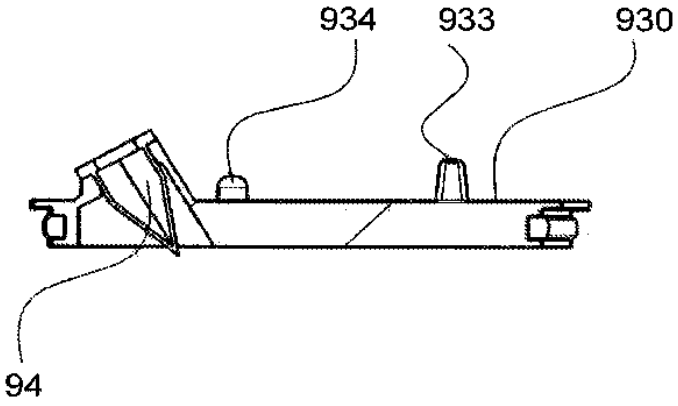


FIG. 16

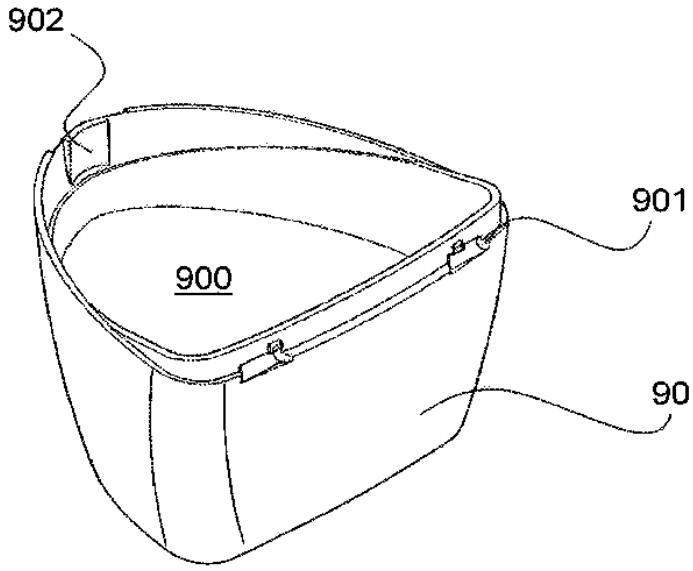


FIG. 17

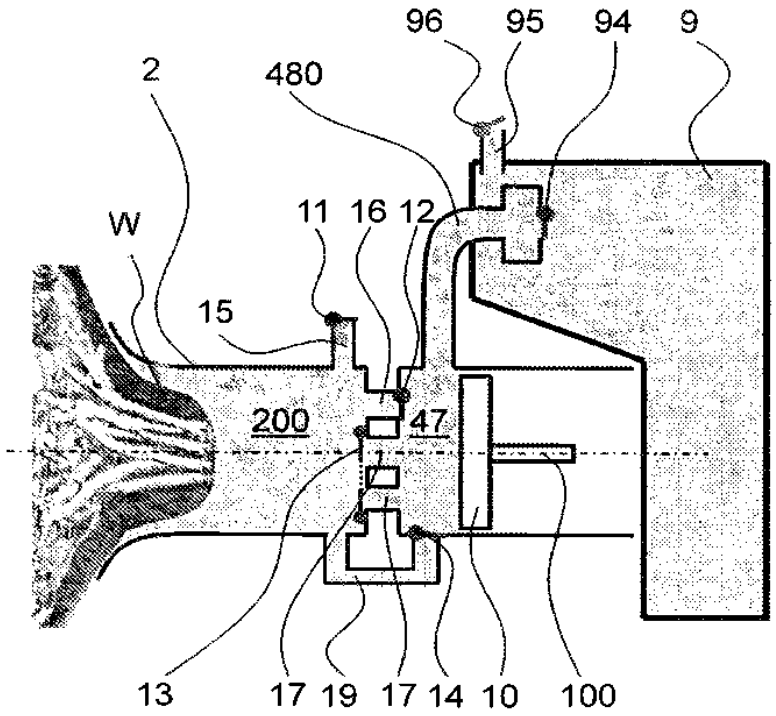


FIG. 18

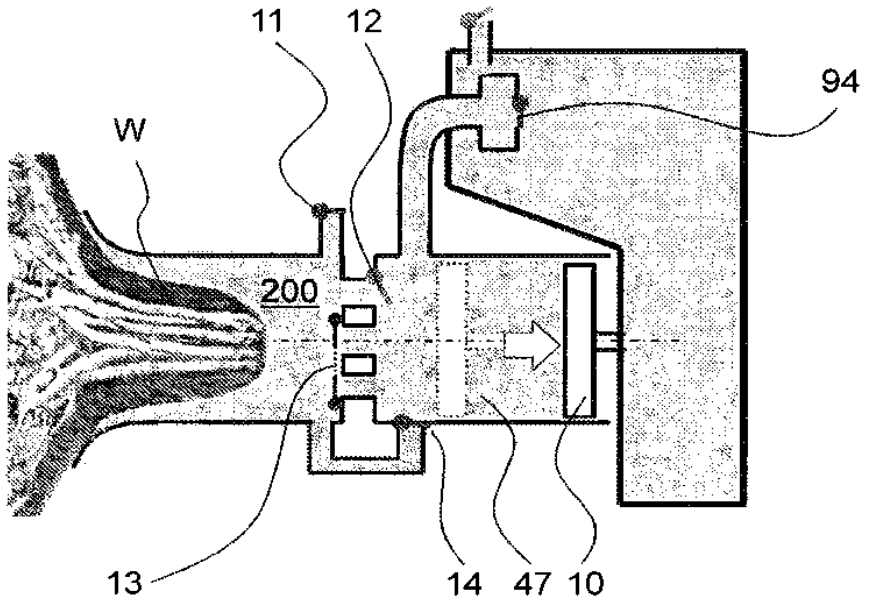


FIG. 19a

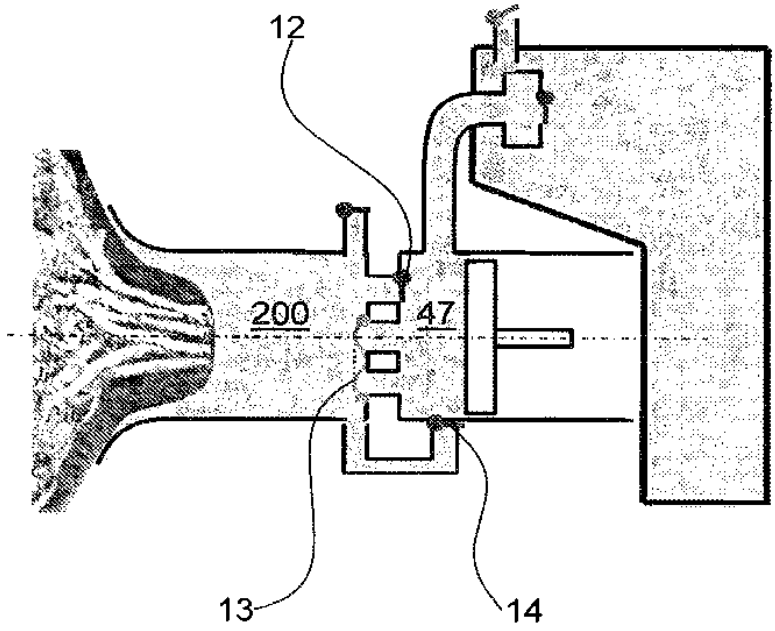


FIG. 19b

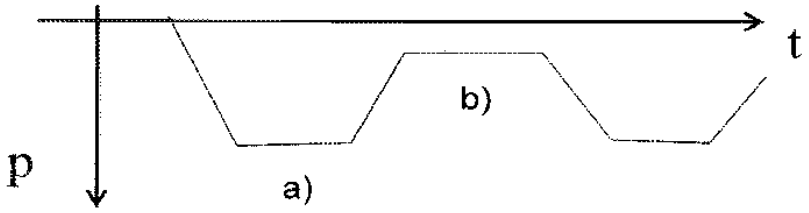


FIG. 19c

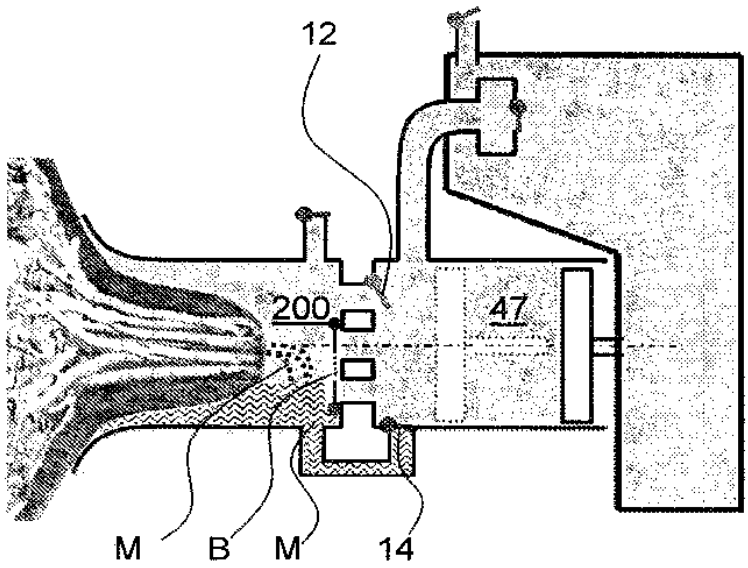


FIG. 20a

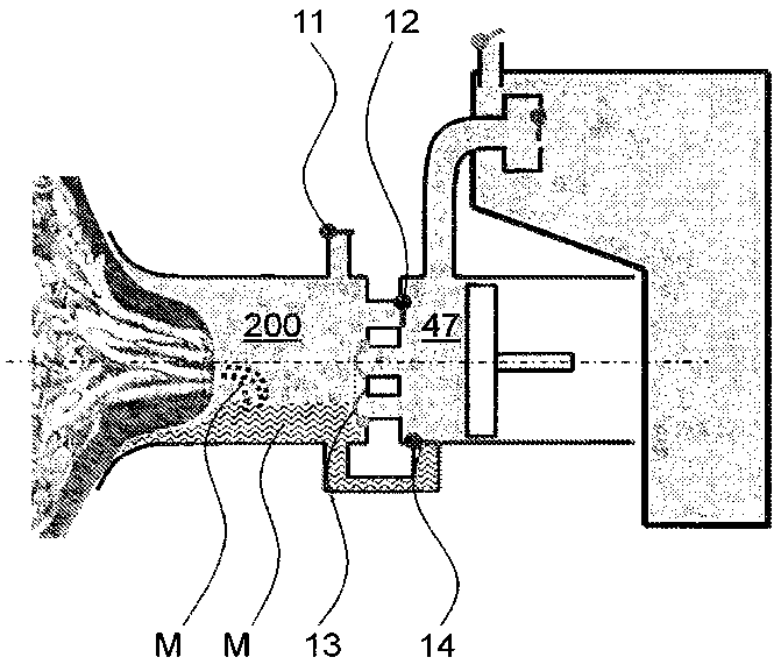


FIG. 20b

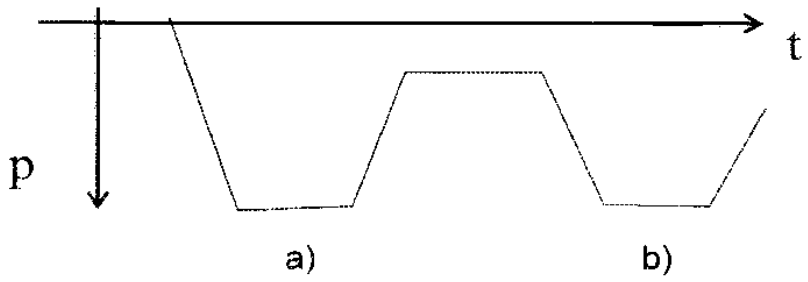


FIG. 20c

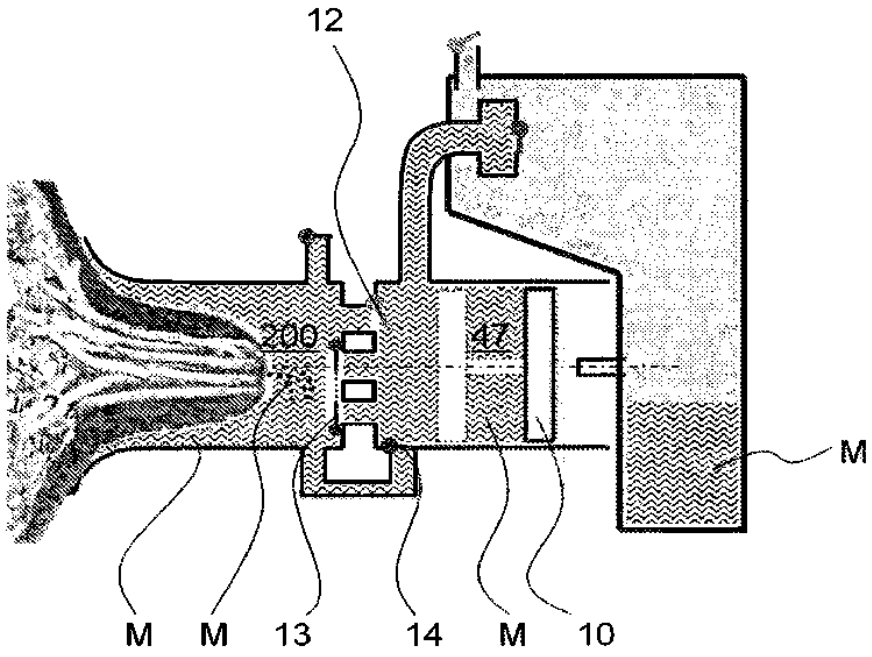


FIG. 21a

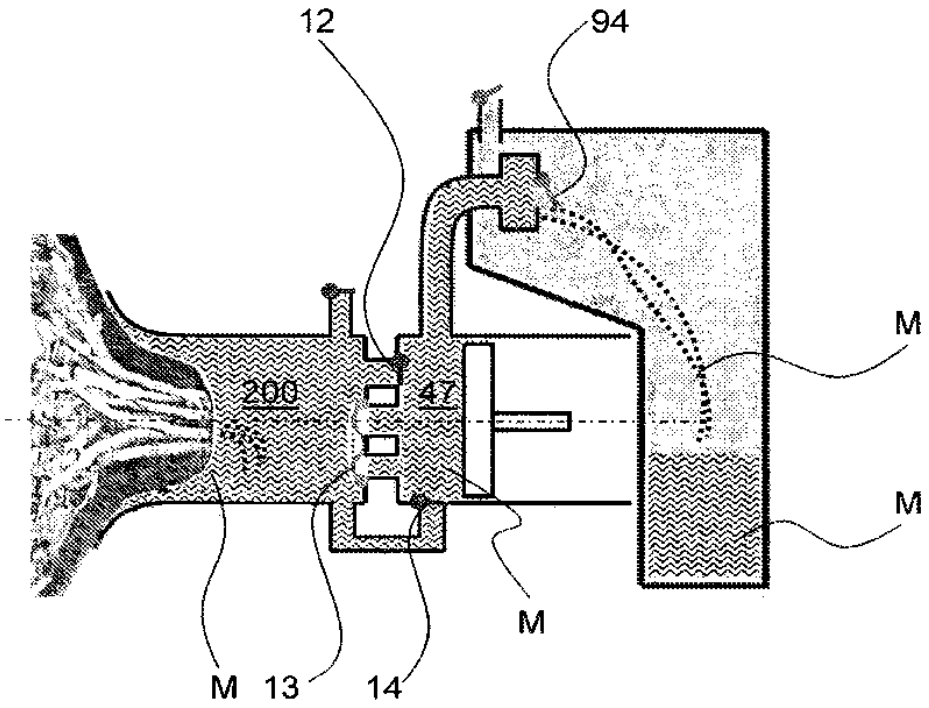


FIG. 21b

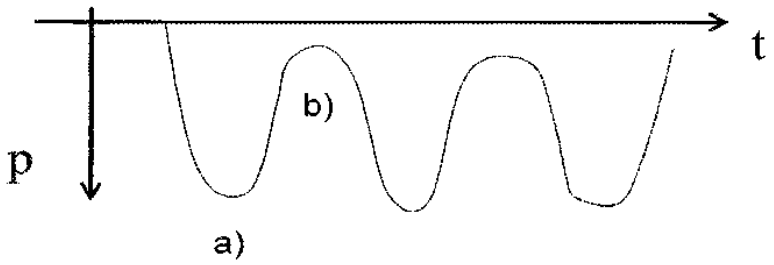


FIG. 21c

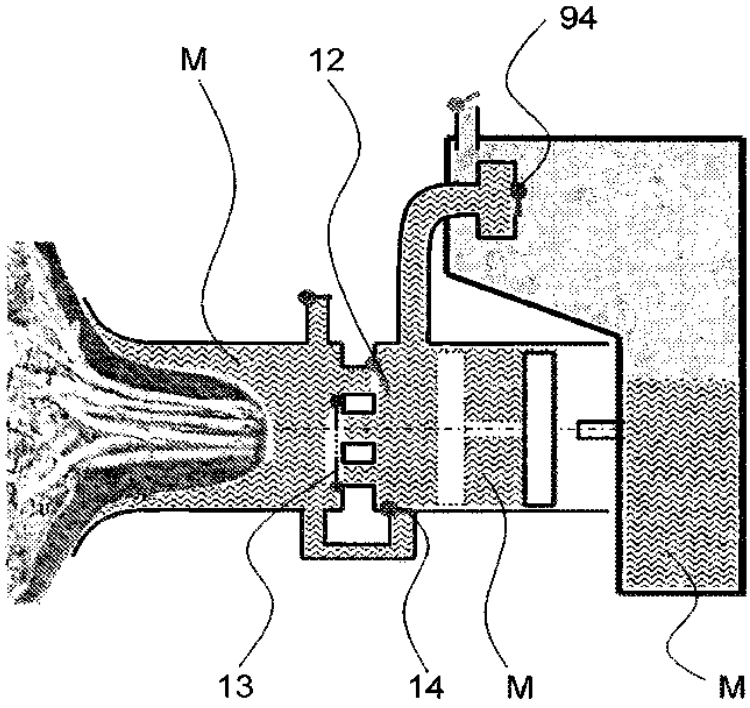


FIG. 22a

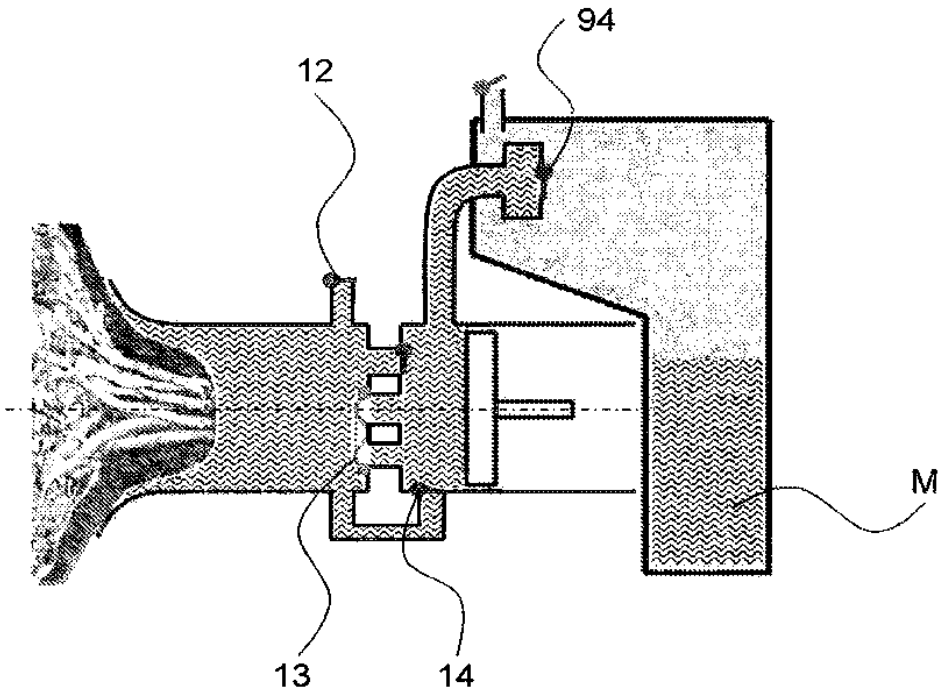


FIG. 22b

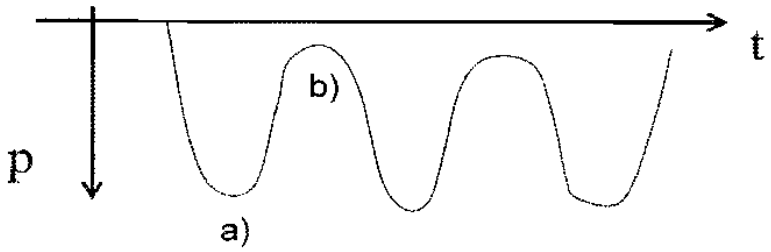


FIG. 22c

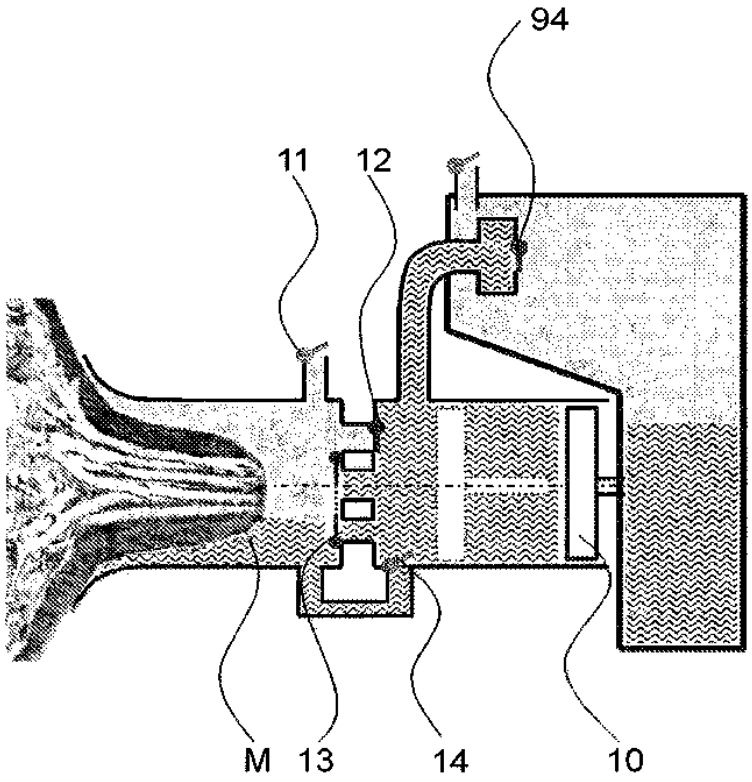


FIG. 23a

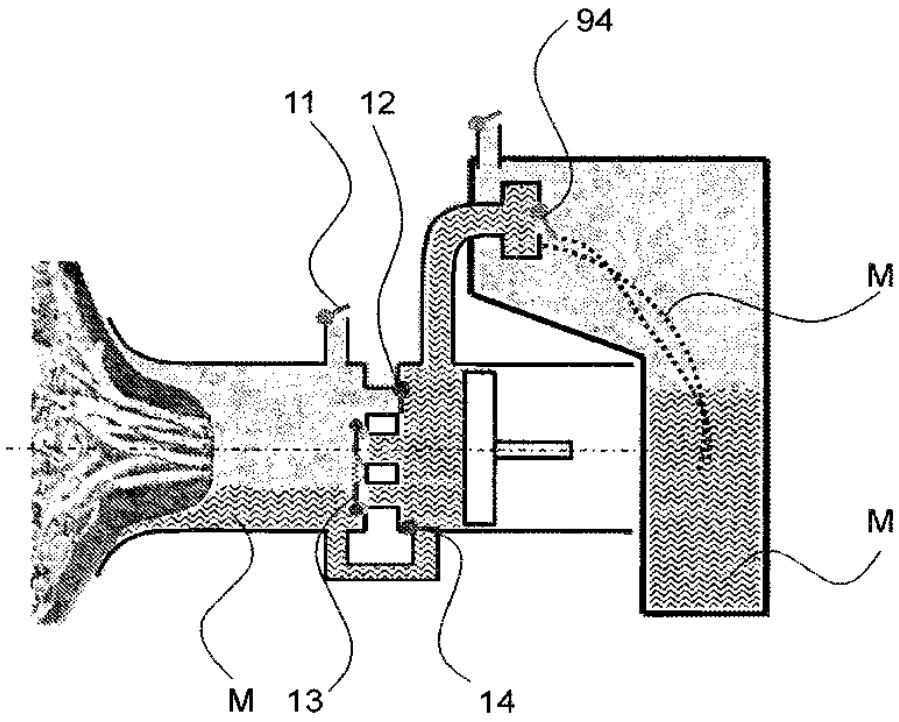


FIG. 23b

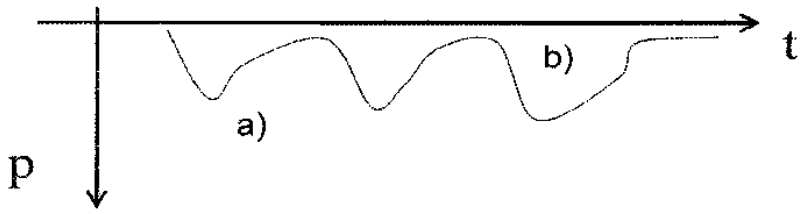


FIG. 23c

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/077141

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2011/035447 A1 (MEDELA HOLDING AG [CH]; WEBER BEDA [CH]; FURRER ETIENNE [CH]; SCHLIENG) 31 March 2011 (2011-03-31) cited in the application page 12, line 4 - page 13, line 28 page 18, line 12 - page 19, line 18 figures 1-4,12-14 -----	1,44
X	US 2012/071820 A1 (LUZBETAK MARK A [US] ET AL) 22 March 2012 (2012-03-22) page 3, paragraph 47 - page 5, paragraph 64 figures 1A-9 ----- -/--	1,2,4,5, 9,10,12, 22-26, 29,30

[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" 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
12 July 2018	20/07/2018

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	Kempeneers, Johanna

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/077141

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/131677 A1 (MEDELA HOLDING AG [CH]) 25 August 2016 (2016-08-25) page 8, line 30 - page 12, line 11 figures 1-13	1,2,4,5, 9,10,12, 22-26, 29,30

X	WO 2016/014494 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) cited in the application	8,15,19, 20,29,30
A	page 25, paragraph 205 - page 29, paragraph 213 page 36, paragraph 227 - page 37, paragraph 227 page 38, paragraph 229 page 58, paragraph 270 - page 60, paragraph 273 page 63, paragraph 279 - page 64, paragraph 279 claim 1 figures 1-4,7A-7C,11A,11B,20,21A,21B,23,31A,31B,32 A-32C,36	44

X	WO 2016/014469 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) cited in the application	8,14, 17-19, 29,30
A	page 16, paragraph 135 - page 18, paragraph 138 page 20, paragraph 145 - page 21, paragraph 145 page 22, paragraph 148 - page 23, paragraph 148 page 25, paragraph 153 - page 27, paragraph 156 page 28, paragraph 159 - page 30, paragraph 161 page 33, paragraph 167 figures 1,3,5A-5C,52C,53A-53E,58A-58E,59A-59G	44

A	EP 3 058 967 A1 (MEDELA HOLDING AG [CH]) 24 August 2016 (2016-08-24) page 5, paragraph 38 page 6, paragraph 49 - paragraph 59 figures 1,2,11a-11c,12,13a,13b,14a,14b,15,16	8,44

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/077141

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying 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.:
1-30, 44-55

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.

The International Searching Authority has found that this international application contains multiple inventions:

1. Claims 1-7, 9 (in full); 10-30 (in part)

A breast pump for pumping human breast milk, the breast pump having a housing with an actuating unit, a pump chamber with a flexible pump membrane actuated by the actuating unit to produce a vacuum, and a breast shield with an interior for receiving a human breast; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein a multi-component hygiene module is provided, the hygiene module having a first component with a flow opening for connection to the interior, a valve body with at least one valve, and a second component with a rigid shell forming the pump chamber; wherein the valve body is positioned between the first and second components, and wherein the hygiene module is sealingly and detachably connectable as a whole unit to the housing of the breast pump.

2. Claims 8, 44-55 (in full); 10-30 (in part)

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein with the breast pump in a vertical working position the outlet opening, at least at the start of a pumping operation, is positioned in an upper part of the pump chamber and/or above the inlet opening; a method for operating a breast pump to pump human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein in a first pumping phase a cyclically varying negative pressure is applied to the interior by way of the pump chamber so as to pump milk from the human breast, the interior being filled with pumped milk without the pumped milk flowing out of the interior; wherein in a second pumping phase pumped milk flows from the interior into the pump chamber and the pump chamber is filled with pumped milk; and wherein in a third pumping phase the pumped milk flows from the pump chamber into a milk collection container, the interior and the pump chamber remaining filled with pumped milk; wherein the changeover from the second pumping phase to the third pumping phase takes place when a fill level of the pumped milk reaches an outlet opening that leads from the pump chamber to the milk collection container, allowing milk to flow from the pump chamber into the milk collection container via the outlet opening.

3. Claim 35

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein between the interior of the breast shield and the pump chamber an emptying duct is provided which runs separately from the milk duct, and wherein the emptying duct can be closed by a valve, the emptying duct being closed during the pumping operation and opened at the end of the pumping operation.

.../...

4. Claims 36-38

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein the breast pump has a pump housing, a pump membrane and a module; wherein the module has at least one rigid shell forming the pump chamber and the breast shield; wherein the module can be attached to the pump housing as a unit, an airtight connection being created between the pump chamber and the interior of the breast shield, and the pump membrane being sealingly held between the module and the pump housing.

5. Claims 31-34, 39, 40

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, a pump chamber, and a milk collection container; wherein the pump housing is detachably connectable to both the breast shield and the milk collection container, the milk collection container being attachable to the pump housing by means of a spring latch.

6. Claim 41

A milk collection container for connecting to a pump housing of a breast pump for pumping human breast milk, the milk collection container having a lid that faces the pump housing and is air-permeable and liquid-impermeable in at least one region.

7. Claims 42, 43

A breast pump for pumping human breast milk, the breast pump having a breast shield for receiving a human breast, and a pump chamber; wherein the breast shield is detachably connectable to the pump housing; wherein the breast shield can be connected to the pump housing by means of a bayonet fastener; a breast shield for attachment to a pump housing of a breast pump according to claim 42; wherein the breast shield has an interior for receiving the human breast and a connection piece for attachment to the pump housing, the connection piece being provided with a bayonet fastener.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/077141

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/077141

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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EP 3058967 A1	24-08-2016	NONE	

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/077141

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 2011/035447 A1 (MEDELA HOLDING AG [CH]; WEBER BEDA [CH]; FURRER ETIENNE [CH]; SCHLIENG) 31. März 2011 (2011-03-31) in der Anmeldung erwähnt Seite 12, Zeile 4 - Seite 13, Zeile 28 Seite 18, Zeile 12 - Seite 19, Zeile 18 Abbildungen 1-4,12-14	1,44
X	US 2012/071820 A1 (LUZBETAK MARK A [US] ET AL) 22. März 2012 (2012-03-22) Seite 3, Absatz 47 - Seite 5, Absatz 64 Abbildungen 1A-9	1,2,4,5, 9,10,12, 22-26, 29,30

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
12. Juli 2018	20/07/2018

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kempeneers, Johanna

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Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 2016/131677 A1 (MEDELA HOLDING AG [CH]) 25. August 2016 (2016-08-25) Seite 8, Zeile 30 - Seite 12, Zeile 11 Abbildungen 1-13	1,2,4,5, 9,10,12, 22-26, 29,30

X	WO 2016/014494 A1 (EXPLORAMED NC7 LLC [US]) 28. Januar 2016 (2016-01-28) in der Anmeldung erwähnt	8,15,19, 20,29,30
A	Seite 25, Absatz 205 - Seite 29, Absatz 213 Seite 36, Absatz 227 - Seite 37, Absatz 227 Seite 38, Absatz 229 Seite 58, Absatz 270 - Seite 60, Absatz 273 Seite 63, Absatz 279 - Seite 64, Absatz 279 Anspruch 1 Abbildungen 1-4,7A-7C,11A,11B,20,21A,21B,23,31A,31B,32 A-32C,36	44

X	WO 2016/014469 A1 (EXPLORAMED NC7 LLC [US]) 28. Januar 2016 (2016-01-28) in der Anmeldung erwähnt	8,14, 17-19, 29,30
A	Seite 16, Absatz 135 - Seite 18, Absatz 138 Seite 20, Absatz 145 - Seite 21, Absatz 145 Seite 22, Absatz 148 - Seite 23, Absatz 148 Seite 25, Absatz 153 - Seite 27, Absatz 156 Seite 28, Absatz 159 - Seite 30, Absatz 161 Seite 33, Absatz 167 Abbildungen 1,3,5A-5C,52C,53A-53E,58A-58E,59A-59G	44

A	EP 3 058 967 A1 (MEDELA HOLDING AG [CH]) 24. August 2016 (2016-08-24) Seite 5, Absatz 38 Seite 6, Absatz 49 - Absatz 59 Abbildungen 1,2,11a-11c,12,13a,13b,14a,14b,15,16	8,44

2

INTERNATIONALER RECHERCHENBERICHT

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Feld Nr. II Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein internationaler Recherchenbericht erstellt:

1. ☐ Ansprüche Nr.
weil sie sich auf Gegenstände beziehen, zu deren Recherche diese Behörde nicht verpflichtet ist, nämlich

2. ☐ Ansprüche Nr.
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, dass eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich

3. ☐ Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefasst sind.

Feld Nr. III Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)

Diese Internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere Erfindungen enthält:

siehe Zusatzblatt

1. ☐ Da der Anmelder alle erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.

2. ☐ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung solcher Gebühren aufgefordert.

3. ☒ Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.
1-30, 44-55

4. ☐ Der Anmelder hat die erforderlichen zusätzlichen Recherchengebühren nicht rechtzeitig entrichtet. Dieser internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfasst:

Bemerkungen hinsichtlich eines Widerspruchs

☐ Der Anmelder hat die zusätzlichen Recherchengebühren unter Widerspruch entrichtet und die gegebenenfalls erforderliche Widerspruchsgebühr gezahlt.

☐ Die zusätzlichen Recherchengebühren wurden vom Anmelder unter Widerspruch gezahlt, jedoch wurde die entsprechende Widerspruchsgebühr nicht innerhalb der in der Aufforderung angegebenen Frist entrichtet.

☒ Die Zahlung der zusätzlichen Recherchengebühren erfolgte ohne Widerspruch.

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Die internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere (Gruppen von) Erfindungen enthält, nämlich:

1. Ansprüche: 1-7, 9(vollständig); 10-30(teilweise)

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe ein Gehäuse mit einer Antriebseinheit, eine Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei ein mehrteiliges Hygienemodul vorhanden ist, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

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2. Ansprüche: 8, 44-55(vollständig); 10-30(teilweise)

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei die Auslassöffnung in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet ist; Verfahren zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird,wobei in einer ersten Pumpphase der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt wird, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst, wobei in einer zweiten Pumpphase abgepumpte Milch aus dem Innenraum in die Pumpkammer fliesst und die Pumpkammer mit abgepumpter Milch gefüllt wird und wobei in einer dritten Pumpphase die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt

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bleiben,wobei der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

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3. Anspruch: 35

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist..

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4. Ansprüche: 36-38

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei die Brustpumpe ein Pumpengehäuse, eine Pumpmembran und ein Modul aufweist, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist, wobei das Modul als Einheit am Pumpengehäuse befestigbar ist, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist.

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5. Ansprüche: 31-34, 39, 40

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter aufweist, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist, wobei der Milchsammelbehälter mittels eines Schnappverschlusses am

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Pumpengehäuse befestigbar ist.

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6. Anspruch: 41

Milchsammelbehälter zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.

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7. Ansprüche: 42, 43

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist, wobei die Brusthaube mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar ist; Brusthaube zur Befestigung an einem Pumpengehäuse einer Brustpumpe gemäss Anspruch 42, wobei die Brusthaube einen Innenraum zur Aufnahme der Mutterbrust und einen Stutzen zur Befestigung am Pumpengehäuse aufweist, wobei der Stutzen mit einem Bajonettverschluss versehen ist.

INTERNATIONALER RECHERCHENBERICHT

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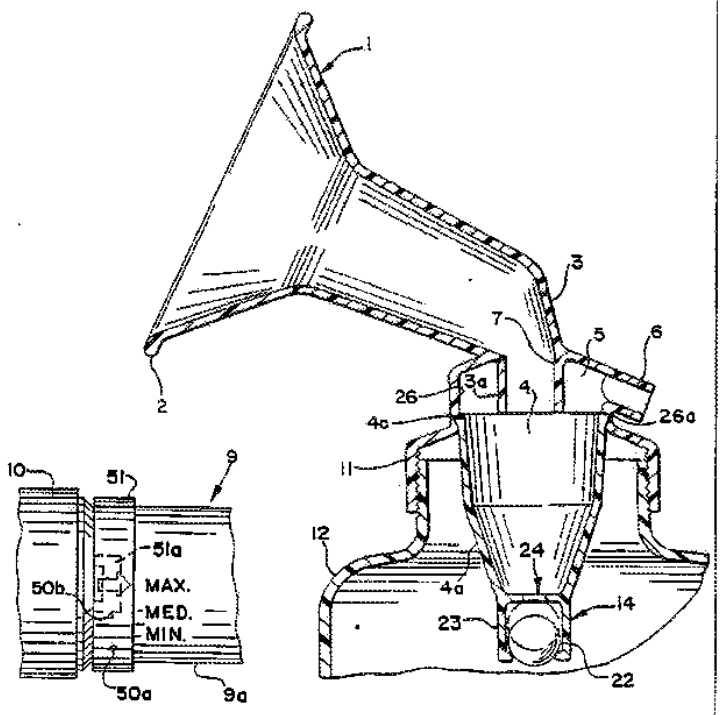
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(57) Abstract

A breastpump is provided with a valve mechanism (14) that closes a collection chamber (4) when a vacuum is applied to a hood member (1) and opens the collection chamber when the vacuum is removed. The valve mechanism (14) is removably attached to the collection chamber for ready cleaning. A baffle (7) in the hood member (1) protects the vacuum line from milk flow. One embodiment of the invention has a connecting sleeve (10) for connecting either a manually driven pneumatic pump (9) or a motor driven pneumatic pump to the hood body to create an intermittent vacuum. A connector (56) is further provided for use with a pair of breastpumps operated simultaneously by a motor driven pneumatic pump. An adjustment piece (36) for decreasing the cross-sectional area of a funnel-shaped hood member (1) is also disclosed for use of the breastpumps with smaller breasts. One type of manually driven piston pump (9) useful with the invention has apertures (50a, 50b) formed through the pump cylinder wall that are selectively opened and closed for adjustment of the piston pump vacuum.



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BREASTPUMP

This is a continuation-in-part application of U.S. Patent Application Serial No. 874,879 filed June 6, 1986, which is a continuation of Serial No. 612,602 filed May 21, 1984 (now abandoned), which is a continuation-in-part of Serial No. 296,081 filed August 25, 1981 (now abandoned).

FIELD OF THE INVENTION

The present invention generally relates to breastmilk pumps, and more particularly relates to a new and improved: valving mechanism for a breastmilk pump; a suction hood for a breastmilk pump; a manually adjustable pump-vacuum control mechanism for a manual pump; and an adaptor for pumping milk from two breasts simultaneously.

BACKGROUND OF THE INVENTION

Breastmilk pumps are well known, and are generally comprised of a hood that fits over the breast, a vacuum pump connected to the hood for generating an intermittent vacuum within the hood, and a receptacle for the expressed milk. Manually driven vaccum pumps as well as those that are driven by a motor are ordinarily used. The vacuum pumps of these devices,

as a rule, intermittently generate a vacuum or negative pressure within the hood, with the hood encompassing the nipple and a substantial amount of the breast. The intermittent suction action of the pump serves to pull on the breast and thereby extract milk in an action reminiscent of suckling. The milk so extracted typically flows from the hood into a collection container for storage and later use.

Apart from the purely hygienic requirements for such equipment, there also exist technical problems which are at least insufficiently solved with regard to prior art devices. One such significant failing of nearly all of the prior art devices is that the milk expressed often reaches the vacuum line or even the pump. In order to eliminate such a serious problem, many prior devices contain so-called safety volumes between the hood and the pump. Such a solution of the problem is expensive and usually cannot provide effective protection of the vacuum line and pump from milk. Also, varying degrees of vacuum can be generated as the milk receptacle fills, which must then be compensated for.

Another important consideration in the design of a breastpump is the vacuum created by the pump and its effect upon the breast. While it is the ultimate desire to design a breastpump that perfectly duplicates a baby's nursing action, this is extremely difficult to achieve. However, there are several important characteristics that a breastpump, properly designed, can simulate. Three things about the vacuum and its application to the breast are considered very important. These are: (a) how much vacuum does a pump create on the breast; (b) how long is that vacuum applied to the breast; and (c) can the vacuum be regulated within safe, natural limits to suit the mother's comfort with proper expression of milk?

First, a vacuum that is much greater than that "vacuum" created by a suckling baby is not only unnatural, it can also cause pain and injury to the breast. Second, just as too much vacuum can hurt the breast, too long an application of vacuum is also unnatural, and may create discomfort and injury. Third, uncontrollable vacuum -- either vacuum in excess of safe, natural limits or vacuum that cannot be fine-tuned for a woman's comfort -- makes a breastpump less effective or even useless.

In utilizing breastpumps, whether they are of a motor driven or manually driven type, it has been found that the wide variety in the size of breasts also gives rise to problems if a single breastpump is to be given universal application. This is particularly true in regard to smaller breasts, since the hoods used by most breastpumps are designed to handle a medium or larger-size breast. For example, the small breast can be sucked into a standard size hood to an extent that, if not necessarily painful, is at least rather uncomfortable. In general, the funnel of such a suction hood should abut the breast at a distance from the nipple that is as large as possible, which condition demands a funnel for the hood which is also as large as possible. While it has become obvious that the provision of different suction hoods having various funnel diameters solves such a problem, it does so in an unsatisfactory way, since providing a product line of different size hoods is expensive from a marketing and manufacturing standpoint.

SUMMARY OF THE INVENTION

One of the principal objects of the present invention is to provide a breastpump that has an improved structure including a simple but effective valv-

ing mechanism which prevents breastmilk from entering the vacuum line or suction pump.

A particularly noteworthy advantage of the valving mechanism of the present invention is that a relatively constant negative pressure or vacuum can be applied to the breastpump, since no variable volumes, (i.e., in the receiving container), are present in this device. This allows the employment of smaller pumps, since the volume of the vacuum or negative pressure which is necessary for intermittent operation can be considerably smaller in comparison to other known solutions. It is also not necessary to create a vacuum to compensate for the volume of the receiving container due to the presence of the valve of the present invention.

Another object of the present invention is to provide a breastpump that has a readily adjustable vacuum in a manually driven (non-motor) application.

Yet another object of the present invention is to provide a new and improved construction of a suction hood for a breastpump, which suction hood is relatively simple in construction and design, economical to manufacture, extremely reliable in operation, not readily subject to breakdown or malfunction, and requires a minimum of maintenance and servicing yet is effective in expressing breastmilk without fouling the equipment.

Still another object of the present invention is to provide a breastpump assembly which collects milk from both breasts simultaneously.

To these ends, which will become more readily apparent in regard to the detailed description of various embodiments of the invention which follows, the present invention comprises a hood body or member to which a collecting or catch chamber is connected. At the outlet

of the collecting chamber there is provided a valve which closes a passage leading from the collecting chamber to a receiving container. When a vacuum or negative pressure is applied to the hood from a suction device, which may be manually operated or motor driven, the valve closes the collecting chamber outlet to the receiving chamber, but opens the outlet on the return cycle of the pump to force the milk expressed from the collecting chamber into the receiving container.

The valve used is extremely effective, simple in construction, and is easily cleaned. In one embodiment the valving mechanism comprises a ball valve. In a second and presently preferred construction, the valving mechanism comprises a reciprocating disk. In this latter construction, the valving mechanism is part of an adaptor that is removably attached to an extension of the hood that forms part of the collecting chamber, so that the valve can be readily removed for cleaning.

It will be noted that due to the provision of the collecting or catch chamber with a valve, milk can be pumped to a receiving container in the form of a plastic bag, since the vacuum or negative pressure no longer affects the receiving container. Moreover, an overflow can be avoided, since the valve opens promptly and the expressed milk quickly flows into the receiving container.

A baffle arrangement is further used in conjunction with the valve mechanism to prevent milk from passing into the vacuum line or from reaching the vacuum pump.

The present invention also provides a breast-pump that, in a manual mode (i.e., using a piston pump that is hand operated), applies a governed vacuum to express milk from the breast. With an electric motor driven pneumatic pump, its maximum vacuum and timing are governed by the machine and remains relatively

constant. With hand-driven piston pumps, too much vacuum could be applied to the breast and for an undesirably long interval, depending on the speed and length of stroke with which the woman is operating the piston pump. The present invention provides for a vacuum release within the piston cylinder that automatically releases the vacuum as soon as the maximum desired vacuum is reached at the end of a predetermined stroke.

The present invention also provides for the adjustment of the vacuum level in the hand-driven piston pump application of the invention. This is accomplished in a preferred form of the invention through the use of a rotatable ring on the piston cylinder that selectively opens and closes apertures in the cylinder to adjust the flow of air into the cylinder during an evacuation stroke of the piston, and thereby adjust the amount of vacuum generated. The vacuum control is readily manipulated for easy adjustment of the vacuum generated.

The problem of the small breast that does not fit the "standardized" construction of the hood is solved in the present invention by providing an improved construction for the suction hood which includes at least one adjusting piece having a shape similar to that of the general funnel structure of the main funnel of the hood, and which is insertable into the main hood funnel to reduce the latter's cross-sectional area. In particular, a preferred funnel-shaped adjusting piece has a generating angle for the outer surface of the adjusting piece funnel which corresponds to the generating angle of the inner surface of the main funnel of the hood, with the inner surface of the adjusting piece having a larger generating angle than that of the inner surface of the main funnel. The adjusting piece effectively reduces the diameter of the main funnel at the base of the main funnel so that the hood can be conveniently used by women with smaller breasts.

Yet another object of the present invention is accomplished in the use of a device that enables a single motor driven pneumatic pump to express milk from two breasts simultaneously. The device comprises a y-shaped tubular connector that permits use of two of the foregoing breastpumps at the same time.

The foregoing objects and advantages of the present invention will be further understood upon consideration of the following detailed description of the invention taken in conjunction with the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial vertical sectional view of a first embodiment of a breastpump made in accordance with the present invention in which a ball valve is used;

FIG. 2 is a view similar to that of FIG. 1 showing another embodiment of a breastpump made in accordance with the present invention using a manually driven suction pump mechanism, and employing a disk valve mechanism, and shows as well the use of an adaptor for small breasts;

FIG. 2A is a view similar to that of FIG. 2 showing yet another embodiment of a breastpump made in accordance with the present invention;

FIG. 2B is an enlarged sectional view of a modified connector for use with a motor driven pump;

FIGS. 3 through 5 show a vacuum adjustment mechanism for use with the manually driven suction pump of the device of FIG. 2A; and

FIG. 6 shows a connector for a double-pump application for use in collecting milk from two breasts simultaneously.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Turning now to FIG. 1, a first embodiment of a breastpump made in accordance with the teachings of the present invention is shown. This arrangement comprises a hood body or hood member 1 having two ends. The first end 2 has a substantially wide cross-section (diameter), and is funnel shaped. During operation of this device, funnel end 2 is placed over the breast of the user. A second end 3 of the hood member constitutes a generally cylindrical extension of the funnel, and has a cross-section substantially narrower than the cross-section of the end 2. The second end 3 communicates with a collecting or catch chamber 4 and with a vacuum passage 5 via a short tubular extension 3a.

The vacuum passage 5 also communicates with a vacuum line 6, which in this embodiment is shown as a short stem which is connected with a flexible tube (not shown) that extends to a vacuum or suction pump, such as an electric motor driven pneumatic pump.

The collecting chamber 4 is arranged substantially immediately after the extension 3a of the hood. Separating means in the form of a depending separation wall 7 (which here is the rear wall of the extension 3a) forms a baffle between the end of the hood extension 3a and the collecting chamber 4, and the vacuum line 6. It will be noted that the bottom of the separation wall 7 is below the level of the top end of the vacuum line 6. Milk expressed into the hood member 1 is thus blocked by the separation wall 7 from thereby entering into the vacuum line 6.

At the lower portion of the collecting chamber 4 is a valve mechanism 14. In this embodiment, this valve mechanism 14 is a ball-type valve having a ball 22 captured within a cage 23 formed in the bottom of a

cup-like receptacle 4a that defines the majority of the collecting chamber 4. The top of the ball valve cage 23 has an upper opening 24 which is opened and closed by action of the ball 22. Opening 24 constitutes the outlet for the collecting chamber 4. In operation, the application of a suction or negative pressure to the hood member 1 and collecting chamber 4 by the suction pump connected to the vacuum line 6 causes the ball 22 to be drawn upwardly (as shown in FIG. 1) to close the upper opening 24. Milk expressed through the suction action will thus collect in the collecting chamber 4. Release of the negative pressure will thereupon cause the ball 22 to drop free of the opening 24 allowing the milk to flow around the ball through the ball valve cage 23 and into a container or receptacle 12.

The collecting receptacle 4a is of a size to allow a typical volume of milk expressed in a single stroke to collect without overflowing, with the action of the ball valve being sufficiently quick to release the milk from the collecting chamber 4 into the container 12 for the next stroke. Milk thus does not substantially collect in the collecting chamber 4 between strokes.

It will be further noted that the collecting chamber receptacle 4a is received in an enlarged portion 26 at the tail-end of the hood member 1. A snap-fit is made using a bead 4c formed around the top edge of the collection chamber receptacle 4a that is received in annular recess 26a. The snap-fit permits easy removal of the collection chamber receptacle 4a and valve mechanism 14 for cleaning, as well as for cleaning of the hood member 1. Also, connecting means in the form of a collar 11 is provided for connection of the hood member 1 and the collecting chamber 4 with the container 12, as through the screw-threaded attachment of the collar 11 to the neck of the container 12.

A second possible embodiment of the invention is shown in FIG. 2, and employs a valving mechanism that is different from that of the preceding embodiment, but operates on the same general principle. This valving mechanism shown in FIG. 2 is not presently preferred, with the valving mechanism of FIG. 2A being considered much more advantageous. It will further be understood that like numbers denominate the same general structure or element in all of the various embodiments shown in the FIGS.

In FIG. 2, the suction or vacuum pump is specifically shown as a manually driven piston pump 9 having a pump cylinder 9a and a piston 9b which reciprocates within the cylinder 9a under action of a piston rod 9e. The pump cylinder 9a is connected to the hood member 1 by means of a connecting means or connecting sleeve 10 which forms part of the hood member 1. Connecting sleeve 10 is internally screw threaded to match with the screw threads formed on the outer part of an end of the piston cylinder 9a. Forward end 9d of the piston cylinder butts against a shoulder formed around the interior of the connecting sleeve 10 in a substantially air-tight fit. An aperture 9c is formed in the wall of the piston cylinder 9a at a point which corresponds to what is presently considered to be the maximum desired vacuum pressure to be reached on an average stroke of the manually driven piston pump. Once the head of the piston 9b passes beyond this aperture 9c in its downward (vacuum-inducing) stroke, the vacuum produced is automatically released. The piston cylinder has a displacement (volume at full outward stroke) of about 40 cc at the point of vacuum release.

The valve 14 in the embodiment of FIG. 2 is of a disk-type valve composed of a tubular housing 15, a perforated plate 16 that extends across the diameter of the housing 15, a disk 17, a guiding member 18 and a stop member 19. The disk 17 is adapted to travel along the guide 18 between a closed and an open position of the valve 14.

The valve 14 includes an upper chamber 20 which forms part of the collecting chamber 4, and collects milk when the valve 14 is in a closed position (with the disk 17 in facial engagement with the bottom of the perforated plate 16, thereby closing the openings 16' of the perforated plate). The tubular housing 15 of valve 14 is removably attached to the hood member 1 by means of a suitable releasable closure attaching means 21. In this embodiment of the invention, this attaching means is accomplished through a threaded engagement with the hood extension 3a.

During the operation of the embodiment of FIG. 2, the hood member 1 is held against the breast of the user with the main funnel body or portion 31 surrounding the nipple and adjacent breast. An intermittent vacuum is created by operation of the pump 9. The vacuum created in the collecting chamber 4 causes the disk 17 to be lifted to an upper position which sealingly closes apertures 16' of the perforated plate 16.

Due to the sealing engagement between an inside portion of the main funnel body 31 of the hood member 1 and the breast during the application of the vacuum, the milk is sucked from the breast of the user. The force of gravity causes the milk to be accumulated in the collecting chamber 4, particularly in the upper portion 20 of the valve housing 15. As soon as the negative pressure is discontinued, the disk 17 drops into its lower position and the milk which has been collected in the collecting chamber 4 thereby flows downwardly into the container 12.

Separation wall 7 combines with a rear wall 8 of the hood member extension 3a to form a baffle to prevent milk from reaching the vacuum line 6. This baffle forms a more restricted vacuum passage 5 than that of FIG. 1 for better protection of the vacuum line 6.

Yet another embodiment of the invention is depicted in FIG. 2A. This embodiment differs from that of FIG. 2 only in respect of the valve 14 and an insert or adjusting piece 36 which is inserted into the main funnel body 31. This adjustment piece 36 will be discussed in further detail hereafter.

The valve mechanism 14 of FIG. 2A also uses a disk-member 17' as the valve member, but does away with a guiding member such as that illustrated at 18 of FIG. 2. Instead, disk 17' is captured within a tubular shaped valve housing 15' that has an upper portion 15a and a lower portion 15b. Lower portion 15b has a slightly smaller interior diameter than that of the upper portion 15a. A small gap 15c is formed between the upper and lower portions 15a, 15b within which the disk 17' is captured and vertically reciprocates. Ribs 15d connect the top and the bottom portions 15a, 15b. Nibs 17a formed on the disk 17' extend beyond the inboard edge of the top portion 15a to further locate the disk member 17' within the gap 15c. These nibs 17a abut against the bottom edge of the upper housing portion 15a when the housing 15' is removed from the hood member 1.

When the vacuum pump 9 is operated with the embodiment of FIG. 2A, the disk 17' is caused to move upwardly under vacuum where it contacts and seats against the bottom edge or lip of an extended length 3b of tubular extension 3a, thus closing the upper portion 20 of the housing 15' and thereby closing the collecting chamber 4. When the vacuum is released, the disk 17' drops from the foregoing seat and rests upon stand-off bosses 15f formed on the top of the lower housing portion 15b.

This allows the milk collected in the upper housing portion 20 and collecting chamber 4 to flow downwardly into the container 12.

As in the embodiment of FIG. 2, the valve 14 of this embodiment is also releasably attached to the end of the hood member 1. That attachment takes the form of a split-collar arrangement for the upper housing portion 15a, as shown by the slot 15e formed in the upper portion 15a. The internal diameter of the upper portion 15a is slightly smaller than the outside diameter of the lengthened portion 3b of extension 3a of the hood end. The slotted portion 15a can thus be releasably wedged on the lengthened portion 3b.

An adjusting piece 36 is shown in both FIGS. 2 and 2A comprising a funnel-shaped section 37 that is made integral with a cylindrical portion 38 that forms an extension of the funnel section 37. The extension portion 38 abuts against the inner surface of a similar cylindrical portion 32 that forms an extension of the main funnel 31 of the hood member 1 through the use of wing-shaped rib or distance pieces 39, 40. The adjusting piece 36 reduces the diameter of the base of main funnel 31 for use of the breastpump with smaller breasts.

The generating angle of the outer surface of the funnel 37 of the adjusting piece 36 corresponds to the generating angle of the inner surface of the main funnel 31. The generating angle of the inner surface of the adjusting piece funnel 37 is slightly larger, however, and thus decreases the operative cross-section of the main funnel 31. The adjusting piece 36 thus reduces the opening into the extension 32 of the hood member 1. This enables the main funnel 31 to still abut a significant amount of the breast along a large distance from the nipple without a smaller breast being sucked into the extension 38 of the adjusting piece 36.

It will also be noted that the funnel 37 of the adjusting piece 36 terminates in a sharp edge 37a to lie ridgelessly on the inner surface of the main funnel 31. This sharp edge 37a provides a good seal between the adjusting piece funnel 37 and the main funnel 31. This in turn provides a correct seal between the breast and the main funnel 31, the result of which is that no significant amount of air will be sucked by the breastpump during use. This sharp-edge engagement between the adjusting piece funnel 37 and the main funnel 31 also provides a smooth surface within the hood member 1 that prevents irritation of the breast during use of the breastpump.

Extension 38 of the adjusting piece 36 is long enough to accommodate the full length of the compressed nipple therein without the nipple extending significantly beyond an inner end 38a of the adjusting piece. The suction force upon the breast nipple causes the nipple areola to extend radially, with the nipple desirably pressed on the inner surface of the adjusting piece 36 but not beyond the inner end 38a of the extension 38. As shown in FIG. 2, the adjusting piece extension 38 is approximately half as long as the extension 32 of the main funnel 31. Adjusting piece 36 has a slightly longer extension 38 in the embodiment of FIG. 2A.

The present invention also provides for adjustment of the amount of vacuum generated during manual pumping. This feature of the invention is illustrated in FIG. 2A and particularly in FIGS. 3 through 5, which show a modification made to the type of hand-operated piston pump 9 of FIG. 2.

A pair of spaced apart apertures in the form of pin holes 50a and 50b are formed through the pump cylinder 9a adjacent the end 9d of the piston cylinder.

The pin holes 50a, 50b each have a diameter of about .6 mm. A ring 51 carried on the piston cylinder 9a overlies the cylinder holes 50a, 50b. An interior chamber or channel 50a is formed on the inside of the ring 51. This interior channel 51a is sufficiently long to allow both of the holes 50a, 50b to fit within the channel 51a simultaneously (FIG. 5). The channel 51a has openings 51b at either end that are open to atmosphere. The ring 51 is preferably made out of a flexible or semi-flexible rubber-like material that grips the outside of the pump cylinder 9a and enables a good seal to be maintained between the ring and the piston cylinder.

The ring 51 is designed to be rotated on the piston cylinder to positions indicated as "Maximum", "Medium" and "Minimum" vacuum, as illustrated in the FIGS. 3 through 5. Maximum vacuum (FIG. 3) has neither hole 50a or 50b within the area of the channel 51a. The holes 50a, 50b are covered by the ring 51 and no air enters the piston cylinder 9a therethrough.

Medium vacuum is established by rotating the ring 51 so that hole 50b is within the channel 51a. Air can thus enter through the channel openings 51b into the channel 51a and through the hole 50b into the pump cylinder 9a to thereby modify the vacuum (FIG. 4).

Minimum vacuum is established by rotating the ring 51 so that both of the holes 50a, 50b are located within the channel 51a (FIG. 5). The amount of vacuum or pull on the breast generated by the manual pump 9 can thus be readily adjusted by the user as circumstances warrant.

Yet another feature of the invention is illustrated in FIG. 6 for operating two breastpumps simultaneously. This is possible when using an electric motor driven pneumatic pump. Two of the breastpumps illustrated in any of FIGS. 1, 2, or 2A could be used in this application. FIG. 6 illustrates

a device to be used when expressing milk from both breasts simultaneously that is particularly adapted for use with the breastpumps of FIGS. 2 and 2A, however. This device comprises a Y-shaped connector formed from a flexible base hose or tube 53 and flexible extension hoses or tubes 54 and 55, the latter tubes forming the arms of the Y. A Y-shaped hollow connector piece 56 includes a plurality of attachment stems that the respective tubes 53 through 55 fit over.

One end of the base tube 53 is connected via a hollow connector piece 57 to the output of a suitable motor driven pneumatic pump 58. Ends of the extension tubes 54, 55 fit over nipples 59 formed on a screw-threaded adapter 60. The nipples 59 have an internal opening 59a which extends into a tubular portion 61 of the adapter 60. Adapters 60 are specifically designed for use in the embodiments of FIGS. 2 and 2A, and are screw threaded to the sleeve 10 in place of the manually driven pump 9. The embodiments of the breastpump depicted in these two FIGS. can thus be used with a motor driven vacuum pump as well as with a manually driven piston pump.

FIG. 2B illustrates another adaptation for the breast pump of this invention which enables hook-up to a pneumatic pump (such as pump 58). A tubular connector 62 has an end sized to snuggly fit, in an interference fit, within a widened opening 5a to the vacuum channel 5, which is provided with an elbow-type bend to this end. A flange 62a around the middle of the connector 62 serves as a stop within the elbow, and also forms a stop for a tube 63 which is connected to the other end of the connector 62. The tube is connected at its opposite end to a motor driven pump. No adapter, such as adapter 60, is thus necessary with this embodiment using the connector 62.

Thus, while the invention has been described with reference to certain present embodiments, those skilled in this art will recognize modifications of structure, arrangement, composition and the like that can be made to the present invention, yet still fall within the scope of the invention as hereafter claimed.

What is claimed is:

1. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

means for connecting said tubular extension of said hood body with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into said main funnel portion and thereby expresses milk from the breast into said tubular extension;

a wall formed interiorally of said tubular extension separating said vacuum line connecting means from the breastmilk flow, said wall depending from an upper interior side wall of said tubular extension with said vacuum line connecting means having a connection with said tubular extension above the bottom of said wall, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet when said vacuum is removed;

means for removably attaching said valve mechanism to said hood body adjacent said catch chamber such that said hood mechanism can be readily removed for cleaning; and

a container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

2. The breastpump of claim 1 wherein the valve mechanism comprises a tubular valve housing having a circumferential slot formed therethrough dividing said housing into an upper portion and a lower portion, said upper and lower housing portions being joined together by connecting means which does not substantially obstruct said slot, a solid disk-shaped valve member sized larger than said collecting chamber outlet and adapted to seat against a lip defining said outlet when a vacuum is applied to said hood body to thereby close said outlet, said valve member being captured for movement within said circumferential slot.

3. The breastpump of claim 2 wherein said disk-shaped valve member has radially extended nibs which engage an edge formed on the bottom of said upper valve housing portion when said valve mechanism is not attached to said hood body, with ribs extended between said upper and lower valve housing portions forming said valve housing portion connecting means, said ribs preventing lateral movement of said disk-shaped valve member out of said circumferential slot, and stand-off bosses formed on said lower housing portion on which said disk-shaped valve member rests in the absence of vacuum.

4. The breastpump of claim 3 wherein said upper valve housing portion is in the form of a split collar, said split collar having a longitudinally extending slot formed therein along part of its length, said upper valve housing portion being removably attached to said collecting chamber by pressing said split collar onto a

tubular portion of said catch chamber, said split collar having an interior diameter slightly smaller than the outside diameter of said catch chamber tubular portion so that said split collar is stretched radially outwardly by said catch chamber tubular portion and thereby wedged in placed thereon.

5. The breastpump of claim 4 wherein said valve housing circumferential slot is located immediately below said outlet lip when said valve mechanism is attached to said collecting chamber, said disk-shaped valve member seating against said outlet lip which lip is formed on the end of said catch chamber tubular portion.

6. The breastpump of claim 1 wherein said valve mechanism comprises a ball valve in a cage which is located at the downstream end of a cup-shaped receptacle, said receptacle having an upper circular edge with a circumferential bead formed about said circular edge, said bead being received in an annular groove formed about the interior of said hood in the area of said collecting chamber with said valve mechanism snap-fitting to said hood body.

7. The breastpump of claim 1 wherein said valve member comprises a tubular valve housing having a perforated plate extending across the interior of said tubular housing, and a disk-shaped valve member movable on a pin that is connected to said perforated plate to close said perforations when a vacuum is applied to said hood body.

8. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

a connecting sleeve formed with said tubular extension for connecting said tubular extension with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into the funnel portion and thereby expresses milk from the breast into said tubular extension, said connecting sleeve having means formed thereon for connection with a manually driven pneumatic pump as well as a motor driven pneumatic pump;

a wall formed interiorally of said tubular extension separating said vacuum line connecting means from the milk flow, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet once the vacuum is removed; and

a receiving container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

9. The breastpump of claim 8 wherein said connecting sleeve is screw-threaded for engagement with a screw-threaded end of a manually driven single piston

pneumatic pump and for engagement with a screw-threaded adapter for a motor-driven pneumatic pump, said motorized pump adapter comprising a threaded member engageable with said connecting sleeve and having a bore extended through said threaded member with an exterior connector for said bore to which a hose from said motor driven pneumatic pump can be connected, said motorized pump adapter and said manually driven pneumatic pump being usable interchangeably with said breastpump.

10. The breastpump of claim 9 wherein a pair of said motorized pump adapters are provided for use with a pair of breastpumps, said adapters each being connected by a length of hose to a Y-shaped tubular connector, a third length of hose connecting said tubular connector to the output end of a motor driven pneumatic pump.

11. The breastpump of claim 9 wherein a pair of said motorized pump adapters are provided for use with a pair of breastpumps, said adapters being connected to the ends of a Y-shaped length of hose with a third end of said hose being connected with the output end of a motor driven pneumatic pump.

12. The breastpump of claim 1 further including an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said main funnel tubular extension, said funnel-shaped adjusting piece having a funnel portion and a cylindrical extension that is insertable into said main funnel tubular extension, said extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said

adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

13. The breastpump of claim 8 further including an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said main funnel tubular extension, said adjusting piece having a funnel portion and an extension that is insertable into said tubular main funnel extension, said extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting

piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

14. The breastpump of claim 8 wherein said breast-pump includes a manually driven piston pump engageable with said connecting sleeve, said piston pump comprising a piston head mounted for reciprocal movement within a piston chamber under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

15. The breastpump of claim 8 wherein said breast-pump includes a manually driven piston pump engageable with said connecting sleeve, said piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on the exterior of said piston cylinder, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum gener-ated in said piston chamber when said piston pump is operated.

16. The breastpump of claim 15 wherein neither aperture is exposed within said ring channel for maximum vacuum, two apertures are exposed within said ring channel for a minimum vacuum, and one aperture is

exposed within said ring channel for an intermediate vacuum between said maximum and minimum vacuums.

17. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

a manually driven piston pump engaged with said tubular extension along a vacuum line for generating an intermittent vacuum in said hood body, said piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated;

a baffle formed interiorally of said tubular extension separating said vacuum line from breastmilk flow, said baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said outlet end of said catch chamber, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet once the vacuum is removed; and

a receiving container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

18. The breastpump of claim 17 wherein said piston cylinder has at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on the exterior of said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

19. A manually driven piston pump with an adjustable piston chamber pressure, comprising:

a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

20. The piston pump of claim 19 wherein said piston cylinder has at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

21. A suction hood for an apparatus for removing mother's milk comprising:

a main body having the shape of a funnel within which the breast is received;

an adjusting piece also having the shape of a funnel, said adjusting piece being insertable into said main body funnel to alter at least a portion of the cross-sectional area of said main funnel body at the base of said funnel adjacent a substantially cylindrical extension of said main funnel body, said funnel-shaped adjusting piece having a cylindrical extension insertable into said cylindrical extension of said main funnel body, said cylindrical extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said tubular extension of said main funnel body, a generating angle of an outer surface of said adjusting piece funnel corresponding to a generating angle of the inner surface of said main funnel body, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream edge of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel body.

22. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extended downstream from said main funnel portion;

a connecting sleeve formed with said tubular extension of said main funnel for connecting said tubular extension with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into said hood body and thereby expresses milk from the breast into said main funnel tubular extension, said connecting sleeve having screw-threads for engagement with a screw-threaded end of a manually driven single piston pneumatic pump and for engagement with an adapter for a motor driven pneumatic pump, said motorized pump adapter comprising a screw-threaded member engageable with said connecting sleeve with a bore extending through said threaded member and an exterior connector for said bore to which a hose from said motor-driven pneumatic pump can be connected, said motorized pump adapter and said manually driven pump being useable interchangeably with said breastpump;

said manually driven piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-drive piston rod, said piston cylinder having at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated;

a wall formed interiorally of said tubular extension separating said connecting sleeve and thereby the vacuum line from milk flow, said wall depending from an upper interior side wall of said main funnel tubular extension with said vacuum line connecting sleeve communicating with said tubular extension above

the bottom of said wall, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said main funnel tubular extension, said catch chamber being located downstream from said main funnel tubular extension and having an inlet end and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism comprising a tubular valve housing has a circumferential slot formed therethrough dividing said housing into an upper and a lower portion, said upper and lower portions being joined together by ribs extending between said upper and lower valve housing portions which ribs to not substantially obstruct said slot, a solid disk-shaped valve member sized larger than said collecting chamber outlet and adapted to seat against a lip defining said outlet when a vacuum is applied to said hood body to thereby close said outlet, said valve member being captured for movement within said circumferential slot with said ribs preventing lateral movement of said disk-shaped valve member out of said circumferential slot, stand-off bosses being formed on said lower housing portion on which said disk-shaped valve member rests in the absence of vacuum, said disk-shaped valve member having radially extending nibs which engage an edge formed on the bottom of said upper valve housing portion when said valve mechanism is not attached to said hood body, said upper valve housing portion being in the form of a split-collar have a longitudinally extending slot formed therein along part of its length, said upper valve housing portion being removably attached to said collecting chamber by pressing said split-collar onto a tubular portion of said catch chamber, said split-collar having an interior diameter slightly smaller than the outside diameter of said catch chamber tubular portion so that

said split-collar is stretched radially outwardly by said catch chamber tubular portion and thereby wedged in place thereon, said valve housing circumferential slot being located immediately below said outlet lip when said valve mechanism is attached to said collecting chamber to enable said disk-shaped valve member to seat against said catch chamber outlet lip;

a container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet; and

an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said tubular main funnel extension, said adjusting piece having a funnel portion and a cylindrical extension of said adjusting piece funnel portion that is insertable into said main funnel tubular extension, said adjusting piece extension being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said adjusting piece extension spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel portion having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

FIG_1_

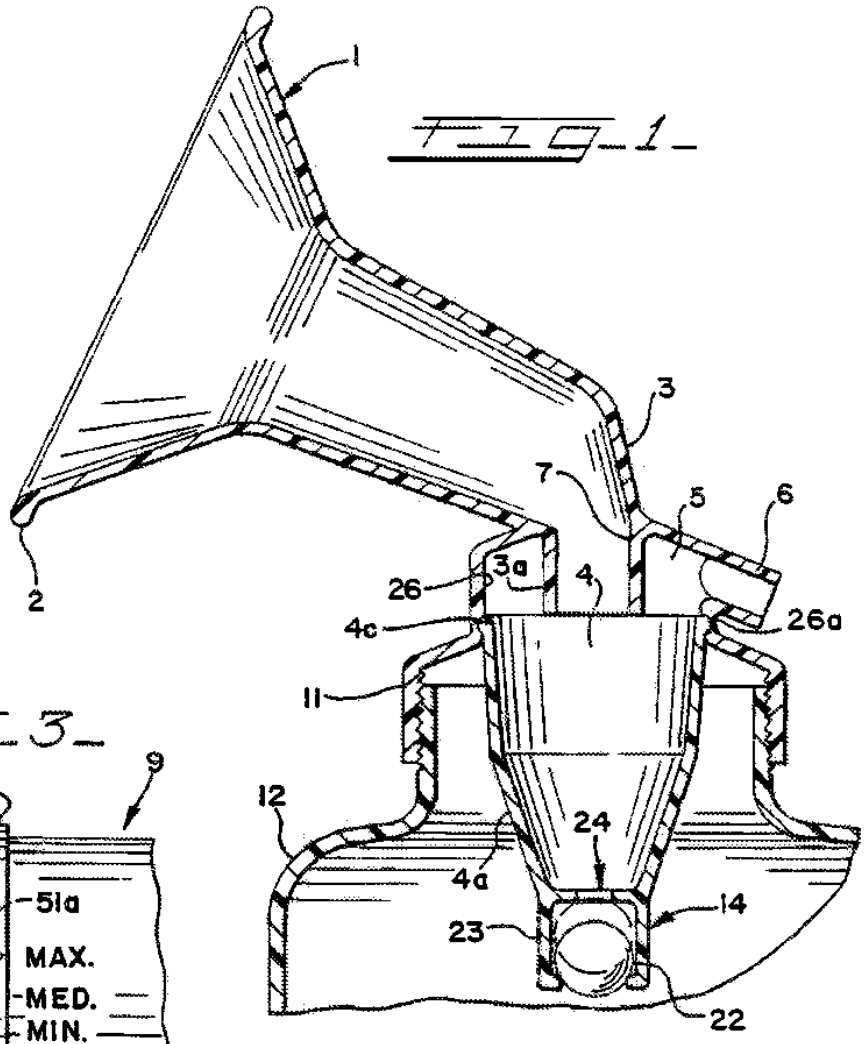


FIG_3_

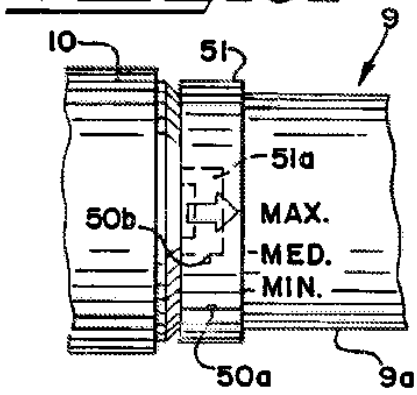


FIG_4_

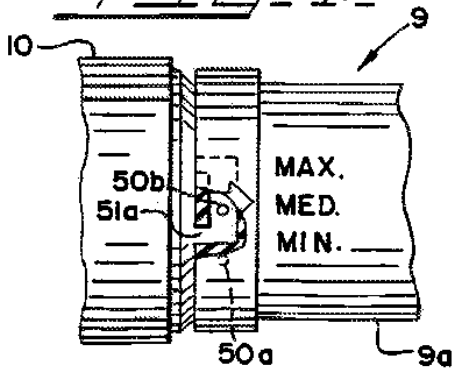


FIG_5_

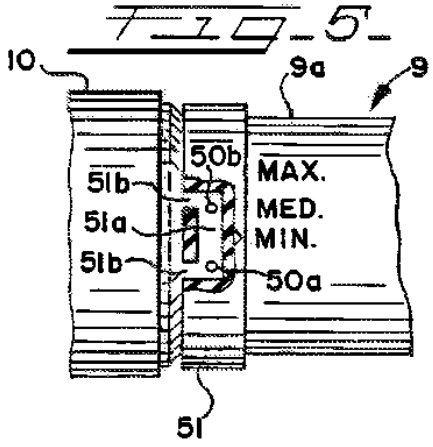


FIG_2

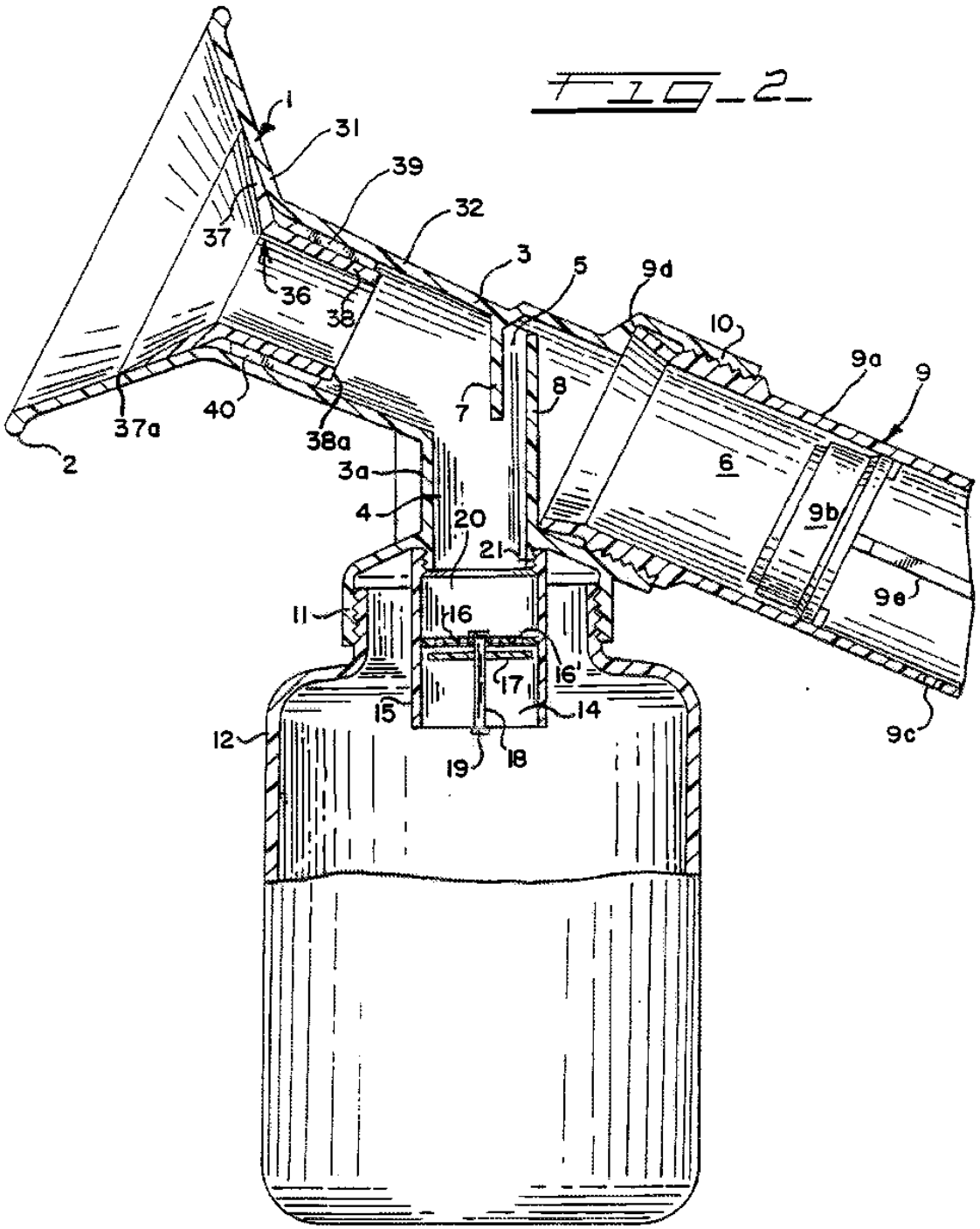
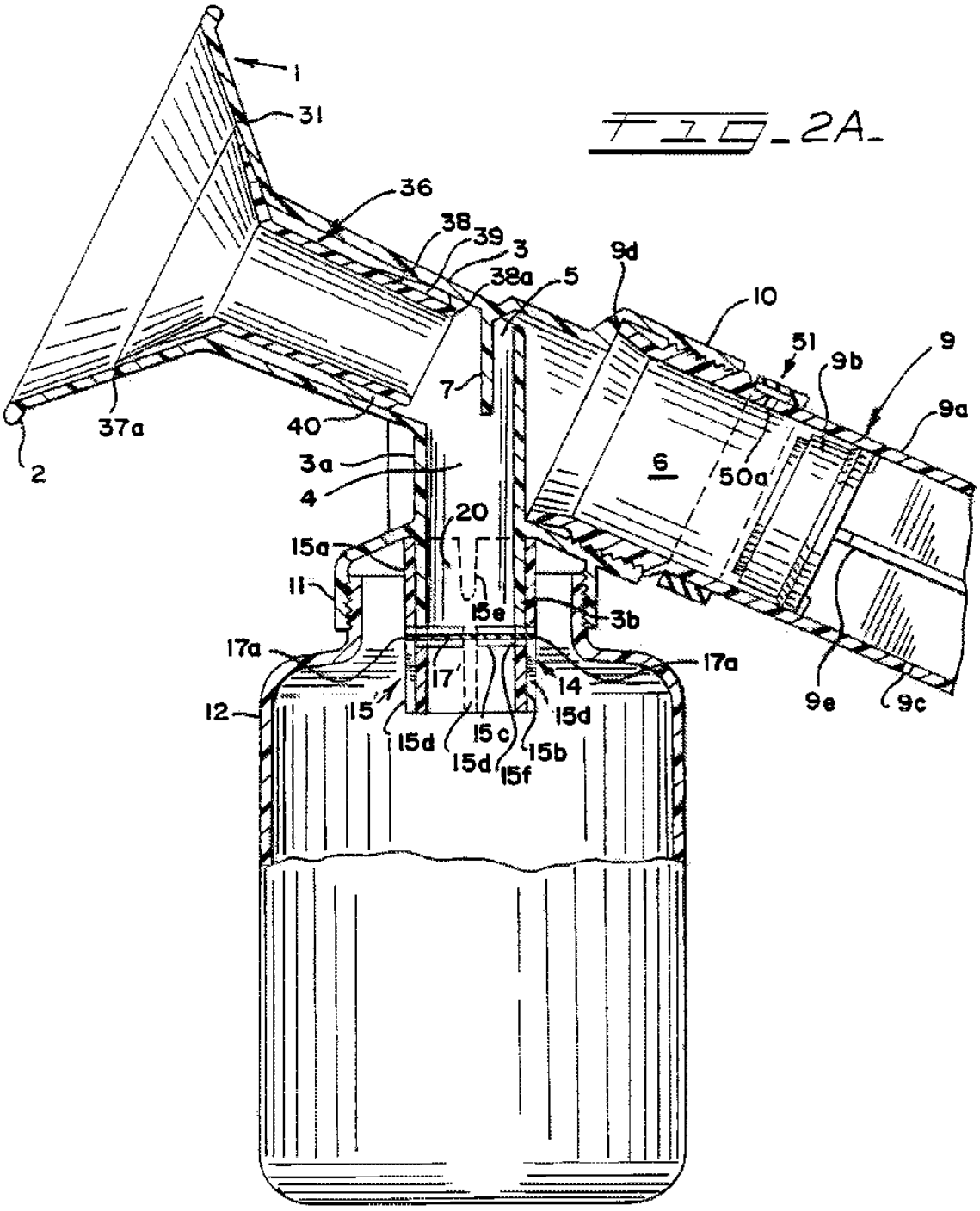

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37a
38a
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3a
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4
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9b
21
9e
11
16
16'
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14
12
9c
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FIG_2A_


1
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36
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38a
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9d
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9b
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9a
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37a
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3a
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50a
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15a
11
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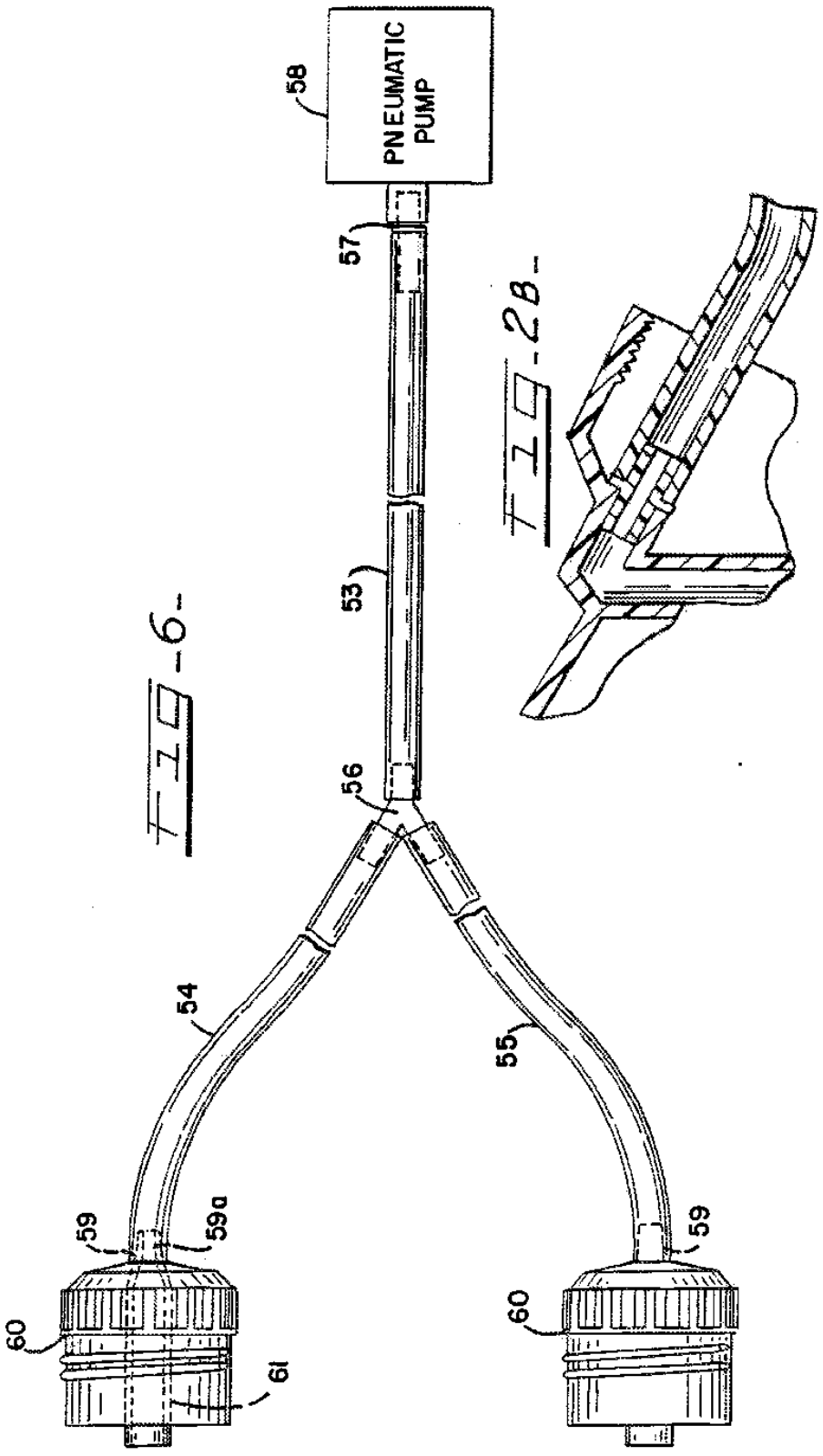


FIG-6-

FIG-2B-

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/01784

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [5]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61M/1/06
U.S.Cl. : 604/74,346

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	137/533,19 604/74-76,118,119,323,335,346 119/14.32,14.33,14.53

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	G.B., 762,701 (KUPFER) 05 December 1956, see fig. 1 and page 2, lines 40-50	1,6,8
Y	It., 407,293 (PUIATTI) 27 September 1944, see the entire document	1,6,8
Y	U.S.,A, 1,184,293 (ZERATSKY) 23 May 1916, see fig. 1, elements G and G'	1,6,8
Y	U.S.,A, 1,596,520 (ESKHOLME) 17 August, 1926 see fig. 2,	6

* Special categories of cited documents: [10]

"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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
05 August 1988	12 SEP 1988
International Searching Authority	**Signature of Authorized Officer**
ISA/US	J.L. Kruter

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers , 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 [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

The separate and distinct species of
a. fig. 1 claims 1,6,8
b. fig. 2 claims 1, 7-9,12,13,21
c. fig. 2,4 claims 1-5,8,9,12,13,21
d. fig. 3,4,5 claims 1-5,8,9,12-20,22
e. fig. 6 claims 6,11

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☒ 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 claim numbers:

1,6,8

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP9** and **NPL1-NPL13** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

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Date: April 17, 2024

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(74) Agent: **HANLEY, John**; 2570 W. El Camino Real, Suite 310, Mountain View, CA 94040 (US).

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,

[Continued on next page]

(54) Title: BREAST PUMP SYSTEM AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

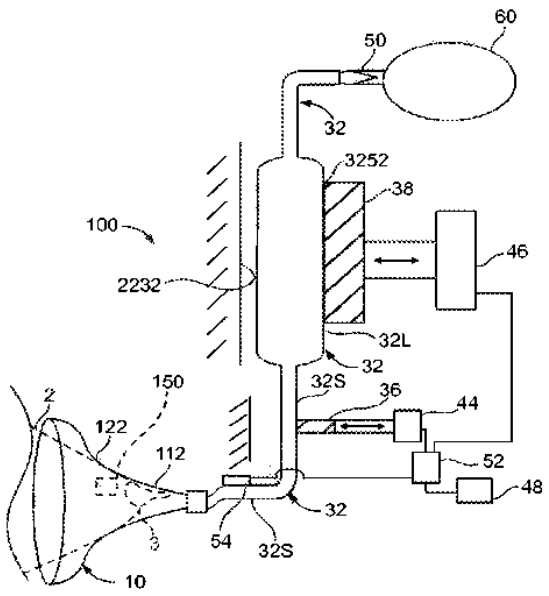


FIG. 20

WO 2016/014494 A1

TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

BREAST PUMP 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.

[0005] To ensure that the nursing baby is receiving adequate nutrition, it is useful to monitor the baby's intake. It would be desirable to provide a breast pump system that easily and accurately monitors the volume of milk pumped by the system, to make it convenient for the nursing mother to know how much milk has been extracted by breast pumping. It would also be desirable to track milk volume pumped per session,

so that the volume of milk contained in any particular milk collection container can be readily known.

[0006] Many existing breast pump systems can cause considerable discomfort to the user over time. One cause of such discomfort is chafing of the nipple against the nipple flange/housing as the nipple stretches and contracts during the pumping session. There is a continuing need for a breast pump system that is more comfortable to the user, even over repeated pumping sessions.

SUMMARY OF THE DISCLOSURE

[0007] Briefly and in general terms, the present disclosure is directed toward breast pump systems or methods. The system includes breast contacting structure and a storage container, and structure that delivers milk from a breast to the storage container. The method involves pumping milk from a breast and delivering the pumped milk into the storage container.

[0008] According to one aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; an external shell; and a milk collection container; wherein the external shell comprises a compartment facing a distal end of the external shell, the external shell further comprising a proximal end surface facing away from the proximal end; wherein the skin contact member, the conduit and the driving mechanism are received in the compartment of the external shell; wherein the milk collection container is positionable over the distal end surface of the shell; and wherein the system is shaped and configured to be contoured to the breast of a user.

[0009] 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.

[0010] In at least one embodiment, the skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere.

[0011] In at least one embodiment, the system is battery powered, the system comprising a battery, wherein the battery is received in the compartment of the external shell.

[0012] In at least one embodiment, the proximal surface of the external shell is shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under clothing worn by the user.

[0013] In at least one embodiment, the proximal surface of the external shell comprises a polygonal, flat, irregular or discontinuously curved shape dissimilar to the curvature of the breast; and the milk collection container is configured to interface with the proximal surface and to be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user.

[0014] In at least one embodiment, the proximal surface comprises flat surfaces that form an angular external surface.

[0015] In at least one embodiment, the proximal surface comprises a flat central portion and convex portions extending radially from the flat central portion.

[0016] In at least one embodiment, the milk collection container is configured and dimensioned to have variable volume when filled, so as to conform to the proximal surface of the external shell as the milk collection container is being filled with milk, while providing a convex shape externally, so as to mimic a natural shape of the breast.

[0017] In at least one embodiment, the milk collection container is pre-shaped to follow contours of the proximal surface of the external shell and to providing a convex shape externally, so as to mimic a natural shape of the breast.

[0018] In at least one embodiment, the milk collection container comprises a rigid distal surface that mates with contours of the proximal surface of the external shell, and a flexible proximal surface that moves as milk enters the milk collection container, to provide a convex shape that mimics a natural shape of the breast.

[0019] In at least one embodiment, the milk collection container comprises a flexible distal surface that changes shape to mate with contours of the proximal surface of the

external shell as milk enters the milk collection container, the milk collection container further comprising a rigid proximal surface that provides a convex shape that mimics a natural shape of the breast.

[0020] In at least one embodiment, the milk collection container comprises a rigid distal surface pre-shaped to mate with contours of the proximal surface of the external shell as milk enters the milk collection container.

[0021] In at least one embodiment, the milk collection container comprises at least one structural element configured to restrict an amount of expansion of the milk collection container or provide shape to the milk collection container even when empty.

[0022] In at least one embodiment, the at least one structural element is selected from the group consisting of baffles, heat seals, struts and restrictions.

[0023] In at least one embodiment, the milk collection container comprises a unique identifier configured to be read by a computer processor and that uniquely distinguished the milk collection container from all other milk collection containers.

[0024] In at least one embodiment, the unique identifier comprises a sensor.

[0025] In at least one embodiment, the sensor comprises a passive sensor.

[0026] In at least one embodiment, the system further includes a controller positioned within the external shell and configured to control operations of the driving mechanism.

[0027] In at least one embodiment, the milk collection container comprises a unique identifier configured to be read by at least one of the controller and an external computer processor and that uniquely distinguished the milk collection container from all other milk collection containers.

[0028] In at least one embodiment, the unique identifier comprises a sensor.

[0029] In at least one embodiment, the sensor comprises a passive sensor.

[0030] In at least one embodiment, the sensor is selected from the group consisting of: RFID device, NFC device, Wi-Fi device, BLUETOOTH device and BLUETOOTH Low Energy (BTLE) device.

[0031] In at least one embodiment, the sensor is selected from the group consisting of: RFID devices and NFC devices.

[0032] In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit.

[0033] In at least one embodiment, the conduit is integral with the milk collection container.

[0034] In at least one embodiment, the system further includes a contour element; wherein the contour element extends distally from a distal perimeter of the external shell and proximally extends over a distal portion of the external shell to provide a contoured extension of the external shell that provides a visually more appealing appearance that more closely mimics a natural appearance of the breast supported by a bra.

[0035] In at least one embodiment, the contour element tapers distally to form a smooth transition with the breast when the system is mounted on the breast.

[0036] In at least one embodiment, the contour element is removably attached to the external shell using at least one of snaps, hook-and-loop type fasteners, buttons, magnets adhesive, or friction fit.

[0037] In at least one embodiment, the contour element comprises a lateral portion that extends distally from the distal perimeter by a first length, and a medial portion that extends distally from the distal perimeter by a second length, wherein the first length is greater than the second length.

[0038] In at least one embodiment, the contour element is formed of lightweight material comprising at least one of foam, plastic or fabric.

[0039] In at least one embodiment, the contour element is formed of a single thin layer of plastic or fabric.

[0040] In at least one embodiment, the external shell comprises a key and the contour element comprises a mating key; wherein the mating key mates with the key when the contour element is mounted on the external shell and ensures that the contour element is positioned relative to the external shell consistently so that orientation of the contour element relative to the external shell upon successive mountings does not vary rotationally, superiorly, inferiorly, laterally or medially.

[0041] In at least one embodiment, the contour element is adjustable to accommodate different breast sizes.

[0042] In at least one embodiment, the contour element comprises a first edge and a second edge, wherein the first edge overlaps the second edge and can be adjusted to reduce, increase or maintain a circumference of a distal perimeter of the contour element.

[0043] In at least one embodiment, the overlap of the first edge relative to the second edge can be adjusted to reduce, increase or maintain a circumference of a proximal perimeter of the contour element.

[0044] In at least one embodiment, the contour element comprises a material that facilitates cutting a portion of a distal perimeter thereof for tailoring a fit of the contour element to the breast.

[0045] In at least one embodiment, the contour element comprises predetermined markings to assist in adjusting the contour element to various predetermined sizes.

[0046] In at least one embodiment, the external shell comprises at least one key and the contour element comprises multiple mating keys that mate with each the at least one key, respectively, to allow adjustment of a size of the contour element.

[0047] In at least one embodiment, the contour element is made of a resilient material that conforms to a shape of an object that the contour element is compressed against.

[0048] In at least one embodiment, the contour element is substantially flat-shaped in an unbiased configuration.

[0049] In at least one embodiment, the contour element is attachable to a proximal end portion of the external shell.

[0050] In at least one embodiment, the contour element, when supported by a bra, contours to the external shell and the bra.

[0051] In at least one embodiment, the system further includes a valve in the conduit adjacent the skin contact member, wherein the valve is configured to open in a first direction when vacuum is generated in the conduit, to close when positive pressure up to a predetermined positive pressure is applied to the valve, and to open in a second direction when positive pressure exceeding the predetermined positive pressure is applied to the valve.

[0052] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: an external shell including a compartment facing a distal end of the external shell, the external shell further comprising a proximal end surface facing away from the proximal end; the external shell carrying a self-contained power source and a pump mechanism; a skin contact member supported by the external shell; an outlet for expelling breast milk received from the breast interfaced with the skin contact member; and a milk collection container in fluid communication with the outlet and positioned against the distal end surface of the external shell; wherein the system is shaped and configured to be contoured to the breast of a user.

[0053] In at least one embodiment, the system is contained within a cup of a brassiere.

[0054] In at least one embodiment, the skin contact member, the external shell and the milk collection container are sized and configured to be supported between the breast and a breast cup of a bra while the system is actively pumping milk from the breast and expelling the milk through the outlet and into the milk collection container.

[0055] According to another aspect of the present disclosure, a milk collection container for use with a breast pump system includes one or more of: a preformed surface shaped to mimic the natural appearance of a breast; and a flexible surface opposing the preformed convex surface, the flexible surface being configured to expand as milk enters the milk collection container.

[0056] In at least one embodiment, the milk collection container is mounted to an external surface of an external shell of a milk pump, wherein upon milk entering the milk collection container, the flexible surface moves outwardly and conforms to a conformation of the external shell.

[0057] In at least one embodiment, the milk collection container comprises at least one structural element configured to restrict an amount of expansion of the milk collection container or provide shape to the milk collection container even when empty.

[0058] In at least one embodiment, the at least one structural element is selected from the group consisting of baffles, heat seals, struts and restrictions.

[0059] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member configured to form

a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member.

[0060] In at least one embodiment, the system further includes a milk collection container, wherein the milk collection container is in fluid communication with the conduit.

[0061] In at least one embodiment, the milk collection container is positionable over the distal end surface of the shell; and the system is shaped and configured to be contoured to the breast of a user.

[0062] In at least one embodiment, the skin contact member includes: a breast contact portion configured and dimensioned to fit over a form a seal with a portion of the breast; and a nipple receiving portion extending from the breast contact portion.

[0063] In at least one embodiment, the nipple receiving portion comprises a non-tapering portion attached to the breast contact portion, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

[0064] In at least one embodiment, the non-tapering portion is cylindrical and the tapering portion is conical.

[0065] In at least one embodiment, the non-tapering portion is ovular or elliptical in cross section.

[0066] In at least one embodiment, the tapering portion is ovular or elliptical in cross section.

[0067] In at least one embodiment, both the non-tapering and the tapering portions are ovular or elliptical in cross section.

[0068] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes are collinear.

[0069] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes are parallel.

[0070] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes intersect.

[0071] In at least one embodiment, a top part of the nipple receiving portion is configured to contact an upper surface of the nipple and a bottom part of the nipple receiving portion is configured to contact a lower surface of the nipple; wherein the top part is formed a material having a first hardness and the bottom part is formed of a material having a second hardness; and wherein the first hardness is greater than the second hardness.

[0072] In at least one embodiment, the breast contact portion comprises at least one region on an inner surface thereof, the at least one region configured to contact the breast and provide friction thereagainst that is greater than friction provided by a remainder of the inner surface of the breast contact portion.

[0073] In at least one embodiment, the system further includes a resilient flap extending radially inwardly from a portion of the breast contact member; wherein when the breast is inserted into the breast contact member, the breast folds down the flap against an inner wall of the breast contact member; and wherein when the breast is removed from the breast contact member, the flap resiliently returns to an unbiased position and extends radially inwardly, thereby retaining milk within the breast contact member that would otherwise have spilled out of the breast contact member.

[0074] In at least one embodiment, the flap comprises a tacky or roughened surface configured to increase friction against the breast when contacting the breast.

[0075] In at least one embodiment, the system further includes a sensor mounted in or on the skin contact member or the conduit; and a controller configured to control operation of the driving mechanism and to receive signals from the sensor.

[0076] In at least one embodiment, the system further includes a first sensor mounted in or on the skin contact member or the conduit, wherein a thickness of the skin contact member or conduit at a location of mounting the first sensor comprises a first

thickness; and a second sensor mounted in or on the skin contact member or the conduit, wherein a thickness of the skin contact member or conduit at a location of mounting the second sensor comprises a second thickness; wherein the second thickness is greater than the first thickness.

[0077] In at least one embodiment, the system further includes one or more of: a controller configured to control operation of the driving mechanism; and a switch in electrical communication with the controller, the switch extending into the skin contact member or the conduit at a distance from an inner wall of the skin contact member or the conduit predetermined as a distance by which the inner wall deflects when a predetermined vacuum pressure has been attained; wherein, upon attaining the predetermined vacuum pressure, the switch is activated by contact with the inner wall and sends a signal to the controller.

[0078] In at least one embodiment, the switch extends into the nipple receiving portion of the skin contact member.

[0079] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, and a controller configured to control operation of the driving mechanism; sealing the skin contact member to the breast; operating the driving mechanism to generate predetermined pressure cycles within the conduit; monitoring by the controller of at least one of position and speed of movement of the compression member relative to the conduit; measuring or calculating pressure within the conduit; maintaining or modifying motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0080] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, the method further including: manually adjusting a maximum suction pressure to modify the predetermined pressure cycles.

[0081] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, the method further including: purging milk from the conduit when the controller identifies that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit.

[0082] In at least one embodiment, the purging includes: controlling the compression member by the controller to drive the compression member to a predetermined inward motion limit of the compression member thereby driving milk out of a portion of the conduit compressed by the compression member.

[0083] In at least one embodiment, the method further includes controlling the compression member to carry out the compression mode cycles after performing the purging.

[0084] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction mode pressure cycles.

[0085] In at least one embodiment, the predetermined pressure cycles comprise latch mode cycles, wherein upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction mode pressure cycles, wherein the predetermined extraction mode cycles differ from the predetermined latch mode cycles by at least one of maximum suction level or cycle frequency.

[0086] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the method further includes: monitoring, by the controller, pressure waves within at least one of the conduit and the skin contact member; monitoring, by the controller, at least one of position and speed of the compression member relative to pressure levels monitored by the monitoring pressure waves; and changing at least one of speed, stroke length and position of the

compression member when a predetermined amount of change in the monitored pressure versus monitored position or speed of the compression member is identified, so as to maintain execution of the predetermined pressure cycles.

[0087] In at least one embodiment, the controller monitors positions of the compression member; and wherein, upon detecting that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit, the controller controls the compression member to purge milk from the conduit.

[0088] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member; a sensor; and a controller configured to control operation of the driving mechanism; wherein upon sealing the skin contact member to the breast, the controller operates the driving mechanism to generate predetermined pressure cycles within the conduit, monitors at least one of position and speed of movement of the compression member relative to the conduit, measures or calculates pressure within the conduit based upon signals received from the sensor, and maintains or modifies motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0089] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the system is configured to allow manual adjustment of a maximum suction pressure to modify the predetermined pressure cycles.

[0090] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller operates the driving mechanism to purge milk from the conduit when the controller identifies that the compression

member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit.

[0091] In at least one embodiment, the purging includes controlling the compression member by the controller to drive the compression member to a predetermined inward motion limit of the compression member thereby driving milk out of a portion of the conduit compressed by the compression member.

[0092] In at least one embodiment, the controller is further configured to control the compression member to carry out the compression mode cycles after performing the purging.

[0093] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction mode pressure cycles.

[0094] In at least one embodiment, the predetermined pressure cycles comprise latch mode cycles and, upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction mode pressure cycles, wherein the predetermined extraction mode cycles differ from the predetermined latch mode cycles by at least one of maximum suction level or cycle frequency.

[0095] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller is further configured to: monitor pressure waves within at least one of the conduit and the skin contact member; monitor at least one of position and speed of the compression member relative to pressure levels monitored by the monitoring pressure waves; and change at least one of speed, stroke length and position of the compression member when a predetermined amount of change in the monitored pressure versus monitored position or speed of the compression member is identified, so as to maintain execution of the predetermined pressure cycles.

[0096] In at least one embodiment, the controller monitors positions of the compression member and, upon detecting that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of

the compression member relative to the conduit, the controller controls the compression member to purge milk from the conduit.

[0097] According to another aspect of the present disclosure, a method of purging milk from a milk pumping system after completion of a milk extraction process includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; and a driving mechanism including a compression member configured to compress and allow decompression of the conduit for pumping milk from a breast during the milk extraction process, wherein the skin contact member is sealed to the breast during the milk extraction process; upon completion of the milk extraction process, reversing a direction the driving mechanism to operate in an opposite direction to a direction of the driving mechanism executed to perform the milk extraction process, to decrease suction within the conduit; breaking the seal of the skin contact member with the breast; and reversing the direction of the driving mechanism again, after breaking the seal, to the direction of the driving mechanism executed to perform the milk extraction process, thereby driving milk from the conduit.

[0098] In at least one embodiment, upon breaking the seal, the reversing the direction of the driving mechanism again is initiated manually by an operator.

[0099] In at least one embodiment, the system detects when the seal is broken and automatically reverses the direction of the driving mechanism upon the detection when the seal is broken.

[00100] In at least one embodiment, the method further includes ending the driving milk from the conduit by ceasing operation of the driving mechanism.

[00101] In at least one embodiment, the ending is initiated manually by an operator.

[00102] In at least one embodiment, the system initiates the ending automatically at a predetermined time after the reversing the direction of the driving mechanism again is initiated.

[00103] In at least one embodiment, the system initiates the ending automatically, by measuring a compliance of the conduit and initiating the ending when the compliance reaches a predetermined compliance value.

[00104] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction to greater than -20mmHg.

[00105] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction and establishing a slight positive pressure.

[00106] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction to about 0mmHg.

[00107] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit, comprises establishing a pressure in the conduit to a value in the range of from about -20mmHG to about -50mmHg.

[00108] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a pair of breast pumps, each breast pump comprising: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; a controller configured to control operation of the driving mechanism; and means for indicating whether the breast pump is attached to a left breast or a right breast, when both of the breast pumps are attached to the left and right breasts.

[00109] In at least one embodiment, each driving mechanism comprises a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member.

[00110] In at least one embodiment, the means for indicating is configured to receive a signal by one of the breast pumps from the other of the breast pumps to establish relative locations of the breast pumps.

[00111] In at least one embodiment, each breast pump further comprises a magnetic coil, wherein a signal sent to one of the magnetic coils by the controller associated with the magnetic coil in one of the breast pumps induces a signal in the magnetic coil of the other of the breast pumps, the signal being interpretable by the controllers to identify relative positioning of the breast pumps.

[00112] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum in the conduit; and means for indicating an amount of wear of at least one of the skin contact member and the conduit.

[00113] In at least one embodiment, the means for indicating comprises a time-based indicator.

[00114] In at least one embodiment, the time-based indicator comprises a marking that fades or appears over time.

[00115] In at least one embodiment, the time-based indicator comprises a clocking mechanism that provides at least one of a visual or audible indication at the end of a predetermined time period.

[00116] In at least one embodiment, the time-based indicator comprises an indicator provided with a plurality of LCD bars that darken upon pressing and holding a reset button and the bars lighten sequentially over predetermined time periods.

[00117] In at least one embodiment, the means for indicating an amount of wear comprises a wear indicator configured such that at least one of a color change or marking appears or fades to indicate wear.

[00118] In at least one embodiment, the system further includes a computer processor, wherein the means for indicating an amount of wear comprises the computer processor configured to track cumulative time of use of at least one of the skin contact member and the conduit.

[00119] In at least one embodiment, the means for indicating amount of wear comprises a processor; wherein the processor is configured to: track a position of the driving mechanism relative to the conduit; correlate pressure changes in the conduit relative to the position of the driving mechanism when the conduit is first used; continue to correlate the pressure changes relative to the position during continued uses of the conduit; compare correlation values from the continued correlations with correlation values from the correlations when the conduit is first used; and indicate an amount of wear of the conduit based on the comparison of correlation values.

[00120] In at least one embodiment, the processor is included in the breast pump system.

[00121] In at least one embodiment, the processor is in an external computer, external to the breast pump system.

[00122] In at least one embodiment, the time-based indicator comprises a processor configured to track usage time of at least one of the skin contact member and the conduit.

[00123] In at least one embodiment, at least one of the skin contact member and the conduit is provided with a passive sensor, and the processor is configured to track the passive sensor during use of the system.

[00124] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, a controller configured to control operation of the driving mechanism and to receive signals from the sensor, and a milk collection container in fluid communication with the conduit; sealing the skin contact member to the breast; operating the driving mechanism to extract milk from the breast and pumping the milk into the milk collection container; and calculating a volume of milk pumped into the milk collection container, based on dimensions of the conduit and positions of the compression member.

[00125] In at least one embodiment, the calculating a volume of milk pumped comprises: calculating a total volume pumped based on the dimensions of the conduit and the positions of the compression member; calculating the volume of milk pumped as a percentage of the total volume, based on a compliance assessment of the conduit performed by comparing pressure changes of the conduit to positions of the compression member.

[00126] In at least one embodiment, the system further includes a one-way valve interconnecting the conduit and the milk collection container, and the method further

includes: monitoring the one-way valve to determine when milk begins to flow into the milk collection container and stops flowing into the milk collection container; wherein the calculating a volume of milk pumped into the milk collection container, is based on dimensions of the conduit and positions of the compression member over a time period during which milk is flowing into the milk collection container.

[00127] According to another aspect of the present disclosure, a nipple shield includes one or more of: a central region configured to cover a nipple of a breast and having a first thickness; an attachment portion surrounding the central region, the attachment region being configured to attach to the breast and having a second thickness; wherein the second thickness is greater than the first thickness; and wherein the central region comprises one or more openings to allow milk to pass therethrough.

[00128] In at least one embodiment, the first thickness is a thickness in the range of about 0.2mm to about 1mm and the second thickness is a thickness in the range of about 2mm to about 5mm.

[00129] In at least one embodiment, the first thickness is about 0.25mm.

[00130] 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

[00131] Fig. 1 shows a side view of a breast pump system (without milk collection container) according to an embodiment of the present disclosure.

[00132] Fig. 2 shows a distal, perspective view of the system of Fig. 1, with the outer shell having been removed/made transparent to show components otherwise covered by the outer shell.

[00133] Fig. 3 shows a view as in Fig. 2, but with the skin contact member removed to illustrate more details of the pumping region.

[00134] Fig. 4 illustrates components of a system according to an embodiment of the present disclosure.

[00135] Fig. 5 is a partial view of the system of Figs. 2-3 showing a compression member and driver in more detail.

[00136] Fig. 6 is a partial view of the system of Figs. 2-3 showing another compression member and driver in more detail.

[00137] Figs. 7A-7C schematically illustrate one exemplary operation mode of the compression members according to an embodiment of the present disclosure.

[00138] Fig. 8 illustrates a side view of a skin contact member according to an embodiment of the present disclosure.

[00139] Fig. 9 illustrates a side view of a prior art breast flange.

[00140] Fig. 10A is a sectional view of structure shown in Fig. 8.

[00141] Fig. 10B is a sectional view of an alternative embodiment of a nipple receiving portion according to an embodiment of the present disclosure.

[00142] Fig. 11A is a longitudinal sectional view of structure shown in Fig. 11B.

[00143] Fig. 11B is a distal end view of a skin contact member according to another embodiment of the present disclosure.

[00144] Fig. 12A is a side, cross-sectional view of a skin contact member according to an embodiment of the present disclosure.

[00145] Fig. 12B is a transverse, cross-sectional view of the skin contact member of Fig. 12A taken from the bottom of the system, showing the skin contact member and tube with the outer shell.

[00146] Fig. 12C is a proximal end view of the skin contact member of Fig. 12A showing a tube connected thereto.

[00147] Fig. 13 is a schematic representation showing components defining the total system volume according to an embodiment of the present disclosure.

[00148] Fig. 14 shows a compression member compressing a tubing portion, according to an embodiment of the present disclosure.

[00149] Fig. 15 is a chart illustrating relationships between tubing volume, tubing deflection and load on the compression member, according to an embodiment of the present disclosure.

[00150] Fig. 16 illustrates compression of a tubing portion by a compression member, according to an embodiment of the present disclosure.

[00151] Fig. 17 shows the power consumption data for a system according to an embodiment of the present disclosure.

[00152] Fig. 18 is an end view of an external shell of a system according to an embodiment of the present disclosure.

[00153] Fig. 19 shows characteristics of systems using various tubing dimensions, according to various embodiments of the present disclosure.

[00154] Fig. 20 is a schematic representation of working components of a system according to an embodiment of the present disclosure.

[00155] Figs. 21A-21B show a proximal perspective view and a side view, respectively, of a skin contact member according to an embodiment of the present disclosure.

[00156] Fig. 21C is a cross-sectional view of Fig. 21C taken along line 21C-21C in Fig. 21A.

[00157] Fig. 21D shows a strain gauge mounted on or in a skin contact member according to an embodiment of the present disclosure.

[00158] Fig. 21E shows a cross-sectional illustration of a nipple receiving portion in which a first non-contact sensor has been attached to a relatively thinner wall of the nipple receiving portion and a second non-contact sensor has been attached to a relatively thicker wall of the nipple receiving portion.

[00159] Fig. 22 shows an indicator mounted on the inside of a breast contact member so that it can be readily viewed by a user prior to mounting the system to the breast, according to an embodiment of the present disclosure.

[00160] Fig. 23 illustrates another location in which an indicator may be placed, according to an embodiment of the present disclosure.

[00161] Fig. 24 illustrates an example of a reusable, time-based indicator that may be employed, according to an embodiment of the present disclosure.

[00162] Fig. 25 illustrates tracking of a skin contact member and/or tubing by a controller of the system and/or an external computer, according to an embodiment of the present disclosure.

[00163] Fig. 26 shows a wear indictor located on a tubing portion, according to an embodiment of the present disclosure.

[00164] Fig. 27 illustrates a wear indicator on a skin contact member, according to an embodiment of the present disclosure.

[00165] Fig. 28 illustrates an example of an arrangement for tracking a compression

member position, according to an embodiment of the present disclosure.

[00166] Figs. 29A-29B illustrate one or more tacky regions provided to facilitate restriction of the breast, according to an embodiment of the present disclosure.

[00167] Figs. 30A-30B illustrate differences between a skin contact member having a relatively larger internal angle and skin contact member having a relatively smaller internal angle, respectively.

[00168] Fig. 30C illustrates a portion of the areola at the juncture with the nipple that needs ample room to expand for optimal extraction of milk.

[00169] Figs. 31A-31B schematically illustrate breast pump systems according to alternative embodiments of the present disclosure.

[00170] Figs. 32A-32B illustrate a milk collection container for use in a system according to another embodiment of the present disclosure.

[00171] Fig. 32C illustrates a milk collection container that is formed so that the distal surface of the container, when filled with milk has a shape that matches the proximal surface contour of the external shell of the system, according to an embodiment of the present disclosure.

[00172] Fig. 33 shows a milk container having baffles that internally connect to the internal walls of portions of the container, according to an embodiment of the present disclosure.

[00173] Fig. 34 illustrates a milk collection container that includes a passive sensor, according to an embodiment of the present disclosure.

[00174] Fig. 35 illustrates a milk collection container wherein the connector contains a one-way valve, according to an embodiment of the present disclosure.

[00175] Fig. 36 illustrates a milk collection container according to another embodiment of the present disclosure.

[00176] Fig. 37 illustrates a milk container provided with an easily identifiable marking, according to an embodiment of the present disclosure.

[00177] Fig. 38 illustrates events that may be carried out to perform a purge according to an embodiment of the present disclosure.

[00178] Figs. 39A-39B illustrate various arrangements that may be provided to the system to help prevent loss of milk out of the system upon detachment of the system

from the breast, according to embodiments of the present disclosure.

[00179] Figs. 40A-40B illustrate two different cross-sectional views of a contour element provided with a breast pump system according to an embodiment of the present disclosure.

[00180] Figs. 41A-41B illustrate a single thin layer of plastic or fabric used as a contour element, according to an embodiment of the present disclosure.

[00181] Fig. 42 illustrates a contour element fitted on an external shell in which the external shell is provided with a key that ensures that the contour element is properly oriented on the external shell each time the two components are mated, according to an embodiment of the present disclosure.

[00182] Fig. 43 illustrates a contour element in which a first edge of the contour element overlaps a second edge, and can be adjusted to reduce, increase or maintain the circumference of the distal perimeter, while at the same time reducing, increasing or maintaining the proximal perimeter, according to an embodiment of the present disclosure.

[00183] Fig. 44 illustrates a contour element provided with predetermined markings that may be provided to assist the user in adjusting the contour element to better contour to the breast that it is to be used on, according to an embodiment of the present disclosure.

[00184] Fig. 45A illustrates an external shell provided with two keys, according to an embodiment of the present disclosure.

[00185] Fig. 45B illustrates a contour element provided with mating keys that are configured to mate with the keys of the external shell of Fig. 45A.

[00186] Figs. 46A-46B illustrate a contour element according to another embodiment of the present disclosure.

[00187] Fig. 47 illustrates events that may be carried out by a system during an extraction mode of pumping milk from a breast, according to an embodiment of the present disclosure.

[00188] Fig. 48 illustrates a nipple shield according to an embodiment of the present disclosure.

[00189] Fig. 49 schematically illustrates apparatus used to perform testing on a light body vinylpolysiloxane breast flange.

[00190] Fig. 50 illustrates results from the testing apparatus used in the testing described with regard to Fig. 49.

[00191] Fig. 51 schematically illustrates modified apparatus used to test the dynamic force-pressure relationship of a system, according to an embodiment of the present disclosure.

[00192] Figs. 52-53 illustrate results from the testing apparatus used in the testing described with regard to Fig. 51.

[00193] Fig. 54 schematically illustrates apparatus used to test the relationship between the position of a target location of a nipple receiving portion and vacuum level within the nipple receiving portion, according to an embodiment of the present disclosure.

[00194] Fig. 55 schematically illustrates apparatus used to test the relationship between the position of a target location of a nipple receiving portion and vacuum level within the nipple receiving portion, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE DISCLOSURE

[00195] 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.

[00196] 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.

[00197] 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.

[00198] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a sensor" includes a plurality of such sensors and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[00199] 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.

Definitions

[00200] The term "dead space" as used herein refers to volume within the system that is not directly acted upon by the pump of the system. Dead space is calculated by the total volume minus the active pump volume. The total volume is the volume in the skin contact member 10 and tubing 32, from the nipple receiving portion 112 to the one-way valve 50, when the system 100 has been attached and sealed to a breast 2, such that the total volume is the space in the nipple receiving portion 112 not occupied by the nipple 3/areola 4, and the remaining volume from there to the one-way valve 50. The active pumping volume is the volume displaced by the compression member (e.g., compression member 38)when the compression member is moved from one limit of a full stroke to the other limit. The nipple will also move with a changing pressure; the total system volume change is the combination of these two (plus any minor system compliance).The dead space is the non-pumping volume of the system.

[00201] "Let down mode", as used herein, refers to a mode where the vacuum profile is characterized by higher frequency and shallower (smaller) magnitude changes in

vacuum level. Let down mode may also be referred to as "non-nutritive suction mode" or "non-nutritive mode".

[00202] "Extraction mode", as used herein, refers to a mode where the vacuum profile is characterized by lower frequency and deeper magnitude changes in vacuum, relative to "let down mode" (non-nutritive mode). Extraction mode may also be referred to as "nutritive suction mode" or "nutritive mode".

[00203] "Purging" refers to an act of transferring milk from the active pumping region of the pump tube into the collection chamber or bag.

[00204] "Latch suction" or "latch vacuum" refers to a minimum vacuum level established when the pump is attached to the breast. This is set at the lowest level of vacuum, a pressure which is below atmospheric pressure, which is effective to attach the system to the breast.

Detailed Description

[00205] Fig. 1 is a side view of a breast pump system 100 (without milk collection container) according to an embodiment of the present disclosure. The outer shell 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. 2 is a distal, perspective view of the system 100 of Fig. 1, with the outer shell 34 having been removed/made transparent to show components otherwise covered by the outer shell 34. System 100 includes a skin contact member 10 (such as the breast flange shown in Fig. 2, 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. 3 shows a view as in Fig. 2, but with the skin contact member 10 removed to illustrate more details of the pumping region 30.

[00206] Fig. 4 illustrates components of a system 100 according to an embodiment of the present disclosure. Conduit 32 includes a large conduit portion 32L that is relatively larger in cross-sectional inside area than the cross-sectional inside area of small conduit portion 32S. Although both portions 32S and 32L are shown as tubular portions being circular in cross-section, the present disclosure is not limited to such, as one or both portions could be shaped otherwise. For example, the conduit region 32L in the embodiment of Fig. 3 is not cylindrical, but is formed as a pump chamber having a substantially oval face 32F and walls that extend substantially perpendicular thereto. Further details of this embodiment of conduit region 32L can be found in US Provisional Application Nos. 62/052,476 filed 09/19/2014 and 62/053,095 filed 09/10/2014, both of which are hereby incorporated herein, in their entireties, by reference thereto. The conduit region 32S2, which joins one way valve 50 and large conduit region 32L in fluid communication, may be, but is not necessarily of the same dimensions as small conduit region 32S. Like regions 32S and 32L, region 32S2 may be cylindrical and circular in cross section, but need not be. When tubular, the cross-sections may be oval square, other polyhedral shape, non-symmetrical, or non-geometric shape.

[00207] In the embodiment of Figs. 2-3, latching, pumping and extraction forces are established by two compression members 36, 38 which are actively driven by drivers 44 and 46 respectively. Although more than two compression members could be used and one or more than two drivers could be used, the currently preferred embodiment uses two compression members respectively driven by two drivers as shown. Fig. 5 is a partial view of the system 100 of Figs. 2-3 showing compression member 36 and driver 44 in more detail. Fig. 6 is a partial view of the system 100 of Figs. 2-3 showing compression member 38 and driver 46 in more detail.

[00208] Figs. 7A-7C schematically illustrate one exemplary operation mode of the compression members 36, 38 according to an embodiment of the present disclosure. In Fig. 7A, tubing portions 32S and 32L are closed off, or substantially closed off by compression members 36 and 38, respectively. Upon powering up the system 100 the

compression member 36 opens as illustrated in Fig. 7B and the compression member 38 begins to withdraw away from anvil surface 2232 which gradually increases the suction level within tubing 32. When a predetermined maximum suction level is achieved (as confirmed by pressure readings taken from a pressure sensor, described below), the compression member 38 ceases its travel in the current direction, and either maintains that position for a predetermined period of time (or moves slightly in the same direction to compensate for decreasing suction as milk enters the system) when the operating mode of the system 100 has a predetermined time to maintain maximum suction, or reverses direction and compresses the tube 32L until the latch suction level is achieved. If the maximum suction level has not yet been achieved by the time that the compression member is fully retracted away from the anvil surface 2232 on the first stroke, then the compression member 36 again compresses the tube 32S to seal off the current vacuum level in the environment of the breast, and the compression member 38 fully compresses the tube portion 32L to squeeze more air out of the system (out through one-way valve 50). Then the compression member 36 reopens to fully open tube portion 32S and compression member carries out another stroke, again moving away from the anvil surface 2232 to generate a greater suction level. This cycling continues until the maximum suction level is achieved. It is noted that it is possible in some cases to achieve the maximum suction level on the first stroke, whereas in other cases, multiple strokes may be required.

[00209] Fig. 7B shows the tubing portion 32S fully open as the compression member 36 is released and compression member 38 is moving away from anvil surface 2232 to increase suction within the tubing 32. Upon achieving the maximum suction, the system may be designed and programmed so that the compression member 38 does not travel to its fullest possible extent in either direction to achieve the maximum and latch suction levels, so as to allow some reserve suction and pressure producing capability. When the maximum suction level has been achieved, and the pumping profile is programmed to return to latch pressure, the compression member 38 advances toward the anvil surface 2232, compressing tubing portion 32L, thereby raising the pressure in the tubing 32. Upon achievement of the latch suction pressure, compression member 36 closes off the tubing 32S again to ensure that the latch pressure is maintained

against the breast, so that sufficient suction is maintained. At this stage, the compression member 38 again begins moving away from the anvil surface 2232 to increase the suction level back to maximum suction, and compression member 36 opens (moves away from anvil surface 2230) to allow tube 32S to open and the breast 2 to be exposed to the maximum suction. Alternatively, the system may be programmed so that the compression member 38 cycles between maximum and latch suction levels without the compression member 36 closing during a point in each cycle, with the compression member 36 closing when the latch pressure is exceeded.

[00210] Upon selection of a milk extraction mode, the compression member 36 and compression member 38 function in the same manners as in the latch mode, but in a manner that follows an extraction waveform determined by the selected extraction mode. During the compression stroke of compression member 38, compression member 36 closes when the latch pressure/suction level is achieved. Continued compression by the compression member 38 (Fig. 7C) increases the pressure in the tubing 32 downstream of the compression member 36 to establish a positive pressure to drive the contents (milk) of tube portion 32L out of the tube portion 32L through smaller tubing portion 32S2 downstream of 32L and out through one-way valve 50. The positive pressure attained is sufficient to open the one-way valve for delivery of the milk out of the tubing 32 and into a milk collection container. In one embodiment, the positive pressure is in the range of 20mm Hg to 40mm Hg, typically about 25mm Hg. Upon reversing the motion of compression member 38, compression member 36 opens when the suction level returns to the latch suction level and compression member 38 continues to open to increase the suction level to the maximum suction level.

[00211] Prior art breast pump systems typically cycle between 0 mmHg (or close to 0) and peak vacuum, which is typically up to 250mmHg vacuum. The flanges of the prior art systems (i.e., the component that contacts and seals to the breast) typically have a shaped, distal portion and a large cylinder section to accommodate the nipple of the breast as it is drawn forward into the cylinder by the application of vacuum. During pumping with these prior art pump systems, the nipple cycles back and forth significantly matching the cycling of vacuum from 0 to peak set vacuum. This motion

is typically at least 1cm of motion (nipple extends and contracts by at least 1 cm) and can be significantly greater. Studies have shown that the nipple motion resulting from a nursing baby is not very large, e.g., on the order of about 4-5mm of motion total (Elad paper, other Hartman group papers).

[00212] The present disclosure establishes a latch vacuum to cause the skin contact member/breast flange 10 to seal to the breast. The latch vacuum established by the system is currently about 60mmHg, but can be any value in a range of from about 20 mmHg to about 80 mmHg. Once the system 100 has been latched to the breast via skin contact member 10, the system then cycles between the latch vacuum and a target (also referred to as "peak" or "maximum") suction level. Due to the fact that the system 100 does not cycle down to 0 mmHg, but maintains suction applied to the breast, with the minimum end of the suction cycle being the latch suction level (e.g., about 60mm Hg), the nipple does not contract as much as it would with use of a prior art breast pump system. It has been observed that the nipple draws into the skin attachment member 10 with the initial latch achievement in an analogous fashion as the formation of a teat during breastfeeding. Once the vacuum cycles between the latch and target vacuum levels, there is significantly less motion of the nipple back and forth with the vacuum changes, as compared to what occurs with use of prior art systems.. The nipple motion (distance between fully extended and fully retracted) during use of the present system is typically less than about 2mm, and in some cases less than about 1mm.

[00213] This greatly reduced motion of the nipple during cycling results from establishment of the latch at latch vacuum level, and then limiting the range of vacuum swing between latch vacuum (suction) and peak vacuum (suction). Typically the difference in vacuum between latch vacuum and peak vacuum is less than 200 mmHg, more typically less than 150 mmHg. In one example, the latch vacuum was 50 mmHg and the peak vacuum was 200 mmHg, resulting in a vacuum difference of 150 mmHg.

[00214] Limiting the nipple motion as described with use of the present system offers several benefits to the user. One benefit is that there is less friction on the side of the nipple against the flange wall, thereby greatly reducing the risk of irritation, skin damage, pain, swelling, etc. As a result, the present system is significantly more comfortable to use by a nursing mother, and this benefit is increasingly noticeable over

repeated uses. By maintaining at least a latch suction level at all times, the present system provides a more secure and persistent seal to the breast and significantly reduces the potential for leaks of air and/or milk. Because the nipple moves significantly less, this provides a more "natural" feel to the user that more closely simulates the feel of a nursing baby. Because the nipple travels less, this allows for the skin attachment member/flange 10 to be designed as a lower profile component, as its length can be shorter since it does not need to accommodate the greater length in nipple movement experienced by prior art systems. This allows the overall amount of protrusion of the system 100 from the breast to less than that in the prior art, as the overall length of the system is reduced by the reduction in length of the skin contact member/flange 10. Thus, the distance from the tip of nipple to exposed end of the housing the system is reduced.

[00215] Fig. 8 illustrates a side view of a skin contact member 10 according to an embodiment of the present disclosure. As shown, the breast contact portion 122 is symmetrical about the nipple receiving portion 112, although, alternatively, the nipple receiving portion 112 could be offset in a manner as described herein. The overall length 110 of the skin contact member 10 in this embodiment is about 63.75mm. Fig. 9 illustrates a longitudinal sectional view of a prior art breast flange 210. The overall length 212 of flange 210 is about 60.6mm. The skin contact member 10 is designed to reduce the internal volume of the nipple receiving portion 112 relative to the internal volume of the nipple receiving portion 214 of the prior art device, which is enabled by the significantly reduced amount of motion experienced by the nipple 3 during a milk extraction process using a system 100 including skin contact member 10, according to the present disclosure. The nipple receiving portion 112 of the skin contact member 10 is contoured to more closely match the natural shape of the nipple, thereby eliminating or significantly reducing dead space that exists around the nipple in prior art systems. In the example shown, the nipple receiving portion 112 is cylindrical in the portion 112A adjoining the breast contact portion 122, and then tapers conically in the portion 112B that extends from portion 112A to the connector 134. This design allows for receiving a portion of the areola 4 into the nipple receiving portion 112A while also limiting dead space by providing the conical portion 112B. The diameters of all cross-

sections of the nipple receiving portion 112 are large enough to allow nipple dilation. The inside diameter of the conically tapering portion 112B tapers from an inside diameter equal to the inside diameter of the cylindrical portion, down to a smaller inside diameter. As noted, the length of the nipple receiving portion 112 is significantly less than that of the prior art. In the example shown in Fig. 8, the length 114 of the nipple receiving portion 112 is about 23mm , as compared to the length 216 of 36.9mm (may be in the range of about 350mm to about 500mm) of the prior art nipple receiving portion 214.. Length 112 may vary within a range of about 22mm to about 29mm. The length 114 of the nipple receiving portion 112 is sufficient to allow engorgement of the nipple 3 under vacuum, without the distal tip of the nipple 3 contacting the proximal end of the nipple receiving portion 112.

[00216] Experimentation with the present system 100 has shown that the majority of women's nipples extend into the nipple receiving portion 112 with a length of about 1.6cm under latch suction of about 50mmHg (-50mmHg pressure). The extra length provided by the nipple receiving portion 112 (beyond the length of the nipple under latch vacuum is provided to allow for a small amount of extension of the nipple under target vacuum, typically about 1-2mm under maximum suction of about 150mmHg, and to allow for a small amount of additional forward motion the nipple may experience as the pump primes. Accordingly, there is provided at least about 2mm, up to about 6mm of space in the nipple receiving portion that extends lengthwise proximally of the tip of the nipple 3 when it is under latch pressure.

[00217] The diameter 116 of the nipple entrance to the nipple receiving portion 112 is large enough to accommodate the majority of nipple sizes so that the nipple is not constricted from some engorgement while under vacuum. The nipple 3 expands in diameter by a large amount at the base (the region that joins the areola 4) than it does at the tip, which allows the nipple receiving portion 112B to be made conical-shaped, as shown. The diameter 116 of the entrance opening of the nipple receiving portion 112, in the embodiment of Fig. 8 is about 24mm, but may be in a range of about 22mm to about 29mm. The inside diameter 118 at the proximal end of the nipple receiving portion 112B is about 13.16mm in Fig. 8, but can be in the range of about 9mm to about 20mm. In contrast, the inside diameter 218 of portion 214 of flange 210 is about

23.5mm over the entire length of the portion 214.

[00218] A portion of the areola 4 may also be drawn into the nipple receiving portion 112, so that it is alternately compressed and at least partially relieved of compression by the pumping system 100 to simulate the way a baby naturally feeds. However, the skin contact member 10 is configured to restrict the areola 4 from completely entering the nipple receiving portion 112 and to restrict portions of the breast 2 other than the nipple 3 and areola 4 from entering the nipple receiving portion 112. This prevents the tip of the nipple 3 from contacting the proximal end of the nipple receiving portion 112, even under maximum vacuum.

[00219] In any of the embodiments of skin contact member 10 disclosed herein, the top part of the nipple receiving portion 112 may be formed of a relatively harder and/or stiffer material and the bottom part of the nipple receiving portion 112 may be formed of a relatively softer and/or more flexible material to better simulate a nursing baby during use, as the baby's tongue, which contacts the bottom of the nipple 3 is softer and more flexible than the baby's palate, which contacts the top of the nipple 3 during nursing.

[00220] To facilitate restriction of the breast 2, the breast contact portion 122 may be provided with one or more tacky regions 360, see Figs. 29A-29B. Although shown as continuous ring about the interior surface of breast contact portion 122 in Figs. 29A-29B, tacky region 360 may span one or more portions of this circumference and can be provided as one or a plurality of segments. The tacky region(s) provide more friction with the breast 2 than does the remainder of the skin contact member 10, thereby providing resistance to the portions of the breast 2 that contact it, preventing it from being drawn in toward nipple receiving portion 112. The tacky region 160 may be formed by a different material than the remainder of the skin contact member 10, and/or may be a coating or roughened area to provide the increase in friction. For example, the tacky region may be silicone, with the remainder of the skin contact member being formed of polyethylene, or one of the other materials described herein for using in making the skin contact member. By preventing these portions of the breast from sliding into the nipple receiving portion 112, this reduces incidences of pain from compression of too much breast tissue, and provides sufficient space in the

nipple receiving portion 112 for the nipple 3 to naturally engorge for milk volume expression.

[00221] The internal angle 120 of the breast contact portion 122 of the skin contact member 10 is designed for use with the present system 100 and to maximize comfort of the user. The internal angle may also facilitate the ability to restrict portions of the breast 2 from moving forward too much into the nipple receiving portion 112. In the embodiment of Fig. 8, the internal angle 120 is about 112°, which is wider than the internal angle of prior art flanges. For example, the angle 218 of the breast contact portion 220 of the prior art flange 210 is ninety degrees. The wider angle 120 helps to prevent the breast tissue from being funneled into the nipple receiving portion 112, so that less breast tissue is received in the nipple receiving portion 112, making use of the present skin contact member 10 more comfortable than flanges of the prior art and providing space for nipple engorgement. By providing the wider angle 120, this also allows the overall system to be effectively shortened and allows the system to lie flatter against the breast to improve both comfort and appearance. In the embodiment of Fig. 8, the length 124 of the breast contact portion 122 is 15mm, but may be in the range of from about 12mm to about 19mm. In contrast, the length 222 of breast contact portion 220 is 25.8mm, which causes a system using flange 210 to extend further out from the breast than would a system using the skin contact member 10.

[00222] Figs. 30A-30B illustrate differences between skin contact members 122A having a relatively larger internal angle 122A and skin contact member 122B having a relatively smaller internal angle 122B. The smaller angle 122B provides the ability to interact with relatively more breast tissue on more variations in breast sizes and shapes. The breast contact portion of 122A of the skin contact member shown in Fig. 30A has an internal angle 120A that is larger than the internal angle 120B of breast contact member 122B shown in Fig. 30B. As a result, when these skin contact members 10 are mounted to the breast 2, the initial contact of the breast tissue to the breast contact member 122A at 362A is lower on (or further into) the breast contact portion 122A than where the breast tissue initially contacts breast contact member 122B at 362B. The higher (or further out) initial contact location 362B of the breast 2 on the breast contact portion 122B provides more contact surface (compare length 364B to 364A) of

the breast 2 on the breast contact portion 122, which better controls the tissue movement in the nipple receiving portion 112 and creates more tension on the teat as it forms, due to the increase surface contact area available. The teat starts to form sooner and the increased tension on the breast aids in holding back breast tissue 2 and the distal portion of the areola 4 from being sucked into the nipple receiving portion 112. A larger length 366B and area for the areola 4 and nipple 3 to form a teat are provided by the smaller angle 120B, relative to the length 366A and area of the embodiment in Fig. 30A, as length 366B is greater than length 366A by an amount sufficient to make the internal volume of the skin contact member over the length 366B greater than the internal volume of the skin contact member over the length 366A. With the larger angle 122A of the embodiment in Fig. 30A, the areola contacts the sides of the breast contact portion 122A upon initial contact of the breast 2 with portion 122A, so that there is no room for the areola 4 to expand. For optimal results, there needs to be a lengthening and widening of the areola 4 during milk extraction, as this is what occurs when a baby suckles. The space provided between the areola 4 and the opening to the nipple receiving portion 112 upon initial contact of the breast 2 to breast contact portion 122, allows the areola 4 to lengthen and expand (widen) as the nipple 3 is drawn into the nipple receiving portion 112. Fig. 30C illustrates the portion 4P of the areola 4 at the juncture with nipple 3 that needs ample room to expand for optimal extraction of milk, as this portion includes milk ducts that will not expel milk as efficiently, or at all, if they are not allowed to expand. The skin contact members 10 of the present disclosure are preferably configured to allow up to about 0.25 inches (about 0.5cm) length of the areola 4 to be drawn into the nipple receiving portion 112, and to prevent additional portions of the areola from entering the nipple receiving portion 112.

[00223] The thickness of the material forming the breast contact portion 122 and nipple receiving portion 112 in the embodiment of Fig. 8B is about 1.5mm, but the thickness may be in the range of from about 1mm to about 4mm. Alternatively, the thicknesses of the breast contact portion 122 and the nipple receiving portion 112 may be different from one another. The breast contact portion 122 and nipple receiving portion 112, as well as the tubing connector 134 can be 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 The inner housing 126 of the breast contact portion 122 can be rigid, semi-rigid or compliant. Likewise, the nipple receiving portion 112 can be rigid, semi-rigid or compliant. Part of the breast contact portion 122 that adjoins and serves as an entrance to the nipple receiving portion 112, is configured to be in contact with at least the perimeter portions of the areola 4 and can be made of a less lubricious material (relative to the lubricity of the nipple receiving portion 112) to provide more frictional resistance on at least the perimeter of the areola to help prevent it from being drawn into the nipple receiving portion 112, and to provide tension on the breast tissue away from the nipple 3 and areola 4, to control the amount of areola 4 that is allowed into the nipple receiving portion 112. Since the present system 100 significantly reduces movement of the nipple 3 during pumping, the surface that provides more friction and tension reduces the risks of chafing or blistering of tissue that would be experienced in a currently available nipple flange, as they experience considerably more nipple 3 movement during pumping. The nipple receiving portion 112 and inner housing 126 can be made of different materials and/or hardnesses and/or rigidity. For example, the inner housing 126 can be rigid and the nipple receiving portion 112 can be compliant, or any other combination of materials, hardnesses and rigidities could be provided. Preferably the breast contact portion 122 and nipple receiving portion 112 are compliant and made from silicone, although other materials and combinations of materials could be used, including, but not limited to or polyethylene terephthalate (PET), polyurethanes, polyethylene, high density polyethylene (HDPE), low density polyethylene (LDPE), polyamides, polyethylene terephthalate (PET) and/or PEBAX. For the embodiments where there is compliance, the nipple receiving portion 112 may be 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.

[00224] In the embodiment of Fig. 8, the nipple receiving portion 112 includes portion 112A which is cylindrical and portion 112B, which is cone-shaped, with the internal

angle 130 of cone-shaped portion 112B being about 60 degrees. The internal angle of the cone may be in the range of from about 55 degrees to about 65 degrees.

[00225] Both the cylindrical portion 112A and the cone-shaped portion 112B are circular in cross-section, as exemplified by the cross-section illustration of Fig. 10A, which is taken along line 10A-10A in Fig. 8. Alternatively, one or both of portions 112A, 112B may be ovular or elliptical in cross-section, as illustrated by 112A', 112B' in Fig. 10B. This ovular or elliptical cross-section more closely resembles the shape of a suckling baby's mouth and will therefore provide a pressure/force contour to the nipple that is more similar to the suckling of the baby.

[00226] Further alternatively, the skin contact member 10 may have an adjustable opening 132 to the nipple receiving portion 112 and also the flange angle 120 may be adjustable, so that both the breast contact portion 122 and opening can be sized to optimize the fit against the areola and reception of the nipple. In at least one embodiment, inserts are provided on the inside of the breast contact portion 122. Additionally or alternatively, inserts can be provided on the back of the breast contact portion 122 In any of these arrangements, inserts change the angle of breast contact portion 122 relative to the breast 2 as it is mounted on the breast. Still further, an insert can be provided to make the opening smaller. Different combinations of flange angle 120 and opening 132 diameter may be required for different sizes and shapes of breasts. For example, a relatively smaller opening 132 and relatively smaller angle 120 may be required for a breast that is relatively more elastic than average, while a relatively larger angle 120 and relatively larger opening 132 may be better for a breast that is more taut than average. Further alternatively, a series of skin contact members 10 may be provided to provide a range in angle 120 and opening 132 variations. The wall thickness 128 may also be varied to accommodate changes in the angle 120 of the breast contact portion 122.

[00227] Portion 134 is the tubing connector that is used to connect the skin contact member 10 in fluid communication with the tubing 32. The diameter 136 of the opening 138 that provides the fluid communication with the tube 32 is about 25mm in Fig. 8, but may be in the range of from about 20mm to about 28mm. The length 142 of portion 134 is about 23.8mm in Fig. 8, but may be in the range of from about 20mm to

about 28mm.

[00228] Fig. 11A is a longitudinal sectional view taken along line 11A-11A in Fig. 11B and Fig. 11B is a distal end view of a skin contact member 10 according to another embodiment of the present disclosure. In this embodiment, the nipple receiving portion 112 is not centered with respect to the breast contact portion 122, in contrast to the embodiment of Fig. 8 where the breast contact portion 122 is concentric with nipple receiving portion 112. Instead, in this embodiment, the central axis 146 of the nipple receiving portion 112 is positioned below the central axis 148 of the breast contact portion 122, when the skin contact portion is placed in the orientation in which it is used for attachment to the breast, see Fig. 11B. In this embodiment, the opening 132 to the nipple receiving portion 112 is slightly larger in diameter than that of the embodiment of Fig. 8, (25mm vs. 23mm) to accommodate users with slightly larger nipples. The opening diameter 219 of the prior art flange 210 shown in Fig. 9 can be in the range of about 21mm to about 32mm. Of course, the offset embodiments of the present disclosure could also use the smaller opening 132 size. Likewise, the embodiment of Fig. 8 could be provided with the larger opening 132 size. In this offset embodiment, the angle 120A of the breast contact portion 122 that is above the nipple receiving portion 112, relative to the central axis 150 of the breast contact portion 122 (and the central axis 164 of the nipple receiving portion 112 when the central axes 150 and 164 are parallel, as in the embodiment of Fig. 11A) is flatter than the angle 120B of the breast contact portion 122 that is below the nipple receiving portion 112, relative to the central axes 150 and 164, see Fig. 11A. In other embodiments, central axis 150 is not parallel with central axis 164. In the example shown in Fig. 11A, angle 120A is about 69 degrees and angle 120B is about 52 degrees. However, angle 120A may be any angle in the range of from about 32 degrees to about 85 degrees and angle 120B may be any angle in the range of from about 32 degrees to about 85 degrees. This configuration provides a better fit to the natural curvature of the breast to which the breast contact portion 122 is contacted, relative to a design where both angles 120A and 120B are equal. To maintain the plane of the perimeter around the distal opening 152 of the breast contact portion 122 substantially normal to the central axis 150 as shown in Fig. 11A, the distance 154 from the top of the opening 132 to the top of the

perimeter of distal opening 152 is greater than the distance 156 from the bottom of the opening 132 to the bottom of the perimeter of distal opening 152, due to the difference in angles 120A and 120B. In the example shown in Fig. 11A, distance 154 is about 36.32mm, but may be any value in the range of from about 15mm to about 62mm; and distance 156 is about 21.3mm, but may be any value in the range of from about 10mm to about 58mm. The outside diameter 158 of the breast contact portion 122 at the distal opening (see Fig. 11B) is about 82.3mm, but may be any value in the range of from about 60mm to about 150mm. The distance 160 from the top of the perimeter of the distal opening 152 to the central axis 164 of the nipple receiving portion is about 49.8mm in the embodiment of Fig. 11A, but may be any value in the range of from about 30mm to about 60mm. The distance 162 from the bottom of the perimeter of the distal opening 152 to the central axis 164 of the nipple receiving portion in the embodiment of Fig. 11A is about 33mm but may be any value in the range of from about 25mm to about 40mm. In contrast, the flange 210 of Fig. 9 is symmetrical, with the distance 254 from the top of the perimeter of the distal opening to the central axis of the flange 210 being 28.2mm and the distance 256 from the bottom of the perimeter of the distal opening to the central axis of the flange 210 being 28.2mm.

[00229] Multiple holes or ports 140 are provided at the interface of the nipple receiving portion 112 with the tubing connector 134 to allow the breast milk drawn from the nipple 3 to enter the tubing 32 connected to the tubing connector 134 and in fluid communication with holes/ports 140. These holes/ports 140 allow milk to be delivered into the tubing connector 134 and tubing 32, and also prevent the nipple 3 from being drawn into the tubing connector 134 and tubing 32.

[00230] Fig. 12A is a side, cross-sectional view of the skin contact member 10 and tube 32 with the outer shell 34. Fig. 12B is a transverse, cross-sectional view from the bottom of the system 100 showing the skin contact member 10 and tube 32 with the outer shell 34. Although tube 32 is shown schematically as a single sized tube for simplicity, the large portion 32L in this embodiment has an inside diameter larger than the inside diameter of smaller tube portions 32S. Fig. 12C is a proximal end view of the skin contact member 10 showing tube 32 connected thereto. In one embodiment, the inside diameter of the tube 32L is about 3/8". In another embodiment, the inside

diameter of the tube 32L is about 7/16". In another embodiment, the inside diameter of the tube 32L is about ½". In another embodiment, the inside diameter of tube portion 32L is about 5/16". In one embodiment, the inside diameter of tube portions 32S and 32S2 is about ¼". In another embodiment, the inside diameter of tube portions 32S and 32S2 is about 3/32". In another embodiment, the inside diameter of tube portions 32S and 32S2 is about 1/8".

[00231] In one embodiment, the total system volume is about 24.0 cc. The total volume is calculated as the space in the nipple receiving portion 112 (that is not occupied by the nipple 3) and tube portions 32S, 32L and 32S2 up to the one-way valve 50, see the schematic representation in Fig. 13. Other embodiments may have a significantly less total system volume, in the range of about 4cc to about 24cc, preferably in the range of about 4.5cc to about 12cc, more preferably in the range of about 5cc to about 8cc or about 8cc to about 10cc. In the embodiment with total system volume of about 24.0 cc, the active pump volume, i.e., the volume displacement achievable by compressing tube portion 32L from fully uncompressed to the limit of compression by compression member 38 is about 3.4 cc. The compression member 38 in this embodiment has a compression member length 38L (with length defined as shown in Fig. 14, 38L) of about 2.5". When there is only air in the tubing 32 of the system 100, pressure swing by moving the compression member 38 inwardly against the tubing portion 32L and outwardly away from the tubing portion is limited, due to the compressibility of the air. In this embodiment, with the system under vacuum of -60 mmHg, a full stroke of the compression member (from compressed to fully uncompressed tube portion 32L) increases the vacuum to -160 mmHg. The ratio of pumping volume to total system volume is important with regard to power and size of the pumping system. In this embodiment, the tube portion 32L was made of silicone (Dow Corning SILASTIC®) having a .375' inside diameter and a wall thickness of .094", with a hardness of 50 Shore A. Using the 2.5" long compression member, the force applied to the tube portion 32L under full compression was 19.6lbf.

[00232] In a preferred embodiment, it is preferred to avoid both completely compressing the tube portion 32L and well as allowing full rebound of the tubing portion 32L. Near full compression, a sharp increase in compression force is required

(see Fig. 15, #302), which is not efficient for the small amount of additional pressure change obtained thereby, given the significant increase in motor power and energy consumption that it would require. Near full rebound of the tubing portion, the resulting pressure changes are less efficient, given the amount of energy expended by the driver 46 to withdraw the compression member 38 fully, see Fig. 15, #305 During let down mode operation of the system 100, the system 100 operates to effect let down of the milk in the breast 2, prior to extraction, with a maximum suction target of up to 120mmHg (typically, about 100mmHg (-100mmHg pressure)) to establish let down. The goal of letdown mode (or non-nutritive suction mode) is to stimulate the breast 2 to express milk. The relatively shallow (small vacuum change range) and relatively fast frequency of the pumping during this phase are meant to mimic the initial suckling action of a child at the breast. In this mode, the first 10% of the tubing compression (Fig. 15, #305) is less productive. This is because during let down phase, the suction pressure is not allowed to exceed the maximum let down suction of 110mmHg or 120mmHg, or whatever the maximum let down suction is set at, so the compression member 38 does not cycle to the range of the first 10% of the tubing compression. Therefore, as the compression member 38 is drawn in a direction away from the tube portion 32L, the system 100 is designed to reach -100mmHg (a suction pressure of 100mmHg) (or -120mmHg, or whatever the maximum let down suction is designed to be), by the time that the compression member 38 has reached a position in which tube 32L is 90% uncompressed, see 307. Further movement of the compression member 38 away from the tube portion 32L from 90% to 100% compressed (see region 305) is less helpful to generate additional vacuum as the tube portion 32L functions like a weak spring during this portion of expansion. The chart in Fig.15 tracks the rebound pressure generation by the tube portion 32L after compression to a specific level. For example, 100% compression of tube portion 32L followed by sealing the tube and letting it rebound would generate >300mmHg. A small deflection generating 10mmHg is not 'useful' for pumping purposes of the system 100. 200mmHg vacuum is established when the tubing 32L is about 25% compressed and then released, see 309. The compression member 38 needs only to actuate within the ranges of vacuum generation that are useful for the pumping purposes of the system 100. Actuating the

compression member 38 to compress the tube portion 32L near 100% is inefficient due to the compression load ramping up. Also, actuating the compression member 38 paddle near 0% compression of the tubing portion 32L is only useful for controlling low vacuum peaks. As the tubing portion 32L rebounds it reaches its capacity for vacuum draw and further withdrawal of the compression member 38 away from the tubing portion 32L only causes the paddle to lose contact with the tubing portion 32L.

[00233] During let down (non-nutritive) mode the system 100 can be configured to operate between -60mmHg and -100mmHg in one example. In this example, the compression member 38 can compress the tubing portion 32L nearly fully (e.g., about 97%) and then be moved away from the tubing portion 32L to generate vacuum. The maximum latch suction pressure of -100mmHg will be reached with a small amount of rebound of the tubing portion 32L and the compression member 38 can be cycled relative to the tubing portion 32L between -100mmHg and -60mmHg in a narrow range or band near full compression of the tube portion 32L. As milk flows, that narrow band shifts (volume in -> paddle lifting) until 100 is generated around 10% (90% rebound) at which point the tube portion 32L will be purged by fully compressing it (up to or near 100% compressed) to drive out the contents and thereby regain more capacity for pumping with relatively less compression of the tube portion 32L again. In another embodiment, compression member 38 operates in a range to compress tube portion 32L from about 10% compressed up to about 97% compressed. Additionally, the compression member 38 can move to a position where tube 32L is 0% compressed to allow for installation, changing, etc. of the tubing 32. Typically during purging, the vacuum level is reduced to minimum vacuum (e.g., about -60mmHg) and the compression member 36 is used to close off (seal) tubing portion 32 to maintain 60mmHg vacuum against the breast 2. Then the compression member 38 fully compresses the tubing portion 32L to purge the contents of tubing portion 32L.

[00234] The contact surface of the compression member 38 can be shaped to improve pumping efficiency and reduce power requirements of the system 100. Fig. 16 shows an end view of compression member 38 during compression of tubing portion 32L. The contact surface 38S of compression member 38 is convex in the direction transverse to the longitudinal axis of the compression member 38, such as by radiusing,

for example, to avoid unproductive crushing of the side walls of the tube portion 32L. This minimizes the peak load on the driver 46. It can be seen in Fig. 16 that the central portion of the tube 32L is completely closed as the inner walls contact one another, while the portions near the sides of the annulus do not completely close off.

[00235] For the embodiment having the total system volume of 24.0 cc, 19.6 lbs. pumping force was provided by the driver 46 and compression member 38. The estimated mechanism capacity was 44 lb. "Mechanism capacity" refers to the maximum compression force that could be applied to the tubing portion 32L by the driver 46 and compression member 38, and is a factor of voltage, driver 46 stall torque, and other characteristics of the drive train, such as gear reduction, etc. The system used a servo motor as the driver 46 connected to the compression member 38 with a 0.188" lever arm 304 (see Fig. 14), to provide a 246:1 gear ratio and 5.9 ft-lb. torque with a 500 mA current draw. The maximum desired speed of this pump system is 90 cycles/min (CPM), with full compression travel limited to about 65CPM. When the compression travel (stroke) is reduced, such as when in letdown mode, the speed can be increased. The pump system has a 'dry' 100 mmHg swing (i.e., change in vacuum is about 100mmHg from one end of a full stroke to the other when there is no fluid in the tubing 32), so the full travel stroke may not be required in letdown mode, as the vacuum swing is less than 100mmHg, e.g., about 60mmHg latch suction to about 100mmHg maximum suction. The force requirements of the pumping system can be greatly reduced by reducing the dead space in the total system volume, which in turn then requires less pumping volume per cycle/stroke. By reducing the gear ratio, this can increase the actuation of the compression member to make it quicker and more responsive to pressure changes.

[00236] The driver 44 and compression member 36 were configured to apply about 1.0 lbf to the tube having 3/8" inside diameter, to fully close (pinch) it off. Driver 44 included an HS-85MG servo motor having dimensions of .51" x 1.14" x 1.2", a 3.0 in-lb. stall torque and .238" lever arm to provide about 12.8 lbf capacity.

[00237] Fig. 17 shows the power consumption data for the system described above having 24.0 cc total system volume, .375" inside diameter tube 32, and 2.5" compression member 38 described above. The drivers 44, 46 were powered by four

alkaline "C" sized batteries which provided a voltage 330 of about 6V. The currents were measured using a multimeter in series with the battery connection to the drivers. The system was set to drive the compression member 38 over the full stroke relative to the tube portion 32L during operation. A single 15 minute pumping session required about 110 mAh of power, see 336. An estimate for a day's worth of pumping was set as four sessions, resulting in the power requirement for a full day 338 to be about 440 mAh. The average current 332 was calculated to be about 440 mA and the maximum current 334 capability was about 0.83A.

[00238] In one embodiment, the external shell 34 that contains the other components of the breast pump system (except for the milk collection container which is mountable over the external shell 34) is configured to have about an 11 cm (4.3") diameter 340 (see Fig. 18) and a length 342 (see Fig. 1) of about 4.1 cm (1.6"), although the diameter 340 may be any value within the range of from about 10 cm to about 14 cm and the length 342 may be a value within the range of from about 3.5 cm to about 6 cm. An external shell 34 having a diameter 340 of about 11 cm and length 342 of about 4.1 cm provides a housing volume for the components of about 151.2 cc. Assuming dead volume in the nipple receiving portion 112 to be about 1.8 cc and a 1 cm length of tubing 32 provided for compression by compression member 36 with the nipple receiving portion 112 off center of the breast contact portion 122 by about 1.5 cm, Fig. 19 shows characteristics of systems 100 using various tubing dimensions. These characteristics were measured using tubing 32 that was uniform throughout and thus did not have a smaller tubing portion 32S and larger tubing portion 32L, but the principle still holds for using tubing 32 having both small 32S and large 32L portions. It can be seen that reducing the dead volumes 350 and 352, the pumping efficiency 354 (pumping volume divided by total system volume 352 + 356) increases. This allows a reduction in the length 38L of compression member 38, resulting in relatively lower pump power and energy consumption requirements.

[00239] The system 100 is responsive to pressure changes within the tubing 32 caused by entry of milk into the tubing 32. Fig. 20 is a schematic representation of working components of the system 100 according to an embodiment of the present disclosure. The compression elements 36 and 38 are driven by dedicated compression drivers 44,

46. Alternatively, compression elements 36 and 38 could be driven by a single compression driver, controlled by controller 52 to drive each of the compression elements 36, 38 in the manner desired. 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. Further characteristics of alternative embodiments of compression members and compression surfaces thereof can be found in U.S. Provisional Application Serial Nos. 62/027,685, filed 07/22/2014; 62/050,810, filed 09/16/2014; 62/052,476, filed 09/19/2014; and 62/053,095, filed 09/19/2014; each of which is incorporated herein, in its entirety, by reference thereto.

[00240] 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, as well as the controller 52 and pressure sensor 54, and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38.

[00241] A sensor 54 is used to provide feedback to the controller 52 for controlling the pumping cycles to achieve and/or maintain desired vacuum levels. 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. As shown, sensor 54 is a non-contact sensor 54, meaning that it is not in fluid communication with the milk or vacuum space of the system 100. Preferably sensor 54 is located nearby where the tip of the nipple 3 of the breast 2 is located to determine actual pressure being exposed to the breast 2/nipple 3, but other sensors 54 may be located within the system 100, for example, near where the one-way valve 50 is located, and can be used to monitor other features such as container 60 contents or expulsion pressure or flow rate. More generally, sensor 54 can be located anywhere in the system between the breast 2 and the one-way valve 50 into the collection container 60. Sensor 54 can be located either on the breast side of the compression member 36 or the other side of the compression

member 36. When located on the breast side (i.e., upstream of the compression member 36), the sensor always provides the pressure experienced by the breast 2 and can thus be used to monitor and determine the pressure environment of the breast 2 even when the compression member 36 has sealed off the tubing portion 32S. If the sensor 54 is on the other side of the compression member 36 (i.e., downstream of the compression member 36), sensor 54 can always provide pressure at the breast 2 except when the compression member 36 has sealed off the tubing portion 32S. Thus, a sensor 54 can be placed anywhere in communication with tube 32 and be used to monitor and control the system via sensor readings feedback to the controller 52. 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.

[00242] 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 (or, alternatively, can be connected in fluid communication with the storage container by another tube. Valve 50 prevents back flow of milk into the tube 32, as well as preventing air from entering the proximal end of the tube 32 and thereby maintains the suction (vacuum) level in the tube 32. Valve 50 can further be designed to open in the reverse direction, for safety purposes, if a predetermined maximum vacuum level is exceed in tubing 32, such as greater than 250 mm Hg vacuum (-250mm Hg pressure), for example. In at least one embodiment, the pressure at which the valve 50 opens to allow flow into the milk collection container 60 is about 25mm Hg. In an alternative embodiment, a pressure relief valve 150 can optionally be provided in the system 100, such as in the skin contact member 10, or other location along tubing 32. The pressure relief valve 150 can be configured to release at vacuums greater than a predetermined amount, (e.g., vacuums greater than 250mm Hg (pressures less than -250mm Hg), or

some other predetermined maximum vacuum level). The one-way valve 50 can be configured and designed such that it allows fluid to flow through it when the pressure in tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "crack pressure". The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from 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. As the compression elements 36, 38 compress the tube 32, the pressure in the system 100 goes up and reaches the minimum suction level (e.g., latch suction level, such as -60mmHg, -30mm Hg, or some other predetermined latch suction level), at which time the compression member (pinch valve) 36 seals off portion 32S thereby maintaining the minimum suction (latch suction) against the breast 2. Continued compression of portion 32L by compression member 38 continues to increase the pressure downstream of compression member 36, until the crack pressure is reached (e.g., 25mm Hg or some other predetermined, positive crack pressure), that opens the one-way valve 50. The compression elements 36, 38 continue compressing tube 32, pumping fluid (milk) through the one-way valve 50 and into the collection container 60 until the compression element 38 reaches an end point in travel (typically before "bottoming out" against the anvil 2232). The end point in travel of the compression element 38 against portion 32L may be predetermined, or may be calculated on the fly by the controller 52 using feedback from pressure sensor 54 and feedback from the driver of the compression element 38, from which the controller 52 can calculate the relative position of the compression element 38 over the course of its travel. The compression member 36 remains closed throughout this process, as it is used to seal off the tube 32 the entire time that the compression element 38 is pumping milk out of the region 42 and into the collection container 60). As the compression elements 36, 38 reverse direction and pull away from the tube 32, they start the cycle again.

[00243] As milk enters the system, the suction level decreases (pressure increases). The feedback provided by pressure monitoring via pressure sensor 54 provides input to a feedback loop that adjusts the position of the compression member 38 to maintain the desired vacuum (pressure) within the tubing 32 by compensating for the changes in

pressure that occur to changing amounts of milk in the tubing 32. For example, for a relatively larger amount of milk in the tubing, this will require a relatively shorter stroke of the compression member 38 toward anvil surface 2232 to achieve the latch pressure. This modification can be addressed by either slowing the movements of the compression member 38 to achieve the same timing cycle for pumping, or increasing the cycle frequency due to the less time taken for the shorter strokes of the compression member 38.

[00244] A contact pressure sensor 54 is shown in Fig. 4, wherein the pressure sensor 54 contacts the vacuum space (and, potentially, the milk) in the system 100. In this embodiment, a T-connector 370 is connected to the proximal end of the nipple receiving portion 112, so that both tube 32S and a tube 32P can be joined in fluid communication with the interior of the nipple receiving portion 112. In this way, pressure sensor 54 is placed in line, in fluid communication with the tube 32 and nipple receiving portion 112, and can measure pressure directly, as a result.

[00245] Alternatively, or additionally, one or more non-contact pressure sensors can be employed in the system 100. In the embodiment of Fig. 20, non-contact pressure sensor is located external of the tubing portion 32S. Various different types of non-contact pressure sensors can be used, such as optical sensors, magnetic sensors, linear variable differential transformer (LVDT) sensors, or the like. Further details about non-contact pressure sensors that may be employed in the present disclosure can be found in U.S. Provisional Application Serial Nos. 62/053,095 and 62/027,685.

[00246] Figs. 21A-21B show a proximal perspective view and a side view, respectively, of skin contact member 10 according to an embodiment of the present disclosure, with four different potential locations for placement of a non-contact sensor 54. At location 350A, a thicker wall is provided relative to the thickness of the nipple receiving portion 112 . In this example, the thickness of location 350A was 4.12mm and the thickness of the nipple receiving portion 112 was 2.38mm. At location 350B, a thinner wall is provided relative to the thickness of the nipple receiving portion 112. In this example, the thickness of location 350B was 1mm and the thickness of the nipple receiving portion 112 was 2.38mm. At location 350C, the thickness was the same as the rest of the nipple receiving portion, but protruding outwardly therefrom, see the cross-

sectional view of Fig. 21C taken along line 21C-21C in Fig. 21A. The thickness at location 350D is the same as the thickness of the nipple receiving portion; in this example, 2.38mm. It has been found that all locations 350A-350D will displace relative to vacuum changes within the system according to a linear relationship (although by different scaling factors, which can be determined empirically), see Example 1 below. Accordingly, a non-contact sensor 54 can be employed at any of locations 350A-350D to measure displacement changes in those locations. Pressure change measurements can then be calculated from the displacement change measurements, due to the linear relationship that exists between force applied to the locations 350A-350D and pressure within the system that causes the force. More generally, pressure changes in the system 100 can be measured by measuring opposition forces of any pre-loaded fluid contacting wall of the system 100.

[00247] Force versus displacement of a portion of the skin contact member 10, such as a portion of the nipple receiving member 112 also exhibits a linear relationship. Thus, displacement of a portion of the skin contact member 10 can be measured and pressure change can be calculated therefrom. Further, strain measurement can be used to calculate pressure changes. Therefore, attachment of a strain gauge 54 (see Fig. 21D) to skin contact member 10, typically on a region of nipple receiving member 112, can be used to measure strain changes in that region, which measurements can be used to calculate pressure changes within the nipple receiving member 112.

[00248] Use of a system 100 provided with a non-contact pressure sensor 54 would include loading the skin contact member 10 onto the main body/pump housing 34 (unless it has already been pre-loaded) and then turning on the pump power. As the pump system 100 goes through a power up routine, the controller 52 reads the force applied by the pressure sensor 54, position of the sensor 54 relative to the potentiometer when a displacement sensor 54 is used, or strain on the strain gauge when a strain gauge is used as the pressure sensor 54. This is the preload force applied by the sensor 54 to the wall of the nipple receiving portion 112 or tube 32, or position, or strain measured by the strain gauge, before the skin contact member 10 has been applied to the breast 2, so it is a state in which the pressure in tube 32 is atmospheric pressure. The controller 52 then calibrates the system such that the preload force or

position or measured strain equates to atmospheric pressure. Based upon a look-up table or a best fit equation, the controller 52 can now convert any changes in force, position or strain read by the pressure sensor 54 against the wall of the nipple receiving portion 112 or tube 32 to pressure readings in the system 100 during operation of the breast pump system 100 upon attachment to the breast 2.

[00249] Optionally, the system 100 may be provided with two or more non-contact sensors 54 for determining pressure within the system 100. For example, by placing sensors 54 on different regions of the nipple receiving portion 112 that have different wall thicknesses, the linearity of the pressure changes measured by the sensors 54 on the different wall thicknesses will occur within different ranges of pressure (vacuum). Fig. 21E shows a cross-sectional illustration of nipple receiving portion 112 in which a first non-contact sensor 54 (see 54A) has been attached to a relatively thinner wall of the nipple receiving portion 112 and a second non-contact sensor 54 (see 54B) has been attached to a relatively thicker wall of the nipple receiving portion 112. The sensor 54B provides data for pressure change calculations at a higher range of vacuum pressures (lower pressures) than that provided by the sensor 54A. The vacuum ranges in which the sensors 54A, 54B provide accurate data (linear relationship) can be designed to overlap, so that the effective range of linearity and thus the range for accurately measuring changes in vacuum pressure can be extended. Furthermore, when the vacuum pressure measured is in the overlap region, where reliable data is provided by both sensors 54A and 54B, this can be used as a check on the accuracy of each of the sensors 54A, 54B, and/or used for calibration purposes. The present disclosure is not limited to the use of one or two sensors 54, as more than two sensors 54 may be applied in this manner, with or without overlapping pressure measurement ranges, preferably with overlap. Fig. 21F illustrates a pressure sensor 55 that may be employed to trigger or indicate when a predetermined vacuum pressure has been attained within the system. Pressure sensor 55 may be a switch that is in electrical communication with the controller 52. Pressure sensor 55 extends into the nipple receiving portion 112 (or, alternatively, tubing 32) at a predetermined distance from an inner wall of the nipple receiving portion 112/tubing 32 that has been calculated or empirically determined to be the distance that the inner wall deflects when the

predetermined vacuum pressure has been attained in the nipple receiving portion 112/tubing 32. Accordingly, when the inner wall contacts the sensor 55 (as indicated by the dashed line in Fig. 21F), sensor 55 sends a signal to the controller 52 and the controller interprets the signal to indicate that the predetermined vacuum level has been reached. This type of sensor 55 could be used, for example, to indicate when maximum vacuum has been achieved. Alternatively, or additionally, sensor 55 could be provided to act as a safety mechanism, wherein the controller 52 would shut down the system if a signal is received from the sensor 55, as this would indicate that an abnormally high level of vacuum has been reached. For example, the system may be shut down if 350mmHg vacuum is reached, or some other predetermined level of vacuum that is considered to be too much vacuum for safe operation.

[00250] To account for the possibility of degradation of pump tubing 32 and/or the skin contact member 10 over time the system can optionally be provided with an indicator that will alert the user when it is time to replace the skin contact member 10 and/or tubing 32. Fig. 22 shows an indicator 352 mounted on the inside of breast contact member 352 so that it can be readily viewed by a user prior to mounting the system 100 to the breast 2. Indicator 352 can measure a predetermined time/lifespan to change tube 32 and/or skin contact member 10 via a time based indicator, such as markings that fade or appear over time, other clocking mechanism that provides a visual and/or audible indication at the end of the measured time. In the event that the skin contact member 10 and/or tubing degrades over time, such as resulting from fatigue and/or oxidation, washing, etc., indicator 352 can track an average expected lifetime of the skin contact member 10 and/or tubing 32, and present a visible and/or audible indication to the user when it is time to replace the current skin contact member 10 and/or tubing with a new component. Average expected lifetimes of these components can be determined experimentally through testing, so that the average expected lifetime can be empirically calculated and programmed into the indicator. Changes in properties (e.g., elasticity, stiffness, etc.) of the tubing 32 and/or skin contact member 10 could result in inaccurate pressure readings, insufficient sealing of the skin contact member 10 to the breast 10 causing air and/or milk leakage, reduced pumping performance etc. Indicator 352 may be a time-based indicator, such as markings that

fade or appear over time.

[00251] Fig. 23 illustrates another location in which indicator may be placed, in this case on the external shell 34 of the system 100. If the situation is that the time to replacement of the skin contact member 10 is different from the time to replacement of the tubing 32, and in which the embodiment has a skin contact member 10 that is configured to be separable from the tubing (some embodiments provide the skin contact member 10 and tubing 32 as an integral unit), then two indicators 352 may be provided, one set for a time to replacement of the skin contact member 10 and the other set to the time to replacement of the tubing.

[00252] Indicator 352 may be disposable, such as the type used on the skin contact member 10 as shown in Fig. 22 or on tubing 32, or may be reusable, where appropriate, such as those mounted on the external shell 34 as shown in Fig. 23 (although indicators 352 on shell 34 could also be made disposable and be removable from and replaceable on shell 34). Fig. 24 illustrates one example of a reusable, time-based indicator 352 that may be employed. In this embodiment, indicator 352 is provided with a plurality of LCD bars 354 that darken upon pressing and holding the reset button 356. Once the bars have darkened, a timer that is initiated, the timer having been programmed for the time to replacement of the skin contact member 10 and/or tubing 32. As shown in Fig. 24, the indicator has four bars 354, although more or fewer could be provided. For the four-bar embodiment, when one-quarter of the time to replacement has elapsed after the resetting of the bars, the top bar becomes clear, or lightens, so that only three bars remain visibly dark. Each bar sequentially lightens or clarifies after each successive passing of a quarter of the time to replacement, until all bars are clear when the time period expires. Thus, this type of indicator not only indicates when the full time to replacement has elapsed, but can also provide the user with an indication of approximately how much time is remaining until replacement is required, i.e., three dark bars indicates that ¾ of the use time still remains prior to the need to replace, etc.

[00253] Alternatively, or additionally, other types of indicators 352 may be provided, including, but not limited to: indicators that change with friction, interaction with moving parts, or the like. For example, a wear indicator 352 can be located anywhere on tubing 32, such as in a location where compression member 38 contacts tube 32L,

where compression member 36 contacts tube 32S, or in another location such as where tubing 32 snaps into the pump housing/region 30. Fig. 26 shows a wear indictor located on tubing portion 32L. Wear indicator 352 may be placed anywhere on tubing 32 where wear is likely to occur. Wear, such as through friction resulting from interaction between tubing 32 and another component (compression member 36 or 38, pump housing 30, etc.) wears away a color of the indicator 352 as the wear occurs. Thus, when the color disappears or changes color, this indicates that it is time to change the tubing 32.

[00254] Likewise, a wear indicator 352 may be used on a component of skin contact member 10 in a location where it contacts the pump housing 30 when it is snapped into position. Fig. 27 illustrates a wear indicator 352 on skin contact member 10. Wear occurs as the skin contact member is attached to, and removed from the pump housing. Color change may be used to indicate when it is time to change the skin contact member, in a way that is described above.

[00255] Further alternatively, or additionally, the system 100 may detect tubing 32 wear. Controller 52 can track the position of the compression member 38 relative to tubing 32. Fig. 28 illustrates one example of an arrangement for tracking compression member 38 position, although the present disclosure is not limited to this arrangement, as alternative arrangements may be provided. In the embodiment of Fig. 28, driver 46 includes a motor 46M, a gear box 46G and an encoder 46E mounted to opposite ends of motor 46M. As motor 46M rotates, encoder 46E, which is fixed relative to the rotating motor shaft, rotates with the motor. An optical monitor 1146, such as an infrared laser or the like is beamed against the encoder 46E, such as the rotating blades of the encoder 46E cross the optical beam emitted by the optical monitor 1146 as the motor rotates. As the blades cross the beam, the beam is reflected back to a sensor 1148. By counting the reflections, the sensor 1148 and controller 52 can calculate the position of the motor 46M from a start position, and thus the position of the compression member 38 that it is driving, relative to a reference or starting position of the compression member 38. A similar arrangement can be provided for the driver 44 of compression member 36.

[00256] Thus controller 52 can keep track of the position of motor 46 and the position

of compression member 38 relative to the tubing 32L. Since the controller 52 also tracks the pressure within tubing 32 via sensor 54 (e.g., as illustrated in Fig. 20), the controller 52 can correlate pressure changes developed in tubing 32 relative to position (and/or optionally, speed) of compression member 38. This correlation can be calculated when tubing 32 is new, i.e., upon initial use. Correlation calculations can be continually performed by controller 52 over subsequent uses of the system, and compared to the correlation values from the first use. The correlation comparisons will show a trend over the lifetime of the tubing 32 with subsequent uses. As the tubing 32 begins to wear out, less pressure change may be produced by the same change in position/speed of compression member 38 compared to when the tubing was new. This difference in pressure change can be tracked, and, when a predetermined amount of difference occurs, the controller 52 can send a warning to display 165 and/or external computer 470, that it is time to change the tubing 32. Also, by tracking the trend in usage of the system 100 over time and the rate of change of difference in pressure change resulting therefrom, the controller can estimate and predict when the time to change the tubing 32 will occur, and thus can send a warning to display 165 and/or external computer 470 at a predetermined time before the tubing 32 will need to be changed. For example, such a warning could be sent one week, one month, or some other predetermined time before it is actually time to change the tubing 32.

[00257] Further alternatively or additionally, usage of the skin contact member 10 and/or tubing 32 can be tracked by controller 52 and/or external computer 470 using a passive sensor 358 (see Fig. 25) via RFID or NFC, for example. One or more sensors 358, each provided with a unique identifier (ID) can be attached to or embedded into skin contact member 10 and or tubing 32. With each use of the system, this/these unique ID('s) can be identified by the controller 52 and/or external computer 470 to know that the skin contact member 10 and/or tubing 32 has been used, and the number of uses can thus be tracked, and/or times or use and/or cycle counts (number of cycles during use that the compression members 38 and/or 3 have executed). By tracking this data, the controller 52 and/or external computer can then indicate when it is time to change/replace the skin contact member 10 and/or tubing.

[00258] Further alternatively or additionally, the usage of the skin contact member 10

and/or tubing 32 can be tracked, such as by using radio-frequency identification (RFID) or near field communication (NFC) tracking. This tracking can be carried out, for example, by embedding a passive sensor/chip 358 configured to RFID or NFC tracking into one or both of the skin contact member 10 and tubing 32, see Fig. 25. The one or more chips 358 can be identified by the controller 52 of the pumping system 100 (by hard wire and/or wirelessly, preferably wirelessly) by an external computer 470, which may be, but is not limited to: a smartphone, a tablet computer, a laptop computer, a notebook computer or a server. The controller 52 and/or external computer 470 communicates with the passive sensor(s)/chip(s) 358 which indicate(s) when the system is in use. By tracking the times of use and/or number of uses, or even pump cycle counts, the controller 52, or external computer can alert the user when it is time to change the skin contact member 10 and/or tube 32. Alerts may be audible and or visual, such as a beep or voice message emitted from the external computer 470 via speaker 472 and/or a visual alert such as text and/or graphics displayed on display 478, or by the controller 52, via optional display 165 and/or optional speaker 168. The tracking provided by the passive sensors 358 provide the ability to assign a unique identifier to each component that a sensor 358 is attached to or embedded in. Thus, the controller 52 and/or external computer 470 can readily distinguish between each skin contact member 10 and tube 32 used.

[00259] This same technology can be provided with the milk collection containers 60, so that tracking of extraction date and time, volume extracted, etc. can be recorded and stored with regard to each milk collection container used with the system 100 to extract milk. Thus, the system 100 can register individual milk collection containers 60, so that the user can readily identify when milk in each container 60 was collected, the volume in each container 60, etc. The breast pump system can record the volume of milk in any given container 60 during a pumping session. The data recorded can be sent to an external computer 470 and/or over the Internet, either automatically or manually.

[00260] There are multiple ways to link data to a particular milk collection container 60. Containers 60 may be provided with easily identifiable marking 60M (see Fig. 37), such as alphanumeric markings (letters, numbers) of other markings that are readily

identifiable and distinguishable from one another. Additionally or alternatively, marking 60M on each container 60 can include a barcode, QR code, RFID, NFC, other magnetic or electromagnetic identifier, or the like pre-printed on the container 60. When initiating a milk pumping session using system 100 with milk collection container 60 mounted thereto, or at the end of the session or anytime in between, the user can scan the mark with a scanner on an external computer 470 (smartphone or the like), or scan using the system 100 itself in embodiments where controller 52 is provided with a scanner 101 on the system 100 as illustrated in Fig. 1, or manually input the identifier of the mark 60M if no barcode is used, and thus link the particular milk collection container with the mark 60M in the database on the external computer. At the end of the milk extraction system, when data is exported to the external computer 470 and/or Internet/cloud-based database, the data, such as volume, extraction date and time, etc. are exported along with the identifier of the mark 60M so the data is linked and stored relative to the identifier for that particular milk collection container 60.

[00261] The mark 60M when in range of the controller 52 and/or external computer 470 may automatically activate the system 100 for a pumping session, or activate an activatable feature of the system, such as a power switch that can be operated by the user to initiate a pumping session. If a container 60 contains a mark 60M that is not recognizable by the controller 52 and or external computer 470, or contains no mark 60M at all, then the system 100 may be configured so as to be prevented from operating for a milk extraction session, as no unique ID has been recognized in this instance. By ensuring that a milk collection container 60 used has a recognizable, unique ID, this can provided additional assurances for safety, sterility and quality of the milk collection container 60 used. The presence of the unique identifier 60M allows the system 100 to track when the milk collection container 60 enters into proximity with the system 100 for use in an extraction session, when it leaves the proximity at the end of the session, as well as other data already described, such as volume of milk extracted, date and time of extraction, length of extraction session, etc. These information capabilities can be useful for managing personal use and consumption by the user's baby, as well as for milk donation services, where milk extracted from one

mother may be donated to a milk bank, or to a baby having a different mother. With regard to milk donation services, a collection bank can scan the milk collection container 60 into the bank database using the same unique identifier provided by the mark 60M and confirm that this is a container 60 that is qualified for the program. In embodiments where container 60 includes the one-way valve 50, this provides further assurance that no milk has been removed from the container 60 prior to it arriving at the milk collection bank.

[00262] The controller 52 and/or external computer 470 may be provided with memory storing a database of registered unique ID's which can be regularly updated by communication with a central database through a network (either wirelessly or by wire) such as the Internet. Alternatively, controller 52 and/or external computer may connect with the central database, such as by WiFi or other wireless connection to the Internet, or even by Ethernet connection.

[00263] As already noted milk collection container 60 may be provided with a passive sensor 358, such as an RFID or NFC chip (see also Fig. 34), which may either be attached thereto or embedded therein, which can be used to link the milk collection container 60 to all data recorded in regard to it..

[00264] As an alternative to pre-marked collection containers 60, a user could manually mark the containers 60 with unique identifiers and manually enter these identifiers into the external computer. Alternatively, the manual marks could be scanned into the external computer.

[00265] The system 100 can calculate the volume of milk pumped into milk collection container 60. By knowing the dimensions of the tubing 32 downstream of the compression member 36 when compression member 36 has sealed off tubing portion 32S, the overall volume capacity of the system 100 downstream of compression member 36 can be calculated. Tracking of the position of the compression member 38 relative to the tube 32 (such as by knowing the driver 46 position at all times, for example), dictates the volume change in the tubing 32. As the pumping process is carried out, pumping/purging of milk into the milk collection container occurs when the compression member 36 has closed off the small tube portion 32S at the location of compression. When the compression member 36 has closed off tube portion 32S, the

change in position of compression member 38 that occurs to carry out the purge of milk from the tubing 32 and into the milk collection container 60 can be used to calculate the change in volume of the tubing 32 downstream of the compression member 36, which equates with volume of milk that is pushed into the milk collection container 60 bag through the one way valve 50.

[00266] Optionally, an estimation of the percentage of milk and air in the system tubing 32 can be calculated based on a compliance assessment of the tubing 32, such as at tubing portion 32L. The more air in the tubing relative to milk, the more the tube portion 32L will move for a given force thereagainst by compression member 38L or a given pressure change. This relationship can be mapped, for example, to provide a look up table to identify the percentage of air and percentage of milk in the tube 32 before purging. Then, knowing the volume that has been purged by knowing the travel of the compression member 38 during the purge, the volume of milk and the volume of air can be calculated.

[00267] Further optionally, the opening of the valve 50 can be monitored or the movement of fluid past the valve 50 can be monitored. By knowing the crack pressure of the valve 50 and knowing the pressure within the tubing 32, this can identify when a purge actually pushes through (i.e., when pressure in tube 32 reaches the crack pressure). This can increase the accuracy of the calculated purge volume by beginning the volume calculation at the position of the compression member at the time that the crack pressure is reached.

[00268] In addition to calculating the volume of milk purged with each purge cycle, the system (via controller 52) can sum the volumes from all purge cycles to calculate the total volume pushed into the milk collection container 60 during a milk extraction session. This volume can be stored with a unique identifier provided to the milk container so that the system 100 keeps a record of how much milk is stored in each milk collection container 60. This information can also be time stamped so that the user will know the time and date that milk was collected, regarding each milk collection container. Additional statistics can be calculated, including, but not limited to: average volume per extraction session, total volume extracted for any given day, average milk extraction volume per day, etc. Any and all of this data can be exported

to an external computer, either manually, or it may be automatically uploaded to the computer 470 when the computer 470 is within range of the system 100 for wireless communication, or when the computer 470 is connected to the system by wire. Further optionally, any or all of this data can be either manually or automatically uploaded to a cloud service over the Internet, either wirelessly or by wire.

[00269] When calculating milk volume pumped from the system 100, there is a need to distinguish between any air pumped by the system versus milk pumped from the system, as well as pumping mixtures of milk and air. When initiating a milk pumping/extraction session, there is air in the tubing 32 this initial volume of air needs to be pumped into the milk collection container 60 to prime the pumping system 100. Distinction between pumping air versus pumping milk can be recognized by correlating pressure changes with the amount of movement of compression member 38 needed to establish the pressure changes. For example, when air is in the tubing, a greater change in position, or more overall travel of the compression member 38 is need to establish the same pressure change than that needed when the tubing 32 is filled with milk. Thus, relatively more motion of the compression member with relatively less pressure change indicates air in the tubing 32. This difference in pressure may also be detected when the compression member 36 is open (i.e., not closing off tube portion 32S) and compression member 38 is retracting and this increasing the vacuum pressure.

[00270] Figs. 31A-31B schematically illustrate breast pump systems 100, according to alternative embodiments of the present disclosure, in which the external shell 34 of the system does not need to be continuously curved, but, instead can have another shape, such as geometrical (all or a portion of which is non-curved) or even irregular or some other custom shape designed to conserve space. In the embodiment of Fig. 31A, shell 34 has substantially flat surfaces that form an angular external surface. These surfaces can more closely contour the internal components of the system than that provided by a continuously convex external shell 34., and thereby eliminate spaces that are devoid of components in a system with a continuously convex external shell 34. In the embodiment of Fig. 32B, external shell has a flat central portion, similar to the embodiment of Fig. 31A, but has convex portions extending radially from the flat

central portion. It is noted that these are two non-limiting shapes provided, as the shape of external shell can take on almost any shape that is well suited to receiving the internal components of the system 100, while eliminating as much void space as possible. Milk collection container 60 is mountable over the external shell 34. The milk collection container 60 can be formed so as to have variable volume when filled, so as to conform to the external surface of the external shell, while providing a convex shape externally, so as to mimic the shape of the breast 2. As shown in Fig. 31A, the peripheral portions of the container 60 are thinner when filled than the central portion of the container 60 when filled. In Fig. 31B, the container is pre-shaped to follow the contours of the external shell 34 when filled, including bulbous portions 34B that conform to the concave portions of the external shell 34. These solutions provide for a more compact overall system, while at the same time maintaining the appearance of the system 100 when worn to resemble that of the natural breast. The external surface 60E of the milk collection bag 60 can be formed so as to maintain a continuously convex appearance even when the milk collection bag is empty. The milk collection bag 60 may have a rigid inner surface that mates with the contours of the external shell 34 and a soft, flexible external surface that inflates/moves as milk enters the bag 60, while maintaining a convex/naturally appearing breast shape. Alternatively, the exterior surface of the milk collection bag 60 may be rigid to maintain breast/convex shape and the inner surface may be soft and flexible to match the contours of the external shell 34, as the bag 60 expands while it fills up with milk. Another option is for both surfaces to be rigid and yet allow some motion as the space/bladder in between fills with milk, allowing the surfaces to move apart as needed to accommodate the volume of milk received.

[00271] Figs. 32A-32B illustrate a milk collection container 60 for use in system 100 according to another embodiment of the present disclosure. In this embodiment, container 60 has a preformed convex surface 60C that is shaped to mimic the natural appearance of the breast 2. Surface 60c may be pre-formed such as by molding or the like, and maintains the convex shape shown, even when the container is empty, as well as when it contains milk. When mounted on the system housing 34 the convex shape 30 provides the appearance of a natural breast, with or without containment by a bra.

The opposite surface 60F of the container 60 is flexible and may even contain wrinkles or folds 60W when container 60 is empty. As the container 60 fills with milk, the container 60 expands by moving the flexible surface outwardly. During the outward movement of the flexible surface 60W, the flexibility of this surface allows it to conform to the shape of the system housing/external shell 34 to maximize conservation of space of the entire system 100. Fig. 32A illustrates in dashed lines the shape of the flexible surface 60W when is moved to contour to the external shell 34 of the embodiment of Fig. 31A. Fig. 32B illustrates in dashed lines the shape of the flexible surface 60W when is moved to contour to the external shell 34 of the embodiment of Fig. 31B.

[00272] In addition or alternative to the flexible surface provided 60F provided with a pre-shaped surface 60C, milk collection container may be further be provided with one or more structural elements, 76, such as baffles, heat seals, struts or other restrictions that restrict the amount of expansion of flexible surface 60F relative to contoured surface 60C and or provide shape to the collection container 60 even when empty. Fig. 33 shows container 60 having baffles 76 that internally connect to the internal walls of portions 60F, 60C to limit the amount of expansion in the areas where the baffles 76 are located, relative to the amount of expansion that the remaining areas can experience. Baffles 76 can be provided in any pattern desired so as to customize the expanded contours of the flexible surface 60F to conform to a particular contour of an external shell 34.

[00273] Fig. 32C illustrates a milk collection container 60 that is formed so that the distal surface 60D of the container, when filled with milk has a shape that matches the proximal surface contour of the external shell 34. The proximal surface 60C may be flexible or pre-formed with the convex shape that mimics the appearance of the breast 2.

[00274] Even in embodiments of the breast pump system 100 wherein the external shell is convex, the milk collection container 60 used therewith with have varying levels of thickness from top to bottom and side to side when milk is collected into the container 60 while mounted on the system. Accordingly the container 60 can be pre-shaped or preconfigured to take on a shape having varying thicknesses between the rear and front

walls when containing milk.

[00275] Fig. 34 illustrates a milk collection container 60 that includes a passive sensor 358 that can be either attached to or embedded in the container 60. Sensor 358 may be an RFID or NFC device, or the like that contains a unique identifier (ID) is created in a manner that is recognizable to controller 52 and/or external computer 470. The controller 52 and/or external computer are provided with a reading application that can wirelessly read the unique ID when the container 60 that includes the sensor 358 having the unique ID is brought into close proximity with the controller 52, such as by mounting the collection container 60 to the external shell 34. Once read, this unique ID is then referenced by the controller 52 and/or external computer 470 into a database application that contains detailed information as to what the sensor 358 is attached to. Upon confirming the specific collection container that the sensor 358 is attached to/embedded in, the system 100 can then track usages of that specific container, including, but no limited to: volume of milk collected, date and time of collection, duration of extraction session, etc. Optionally, if a collection container 60 does not include a sensor 358 with a unique ID that is recognizable to the system 100, then the system will not operate with that collection container.

[00276] Fig. 35 illustrates a milk collection container 60 wherein the connector 62 contains one-way valve 50, according to an embodiment of the present disclosure. With this embodiment, the external shell 34 or tubing 32 would not be provided with the one-way valve 50, but would be provided with a mating connector to connect to connector 62 containing the one-way valve. Whether one-way valve 50 is provided with the connector 62/collection container 60 or provided at the end of tubing 32, the mating connector for connecting to connector 62 can otherwise be the same. Examples of mating connector arrangements can be found, for example in Provisional Application Serial no. 62/027,685. Other examples of connector types that can be used for connector 62 and mating connector include, but are not limited to: bayonet-type, threaded connectors, compression fittings, flared fittings, etc.

[00277] Fig. 36 illustrates a milk collection container 60 according to another embodiment of the present disclosure. In this embodiment, tubing 32 is made integral with the milk collection container 60 and one-way valve 50 as shown. The open end of

tubing 32 is provided with a connector 62 configured to mate with connector 134 of skin contact member 10.

[00278] When a user has completed the pumping phase of extracting milk from a breast 2, it is useful and efficient to purge as much milk that remains in the tubing 32 from the tubing 32 and into the milk collection container 60. Fig. 38 illustrates events that may be carried out to perform a purge according to an embodiment of the present disclosure. At event 3802 the system 100 ends the pumping cycle having been carried out during the extraction phase. Ending of the extraction phase can be performed upon elapse of a predetermined extraction phase time, calculation of a predetermined amount of milk having been pumped, manual cessation of the extraction phase by the operator, or some other predetermined value having been achieved after performing the extraction. At event 3804 the direction of the pumping stroke of compression member 38 is reversed and the compression member 38 is run in the reverse direction to decrease suction within the tubing 32 and optionally create a small positive pressure within the tubing 32 to facilitate removal of the system 100 from the breast 2. Alternatively, the suction may be decreased to a level where a slight suction remains so that the user still pulls the system 100 of the breast 2 to detach it. Preferably the vacuum is reduced to 0mmHg, or a slightly positive pressure to automatically detach the system 100 from the breast 2. The end pressure value where the pressure reduction by reverse pumping is ceased can be in the range of about -20mmHG (weak vacuum) to a positive 50mmHg (e.g., the crack pressure of the valve 50). The compression member 36 does not close off the tubing portion 32S during this process, rather, tubing portion 32S remains open. Initiation of this reverse pumping may occur automatically after executing event 3802 or, alternatively, may be initiated by the user actuating a purge actuator on the optional control panel 166 provided on the system 100 (see Fig. 23). This process continues until the seal of the system 100 to the breast 2 is broken, which is detected by the controller 52 via sensor 54 at event 3806. Once exposure of the tubing 32 to atmospheric pressure is detected at event 3806, the stroke direction of pumping is again reversed thereby pumping the milk in tubing 32 under positive pressure and driving the milk from the tubing 32 into the container 60 at event 3808. At event 3810 the purge process ends. Event 3810 can occur at some predetermined

time after initiation of event 3808, or can be initiated by measuring the compliance of tubing portion 32L and executing event 3808 when the compliance of tubing portion 32L indicates that the contents in tubing portion 32L have a least a predetermined percentage of air therein (such as 90% 95%, 97% or some other predetermined percentage). If by chance, the system 100 accidentally or otherwise becomes resealed to the breast 2 during purge pumping, the system 100 can automatically shut down as it senses vacuum pressure being regenerated in the vicinity of the breast 2/skin contact member 10.

[00279] Figs. 39A-39B illustrate various arrangements that may be provided to the system 100 to help prevent loss of milk out of the system upon detachment of the system 100 from the breast 2. These arrangements can be provided in embodiments that are configured to execute a purge operation in a manner described with regard to Fig. 38 above, but can also be provided in systems 100 that used different purge techniques other than that described with regard to Fig. 38.

[00280] A weak valve 390, such as a flap valve of the like can be provided in small tube portion 32S, near where it connects to the skin contact member 10, as illustrated in Figs. 39A-39B. Valve 390 is very flexible so that it opens in a first direction (upwardly as shown in Figs. 39A-39B) when vacuum is generated in tubing 32. A very small amount of vacuum (much less than latch vacuum, for example about 5-15mmHg) is sufficient to open the valve 390 in the upward direction, see 390A. The valve 390 is sufficiently stiff to remain closed under a positive pressure equal to the hydrostatic pressure generated when the tubing 32 is completely filled with milk. A positive pressure that is generated which is above this hydrostatic pressure by a predetermined amount (e.g., 5-15mmHg positive pressure greater than the positive pressure generated by a full column of milk) forces the valve 390 open in the opposite direction, see 390B (i.e., downwardly, as illustrated in Figs. 39A-39B). With this arrangement, the breast pump system 100 can be unsealed and detached from the breast 2 after extracting milk therefrom and the milk remaining in the tubing 32 will be prevented from escaping out of the skin contact member 10 by the closed valve 390. The system 100 can then be run in a forward stroke motion to generate positive pressure using compression member 38 to drive the milk from the tubing 32 and into the milk collection container

60.

[00281] Additionally or alternatively, a valve or flap may be provided to extend radially inwardly from the bottom portion of the breast contact member 122 as shown in Fig. 39A. When the breast 2 is inserted into the breast contact member 122 for carrying out an extraction session, the breast 2 folds down the flap/valve 522 against the inner wall of the breast contact member 122, see 522-2, When the breast 2 is removed from the breast contact member 122, the flap/valve 522 resiliently returns to is its unbiased position (see 522-1), where it extends radially inwardly and thereby retains milk within the breast contact member 122 that would otherwise have spilled out of the system. By tipping the breast contact member 122 up, the user can cause the milk in the breast contact member 122 to flow into the nipple receiving portion 112 under gravity, where it can be pumped into and through the tubing 32 to be purged into the milk collection container. Further alternatively, flap 522 may be provided with a tacky surface that contacts the breast 2 so as to assist in providing tension to the breast 2 to control the amount of breast tissue that enters the nipple receiving portion 112, similar to the function of the tacky regions 360 described above. Further optionally or additionally, the stiffness or strength of the valve/flap 522 can be such that the breast contact member 10 has to be pressed against the breast 2 to deflect the valve/flap 522, which thereby establishes tension. Still further, flap 522 can be provide at both top and bottom locations of the breast contact member 122 (rather than just at the bottom as shown in Fig. 39A), or at other locations intermediate the top and bottom, or could be formed continuously around the entire perimeter of the breast contact member 122.

[00282] Figs. 40A-40B illustrate two different cross-sectional views of a contour element 410 provided with a breast pump system 100. Contour element 410 extends distally from the distal perimeter 34D of the external shell 34 and proximally extends over the distal portion of external shell 34 to provide a contoured extension of the external shell that provides a visually more appealing appearance the more closely mimics the natural appearance of a breast 2 supported by a bra. The contour element 410 tapers 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 contour member 410 can be configured to snap around the

circumference of the main body 34 of system 100 or form a friction fit therewith, for example.

[00283] Fig. 40A shows a cross-sectional view illustrating the upper and lower portions of the contour element 410. Fig. 40B shows that contour element on the left and right sides of the external shell 34. The embodiment shown in Fig. 40B is for the right breast. A contour element for the left breast would be a mirror image of that shown in Fig. 40B, as, in both cases, the contour element 410 has a lateral portion 410A that extends further distally from perimeter 34D than the distance that medial portion 410B extends distally from the perimeter 34D. The lateral portions of the systems 100 are contoured more by the contour element 410 then are the medial portions, as the medial portions are where the cleavage of the breasts is formed, so deviation from the natural appearance is less visible on the medial sides. Further, the medial extensions are less as there is less space to extend into. Additionally, the contour element 410 may extend over a portion of the proximal end portion of the external shell 34 to provide additional "flatness" to the proximal end of the system 100 to make it appear more like a natural breast 2 as opposed to a more pointy "ice cream scoop" shape, Although the sections of component 410 in Figs. 40A-40B are illustrated as solid material in Figs. 40A-40B, such as being made of foam, plastic, or other lightweight material, they could alternatively be made hollow, or even made of one layer of material to provide the same contouring shapes. Thus a single thin layer of plastic or fabric could be alternatively used, for example as illustrated in Figs. 41A-41B. The material of the contour element 410 may be resilient so that if it is depressed or distorted, it will naturally spring back to a contour that appears natural.

[00284] Attachment members 412 such as snaps, hook-and-loop type fasteners, buttons, magnets or other attachment members may be provided on one, or preferably more than on locations of the external shell 34 and internal surface(s) of the contour element 410 to ensure securement of the contour element 410 relative to the external shell, and to ensure that the proper orientation of the contour element 410 relative to the external shell 34 is achieved each time they are connected, so as to provide the desired appearance,

[00285] Fig. 42 illustrates an embodiment of a contour element 410 fitted on an external

shell 34 in which the external shell 34 is provided with a key 34K that ensures that the contour element 410 is properly oriented on the external shell 34 each time the two components are mated. The contour element 410 has a mating key 410K that mates with key 34K and ensures that the contour element 410 position relative to the external shell 34 does not rotationally vary nor does it vary superiorly, inferiorly, laterally or medially, but rather is positioned substantially exactly the same relative to the external shell 34 each time it is mounted thereover. As shown, the key 34K extends from the surrounding surface of the external shell 34K and the mating key 410K is an opening in the contour element 410 that mates to the mating key 34K. Alternatively key 34K could be formed as a depression in the external shell 34 and mating key 410K could be a ridge extending inwardly (or a solid shape extending inwardly) from the surrounding inner surface of the contour element 410 and shaped to mate with key 34K. It is further noted that the shapes of the key 34K and mating key 410 are not limited to those shown, but could be any shape that ensures that the contour element 410 can be mounted to the external shell 34 in one orientation and position. Further, the key 34K and mating key 410K do not need to be centrally located, but could be at any location on the external shell 34 (and corresponding location of contour element 410). Also, multiple keys 34K and mating keys 410K could be provided at multiple locations.

[00286] The contour element can be adjustable, so that it can be adjusted for a best fit relative to the breast 2, and so that it can be fitted to different sizes and shapes of breasts 2 and still provided a more natural appearance in each case. Fig. 43 illustrates an embodiment of contour element in which a first edge 414 of the contour element 410 overlaps a second edge 416, and can be adjusted to reduce, increase or maintain the circumference of the distal perimeter 410D, while at the same time reducing, increasing or maintaining the proximal perimeter 410P. After adjustment, the first edge 414 can be fixed to the underlying surface of the contour element 410 that it overlies, such as by use of hook-and-loop type fasteners, snaps, adhesive, or the like. The contour element can be further tailored for a better fit, if needed, but cutting away all or a portion of the distal perimeter 410D to a length desired, so as to adjust the length by which the contour element 410 extends from the distal perimeter 34D on the top, bottom and sides of the device. All of these distances can be tailored to be as

needed.

[00287] Fig. 44 illustrates an embodiment of contouring element 410 provided with predetermined markings that may be provided to assist the user in adjusting the contouring element 410 to better contour to the breast 2 that it is to be used on. For example, markings 418, 420, 422 and 424 can be provided as suggested starting locations for placement of the edge 414 overlapping edge 416 and placed at the appropriate marking for D cup, C cup, B cup and A cup sizing, respectively. Markings 426, 428 and 430 are suggested locations to cut away the distal edge 410D to fit 36", 34"" and 32" breasts 2, respectively.

[00288] Fig. 45A illustrates an embodiment in which external shell 334 is provided with two keys 34K1 and 34K2. The contour element of Fig. 45B is provided with mating keys 410K1A and 410K2 that are configured to mate with keys 34K1 and 34K2, respectively, when the contour element 410 is in a first sizing configuration. Additional mating keys 410K1B and 410K1C are provided to mate with key 34K1 when the contouring element 410 is adjusted in a manner described above to better contour with smaller size breasts 2. Although two additional mating keys 410K1 and 410K2 are shown, more or fewer can be provided where more or less adjustability is needed. Likewise, additional mating keys could be provided for 410K2, in addition to, or alternative to the provision of multiple mating keys 410K1.

[00289] Figs. 46A-46B illustrate a contour element 410 according to another embodiment of the present disclosure. In this embodiment, contour element 410 is made of an easily compressible material such as a light, resilient foam that readily conforms to the shapes of objects that it is compressed against. In the embodiment shown, the contour element 410 is a substantially straight plate-shaped element that tapers at its ends, but other shapes could be employed. The center portion of the contour element 410 can be attached to the external shell 34 as shown in Fig. 46A, using any of the connectors, adhesives or the like described previously. When the system 100 is supported by a bra 440 as shown in Fig. 46B, the contour element 410 contours to the external shell 34 of the system, and also contours to the bra 440, thereby providing a natural breast shaped appearance. Further alternatively, the contour element 410 of Fig. 46A could be made thinner and would not be required to

contour to the external shell 34, as the bra 440 provides a contouring shape.

[00290] The system 100 can be configured to distinguish whether it has been attached to the left breast 2 or the right breast 2 of the user. This can be useful for tracking milk volume output per breast, per session, total daily volume per breast, etc. When using two of the pump systems, the tracking of data for each breast can still be maintained accurately, even when one of the pump systems 100 is attached to the left breast during a current pumping session after having been attached to the right breast during a previous pumping session. In one embodiment, the pumping systems 100 can establish current location (i.e., left or right breast) by receiving a signal from the other pumping system having been attached to the other breast 2. This established relative left-right locations of the two pumping systems 100, so that each system 100 can accurately record as to whether milk is being extracted from the right breast 2 or left breast 2. This identification is automatic, without any user input required and it also relieves the burden on the user to otherwise keep track of which pump system 100 is placed on each breast and to maintain this order with each successive pumping session.

[00291] An orientation signal, such as by Wi-Fi, BLUETOOTH, BLUETOOTH Low Energy (BTLE), RFID, NFC or the like may be used to automatically determine which pump 100 is on which breast 2. One or more magnetic coils 450 may optionally be provided in each pump system 100 (e.g., see Fig. 23) such that the relative positions of the pump systems 100 can be determined to each other by the signal, akin to the way that surgical tracking is performed with coil magnetic sensors. By placing magnetic coils on the left and right sides of the pump systems 100, and running a small current through the coil 450 in one of the pump systems 100, the current induces a signal in the coil 450 in the other pump system 100. The signal strength is low and is only induced when the breast pump systems are close together, such as when mounted on adjacent breasts 2. This signal can be used to determine the relative locations of the pump systems 100, i.e., which system 100 is mounted on the left breast 2 and which system 100 is mounted on the right breast 2.

[00292] The system 100 can calculate the pressure during operation in any of the manners described above. The suction (pressure) level can be varied as desired, and by continuously or repeatedly measuring/calculating pressure, the feedback provided by

sensor(s) 54 to controller 52 provides a control loop that can be used to adjust the compression member 38 position and/or speed to vary the suction pressure to a level desired, or maintain a desired suction pressure. Thus, controller 52 can control the positions and speeds of compression members 36, 38 to achieve any vacuum pressure pumping profile desired, and provide automatic, real time adjustments to maintain a desired vacuum pressure within the system.

[00293] The controller 52 tracks the position of the compression member 38 relative to the tubing 32L, such as by keeping track of the driver 46 position or shaft position (interconnecting linkage between driver 46 and compression member 38), and calculates (or looks up) pressure based upon data received from sensor 54. Thus, changes in position and/or speed of the compression member 38 by controller 52 can be controlled by resulting changes in pressure calculated or looked up, relative to the pressure sought to be achieved. Controller 52 can control compression member 36 in a similar manner, but control of member 36 is more focused on position control, as the compression member 36 needs to fully close off tube portion 32S when maintaining latch suction against the breast 2/nipple3. However, the closing off is timed and performed at the determined latch pressure, which is known from the data received from sensor 54.

[00294] During extraction, the compression member 38 cycles between latch suction and maximum suction to extract milk from the breast 2. The suction level of the maximum suction can optionally be adjusted to the comfort of the user, anywhere between latch suction pressure to a maximally allowed suction pressure, such as -250mmHg or some other predetermined maximally allowed suction pressure. As the tubing 32 receives more and more milk volume, the compression member moves farther and farther in the direction away from tube portion 32L to achieve/maintain maximum suction. As the compression member 38 begins to near its position limit away from the tube portion 32L (near the fully uncompressed state of tube portion 32L), the controller 52, knowing the position of the compression member 38 at all times, controls the driver 46 to purge the milk currently held in the large tube portion 32L, by driving the compression member 38 to its opposite position limit (where it compresses the large tube portion 32L the most). This reestablishes, or resets the

compression member, so that it again can establish the maximum suction level without nearing its position limit. This process is repeated each time the compression member 38 comes within a predetermined distance from its position limit.

[00295] Fig. 47 illustrates events that may be carried out by the system 100 during an extraction mode of pumping milk from a breast. At event 4702, after latch and let down of milk have been achieved, the system begins operating in extraction mode. In extraction mode, the system cycles between latch suction (e.g., about 55mmHg, or a value preselected from the range of about 25mmHg to about 80mmHg suction) and maximum suction (e.g., about 150mmHg, or a value preselected from the range of about 130mmHg to about 200mmHg suction). The pumping cycle may be a regular, continuous cycle, or may be pre-programmed to provide some irregularity, such as occasional pauses in pumping action to simulate when a breastfeeding baby pauses to take a break before resuming suckling. The cycle speed of the pumping action is predetermined in the embodiment, such as 60 cycles per minute, or some other predetermined rate. Optionally, the operator may be able to set or adjust the cycle speed to be used when initiating the extraction mode and/or at any time during operation in extraction mode. The controller 52 monitors the pressure waves within the system 100 at event 4704 and the motion of the compression member 38. If there has been no expression of milk, the pressure wave profile and the motion of the compression member 38 are fairly consistent, with little or no changes in end points of the travel of the compression member. As milk enters the system, the controller will need to move the compression member further to achieve the same target maximum vacuum level and this change in the pressure versus compression member 38 position relationship is identified by the controller as an indicator that milk has entered the tubing 32. When substantially no change in the pressure versus compression member 38 position has occurred, pumping continues with the current pumping cycle parameters as to speed and movement of the compression member 38. When the pressure versus compression member 38 position changes, such as due to milk entering the system, the controller 52 at event 4704 identifies the change in the relationship between compression member 38 position and vacuum pressure achieved, via feedback from sensor 54 and monitoring of the motor, gear train and/or compression

member positions, and adjusts the speed, travel range and/or position of compression member 38 at event 4708 in an effort to maintain the desired pressure profile, cycling between latch vacuum and maximum vacuum levels. If no pressure/position relationship change (within a predetermined minimal range) is sensed at 4704, then the system continues pumping with the current cycle control parameters at event 4706.

[00296] At event 4710 the controller checks to determine whether the outward position limit of the compression member 38 has been reached during the attempt to maintain the system operating according to the predetermined pressure profile. If the position limit has been reached, then the controller 52 at event 4712 controls the system to perform a purge procedure by reducing the pressure to latch pressure; sealing off tubing portion 32S by compressing it with compression member 36, and operating driver 46 to drive the compression member 38 inwardly against the tube portion 32L to the other position limit to purge the milk from the tube portion 32L and then processing proceeds to event 4714. If the position limit has not been reached at event 4710 then processing proceeds directly to event 4714. At event 4714 the pressure is again checked to see if predetermined pressure parameters have been achieved. If the pressure profile has been returned to target (the predetermined pressure profile) then the controller checks to see whether processing should continue at event 4716. Optionally, event 4716 can be omitted and the extraction mode can be ended manually by the operator. Even when event 4716 is adopted, the user can manually stop the extraction mode at any time by actuating a manual switch on control panel 166. Extraction mode pumping may automatically end after a predetermined time period, or when some other event has been achieved. For example, flow of milk can be calculated based upon the pressure change calculations made by the controller, and total volume of milk extracted can also be calculated. Accordingly, extraction mode pumping can be ended after a predetermined volume of milk has been pumped, for example, or when the controller 52 estimates that the milk flow has diminished below a predetermined flow rate for a determined amount of time. Further alternatively, the system 100 can be automatically shut down after the controller 52 determines that a predetermined time period (e.g., one minute or some other predetermined time period) has elapsed during which there has been zero flow of milk. Further alternatively, the

system can be automatically shut down after the controller 52 has determined that a combination of events have occurred, e.g., after five minutes if flow is at zero for at least one minute, or some other predetermined combined logic.

[00297] If extraction mode is to continue at event 4716, the processing proceeds to event 4704. If extraction mode is to end, then the process ends at event 4718. If the predetermined pressure profile has not been achieved at event 4714, the processing proceeds to event 4708.

[00298] A build supply mode can be programmed into the system that can be used by the user to help increase milk production. Using characteristics of the system 100, when in build supply mode, with a milk extraction volume goal having been set, the system 100 will conduct the pumping session including the extraction mode as usual, but once the historical volume has been achieved, the system 100 will continue pumping with pumping characteristics that simulate a hungry, growing baby such as increasing the maximum suction and holding that level for slightly longer during a pumping cycle to simulate a baby trying to draw more milk out of the breast 2, before shutting down.

[00299] In another embodiment, the predetermined pumping cycle speed of the system 100 in extraction mode can automatically increase according to the age of the user's baby. It has been found that the sucking frequency of a newborn infant is slower than that of the same baby at six months old, for example. By tracking the age of the user's baby, the controller 52 can automatically scale the increase of the predetermined pumping cycle speed to the age of the user's baby. Thus, for example, when using the system 100 when the user's baby is a newborn, the cycle speed might be 60 CPM (cycles per minute), and might be 65 CPM when the baby is two months old, and might be 70 CPM when the baby is six months old. These numbers are only exemplary and the disclosure is not to be limited to them, as the more general concept of automatically increasing the predetermined cycling frequency based on age of the baby is what is disclosed.

[00300] If the total volume of the tubing 32 and skin contact member 10 (minus the volume occupied by the breast 2 and nipple 3) is represented as T and the volume that is displaceable by compression member is represented as P, then P should be greater

than 16.2% of T for purposes of this disclosure, i.e., P/T>.162

[00301] Fig. 48 illustrates a nipple shield 480 according to an embodiment of the present disclosure. Nipple shield 480 can be attached to the breast 2 as shown in Fig.48 (such as by suction, reattachable adhesive, etc.) to cover the nipple 3 when the mother is breastfeeding her baby. One of more openings 482 are provided in the tip region of the nipple shield 480 to allow the baby to draw milk through the nipple shield 480. The tip portion 484 that overlies the nipple 3 and at least part of the areola 4 is made much thinner than the attachment portion 486 that surrounds the tip portion 484. For example, the nipple shield 480 may be made of a single material, such as silicone, or other biocompatible elastomer with similar elasticity properties, with the tip section being about 0.25mm in thickness (or in the range of about 0.1 mm to about 1mm), while the attachment portion 486 may have a thickness in the range of about 2mm to about 5mm. This provides the attachment portion 486 with more structural support and a better retention ability on the breast 2, while the thinner tip portion 484 can easily expand, thereby providing minimal resistance to the engorgement of the nipple 3 and areola 4, so as not to restrict the milk flow from the breast.

EXAMPLES

[00302] The following examples are put forth so as to provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the present disclosure, and are not intended to limit the scope of what the inventors regard as their disclosure nor are they intended to represent that the experiments below are all or the only experiments performed. Efforts have been made to ensure accuracy with respect to numbers used (e.g. amounts, forces, pressure, etc.) but some experimental errors and deviations should be accounted for.

EXAMPLE 1

[00303] Testing was done on a light body vinylpolysiloxane breast flange (Danville Star VPS #80011-01 (manufactured by Danville Materials in Ramon, CA), to determine the relationship between force applied to the nipple receiving portion 494 and pressure (vacuum) within the nipple receiving portion 494. The nipple receiving portion 494

was immobilized by a support 496 and a predetermined force was applied by a load cell 490 (see Fig. 49 to the nipple receiving portion 494 opposite the supported side of the nipple receiving portion 494. A stopper 498 was used to allow establishment of a vacuum within the nipple receiving portion 494 and a tube 502 was used to connect syringe 504 and pressure gauge 506 in fluid communication with the interior space of the nipple receiving portion 494. Various runs were made with different preload forces applied to the nipple receiving portion 494 by load cell 490, ranging from 1.5N to 4N, which corresponded to preload displacements (at atmospheric pressure) of the wall of the nipple receiving portion ranging from -1.41mm to -11.60 mm, see Fig. 50. The pressure changes in the nipple receiving portion 494 generated by withdrawing the plunger of syringe 504 were measured by pressure gauge 506 and recorded and plotted relative to the forces on the nipple receiving portion measured by the load cell 490.

[00304] Fig. 50 shows the plotted results, with the recorded data points interconnected by best fit lines to show that the data shows a substantially linear relationship between pressure (vacuum) 510 within the nipple receiving portion 494 and force 512 measure on the external surface of the nipple receiving portion 494. As the vacuum increased (pressure decreased), the force exerted by the nipple receiving portion on the load cell sensor 490 decreased according to a linear force-pressure relationship.

EXAMPLE 2

[00305] The arrangement of Example 1 was modified to test the dynamic force-pressure relationship of the system. An oscilloscope 508 (see Fig. 51) was electrically connected to receive output pressure reading and force readings from pressure gauge 506 and load cell/sensor 490 respectively. Like Example 1, preload displacements at atmospheric pressure were varied for different runs of the test, ranging from -11.60mm to -1.41mm. For each run, the vacuum was cycled between high vacuum to low vacuum three times. For each run, the force exerted by the nipple receiving portion on the sensor of load cell 490 was observed to decrease as the vacuum increased, according to a substantially linear force-pressure relationship. Fig. 52 shows a plot of vacuum 512 and force 514 plotted as voltage received by the oscilloscope 508 versus time, for the run with the preload displacement of -11.60mm. It can be observed that

the force 514 decreases linearly proportionally to the increase in vacuum 512 and vice versa. The same can be observed in Fig. 53, which plots vacuum 512 and force 514 as voltage received by the oscilloscope 508 versus time, for the run with the preload displacement of -1.41mm. Similar results were observed for additional runs having initial displacements of -10.47mm, -8.50mm. -7.47mm, -6.22mm, -5.65mm, -3.54mm, -4.69mm and -2.44mm, respectively. I

EXAMPLE 3

[00306] The arrangement of Example 1 was modified to test the relationship between the position of a target location of the nipple receiving portion 494 and vacuum level within the nipple receiving portion 494, see Fig. 54. In this Example, the load cell 490 of Example 1 was replaced by a marker block 516 preloaded against the nipple receiving portion 494 with a spring 518 at atmospheric pressure. Upon pulling a vacuum in the system by withdrawing the plunger of the syringe 504, the marker block 516 moves with the wall of the nipple receiving portion 494 as it flexed inwardly due to the reduction in pressure.

EXAMPLE 4

[00307] The arrangement of Example 1 was modified to test the relationship between the position of a target location of the nipple receiving portion 494 and vacuum level within the nipple receiving portion 494, see Fig. 55. In this Example, the load cell 490 of Example 1 was replaced by a first and second marker block 522, 524, connected by arms to a potentiometer 520, with the first marker block 522 being fixed to a stationary reference location and the second marker block 524 being fixed to the nipple receiving portion 494 and thus movable directly with movements of the nipple receiving portion. The second marker 524 was preloaded against the nipple receiving portion 494 at atmospheric pressure. Upon pulling a vacuum in the system by withdrawing the plunger of the syringe 504, the marker block 524 moves with the wall of the nipple receiving portion 494, relative to the fixed marker block 522, as the nipple receiving portion 494 is flexed inwardly due to the reduction in pressure. The movement of marker 524 angularly moves the arm 526 relative to arm 528 and this angular

movement was registered by the potentiometer and sent to oscilloscope 508. The change in angle 530 was measured by the potentiometer, and the linear change in the distance 532 between the position of marker 524 and marker 522, can be calculated by a difference in the original distance 532 and the distance corresponding to the angle calculated from the angle change measured, relative to the original angle.

[00308] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure.

CLAIMS:

That which is claimed is:

1. An automated method of pumping milk from a breast, the method comprising:

providing a breast pump system including breast contacting structure and a collection container;

forming a seal between the breast pump system and the breast; and

pumping milk expressed from the breast to the collection container;

wherein the milk is pumped upwards from the breast and routed to the collection container.

2. The method of any preceding claim, further comprising maintaining at least a latch suction on the breast throughout a pumping cycle.

3. The method of any preceding claim, further comprising a tube in communication with the breast contacting structure, wherein the tube is substantially directed upwards so that milk extracted from a breast flows upwardly upon exiting the nipple.

4. The method of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.

5. The method of any preceding claim, wherein the collection container is formed to maintain a continuously convex appearance even when the collection container is empty.

6. The method of any preceding claim, further comprising limiting nipple motion to reduce risk of irritation.

7. The method of any preceding claim, wherein the system includes a nipple receiving portion, wherein the nipple receiving portion is configured to restrict an areola from completely entering the nipple receiving portion.

8. The method of any preceding claim, wherein the system includes a nipple receiving portion, wherein the nipple receiving portion includes a non-tapering portion attached to a breast contact portion, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

9. The method of any preceding claim, wherein the system includes a breast contact portion having a first central longitudinal axis and a nipple receiving portion having a second central longitudinal axis, wherein the first and second central longitudinal axes intersect.

10. The method of any preceding claim, further comprising providing a controller, the controller remotely controlling operational settings of the breast pump system.

11. An automated system for controlling pumping cycles to pump milk from a breast, the system comprising:

a breast contacting structure configured and dimensioned to form a seal with the breast;

a collection container for storing the milk pumped from the breast; and

a tube in fluid communication with the collection container, the tube extending upwardly;

wherein milk extracted from the breast flows upwardly from the nipple.

12. The system of any previous claim, wherein the milk is pumped through the tube against gravity.

13. The system of any previous claim, wherein at least a latch suction is maintained throughout a pumping cycle.

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, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.

16. The system of any preceding claim, further comprising a nipple receiving portion including a non-tapering portion attached to the breast contacting structure, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

17. The system of any preceding claim, wherein the non-tapering portion is cylindrical and the tapering portion is conical.

18. The system of any preceding claim, wherein the non-tapering portion is ovular or elliptical in cross section.

19. The system of any preceding claim, wherein the tapering portion is ovular or elliptical in cross section.

20. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is under 1mm.

21. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is less than about 2mm.

22. The system of any preceding claim, further comprising a controller, the controller controlling sensing pumping function and modifying pumping to reach target waveforms in response to changes in one or more of flow, gravity, and movements and positions of the user.

23. The system of any preceding claim, wherein the nipple receiving portion is configured to contact an upper surface of a nipple and a bottom part of the nipple receiving portion is configured to contact a lower surface of the nipple, wherein the top part is formed of a material having a first hardness and the bottom part is formed of a material having a second hardness, the fist hardness being greater than the second hardness.

24. The system of any preceding claim, wherein the routing the extracted milk upwardly facilitates removal of air from the collected milk.

25. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is from under 1mm to less than about 2mm.

26. The system of any preceding claim, further comprising a nipple receiving portion, wherein the nipple receiving portion is configured to restrict an areola from completely entering the nipple receiving portion.

27. The system of any preceding claim, further comprising a resilient flap extending radially inwardly from a breast contact structure, wherein when the breast is inserted into the breast contact structure, the breast folds down the flap and the flap returns to an unbiased position and extends radially inwardly, thereby retaining milk within the breast contact structure.

28. The system of any preceding claim, further comprising a compression member functioning to facilitate pumping of milk, and a controller monitoring pressure feedback information and at least one of position and speed of movement of the compression member to ensure that predetermined pressure cycles continue to be generated.

29. The system of any preceding claim, further comprising a compression member configured to facilitate pumping of milk, predetermined pressure cycles including extraction mode pressure cycles, and a controller that increases stroke distance of the compression member relative to an amount of milk being extracted to maintain predetermined pressures during an extraction mode pressure cycle.

30. The system of any preceding claim, further comprising a time based indicator indicating passage of time.

31. The system of any preceding claim, further comprising a nipple shield.

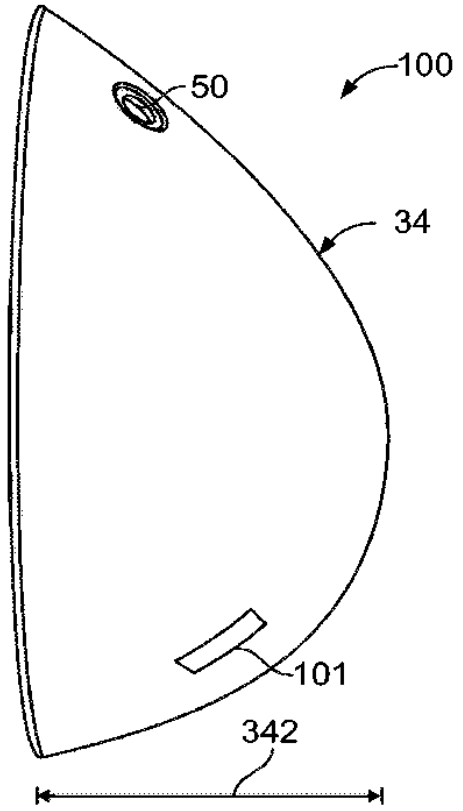


FIG. 1

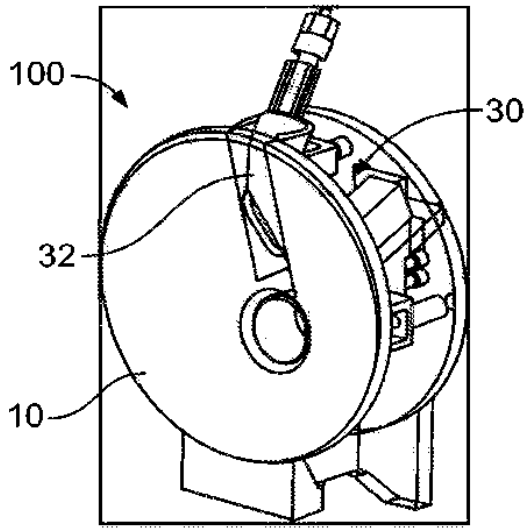


FIG. 2

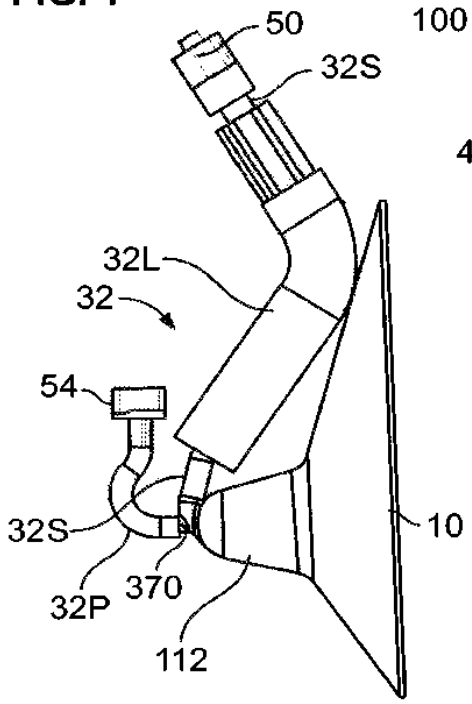


FIG. 4

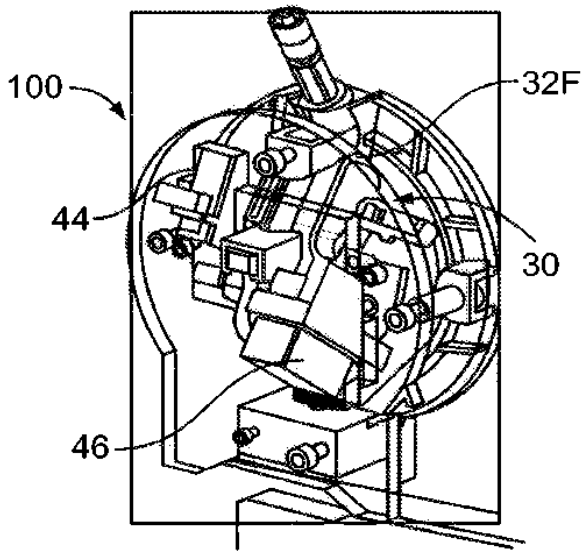


FIG. 3

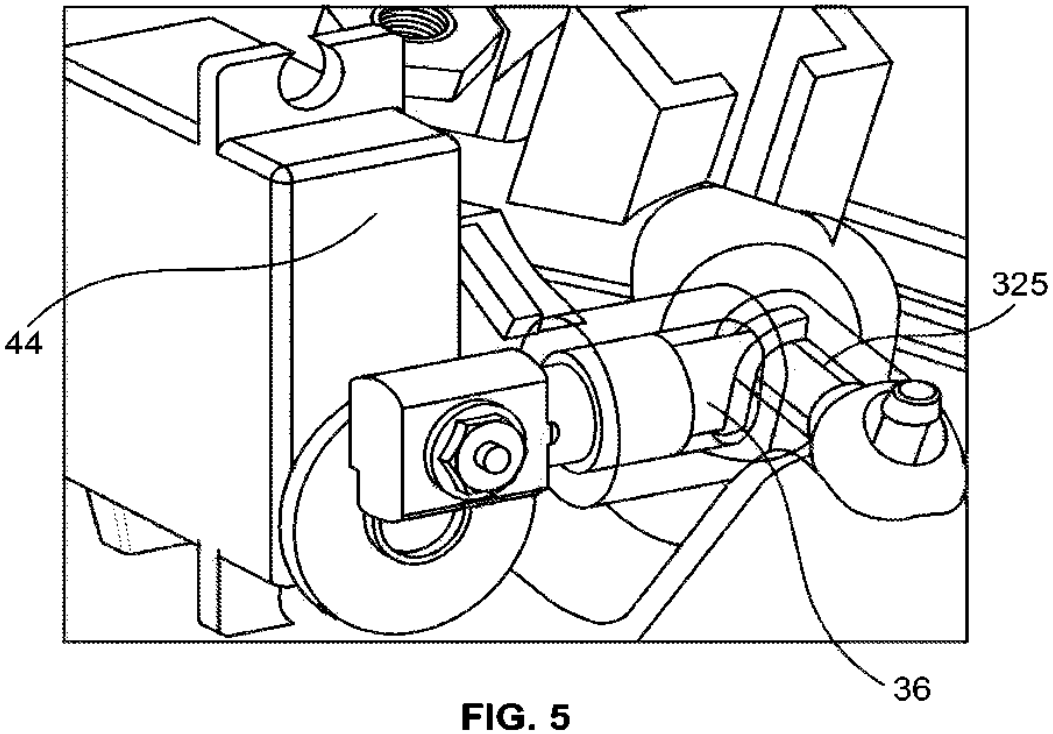


FIG. 5

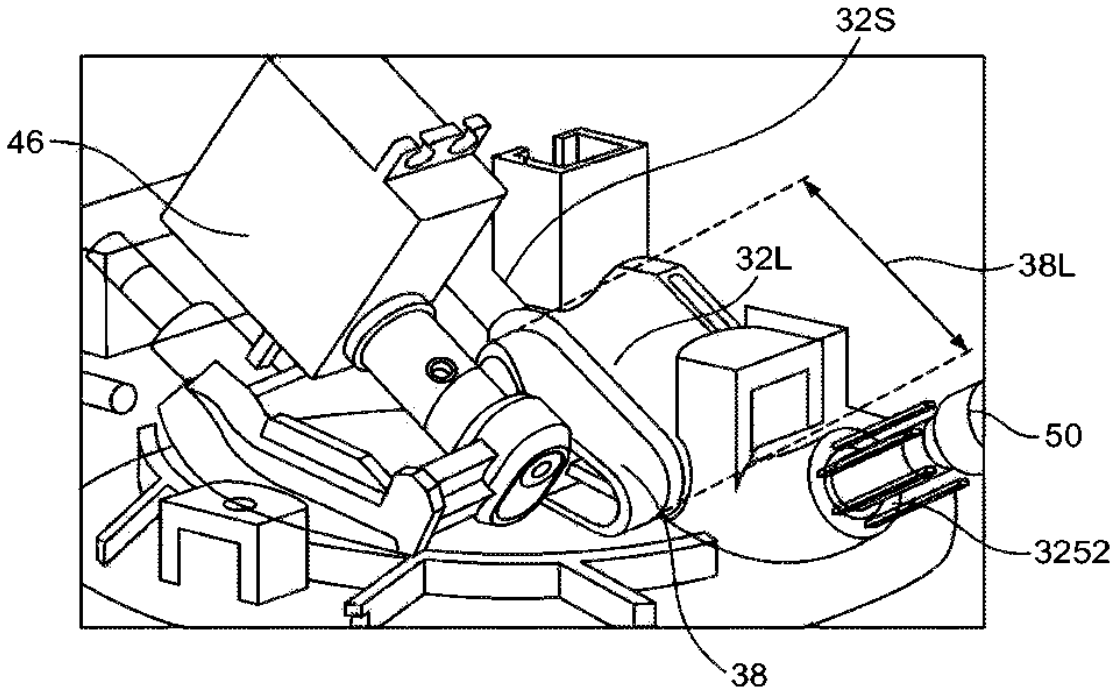


FIG. 6

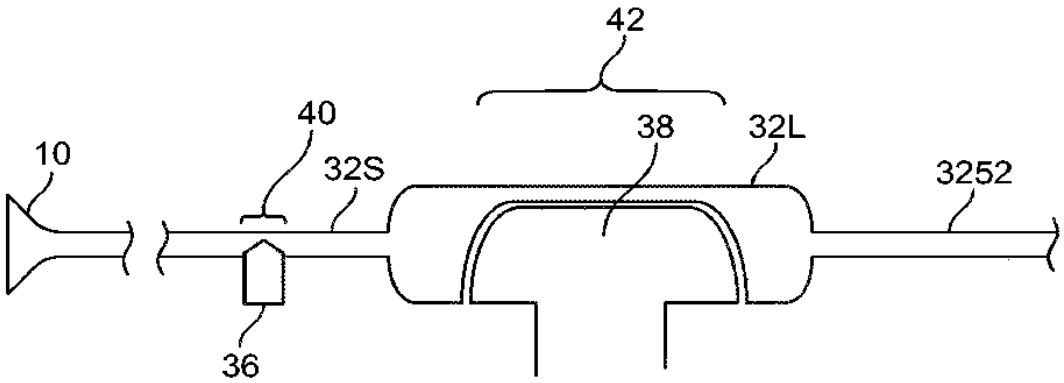


FIG. 7A

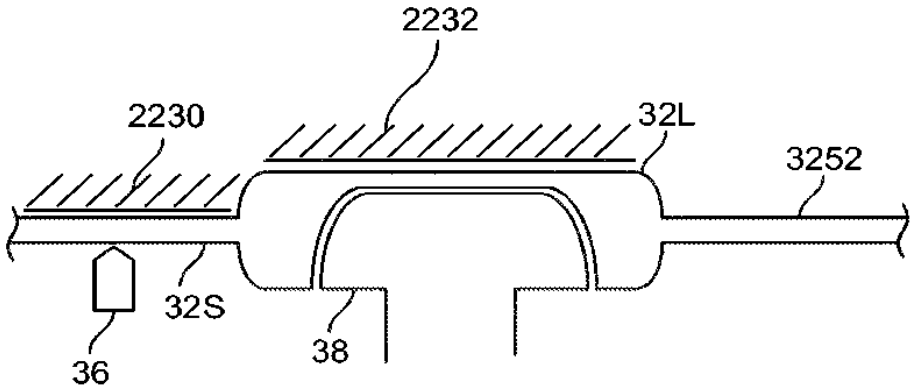


FIG. 7B

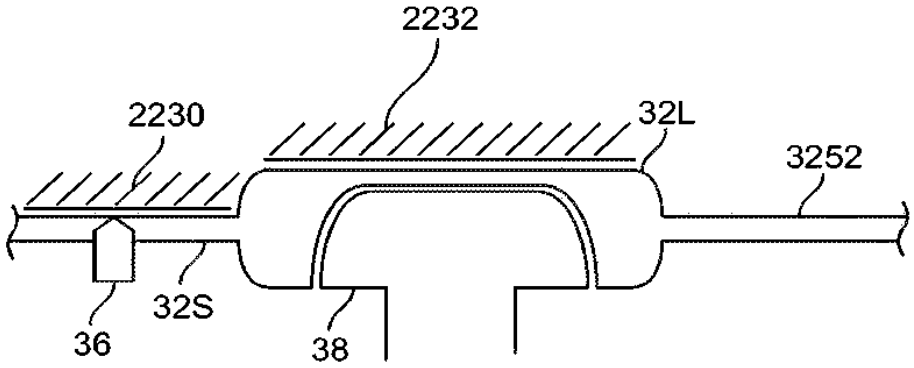


FIG. 7C

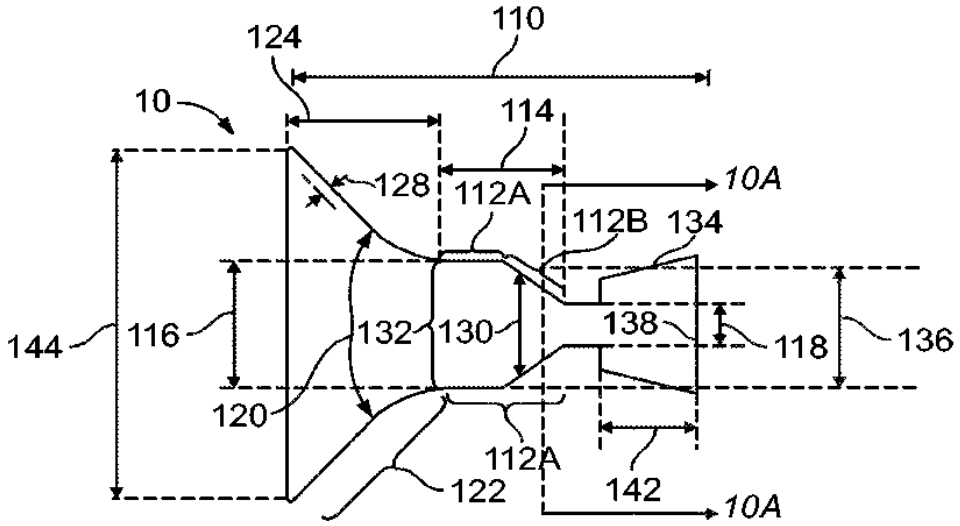


FIG. 8

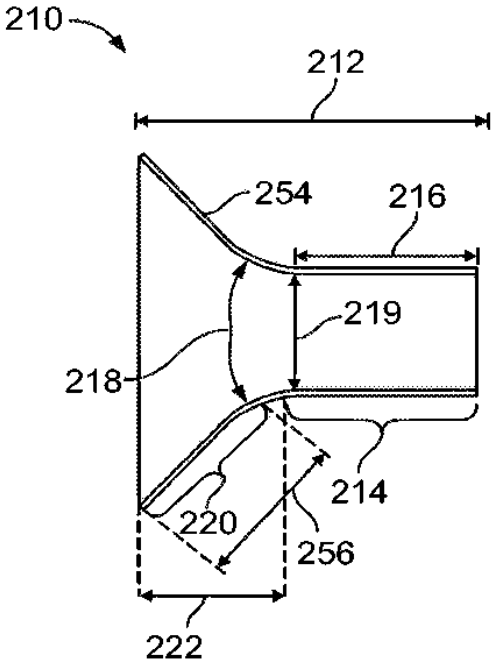


FIG. 9
PRIOR ART

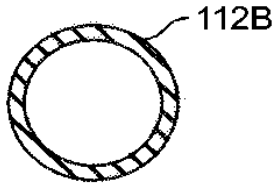


FIG. 10A



FIG. 10B

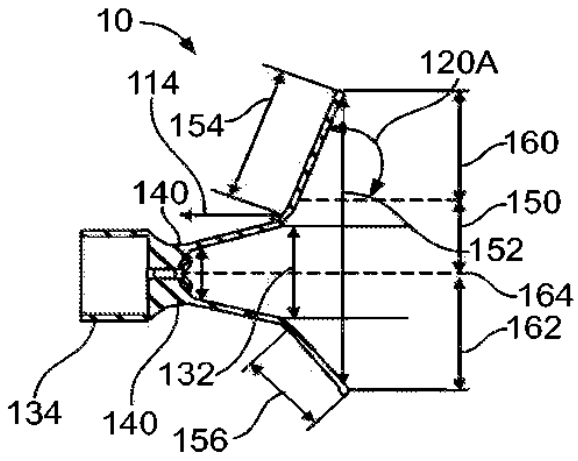


FIG. 11A

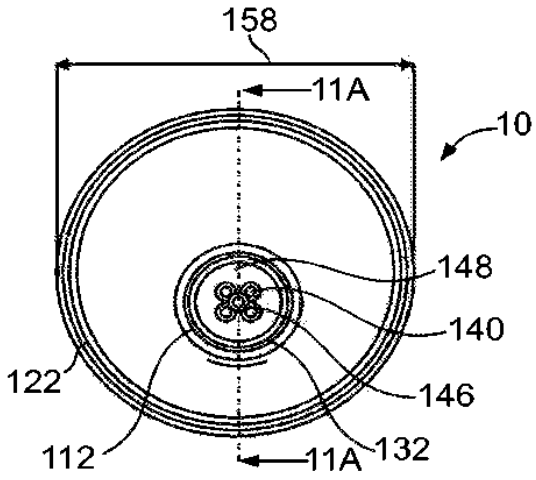


FIG. 11B

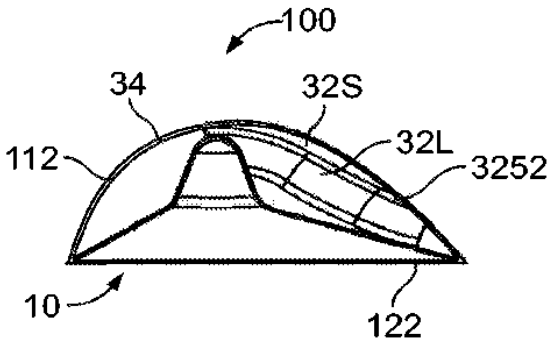


FIG. 12A

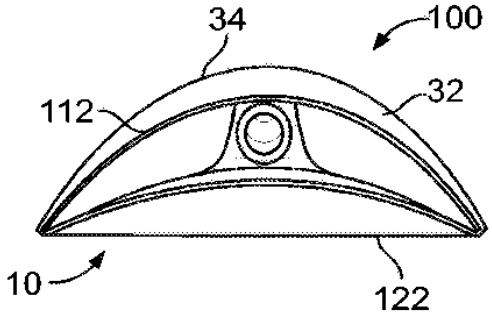


FIG. 12B

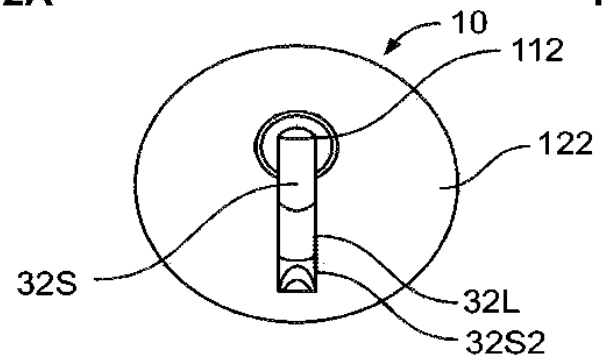


FIG. 12C

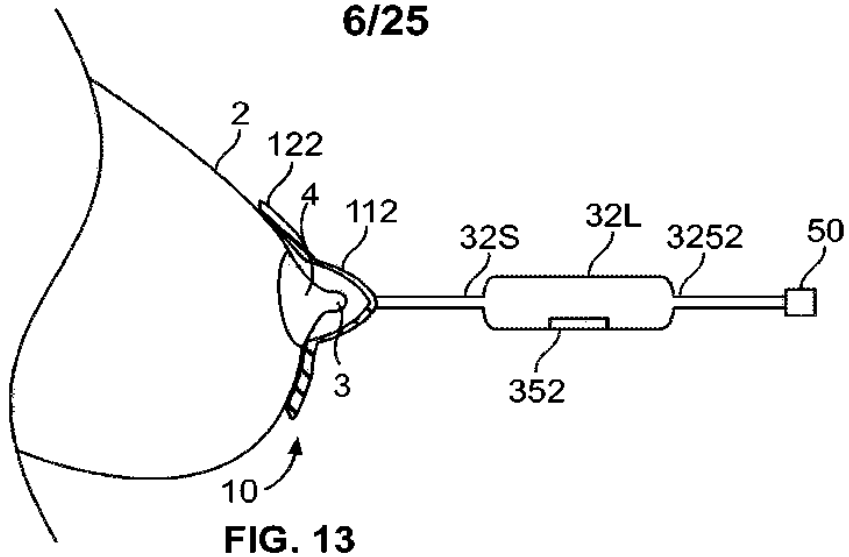


FIG. 13

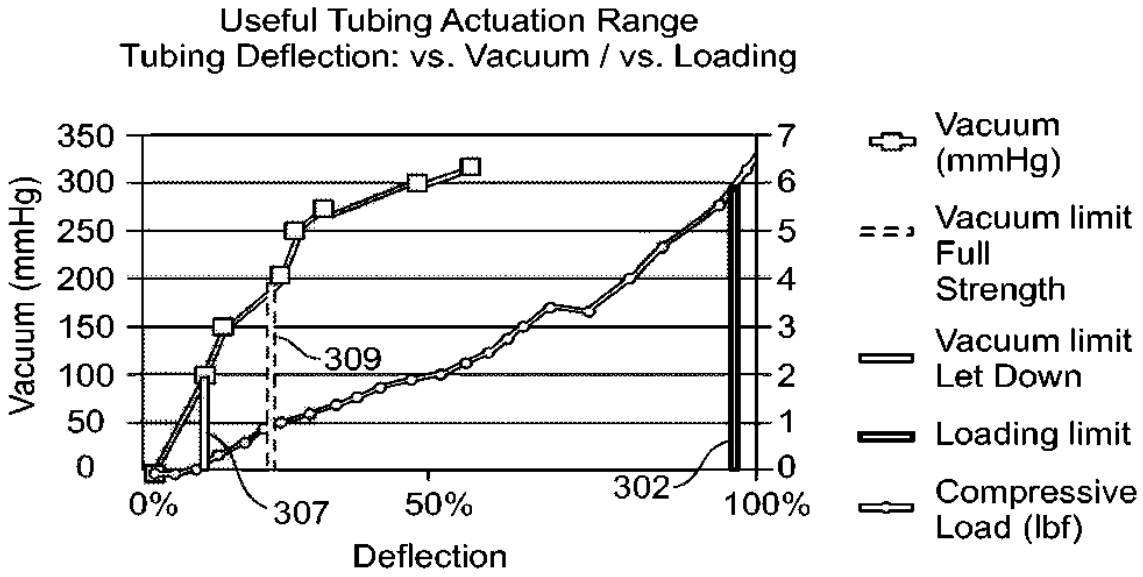


FIG. 15

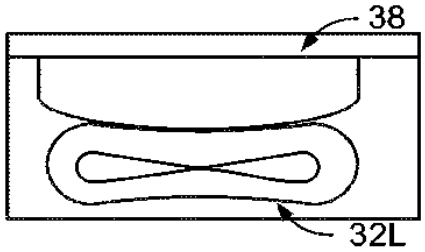


FIG. 16

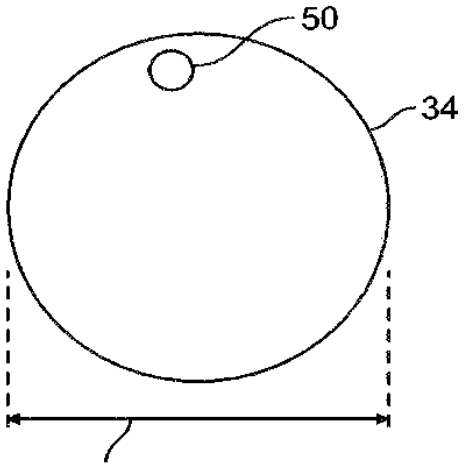


FIG. 18

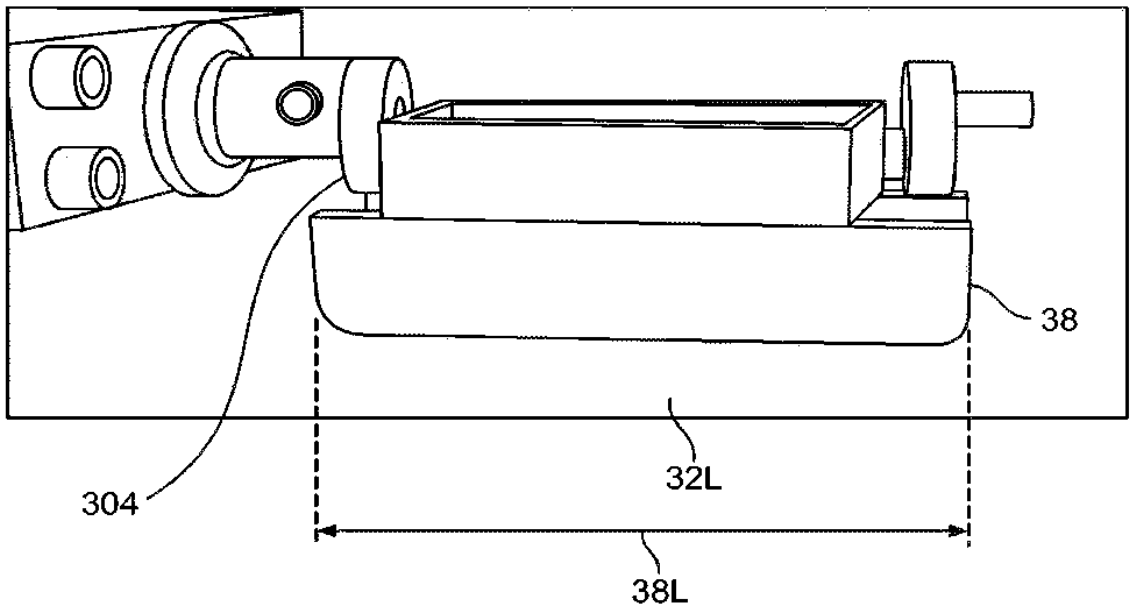


FIG. 14

Run Time	minutes	hours	sessions
Single Session	15	0.250	1
Full Day	60	1.000	4

	Voltage (V)	MAX Current (A)	Average Current (mA)	Required capacity-single session (mAh)	Required Capacity-full day (mAh)
Alkaline - C(x4)	6	0.83	440	110	440
	330	334	332	336	338

FIG. 17

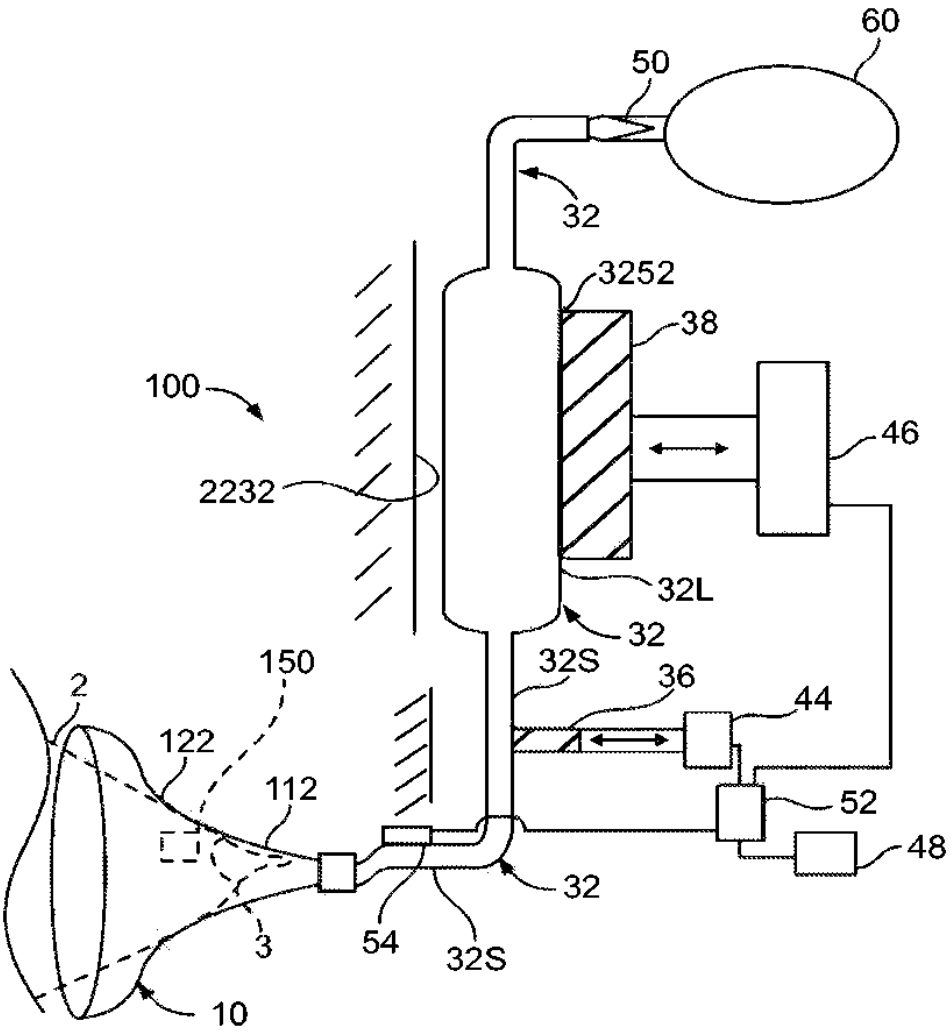

60
50
32
3252
38
100
46
2232
32L
32
150
32S
36
44
2
122
112
52
48
32
3
54
32S
10

FIG. 20

			Option 1	Option 2	Option 3	Option 4
Tubing Dimension	ID (in)		0.375	0.313	0.250	0.375
	OD (in)		0.563	0.439	0.376	0.563
350	Tubing Dead Volume(cc)		2.36	1.56	0.63	10.7
	Length of compression member 38 (mm)		23	35	40	62
	Active Pumping Volume(cc)-A		1.64	1.73	1.30	4.8
356	Total Tubing Volume (cc)-B		4.00	3.29	1.93	15.5
352	Nipple Dead Volume(cc)-B-C		1.80	1.80	1.80	14.1
354	Pump/ Total Volume Ratio: A/(B+C)		28.3%	34.0%	34.9%	16.2%

FIG. 19

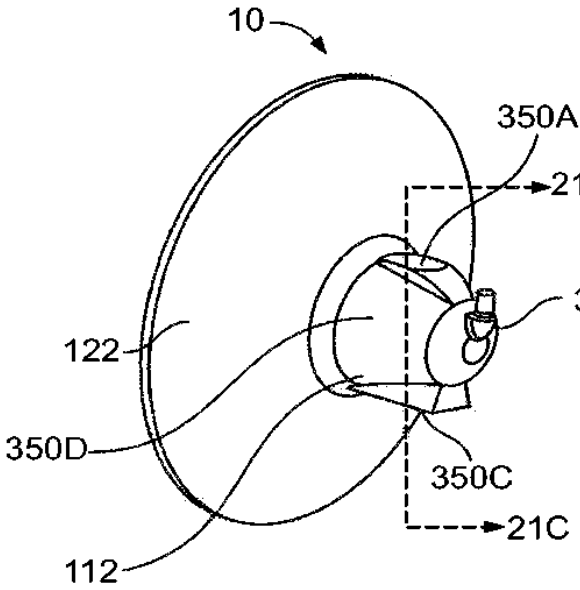


FIG. 21A

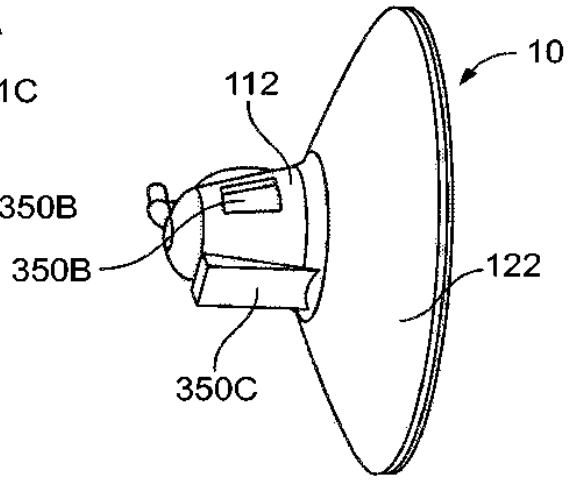


FIG. 21B

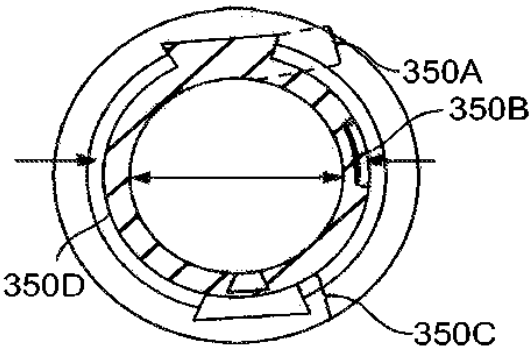


FIG. 21C

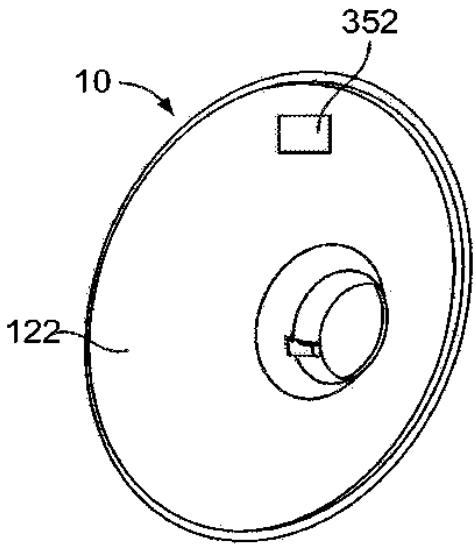


FIG. 22

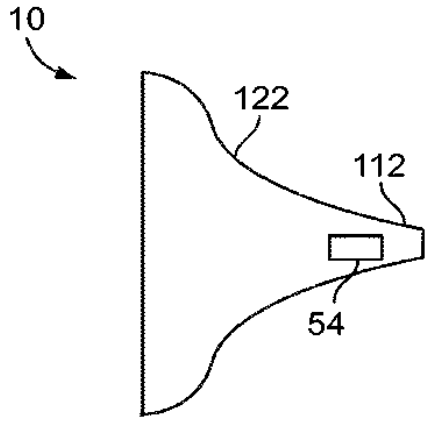


FIG.21D

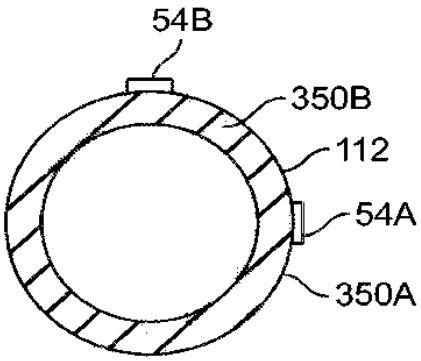


FIG.21E

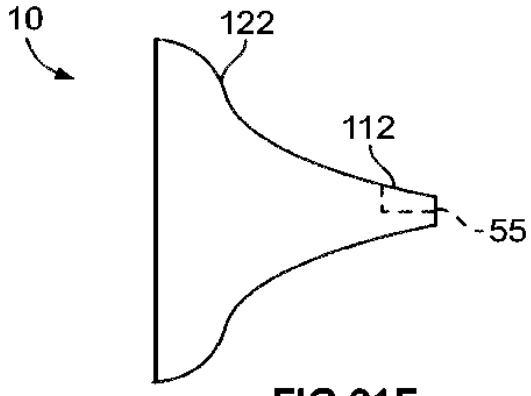


FIG.21F

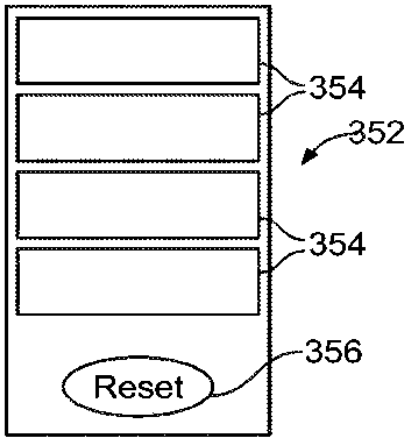


FIG. 24

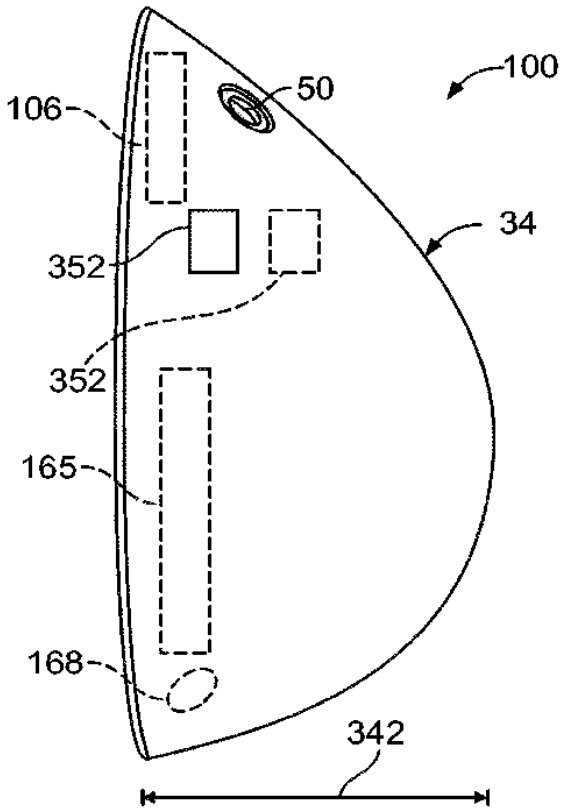


FIG. 23

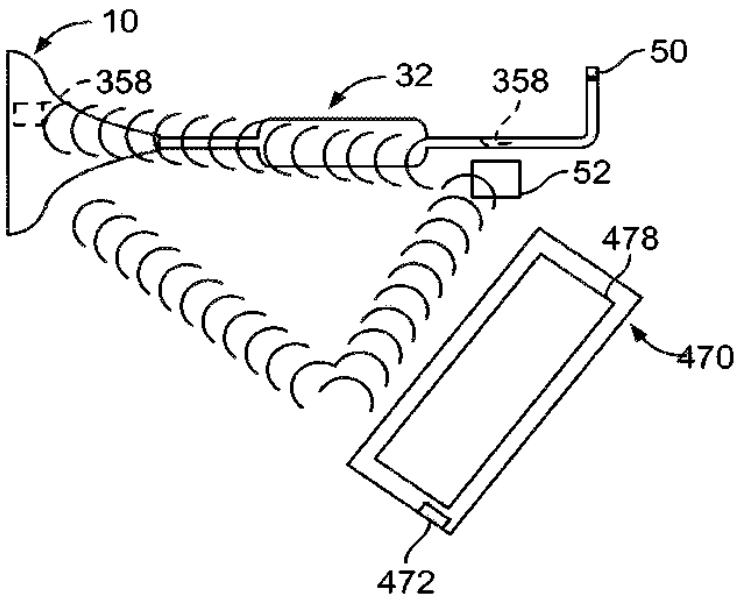


FIG. 25

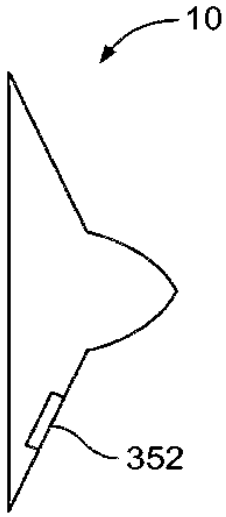


FIG. 27

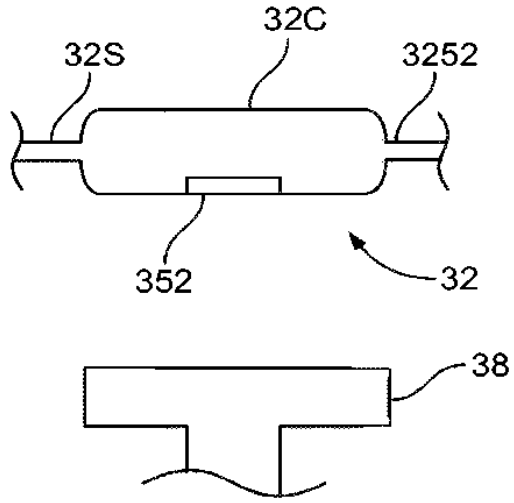


FIG. 26

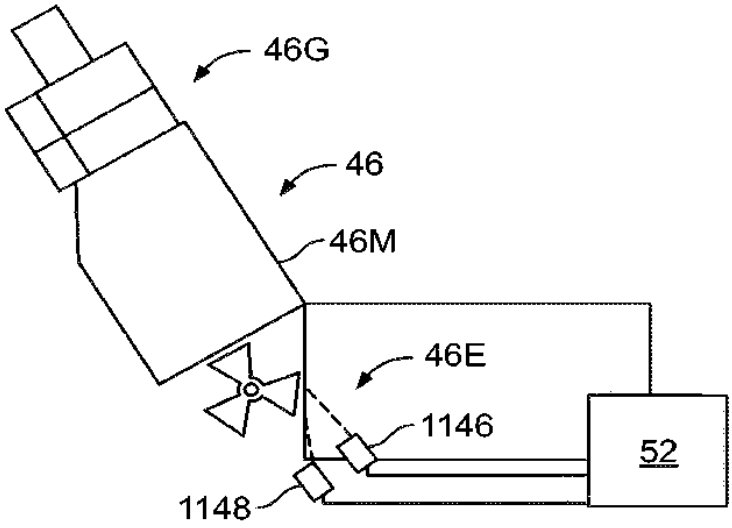


FIG. 28

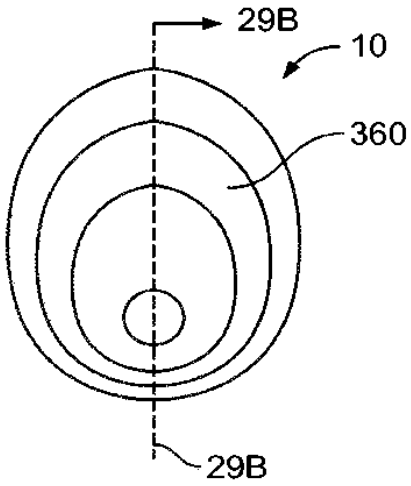


FIG. 29A

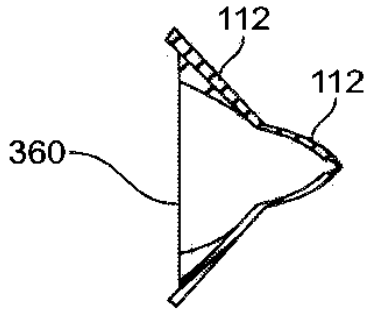


FIG. 29B

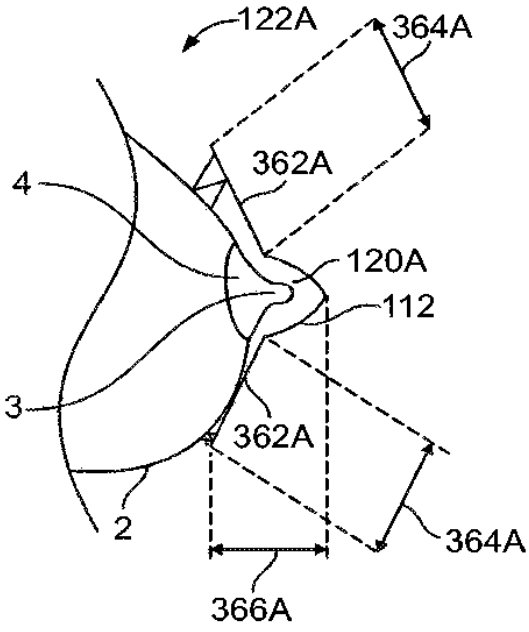


FIG. 30A

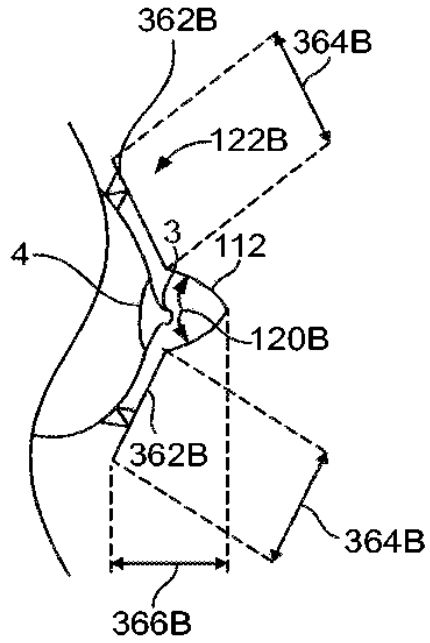


FIG. 30B

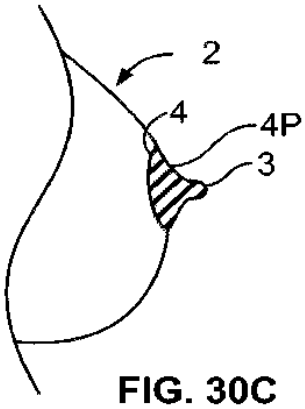


FIG. 30C

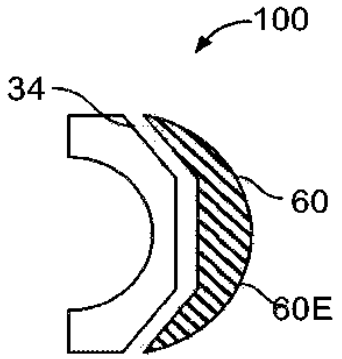


FIG. 31A

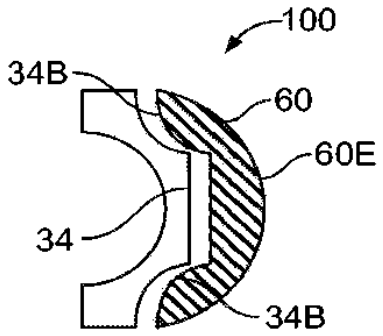


FIG. 31B

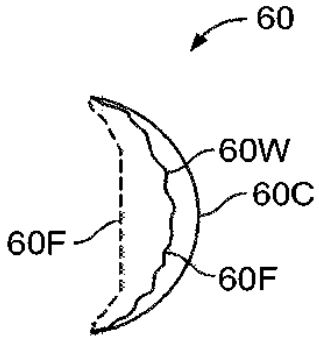


FIG. 32A

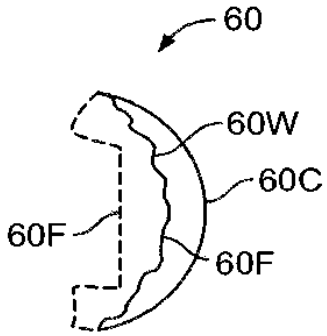


FIG. 32B

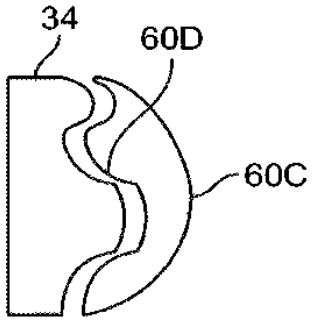


FIG. 32C

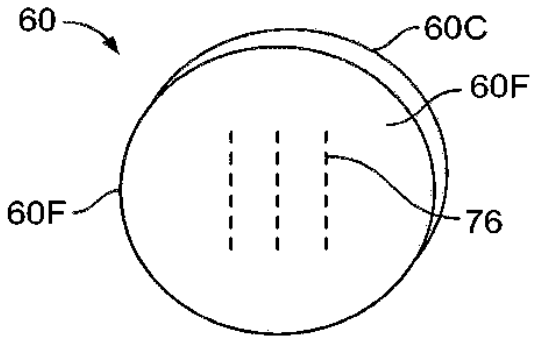


FIG. 33

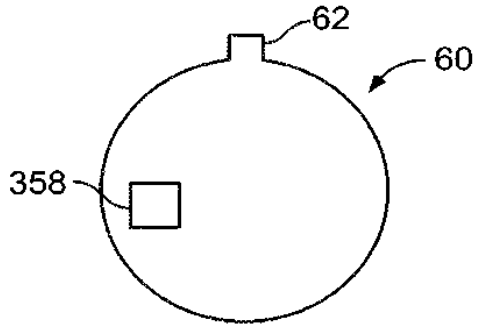


FIG. 34

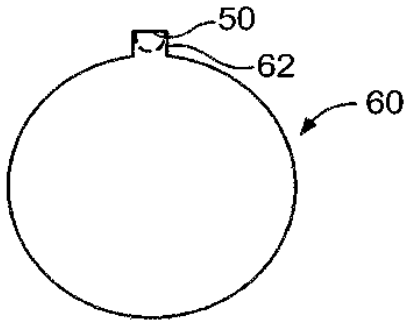


FIG. 35

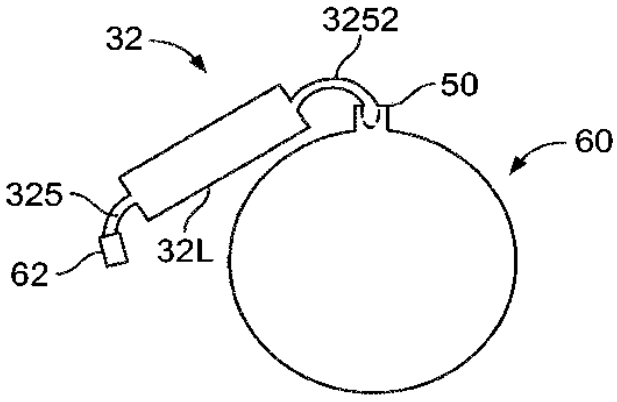


FIG. 36

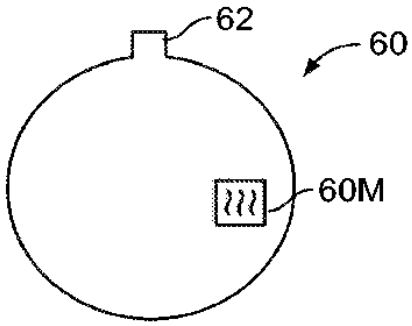


FIG. 37

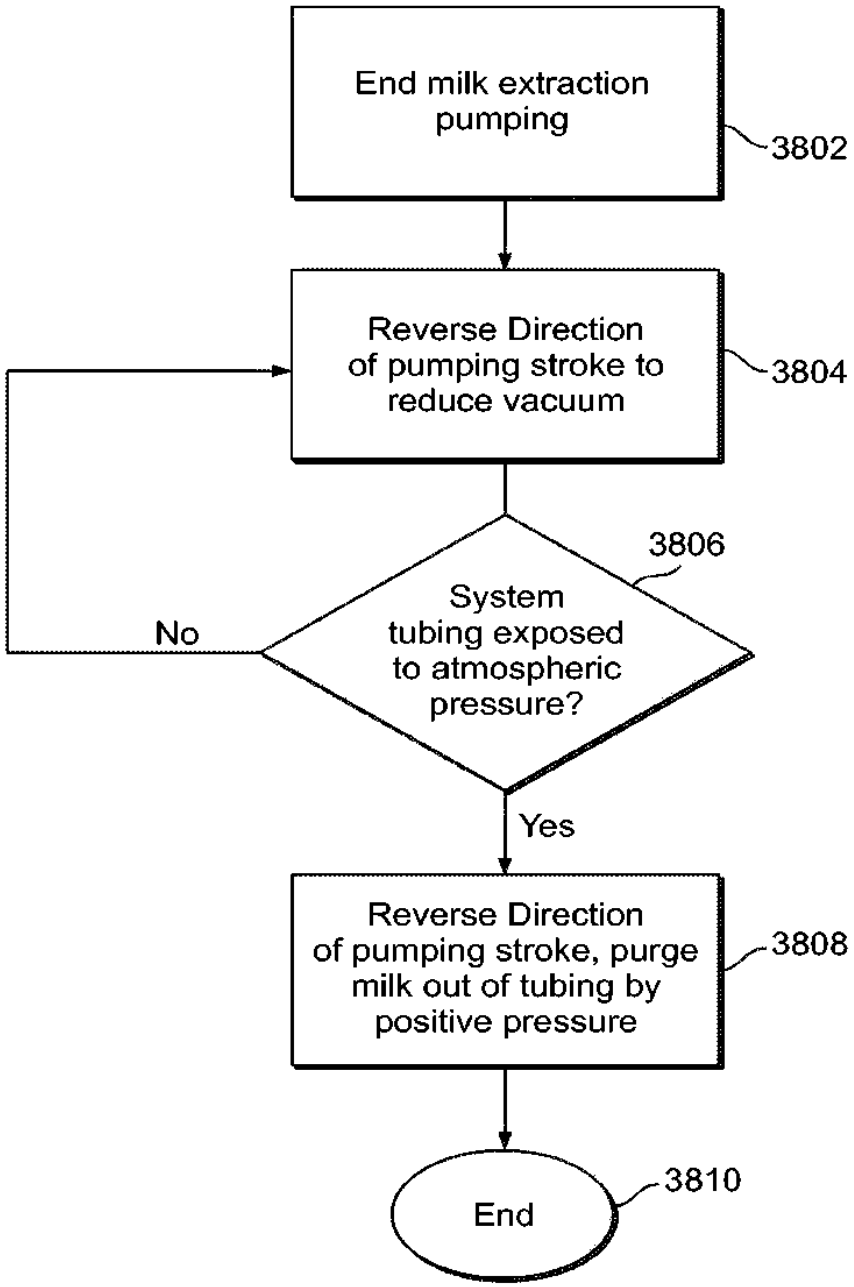

End milk extraction pumping
3802
Reverse Direction of pumping stroke to reduce vacuum
3804
3806
System tubing exposed to atmospheric pressure?
No
Yes
Reverse Direction of pumping stroke, purge milk out of tubing by positive pressure
3808
End
3810

FIG. 47

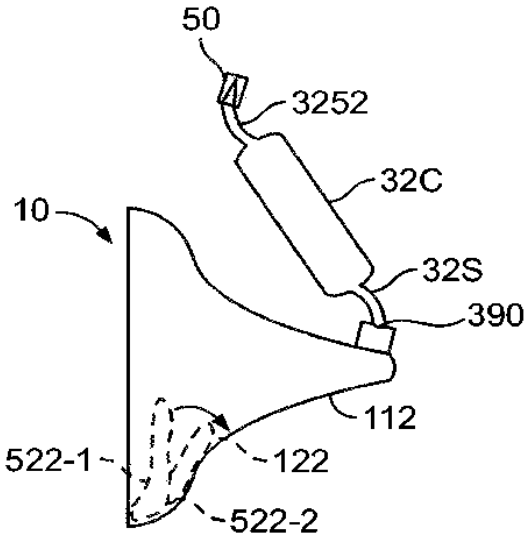


FIG. 39A

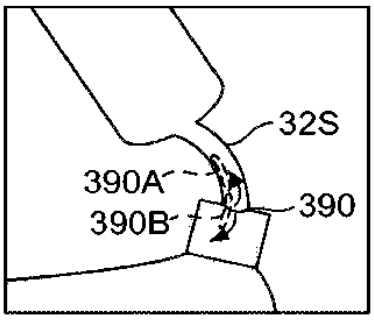


FIG. 39B

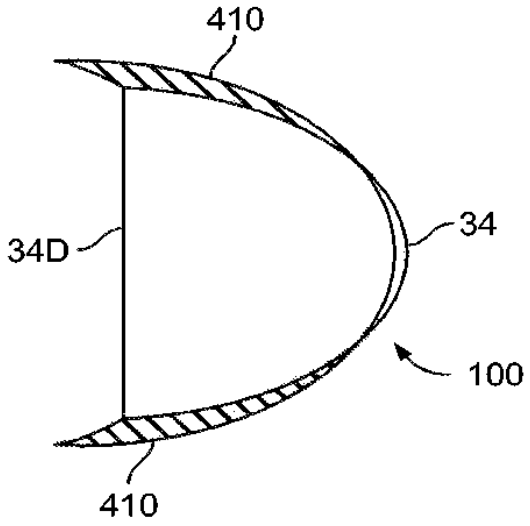


FIG. 40A

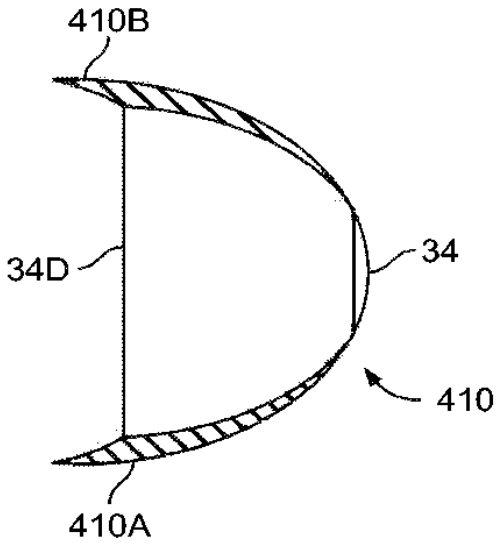


FIG. 41A

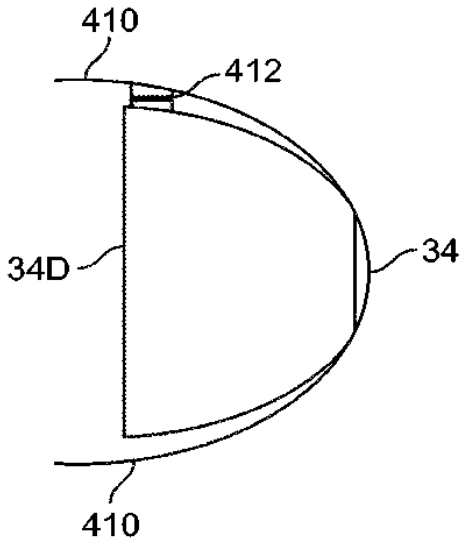


FIG. 41A

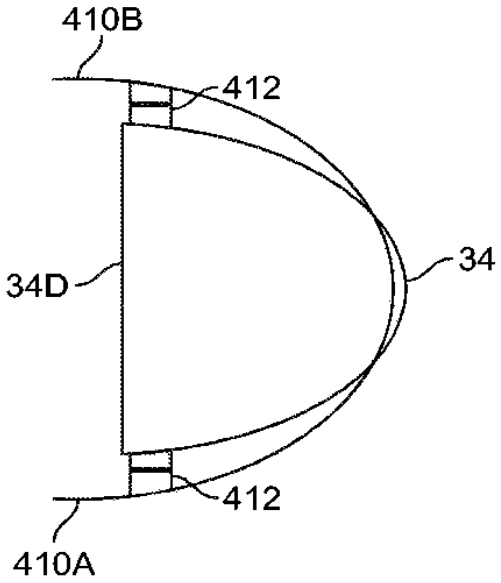


FIG. 41B

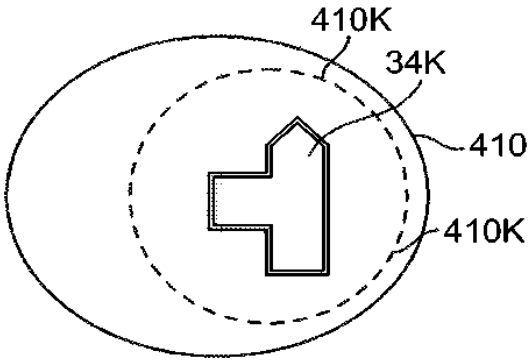


FIG. 42

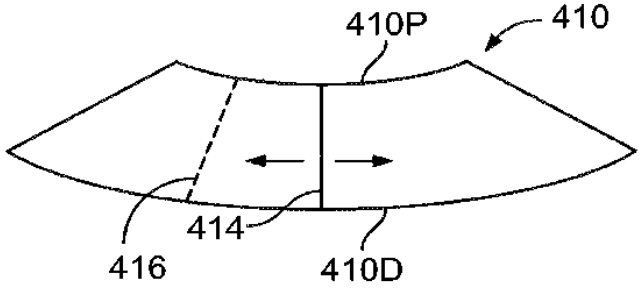


FIG. 43

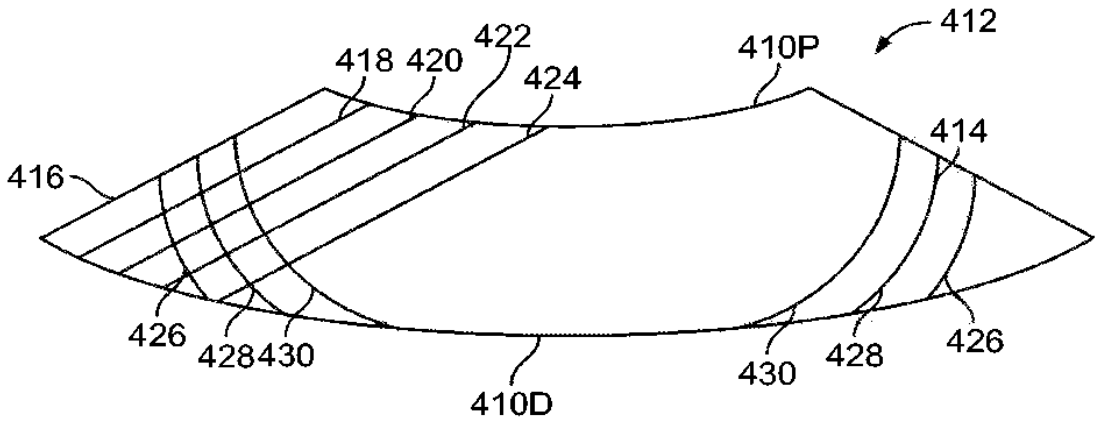


FIG. 44

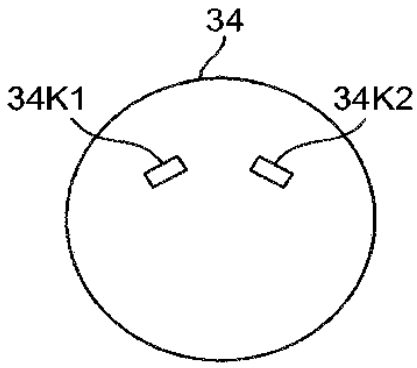


FIG. 45A

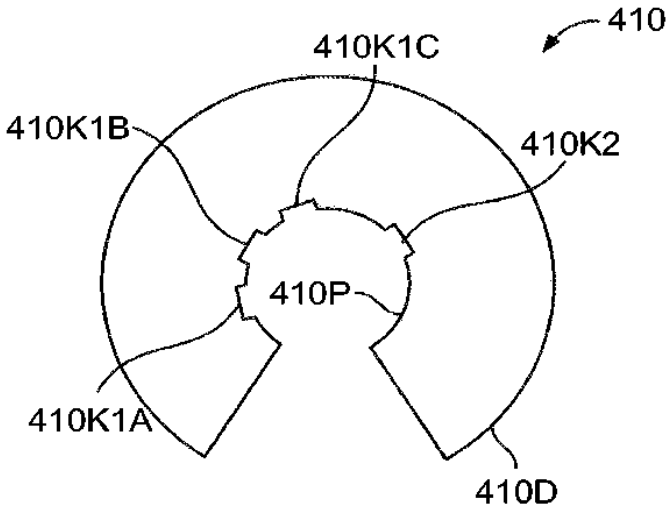


FIG. 45B

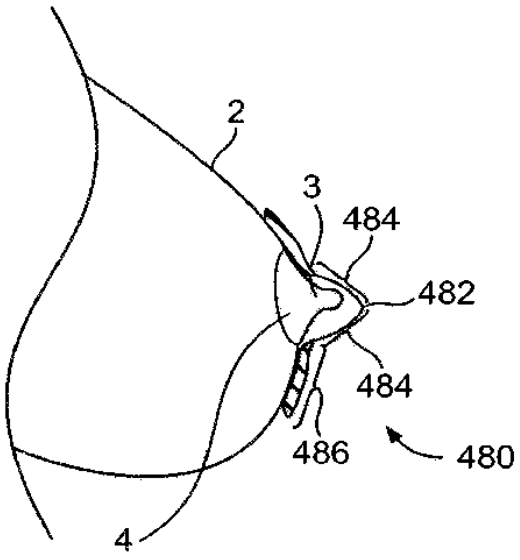


FIG. 48

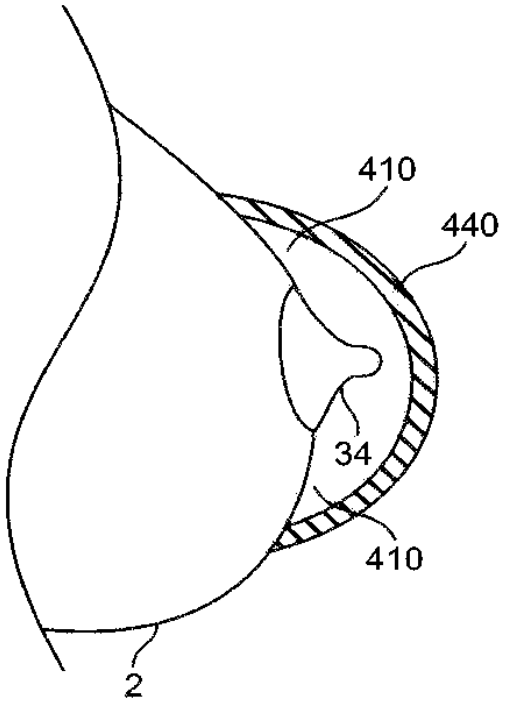


FIG. 46B

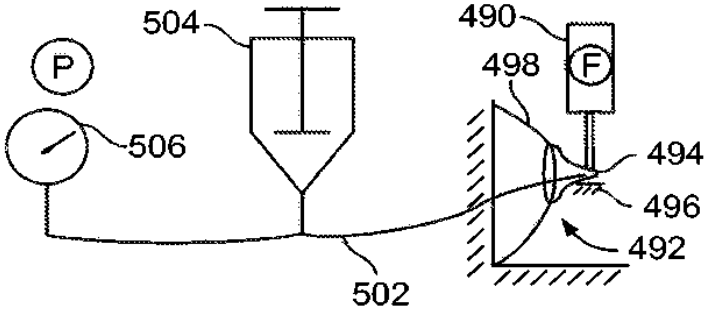


FIG. 49

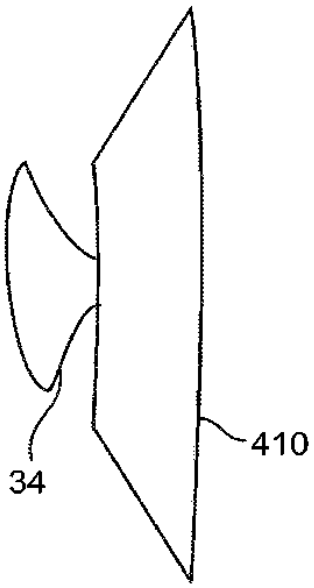


FIG. 46A

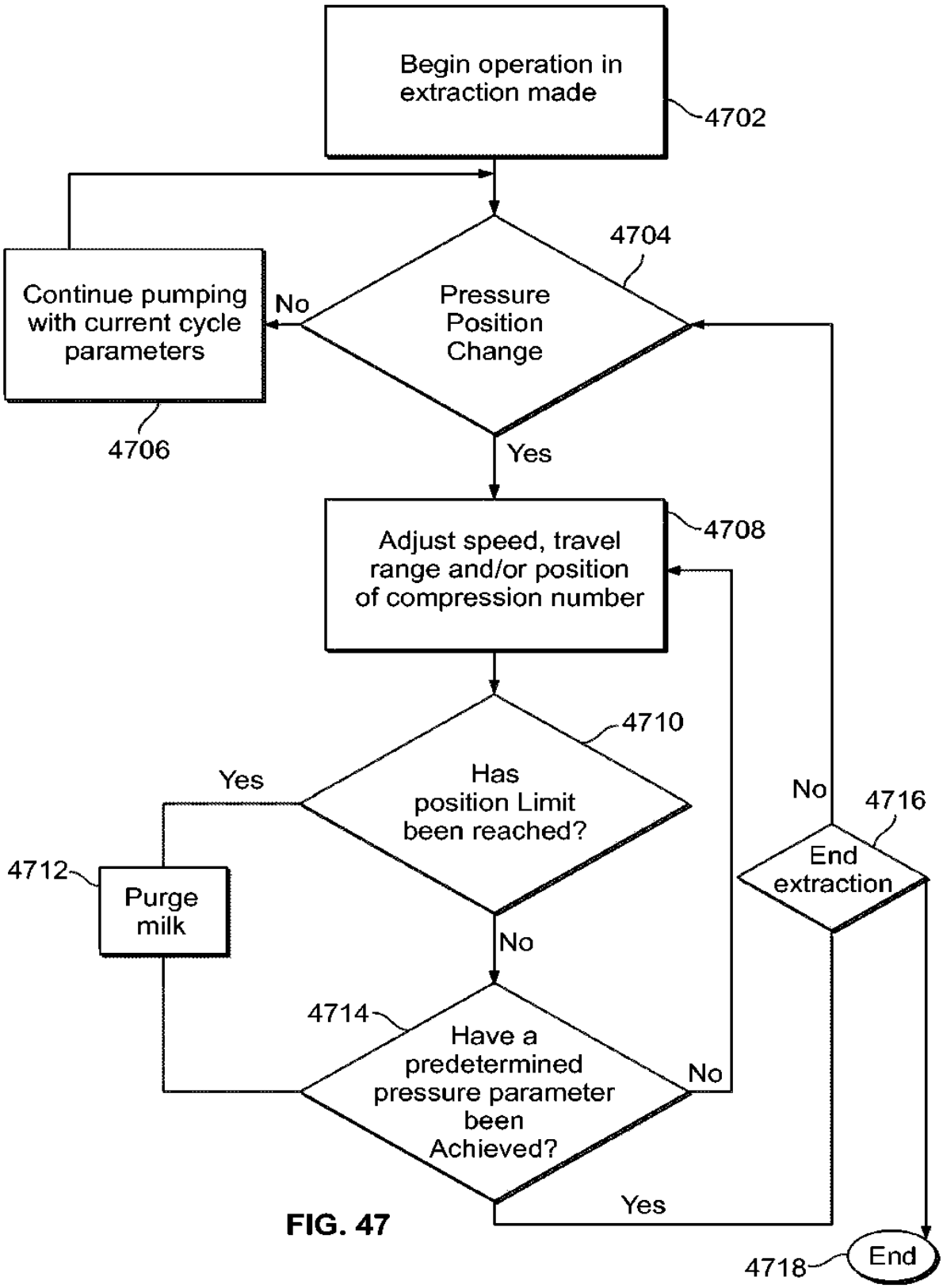

Begin operation in extraction made
4702
4704
Pressure Position Change
No
Continue pumping with current cycle parameters
4706
Yes
Adjust speed, travel range and/or position of compression number
4708
4710
Has position Limit been reached?
Yes
4712
Purge milk
No
4714
Have a predetermined pressure parameter been Achieved?
No
Yes
No
4716
End extraction
4718
End

FIG. 47

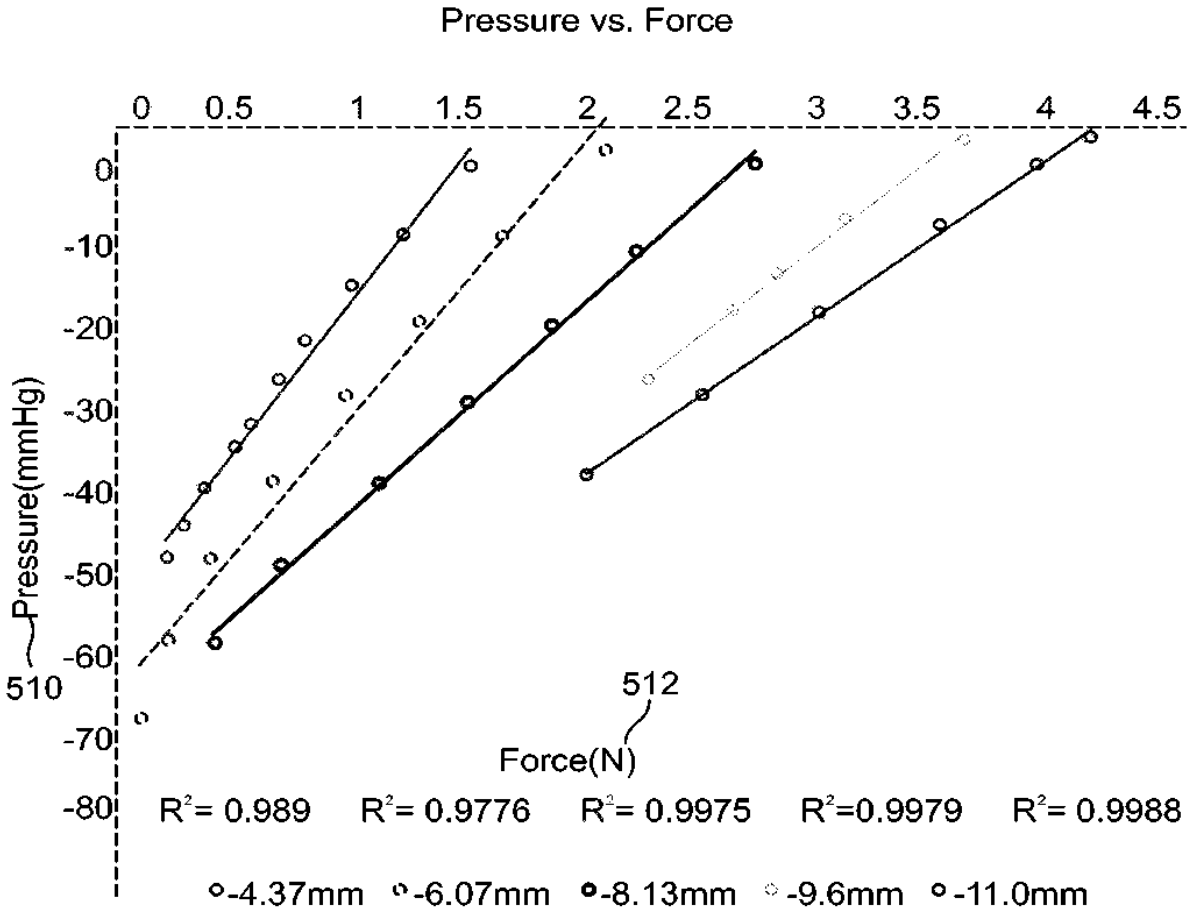

Pressure vs. Force
0 0.5 1 1.5 2 2.5 3 3.5 4 4.5
0
-10
-20
-30
-40
-50
-60
-70
-80
Pressure(mmHg)
510
512
Force(N)
R²= 0.989
R²= 0.9776
R²= 0.9975
R²=0.9979
R²= 0.9988
-4.37mm
-6.07mm
-8.13mm
-9.6mm
-11.0mm

FIG. 50

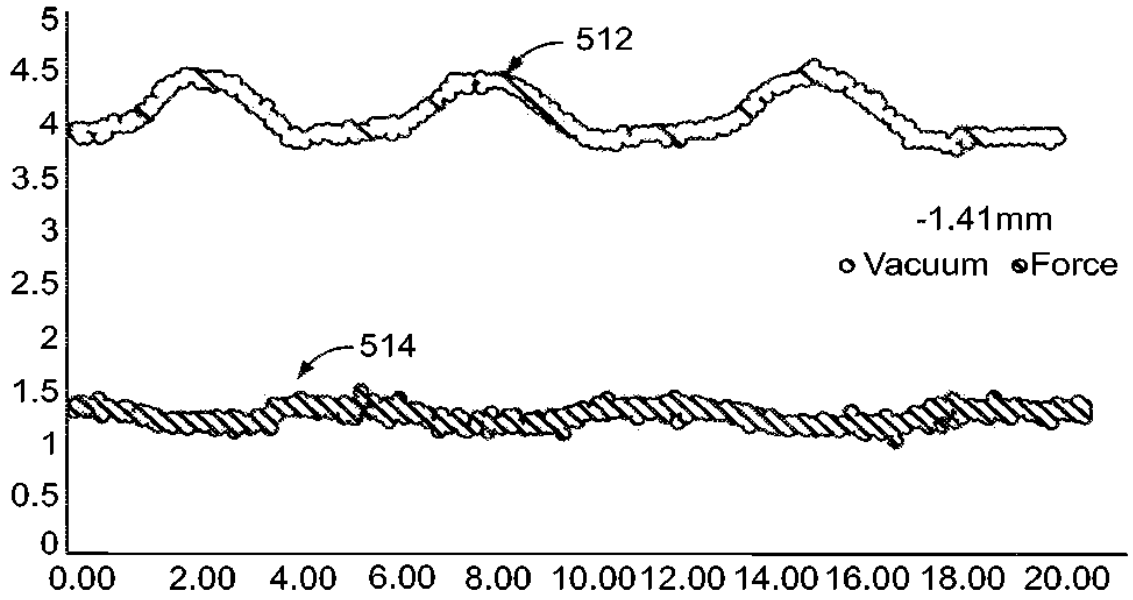

5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
512
514
-1.41mm
Vacuum
Force
0.00 2.00 4.00 6.00 8.00 10.00 12.00 14.00 16.00 18.00 20.00

FIG. 53

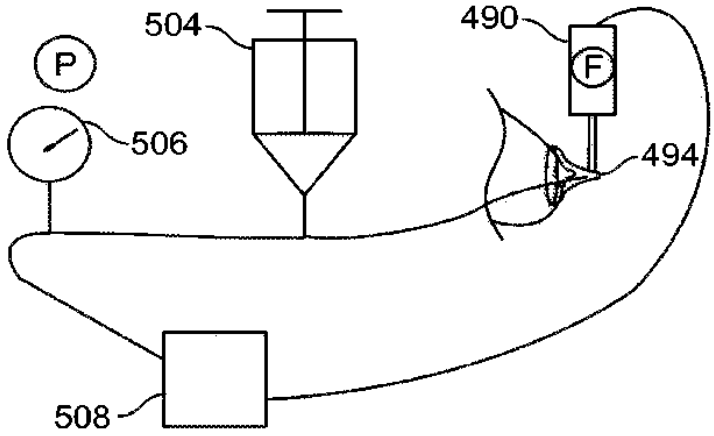

504
490
P
F
506
494
508

FIG. 51

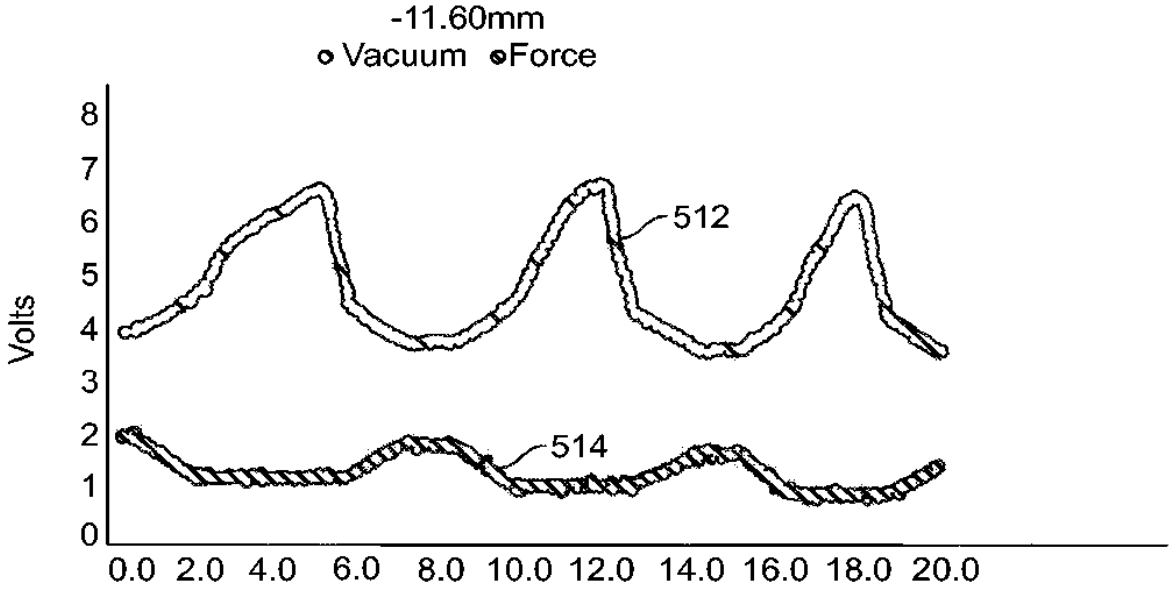

-11.60mm
Vacuum
Force
Volts
8
7
6
5
4
3
2
1
0
512
514
0.0 2.0 4.0 6.0 8.0 10.0 12.0 14.0 16.0 18.0 20.0

FIG. 52

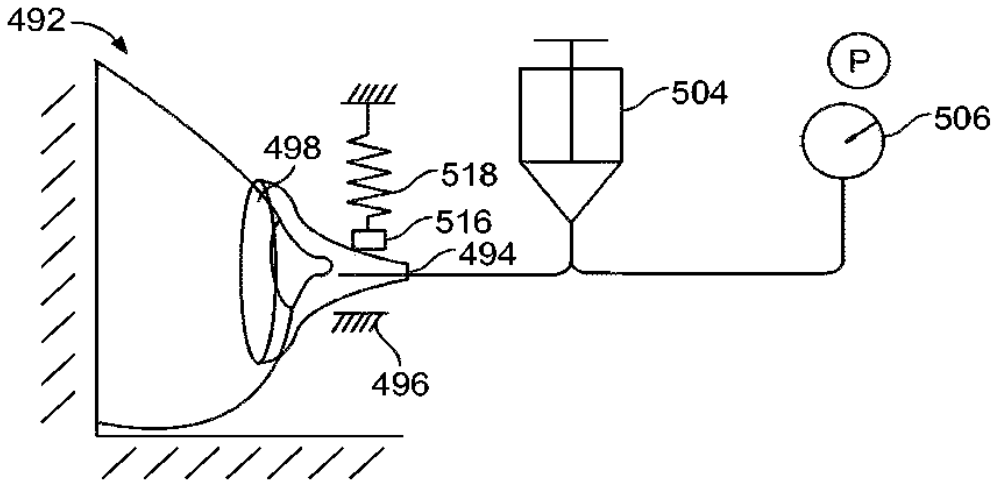

492
498
518
516
494
496
504
P
506

FIG. 54

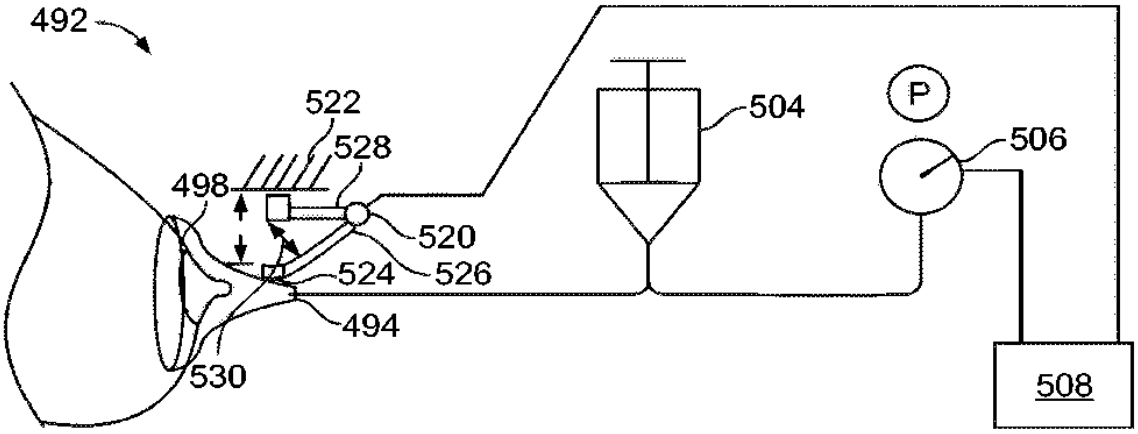

492
522
528
498
520
524
526
494
530
504
P
506
508

FIG. 55

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041285

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 *(2006.01)*

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/06

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Espacenet, USPTO, CIPO, PatSearch, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6840918 B1 (THE FIRST YEARS INC.) 11.01.2005, col. 3 lines 8-31, 49-54, claims 1, 12, 19, fig. 1-3	1-3, 11-13
A	CN 201692384 U (HONGJI LIAO) 05.01.2011	1-3, 11-13
A	US 5810772 A (ANTON NIEDERBERGER) 22.09.1998	1-3, 11-13

☐ 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
24 September 2015 (24.09.2015)	01 October 2015 (01.10.2015)

Name and mailing address of the ISA/RU:	Authorized officer
Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	E. Nosova Telephone No. (495) 531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041285

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, 14-31
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.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**04/17/2024 05:03:54 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	65131167	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 25

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-04-17-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	166 KB
2024-04-17-sIDS-Pleading-4944-0120006.pdf	2	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-04-17-sIDS-SB08-4944-0120006.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	170 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_CN2452494Y.pdf	15	Foreign Reference	535 KB

FOR_2_EP3299043A1.pdf	25	Foreign Reference	282 KB
FOR_3_WO9000413A1.pdf	38	Foreign Reference	805 KB
FOR_4_WO02102437A2.pdf	61	Foreign Reference	1298 KB
FOR_5_WO2008137678A1.pdf	52	Foreign Reference	842 KB
FOR_6_WO2016014494A1.pdf	110	Foreign Reference	1380 KB
FOR_7_WO2017139437A1.pdf	77	Foreign Reference	1621 KB
FOR_8_WO2018054758A1.pdf	25	Foreign Reference	313 KB
FOR_9_WO2019080995A1.pdf	129	Foreign Reference	2315 KB
NPL_1_Rule 71-3-Amended-CI.pdf	4	Non Patent Literature	23 KB
NPL_2_AAP.pdf	5	Non Patent Literature	75 KB
NPL_3_Courage.pdf	17	Non Patent Literature	350 KB
NPL_4_GB201709566.2-Priority-document1.pdf	44	Non Patent Literature	1144 KB
NPL_5_GB201709564.7-Priority-document2.pdf	24	Non Patent Literature	287 KB
NPL_6_GB201709561.3-Priority-document3.pdf	24	Non Patent Literature	476 KB
NPL_7_GB201809036.5-Priority-document4.pdf	169	Non Patent Literature	2876 KB

NPL_8_Illinois-Nursing-Mothers-Act.pdf	2	Non Patent Literature	45 KB
NPL_9_Silicone-Rubber-Complete-Guide.pdf	4	Non Patent Literature	130 KB
NPL_10_Rule71-3-Reply.pdf	1	Non Patent Literature	15 KB
NPL_11_British-Columbia.pdf	2	Non Patent Literature	29 KB
NPL_12_How-to-choose.pdf	8	Non Patent Literature	425 KB
NPL_13_Wyatt.pdf	6	Non Patent Literature	97 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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DESCRIPTION EP3299043A1

10 TECHNICAL FIELD

[0001]

14 The present invention relates to a breast shield unit of a breast pump for pumping out human breast milk and a valve head of such a breast shield unit.

16 STATE OF THE ART

[0002]

20 To pump human breast milk, a breast shield is placed on the mother's breast, which is connected to a vacuum pump in order to apply a cyclically varying negative pressure to the breast. The pumped milk passes through a milk duct from the breast shield into a milk collection container. In order to keep the dead volume as small as possible when pumping, a milk channel from the breast shield to the milk collecting container is usually provided with a check valve, which opens to allow the pumped milk to enter the milk collecting container. This check valve is preferably arranged on an adapter which connects the breast shield to the milk collection container and usually also the breast shield to the vacuum pump or to a vacuum hose leading to the vacuum pump. The check valve can be arranged on a valve head, which is permanently or detachably connected to the adapter, also called a coupling part.

[0003]

33 Such a device is known, for example, from WO 2014/161099 A1.

34 The breast shield unit described there has a flow sensor which detects the change in a valve flap of the check valve, so that conclusions can be drawn about the flow of milk from the breast shield into the milk collection container.

[0004]

US 2016/0082166 A1 discloses an adapter with a sensor for detecting milk production, the sensor communicating via a wireless connection with a mobile data receiver or with the breast pump.

[0005]

WO 2006/003655 A1 shows a nipple shield which is placed on the mother's breast while breastfeeding a baby.

This nipple shield is equipped with a sensor that measures the volume of milk emerging from the milk.

[0006]

WO 2009/081313 A1 discloses a breast shield with at least one sensor for optimizing and personalizing the pumping process.

[0007]

These breast shield units are relatively complex and therefore cost-intensive to construct.

Since the breast shields and milk collection containers can or may often only be used once or a few times, they should be able to be manufactured as cost-effectively as possible and/or they should be easy to clean.

PRESENTATION OF THE INVENTION

[0008]

It is therefore an object of the invention to create a breast shield unit that is as cost-effective as possible, but which still allows the amount of milk pumped out to be recorded.

[0009]

This task is solved by a breast shield unit and a valve head with the features of patent claim 1 or 15.

[0010]

The breast shield unit according to the invention of a breast pump for pumping out human breast milk has a breast shield for resting on a mother's breast, a milk collection container for receiving pumped breast milk, an adapter for connecting the breast shield to the milk collection container and a valve head.

80 A milk channel extends from the breast shield through the adapter and through the valve head into the milk collection container.

82 The valve head has a valve which closes and opens the milk channel during pumping, with a fill level sensor being arranged in the valve head to measure a fill level of the milk collecting container.

[0011]

88 Since the fill level sensor is arranged in the valve head, the breast shield, the adapter and the milk collection container can be designed cost-effectively.

90 In particular, standard parts can be used.

91 It is also advantageous that the valve head can be designed in such a way that it can be used as an accessory in existing breast shield units. This makes it unnecessary to redesign known breast shield units.

[0012]

97 The milk collecting container is preferably designed to be rigid or semi-rigid.

98 It is preferably a milk bottle, which can be closed airtight with a lid after removing the valve head, the adapter and the breast shield. Preferably, the same bottle can be used together with a teat to be attached during use as a feeding bottle for administering breast milk to an infant.

[0013]

104 By measuring the level in the milk collection container, an exact measure of the breast milk actually available is obtained.

106 The measurement is preferably carried out during pumping. The fill level information is preferably updated promptly during pumping.

[0014]

111 The measurement data can be forwarded to an evaluation unit and/or a controller and/or a display of the breast pump as raw data or as data that has already been evaluated using an electronic unit integrated in the valve head.

114 In a simple embodiment, the breast pump simply displays this data. In other embodiments, the data is used additionally or alternatively for current or later control of the pump, e.g. B. to automatically switch from a stimulation to an expression mode or vice versa. In further embodiments, the data is used alternatively or in addition to automatically changing the pumping parameters or the patterns of the vacuum curves, whereby this is also carried out for the current and/or for a later pumping process, depending on the embodiment.

[0015]

123 The raw data and/or the evaluated data can also be sent to other recipients, for example to a smart device such as a smartphone or to another personal device belonging to the mother.

125 This makes it easier for her to record the level, even if she cannot see the milk collection container. In addition, the data can be transferred directly to the Internet, for example to a cloud, so that it is also available to third parties.

[0016]

131 Thanks to the level measurement, the volume of milk pumped out can be determined.

132 By deriving the volume signal, the milk flow can also be detected.

[0017]

136 Preferably, the fill level sensor is a distance sensor for measuring a distance from a surface of the pumped breast milk located in the milk collection container, i.e. the pool of milk located in the container.

139 In this way, the filling level can be measured in a simple manner, without the container itself having to be equipped with a filling level sensor and without having to contact the milk using mechanical means.

[0018]

145 A transit time sensor, also called a TOF sensor (time of flight sensor), is particularly suitable as a fill level sensor.

147 It has been shown that such TOF sensors are suitable for measuring the level of milk, although they are unsuitable for measuring the level of water, for example.

[0019]

152 The distance sensor, in particular the TOF sensor, allows a distance measurement from the sensor to the filling level within the milk collection container.

154 If the geometry of the milk collection container is known, preferably if the position angle of the milk collection container in three-dimensional space is also known, the fill level and thus the milk volume can be calculated.

[0020]

160 If a TOF sensor is used, an optical connection from the sensor to the opposite bottom of the milk collection container is necessary.

162 Preferably, the TOF sensor is positioned so that it is located on a longitudinal central axis of the milk collection container. This longitudinal central axis preferably forms an axis of rotational

symmetry of the milk collecting container.

[0021]

168 In a simple embodiment, only the fill level sensor is arranged in the valve head, which measures the fill level of the milk in the container as a parameter.

170 However, there is preferably at least one additional sensor in the valve head, preferably two or more additional sensors for measuring further parameters.

[0022]

175 Such an additional sensor is, for example, a flow sensor that measures the flow through the valve.

177 This flow sensor is, for example, an optical sensor which detects a deflection of a valve flap of the valve. The sensor is preferably a light barrier which detects the position of the valve flap. For this purpose, a protruding wing is preferably arranged on the valve flap, which penetrates the light path of the light barrier. Such a flow sensor is disclosed, for example, in WO 2014/161099.

[0023]

185 This additional measurement of the flow enables the level measurement to be corrected by the level sensor, especially when there are only small volumes of milk in the milk collection container.

188 This flow sensor can also be used during movements of the milk collection container to correct or completely replace the measurements of the fill level sensor, which is inaccurate during this period. Furthermore, this flow sensor can be used as a control device that determines whether the valve has opened at all or how often and/or when it opens. This information can be used to control the level sensor. For example, there is no need to measure the level if the valve has not opened and therefore no new milk has entered the milk collection container.

[0024]

197 Alternatively or additionally, a position sensor is preferably present as a further sensor, which detects the position of the milk collecting container in three-dimensional space and thus its tilt position in three-dimensional space.

200 An acceleration sensor is particularly suitable as a position sensor. The data from the position sensor are preferably used to compensate for the signals from the fill level sensor when the milk collecting container is tilted. The position sensor is preferably additionally used to determine whether the milk collecting container 5 is actually in a position to ensure a meaningful level measurement.

[0025]

208 The fill level sensor and at least the position sensor, preferably also all other sensors, are preferably arranged in a fixed position relative to one another in the valve head.

[0026]

213 The signals, also called raw data, from the fill level sensor and, if present, from the at least one further sensor, are preferably forwarded directly to external units, such as, for example, to an evaluation and control unit of the breast pump or to another external evaluation unit.

[0027]

219 However, an electronic unit for processing the signals from the fill level sensor is preferably arranged in the valve head.

221 This internal electronic unit preferably also processes the signals from at least one further sensor, if present.

[0028]

226 Preferably, the electronic unit is designed to exchange data with at least one of the following units: breast pump, information technology-equipped "smart device" such as a smartphone; external data processing unit such as personal computers; Cloud; Internet, Internet access unit.

[0029]

233 For easy use of the valve head, it is preferably designed to be wireless to the outside and plugless in terms of electronic plugs.

235 This also makes cleaning easier and allows the valve head to be reused multiple times.

[0030]

239 In one embodiment, the valve head is an integral part of the adapter.

240 In this case, the entire adapter can be designed as a valve head, i.e. the further sensors can be arranged distributed over the adapter and do not have to be located adjacent to the connection to the milk collecting container.

[0031]

246 In another embodiment, the valve head can be detachably connected to the adapter and/or the milk collection container.

248 This embodiment is particularly suitable as a retrofit kit.

[0032]

252 Preferably, the fill level sensor and, if present, the at least one further sensor and, if also present, the electronic unit are protected against the ingress of liquid.

254 The valve head is preferably dishwasher-safe.

[0033]

258 Further embodiments are specified in the dependent claims.

259 BRIEF DESCRIPTION OF THE DRAWINGS

[0034]

263 A preferred embodiment of the invention is described below with reference to the drawings, which serve only for explanation and are not to be interpreted in a restrictive manner.

265 Shown in the drawings:

266 Figure 1

267 a schematic representation of a breast shield unit according to the invention when placed on a mother's breast and

269 Figure 2

270 a schematic representation of the breast shield unit according to Figure 1 in communication with external units.

272 DESCRIPTION OF PREFERRED EMBODIMENTS

[0035]

276 A breast shield unit according to the invention is shown in Figure 1.

277 It has a breast shield 1 for receiving a mother's breast B, in particular the nipple.

278 The breast shield 1 is firmly or preferably detachably connected to an adapter 2, also called a coupling part.

280 The adapter 2 can be connected directly to a manual or electric motor-operated breast pump.

281 As shown here, it is preferably connected to the breast pump via a vacuum line 3, in particular via a silicone hose.

283 The breast pump is shown in Figure 2 and provided with the reference number 30 there.

[0036]

287 The adapter has an interior 20, which forms part of a milk channel from the breast shield 1 to a milk collecting container 5.

289 The milk collecting container 5 is releasably attached to a connecting piece 21 of the adapter 2.

[0037]

293 A valve head 4 is fixedly or detachably arranged on the adapter 2, the valve head 4 preferably being fixed in position relative to the adapter 2.

295 For example, the valve head 4 is formed in one piece with the adapter 2 or can be connected to it via a plug or screw connection.

[0038]

300 The adapter 2 and the valve head 4 are preferably made of a rigid plastic.

301 The milk collecting container 5 is preferably designed to be rigid or semi-rigid.

302 The milk collecting container 5 is also preferably made of plastic.

303 It can be transparent, semi-transparent or opaque.

[0039]

307 The valve head 4 preferably projects into the milk collecting container 5.

308 The valve head 4 has a check valve.

309 In this exemplary embodiment, the valve has a valve flap 40 articulated on one side.

310 The reference number 40 'designates the valve flap in the open position, the reference number 40 in the closed position.

[0040]

315 The path of the pumped milk is shown in Figure 1 by individual milk drops.

316 The milk emerging from the mother's breast B is designated by the reference symbol a, the milk flowing into the valve head 4, which usually falls, is designated by b, the milk collecting in front of the closed valve flap 40 is designated by c and the milk that finally reaches the milk collecting container 5 is designated by d.

320 The milk lake in the milk collecting container 5, i.e. the milk that has already been collected, is provided with the reference number e.

322 Depending on the embodiment, the valve flap 40 opens due to the prevailing pressure conditions during each suction cycle or only when enough milk c has accumulated in front of the flap to open it.

325 Other ways of opening the valve are also possible.

[0041]

329 In the area of the valve flap 40 there is preferably a flow sensor 8, here an optical sensor designed as a light barrier.

331 In the schematic representation according to Figure 1, it appears to be floating within the milk

collecting container 5.
333 However, it is also attached to the valve head 4.

[0042]
337 The flow sensor 8 measures the opening angle of the valve flap 40.
338 The detection area of the flow sensor 8, i.e. the light path, is provided with the reference number 80 in Figure 1.
340 The opening angle of the valve flap 40 is approximately proportional to the amount of milk "flowing out" d.
342 In order to optimize the measurement accuracy, the opening angle of the valve flap 40 is preferably scanned with at least 30 measurements/sec.
344 As mentioned at the beginning, this measurement signal is used to correct the measurement of the fill level sensor described below, especially for small fill heights.
346 This sensor can also be used to determine whether and when the valve flap 40 has opened.

[0043]
350 A fill level sensor 6 is arranged in an electronics area 42 of the valve head 4 that is separate from the milk channel.
352 The electronics area 42 is preferably designed as a closed chamber.
353 The separation from the rest of the valve head can take place, for example, via a partition 41.
354 If this is designed at an angle, it also facilitates the flow of milk to the valve flap 40.

[0044]
358 The fill level sensor 6 has a detection area 60, which is directed towards the opposite bottom of the milk collecting container 5.
360 The fill level sensor 6 is therefore preferably arranged on the lower end face of the valve head 4.
362 The fill level sensor 6 is preferably located on the longitudinal central axis of the milk collecting container 5, which preferably simultaneously forms the rotational symmetry axis R of the milk collecting container 5.
365 The fill level sensor 6 is preferably a distance sensor, preferably an optical distance sensor and even more preferably a TOF sensor (time of flight sensor).

[0045]
370 The TOF sensor measures a distance from the sensor surface to the milk surface.
371 This distance is converted into volume by a microcontroller of an electronic unit 9, taking into account the bottle geometry.
373 The radiation and thus the detection area 60 of the TOF sensor is usually conical or collimated.

[0046]

377 A position sensor 7, here a motion sensor, is preferably also arranged in the electronics area 42.

379 This position sensor 7 measures the movement or tilting position of the valve head 4 and thus of the milk collecting container 5 connected to it via the adapter 2.

381 The signals or data are delivered to the above-mentioned electronic unit 9, in particular the same microcontroller.

383 They serve to compensate for the signals from the fill level sensor 6 when the milk collecting container 5 is tilted and thus increase the accuracy of the measurement.

385 The tilt position is designated in Figure 1 with a double arrow and the reference symbol P.

[0047]

389 The level sensor 6 and the position sensor 7 are arranged in a fixed position relative to one another; i.e. if one sensor gets into a tilted position and/or is moved, the same applies to the other sensor.

392 The same preferably also applies to the flow sensor 8.

393 The milk collecting container 5 is also arranged in a fixed position relative to the fill level sensor 6 and, if present, to the position sensor 7.

395 This is done via the corresponding connection with the adapter 2 and the corresponding connection between the adapter 2 and the valve head 4.

[0048]

400 The above-mentioned electronics unit 9 is preferably also arranged in the electronics area 42 of the valve head 4.

402 It preferably has an energy supply integrated in the valve head 4, in particular an energy storage device.

404 Preferably no cables or plug connections lead to the outside.

405 The data transfer from the electronics unit 9 to the outside and, if available, also from the outside to the electronics unit 9, preferably takes place wirelessly.

407 The energy transmission is preferably also carried out wirelessly.

408 The electronics area 42 is preferably sealed off from the outside in a liquid-tight manner.

[0049]

412 2 shows various communication paths 90 of the breast shield unit according to the invention with external information storage and/or information processing units.

414 The measured values provide the mother, lactation consultants or other experts with information about the amount of milk pumped.

416 Since the mother cannot necessarily see the milk collection container 5 while pumping, it is possible for her to have this fill level displayed on a display of the breast pump 30, on a smart device SD, such as her smartphone or tablet, or on another suitable device .

419 In addition, this data can be made available to the Internet via an Internet access unit I without any further action on the part of the mother.

421 For example, they can be stored in a suitable cloud C or transmitted to another unit OD, such as a personal computer.

423 These measured fill level curves can be used to optimize pumping parameters or measurement algorithms at the same time or later.

425 Pumping parameters include, for example, vacuum level and pumping frequency, duration of a stimulation program (let-down) of the pump before an automatic or manual switch to the expressive, i.e. normal pumping process, and the like.

[0050]

431 The breast shield unit according to the invention and the valve head according to the invention enable filling level measurement without structural changes to the breast shield and milk collection container.

434 They also enable data exchange with external information storage and/or information processing units.

436 REFERENCE SYMBOL LIST

1

440 breast shield

441 9

442 Electronics unit

2

446 adapter

447 90

448 Way of communication

449 20

450 inner space

451 21

452 Connection piece

453 b

454 mother's breast

3

458 Vacuum line
459 a
460 milk emerging from the mother's breast
461 30
462 breast pump
463 b
464 Milk falling into the valve head

4
468 Valve head
469 c
470 Milk collecting in the valve head
471 40
472 valve flap
473 40'
474 Valve flap in open position
475 d
476 emerging from the valve head
477 41
478 partition wall
479 milk
480 42
481 Electronics area
482 e
483 Milk collected in the milk collection container

5
487 Milk collection container
488 P
489 Rotating position of the milk collection container in the room

6
493 Level sensor
494 60
495 Detection range of the level sensor
496 I
497 Internet access unit
498 SD
499 Smart device

7

503 Position sensor

504 C

505 Cloud

506 O.D

507 Other units

8

511 Flow sensor

512 80

513 Flow sensor detection range

514 R

515 Axis of rotation

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(54) **BRUSTHAUBENEINHEIT**

(57) Eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) auf. Ein Milchkanal erstreckt sich von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5). Der Ventilkopf (4) weist ein Ventil (40) auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5). Die erfindungsgemässe Brusthaubeneinheit ermöglicht eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglicht zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

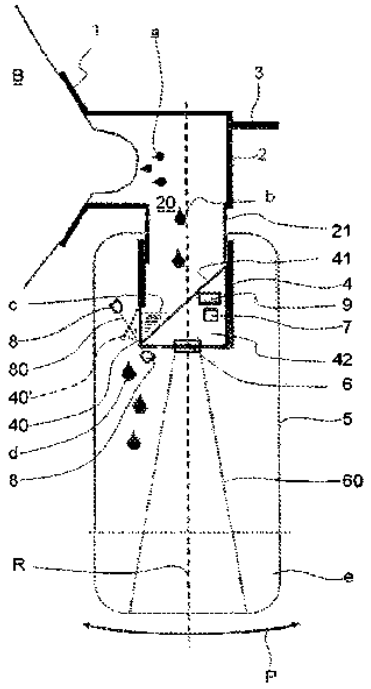


FIG. 1

EP 3 299 043 A1

Beschreibung

TECHNISCHES GEBIET

[0001] Die vorliegende Erfindung betrifft eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie einen Ventilkopf einer derartigen Brusthaubeneinheit.

STAND DER TECHNIK

[0002] Zum Abpumpen von menschlicher Muttermilch wird auf die Mutterbrust eine Brusthaube aufgesetzt, welche mit einer Vakuumpumpe verbunden ist, um die Brust mit einem zyklisch variierenden Unterdruck zu beaufschlagen. Die abgepumpte Milch gelangt durch einen Milchkanal von der Brusthaube in einen Milchsammelbehälter. Um das Totvolumen beim Abpumpen möglichst klein zu halten, ist ein Milchkanal von der Brusthaube zum Milchsammelbehälter üblicherweise mit einem Rückschlagventil versehen, welches sich für den Einlass der abgepumpten Milch in den Milchsammelbehälter öffnet. Dieses Rückschlagventil ist vorzugsweise an einem Adapter angeordnet, welcher die Brusthaube mit dem Milchsammelbehälter und üblicherweise auch die Brusthaube mit der Vakuumpumpe oder mit einem zur Vakuumpumpe führenden Vakuumschlauch verbindet. Das Rückschlagventil kann auf einem Ventilkopf angeordnet sein, welcher fest oder lösbar mit dem Adapter, auch Kopplungsteil genannt, verbunden ist.

[0003] Eine derartige Vorrichtung ist beispielsweise aus WO 2014/161099 A1 bekannt. Die dort beschriebene Brusthaubeneinheit weist einen Durchflusssensor auf, welcher die Veränderung einer Ventilklappe des Rückschlagventils detektiert, so dass Rückschlüsse auf den Durchfluss der Milch von der Brusthaube in den Milchsammelbehälter gezogen werden können.

[0004] US 2016/0082166 A1 offenbart einen Adapter mit einem Sensor zur Detektion der Milchproduktion, wobei der Sensor über eine drahtlose Verbindung mit einem mobilen Datenempfänger oder mit der Milchpumpe kommuniziert.

[0005] WO 2006/003655 A1 zeigt ein Brusthütchen, welches während dem Stillen eines Babys auf die Mutterbrust aufgesetzt wird. Dieses Brusthütchen ist mit einem Sensor versehen, welches das aus der Milch austretende Milchvolumen misst.

[0006] WO 2009/081313 A1 offenbart eine Brusthaube mit mindestens einem Sensor zur Optimierung und Personalisierung des Pumpvorgangs.

[0007] Diese Brusthaubeneinheiten sind relativ aufwändig und deshalb kostenintensiv aufgebaut. Da die Brusthauben und Milchsammelbehälter oft jedoch nur einmal oder wenige Male verwendet werden können oder dürfen, sollten sie möglichst kostensparend gefertigt werden können und/oder sie sollten einfach zu reinigen sein.

DARSTELLUNG DER ERFINDUNG

[0008] Es ist deshalb eine Aufgabe der Erfindung, eine möglichst kostengünstige Brusthaubeneinheit zu schaffen, welche aber dennoch eine Erfassung der abgepumpten Milchmenge erlaubt.

[0009] Diese Aufgabe lösen eine Brusthaubeneinheit sowie ein Ventilkopf mit den Merkmalen des Patentanspruchs 1 bzw. 15.

[0010] Die erfindungsgemässe Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube zur Auflage an eine Mutterbrust, einen Milchsammelbehälter zur Aufnahme von abgepumpter Muttermilch, einen Adapter zur Verbindung der Brusthaube mit dem Milchsammelbehälter sowie einen Ventilkopf auf. Ein Milchkanal erstreckt sich von der Brusthaube durch den Adapter und durch den Ventilkopf in den Milchsammelbehälter. Der Ventilkopf weist ein Ventil auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf ein Füllstandsensor angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters.

[0011] Da der Füllstandsensor im Ventilkopf angeordnet ist, lassen sich die Brusthaube, der Adapter und der Milchsammelbehälter kostengünstig ausbilden. Es lassen sich insbesondere Standardteile verwenden. Vorteilhaft ist ferner, dass sich der Ventilkopf so ausbilden lässt, dass er in bereits vorhandenen Brusthaubeneinheiten als Zubehörteil verwendet werden kann. Ein Redesign bekannter Brusthaubeneinheiten erübrigt sich dadurch.

[0012] Vorzugsweise ist der Milchsammelbehälter steif oder halbsteif ausgebildet. Vorzugsweise ist er eine Milchflasche, welche nach dem Entfernen des Ventilkopfes, des Adapters und der Brusthaube mit einem Deckel luftdicht verschliessbar ist. Vorzugsweise lässt sich dieselbe Flasche gemeinsam mit einem im Gebrauch aufzusetzenden Sauger als Saugflasche zur Verabreichung der Muttermilch an einen Säugling verwenden.

[0013] Durch die Messung des Füllstandes im Milchsammelbehälter wird ein genaues Mass über die tatsächlich zur Verfügung stehende Muttermilch erhalten. Die Messung wird vorzugsweise während des Abpumpens durchgeführt. Die Angabe zum Füllstand wird vorzugsweise während des Abpumpens zeitnah aktualisiert.

[0014] Die Messdaten lassen sich als Rohdaten oder als mittels einer im Ventilkopf integrierten Elektronikeinheit bereits ausgewertete Daten an eine Auswerteeinheit und/oder eine Steuerung und/oder eine Anzeige der Brustpumpe

weiterleiten. In einer einfachen Ausführungsform zeigt die Brustpumpe diese Daten lediglich an. In anderen Ausführungsformen werden die Daten zusätzlich oder alternativ zur aktuellen oder späteren Steuerung der Pumpe verwendet, z.B. um automatisch von einem Stimulations- in einen Expressionsmodus oder umgekehrt zu schalten. In weiteren Ausführungsformen werden die Daten alternativ oder zusätzlich zur automatischen Veränderung der Pumpparameter oder der Muster der Vakuumkurven verwendet, wobei auch dies je nach Ausführungsform für den aktuellen und/oder für einen späteren Pumpvorgang durchgeführt wird.

[0015] Die Rohdaten und/oder die ausgewerteten Daten lassen sich auch an andere Empfänger senden, beispielsweise an ein Smart Device wie einem Smartphone oder an ein anderes persönliches Gerät der Mutter. Dies erleichtert ihr die Erfassung der Füllstandmenge, auch wenn sie den Milchsammelbehälter nicht sehen kann. Zudem lassen sich die Daten direkt dem Internet, beispielsweise einer Cloud, zuführen, um auch Dritten zur Verfügung zu stehen.

[0016] Dank der Messung der Füllstandmenge lässt sich das abgepumpte Milchvolumen bestimmen. Durch Ableitung des Volumensignals lässt sich auch der Milchfluss detektieren.

[0017] Vorzugsweise ist der Füllstandsensor ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter befindlichen abgepumpten Muttermilch, d.h. des im Behälter befindlichen Milchsees. Auf diese Weise lässt sich der Füllstand auf einfache Weise messen, ohne dass der Behälter selber mit einem Füllstandsensor versehen werden muss und ohne dass die Milch mit mechanischen Mitteln kontaktiert werden muss.

[0018] Als Füllstandsensor eignet sich insbesondere ein Laufzeitverfahren-Sensor, auch TOF Sensor genannt (Time of flight Sensor). Es hat sich gezeigt, dass sich derartige TOF Sensoren zur Füllstandmessung von Milch eignen, obwohl sie beispielsweise für eine Füllstandmessung von Wasser ungeeignet sind.

[0019] Der Distanzsensor, insbesondere der TOF Sensor, erlaubt eine Distanzmessung vom Sensor bis zur Füllstandhöhe innerhalb des Milchsammelbehälters. Sofern die Geometrie des Milchsammelbehälters bekannt ist, vorzugsweise wenn zusätzlich der Lagewinkel des Milchsammelbehälters im dreidimensionalen Raum bekannt ist, lässt sich damit der Füllstand und somit das Milchvolumen berechnen.

[0020] Wird ein TOF Sensor verwendet, so ist eine optische Verbindung vom Sensor zum gegenüberliegenden Boden des Milchsammelbehälters notwendig. Vorzugsweise ist der TOF Sensor so positioniert, dass er sich auf einer Längsmittelachse des Milchsammelbehälters befindet. Vorzugsweise bildet diese Längsmittelachse eine Rotationssymmetrieachse des Milchsammelbehälters.

[0021] In einer einfachen Ausführungsform ist im Ventilkopf lediglich der Füllstandsensor angeordnet, welcher als Parameter den Füllstand der Milch im Behälter misst. Vorzugsweise ist im Ventilkopf jedoch mindestens ein zusätzlicher Sensor, vorzugsweise sind zwei oder mehrere zusätzliche Sensoren zum Messen von weiteren Parametern vorhanden.

[0022] Ein derartiger zusätzlicher Sensor ist beispielweise ein Durchflusssensor, welcher den Durchfluss durch das Ventil misst. Dieser Durchflusssensor ist beispielsweise ein optischer Sensor, welcher eine Auslenkung einer Ventilklappe des Ventils detektiert. Vorzugsweise ist der Sensor eine Lichtschranke, welche die Position der Ventilklappe detektiert. Vorzugsweise ist auf der Ventilklappe hierfür ein vorstehender Flügel angeordnet, welcher den Lichtpfad der Lichtschranke durchdringt. Ein derartiger Durchflusssensor ist beispielsweise in WO 2014/161099 offenbart.

[0023] Diese zusätzliche Messung des Durchflusses ermöglicht eine Korrektur der Füllstandmessung durch den Füllstandsensor insbesondere wenn sich erst kleine Milchvolumen im Milchsammelbehälter befinden. Auch lässt sich dieser Durchflusssensor während Bewegungen des Milchsammelbehälters verwenden, um die Messungen des während dieses Zeitraums ungenauen Füllstandsensors zu korrigieren oder ganz zu ersetzen. Des Weiteren lässt sich dieser Durchflusssensor als Kontrollmittel einsetzen, welches feststellt, ob sich das Ventil überhaupt geöffnet hat bzw. wie oft und/oder wann es sich öffnet. Diese Angaben lassen sich zur Steuerung des Füllstandsensors verwenden. Beispielsweise erübrigt sich eine Füllstandmessung, wenn sich das Ventil nicht geöffnet hat und somit keine neue Milch in den Milchsammelbehälter gelangt ist.

[0024] Alternativ oder zusätzlich ist als weiterer Sensor vorzugsweise ein Positionssensor vorhanden, welcher die Lage des Milchsammelbehälters im dreidimensionalen Raum und somit seine Kipplage im dreidimensionalen Raum detektiert. Als Positionssensor eignet sich insbesondere ein Beschleunigungssensor. Die Daten des Positionssensors werden vorzugsweise verwendet, um die Signale des Füllstandsensors in Kipplagen des Milchsammelbehälters zu kompensieren. Der Positionssensor wird vorzugsweise zusätzlich dazu verwendet, um festzustellen, ob der Milchsammelbehälter 5 überhaupt in einer Position ist, um eine sinnvolle Füllstandmessung zu gewährleisten.

[0025] Der Füllstandsensor und mindestens der Positionssensor, vorzugsweise auch alle anderen weiteren Sensoren, sind vorzugsweise zueinander lagefixiert im Ventilkopf angeordnet.

[0026] Die Signale, auch Rohdaten genannt, des Füllstandsensors und falls vorhanden, des mindestens einen weiteren Sensors, werden vorzugsweise direkt an externe Einheiten weitergeleitet, wie beispielsweise an eine Auswerte- und Steuereinheit der Brustpumpe oder an eine andere externe Auswerteeinheit.

[0027] Vorzugsweise ist jedoch im Ventilkopf eine Elektronikeinheit zur Verarbeitung der Signale des Füllstandsensors angeordnet. Vorzugsweise verarbeitet diese interne Elektronikeinheit auch die Signale des mindestens einen weiteren Sensors, falls vorhanden.

[0028] Vorzugsweise ist die Elektronikeinheit zum Datenaustausch mit mindestens einer der folgenden Einheiten

ausgebildet: Brustpumpe, informationstechnisch aufgerüstetes "Smart Device" wie Smartphone; externe Datenverarbeitungseinheit wie Personal Computer; Cloud; Internet, Internetzugangseinheit.

[0029] Zur einfachen Verwendung des Ventilkopfes ist dieser vorzugsweise nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet. Dies erleichtert zudem die Reinigung und ermöglicht eine mehrfache Wiederverwendung des Ventilkopfes.

[0030] In einer Ausführungsform ist der Ventilkopf ein integraler Bestandteil des Adapters. In diesem Fall kann der gesamte Adapter als Ventilkopf ausgebildet sein, d.h. die weiteren Sensoren können über den Adapter verteilt angeordnet sein und müssen sich nicht benachbart zum Anschluss an den Milchsammelbehälter befinden.

[0031] In einer anderen Ausführungsform ist der Ventilkopf lösbar mit dem Adapter und/oder dem Milchsammelbehälter verbindbar. Diese Ausführungsform eignet sich insbesondere als Nachrüstset.

[0032] Vorzugsweise sind der Füllstandsensor und falls vorhanden der mindestens eine weitere Sensor sowie falls ebenfalls vorhanden die Elektronikeinheit gegen Eindringen von Flüssigkeit geschützt. Vorzugsweise ist der Ventilkopf spülmaschinenfest ausgebildet.

[0033] Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

[0034] Eine bevorzugte Ausführungsform der Erfindung ist im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine schematische Darstellung einer erfindungsgemässen Brusthaubeneinheit bei Anlage auf einer Mutterbrust und

Figur 2 eine schematische Darstellung der Brusthaubeneinheit gemäss Figur 1 in Kommunikation mit externen Einheiten.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

[0035] In Figur 1 ist eine erfindungsgemässe Brusthaubeneinheit dargestellt. Sie weist eine Brusthaube 1 zur Aufnahme einer Mutterbrust B, insbesondere der Brustwarze, auf. Die Brusthaube 1 ist fest oder vorzugsweise lösbar mit einem Adapter 2, auch Kopplungsteil genannt, verbunden. Der Adapter 2 kann direkt mit einer manuell oder elektromotorisch betriebenen Brustpumpe verbunden sein. Vorzugsweise ist er, wie hier dargestellt, über eine Vakuumleitung 3, insbesondere über einen Silikonschlauch, mit der Brustpumpe verbunden. Die Brustpumpe ist in Figur 2 dargestellt und dort mit dem Bezugszeichen 30 versehen.

[0036] Der Adapter weist einen Innenraum 20 auf, welcher einen Teil eines Milchkanals von der Brusthaube 1 zu einem Milchsammelbehälter 5 bildet. Der Milchsammelbehälter 5 ist an einem Anschlussstutzen 21 des Adapters 2 lösbar befestigt.

[0037] Am Adapter 2 ist ein Ventilkopf 4 fest oder lösbar angeordnet, wobei der Ventilkopf 4 vorzugsweise lagefixiert zum Adapter 2 ist. Beispielsweise ist der Ventilkopf 4 gemeinsam einstückig mit dem Adapter 2 ausgebildet oder über eine Steck- oder Schraubverbindung mit ihm verbindbar.

[0038] Der Adapter 2 und der Ventilkopf 4 sind vorzugsweise aus einem steifen Kunststoff gefertigt. Der Milchsammelbehälter 5 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise besteht auch der Milchsammelbehälter 5 aus Kunststoff. Er kann durchsichtig, halbdurchsichtig oder opak ausgebildet sein.

[0039] Der Ventilkopf 4 ragt vorzugsweise in den Milchsammelbehälter 5 hinein. Der Ventilkopf 4 weist ein Rückschlagventil auf. In diesem Ausführungsbeispiel weist das Ventil eine einseitig angelenkte Ventilklappe 40 auf. Das Bezugszeichen 40' bezeichnet die Ventilklappe in geöffneter Stellung, das Bezugszeichen 40 in geschlossener Position.

[0040] Der Weg der abgepumpten Milch ist in Figur 1 durch einzelne Milchtropfen dargestellt. Die aus der Mutterbrust B austretende Milch ist mit dem Bezugszeichen a bezeichnet, die in den Ventilkopf 4 fliessende, üblicherweise fallende Milch mit b, die sich vor der geschlossenen Ventilklappe 40 sammelnde Milch mit c und die schliesslich in den Milchsammelbehälter 5 gelangende Milch mit d. Der Milchsee im Milchsammelbehälter 5, also die bereits gesammelte Milch, ist mit dem Bezugszeichen e versehen. Je nach Ausführungsform öffnet die Ventilklappe 40 aufgrund der herrschenden Druckverhältnisse bei jedem Saugzyklus oder erst, wenn sich genügend Milch c vor der Klappe angesammelt hat, um diese zu öffnen. Andere Arten, das Ventil zu öffnen, sind auch möglich.

[0041] Im Bereich der Ventilklappe 40 ist vorzugsweise ein Durchflusssensor 8, hier ein als Lichtschranke ausgebildeter optischer Sensor vorhanden. In der schematischen Darstellung gemäss Figur 1 erscheint er innerhalb des Milchsammelbehälters 5 zu schweben. Er ist jedoch ebenfalls am Ventilkopf 4 befestigt.

[0042] Der Durchflusssensor 8 misst den Öffnungswinkel der Ventilklappe 40. Der Erfassungsbereich des Durchflusssensors 8, d.h. der Lichtpfad, ist in Figur 1 mit dem Bezugszeichen 80 versehen. Der Öffnungswinkel der Ventilklappe

40 ist in etwa proportional zur "abfliessenden" Milchmenge d. Um die Messgenauigkeit zu optimieren, wird der Öffnungswinkel der Ventilklappe 40 vorzugsweise mit mindestens 30 Messungen/sec abgetastet. Dieses Messsignal wird, wie eingangs erwähnt, zur Korrektur der Messung des nachfolgend beschriebenen Füllstandsensors verwendet, insbesondere bei kleinen Füllhöhen. Zudem lässt sich mittels dieses Sensors feststellen, ob und wann sich die Ventilklappe 40 geöffnet hat.

[0043] In einem von vom Milchkanal getrennten Elektronikbereich 42 des Ventilkopfes 4 ist ein Füllstandsensor 6 angeordnet. Der Elektronikbereich 42 ist vorzugsweise als geschlossene Kammer ausgebildet. Die Trennung vom restlichen Ventilkopf kann beispielsweise über eine Trennwand 41 erfolgen. Ist diese schräg ausgebildet, erleichtert sie zudem den Milchfluss zur Ventilklappe 40.

[0044] Der Füllstandsensor 6 weist einen Erfassungsbereich 60 auf, welcher zum gegenüberliegenden Boden des Milchsammelbehälters 5 hin gerichtet ist. Der Füllstandsensor 6 ist deshalb vorzugsweise an der unteren Stirnfläche des Ventilkopfes 4 angeordnet. Bevorzugterweise befindet sich der Füllstandsensor 6 auf der Längsmittelachse des Milchsammelbehälters 5, welche vorzugsweise gleichzeitig die Rotationssymmetrieachse R des Milchsammelbehälters 5 bildet. Der Füllstandsensor 6 ist vorzugsweise ein Distanzsensor, bevorzugt ein optischer Distanzsensor und noch bevorzugter ein TOF Sensor (Time of flight Sensor).

[0045] Der TOF Sensor misst eine Distanz von der Sensoroberfläche bis zur Milchoberfläche. Diese Distanz wird, unter Einbezug der Flaschengeometrie, von einem Mikrokontroller einer Elektronikeinheit 9 in Volumen umgerechnet. Die Abstrahlung und somit der Erfassungsbereich 60 des TOF Sensors ist üblicherweise konisch oder kollimiert.

[0046] Im Elektronikbereich 42 ist vorzugsweise zudem ein Positionssensor 7, hier ein Bewegungssensor, angeordnet. Dieser Positionssensor 7 misst die Bewegung oder Kipplage des Ventilkopfes 4 und somit des mit diesem über den Adapter 2 verbundenen Milchsammelbehälters 5. Die Signale oder Daten werden an die oben genannte Elektronikeinheit 9, insbesondere demselben Mikrokontroller, geliefert. Sie dienen der Kompensation der Signale des Füllstandsensors 6 bei Kipplagen des Milchsammelbehälters 5 und erhöhen somit die Genauigkeit der Messung. Die Kipplage ist in Figur 1 mit einem Doppelpfeil und dem Bezugszeichen P bezeichnet.

[0047] Der Füllstandsensor 6 sowie der Positionssensor 7 sind zueinander lagefixiert angeordnet; d.h. gerät der eine Sensor in eine Kipplage und/oder wird er bewegt, so gilt gleiches für den anderen Sensor. Vorzugsweise gilt gleiches auch für den Durchflusssensor 8. Der Milchsammelbehälter 5 ist ebenfalls lagefixiert zum Füllstandsensor 6 und, falls vorhanden, zum Positionssensor 7 angeordnet. Dies erfolgt über die entsprechende Verbindung mit dem Adapter 2 und der entsprechenden Verbindung zwischen Adapter 2 und Ventilkopf 4.

[0048] Die oben genannte Elektronikeinheit 9 ist vorzugsweise ebenfalls im Elektronikbereich 42 des Ventilkopfes 4 angeordnet. Vorzugsweise verfügt sie über eine im Ventilkopf 4 integrierte Energieversorgung, insbesondere einen Energiespeicher. Vorzugsweise führen keine Kabel oder Steckverbindungen nach aussen. Der Datentransfer von der Elektronikeinheit 9 nach aussen und falls vorhanden, auch von aussen zur Elektronikeinheit 9, findet vorzugsweise drahtlos statt. Die Energieübertragung erfolgt vorzugsweise ebenfalls drahtlos. Der Elektronikbereich 42 ist vorzugsweise flüssigkeitsdicht nach aussen abgeschottet.

[0049] In Figur 2 sind verschiedene Kommunikationswege 90 der erfindungsgemässen Brusthaubeneinheit mit externen Informationsspeicher- und/oder Informationsverarbeitungs-Einheiten dargestellt. Die Messwerte geben der Mutter, Stillberaterinnen oder anderen Experten Auskunft über die abgepumpte Milchmenge. Da die Mutter den Milchsammelbehälter 5 während des Abpumpens nicht unbedingt sehen kann, wird es ihr ermöglicht, diese Füllstandmenge auf einem Display der Brustpumpe 30, auf einem Smart Device SD, wie beispielsweise ihr Smartphone oder ihr Tablet, oder auf einem anderen geeigneten Gerät anzeigen lassen. Zudem können diese Daten ohne weiteres Zutun der Mutter über eine Internetzugangseinheit I dem Internet zur Verfügung gestellt werden. Sie können beispielsweise in eine dafür geeignete Cloud C gespeichert werden oder einer anderen Einheit OD, wie zum Beispiel einem Personal Computer, übermittelt werden. Diese gemessenen Füllstandmengenverläufe lassen sich zur zeitgleichen oder späteren Optimierung von Abpumpparametern oder Messalgorithmen einsetzen. Abpumpparameter sind beispielsweise Vakuumhöhe und Pumpfrequenz, Dauer eines Stimulationsprogramms (let-down) der Pumpe vor einem automatischen oder manuellen Wechsel auf den expressiven, d.h. normalen Abpumpvorgang und ähnliches.

[0050] Die erfindungsgemässe Brusthaubeneinheit und der erfindungsgemässe Ventilkopf ermöglichen eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglichen zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

BEZUGSZEICHENLISTE

1	Brusthaube		
		9	Elektronikeinheit
2	Adapter	90	Kommunikationsweg
20	Innenraum		
21	Anschlussstutzen	B	Mutterbrust

(fortgesetzt)

	3	Vakuumleitung	a	aus der Mutterbrust austretende Milch
	30	Brustpumpe		
			b	in den Ventilkopf fallende Milch
	4	Ventilkopf	c	im Ventilkopf sich sammelnde Milch
	40	Ventilklappe		
	40'	Ventilklappe in geöffneter Stellung	d	aus dem Ventilkopf austretende
	41	Trennwand		Milch
	42	Elektronikbereich	e	im Milchsammelbehälter gesammelte Milch
	5	Milchsammelbehälter		
			P	Drehposition des Milchsammelbehälters im Raum
	6	Füllstandsensor		
	60	Erfassungsbereich des Füllstandsensors		
			I	Internetzugangseinheit
			SD	Smart Device
	7	Positionssensor	C	Cloud
			OD	Andere Einheiten
	8	Durchflusssensor		
	80	Erfassungsbereich des Durchflusssensors	R	Rotationsachse

Patentansprüche

1. Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) aufweist, wobei sich ein Milchkanal von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5) erstreckt und wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, **dadurch gekennzeichnet, dass** im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

2. Brusthaubeneinheit nach Anspruch 1, wobei der Füllstandsensor (6) ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter (5) befindlichen abgepumpten Muttermilch, vorzugsweise ein Laufzeitverfahen-Sensor (Time of flight Sensor), ist.

3. Brusthaubeneinheit nach einem der Ansprüche 1 bis 2, wobei im Ventilkopf (4) mindestens ein weiterer Sensor (7, 8) angeordnet ist.

4. Brusthaubeneinheit nach Anspruch 3, wobei einer des mindestens einen weiteren Sensors ein Durchflusssensor (8) ist, welcher den Durchfluss durch das Ventil (40) misst.

5. Brusthaubeneinheit nach Anspruch 4, wobei der Durchflusssensor (8) ein optischer Sensor ist, welcher eine Auslenkung einer Ventilklappe (40) des Ventils detektiert.

6. Brusthaubeneinheit nach einem der Ansprüche 1 bis 5, wobei einer des mindestens einen weiteren Sensors ein Positionssensor (7) ist, welcher die Position des Milchsammelbehälters (7) im dreidimensionalen Raum und somit seine Schräglage im dreidimensionalen Raum detektiert.

7. Brusthaubeneinheit nach Anspruch 6, wobei der Positionssensor (7) ein Beschleunigungssensor ist.

8. Brusthaubeneinheit nach einem der Ansprüche 6 oder 7, wobei der Füllstandsensor (6) und der Positionssensor (7) zueinander lagefixiert im Ventilkopf (4) angeordnet sind.

9. Brusthaubeneinheit nach einem der Ansprüche 1 bis 8, wobei im Ventilkopf (4) eine Elektronikeinheit (9) zur Ver-

arbeitung von Signalen des Füllstandsensors (6) angeordnet ist.

10. Brusthaubeneinheit nach Anspruch 9 und mindestens einem der Ansprüche 4 bis 8, wobei die Elektronikeinheit (9) zur Verarbeitung von Signalen des mindestens einen weiteren Sensors (7, 8) ausgebildet ist.

11. Brusthaubeneinheit nach einem der Ansprüche 9 oder 10, wobei die Elektronikeinheit (9) zum Datenaustausch (91, 92, 93, 94, 95, 96, 97) mit mindestens einer der folgenden Einheiten ausgebildet ist: Brustpumpe (30), informationstechnisch aufgerüstetes "Smart Device" (SD) wie Smartphone, externe Datenverarbeitungseinheit wie Computer (OD), Cloud (C), Internet, Internetzugangseinheit (I).

12. Brusthaubeneinheit nach einem der Ansprüche 1 bis 11, wobei der Ventilkopf (4) nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet ist.

13. Brusthaubeneinheit nach einem der Ansprüche 1 bis 12, wobei der Ventilkopf (4) integraler Bestandteil des Adapters (2) ist.

14. Brusthaubeneinheit nach einem der Ansprüche 1 bis 13, wobei der Ventilkopf (4) lösbar mit dem Adapter (2) und/oder dem Milchsammelbehälter (5) verbindbar ist.

15. Ventilkopf einer Brusthaubeneinheit nach einem der Ansprüche 1 bis 14, wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, und wobei im Ventilkopf ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

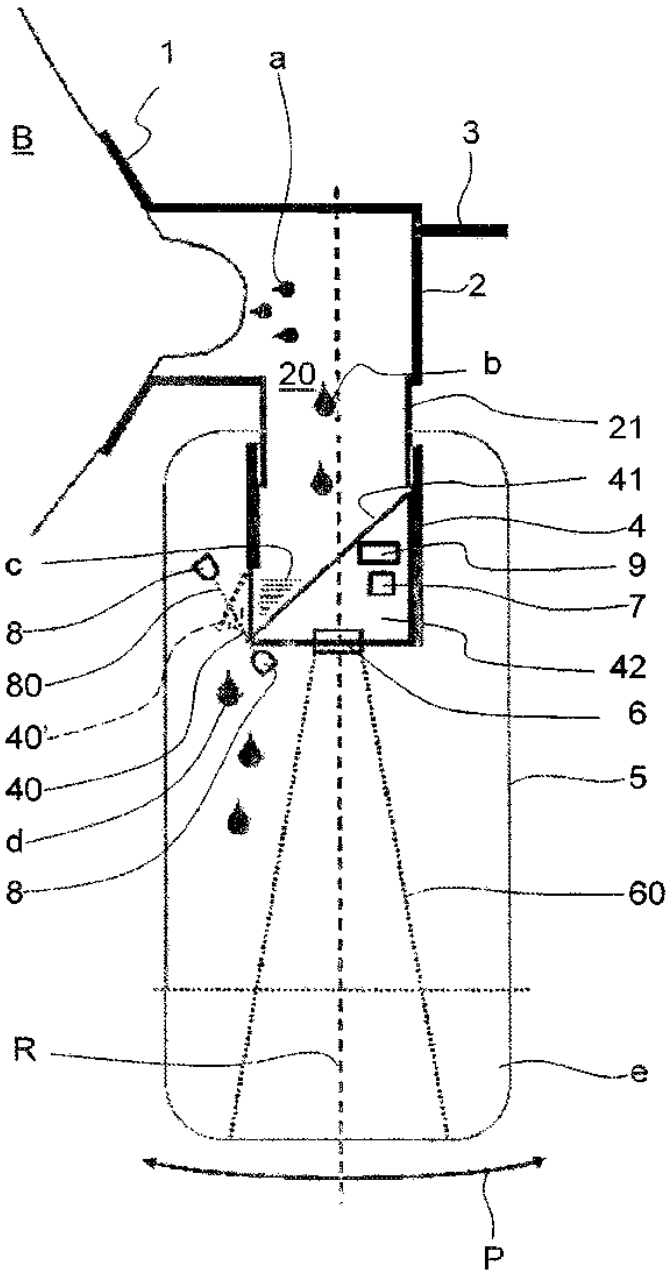


FIG. 1

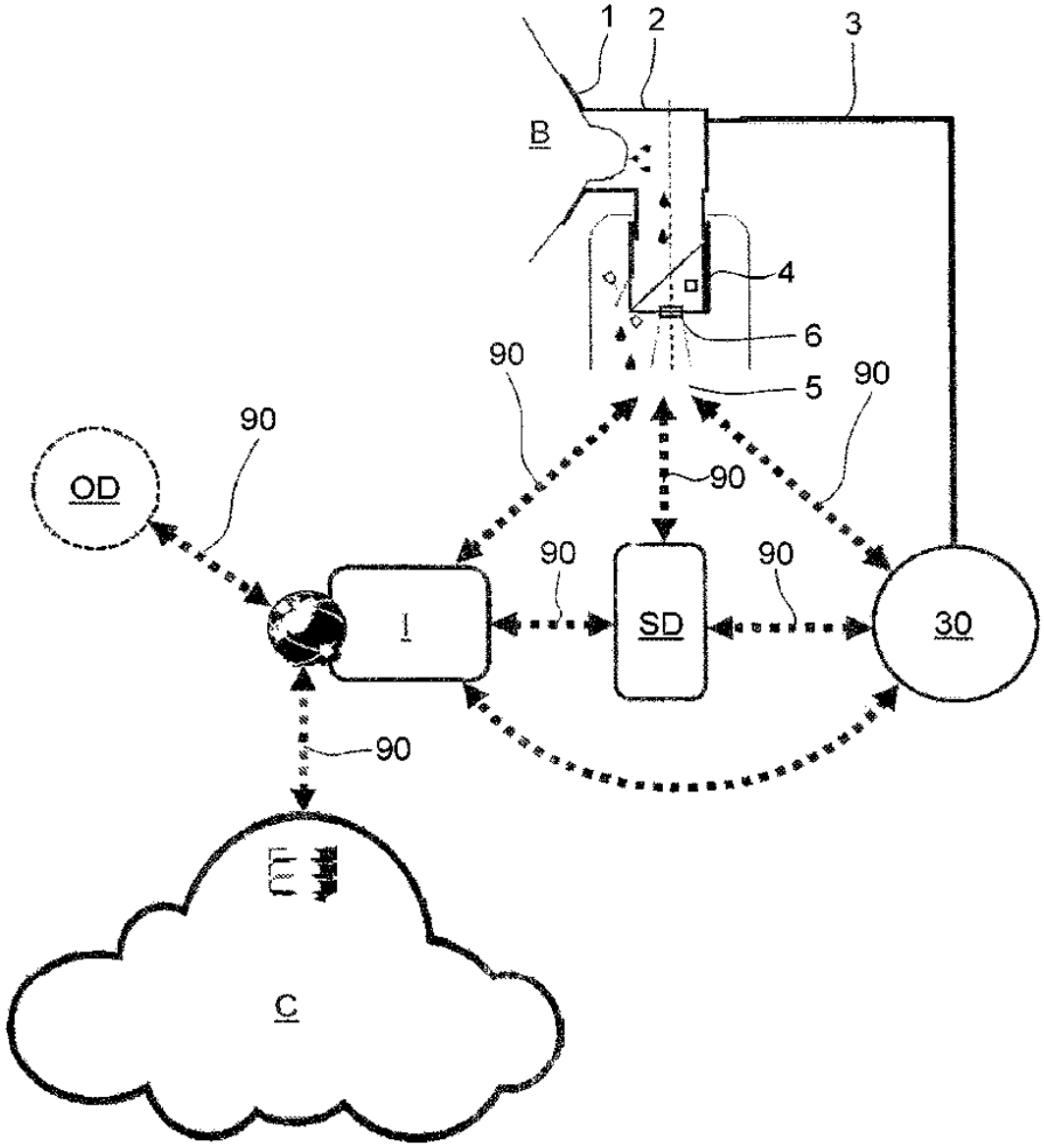


FIG. 2

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 16 19 0122

EINSCHLÄGIGE DOKUMENTE

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Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
Den Haag	8. März 2017	Schlaug, Martin

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
O : nichtschriftliche Offenbarung
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T : der Erfindung zugrunde liegende Theorien oder Grundsätze
E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist
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& : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument

EPO FORM 1503 03.82 (P04C03)

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In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

08-03-2017

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	2	of	4	Attorney Docket Number	4944.0120006

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
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				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	4	of	4	Attorney Docket Number	4944.0120006

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.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-04-17
Name/Print	Yangbeini Wang	Registration Number	800,005

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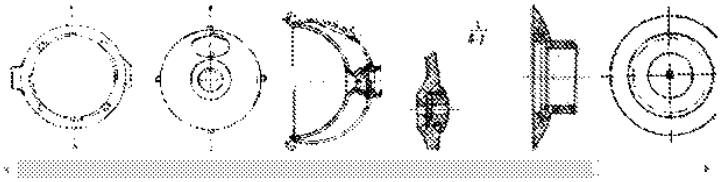
Patents CN2452494Y

Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Abstract

The utility model relates to a special milk collection device for lactation women. The external shape of the utility model forms a brassiere shape. A body is optionally combined and detached with a frame. The body is a hollow hemisphere structure. The component parts of the body is respectively a milk loading device, an elastic rubber sheet, an air valve, a connecting cover, a rubber nipple, a nipple cover, etc., from interior to exterior. The utility model fundamentally solves the problem that the breasts of antepartum women have galactozemia (galactorrhea named as the traditional Chinese medicine) and milk expansion. The utility model has the advantages of portability and milk collection and milk suction at any time, and also has many functions of beneficial milk secretion, recovery of breast shape, etc.

Images (7)



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Current Assignee : Individual

Worldwide applications

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External links: Espacenet, Global Dossier, Discuss

Claims (6)

Hide Dependent

1. medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type have an elastic sheet rubber and an air valve in body, it is characterized in that: body is common medicated bra shape; Body is connected and composed by milk receptacle, elastic sheet rubber, air valve, linking lid, pacify, milk skull and circular frame; Be connected lid and use with milk receptacle and milk skull and be threaded, elastic sheet rubber glue is attached on the milk receptacle, and air valve is embedded in the elastic sheet rubber, and the pacify lower end is pressed to be attached to and is connected in the lid, and that milk receptacle and circular frame use block is protruding, draw-in groove is connected.

2. the milk device that connects according to claim 1, it is characterized in that: the milk receptacle medial and lateral are semi-spherical shape, form central space, Porose in the middle of the medial wall, what link to each other with the hole is horn-like body and semicylinder, is identical shaped hole in it; The semicylinder front end is arranged with some apertures, and end has external screw thread; The circular periphery of milk receptacle is distributed with arc boss, with the groove in the corresponding circular frame; Milk receptacle is inboard with soft cloth or sponge.

3. the milk device that connects according to claim 1 is characterized in that: linking is covered the inboard and is a plane, scribbles one deck rubber around the plane, there is a screw centre, outside the screw and in the arc lateral wall space is arranged, a circular hole is arranged in the middle of the lateral wall, circular hole is outer for having externally threaded cylinder

4. the milk device that connects according to claim 1 is characterized in that: the hatch frame of pacify is, the nipple crown center is out one or multi-channel osculum (cut rubber till) by cutter.

5. the milk device that connects according to claim 1 is characterized in that: milk skull inwall is porose, and female thread is arranged in the hole, and the sealing of hole primary coat one deck is with rubber or fill up a sheet rubber

6. the milk device that connects according to claim 1 is characterized in that: milk receptacle and circular frame adopt arc can close, from connected mode.

Description

Medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type

This utility model relates to a kind of milk device that connects, and what particularly relate to women breast-feeding their children connects the milk utensil

" galactozemia " phenomenon of women breast-feeding their children (" Chinese medicine " claims " galactorrhea " again), it is not bright so far that it produces reason, The treatment aspect, Western medicine does not have specially good effect, and the middle medication phase is long. This phenomenon is seriously perplexing women's orthobiosis for a long time.To this, people do not have the fixed milk utensil that connects at all things such as the pitiuous paper of the usefulness that has, cloth,

sponge connect milk, and what have connects milk with vessel such as feeding bottle, teacups.Take above measure, though can solve " galactozemia " for the moment, inconvenience is arranged: connect milk with things such as paper, cloth, sponges, it is too little to connect the milk amount, can cause outer, garment to be soaked; Connect milk with vessel such as bottle, cups, should not be away from home or public situation.If be on duty, sleep, connect milk under the situation such as travelling, usually can be hard to guard against, make us in a dilemma.

As for the milk that expands, people's breast pump commonly used is handled now, and breast pump has alleviated many miseries really, but it should not public situation use, and can not in time suck or the like in sleep, has produced many unnecessary troubles.

The multiple undesirable condition that connects milk in processing, occurs in the problem that the sucks process at prior art, I have succeeded in developing medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type, not only fundamentally alleviated " galactozemia ", that the milk that expands is brought is painful and overcome all drawbacks of the prior art, and possesses multiple new beneficial functions.Its function is specific as follows:

(1) this utility model be a kind of women breast-feeding their childrens of being specifically designed to breast " galactozemia ", the milk that expands connect the milk utensil.

(2) use of the present utility model is very convenient, and use next to the skin is fit to use under the situations such as sleep, work, travelling

(3) connect milk in time, thoroughly.

(4) help the making full use of of secretion, nursing and milk of breast milk.

(5) suck rapidly, in time.

(6) protection breast, make breast comfortable.

(7) be of value to breast health, make its natural relaxation, can impel breast normal recovery and the prevention mastoptosis

(8) give the aesthetic feeling of breast enlargement.

The purpose of this utility model is in order to scheme realization down.

The outward appearance of medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type and typical circular medicated bra are approximate, and main body is the front and breast, and appendage is for connecting circular frame and two elastic frenulums of main body.The combining of main body and framework adopted the bayonet socket mode that is rotatably connected, can make main body with people's liberty in conjunction with separate, thereby reach purpose easy to use.

Connecting milk device main body outwards is made up of six parts such as milk receptacle, elastic sheet rubber, air valve, linking lid, pacify, milk skulls successively from the lining.Wherein, milk receptacle, milk skull are threaded with the use that is connected lid, and elastic sheet rubber glue is attached on the milk receptacle, and air valve is embedded in the elastic sheet rubber, and the pacify lower end is pressed to be attached to and is connected in the lid.

Milk receptacle is close to breast, and inside and outside sidewall is hemispherical design, forms intermediate space, splits or the milk of sucking-off in order to Sheng.In the middle of its medial wall a hole is arranged, so that nipple reaches in the milk receptacle, what the hole linked to each other therewith is to be horn-like cylinder, and what bulk phase connected therewith is semicylinder.Horn-like body is the hole identical with profile with semicylinder inside.Evenly distributed on the semicylinder front end arewall have some apertures, so that milk flows at the bottom of the device, end has external screw thread.One round and elastic sheet rubber is arranged at the top, lateral wall of milk receptacle, and the shell fragment middle and lower part has a circular air valve again, and this structure is in order to suck.Four semicircle boss that join with circular frame of the circular periphery uniform distribution of milk receptacle are with the groove in the corresponding circular frame.The milk receptacle inboard is close to breast portion and is stained with one deck sponge or soft cloth, guarantees to use comfortable.

Be connected lid in order to be connected milk receptacle and nipple and milk skull.Its inboard is a plane, and the plane periphery scribbles one deck rubber in order to sealing, in the middle of the plane screw is arranged, and links to each other with the double-screw bolt of milk receptacle.Screw outwards has a space and circular hole, is the ground of staying in of nipple, and the circular hole outer periphery is used for connecting the milk skull for having externally threaded cylinder.

Nipple is common pacify commonly used, and opening is cut together by cutter or several forms.

The milk skull design for cylinder, in have screw to match with being connected the double-screw bolt that covers, fill up a caulking gum thin slice bottom it.

Above-mentioned except that individual explanations, all the other materials are all plastics.

Owing to adopt such scheme, the utility model has following advantage:

What at first, originally connect the milk device and be a kind of women breast-feeding their children of being specifically designed to " galactozemia " or " galactorrhea " (" Chinese medicine " claims) connects the milk utensil.Its appearance will be filled a hole in the market.It compared with prior art have connect milk in time, convenient, advantage such as amount is big, connect the trouble of milk before fundamentally having eliminated, use it, no matter when and where " galactozemia " can not influence orthobiosis of people.

Secondly, originally connect the milk device and help making full use of of breast feeding and milk.Use and originally connect the milk device, when the baby need suck the breast, can take away rapidly and connect the milk device, in time feed; Do not have enough to eat as the baby, the also available milk that connects in the milk device is directly fed, and does not need to pour in other nursing devices again, uses very convenient.

The 3rd, use originally to connect the milk device and be of value to udder health, can hold up and protect breast, make its natural relaxation, thereby improve blood circulation, the promotion galactopoiesis; For the wean rear udder attachment intact recovery and prevent that the mastoptosis is useful especially.

The 4th, originally connect the use next to the skin of milk device, change the use inconvenience of existing breast pump, any occasion is ever can to suck, and makes breast have plentiful aesthetic feeling.

Below in conjunction with drawings and Examples, this utility model is further specified.

Figure 1 shows that the front view (elastic frenulum partly omits) that originally connects the milk device.

Figure 2 shows that the single milk device circular frame front view that connects. A-A is a slice location.

Fig. 3 is the single full sectional view that connects milk device circular frame.

Fig. 4 is the single front view that connects milk device main body, and B-B is a slice location.

Fig. 5 is the single full sectional view (air valve slightly) that connects milk device main body.

Fig. 6 is the complete section front view (air valve slightly) of milk receptacle.

Fig. 7 is the full sectional view (I is the labelling of partial enlarged drawing among Fig. 6) of air valve.

Fig. 8 is for being connected the complete section front view of lid.

Fig. 9 is the hatch frame sketch map of nipple.

Figure 10 is the complete section front view of milk skull.

Originally connect the size of milk device according to women breast-feeding their children's breast, design different model, with milk receptacle medial wall semi-round ball radius (being the radius of breast) is the size of its specification of representative, this radius increases then partly increases such as milk receptacle lateral wall, the cross section that is connected lid, the diameter of circular frame, guarantees that again breast is comfortable when containing the increase of milk amount.

Be suitable for radius be 60mm breast to connect the milk device be embodiment, be described below:

This connects the mutual alignment of milk device each component part and assembly relation as shown in Figure 1, wherein, 1, elastic frenulum; 2, circular frame, 3, milk receptacle, 4, elastic sheet rubber, 5, air valve, 6, be connected lid, 7, pacify; 8, milk skull.

Be auxiliary with each accompanying drawing below, construction features, size and performance, the material etc. of each part that originally connects the milk device are described.

1, elastic frenulum (Fig. 1)

Connect human body and the usefulness that connects the milk device.

Elastic frenulum is wide to be 30mm, length overall is about 400mm (can design several specifications according to different chest measurements), the left side elastic webbing is connected the left side frame left side, the right side elastic webbing is connected right side frame the right, can stick with glue or modes such as framework Bao Qi are connected, the other end of left and right side elastic frenulum has hook for the usefulness of binding mutually.There are the long 35mm of being, wide elastic frenulum to link to each other in the middle of the framework of the left and right sides for 30mm (deciding) according to two colpus distance.

Material is general elasticity strap.

2, circular frame (Fig. 2, Fig. 3)

Its effect be make connect milk device main body can close by people's liberty, from, reach purpose easy to use.

Framework inner edge diameter is 120mm, and the outside diameter is 144mm, the symmetrical center line of bayonet socket and framework vertical axis angle at 45. the long 10mm of bayonet socket, wide 9mm, the thick 2mm that is of the inside and outside edge of bayonet socket, the thick 8mm of framework.It is the arc groove of 4mm (draw-in groove) that four sections radiuses are arranged in the framework, be evenly distributed in the framework, its bayonet socket and groove all with boss (the blocking protruding) fit of milk receptacle periphery.

3, milk receptacle (Fig. 6)

Spill or the milk of sucking-off in order to Sheng.

Its inside and outside sidewall is all hemisphere, and the lateral wall diameter is 130mm, and the medial wall radius is 60mm, wall thickness 2mm.The same axis of inside and outside sidewall, the center of circle be at a distance of 20mm, the center of circle, lateral wall partially outside.It is that the opening of 50mm matches with being connected to cover that there is diameter in the milk receptacle outside.It is the elastic sheet rubber of 50mm that there is a diameter at 10mm place, opening top, the air valve that has an elastomeric material to make on it.In the middle of the milk receptacle medial wall hole, diameter being arranged is 30mm, and what link to each other with the hole is tubaeform cylinder, and the centre is a flared hole, wall thickness 2mm, and " loudspeaker " arc is 40mm, " loudspeaker " internal orifice diameter is 15mm.What link to each other with internal orifice is semicylinder, and diameter is 30mm, in the post hole of same shape, wall thickness 2mm are arranged.Semicylinder, front end is evenly distributed, and some diameters are arranged is the aperture of 1-4mm, flows into usefulness at the bottom of the device for milk; It is the external screw thread of 30mm that end has nominal diameter, the high 4mm of this cylinder.It is the boss (blocking protruding) of bayonet socket and draw-in groove in the suitable circular frame of 8mm, long 8mm, thick 2mm that the milk receptacle periphery has diameter.Comfortable for guaranteeing to use, the inner surface of milk receptacle (promptly with the breast contact site) is covered with one deck soft cloth or sponge, clad can from distance inboard aperture 20mm to outward flange.

Except that individual indicating, other material is plastics.

4, elastic sheet rubber (Fig. 4)

In order to negative pressure in the supercharge, suck to finish.

10mm place above the opening of milk receptacle lateral wall, it is the elastic sheet rubber of 50mm that diameter of section is arranged, and the centre is thin (thick is 2mm), and firmly periphery is saturating cumulative thick, and the thick 3mm of edge is to increase elasticity.

Material is the strong rubber of elasticity.

5, air valve (Fig. 7)

Connect gas in the milk device in order to discharge, with negative pressure in the supercharge.

Air valve is positioned at the middle and lower part of elastic sheet rubber, is made up of base, rubber closure, rubber tissue.One diameter is arranged at the base bottom is the hole of 2mm, hole depth 2mm, the cylinder space of Kong Shangwei diameter 8mm, dark 2.5mm, To be fit to rubber closure.This space opening diameter is 6mm.Rubber closure bottom surface diameter is 8mm, and bottom edge has the wide arc boss of 2mm, in order to push down rubber tissue one side.The rubber closure upper end is that diameter is the arc boss of 10mm, and there is the dark 1mm of a groove middle and upper part, with suitable base openings, and can seal.Rubber closure is 2mm by a diameter, and is long for running through in the circular columns hole of 4.5mm.Rubber tissue is diameter 7mm, the thin slice of thick 0.5mm, and pad is in the rubber closure bottom.

Material is a rubber.

6, be connected lid (Fig. 8)

In order to connect milk receptacle, pacify and milk skull.

Linking is covered the inboard and is a plane, and diameter is 57mm, with the outer side-to-side anastomosis of the outer hole wall of milk receptacle.Scribble the rubber of one deck of wide 3mm in order to sealing at the plane periphery.This planar thick 2mm, there is a screw centre, and nominal diameter is 30mm, adapts with screw thread in the milk receptacle.Between screw and the arc lateral wall (radius is 65mm) is a space, is used for installing pacify.Outside wall thickness 2mm, it is the circular hole of 23mm that there is a diameter centre, is the cylinder that has external screw thread (nominal diameter is 28mm) outside the hole, the high 8mm of tube, thick 2mm.

Material is plastics.

7, pacify (Fig. 9)

Make the usefulness of feeding infant.

Pacify for general requirements.The nipple crown center is cut together by cutter or is intersected several (cutting till the rubber) osculum of long 2mm.This opening is changed circular open in the past, and benefit is only just to go out milk when the baby sucks.

8, milk skull (Figure 10)

In order to the protection nipple.

The milk skull is a cylinder, and height is 9mm, and diameter is 30mm.Cylinder one side is porose, hole depth 8mm, and it is the female thread of 28mm that nominal diameter is arranged in the hole, is connected lid in order to connect.Be primed with one deck rubber in the hole or fill up a sheet rubber, in order to sealing.

Material is plastics.

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CN101155606B *	2005-04-07	2010-09-01	美德乐控股公司	Valve, especially for a breast cup set
CN105434178A *	2016-01-10	2016-03-30	陈文婷	Nipple stickers and bra with nipple stickers
CN106535814A *	2014-04-29	2017-03-22	金特股份有限公司	Protective hood for a surgical operation field

Family To Family Citations

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
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US20090062731A1	2009-03-05	Breast Pump
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CN207720982U	2018-08-14	A kind of nipple warm bath and the breast that overflows collect cup
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Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
CN 00214870	2000-05-23	2000-05-23	Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Applications Claiming Priority (1)

Application	Filing date	Title
CN 00214870	2000-05-23	Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Legal Events

Date	Code	Title	Description
2001-10-10	C14	Grant of patent or utility model	
2001-10-10	GR01	Patent grant	
2005-07-13	C19	Lapse of patent right due to non-payment of the annual fee	
2005-07-13	CF01	Termination of patent right due to non-payment of annual fee	

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[19]中华人民共和国国家知识产权局

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[12]实用新型专利说明书

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[22]申请日 2000.5.23

[21]申请号 00214870.6

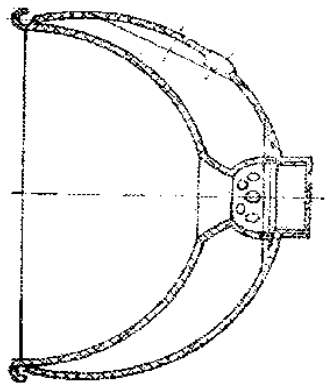
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权利要求书 1 页 说明书 5 页 附图页数 3 页

[54]实用新型名称 乳罩、合离式多功能健乳接奶器

[57]摘要

一种专门用于哺乳期妇女的接奶器具，它的外观呈乳罩形状，主体与框架 可随意合、离；主体为中空半球体结构，其构成部分由里至外依次为：盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖等。它从根本上解决了产前妇 女的乳房“漏乳”（《中医学》又称“乳汁自出”）、胀奶所带来的困扰，具有 随身携带，随时接奶、吸奶的特点，还具备了有益于乳汁分泌及乳房形体的恢 复等诸多功能。



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权　利　要　求　书

1. 乳罩、合离式多功能健乳接奶器，在器体中有一弹性橡胶片和一气阀，其特征是：器体呈普通乳罩形状；器体由盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖及圆形框架连接构成；衔接盖与盛奶器及奶头盖使用螺纹连接，弹性橡胶片胶附在盛奶器上，气阀镶嵌在弹性橡胶片中，橡皮奶头下端压附在衔接盖中，盛奶器与圆形框架使用卡凸、卡槽连接。

2. 根据权利要求1所述的接奶器，其特征是：盛奶器内、外侧呈半球形状，形成中部空间；内侧壁中间有孔，与孔相连的是喇叭状体和半圆柱体，其内为相同形状的孔；半圆柱体前端排列有若干小孔，末端带有外螺纹；盛奶器的圆形周边分布有弧形凸台，以对应圆形框架中的凹槽；盛奶器内侧附有软布或海绵。

3. 根据权利要求1所述的接奶器，其特征是：衔接盖内侧呈一平面，平面周围涂有一层橡胶，中间有一螺孔，螺孔外与弧形外侧壁内有一空间，外侧壁中间有一圆孔，圆孔外为带有外螺纹的圆筒。

4. 根据权利要求1所述的接奶器，其特征是：橡皮奶头的开口结构是，奶头顶部中间被刀切一道或多道小口(切透橡皮为止)。

5. 根据权利要求1所述的接奶器，其特征是：奶头盖内壁有孔，孔内有内螺纹，孔底涂一层密封用橡胶或垫一橡胶片。

6. 根据权利要求1所述的接奶器，其特征是：盛奶器与圆形框架采用可合、离的连接方式。

乳罩、合离式多功能健乳接奶器

本实用新型涉及一种接奶器，特别是涉及哺乳期妇女的接奶器具。

哺乳期妇女的“漏乳”现象(《中医学》又称“乳汁自出”)，其产生原因至今未明；治疗方面，西药无特效，中药疗期过长；此现象长期严重困扰着妇女的正常生活。对此，人们根本没有固定的接奶器具：有的用吸水性强的纸、布、海绵等物接奶，有的用奶瓶、茶杯等器皿接奶。采取以上措施，虽能解决一时“漏乳”，却有诸多不便：用纸、布、海绵等物接奶，接奶量太小，会导致外部衣物浸湿；用瓶、杯等器皿接奶，不宜出门在外或公众场合。如果在上班、睡眠、旅行等情况下接奶，常常会防不胜防，令人狼狈不堪。

至于胀奶，现在人们常用吸奶器处理，吸奶器的确减轻了不少痛苦，但其不宜公众场合使用，也不能在睡眠中及时吸奶等等，产生了不少不必要的麻烦。

针对现有技术在处理接奶、吸奶问题过程中出现的多种不良状况，我研制成功了乳罩、合离式多功能健乳接奶器，不但从根本上减轻了“漏乳”、胀奶所带来的痛苦和克服了现有技术中的种种弊端，而且具备多种新的有益功能。其功能具体如下：

㈠本实用新型系一种专门用于哺乳期妇女乳房“漏乳”、胀奶的接奶器具。

㈡本实用新型的使用十分方便，贴身使用，适合睡眠、工作、旅行等情况下使用。

㈢接奶及时、彻底。

㈣有利于母乳的分泌、喂养及乳汁的充分利用。

㈤吸奶迅速、及时。

㈥保护乳房、使乳房舒适。

㈦有益于乳房的健康、使其自然放松，可促使乳房的正常恢复并预防乳房下垂。

㈧给人以乳房丰满之美感。

本实用新型的目的是用以下方案实现的。

乳罩、合离式多功能健乳接奶器的外观与普通圆形乳罩近似，主体为前端乳房状物，附属部分为连接主体的圆形框架及两条弹性系带。主体与框架的结合采用卡口旋转连接方式，可使主体随人的意志自由结合与分离，从而达到使

用方便的目的。

接奶器主体从里向外依次由盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖等六部分组成。其中，盛奶器、奶头盖与衔接盖的使用螺纹连接，弹性橡胶片胶附在盛奶器上，气阀镶嵌在弹性橡胶片中，橡皮奶头下端压附在衔接盖中。

盛奶器紧贴乳房，内、外侧壁均为半球形设计，形成中间空间，用以盛漏出或吸出的乳汁。其内侧壁中间有一孔，以使乳头伸到盛奶器内，与此孔相连的是呈喇叭状柱体，与此体相连的是半圆柱体。喇叭状体与半圆柱体内部为与外形相同的孔。半圆柱体前端弧形壁上均匀排列有若干小孔，以使乳汁流入器底，末端带有外螺纹。盛奶器的外侧壁上部有一圆形弹性橡胶片，弹片中下部又有一圆形气阀，此结构用以吸奶。盛奶器的圆形周边均匀分布四个与圆形框架相接的半圆形凸台，以对应圆形框架中的凹槽。盛奶器内侧紧贴乳房部位粘附有一层海绵或软布，确保使用舒适。

衔接盖用以衔接盛奶器与奶头及奶头盖。其内侧呈一平面，平面周边涂有一层橡胶用以密封，平面中间有一螺孔，与盛奶器的螺柱相连。螺孔向外有一空间与圆孔，是奶头的栖身之地，圆孔外侧周围为带有外螺纹的圆筒，用来连接奶头盖。

奶头为普通常用橡皮奶头，开口由刀切一道或数道而成。

奶头盖为圆柱体设计，内有螺孔与衔接盖的螺柱相吻合，其底部垫一密封橡胶薄片。

上述除个别说明外，其余材料皆为塑料。

由于采用上述方案，本实用新型具有以下优点：

首先，本接奶器是一种专门用于哺乳期妇女“漏乳”或“乳汁自出”（《中医学》称）的接奶器具。它的出现，将填补市场空白。它与现有技术相比具有接奶及时、方便、量大等优点，从根本上消除了以前接奶的麻烦，使用它，无论何时何地“漏乳”，都不会影响人的正常生活。

其次，本接奶器有利于母乳喂养及乳汁的充分利用。使用本接奶器，当婴儿需要吃奶时，可迅速拿掉接奶器，及时喂养；如婴儿吃不饱，还可用接奶器内的乳汁直接喂养，不需再倒入其他喂奶器内，使用十分方便。

第三，使用本接奶器有益于乳房健康，能托起并保护乳房，使其自然放松，从而改善血液循环，促进乳汁分泌；对于断奶后乳房的完好恢复及防止乳房下垂特别有益。

第四，本接奶器贴身使用，一改现有吸奶器的使用不便，任何场合匀可进行吸奶，而且使乳房具有丰满之美感。

下面结合附图和实施例，对本实用新型进一步说明。

图1所示为本接奶器的主视图(弹性系带部分省略)。

图2所示为单个接奶器圆形框架主视图，A--A为剖切位置。

图3为单个接奶器圆形框架的全剖视图。

图4为单个接奶器主体的主视图，B--B为剖切位置。

图5为单个接奶器主体的全剖视图(气阀略)。

图6为盛奶器的全剖主视图(气阀略)。

图7为气阀的全剖视图(Ⅰ为图6中局部放大图的标记)。

图8为衔接盖的全剖主视图。

图9为奶头的开口结构示意图。

图10为奶头盖的全剖主视图。

本接奶器根据哺乳期妇女乳房的大小，设计出不同型号，以盛奶器内侧壁半圆球半径(即乳房的半径)为代表其规格的尺寸，此半径增大则盛奶器外侧壁、衔接盖的截面、圆形框架的直径等部分增大，在盛奶量增大的同时又确保乳房舒适。

以适用半径是60mm的乳房的接奶器为实施例，描述如下：

此接奶器各组成零件的相互位置和装配关系如图1所示，其中：1、弹性系带；2、圆形框架；3、盛奶器；4、弹性橡胶片；5、气阀；6、衔接盖；7、橡皮奶头；8、奶头盖。

下面以各附图为辅，说明本接奶器的各零件的结构特点、尺寸大小及性能、材料等。

1、弹性系带(图1)

作连接人体与接奶器之用。

弹性系带宽为30mm，总长约为400mm(可依据不同胸围设计几种规格)，左侧弹性带连接在左侧框架左边，右侧弹性带连接在右侧框架右边，可用胶粘或把框架包起等方式连接，左、右侧弹性系带的另一端有挂钩供相互连结之用。左右框架中间有长为35mm、宽为30mm(据两乳间距而定)的弹性系带相连。

材料为一般弹性布带。

2、圆形框架(图2、图3)

其作用是使接奶器主体可按人的意志自由合、离，达到使用方便的目的。

框架内边直径为120mm，外边直径为144mm，卡口的对称中心线与框架垂直轴线成45°角，卡口长10mm，宽9mm，卡口内、外缘厚均为2mm，框架厚8mm 。框架内有四段半径为4mm的弧形凹槽(卡槽)，均匀分布在框架中， 其卡口与凹槽皆与盛奶器周边的凸台(卡凸)相适合。

3、盛奶器(图6)

用以盛漏出或吸出的乳汁。

其内、外侧壁皆为半球体，外侧壁直径为130mm，内侧壁半径为60mm， 壁厚2mm。内．外侧壁同一轴线，圆心相距20mm，外侧壁圆心偏外。 盛奶器外侧有直径为50mm的开口与衔接盖相吻合。开口上方10mm处有一直径为50mm的弹性橡胶片，其上有一橡胶材料制成的气阀。 盛奶器内侧壁中间有一孔， 直径为30mm，与孔相连的是喇叭形柱体，中间为喇叭形孔，壁厚2mm， “喇叭”弧为40mm，“喇叭”内口直径为15mm。与内口相连的是半圆柱体，直径为30mm，内有同样形状的柱孔，壁厚2mm。半圆柱体，前端均匀排列有若干直径为1-- 4mm的小孔，供乳汁流入器底之用；末端有公称直径为30mm 的外螺纹， 此柱体高4mm。盛奶器周边有直径为8mm、长8mm、厚2mm的适合圆形框架中卡口与卡槽的凸台(卡凸)。为确保使用舒适，盛奶器的内侧表面(即与乳房接触部位)覆上一层软布或海绵，覆面从距内侧孔20mm处至外边缘。

除个别注明外，其它材料为塑料。

4、弹性橡胶片(图4)

用以增加器内负压，以完成吸奶。

在盛奶器外侧壁开口上方10mm处，有截面直径为50mm的弹性橡胶片，中间较薄(厚为2mm)，往周边逐渐增厚，边缘处厚3mm，以增加弹性。

材料为弹性强的橡胶。

5、气阀(图7)

用以排出接奶器内气体，以增加器内负压。

气阀位于弹性橡胶片的中下部，由底座、橡皮塞、橡皮片组成。底座底部有一直径为2mm的孔，孔深2mm，孔上为直径8mm、深2.5mm的柱体空间；以适合橡皮塞。此空间开口直径为6mm。橡皮塞底面直径为8mm，底面边缘有2mm 宽的弧形凸台，用以压住橡皮片一侧。橡皮塞上端是直径为10mm的弧形凸台，中上部有一凹槽深1mm，以适合底座开口，并能密封。橡皮塞被一直径为2mm，长为4.5mm的圆形柱孔贯穿。橡皮片为直径7mm，厚0.5mm的薄片，垫在橡皮塞底部。

材料为橡胶。

6、衔接盖(图8)

用以连接盛奶器，橡皮奶头及奶头盖。

衔接盖内侧呈一平面，直径为57mm，与盛奶器外孔壁外侧吻合。在平面周边涂有宽3mm的一层用以密封的橡胶。此平面厚2mm，中间有一螺孔，公称直径为30mm，与盛奶器中螺纹相适应。螺孔与弧形外侧壁(半径为65mm)之间为一空间，用来安装橡皮奶头。外侧壁厚2mm，中间有一直径为23mm的圆孔，孔外为带有外螺纹(公称直径为28mm)的圆筒，筒高8mm，厚2mm。

材料为塑料。

7、橡皮奶头(图9)

作喂养婴儿之用。

为一般规格的橡皮奶头。奶头顶部中间被刀切一道或交叉数道(切透橡皮为止)，长2mm的小口。此开口一改以往圆形开口，好处是只有在婴儿吮吸时才出奶。

8、奶头盖(图10)

用以保护奶头。

奶头盖为圆柱体，高为9mm，直径为30mm。柱体一侧有孔，孔深8mm，孔内有公称直径为28mm的内螺纹，用以连接衔接盖。在孔底涂有一层橡胶或垫一橡胶片，用以密封。

材料为塑料。

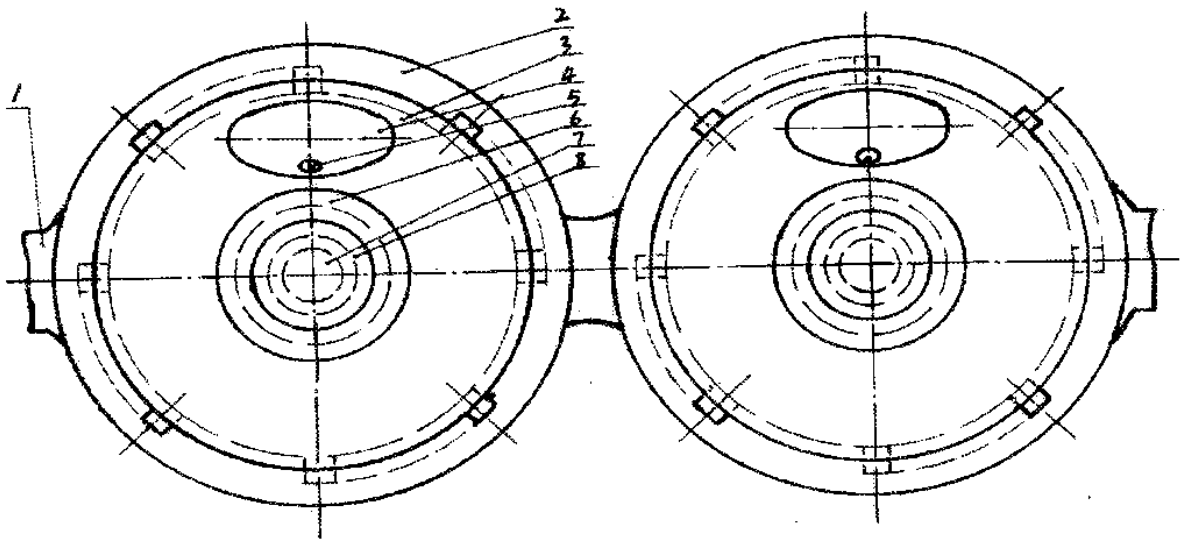


图 1

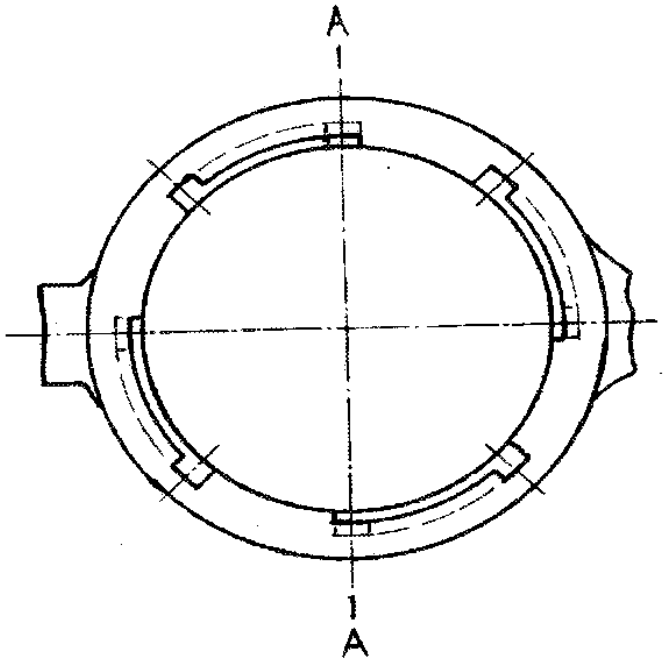


图 2

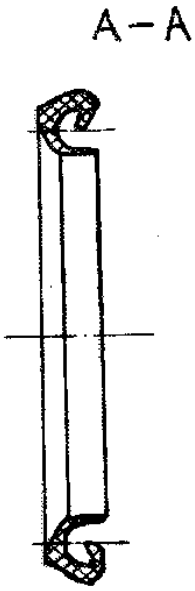


图 3

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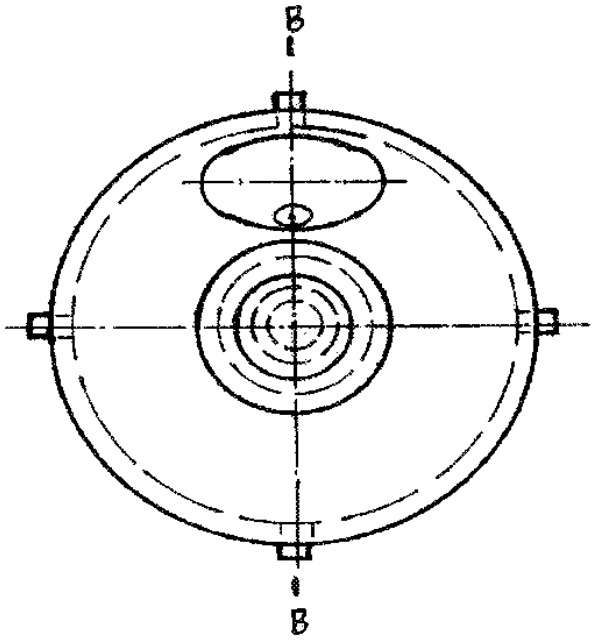


图 4

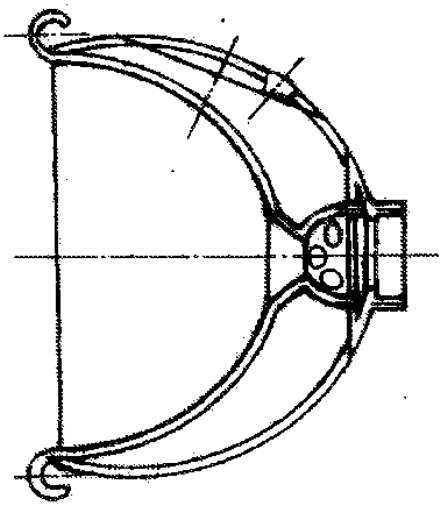


图 5

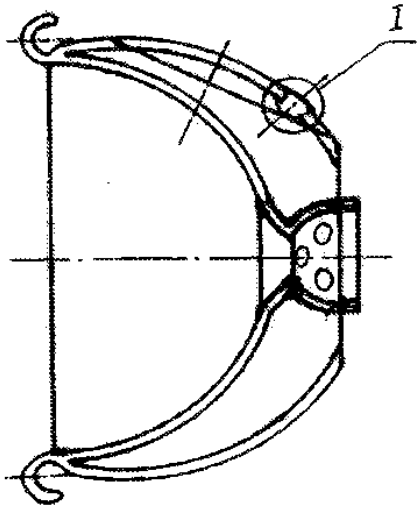


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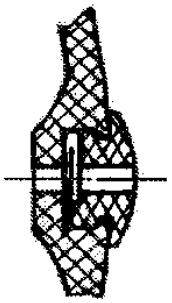


图 7

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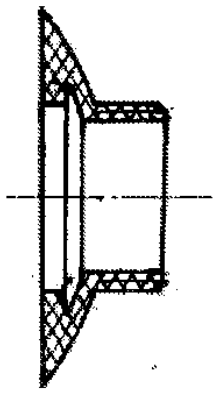


图 8

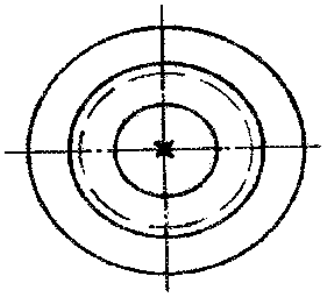


图 9



图 10

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ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☑ 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
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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.		
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Date	April 17, 2024	Reg. No.	800,005

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[Continued on next page]

(54) Title: BREAST PUMP ASSEMBLY AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

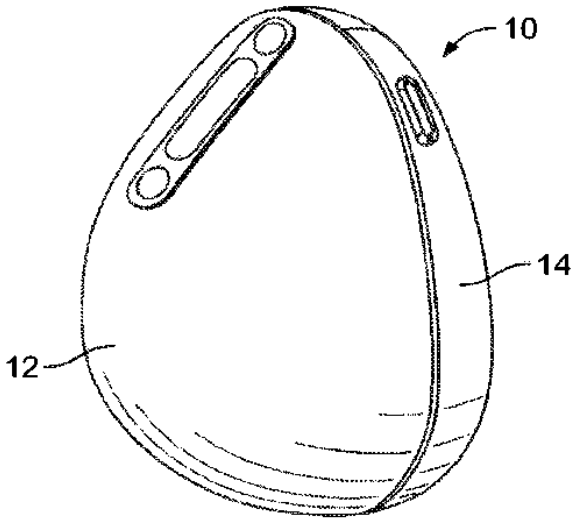


FIG. 1A

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BREAST PUMP ASSEMBLY AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to portable breast pump systems and methods for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, a number are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be inconvenient to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. 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, that mimics natural nursing, and is discrete by not exposing the breast of the user and nearly unnoticeable when worn.

[0005] To ensure that the nursing baby is receiving adequate nutrition, it is useful to monitor the baby's intake. It would be desirable to provide a breast pump system that easily and accurately monitors the volume of milk pumped by the system, to make it convenient for the nursing mother to know how much milk has been extracted by

breast pumping. It would also be desirable to track milk volume pumped per session, so that the volume of milk contained in any particular milk collection container can be readily known.

[0006] There is a continuing need for a breast pump system that is effective and convenient to use. The present disclosure addresses these and other needs.

SUMMARY OF THE DISCLOSURE

[0007] Briefly and in general terms, the present disclosure is directed toward breast pump systems or methods. The system includes breast contacting structure and a collection or storage container or assembly, and structure that delivers milk from a breast to the collection assembly. The method involves pumping milk from a breast and delivering the pumped milk into the collection assembly or storage container. In one particular aspect, the breast pump system responds in real time to optimize pumping action for a particular user during a particular pumping session.

[0008] According to one aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member or flange configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; an external shell; a milk collection container; and a non-transitory computer readable medium having stored thereon instructions executable by a computing device to cause the computing devices to perform functions associated with and directed by the instructions; wherein the external shell comprises a compartment; wherein the skin contact member, the conduit and the driving mechanism are received in the compartment of the external shell; wherein the milk collection container is positionable within the shell; and wherein the system is shaped and configured to be contoured to the breast of a user.

[0009] In one or more embodiments, the system can include one or more of structure configured to address fluid ingress, pinch protection structure, a flex-tube structured to accomplish efficient and predictable pumping of fluid and the creation of desirable pressure profiles, and cooperating structure for fluid collection secure attachment and removal.

[0010] In various embodiments, the storage container can be specifically configured to prevent kinking and for durability and handling. The storage container can be designed to hold, accept or retain milk or other fluids. A flow feature can be incorporated into the storage container in the form of a scallop structure, valves and materials can be chosen to facilitate removing air or gases, tabs and wings can be provided for handling, and structure adapted for the removal of milk from a collection assembly.

[0011] In various of the disclosed embodiments, the system defines a 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. In one aspect, the system defines a breast enhancement system for enlarging the appearance of the user's breast.

[0012] In at least one embodiment, the system functions by operating a control system that tracks internal pressure of the system against a known waveform. In this regard, the waveform can be a vacuum waveform indicative of pressures applied to a breast, and can define a sine wave fluctuating between about 60mmHg of vacuum to a vacuum from about 120mmHg to about 250mmHg, or other desirable or useful waveform.

[0013] In one or more embodiments, the system includes a controller that accomplishes real time pressure control inside the system.

[0014] In one or more embodiments, the system includes a controller providing automated compliance sensing and response.

[0015] In one or more embodiments, the system includes a non-contact pressure sensing arrangement that does not touch the skin or the milk inside the tube while accurately determining internal pressure of the tube.

[0016] In one or more embodiments, the system includes one or more controllers that automatically detects one or more of letdown, overfill and flow.

[0017] In one or more embodiments, the system is disabled when the flange is not placed in an operating position.

[0018] In one or more embodiments, the system can be adapted to visualize a user's data and trends as it relates to volume (from each breast and total), and number of

sessions on several dimensions (per day, per week and per month). Data and analytics can also be provided on pumping session.

[0019] In at least one embodiment, the flange or skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere. In other embodiments, the container need not be contained within the housing, and the pump need not be in a cup of a brassiere, but can be unsupported or supported by itself or by other clothing or a nursing tank top or a band surrounding the user's body.

[0020] In at least one embodiment, the system is battery powered, the system comprising a battery, wherein the battery is received in the compartment of the external shell.

[0021] In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit. In one embodiment, the collection container or container assembly includes an extra part, valve or fitment that is attached thereto and facilitates creating a seal with the container to establish a closed system. In one embodiment, the milk container can include a one-way valve that cannot be removed without destroying milk container or valve function. The valve can assume a myriad of shapes and kinds including an umbrella valve, a duckbill valve, a ball valve or other valve. Moreover, in one or more embodiments, the container can be flexible or rigid, or disposable or reusable.

[0022] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a flange or skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member.

[0023] In at least one embodiment, the system further includes a milk collection container, wherein the milk collection container is in fluid communication with the conduit.

[0024] In at least one embodiment, the skin contact member includes: a breast contact portion configured and dimensioned to fit over and form a seal with a portion of the breast; and a nipple receiving portion extending from the breast contact portion.

[0025] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, and a controller configured to control operation of the driving mechanism; sealing the skin contact member to the breast; operating the driving mechanism to generate predetermined pressure cycles within the conduit; monitoring by the controller of at least one of position and speed of movement of the compression member relative to the conduit; measuring or calculating pressure within the conduit; maintaining or modifying motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of force, position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0026] In at least one embodiment, the predetermined pressure cycles comprise extraction pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction pressure cycles.

[0027] In at least one embodiment, the predetermined pressure cycles comprise latch cycles, wherein upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction pressure cycles, wherein the predetermined extraction cycles differ from the predetermined latch cycles by at least one of maximum suction level, cycle frequency or waveform shape. Moreover, in one or more embodiments, the system includes structure or functions to recognize when a user is done pumping, or includes structure or functions such that when there is a loss of vacuum recognition which allows the user to easily end a pumping session by simply

pausing and pulling the device off of the breast. Additionally, in one or more embodiments, the system can include an auto-purge function or an accelerometer functioning as gesture recognition so that the device can interpret what the user is attempting to accomplish.

[0028] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a flange or skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member; a sensor; and a controller configured to control operation of the driving mechanism; wherein upon sealing the skin contact member to the breast, the controller operates the driving mechanism to generate predetermined pressure cycles within the conduit, monitors at least one of position and speed of movement of the compression member relative to the conduit, measures or calculates pressure within the conduit based upon signals received from the sensor, and maintains or modifies motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of force, position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0029] 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

[0030] Fig. 1A shows a perspective view of a breast pump system according to an embodiment of the present disclosure.

[0031] Fig. 1B is a rear view, depicting the flange of the pump system of Fig. 1A.

[0032] Fig. 2 shows a front view of the system of Fig. 1 with the shell removed.

[0033] Fig. 3 depicts a back view of the system of Fig. 1 with the flange removed..

[0034] Fig. 4 is a cross-sectional side view of the system of Fig. 1.

[0035] Fig. 5 is an inside view of the system of Fig. 1, depicting the flex conduit of the pump assembly.

[0036] Fig. 6A is an exploded view of the system of Fig. 1, depicting mechanical components of the system.

[0037] Figs. 6B-D depict views of an alternative approach to housing structure.

[0038] Figs. 6E-G depict views of yet another alternative approach to housing structure.

[0039] Fig. 6H is a perspective view, depicting a first approach to a system including a removable battery structure.

[0040] Fig. 6I is a perspective view, depicting a second approach to a system including a removable battery structure.

[0041] Fig. 6J is a perspective view, depicting a third approach to a system including a removable battery structure.

[0042] Fig. 7A is a schematic representation, depicting operational components of the system.

[0043] Fig. 7B is a graphical representation, depicting motor position and vacuum versus time.

[0044] Fig. 7C is a graphical representation, depicting motor position versus volume.

[0045] Fig. 8 is a top view, depicting one embodiment of a storage collection assembly of the present disclosure.

[0046] Fig. 9 is an enlarged view, depicting a neck and valve of the storage collection assembly of Fig. 8.

[0047] Fig. 10 is an enlarged view, depicting a valve assembly of the storage collection assembly.

[0048] Fig. 11A is a perspective view, depicting a storage collection assembly connected to the system.

[0049] Fig. 11B is a perspective view, depicting a first step in installing a collection assembly.

[0050] Fig. 11C is a perspective view, depicting a second step in installing a collection assembly.

[0051] Fig. 11D is a top view, depicting a third installation step.

[0052] Fig. 11E shows yet another collection assembly installation step.

[0053] Fig. 12 is a cross-sectional view, depicting a portion of the system.

[0054] Fig. 13 is a perspective view, depicting a door assembly of the system.

[0055] Fig. 14 is a cross-sectional view, depicting details of the door assembly.

[0056] Fig. 15 shows details of the door assembly.

[0057] Fig. 16 is an enlarged view, depicting structure of a pinch protection assembly.

[0058] Fig. 17 is an enlarged view, depicting other structure of a pinch protection assembly.

[0059] Fig. 18 is a perspective view, depicting a flex circuit of the system.

[0060] Fig. 19 is a top view, depicting a user interface assembly.

[0061] Fig. 20 is a bottom view, depicting further details of the user interface assembly

[0062] Fig. 21 shows power access support structure of the system.

[0063] Figs. 22-28 depict various aspects of a remote user interface system.

[0064] Figs. 29-41 depict various further aspects of a remote user interface system.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0065] 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.

[0066] 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.

[0067] 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.

[0068] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a sensor" includes a plurality of such sensors and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[0069] 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.

[0070] Various details of the present system can be found in PCT Application Nos. PCT/US15/41257, PCT/US15/41271, PCT/US15/41277, and PCT/US15/41285 each filed 07/21/2015, and PCT/US15/50340 filed 09/16/2015, each of which are hereby incorporated herein, in their entireties, by reference thereto.

[0071] Figs. 1A-B are perspective and back views of a breast pump system 10 according to an embodiment of the present disclosure. The breast pump system 10 can include one or more of the below introduced or described features or functions, or a combination thereof. The housing or outer shell 12 of system 10 can be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. An opposite side of the pump system 10 is

configured with a flange 14 which is sized and shaped to engage a breast of a user. The flange 14 is contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue. In one particular embodiment, the flange 14 can form generally rigid structure, and alternatively or additionally unlike a standard flange can lack sharp edges or a lip portion against which breast tissue might be engaged during use. In this regard, the flange includes surfaces that extend outwardly from a nipple receiving portion of the flange to engage breast tissue, thus providing extra surface area for comfortably contacting tissue. Various approaches are contemplated to the flange with respect to a user's nipple. One approach involves aligning a horizontal line formed within the flange structure a bit higher than center with the rationale that the perspective of the mother is from above. This perspective allows the user to better align the breast with the horizontal line to better center the nipple in the actual center of a nipple receiving portion of the flange, thus offsetting any tendency to aim/line up low associated with centered lines because the user's perspective is from above the line and also because the device is pivoted into place in certain instances.

[0072] Fig. 2 is a front view of the system 10 of Fig. 1, with the housing or outer shell 12 having been removed and made transparent to show components otherwise covered by the housing 12. In particular, with the housing 12 removed, various electronic components can be identified. The system controller is embodied in a circuit board 15 that is in communication with a flex-circuit 16, each cooperating to connect to and control various electro-mechanical components of the system 10. A control panel 17 is in electronic communication with the controller via the flex-circuit 16 and provides the user with the ability to power the system on and off as well as to alter functioning. One or more motors 44, 46 are further provided and controlled electronically by the system to effect manipulation of actuators (described below) operating on a conduit or flex-tube 32 (See Figs. 4 and 5). A battery 48 is included to provide a rechargeable power source and is configured to be plugged into a power source for charging. Further, there is provided a load cell assembly 54 that is configured to provide a pressure sensing function as described below. It is contemplated that at least in one embodiment, the conduit or flex-tube 32 is oriented to run from inferior to superior relative to the nipple

of a breast when the user is upright.

[0073] Fig. 3 shows an opposite side of the system 10 with the flange 14 removed to illustrate more details of the pumping function. The conduit or flex-tube 32 (See Figs. 4-6) includes generally spherically shaped connectors 33 that are sized and shaped to be removably received in recesses 34 formed in a pump chassis 35. The connectors 33 are designed to automatically engage with moving motor paddles without the user being aware or having to make adjustments, or assemble parts. The pump chassis 35 functions to support the electronic and electro-mechanical structures of the system 10 (See also Fig. 2). It also provides spacing for a pinching actuator 36 that is configured to be advanced and retracted toward and away from the conduit or flex-tube 32 as described further below. Other pumping action is accomplished through the engagement of the conduit or flex-tube 32 with recesses 34 by a compression and expansion member 38 (See Fig. 7A). Embossed engraving is further provided within a well formed in the chassis 35, the engraving providing product and other information relevant to the breast pump. In this way, certain adhesive labels need not be applied to the breast pump structure.

[0074] In general, real-time pressure control can be managed by a controller of the system 10. The controller tracks pressure and moves a pump motor either in or out to influence the pressure in the direction of its choosing. By way of oscillating motion of the motor, the pump can be configured to pull on the connectors 33 of the conduit or flex-tube 32 structure to increase its volume. If there is vacuum in the system 10 that vacuum can be increased as the volume of the tube increases. Pushing in the tube decreases its volume. This in turn causes the vacuum level to decrease in the tube, and can cause a relative positive pressure if vacuum decreases enough. The pump controller applies these principles, sensing the current pressure and then nudging a compression member or paddle of the motor assembly in a direction required to generate a pressure target. By doing this repeatedly in real time, the system can create a controlled vacuum waveform that matches waveforms desired to be applied to a user's nipple.

[0075] The pump can slowly pull the compression member or paddle out until it hits a pre-determined target. Should the paddle be moved to the end of its range without

being able to generate a desired vacuum, the system will be purged to generate more vacuum potential. The purge functions to push material out of the system to create a strong vacuum potential. It accomplishes this by first closing a pinch on the conduit or flex-tube or closing off the flex-tube with a flap, dam, etc., then evacuating the flex-tube, for example, by pushing closed the paddle, which forces volume out of the flex-tube and any fluid or air that was inside that volume is also ejected through the one-way valve and into the collection receptacle. When the paddle retracts again, it can then generate much higher vacuum as contents of the tube had been previously purged. Once a higher vacuum can be generated, the system can open the pinch valve so that the desired vacuum profile can be applied to a breast and desired pressure waveform can be produced.

[0076] When the system is filled with air, it is very compliant such that a large change in motor positioning makes only a small change in vacuum. When the system is filled with fluid on the other hand, a small change in motor positioning makes a big change in vacuum. In one particular approach, an encoder including a plurality of spaced magnets is associated with the motor. The magnets can be placed along a periphery of a generally disc shaped encoder with the magnets oriented parallel to the axis of rotation of the encoder. One or more hall effect sensors can be configured on or surface mounted to the circuit board 15 and positioned to read the motion and position of the magnets. In this way, the position of the motor can be determined and monitored. Thus, a challenge can be to configure the system so that it is stable when the system is responsive, and effective when it is not as responsive. One contemplated approach is to tune the controller for a relatively rigid system and to input unit-less quantities that move the motor in required directions where the amplitude of which is modified depending on the output of the system. Accordingly, a cascade controller can be created to grow an input wave if system output is smaller than desired to hit pressure targets and can be shrunk if the system output is larger than required. This can be accomplished in real time by observing output verses input. In this way, the controller can be continuously adjusting target waveforms. Top half and bottom half waveforms can have independent control which facilitates centering waveforms in an effective manner, and results in a system that is both very accurate and quick to adjust.

[0077] The system can further be provided with automated letdown detection. The pump can sense when it is full of fluid and responds accordingly by switching between pumping and letdown when fluid has begun to flow. In one approach an algorithm incorporated into the system can operate to look at the ratio of maximum and minimum of a target wave in the pump and compare that against the output of the pump. The result is a unit-less but very reliable sensing of system compliance. This can be tuned to trigger an internal event when the compliance crosses some known values that represent when the system is full of fluid. Any other measurement of compliance can be used in an equivalent way.

[0078] In another approach to letdown detection, it is noted that pushing a tube of air does not generate the same forces as pushing a tube of fluid. Tracking the force generated during a purge can also give a strong indication of when the system is full of fluid. An event can be generated to track this such that when the force of a purge crosses some known threshold the system can be said to be full of fluid rather than air. This approach may involve less tracking of data and less tuning that is subject to change with pump design or breast tissue. In yet another approach, letdown detection can be based upon tracking flow. That is, when flow begins, letdown must have occurred and when a small volume of flow has been collected the system can switch to pumping. Further, letdown can be tracked by looking at the relative rate of change of vacuum measured to motor position. Note that this relative rate of change is a measurement of compliance. As this ratio goes up in magnitude, it can be concluded that the system is filling with fluid.

[0079] Fig. 4 illustrates a cross-section of components of a system 10 according to an embodiment of the present disclosure. Flex-tube or conduit 32 (isolated in Fig. 5) includes a large conduit portion 32L that is relatively larger in cross-sectional inside area than the cross-sectional inside area of small conduit portion 32S. The large conduit portion 32L terminates with an opening sized for cleaning and is generally sized to accept a small finger tip. Although both portions 32S and 32L are shown as tubular portions, the present disclosure is not limited to such, as one or both portions could be shaped otherwise. When tubular, the cross-sections may be oval, square, other polyhedral shape, non-symmetrical, or non-geometric shape. Further, the flex-tube 32

can include an enlarged bulbous portion 32B configured near a terminal end of the large conduit portion 32L that is provided to help accommodate system hysteresis.

[0080] Figure 6A depicts an exploded view of structural and mechanical components of the system 10. Configured between the housing 12 and flange 14 is the chassis 35. Notably, the chassis can be configured to snap into engagement with the housing 12. Moreover, in a preferred embodiment, the chassis 35 supports directly or indirectly all of the pump components. In particular, a PCB controller mount 62 is supported by the chassis 35 and is configured to be connected to and support the circuit board 15 (See also Fig. 2). A battery bracket 64 is also supported by the chassis 35 and is sized and shaped to receive a rechargeable battery 48 assembly that powers the system 10. A cover jack 65 is further included to provide access to the battery assembly and for accepting a power cord connector (not shown). Motor mounting 66 and motor receiver structure 67 is also supported by the chassis 35 and are configured to receive and support the system motor which is powered by the battery and which functions to move actuators operating on the conduit or flex-tube 32. Also supported by the chassis 35 are an actuator bracket 69, and a load cell bracket 70 and load cell receiver 71. Moreover, user interface panel can include a button membrane 72 and a button membrane housing 73 each supported on the housing 12 and placed in engagement with the flex-circuit 16 that provides the user with system control.

[0081] In order to connect the conduit or flex-tube assembly 32 to the system 10, there are provided a flex-tube ring 80 and a flex-tube collar 82. The flex-tube collar 82 is sized and shaped to be received into slots 84 on the flange. A fluid container fitment 86 (shown in isolation from the container) is sized and shaped to be received into the flex-tube collar 82. A door assembly 90 is attached to the flange 14 and configured to swing open and closed to both provide access to an interior of the system 10 as well as to support a robust connection between the fitment 86 and flex-tube collar 82. Accordingly, it is contemplated that in at least one embodiment, the collection or container assembly is supported and maintained in attachment by friction around a shaft of the conduit to the collection or container assembly, and partially by the door assembly 90 which can enclose and hold the collection or container assembly in place. In alternative embodiments, the breast pump assembly can omit a door assembly

entirely. Thus, the flange itself can include structure for retaining the container assembly in place. Moreover, the door assembly or other structure that replaces the door assembly can be transparent so that a direct view to the container assembly is provided.

[0082] In alternative embodiments, the housing 14 is defined by an irregular shape that includes contours that track or mimic the internal components and structure of the pump system. In one particular approach as shown in Figs. 6B-D, an outer surface of the housing 14 is characterized by an irregular shaped indentation 91, providing the outer surface with an irregular shape. Various differently shaped indentations 91 can be employed (See also Figs. 6E-G). Various configurations of a separate breast cup skin or interface structure 98 is sized and shaped to fit over the housing 14 and indentation 91 to form a desired shape such as the breast shape depicted in the figures. It is noted that the breast pump system can work with or without the breast cup skin or interface structure. Alignment and attachment structure or holes can be further provided to facilitate the mating of the interface structure 91 with the housing 14 and the interface structure can assume a myriad of colors, textures and durometer to enhance or change tackiness, softness for security and outer feel in the bra. Various other breast and other shaped can also be provided.

[0083] In yet further combined or separate embodiments (See Figs. 6H-J), the housing 14 can be adapted or configured to additionally or alternatively accommodate a replaceable battery. Here, the housing 14 includes various other shaped indentations 91 sized and shaped to accommodate the battery. In this approach, the battery includes its own attachable housing 99 that mates with the housing 14 indentation 91, the housing 14 covering other pumping structures. In one approach, mating features include flat, right-angled structures, and alignment and attachment holes and structures are further provided.

[0084] As shown schematically in Fig. 7, latching, pumping and extraction forces can be established by two compression members 36, 38 that are actively driven by motor drivers 44 and 46 respectively. Although more than two compression members could be used and one or more than two drivers could be used, the currently preferred embodiment uses two compression members respectively driven by two drivers as

shown. A system controller or system software and/or firmware controls the action of the drivers in real time, responsive to pre-determined latching and production targets or schemes as detected by the pressure sensor or load cell assembly. The firmware can be written so that such targets can be approached at various speeds, sometimes relatively quickly and other times more slowly or gently to thereby provide multiple stimulation and expression levels. Thus, for example, latch can be achieved taking alternatively more gradual or quicker approaches, and there can be controls determining the level at which latch is achieved. Various levels of suction can be present during expression as well. Tubing portions 32S and 32L can be closed off, or substantially closed off by compression members 36 and 38, respectively. Moreover, such active pumping members can be configured to engage upon a tubing channel generally perpendicularly to the net flow of fluid or milk within the channel. Also, a pinch region of the tubing channel can be configured to open through passive recoil located next to a compression region of the tubing channel which opens through an assistive active support. Upon powering up the system 10 the compression member 36 opens and the compression member 38 begins to withdraw away and through its connection to structure such as the ball connector of the conduit or flex-tube 32 thereby gradually increases the suction level within tubing 32. When a predetermined maximum suction level is achieved (as confirmed by pressure readings taken from a pressure sensor, described below), the compression member 38 ceases its travel in the current direction, and either maintains that position for a predetermined period of time (or moves slightly in the same direction to compensate for decreasing suction as milk enters the system) when the operating mode of the system 10 has a predetermined time to maintain maximum suction, or reverses direction and compresses the tube 32L until the latch suction level is achieved. If the maximum suction level has not yet been achieved by the time that the compression member can be fully retracted away on the first stroke, then the compression member 36 again compresses the tube 32S to seal off the current vacuum level in the environment of the breast, and the compression member 38 fully compresses the tube portion 32L to squeeze more air out of the system. Then the compression member 36 reopens to fully open tube portion 32S and compression member carries out another stroke, again moving away to generate a greater suction

level. This cycling continues until the maximum suction level is achieved. It is noted that it is possible in some cases to achieve the maximum suction level on the first stroke, whereas in other cases, multiple strokes may be required.

[0085] Upon achieving the maximum suction, the system may be designed and programmed so that the compression member 38 does not travel to its fullest possible extent in either direction to achieve the maximum and latch suction levels, so as to allow some reserve suction and pressure producing capability. When the maximum suction level has been achieved, and the pumping profile can return to latch vacuum, the compression member 38 advances compressing tubing portion 32L, thereby raising the vacuum in the tubing 32. Upon achievement of the latch suction vacuum, compression member 36 closes off the tubing 32S again to ensure that the latch vacuum is maintained against the breast, so that sufficient suction is maintained. At this stage, the compression member 38 again begins moving away to increase the suction level back to maximum suction, and compression member 36 opens to allow tube 32S to open and the breast 2 to be exposed to the maximum suction. Alternatively, the system may be programmed so that the compression member 38 cycles between maximum and latch suction levels without the compression member 36 closing during a point in each cycle, with the compression member 36 closing when the latch vacuum is exceeded.

[0086] Upon commencing milk extraction, the compression member 36 and compression member 38 can function in the same manner as in latching, but in a manner that follows an extraction waveform determined by the selected extraction pumping determined in real time by system controls which are responsive to the load cell assembly or pressure sensing assembly. At this stage, any sounds created by the pumping action of the system are decreased as milk or fluid flows through the pump mechanism. During the compression stroke of compression member 38, compression member 36 closes when the latch pressure/suction level is achieved. Continued compression by the compression member 38 increases the pressure in the tubing 32 downstream of the compression member 36 to establish a positive pressure to drive the contents (milk) of tube portion 32L out of the tube portion 32L through smaller tubing portion 32S2 downstream of 32L and out through a one-way valve. The positive

pressure attained is sufficient to open the one-way valve for delivery of the milk out of the tubing 32 and into a milk collection container. In one embodiment, the positive pressure is in the range of 20mm Hg to 40mm Hg, typically about 25mm Hg. Upon reversing the motion of compression member 38, compression member 36 opens when the suction level returns to the latch suction level and compression member 38 continues to open to increase the suction level to the maximum suction level.

[0087] The present disclosure can establish a latch vacuum to cause the flange or skin contact member/breast 14 to seal to the breast. The latch vacuum established by the system is currently about 60mmHg, but can be any value in a range of from about 20 mmHg to about 100 mmHg. Once the system 10 has been latched to the breast via skin contact member 14, the system then cycles between the latch vacuum and a target (also referred to as "peak" or "maximum") suction level. Due to the fact that the system 10 does not cycle down to 0 mmHg, but maintains suction applied to the breast, with the minimum end of the suction cycle being the latch suction level (e.g., about 60mm Hg), the nipple does not contract as much as it would with use of a prior art breast pump system. It has been observed that the nipple draws into the skin attachment member 10 with the initial latch achievement in an analogous fashion as the formation of a teat during breastfeeding. Once the vacuum cycles between the latch and target vacuum levels, there is significantly less motion of the nipple back and forth with the vacuum changes, as compared to what occurs with use of prior art systems. The nipple motion (distance between fully extended and fully retracted) during use of the present system is typically less than about 2mm, and in some cases less than about 1mm. Accordingly, the system provides latching that is not only more like natural nursing, but the reduced nipple motion is also more like natural nursing as evidenced by scientific literature. In one particular approach, the system can employ ultrasound to observe nipple motion during pumping to ensure that desired nipple motion is achieved.

[0088] This greatly reduced motion of the nipple during cycling results from establishment of the latch at latch vacuum level, and then limiting the range of vacuum swing between latch vacuum (suction) and peak vacuum (suction). Typically the difference in vacuum between latch vacuum and peak vacuum is less than 200 mmHg,

more typically less than 150 mmHg. In one example, the latch vacuum was 50 mmHg and the peak vacuum was 200 mmHg, resulting in a vacuum difference of 150 mmHg.

[0089] Limiting the nipple motion as described with use of the present system offers several benefits to the user. One benefit is that there is less friction on the side of the nipple against the flange wall, thereby greatly reducing the risk of irritation, skin damage, pain, swelling, etc. As a result, the present system is significantly more comfortable to use by a nursing mother, and this benefit is increasingly noticeable over repeated uses. By maintaining at least a latch suction level at all times, the present system provides a more secure and persistent seal to the breast and significantly reduces the potential for leaks of air and/or milk. Because the nipple moves significantly less, this provides a more "natural" feel to the user that more closely simulates the feel of a nursing baby. Because the nipple travels less, this allows for the skin attachment member/flange 14 to be designed as a lower profile component, as its length can be shorter since it does not need to accommodate the greater length in nipple movement experienced by prior art systems. This allows the overall amount of protrusion of the system 10 from the breast to less than that in the prior art, as the overall length of the system is reduced by the reduction in length of the skin contact member/flange 14. Thus, the distance from the tip of nipple to exposed end of the housing the system is reduced.

[0090] The breast contact portion can be symmetrical about the nipple receiving portion although, alternatively, the nipple receiving portion could be offset. The skin contact member 14 is designed to reduce the internal volume of the nipple receiving portion, which is enabled by the significantly reduced amount of motion experienced by the nipple during a milk extraction process using a system 10 including skin contact member 14, according to the present disclosure. The nipple receiving portion of the skin contact member 14 is contoured to more closely match the natural shape of the nipple, thereby eliminating or significantly reducing dead space that exists around the nipple in prior art systems. The nipple receiving portion can be cylindrical in the portion adjoining the breast contact portion, and then can taper conically. This design allows for receiving a portion of the areola into the nipple receiving portion while also limiting dead space. The diameters of all cross-sections of the nipple receiving portion

are contemplated to be large enough to allow nipple dilation. The length of the nipple receiving portion can be about 23mm and the length may vary within a range of about 22mm to about 29mm. The length of the nipple receiving portion is sufficient to allow engorgement of the nipple under vacuum, without the distal tip of the nipple contacting the proximal end of the nipple receiving portion. In an alternative approach, the nipple receiving portion can be sized and/or shaped to mimic the anatomy of a child that is nursing. In this regard, rather than being generally cylindrical, the nipple receiving portion define more of a natural mouth shape or a generally rectangular sleeve with rounded corners and curved surfaces. The teat of the breast is thus formed into a more natural nursing shape by the natural shaped nipple receiving portion.

[0091] The internal contour 120 of the flange 14 is designed for use with the present system 10 and to maximize comfort of the user. The internal angles and generally flat portions also facilitate the ability to restrict portions of the breast from moving forward too much into the nipple receiving portion. The wider angle helps to prevent the breast tissue from being funneled into the nipple receiving portion, so that less breast tissue is received in the nipple receiving portion, making use of the flange 14 more comfortable than flanges of the prior art and providing space for nipple engorgement. By providing the wider angles, this also allows the overall system to be effectively shortened and allows the system to lie flatter against the breast to improve both comfort and appearance.

[0092] In one embodiment, the total system volume is about 24.0 cc. The total volume is calculated as the space in the nipple receiving portion (that is not occupied by the nipple) and tube portions 32S, 32L and 32S2 up to the milk collection or container assembly. In the embodiment with total system volume of about 24.0 cc, the active pump volume, i.e., the volume displacement achievable by compressing tube portion 32L from fully uncompressed to the limit of compression by compression member 38 is about 3.4 cc. When there is only air in the tubing 32 of the system 10, pressure swing by moving the compression member 38 inwardly against the tubing portion 32L and outwardly away from the tubing portion is limited, due to the compressibility of the air. In this embodiment, with the system under vacuum of -60 mmHg, a full stroke of the compression member (from compressed to fully uncompressed tube portion 32L)

increases the vacuum to -160 mmHg. The ratio of pumping volume to total system volume can be important with regard to power and size of the pumping system. In this embodiment, the tube portion 32L was made of silicone. It has been recognized that reduced motion of the compression members when pumping allows for more quiet action of the pump motor, and a more quiet system overall. Further, the present system employs the milk expressed as the medium for system hydraulics, and this medium is in direct contact with the user's breast against which a vacuum is drawn. Thus, the system can employ air suction against the breast for initial latching and pumping and then converts to utilize expressed breast milk for pumping action or power.

[0093] During let down operation, the system 10 operates to effect let down of the milk in the breast, prior to extraction, with a maximum suction target of up to 120mmHg (typically, about 100mmHg (-100mmHg pressure)) to establish let down. The goal of letdown (or non-nutritive suction) is to stimulate the breast to express milk. The relatively shallow (small vacuum change range) and relatively fast frequency of the pumping during this phase are meant to mimic the initial suckling action of a child at the breast. This is because during let down phase, the suction pressure is not allowed to exceed the maximum let down suction of 110mmHg or 120mmHg, or whatever the maximum let down suction is set at. Therefore, as the compression member 38 is drawn in a direction away from the tube portion 32L, the system 10 is designed to reach -100mmHg (a suction pressure of 100mmHg) (or -120mmHg, or whatever the maximum let down suction is designed to be), by the time that the compression member 38 has reached a position in which tube 32L is mostly uncompressed.

[0094] During let down (non-nutritive) the system software and/or firmware communicates instructions to system motors based upon readings taken and communicated from the pressure sensing assembly so that the system is configured to operate between -60mmHg and -100mmHg in one example. In this example, the compression member 38 can compress the tubing portion 32L nearly fully and then be moved away from the tubing portion 32L to generate vacuum. The maximum latch suction pressure of -100mmHg will be reached with a small amount of rebound of the tubing portion 32L and the compression member 38 can be cycled relative to the tubing

portion 32L between -100mmHg and -60mmHg in a narrow range or band near full compression of the tube portion 32L. As milk flows, that narrow band shifts at which point the tube portion 32L will be purged by fully compressing it to drive out the contents and thereby regain more capacity for pumping with relatively less compression of the tube portion 32L again.

[0095] The system 10 is responsive to pressure changes within the tubing 32 caused by entry of milk into the tubing 32. Referring again to Fig. 7, the compression elements 36 and 38 are 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, as well as the controller 52 and pressure sensor 54, and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38.

[0096] The sensor 54 is used to provide feedback to the controller 52 for controlling the pumping cycles to achieve and/or maintain desired vacuum levels. Sensor 54 is preferred to be a load cell sensor providing data utilized to calculate system pressure, but could also be a pressure, 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 10. As shown, sensor 54 is a non-contact sensor 54, meaning that it is not in fluid communication with the milk or vacuum space of the system 10.

[0097] As described above, the conduit or flex-tube 32 is placed in operative connection with a motor. An opposite side of the flex-tube 32 is equipped with the sensor 54 that takes the form of a load cell. The positioning of the motor is tracked and the force on the tube 34 is assessed to determine internal vacuum. By employing machine learning or supervised learning regression techniques, the system 10 can be trained to interpret the motor positioning and tubing strain (as well as motor speed or pump settings), while compensating for noise and hysteresis, to arrive at a pressure/vacuum level. More specifically, a neural net system or any mathematical regression of the data can be incorporated into system firmware so that sensor input can be translated to pressure/vacuum levels. In this regard, the system 10 can include

or communicate with a non-transitory computer readable medium having stored thereon instructions executable by a computing device of the system or external to the system to cause the computing devices to perform functions associated with and directed by the firmware.

[0098] To train the neural net, large amount of data is generated, both from an accurate vacuum reading as well as strain gauge readings. All of the data is sent to software so that post processing can be conducted. It has been determined that data taken during normal pump flow lends itself best to training the system 10. For example, data can be gathered when flow is at 2-3 ml/min, and when system pumping is slow at each pressure target. This approach ensures that the motor moves along its entire travel cycle relatively evenly and noise associated with high flow is not introduced into calculations. Highly controlled settings are also used to generate data so that unbiased data is generated. Further, system accuracy can be increased when using specifically generated neural nets for specific ranges of pressures. A special code is employed to isolate data from different pumping limits in training data, and uses only that data to generate a neural net that is used later when pumping to the same limits.

[0099] Turning now to Figs. 8-10, one embodiment of a collection or container assembly 60 is shown. In one particular embodiment, the collection or container assembly 60 can be formed from two 2.5-3.0 mil sheets of material that can be band welded or otherwise joined together along a perimeter 92 of the assembly, and can be sized to retain up to 4.5 ounces, or alternatively 8 ounces of fluid. In particular, the collection or container assembly 60 can be pre-formed to optimize or maximize the space inside the pump system and flange. For shipping, the collection or container assembly can be pulled closed with a vacuum to make it flat or thin for packaging or handling. A body of the collection or container assembly is generally bladder shaped and includes a generally asymmetrical oval central opening 93 created by an interior band seal. In one particular approach, the body can additionally include gussets to provide more volume. A pair of wings 94 extend into the central opening 93 and are provided for handling and facilitating positioning of the collection or container assembly 60 within a pump system 10. A narrow neck portion 95 is centrally positioned and extends longitudinally away from the central opening 93. The neck

portion 95 includes a tab portion 96 that provides structure for grasping and removal, and can further include one or more cut-outs or tear-able elements 97 provided for aiding in tearing the container 90. Further scoring is also contemplated to help in the tearing of the bag assembly 90. Also, in alternative embodiments, the collection or container assembly 90 can be re-sealable, re-usable, include larger or smaller openings or include spout structure for pouring contents. A spout can also be attached to the fitment or valve of the collection assembly to facilitate pouring. Such a spout could further include structure which temporarily or permanently defeats the valve or fitment. The valve of the collection or container assembly can also be re-usable with a second or subsequent collection or container assembly, and therefore is removable from the container assembly.

[00100] Moreover, in one particular embodiment, the collection or container assembly 90 can be made from polyethylene and can be bisphenol A free, as well as food grade material. It should be freezable without tearing and withstand approximately 0-80 degree Celsius temperatures. Additionally, tensile strength can be from 2300-2900 psi and tear strength from 440-600 psi, with a water vapor transmission rate max of about 0.5g/100in^2/24hrs and an oxygen transfer rate of about 150cc/100in^2/24hrs. In alternate embodiments, the material of the collection or container assembly can be Gore-tex or Tyvek, for example. Such alternative materials can permit out-gasing. Accordingly, a non-closed or un-sealed system is also contemplated. In this specific regard, other vents or approaches to venting the system can be incorporated into one or more embodiments. Thus, self-venting of the container assembly or active venting while using the pump system or after use can be accommodated. In one approach, a pressure valve can be incorporated into the system and configured to activate after some system pressure is reached, and further the valve can be designed to act as a fluid barrier, only allowing air and not fluid to escape.

[00101] It is contemplated that the system is configured to pump into a sealed collection or container assembly 60, or one that incudes an integral valve or an otherwise airtight collection or container assembly 60, or combinations thereof. In this specific regard, the system can alternatively or additionally be closed and never vented to the atmosphere, and/or the system suction is only reduced through the flow of milk

into the system. Thus, in at least one approach, milk or fluid that is pumped through the system is never exposed to new outside air from the environment once it enters the collection or container assembly. Accordingly, the orientation of the pump system or person has virtually no impact on the functioning of the system (i.e., no spills). The collection or container assembly can include a rigid or flexible sealing component, such as a ring or gasket into which the pump or container valve is pushed or twisted and sealed. The collection or container assembly can also include an opening or hole or structure that is pierced such that the container assembly seals about the member that goes into it. Moreover, there are contemplated a range of disposable and durable combinations of container 101 and valve fitment 102 arrangements such that one or both of the container bag 101 and fitment 102 are disposable or reusable. Additionally, the container can configured to be inside or outside of the pump housing.

[00102] The fitment 102 can embody a valve such as an umbrella valve assembly 103 or other type of one-way valve connected in fluid communication with the storage container 101. The fitment can also assume a myriad of alternative embodiments, and can additionally or alternatively be formed integral with the container. For example, in one contemplated approach, the fitment and/or the valve can be formed as part of the container rather than define a separate component attached to the container. As shown in Figs 8-10, however, the tail 104 of the umbrella valve 103 can be employed to defeat the valve when desired such as to remove gases, by turning it and engaging the tail against the valve body. Additionally, the valve includes a generally cylindrical portion having a diameter of approximately .585 inches extending from a flat base 104 having a width of approximately .875 inches. It is the flat base portion 104 that is captured and sealed between the two sheets of bag container material and includes a tail 106. The tail 106 functions to ensure flow through the neck portion of the container assembly 60 particularly when it is placed into the pump assembly (See Fig. 11A), and has a narrow, elongated shape that permits flow thereabout. That is, the tail 106 maintains flow through the neck even when the neck is folded as the container assembly is attached to the breast pump body. Valve 103 prevents back flow of milk into the flex-tube 32, and facilitates maintaining the suction (vacuum) level in the flex-tube 32. In other embodiments, other features can

be provided or built into a valve to allow for depression or otherwise overcome the valve to vent air. Such approaches can involve a protrusion that is attached or associated with the valve so that as the protrusion is pushed toward the collection or container assembly, an edge of the valve is translated to thereby break the valve internal seal. Moreover, a nub can be attached to valve structure and configured inside the container assembly. Tugging on the nub through a layer of the container assembly thus results in freeing an edge of the valve and breaking the valve seal.

[00103] In at least one embodiment, the pressure at which the valve 103 opens to allow flow into the milk collection container 60 is about 25mm Hg. The valve 103 can be configured and designed such that it allows fluid to flow through it when the pressure in conduit or flex tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "crack pressure". The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from flex-tube 32 and decreasing when the compression elements compress the flex-tube 32, but typically should not increase the vacuum to greater than the predetermined maximum vacuum. As the compression elements 36, 38 compress the flex-tube 32, the pressure in the system 10 goes up and reaches the minimum suction level (e.g., latch suction level, such as -60mmHg, -30mm Hg, or some other predetermined latch suction level), at which time the compression member (pinch valve) 36 seals off portion 32S thereby maintaining the minimum suction (latch suction) against the breast. Continued compression of portion 32L by compression member 38 continues to increase the pressure downstream of compression member 36, until the crack pressure is reached (e.g., 25mm Hg or some other predetermined, positive crack pressure), that opens the valve 103. The compression elements 36, 38 continue compressing flex-tube 32, pumping fluid (milk) through the valve 103 and into the collection container assembly 60 until the compression element 38 reaches an end point in travel. The end point in travel of the compression element 38 against portion 32L may be predetermined, or may be calculated in real time by the controller 52 using feedback from pressure sensor 54 and feedback from the driver of the compression element 38, from which the controller 52 can calculate the relative position of the compression element 38 over the course of its travel. The compression member 36 remains closed throughout this

process, as it is used to seal off the tube 32 the entire time that the compression element 38 is pumping milk out into the collection container assembly 60. As the compression elements 36, 38 reverse direction and pull away from the flex-tube 32, they start the cycle again.

[00104] As milk enters the system, the suction level decreases (pressure increases). The feedback provided by pressure monitoring via pressure sensor 54 provides input to a feedback loop that adjusts the position of the compression member 38 to maintain the desired vacuum (pressure) within the conduit or flex tubing 32 by compensating for the changes in pressure that occur to changing amounts of milk in the flex tubing 32. For example, for a relatively larger amount of milk in the tubing, this will require a relatively shorter stroke of the compression member 38 to achieve the latch pressure. This modification can be addressed by either slowing the movements of the compression member 38 to achieve the same timing cycle for pumping, or increasing the cycle frequency due to the less time taken for the shorter strokes of the compression member 38.

[00105] Use of a system 10 provided with a non-contact pressure sensor 54 would include loading the collection or container assembly 60 into the system 10 (See Figs. 11A-E). In a first step (Fig. 11B), the flange 14 is removed from engagement with the remainder of the system 10. Attached to the flange is the conduit or flex-tube 32. The central opening 93 is placed over a central projection of the flange 14 and the flex-tube 32. Next, the user can pinch the wings 94 under the flex-tube 32 (Fig. 11C) followed by tucking the collection or container assembly 60 into the flange 14. The fitment 102 is placed within the collar 82 of the flex-tube 32 (See Figs. 11A and 11E). In certain embodiments, the collection or container assembly 60 can have useful labels, icons or notifications. For example, milk droplet icons can be printed on the collection or container assembly 60 in increasing size to indicate the degree to which the container is filled, and a "this side up" message can be included to aid the user in properly installing collection or container assembly 60. Also, the container assembly 60 includes a number of surfaces away from storage areas where printing or handwriting can be placed. For example, the wings 94 can be used as a writing or printing surface as can the pull tab 96. Similar labeling or messages (for example, a

"thanks mom" message) can be included on the collar 84 or other portion of the flex-tube 32 to aid in properly orienting the flex-tube with respect to the flange 14. It is to be recognized that the collection or container assembly can be placed in alternative locations as well. For example, the collection or container assembly can be configured around the nipple of the breast. In this regard, the container assembly itself can form the desired flange or breast contacting structure into its core construction. In one specific approach, the container assembly can also include more surface area facing the breast superior to the nipple than inferior thereto.

[00106] It is contemplated that the door assembly 90 be employed to both provide a continuous contour of the flange 14 for engaging a user's breast as well as to support the engagement of the collection or container assembly 60 with the system 10. Thus, the door assembly 90 can be configured to pivot with respect to the flange 14, and employed to close the system 10 as it is snapped over and closes the pump. With this approach, the fitment 102 and container bag 101 are securely sandwiched between the collar 82 of the conduit or flex-tube 32 and the door assembly 90, with a cylindrical portion of the fitment 102 received within the collar 82. The collar 82 can also provide rigidity to the flex-tube 32 so that it can be loaded into the flange 14 as well as to provide an annular back-up when the fitment 102 is inserted. Ribs or o-rings can be provided on an interior surface of the flex-tube to facilitate sealing with the fitment 102 and can have a radius of approximately .64mm. In one embodiment, the interior diameter of the flex-tube between the ribs can be approximately 14.6 +/- .17mm, while the outer diameter of the fitment 102 can be on the order of 14.8 +/-.17mm so that an interference fit results, with a force of around 1-2.5lbs.

[00107] As best seen in Figs. 12 and 13, the door assembly 90 further includes a pair of spaced and curved guiding arms 105. The arms 105 are contoured to guide the door assembly 90 as it closes over and about a pair of curved railings 107. In this way, as the door assembly 90 rotates toward the conduit or flex-tube 32, a latch 109 of the door assembly 90 first clears and then seats beyond and behind the railings 107 to thereby provide a robust engagement with the flange 14 and bag assembly 60 when it is loaded in the system 10 (See also Fig. 11). As best seen in Figs. 8 and 9, the fitment 102 includes a scalloped portion 110 which functions to facilitate this robust

engagement and provide relief of undue stresses being placed upon the bag assembly when securely mounted within the system by resisting kinking. The door assembly can further include one or more ribs 111 (Fig. 15) that engage and provide directed support to the fitment 102.

[00108] Turning now to Figs. 16-18, there is shown an approach to protecting against pinching by moveable parts of the pump system 10. One or more magnets 118 can be attached to the flange 14. A corresponding sensor 119 (such as a hall effect sensor) can be attached to the flex circuit 16 that is mounted to a mounting bracket 120 (See also Fig. 3). The system 10 can be configured to only permit the motor to be activated when the sensor detects the magnet 118. In this way, the pumping action of the system and in particular, the compression members will not move until the flange 14 is attached properly to the housing 12, consequently avoiding any pinching or engagement of such components with the user. In other approaches, mechanical or electronic switches or RFID technology, or optical sensor or sonar technology can be incorporated into the system to provide the desired safeguards, such that the system will not operate unless all components of the system (i.e., flange, tubing and storage) are fully connected.

[00109] In another approach, the system 10 can include firmware that operates to track system pressure on a load cell. Here, the motor paddle can be arranged and controlled by firmware so that it is moved outwardly .5mm or some defined distance and pressure on the load cell is observed to see if the conduit or flex-tube is properly installed. Where the pressure observed is not as expected, such as if there is no pressure, the motors will not be permitted to move inward for pumping. Using a similar technique, proper collection container install can be tested. After the motor extends, the pinch can seal the flex-tube. Once the motor comes back out, a vacuum will only be measured if the bag is properly installed, sealing air from filling the tube on the container side.

[00110] It has also been recognized that fluid ingress protection may be necessary for the pump system. Thus, it is contemplated that various gaskets can be configured within the structure of the system. One particular location for a gasket is the interface between the chassis and housing, and accordingly, a specially designed gasket is

configured about a perimeter of the chassis along a section which is intended to engage the housing. In this regard, a .3mm interference fit is contemplated between the gasket and the housing. Also, gaskets can be configured about moving receiver structure such as that of the load cell and motor to help prevent fluid ingress.

[00111] Once the flange or skin contact member 14 is placed onto the main body/pump housing 34 then pump power can be engaged. Referring now to Figs. 19-20, there is shown an enlarged view of the user interface panel which as stated above includes a button membrane 72 and a button membrane housing 73 each supported on the housing 12 and placed in engagement with the flex-circuit that provides the user with system control. Here, the membrane 72 acts as a light pipe. Light emission, intensity and button deflection forces are configured for convenient and effective interaction by the user. Accordingly, pressing the power button 130 functions to start the pump system 10 through its interaction with a switch 131 configured on the flex circuit 16 (See Fig. 18). It is noted that other switches 132 can further be provided on the flex circuit which line up with other contemplated system control buttons included on the flex membrane 72. Should the system 10 require external power or the battery charged, access to supporting electronics is gained through the cover jack 65 that is configured in the shell 12 (Fig. 21).

[00112] As the pump system 10 goes through a power up routine, the controller 52 reads force on the load cell when a load cell is used as the pressure sensor 54. This is the load measured by the load cell, before the skin contact member 14 has been applied to the breast, so in one approach it is a state in which the pressure in the conduit or flex-tube 32 is atmospheric pressure. The controller 52 then calibrates the system such that the preload force or position or measured load or strain equates to atmospheric pressure. Based upon a neural network or computer learning, load or strain detected at the flex-tube 32 can be converted to pressure readings in the system 10 during operation of the breast pump system 10 upon attachment to the breast.

[00113] The system 10 can calculate the volume of milk pumped into system or alternatively the volume collected in the milk collection container assembly 60. By knowing the dimensions of the conduit or flex tubing 32 downstream of the compression member 36 when compression member 36 has sealed off tubing portion

32S, the overall volume capacity of the system 10 downstream of compression member 36 can be calculated. With reference again to Fig. 7, tracking of the position of the compression member 38 relative to the tube 32 (such as by knowing the driver 46 position at all times, for example), dictates the volume change in the tubing 32. As the pumping process is carried out, pumping/purging of milk into the milk collection container occurs when the compression member 36 has closed off the small tube portion 32S at the location of compression. When the compression member 36 has closed off tube portion 32S, the change in position of compression member 38 that occurs to carry out the purge of milk from the flex tubing 32 and into the milk collection container 60 is used to calculate the change in volume of the tubing 32 downstream of the compression member 36, which equates with volume of milk that is pushed into the milk collection container 60 bag.

[00114] In particular, under one algorithm, as flow enters the system 10, it is recognized that the motor must move further and further out to generate latch vacuum. Tracking this movement and the rate of position change of compression or paddle members as they generate latch vacuum is one way of measuring flow. The slope of a line that is associated with tracking paddle locations for latch vacuum, for example, is directly proportional to flow. After a tuning step to correlate this relationship, calculating flow from the slope of this line can be readily accomplished.

[00115] Using another approach, the number of purges can be tracked when the system is full for the purpose of measuring flow. As stated, it can be determined when the system 10 is purging fluid versus purging air since the forces are much higher for purging fluid than purging air. Thus, counting the number of purges that contain fluid, and knowing the volume that is purged for each purge leads to a calculation of flow without requiring significant system tuning or calibration, and avoiding confusing a slow air leak with flow. Leaks can also be detected by employing an algorithm involving closing the pinch compression member, followed by closing the pump compression or paddle member, and then pulling the pump compression member outwardly to create a vacuum. By then holding the pump compression member in this position and verifying the vacuum is maintained, it can be determined if there is a leak in the system 10.

[00116] In addition to calculating the volume of milk purged with each purge cycle, the system (via controller 52) can sum the volumes from all purge cycles to calculate the total volume entering the pump or alternatively pushed into the milk collection container 60 during a milk extraction session. This volume can be stored with a unique identifier provided to the milk container so that the system 10 keeps a record of how much milk is stored in each milk collection container 60. This information can also be time stamped so that the user will know the time and date that milk was collected, regarding each milk collection container. Additional statistics can be calculated, including, but not limited to: average volume per extraction session, total volume extracted for any given day, average milk extraction volume per day, etc. Any and all of this data can be exported to an external computer, either manually, or it may be automatically uploaded to the computer when the computer is within range of the system 10 for wireless communication, or when the computer is connected to the system by wire. Further optionally, any or all of this data can be either manually or automatically uploaded to a cloud service over the Internet, either wirelessly or by wire.

[00117] In one preferred approach, volume that is extracted from a breast is calculated by building a map of motor location versus volume at a specific vacuum such as -60mmHg, since the same is a reliable and predictably repeatable vacuum level. To build this relationship, various known rates of flow are created within the breast pump, and motor locations at -60mmHg are identified and stored as data. A script is then employed to extract such data to build this motor versus volume scale. In particular, as shown in Fig. 7B line M represents motor location versus time and line V represents vacuum versus time. This data is entered into the script to arrive at a graph of volume over time. The script looks at indications of times of purge and tosses out data except a first clean start and finish of a cycle between purges represented by the spike S in Fig. 7B. An adjustment is made for time such that relative time for the data selected replaces absolute time. The script also functions to filter out data that is too far above or below -60mmHg. Relative time is then turned into volume in that motor location becomes volume difference over a relative time span. This data can be plotted as a line (See Fig. 7C), the area under which represents volume. The output of the script

represented as a line having a particular slope is expressed as numbers and as a 6th order equation representing the line. This 6th order equation is incorporated into the code base and is employed during real time to convert measured motor locations during pumping at approximately -60mmHg into volume. Calculus is thus ultimately employed to arrive at this volume calculation in that motor location versus volume is integrated between two points to determine differences in volume. At certain levels of flow there can be an adjustment factor multiplied by volumes calculated when comparing calculated flows with real world experimentation, in particular to accommodate for flows shortly before and after purging, for example, or for flow above 15ml/minute. Additionally based upon empirical observations, when the pump is filled with air, a mathematical constant is incorporated into the volume calculations. A determination that the pump is filled with air can be made by observing how hard the motor has to work, and knowing that the motor has to work harder to create vacuum changes when the system is filled with air as opposed to when the system is fluid filled.

[00118] When calculating milk volume pumped from the system 10, as stated, there is a need to distinguish between any air pumped by the system versus milk pumped from the system, as well as pumping mixtures of milk and air. When initiating a milk pumping/extraction session, there is air in the tubing 32 this initial volume of air needs to be pumped into the milk collection container 60 to prime the pumping system 10. Again, distinction between pumping air versus pumping milk can be recognized by correlating pressure changes with the amount of movement of compression member 38 needed to establish the pressure changes. For example, when air is in the tubing, a greater change in position, or more overall travel of the compression member 38 is needed to establish the same pressure change than that needed when the tubing 32 is filled with milk. Thus, relatively more motion of the compression member with relatively less pressure change indicates air in the tubing 32. This difference in pressure may also be detected when the compression member 36 is open (i.e., not closing off tube portion 32S) and compression member 38 is retracting and this increasing the vacuum pressure.

[00119] When a user has completed the pumping phase of extracting milk from a breast, it is useful and efficient to purge as much milk that remains in the tubing 32 from the

tubing 32 and into the milk collection container 60. Ending of the extraction phase can be performed upon elapse of a predetermined extraction phase time, calculation of a predetermined amount of milk having been pumped, manual cessation of the extraction phase by the operator, or some other predetermined value having been achieved after performing the extraction. The direction of the pumping stroke of compression member 38 is reversed and the compression member 38 is run in the reverse direction to decrease suction within the tubing 32 and optionally create a small positive pressure within the tubing 32 to facilitate removal of the system 10 from the breast. Alternatively, the suction may be decreased to a level where a slight suction remains so that the user still pulls the system 10 of the breast to detach it. Preferably the vacuum is reduced to 0mmHg, or a slightly positive pressure to automatically detach the system 10 from the breast. The end pressure value where the pressure reduction by reverse pumping is ceased can be in the range of about -20mmHG (weak vacuum) to a positive 50mmHg (e.g., the crack pressure of the valve to the container). The compression member 36 does not close off the tubing portion 32S during this process, rather, tubing portion 32S remains open. Initiation of this reverse pumping may occur automatically or, alternatively, may be initiated by the user. This process continues until the seal of the system 10 to the breast is broken, which is detected by the controller via sensor 54. Once exposure of the tubing 32 to atmospheric pressure is detected, the stroke direction of pumping is again reversed thereby pumping the milk in tubing 32 under positive pressure and driving the milk from the tubing 32 into the container 60. If by chance, the system 10 accidentally or otherwise becomes resealed to the breast during purge pumping, the system 10 can automatically shut down as it senses vacuum pressure being regenerated in the vicinity of the flange or breast/skin contact member 14.

[00120] The system 10 can be configured to distinguish whether it has been attached to the left breast or the right breast of the user. This can be useful for tracking milk volume output per breast, per session, total daily volume per breast, etc. When using two of the pump systems, the tracking of data for each breast can still be maintained accurately, even when one of the pump systems 10 is attached to the left breast during a current pumping session after having been attached to the right breast during a previous pumping session. In one embodiment, the pumping systems 10 can establish

current location (i.e., left or right breast) by receiving a signal from the other pumping system having been attached to the other breast. This established relative left-right locations of the two pumping systems 10, so that each system 10 can accurately record as to whether milk is being extracted from the right breast or left breast. This identification is automatic, without any user input required and it also relieves the burden on the user to otherwise keep track of which pump system 10 is placed on each breast and to maintain this order with each successive pumping session. Left and right pump labeling is also contemplated such as by placing markings on the system housing or cover jack, for example, near the power connector.

[00121] Various approaches to assessing milk volume can be included in the pump system. Certain approaches are describe in co-pending International Application No. PCT/US15/50340, the entirety of contents of which are incorporated herein by reference. A further approach to assessing expressed milk volume involves placing one or more disposable data collection devices on the mom or child. One specific approach involves creating a boundary on the skin of a breast and employing a fiducial to conveniently measure the change in size of the boundary. This change in size is then correlated to milk production to arrive at a volume of milk expressed or pumped. A crib or bassinet can also include sensors and communication hardware that communicate with the pump system so both assess and management milk consumption and needs, and baby health.

[00122] The system 10 can calculate the pressure during operation in any of the manners described above. The suction (pressure) level can be varied as desired, and by continuously or repeatedly measuring/calculating pressure, the feedback provided by sensor(s) 54 to controller 52 provides a control loop that can be used to adjust the compression member 38 position and/or speed to vary the suction pressure to a level desired, or maintain a desired suction pressure in real time. Thus, controller 52 can control the positions and speeds of compression members 36, 38 to achieve any vacuum pressure pumping profile desired, and provide automatic, real time adjustments to maintain a desired vacuum pressure within the system. Also contemplated is responding in real time to maintain flow. This can accomplished independent or in conjunction with monitoring and regulating pressure in real time.

[00123] The controller 52 tracks the position of the compression member 38 relative to the tubing 32L, such as by keeping track of the driver 46 position or shaft position (interconnecting linkage between driver 46 and compression member 38), and calculates (or looks up) pressure based upon data received from sensor 54. The system controller or firmware is programmed with or retains information relating values detected by system sensors with driver positions and speed and system pressure. Thus, changes in position and/or speed of the compression member 38 by controller 52 can be controlled by resulting changes in pressure calculated or looked up, relative to the pressure sought to be achieved. As stated above, by using machine learning or supervised learning regression techniques, the system 10 can be trained to interpret the motor positioning and tubing strain (as well as motor speed or pump settings), while compensating for noise and hysteresis, to arrive at a pressure/vacuum level. More specifically, a neural net system or other mathematical regression can be incorporated into system firmware so that sensor input can be translated to pressure/vacuum levels. Controller 52 can thus control compression member 36 in a similar manner, but control of member 36 is more focused on position control, as the compression member 36 needs to fully close off tube portion 32S when maintaining latch suction against the breast/nipple. However, the closing off is timed and performed at the determined latch pressure, which is known from the data received from sensor 54.

[00124] Turning now to Figs. 22-28, various aspects of remote control and data collection approaches are presented. In at least one contemplated embodiment, the system 10 can be configured to communicate with a server, a remote computer, smartphone or other device such as through signal, such as by Wi-Fi, BLUETOOTH, BLUETOOTH Low Energy (BTLE), RFID, NFC or the like. In particular, one or more chips can be incorporated into the controller of the pumping system 10 (by hard wire and/or wirelessly, preferably wirelessly) and configured to be in communication with an external computer. The controller and/or external computer communicates with the sensor(s)/chip(s) which indicate(s) when the system is in use, and can track usage. By tracking the times of use and/or number of uses, or even pump cycle counts, for example, the controller, or external computer can alert the user when it is time to change components or to report on usage aspects. In this way, information such as the

tracking of extraction date and time, volume extracted, etc. can be recorded and stored with regard to each milk collection container used with the system 10 to extract milk. Thus, the system 10 can register individual milk collection containers, so that the user can readily identify when milk in each container was collected, the volume in each container, etc. The breast pump system can record the volume of milk in any given container during a pumping session. The data recorded can be sent to an external computer and/or over the Internet, either automatically or manually. Thus, user data and trends can be collected, stored and analyzed as they relate to volume (from each breast and in total), as can be the number of sessions on several dimensions (per day, week or month). Data and analytics can thus be provided to a user concerning pumping sessions.

[00125] In one particular approach, at least the session start time, the session end time and total volume of milk extracted from the breast can be stored and tracked. Sessions can be defined as the commencement of latch and can continue up to and through pauses of up to 5 minutes, for example. Thus, a pause of over 5 minutes can be defined as the end of the previous session. A language protocol is generated so that there is a two-way communication between an external device or program and the breast pump. That is, both the pump and external device can create and understand and are responsive to specific messages. Further, live data and historical data can be treated differently, and their data streams maintained separately. Live updates are generated and stored at the pump and are available by the external device to retrieve (for example, up or down button activations or volume updates). Accordingly, such live data can be reflected on and update the screen of the external device. Historical data is stored inside the pump in a stream and the pump can communicate with this stream to extract or act upon the same. An internal pump memory such as a disc within a chip or other internal flash stores, communicates with the pump so that session data is written to an internal history log. At the end of a session, for example, the pump will write the session data to its internal history log and the external device will ask if there is any data and if the pump indicates that there is, then the external device will download this historical data to update its non-live view screens. The external device can also make this same query after an extended time and then download multiple session data, and

the query also can be made during a session. In one particular embodiment, as much as 600 sessions of data can be stored.

[00126] In one or more embodiments, the system can additionally or further include structure configured to accomplish or functionality operating as an Active Pause Mode, that allows the system to maintain latch vacuum, while remaining (especially under no/low flow) virtually silent. Such a system stays much quieter than pump mode, but ensures the system does not fall off the breast. It can be employed by the user mom when she needs to interact with others and does not want them to hear the pump, or for some other reason where she might not be ready to remove the device but does not want active pumping either.

[00127] The remote user interface 140 on an external device can take a myriad of forms. The pump system can also be personalized such as by giving one or more pumps a name (Fig. 22). A user profile can be created for a child and linked to a child's birthdate (Fig. 23). Other details such as tracking the child's age when use of the system commenced can be gathered so that analytics pertinent to the child's age can be generated. In this way, pump performance can be tracked to the growth of the child. Reminders can be entered into the system (Figs. 24) so that the user can focus on matters other than breast pumping. Notifications can be keyed to time or volume of milk pumped while both of such criteria as well as battery life can be tracked and reflected on the remote computer (Figs. 25-28). Easily understood and convenient graphics are contemplated for expressing status such as curved hemispherical strips 150 reflecting volumes pumped for each pump system, the same information also being shown in numerical form 152. Timing countdowns as well as information from one or more previous sessions can also be graphically displayed for effectively communicating with a user. The ability to remotely begin a new session can also be made available to the user.

[00128] The remote user interface 140, whether provided as an App, on a cell phone, computer or other computing device, can also include specific user control functionality, and various related easy to understand displays (See Figs. 29-41). As shown in Fig. 29, in one or more approaches, the amount of milk pumped is tracked by day, and an option is provided to the user to set a session tracker by day. The amounts

pumped are also tracked by breast. A user can set one or more of time and volume of pumping by breast for one or more pumping sessions. For example (Figs. 30-31), a volume target can be set by the user by various increments such as .1 ounces. This setting can be set and saved, or canceled. As shown in Fig. 32, the user can then control whether to pump with one or both breasts, and then the system starts tracking pumped volume (see Fig. 33). As pumping progresses (Fig. 34), easily readable curved bars reflect the amount of volume being pumped by each breast, the bars becoming thicker as more volume is pumped. The user can adjust suction levels for one or both of the pumps attached to a breast (Figs. 35-36) to coordinate pumping or to otherwise pump as desired. After reflecting the changes in suction level, the user can return the system to tracking volumes pumped by breast (Fig. 37), and an indication of volume remaining to be pumped is also provided. Once the pumping target is met, such as a target volume (Fig. 38), the user interface will indicate that the session has been completed. Thereafter, an updated set tracker is presented, with an ability to set further pumping schedules (Fig. 39). The user can then select an option to depict a summary of pumping or a history of pumping (see Figs. 40 and 41). The data provided by the user interface can include bar graphs and numerical data showing pumping by day and by breast and session times and number of session. Additionally, circles can be sized to represent relative amounts of pumping by date, and color coated by breast.

[00129] The pump system can also include a power management system that functions to save power. In one aspect, the pump system can be characterized as having multiple modules or threads, each running separate programs. Each thread, such as fifteen to twenty different threads, is designed to operate in a manner to save power. That is, each thread is controlled so that it seeks and finds its own maximum, minimum required power mode.

[00130] The pump system can be further configured so that the power management system includes a power hierarchy including various different levels at which the threads seek to achieve maximum, minimum required power. In one approach, the levels can include one or more of hibernate, standby, standby with LED's and active. Hibernate can be characterized as a deep sleep state and standby can be defined at a level where the system is running the computer chip and running calculations but not

external components are being run. Standby with LED's can mean just that the LED's are engaged and active can mean that external components like the motors and sensors are working. The power system can thus function so that a query is sent to each thread asking for the thread's current state and it's minimum required mode. The power system then cycles through each thread and sets the power level at the maximum, minimum power level required so that each thread can properly operate.

[00131] In still yet further embodiments and approaches, the pump system can alternatively or additionally include built-in or computer or App based functionality to de-stress the user's life, empower the user to better take care of the nursing baby's health, maximize the user's mobility and freedom, and support all that is involved in becoming or being a parent. In these regards, pump system structure and functionality can include one or more of keying on pain points, physical conditions, sleep, pain relief, and post partum issues, tracking sleep, sensing and tracking baby vitals and movement, focusing on connected health with the mom as the caregiver, and/or providing education, guidance or instruction on movement and ways to carry a baby, fertility, post baby needs, health of the mom, ultrasound and fertility. The pump system can additionally include App integration with smart bottles, smart scales or the like to facilitate managing overall baby health and nutrition. App updates can additionally be provided about stimulation and letdown, and timing of pumping based upon such information, such as suggestion to begin pumping. System structure and functionality can also involve updating pumping profiles based upon baby age and needs, developing pumping functionality which enhance milk production, enhance efficiency or comfort or better mimic baby. Data can be stored in the cloud for analysis, and additional functionality can be provided to modify speeds and alternated between and among customized modes and profiles. Additional or a myriad of sizes of flanges and bag or container assemblies can be provided to the user as can nighttime pump functionality or programming including automated sessions with starts and stops.

[00132] Inventory management is further functionality that is provided as part of the structure of the pump system. In connection with the same, container assemblies can include structure that is scannable or which otherwise communicates with the inventory management system (eg., via bar codes, RFID chips). Further, operative

communication structure can be provided so that the user can transmit data with and between a baby-center platform that stores data thus facilitating an avenue for the effective management of the baby's nutrition, and links can be made to automatically communicate with milk banks and donation centers. Additionally, a caregiver data share system can be included within the functionality and structure of the pump system. Texting is added to other forms and avenues for communicating such important and useful information.

[00133] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure.

CLAIMS:

That which is claimed is:

1. A wearable system to pump fluid from a breast, the system comprising:

a skin contacting structure configured and dimensioned to form a seal with the breast; and

a conduit in fluid communication with the skin contacting structure;

wherein fluid extracted from the breast flows into a sealed collection assembly, or sealed collection assembly having an integral valve system or an airtight collection assembly for storing the fluid pumped from the breast.

2. The system of claim 1, wherein the wearable system pumps fluid through the conduit against gravity.

3. The system of any previous claim, wherein the wearable system maintains at least a latch suction throughout a pumping cycle.

4. The system of any previous claim, further comprising a controller configured to control operational settings of the wearable system.

5. The system of any previous claim, the collection assembly further having a fitment sized to be received within the conduit.

6. The system of any preceding claim, further comprising a controller configured to adjust pumping in real time.

7. The system of any preceding claim, further comprising a flange and door configured in the flange, wherein the door engages the collection assembly and maintains an engagement between the collection assembly and the conduit.

8. The system of any preceding claim, wherein the conduit includes spherical connectors, one spherical connector being placed into engagement with a compression member configured to facilitate pumping of fluid through the conduit.

9. The system of any preceding claim, wherein the conduit includes a bulged portion configured to accommodate system hysteresis.

10. The system of any preceding claim, further comprising a flange, a chassis and a housing, wherein the flange, chassis and housing snap together.

11. The system of any preceding claim, further comprising structure for impeding fluid ingress into the wearable system.

12. The system of any preceding claim, further comprising a controller, the controller controlling a pumping function and modifying pumping to reach targets in real time.

13. The system of any preceding claim, further comprising further comprising a flange, a chassis and a housing, wherein the chassis supports internal components of the wearable system.

14. The system of any preceding claim, further comprising structure configured to provide pinch protection.

15. The system of any preceding claim, further comprising a sensor configured to sense whether the system is properly assembled and a controller adapted to prohibit pumping until the sensor detects that the system is properly assembled.

16. The system of any preceding claim, wherein the collection assembly is placed within an interior of the system.

17. The system of any preceding claim, wherein the collection assembly includes an umbrella valve.

18. The system of any preceding claim, wherein the collection assembly is formed from two sheets bonded together.

19. The system of any preceding claim, wherein the collection assembly includes a central opening and a pair of wings extending into the central opening.

20. The system of any preceding claim, further comprising a computer configured to remotely control the system, the computer configured to collect, store and analyze user data and trends as related to volume from each breast and in total, and the number of sessions on several dimensions such as per day, week or month.

21. The system of any preceding claim, wherein the collection assembly includes a fitment that is integral with the collection assembly.

22. The system of any preceding claim, wherein the collection assembly includes a fitment that is attached to the collection assembly.

23. The system of any preceding claim, wherein removing the fitment from the collection assembly destroys the collection assembly or fitment.

24. The system of any preceding claim, wherein the collection assembly is disposable.

25. The system of any preceding claim, wherein the collection assembly is reusable.

26. The system of any preceding claim, wherein the system is sealed.

27. The system of any preceding claim, wherein the system pumps milk.

28. The system of any preceding claim, wherein a valve can be reattached to a second or subsequent collection assembly.

29. The system of any preceding claim, wherein the system is not closed.

30. The system of any preceding claim, further comprising a flange configured to engage breast tissue, wherein the flange includes a generally rigid flat section.

31. The system of any preceding claim, wherein the container assembly is positioned around a nipple of a breast.

32. The system of any preceding claim, wherein the breast contacting structure is incorporated into the collection assembly.

33. The system of any preceding claim, wherein the container assembly includes more surface area superior to a nipple of a breast than inferior thereto.

34. The system of any preceding claim, wherein the tube is configured to run inferior to superior relative to a nipple of the breast when the user is upright.

35. The system of any preceding claim, wherein a tube channel of the conduit includes a section that opens through passive recoil configured next to a section that opens through an assistive support.

36. The system of any preceding claim, wherein the collection assembly is at least partially supported and maintained in attachment to the system by friction with the conduit, and partially by a door assembly that encloses and holds the collection assembly in place.

37. The system of any preceding claim, wherein the collection assembly includes a one-way valve allowing fluid ingress but preventing backflow.

38. The system of any preceding claim, wherein the collection assembly includes a tear-able element to allow removal of fluid.

39. The system of any preceding claim, further comprising a safety mechanism configured to prohibit system functioning unless the system is completely assembled for use.

40. The system of any preceding claim, wherein an air-tight passageway is provided from a nipple source to the collection assembly.

41. The system of any preceding claim, wherein the system is never vented to the atmosphere.

42. The system of any preceding claim, wherein suction in the system is reduced only through the flow of fluid therethrough.

43. The system of any preceding claim, wherein any sounds generated by the system are reduced by fluid flow through the system.

44. The system of any preceding claim, wherein orientation of the system has no effect on functioning on the system.

45. The system of any preceding claim, wherein the system defines a breast enhancement system for enlarging the appearance of the user's breast, the system defining a natural breast profile.

46. A method of power management for a breast pump system having a plurality of modules each running individual programs, comprising:

providing a power hierarchy including a plurality of levels;

controlling the modules so that each module seeks and finds its maximum, minimum required power level;

generating a query asking for a current state and a minimum required mode for each module; and

cycling through each module and setting a power level for each module at its maximum, minimum power level required so that each modul can properly operate.

47. The method of claim 45, wherein the power levels include one or more of a hibernate level, a standby level, a standby with LED level and an active level.

48. A container assembly for a breast pump system, comprising;

a body, the body including a neck and a central opening;

a neck portion extending from the body; and

a fitment configured in the neck portion, the fitment including a tail sized and shaped to maintain the neck portion in an open position when the neck is bent.

49. The container assembly of claim 48, further comprising wings, the wings defining structure for manipulating the container assembly.

50. The container assembly of claim 48, the fitment further including a one-way valve.

51. The container assembly of claim 48, further comprising a tab extending from the neck portion.

52. The container assembly of claim 48, further comprising a tear-able section configured into the neck portion.

53. The container assembly of claim 48, wherein the tail has a narrow and elongated shape so that fluid can flow around the tail.

54. A method for calculating volumes extracted from a breast by a breast pump, comprising:

tracking and storing motor location versus time;

tracking and storing vacuum versus time; and

determining a relationship between motor location and volume of milk extracted from a breast by the breast pump.

55. The method of claim 54, comprising mapping motor location versus volume at a specific vacuum.

56. The method of claim 55, wherein the specific vacuum level is -60mmHg.

57. The method of claim 54, further comprising generating known rates of flow within the breast pump at a known specific vacuum within the breast pump and identifying motor location.

58. The method of claim 54, further comprising observing indications of purging of the breast pump and eliminating data other than that associated with a clean start and a clean finish between purges.

59. The method of claim 54, further comprising adjusting for relative time to calculate volume.

60. The method of claim 54, further comprising filtering out data associated with vacuum levels other than a range about a target specific vacuum level.

61. The method of claim 54, further comprising adjusting volume calculations for flows above a pre-determined level.

62. The method of claim 54, further comprising incorporating a mathematical constant into volume calculations to take into account when air is in the breast pump.

63. A method of handling data associated with a breast pump system, comprising;

generating and storing live data from operating the breast pump system;

generating and storing historical data from operating the breast pump system; and

maintain live data streams separate from historical data streams.

64. The method of claim 63, wherein historical data is stored in the breast pump system.

65. The method of claim 63, wherein live data is employed to update a device external to the breast pump system.

66. The method of claim 63, further comprising updating an external device with historical data.

67. The method of claim 63, further comprising storing session data, wherein a session is defined as commencing upon achieving latch and ending when latch ceases or there is a pause in pumping for over five minutes.

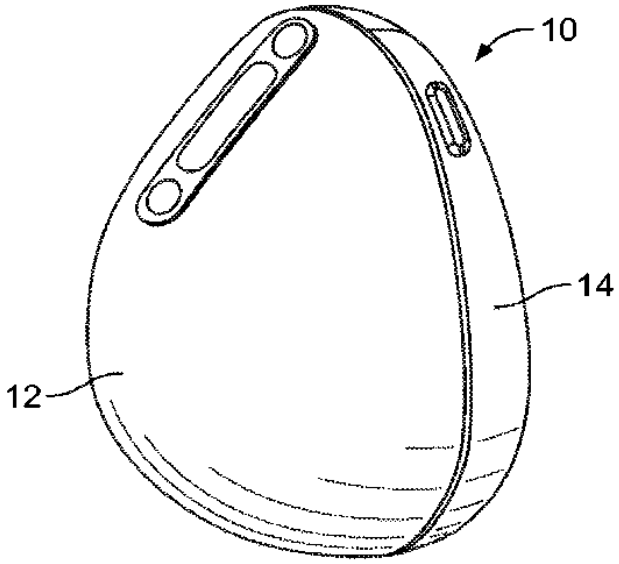


FIG. 1A

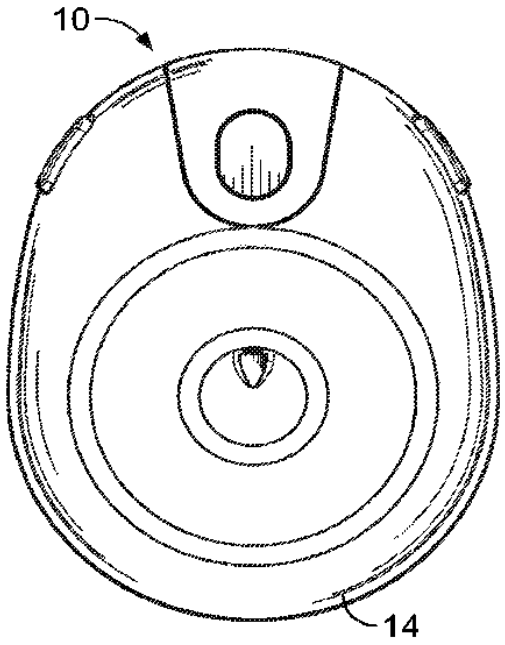


FIG. 1B

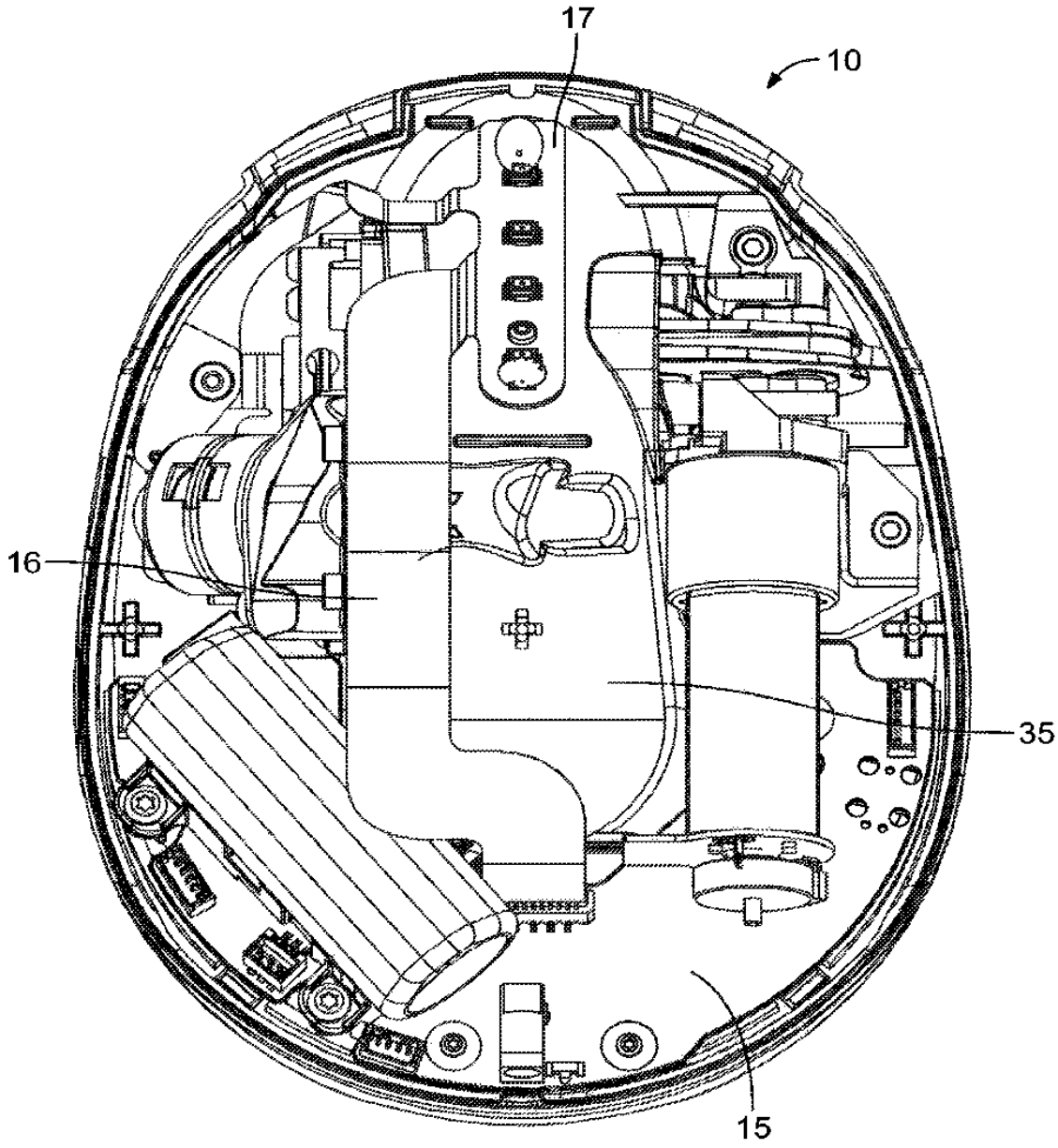


FIG. 2

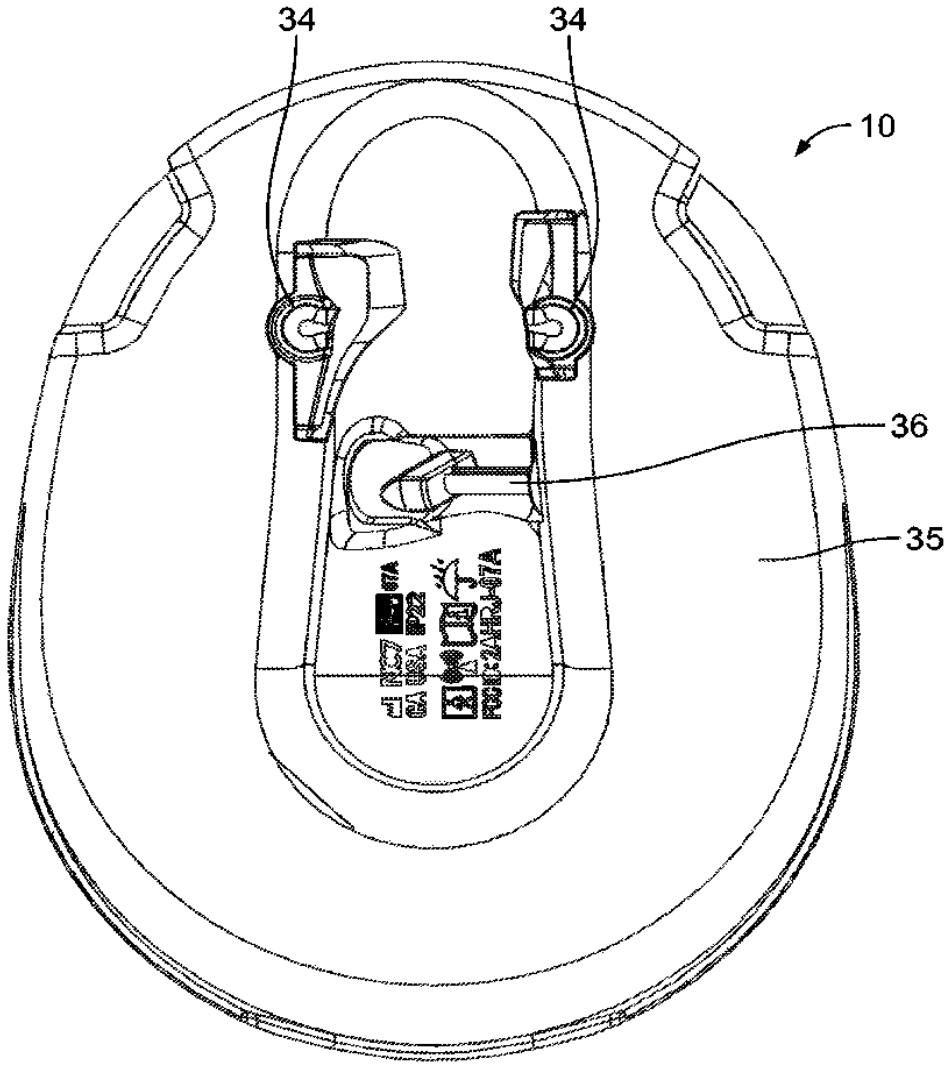


FIG. 3

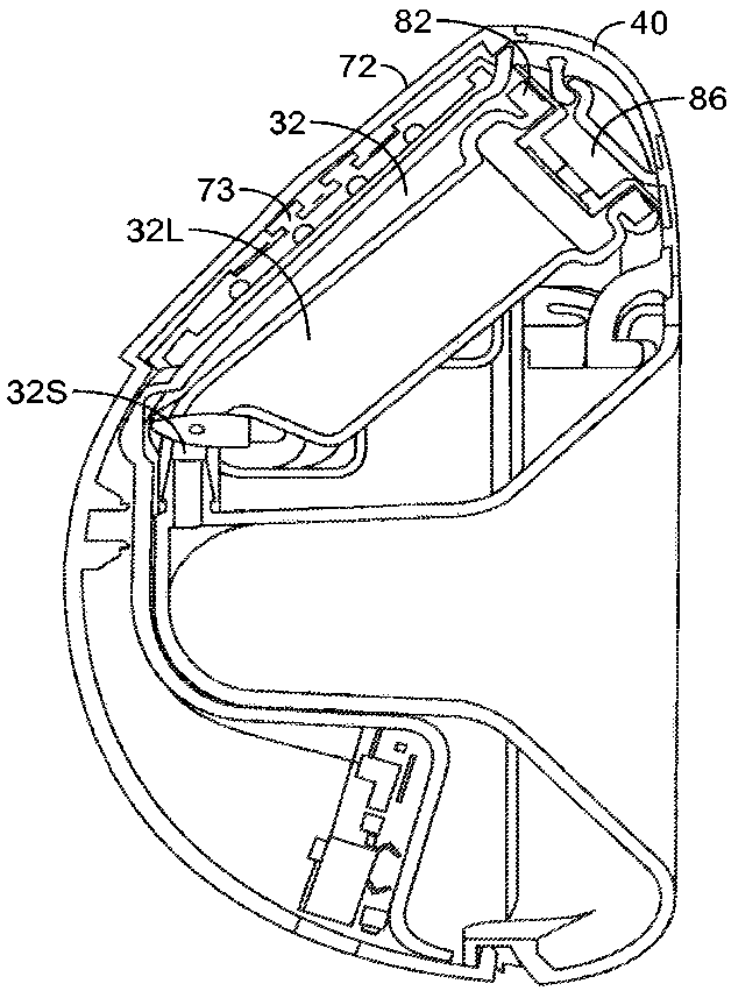


FIG. 4

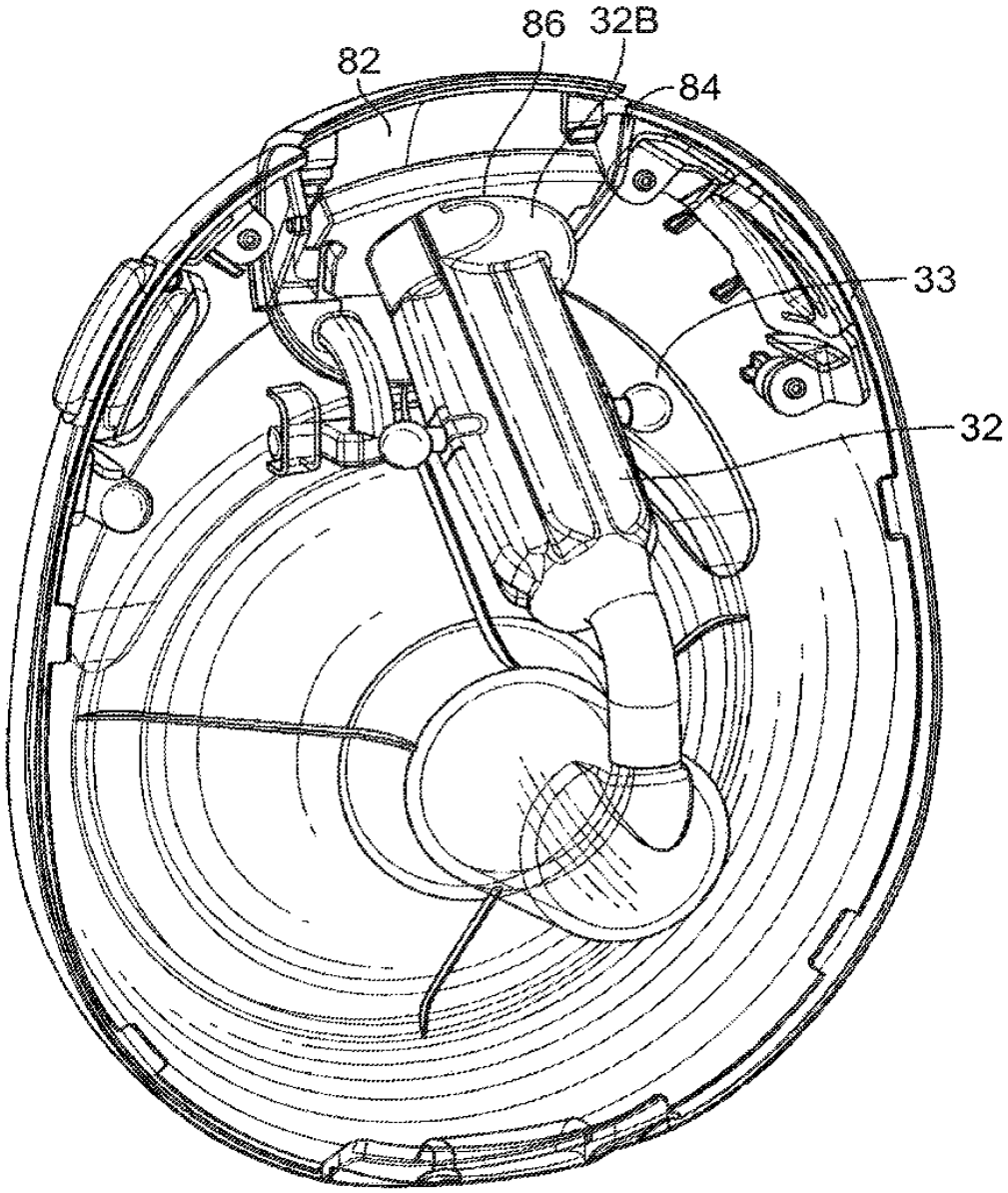


FIG. 5

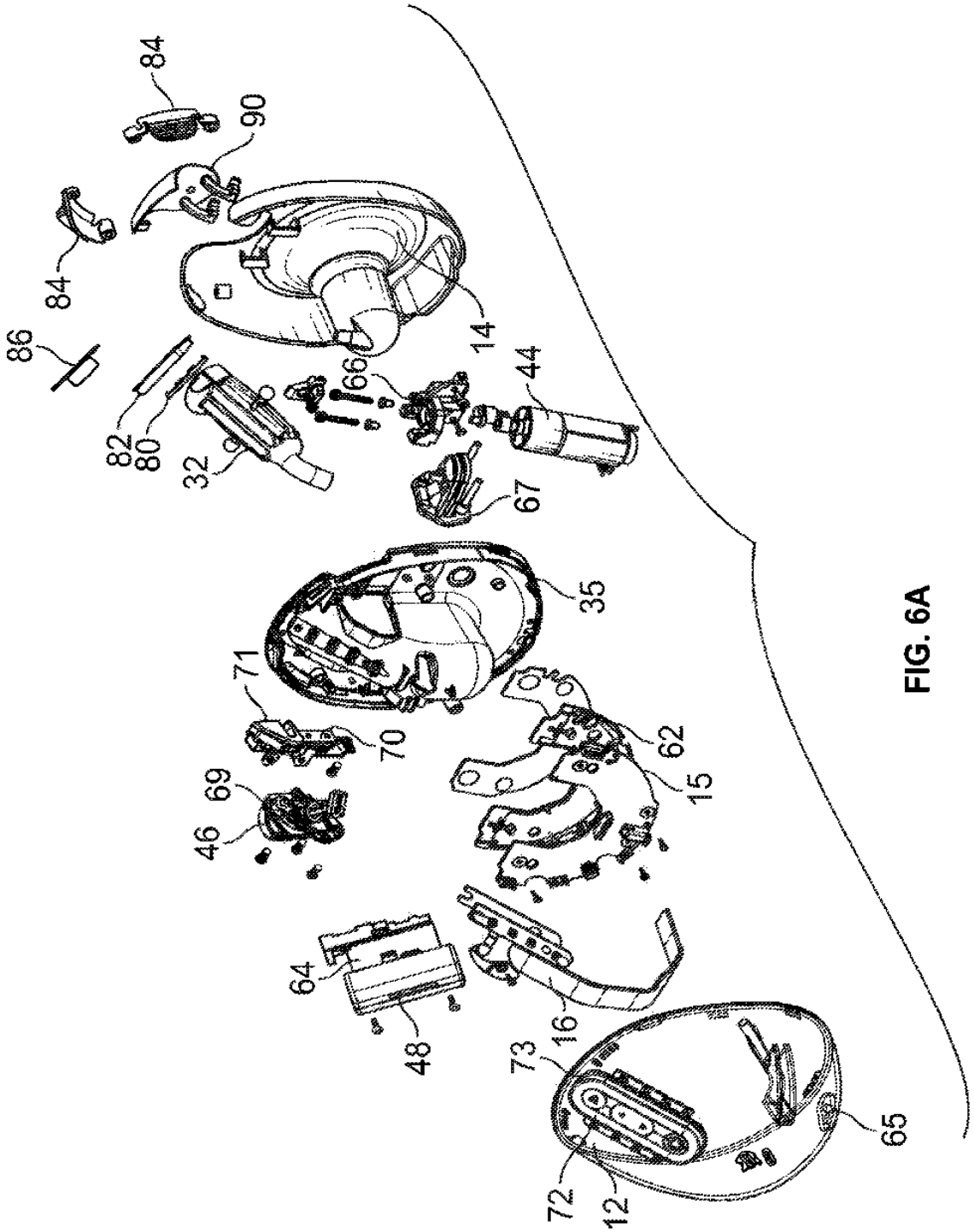
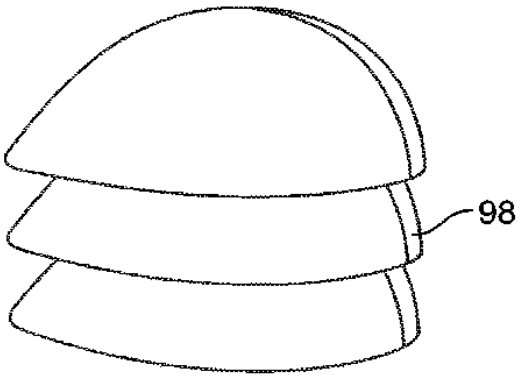

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12

FIG. 6A



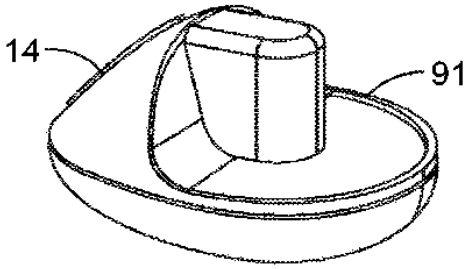


FIG. 6B

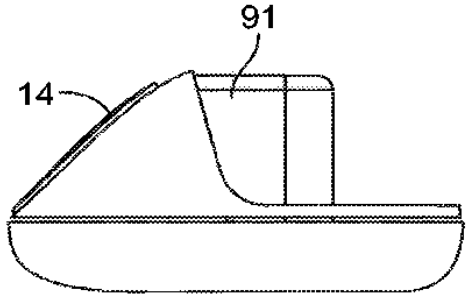


FIG. 6C

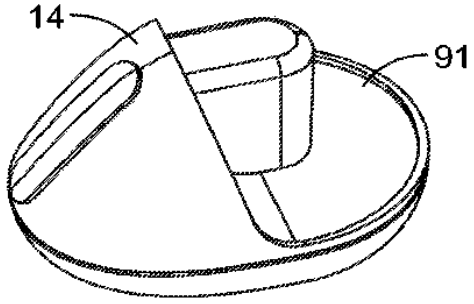


FIG. 6D

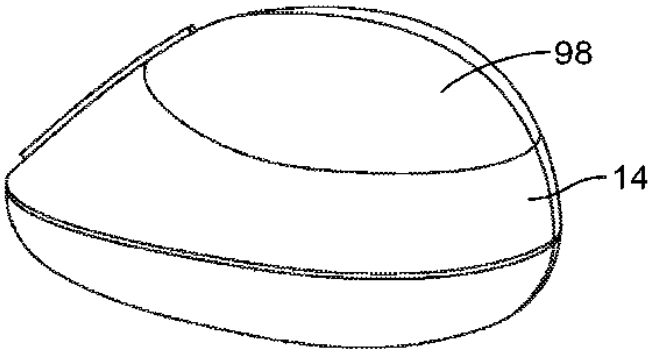
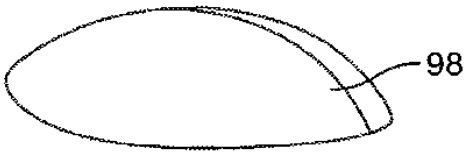


FIG. 6E



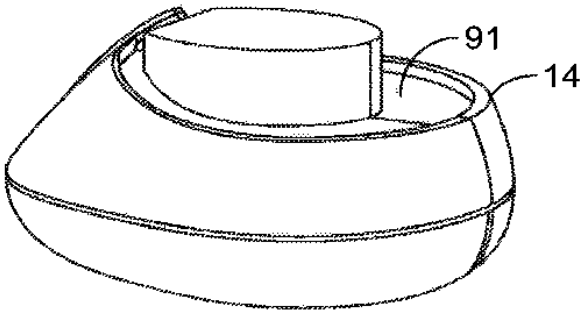


FIG. 6F



FIG. 6G

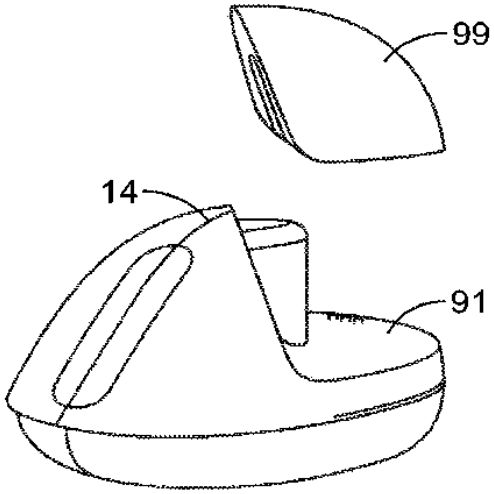


FIG. 6H

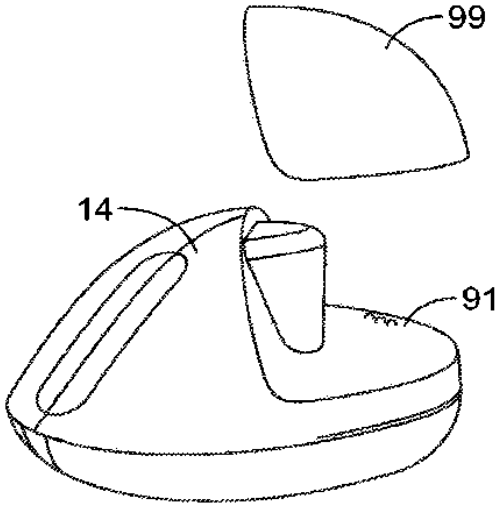


FIG. 6I

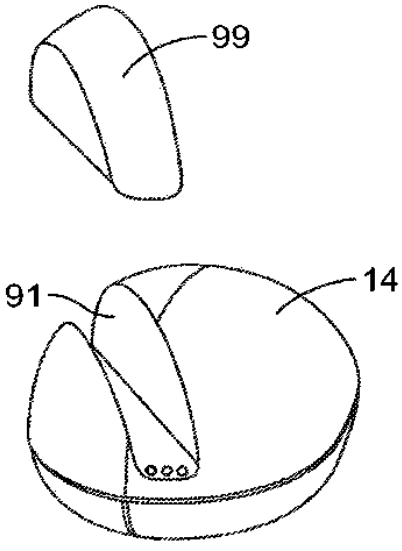


FIG. 6J

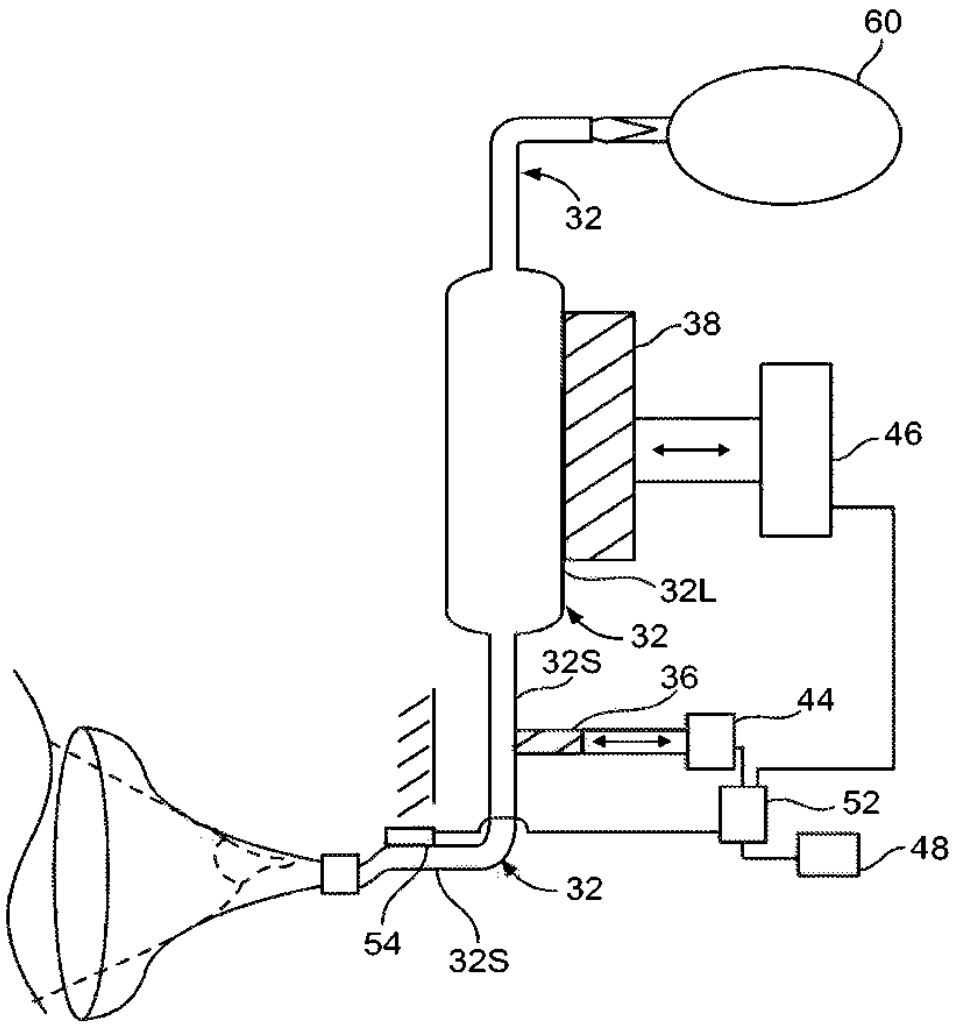


FIG. 7A

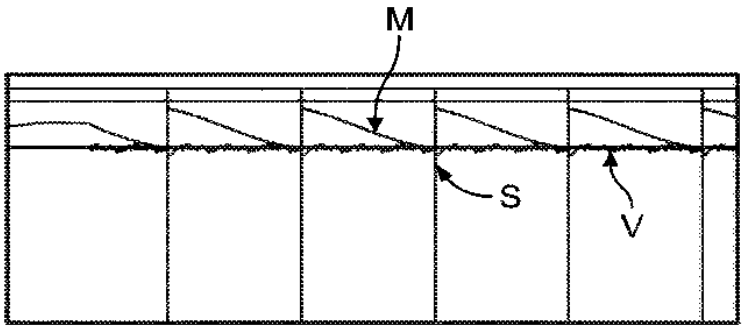


FIG. 7B

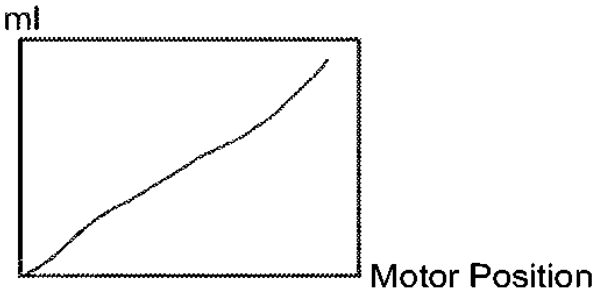


FIG. 7C

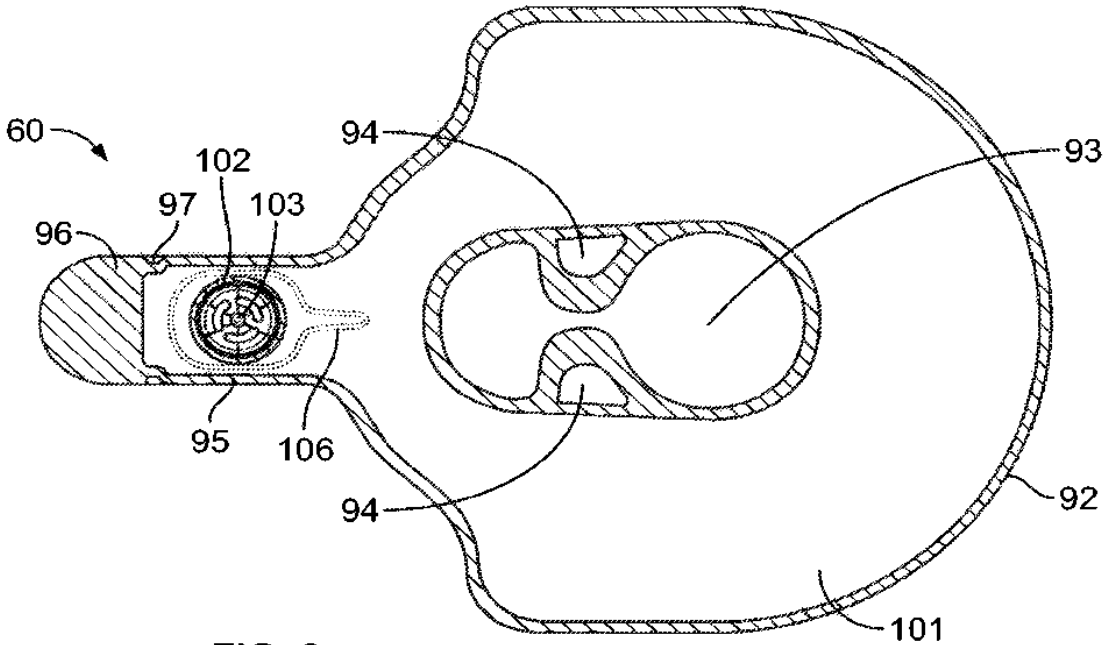


FIG. 8

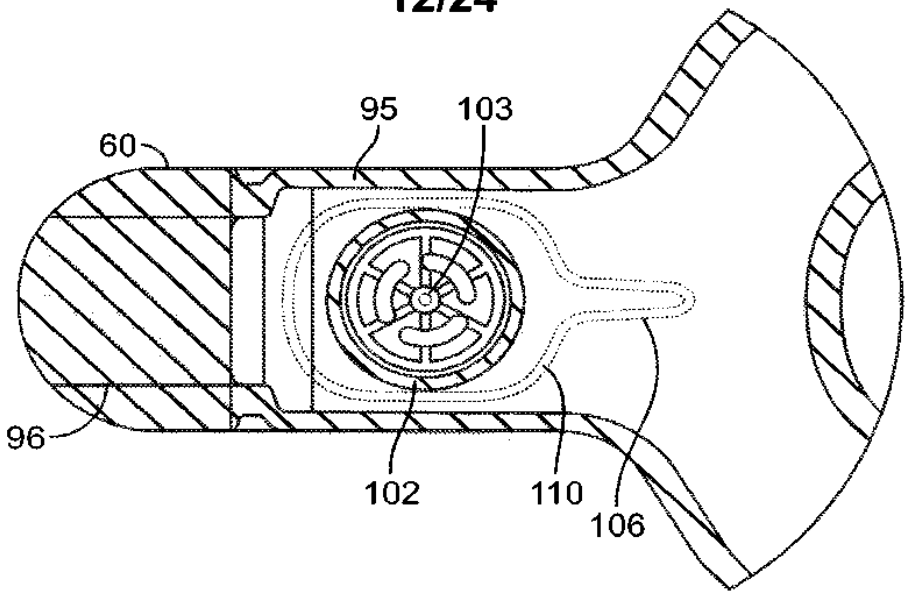


FIG. 9

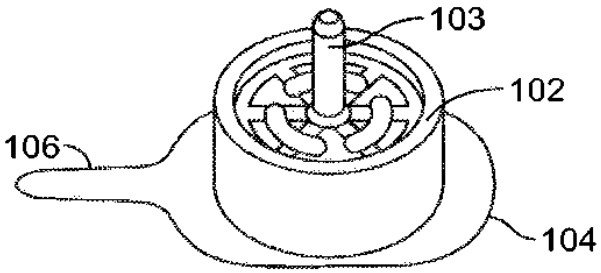


FIG. 10

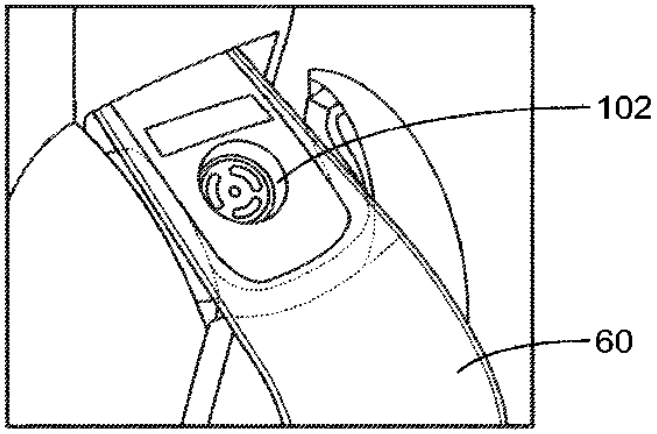


FIG. 11A

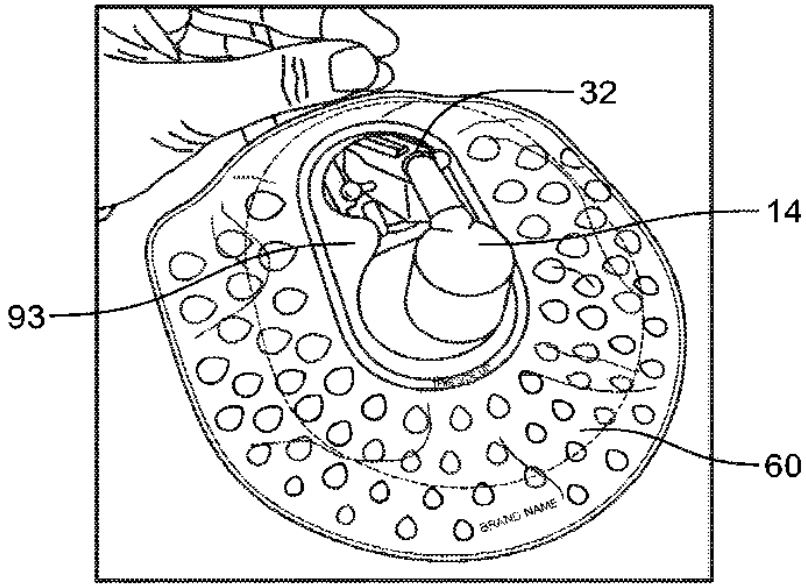


FIG. 11B

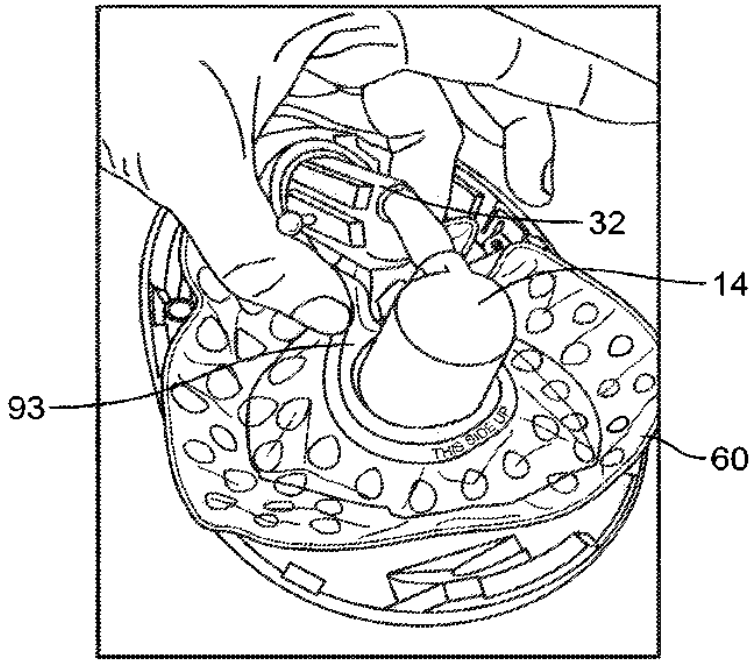


FIG. 11C

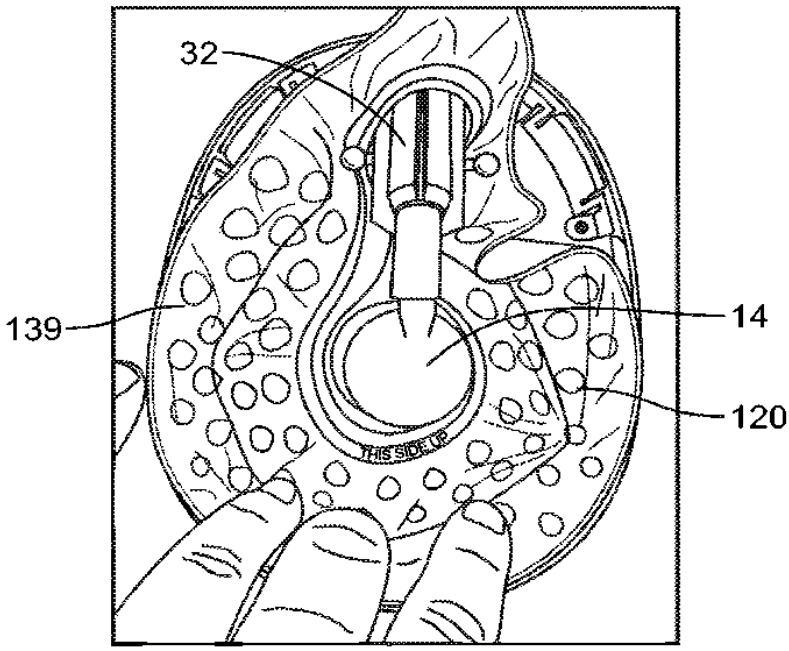


FIG. 11D

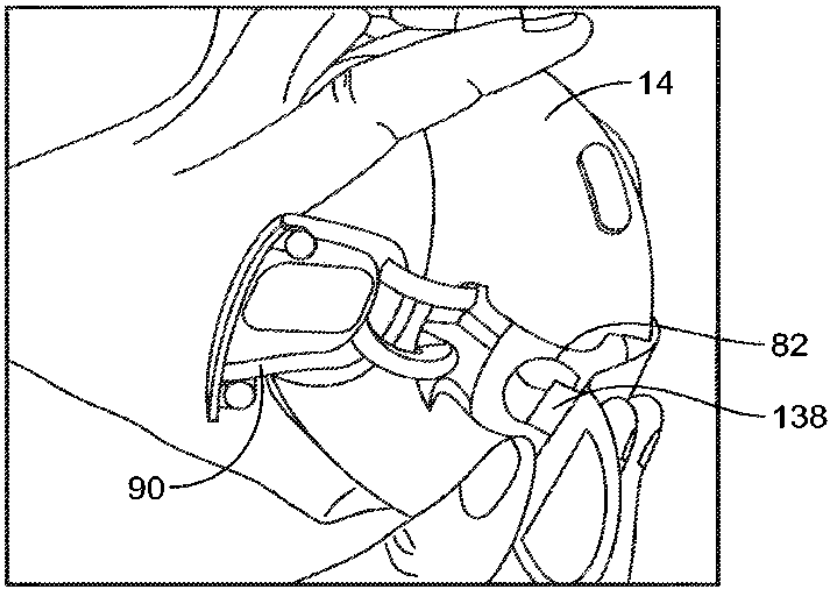


FIG. 11E

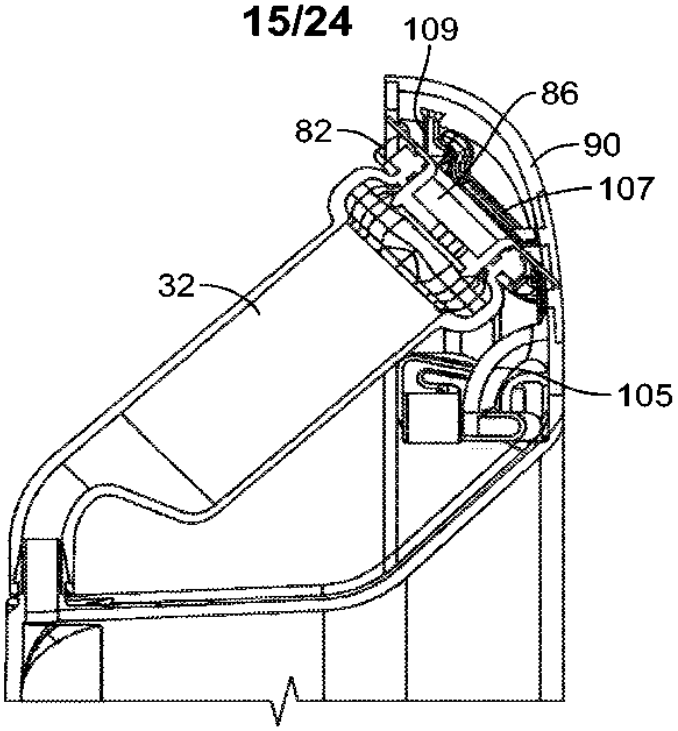


FIG. 12

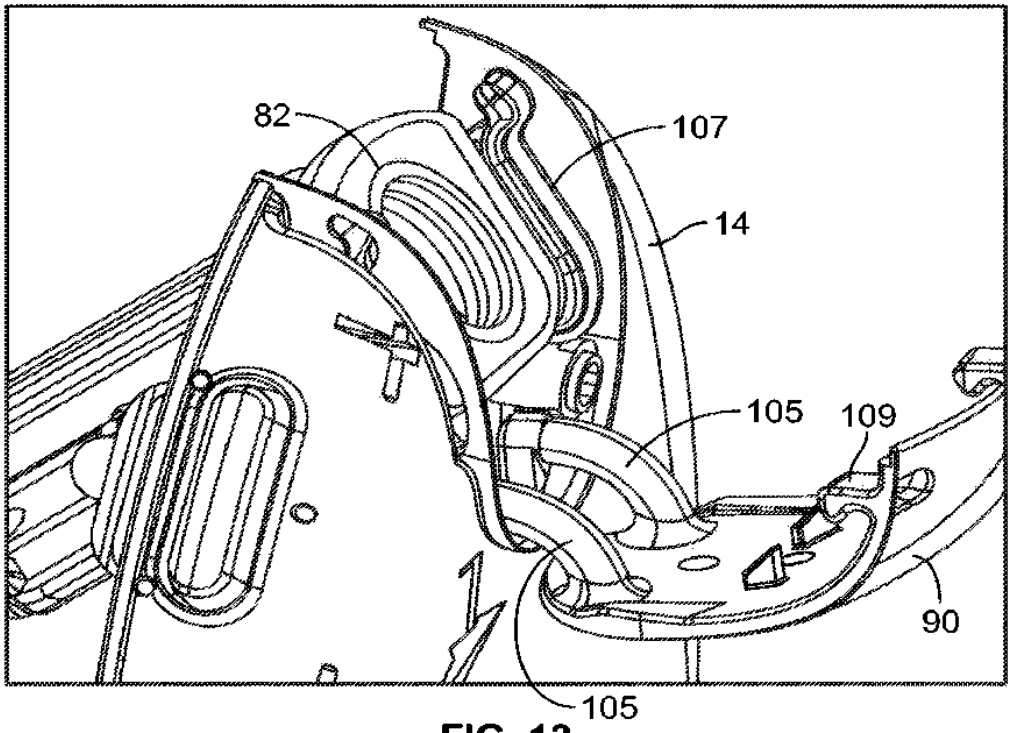


FIG. 13

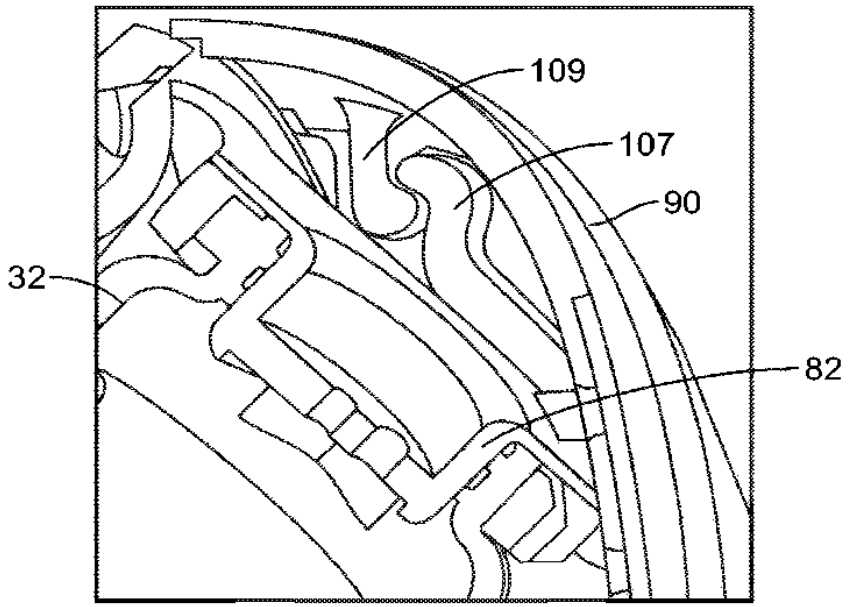


FIG. 14

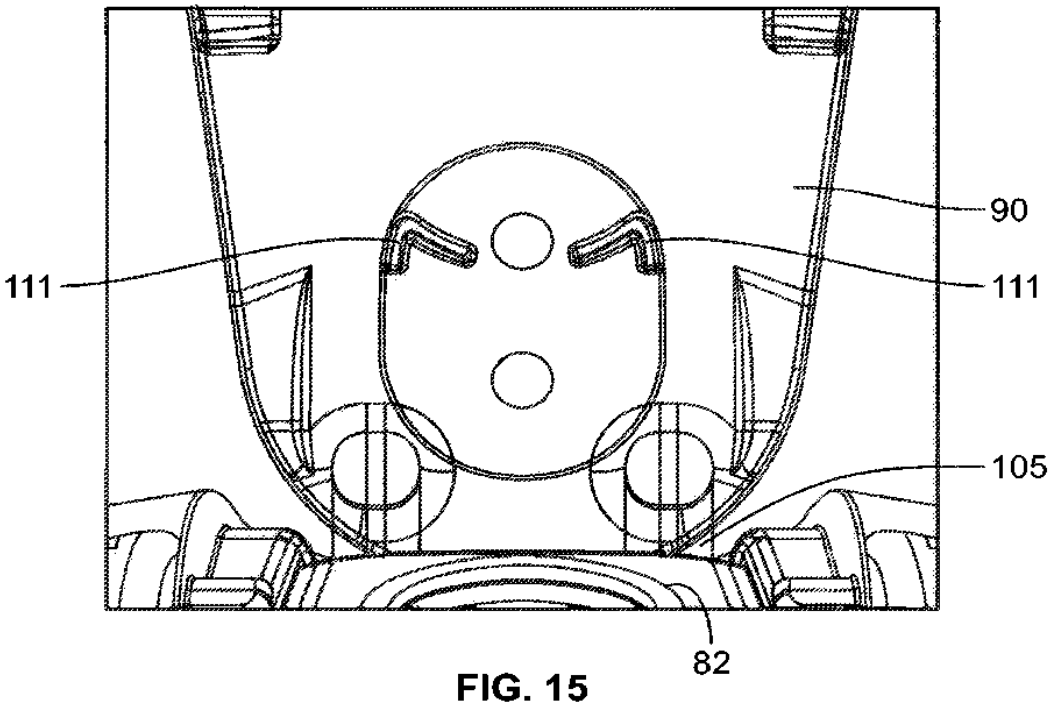


FIG. 15

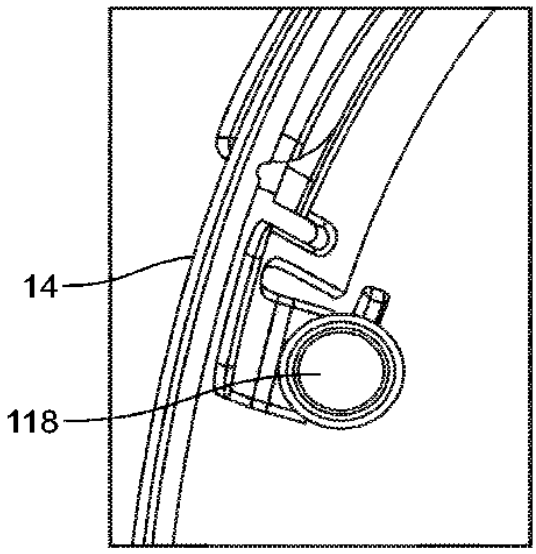


FIG. 16

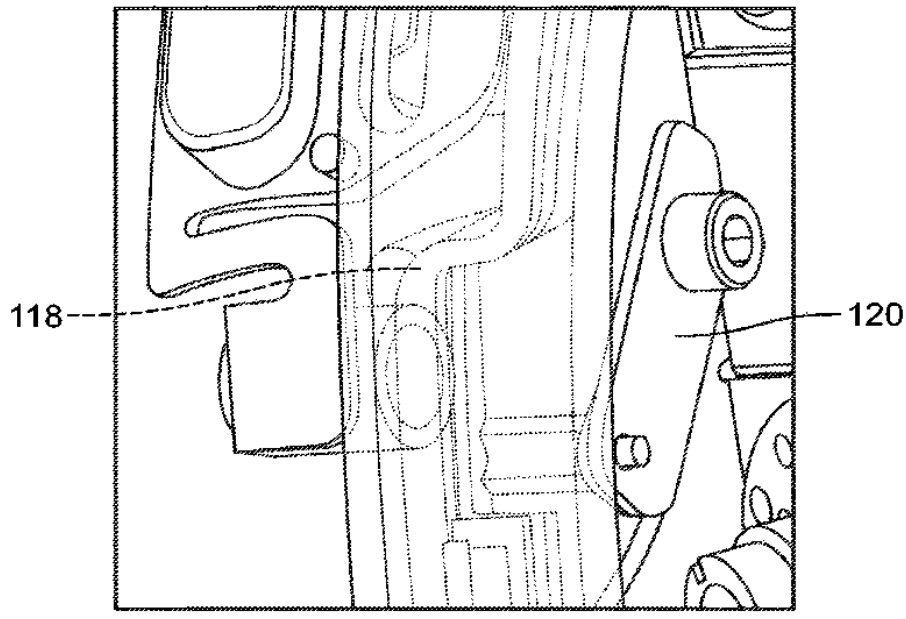


FIG. 17

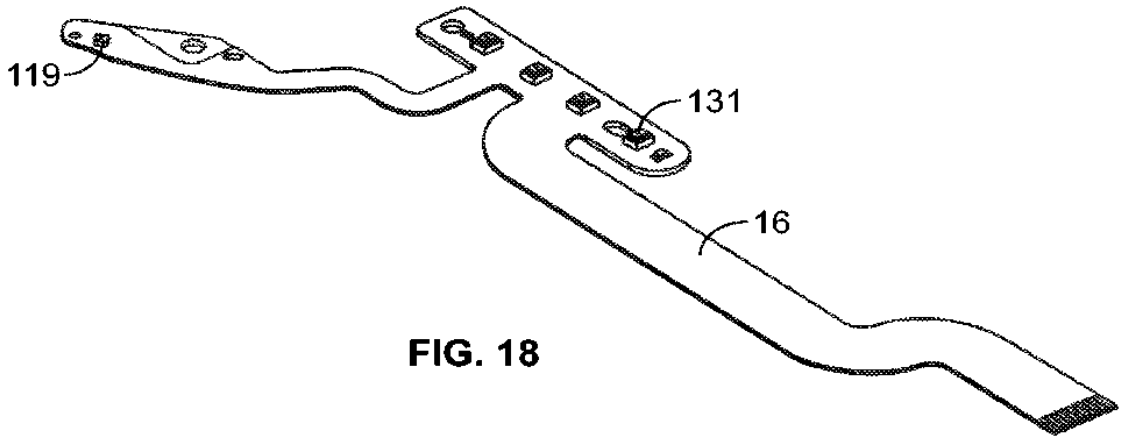


FIG. 18

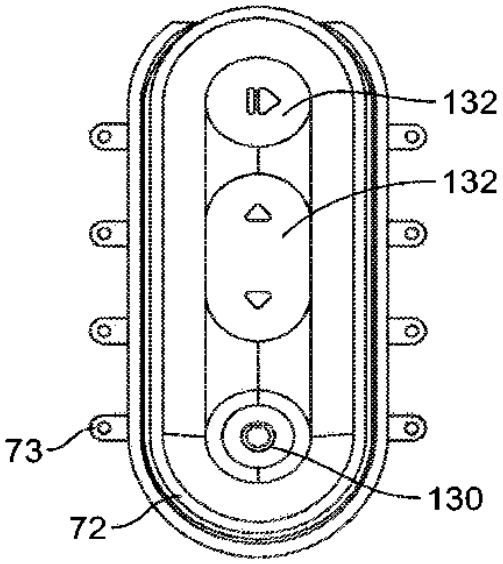


FIG. 19

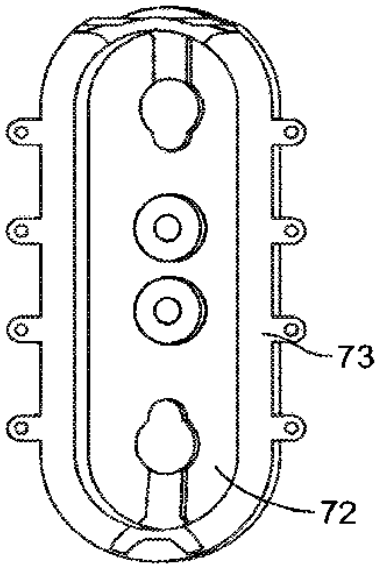


FIG. 20

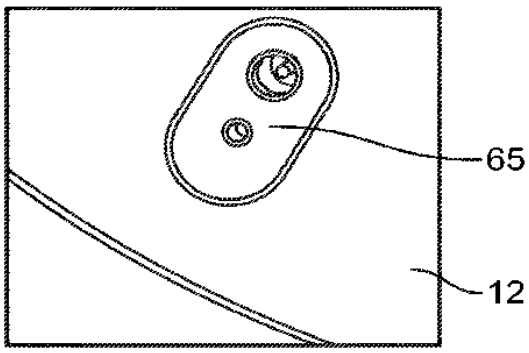


FIG. 21

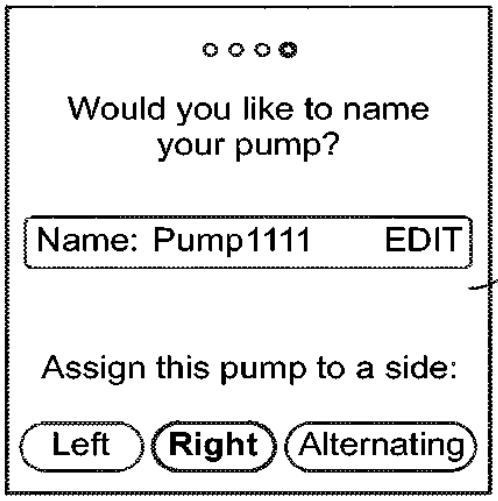

Would you like to name your pump?
Name: Pump1111 EDIT
140
Assign this pump to a side:
Left
Right
Alternating

FIG. 22

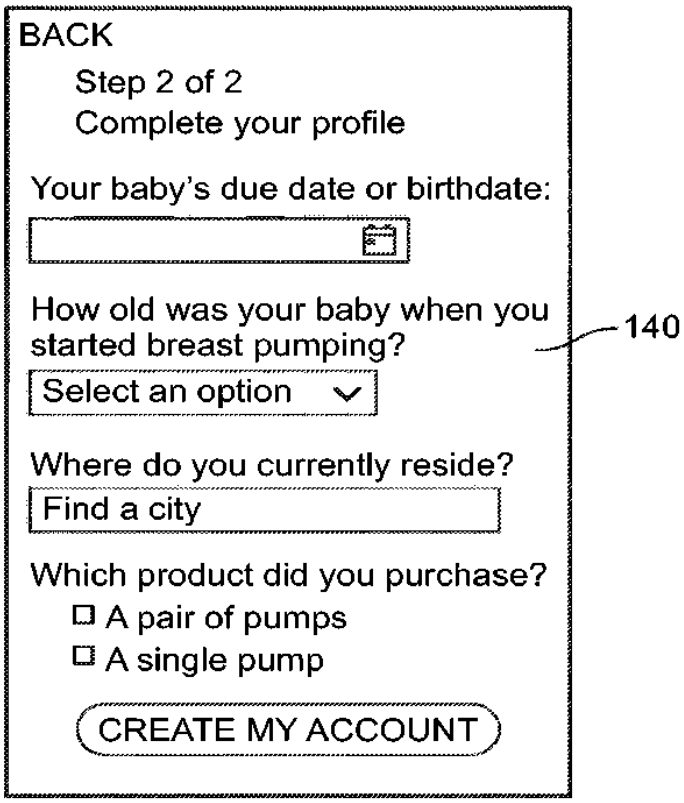

BACK
Step 2 of 2
Complete your profile
Your baby's due date or birthdate:
How old was your baby when you started breast pumping?
140
Select an option
Where do you currently reside?
Find a city
Which product did you purchase?
A pair of pumps
A single pump
CREATE MY ACCOUNT

FIG. 23

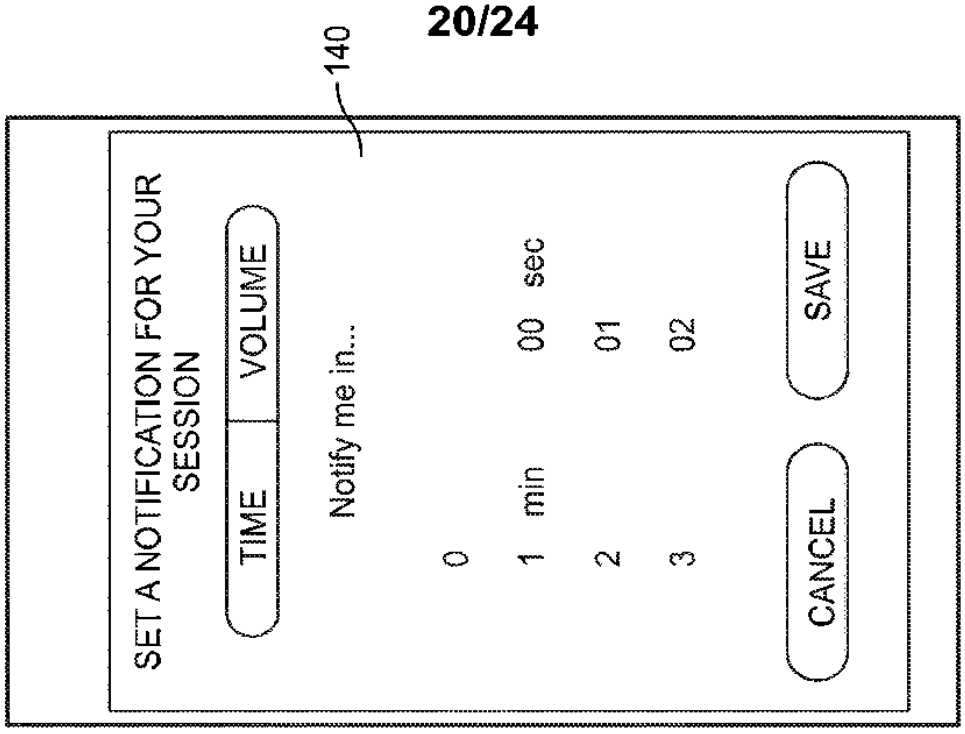

140
SET A NOTIFICATION FOR YOUR SESSION
TIME
VOLUME
Notify me in...
0
1 min
2
3
00 sec
01
02
CANCEL
SAVE

FIG. 25

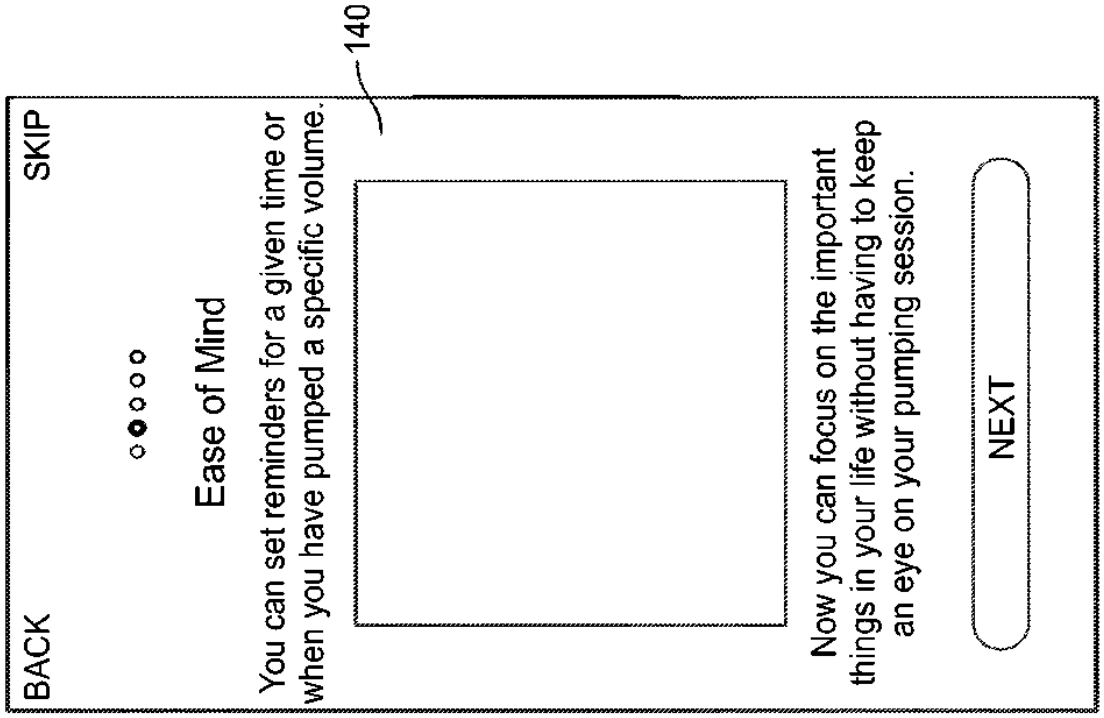

140
BACK
SKIP
Ease of Mind
You can set reminders for a given time or when you have pumped a specific volume.
Now you can focus on the important things in your life without having to keep an eye on your pumping session.
NEXT

FIG. 24

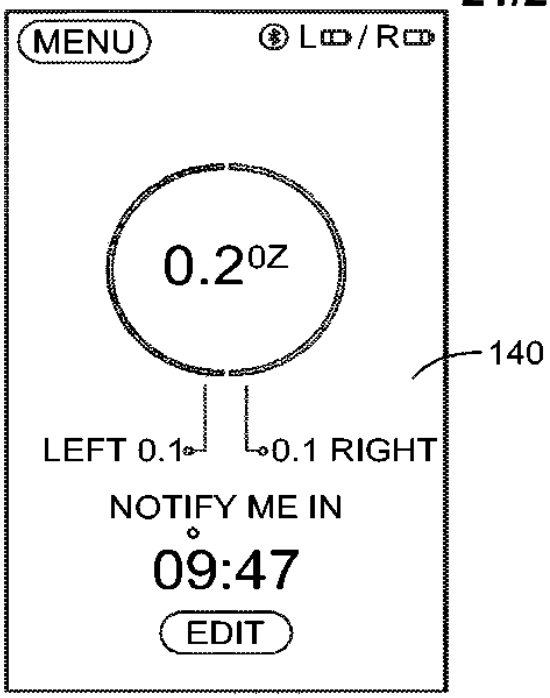


FIG. 26

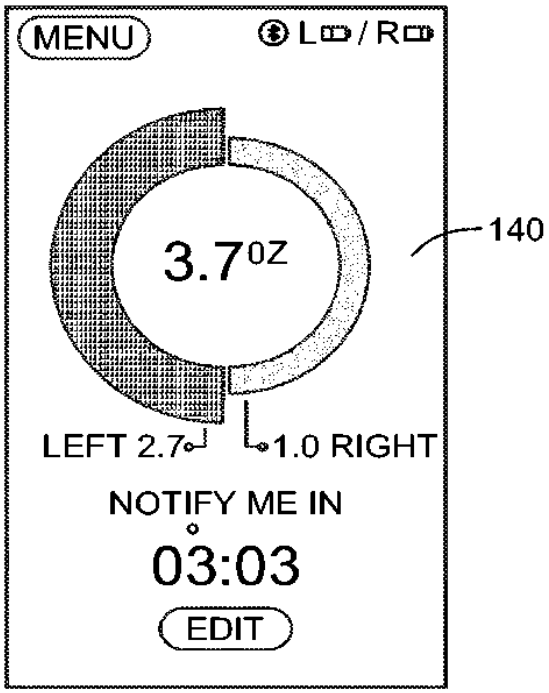


FIG. 27

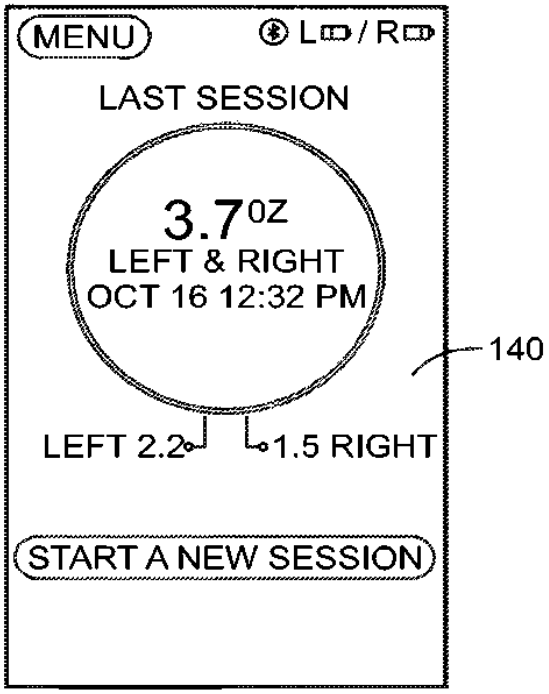


FIG. 28

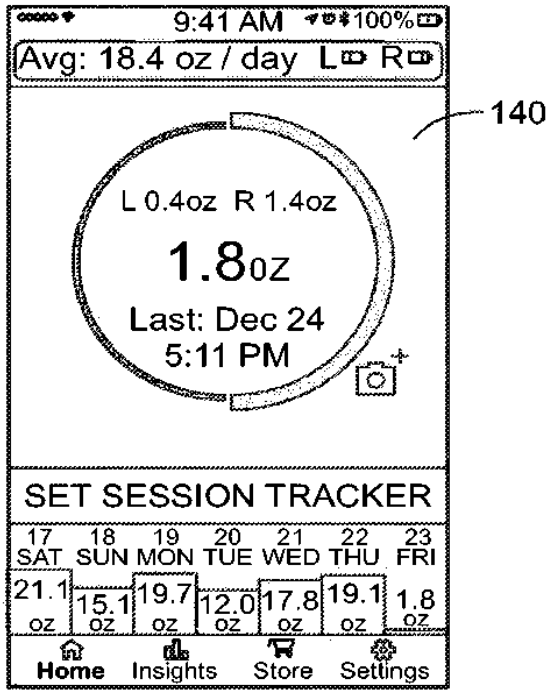


FIG. 29

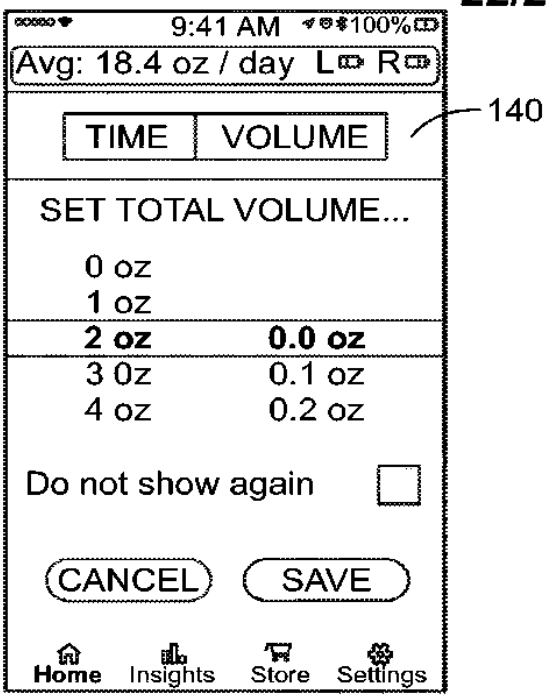


FIG. 30

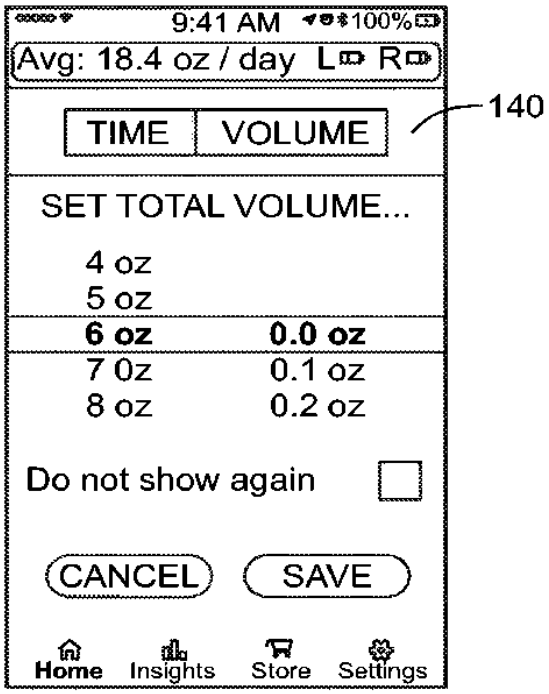


FIG. 31

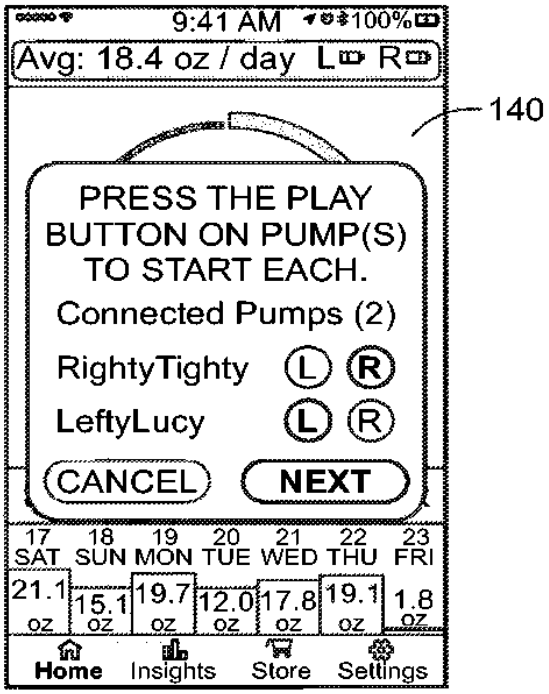


FIG. 32

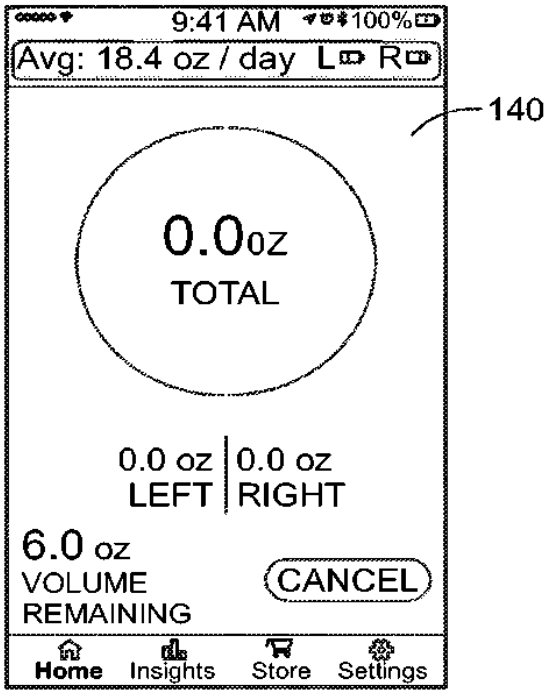


FIG. 33

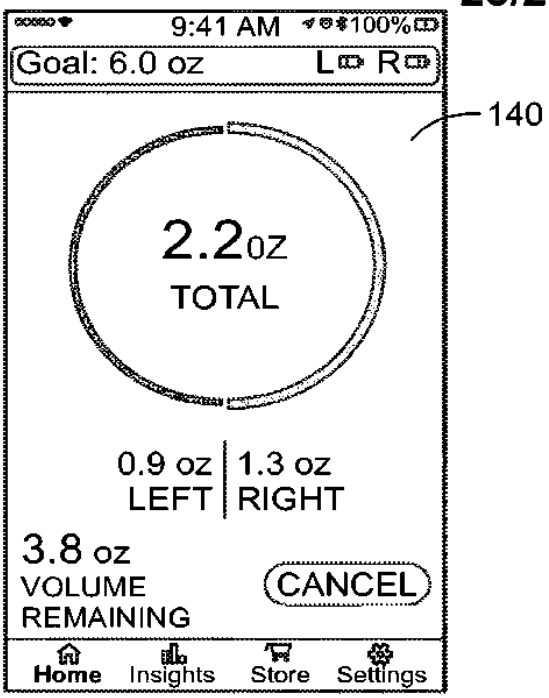


FIG. 34

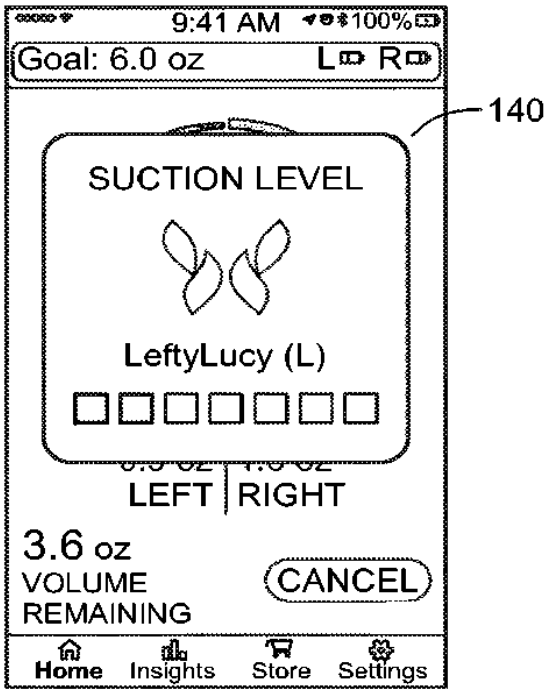


FIG. 35

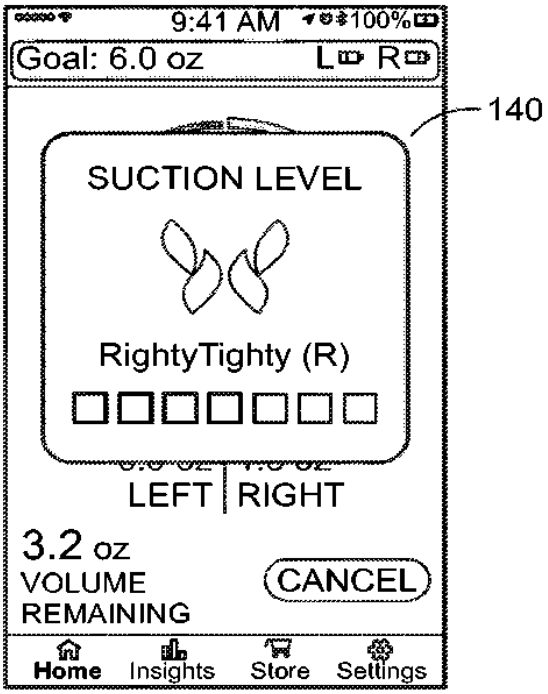


FIG. 36

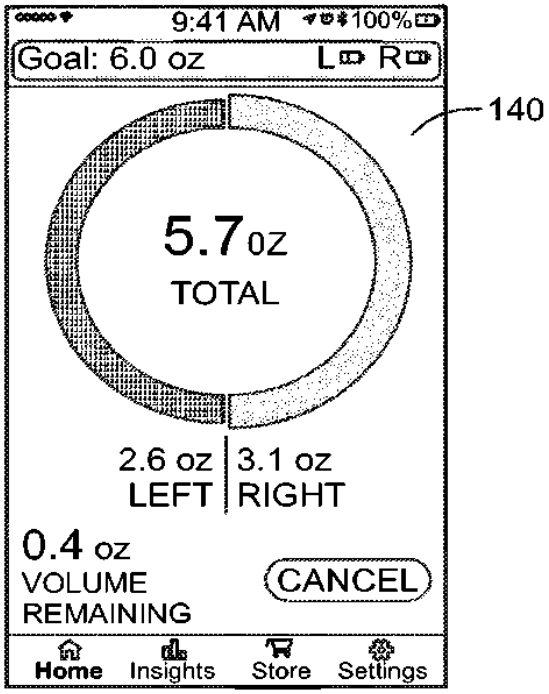


FIG. 37

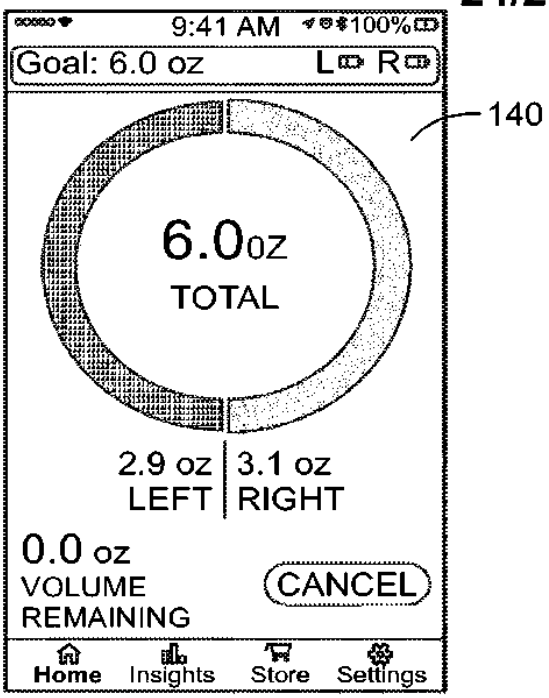


FIG. 38

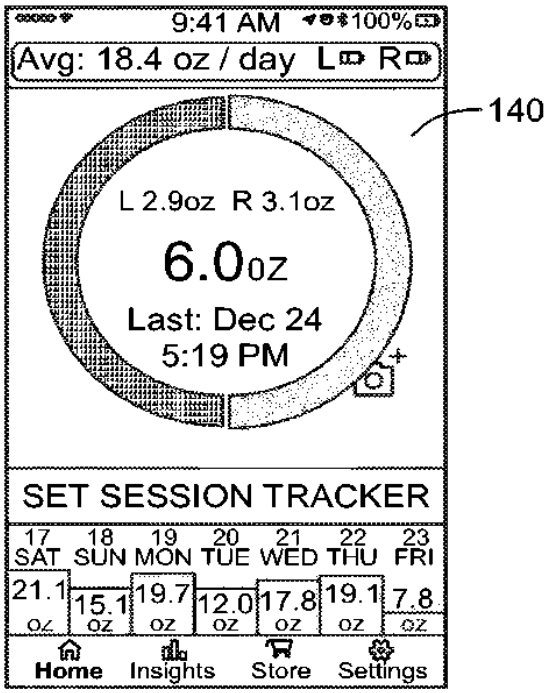


FIG. 39

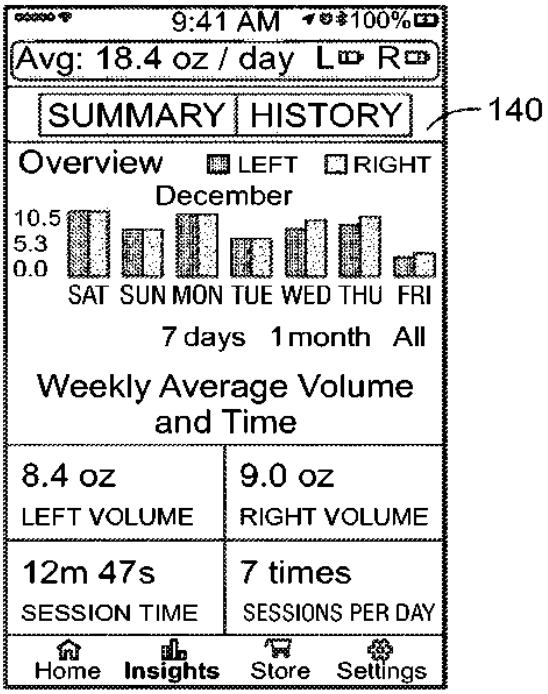


FIG. 40

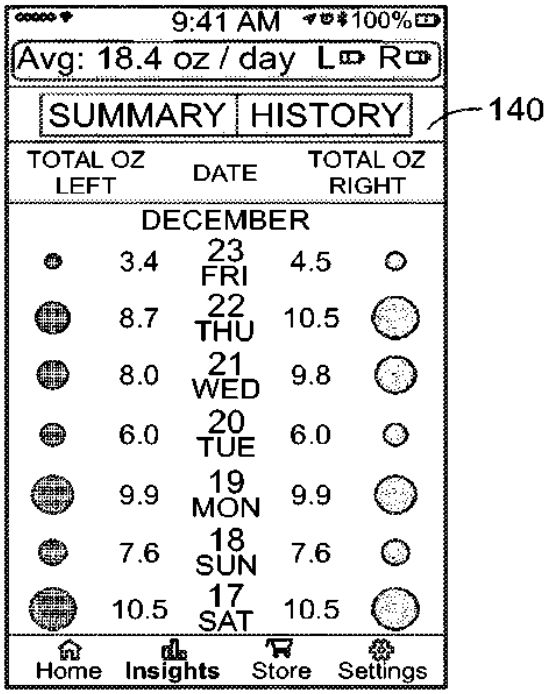


FIG. 41

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2017/017112

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.: 4-45
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.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US 2017/017112

A. CLASSIFICATION OF SUBJECT MATTER

A61M1/06 *(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 1/00, 1/06, A61H 7/00

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, DWPI, ESP@CENET, Google, WIPO, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014205436 A3 (DS LABS INC) 24.12.2014, abstract, paragraphs [0072]-[0073], [0075]-[0076], [0089], [0091]-[0095], [0100], [0106]-[0109], figs 1, 10A-C, 11A-B, 12A-B, 13, 14A-B, 17A-C, 23A-D, 24-25	1-3, 46-53
X	WO 2016014488 A1 (EXPLORAMED NC7 LLC) 28.01.2016, claims 9,19, [0011], [00154], [00156], [00184], [00188], [00190], [00195], [00199], [00220], fig.41	54-57, 59, 61
Y		58, 60, 62
X	US 2014378895 A1 (CLINICARE LTD) 25.12.2014, abstract, paragraphs [0040]-[0045], [0052], [0054]-[0056], figs. 1, 2	63-67
Y	WO 2016014494 A1 (EXPLORAMED NC7 LLC) 28.01.2016, paragraphs [0081]-[0083], [00268]	58
Y	US 2015148709 A1 (MILKOTECH SYSTEMS LTD) 28.05.2015, paragraphs [0040]-[0044], [0051]	60, 62

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Freemie Collection Cups, A Hands-free, Concealable Single or Double Breast Pump Collection System, User Manual , 17.03.2015, pp. 1-20 Retrieved from <www.freemie.com>	1-3, 46-53
A	US 8357116 B2 (MEDELA HOLDING AG) 22.01.2013	48-53

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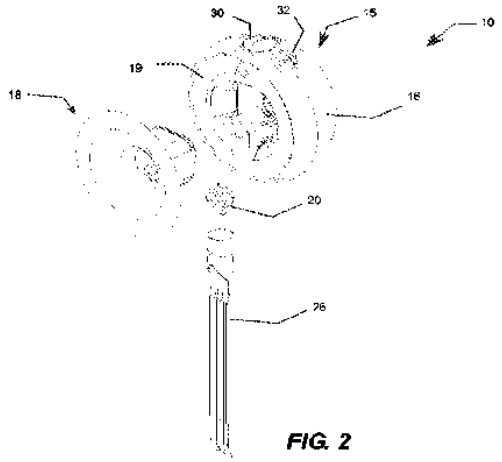


FIG. 2

(57) Abstract: A hands-free breast pump that includes a balanced push-pull reciprocating drive system that applies pumping force to a vacuum chamber formed by a breast interface cup during inward and outward pump strokes. The breast pump includes a breast cup that has a resilient bellows structure that partially collapses the volume of the vacuum chamber during the inward stroke and recovers the volume of the vacuum chamber during the outward stroke. The pump mechanism includes a cam drive system that translates rotary electric motor power into reciprocating linear action of an actuator arm that drives the bellows structure. The bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is designed to produce a desired operating profile for the pump.

WO 2008/137678 A1

Hands-Free Breast Pump with Balanced Reciprocating Drive

REFERENCE TO RELATED APPLICATION

This application claims priority to United States Provisional Patent Application Serial No. 60/915,937 filed May 4, 2007 entitled "Hands-Free Breast Pump with Balanced Reciprocating Drive," which is incorporated herein by reference.

TECHNICAL FIELD

The present invention is generally related to breast pumps that cause nursing mothers to express breast milk and, more particularly, to a hands-free breast pump with a balanced push-pull vacuum generation system that applies pumping force to a bellows structure of a vacuum chamber formed by a breast interface cup during inward and outward pump strokes.

BACKGROUND OF THE INVENTION

The first hands-free breast pump including a self-contained pump mechanism and power source configured to be held in place between a nursing mother's breast and bra is described in U.S. Patent No. 7,223,255 entitled "System For a Portable, Hands-Free Breast Pump and Method of Using the Same," which is incorporated herein by reference. The hands-free breast pump described in this patent, which will be referred to as the Gen-1 design, has been a successful commercial product. The present patent is directed to a second generation breast pump, which is referred to as the Gen-2 design, that includes significant improvements over the initial Gen-1 design.

More specifically, the Gen-1 design operates by applying force generated by a motor during the inward stroke of a pump mechanism to a movable part (referred to as a bellows structure) of a vacuum chamber located at the end of the breast cup (also referred to as breast interface flange). The force applied by the pump mechanism to the bellows structure of the vacuum chamber causes the bellows structure to partially collapse, thereby reducing the volume of the vacuum chamber to create positive pressure that forces any expelled milk located in the breast cup through a one-way valve and into a collection bag. Upon the release of the inward stroke of the pump

mechanism, the bellows structure of the Gen-1 design is configured to resiliently recover its shape during an outward stroke to restore the original volume of the vacuum chamber, thereby increasing the volume of the vacuum chamber to create negative pressure within the vacuum chamber. The one-way valve vents the vacuum chamber during the inward stroke and seals the vacuum chamber during the outward stroke to create a milking action. That is, the outward stroke of the pump applies suction to the breast and the inward stroke forces the expressed milk through the one-way valve and into a collection bag.

As described above, the Gen-1 design utilizes an unbalanced pump mechanism that applies force to the vacuum chamber only during the inward stroke, whereas the resiliency of the bellows structure of the breast cup creates the suction during the outward stroke. Therefore, the pump mechanism is required to compress the bellows structure of the breast cup during the inward stroke, much like compression of a spring, sufficiently to allow the resiliency of the breast cup to generate the negative pressure that creates the suction action. Like a compressed spring, the bellows structure of the breast cup resiliently recovers its shape upon the release of the compression force to create the suction action without assistance from the pump motor, which applies force only during the inward stroke. While this type of pump mechanism is highly functional, it requires application of a significant force to the breast cup during the inward stroke, which tends to urge the breast cup out of its seat within the breast pump housing. Unless properly constrained, the force can be sufficient to cause the breast cup to pop out of its seat in the pump housing, which can cause the pump to malfunction. Although the breast cup can be restrained within its seat in the housing using a suitable device, such as tabs, detent mechanisms or a support ring, these features add complexity and cost to the pump.

Perhaps more importantly, the additional breast cup restraining features make the pump more difficult to assemble with the breast cup properly seated within the pump housing. Inevitably, a certain number of users are unable to assemble the pump correctly. Unfortunately, the pump looks and sounds like it is working properly even when the breast cup is not seated properly, and the user can find it difficult to detect that the breast cup is not seated properly. This gives some users who experience this

problem the misimpression that the pump is assembled correctly and yet performs poorly, when the real problem is that the breast cup is not properly seated in the pump housing. Apparent pump malfunction due to improper breast cup seating has, therefore, been a recurring problem with the Gen-1 design.

The unbalanced nature of the Gen-1 pump design (i.e., the application of motor force only during the inward stroke) also requires a relatively powerful pump motor to compress the bellows structure of the breast cup on the inward stroke against an amount of natural resiliency of the silicon that is sufficient to generate the desired suction within the breast cup on the outward stroke. Pumping against this amount of spring force on the inward stoke, without the assistance of the motor on the outward stroke, is inefficient because the motor is used in an unbalanced manner in that high force is applied from the motor on the inward stroke, whereas no force is applied by the motor on the outward stroke. This unbalanced pump design requires higher power, reduces the cycle rate, taxes the motor, and stresses the internal gear train components to a higher degree than could be obtained from a more balanced design. Accordingly, there remains a need for more effective, efficient and user friendly hands-free breast pump designs.

SUMMARY OF THE INVENTION

The present invention meets the needs described above in a second generation hands-free breast pump, referred to as the Gen-2 design, that includes a balanced push-pull vacuum generation system that applies pumping force to a bellows structure of a vacuum chamber formed by a breast interface cup during the inward and outward pump strokes. More specifically, the breast pump includes a breast cup that has a resilient bellows structure that partially collapses the volume of the vacuum chamber during the inward stroke and recovers the volume of the vacuum chamber during the outward stroke. The pump mechanism, which includes a cam drive system that translates rotary electric motor power into reciprocating linear action of an actuator arm that drives the bellows structure, applies force to the bellows structure during the inward pump stroke causing a reduction in the volume of the vacuum chamber and during the outward pump stroke causing an expansion of the volume of the vacuum chamber. The

bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is designed to produce a desired operating profile for the pump. In addition, the shape of the cam track is carefully designed and fine tuned to produce a desired operating profile for the pump to mitigate motor current spikes, undue gear stress and reduce noise while producing a desired suck-release profile for the pump.

The use of a balanced drive system that applies force to the bellows structure of the breast cup during both the inward and outward pump strokes reduces the resiliency required of the bellows structure of the breast cup from that of the Gen-1 design, resulting in a more effective, efficient and user friendly hands-free breast pump design. For example, the Gen-2 pump running on a single AA battery achieves comparable suction levels at a comparable cycle rate when compared to the Gen-1 design running on two AA batteries. In addition, the reduced pumping force of the Gen-2 design allows this embodiment to achieve improved performance with a motor operating at significantly lower RMP and a significantly smaller gear ratio, which reduces the required number of gear meshes and allows for larger, more robust gears. These design improvements result in a lower cost, better performing, quieter and more robust breast pump that is easier to manufacture, easier to assemble, and has significantly fewer parts in the pump drive train. The Gen-2 pump also incorporates a number of other important design improvements, as described in more detail below. These additional features and advantages of the Gen-2 pump will become apparent to the skilled artisan upon examination of the following drawings and detailed description. It is intended that all such additional features and advantages be included within the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross sectional side view of a hand-free breast pump held in its operative position between the breast of a nursing woman and the cup of a bra worn by the woman while the pump is actively pumping breast milk into a collection bag supported by the breast pump and bra.

FIG. 2 is a an exploded perspective view showing the major components of the hand-free breast pump and accessories including the breast pump, the breast cup, the one-way valve, and the milk transport stem.

FIG. 3 is a perspective view of an assembled hands-free breast pump with the breast cup installed in its operative position.

FIG. 4 is a perspective view of an assembled hands-free breast pump of FIG. 3 with the breast cup removed.

FIG. 5 is a perspective view of a breast cup for a hands-free breast pump prior to engagement with the actuator arm of the breast pump.

FIG. 6 is a perspective view of the breast cup of FIG. 5 after engagement with the actuator arm of the breast pump.

FIG. 7 is a perspective view of the breast cup showing the opening for receiving the one-way valve.

FIG. 8 is a side view of the breast cup.

FIG. 9A is a cut-away side view of the breast cup showing the flange top in the outward position.

FIG. 9B is a cut-away side view of the breast cup showing the flange top in the inward position.

FIG. 10 is a first perspective view of the internal configuration of the breast pump.

FIG. 11 is a second perspective view of the internal configuration of the breast pump.

FIG. 12 is an assembled perspective view of the drive train of the breast pump.

FIG. 13 is a first exploded perspective view of the drive train of the breast pump.

FIG. 14 is a second exploded perspective view of the drive train of the breast pump.

Fig. 15 is an end view of the breast cup.

Fig. 16 is a bottom view of the breast cup.

FIG. 17 is a perspective view of the breast cup with the flange top in the outward position.

FIG. 18 is a perspective view of the breast cup with the flange top in the inward position.

FIG. 19 is a perspective view of the breast pump with an installed breast cup showing the actuator arm and flange top in the outward position.

FIG. 20 is a perspective view of the breast pump with an installed breast cup showing the actuator arm and flange top in the inward position.

FIG. 21 is a perspective view of the breast pump with the valve, stem and collection bag assembled in their operative positions.

FIG. 22 is another perspective view of the breast pump with the valve, stem and collection bag assembled in their operative positions.

FIG. 23 is a disassembled perspective view of the breast pump showing the major components and accessories.

FIG. 24 is a front view of the drive cam of the breast pump.

FIG. 25 is a perspective view of the drive cam of the breast pump.

FIG. 26 is an illustrative operating curve for a breast pump with a duty cycle of approximately one-half.

FIG. 27 is an illustrative operating curve for a breast pump with a duty cycle of approximately two-thirds.

FIG. 28 is an assembled perspective view of a modified drive train for the breast pump that includes a belt drive.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The present invention may be embodied in a hands-free breast pump with a balanced push-pull mechanical actuator and cam drive system that applies pumping force to a bellows structure of a breast interface cup during inward and outward pump strokes. As the Gen-1 design applied no motor force to the bellows structure on the outward pump stroke, configuring the Gen-2 pump to apply any amount of motor force to the bellows structure during both the inward (push) and outward (pull) strokes achieves some level of balance in the drive system and therefore improves the balance over the Gen-1 design. Significant attention has been paid to this design feature in the Gen-2 pump, which achieves a relatively high level of balance, for example where the force applied by the pump during the inward stroke is within eighty percent (80%) of the force applied during the outward stroke. In the particular embodiment shown in the

figures and described below, the Gen-2 pump is well optimized to achieve even higher levels of balance, for example where the force applied by the pump during the inward stroke is within ninety percent (90%) or more of the force applied during the outward stroke during the normal operating mode. This high level of balance is achieved through careful design of the resilient bellows structure of the breast cup and the cam drive system of the breast pump that translates rotary electric motor power into reciprocating linear action of the actuator arm to efficiently develop a desired pump operating profile. The bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is carefully designed and fine tuned to produce a desired operating profile for the pump.

In the Gen-2 breast pump, the primary components of the milk collection system include a silicone breast cup with a collapsible bellows structure at the end of the nipple tunnel (also called the vacuum chamber) which serves to displace air and produce a vacuum within the breast cup. The vacuum chamber is vented by a silicone one-way valve that opens during the inward (positive pressure) pump stroke to allow air and milk to be exhausted from the nipple tunnel, and then closes during the outward (negative pressure) pump stroke to seal the nipple tunnel and allow vacuum to be created within the nipple tunnel. The milk expressed from the breast is expelled from the breast cup through the one-way valve, along a wave-shaped splint or open straw (also called a stem), and into a freezer grade, polyethylene or similar milk collection bag. The breast pump is held between the user's breast and the cup of her bra (also called a brassier), the stem and neck of the collection bag pass between the user's chest and the bottom edge of the bra, and the retention area (pouch portion) of the collection bag is supported below the bra. The flexible, wave-shaped splint or open straw that inserts into the neck of the milk collection bag allows a simple snap connection to the breast pump housing, while also serving as a splint to keep an open path in the neck of the milk collection bag for the milk to travel under the taut band of the user's bra and into the retention area of the milk collection bag.

The Gen-2 pump mechanism includes a rotary electric motor that moves an actuator arm through a reciprocating linear motion. The actuator arm interfaces with a

barb connected to a disc, which is connected to the flange top at the end of the nipple tunnel of the breast cup. The nipple tunnel forms a vacuum chamber when the breast cup forms an air-tight seal with the user's breast. The linear reciprocating motion of the actuator arm moves a bellows structure at or near the end of the nipple tunnel reciprocally through an inward stroke and an outward stroke. The inward stroke partially collapses the volume of the vacuum chamber and the outward stroke restores the volume in a repeating cycle to alternately create and release suction within the nipple tunnel.

The Gen-2 pump includes a self-contained pump unit and power source enclosed within a dome shaped housing that receives and supports the removable breast cup. The housing compactly contains the pump motor, the drive train, and a power source, such as one or more batteries, and the associated electrical and mechanical features of the pump. In the embodiment described in detail below, for example, the pump achieves acceptable performance using a single AA battery as the power source. The pump housing with a received breast cup fits discreetly between the user's breast and a breast cup of a normal brassiere. It should also be appreciated that the motorized drive train could be replaced by a manually operated drive mechanism. In addition, the battery could be replaced by a connector to an external power source, such as an electrical plug connected to a DC power source (such as an automotive power supply) or an AC power converter configured to plug into a conventional AC power outlet.

Balanced operation of the motor and drive train, which results in motor force applied to the vacuum chamber during the inward and the outward strokes during the normal use mode, represents a key improvement of the Gen-2 design over the Gen-1 design. In fact, the Gen-2 pump achieves a high level of balance in the motor and drive train operation, resulting in a substantially similar amount of motor force applied to the vacuum chamber during the inward and the outward strokes. This highly balanced motor and drive train operation reduces the maximum force required from the motor and drive train, which allows the Gen-2 pump to use a lower-RPM motor and a lower gear ratio while achieving higher pump cycling rates, lower power consumption, and longer battery life.

Another Gen-2 improvement is found in the design of the bellows structure that creates the suction within the breast cup. The Gen-2 bellows structure has a substantially reduced surface area translating at the end of nipple tunnel, presenting reduced resistance to the inward stroke and a more efficient movement of the resilient silicon. The reduced resistance of the bellows structure, which allows for the reduction in pump force applied to the bellows structure, also improves the vacuum retention of the breast cup by significantly reducing vacuum lost due to collapse and flexure of the nipple tunnel portion of the breast cup area near the bellows structure. The breast interface portion of the breast cup has also been improved to include an extended funnel-shaped section, which extends further up the breast surface to contact a larger portion of the breast to more evenly distribute the pressure between the breast cup and the breast. This avoids pressure points on the breast that could otherwise result from tight or unevenly fitting brassieres that tend to press the breast pump firmly against the breast. The improved pressure distribution allows less compression of milk ducts, thereby improving milk flow from the breast and into the pump.

The Gen-2 breast cup includes additional improvements, including side walls of the nipple tunnel that are sufficiently thick to be rigid enough to retain its shape (i.e., avoid partial collapse of the nipple tunnel and resulting vacuum loss) under the highest vacuum applied by the pump mechanism without a supplemental rigid support ring. The breast cup retention features, including the retention rib and detent mechanisms retaining the breast cup within the pump housing, have been relocated to be proximate to the bellows structure at the extreme rear of breast cup (i.e., near the flange top or end of the nipple tunnel) to counter the pump force applied during the inward stroke that tends to urge the breast cup out of its seat in the housing. Locating the breast cup support features adjacent to the bellows structure also helps to provides shape retention assistance in that area of the breast cup.

The barb shaped breast cup retention rib on the rear flange perimeter also allows easy insertion by the user while offering good retention in the housing while in use. Side barbs on the outer walls of the nipple tunnel function as detent mechanisms that provide tactile and audible feedback letting user know when breast cup has been fully inserted into the pump housing. The rounded shape of the ends of these barbs

facilitates removal of the breast cup from the housing and prolongs the life of the breast cup. Recessed seating of the one-way valve provides a helpful visual cue to the user when the valve is fully seated and aids in valve retention in the breast cup when the cup is inserted and removed from housing.

On the interior of the nipple tunnel, the length of the vacuum chamber has been increased to reduce the chance of end of the user's nipple "bottoming out" or contacting the flange top at the end of the nipple tunnel attached to the movable bellows structure during the inward pump stroke. The thick and rigid side walls of the nipple tunnel prevent the tunnel from collapsing and pinching the user's nipple under the vacuum created during the outward stroke. The bottom surface of the nipple tunnel on the interior of the nipple tunnel is angled downward toward the outlet to prevent milk from pooling in the end of the nipple tunnel, which could otherwise lead to spills or waste. The bottom surface of the nipple tunnel also includes a distinct trough or milk flow channel leading to a larger, more funnel shaped outlet in the bottom of the nipple tunnel to aid in effective flow of milk out of the nipple tunnel area and into the outlet for efficient transport into the milk collection bag. In addition, a lofted "dam" of material is located between the outlet and the front of the nipple tunnel where the breast cup interfaces with the user's breast to minimize the chance that milk could flow back out of the nipple tunnel and onto the user's clothing.

The push-pull vacuum generation action of the Gen-2 design actively creates consistent vacuum levels by forcing a repeatable level of nipple tunnel volume expansion and contraction. The barb at the end of the nipple tunnel, which allows the actuator arm to both push and pull on the flange top, is shaped to facilitate both engagement with, and disengagement from, the detent opening in the actuator arm without special user intervention. The breast cup mold includes slots that allow sufficient silicon to flow into the disc retention area of the breast cup to create a strong connecting layer of material holding the disc in place to produce a durable breast cup. The one-way valve has a larger opening that allows milk to flow more freely and evacuate the nipple tunnel of the breast cup more efficiently.

In the Gen-2 pump, an electro-mechanical movement replaces the electronically controlled drive of the Gen-1 design, yet still allows for adjustment of both vacuum level

and cycle rate. The cam drive system of the Gen-2 pump reduces the complexity and cost of the pump. In addition, the cam drive system allows the reciprocating, push-pull linear action of the actuator arm with a force distribution curve that can be controlled by carefully designing the shape of the cam track to maximize efficiency and reduce gear and motor stress. The net benefit is a higher pump cycling rate with a lower speed, quieter motor. The smaller gear ratio allows the Gen-2 pump to utilize a smaller number of larger, more robust and quieter gears. The reduction in total gear ratio requirement provided by the Gen-2 cam drive system allows for larger gears with more tooth surface contact. In addition to higher strength and reliability, these larger toothed gears can be fabricated in softer materials which, combined with the additional surface contact and lower operating speed, serves to significantly quiet the drive train operation.

The Gen-2 pump also includes an interference-based vacuum adjustment mechanism. Specifically, two parallel, partially co-planar sliding panels (i.e., the cam follower and the actuator arm) are joined by a coil spring that is preloaded to effectively lock the two panels together during normal, maximum vacuum operation. However, when the linear motion of the actuator arm panel is impeded by the shaft of the vacuum adjust mechanism, the actuator arm panel no longer translates inward with the movement of the cam follower panel. Instead, the cam follower panel continues to move according to its relationship with the cam path of the cam gear. The difference in translation of the two panels is absorbed by the compression of the spring linkage of the two panels. Under expected normal use, the user will operate the pump at full vacuum and no interference by the vacuum adjustment mechanism, and therefore no additional, forced compression of the linking spring. Thus, the normal use is the most efficient operating mode. The spring linkage between the cam follower and the actuator arm also produces the benefit of allowing the motor and gear train to continue to cycle without becoming jammed in the event that the motion of the actuator arm is impeded, for example when the actuator arm is blocked by an external object or manually held in place.

Turning now to the figures, in which like element numerals refer to like elements throughout the several figures, a particular embodiment of the Gen-2 breast pump is shown in the figures and described in the accompanying text. The Gen-2 breast pump

leverages the successful technology from the original Gen-1 pump design and significantly improves upon performance, ease of use, manufacturability and reliability. The intended use of the Gen-2 pump as supported between the user's breast and the cup of a normal brassier and the overall approach to milk collection remains largely unchanged from the Gen-1 design, whereas the Gen-2 pump mechanism and breast cup have been substantially redesigned to achieve a number of major improvements.

FIG. 1 is a cross sectional side view of a hand-free Gen-2 breast pump **10** held in its operative position between the breast **12** of a nursing woman and the cup **14** of a brassier worn by the woman while the pump is actively pumping breast milk from the woman's breast. The breast pump **10** includes a dome-shaped outer housing **16** that faces the inner surface of the brassier cup **14** and an inner housing **19** that receives the breast cup **18**, which interfaces with the woman's breast **12**. The breast cup **18** includes a nipple tunnel that forms a vacuum chamber **22** between the breast cup and the woman's breast, which is vented through an opening or outlet **24** through the bottom of the breast cup. The outer housing **16** can include a transparent window (e.g., the removable cover plate **65** shown in FIG. 23) to allow the user to see the position and condition of the nipple after the breast pump has been placed in its operative position against the breast. This allows the user to adjust the position of the pump against the breast to center the nipple in the nipple tunnel, and also allows the user to observe the nipple during pumping, which can be helpful, for example, to maintain awareness of milk letdown, milk flow and nipple inversion.

During its inward stroke, the pump mechanism (shown best in Figs. 12-14) pushes on an integrated (molded-in) disk located at the end of the vacuum chamber (also called the flange top) to cause a bellows structure (shown best in Figs. 9A-B, 17 and 18) located at or near the end of the vacuum chamber to partially collapse (move inward) and thereby reduce the volume of the vacuum chamber to create positive pressure within the vacuum chamber. During its outward stroke, the pump mechanism pulls on the barb attached to the disk at the top of the vacuum chamber causing the bellows structure to recover its original shape (move outward) to restore the original volume of the vacuum chamber, thereby increasing the volume of the vacuum chamber to create negative pressure within the vacuum chamber. A one-way valve **20** vents the

vacuum chamber during the inward stroke and seals the vacuum chamber during the outward stroke to create a milking action. The expressed milk is forced through the outlet **24**, through the one-way valve **20**, along the exterior surface of the wave-shaped stem **26**, and into a collection bag **28** that is supported by the breast pump and the elastic, wire or other structure at the bottom edge of the brassier.

FIG. 2 is an exploded perspective view showing the major components of the hand-free breast pump **10** including the pump enclosure **15** that contains the pump mechanism and power source, the breast cup **18**, the one-way valve **20** and the stem **26**. The pump enclosure **15** includes a dome-shaped outer housing **16** and an inner housing **19** configured to receive the breast cup **18**. The breast pump **10** also includes a sliding power control switch **30** and a vacuum control knob **32**. In this particular embodiment, the power control switch **30**, which affects the cycling rate of the pump, includes three settings, fast, slow and off. The vacuum control knob **32** may be turned through a rotation range that is slightly less than a full rotation to adjust the vacuum level by adjusting the pump stroke length.

FIG. 3 is a perspective view of an assembled hands-free breast pump **10** with the breast cup **18** installed in its operative position. FIG. 4 is a perspective view of the breast pump with the breast cup removed. These views also show the power switch control knob **30** and the vacuum control knob **32**. Although this embodiment includes a three-position power switch, the cycle rate adjustment mechanism may include a larger number of available rate settings, such as a slider, dial or multi-position selection switch that allows the user to control the cycle rate of the pump. Cycle rate adjustment is typically accomplished by adjusting the voltage applied to the pump motor, for example through a resistive voltage divider or voltage-limiting diodes. The vacuum adjustment knob **32** allows the user to adjust the strength of the vacuum or suction generated by the pump. Vacuum adjustment is typically accomplished by adjusting the stroke length of the pump actuator arm, in this embodiment through an eccentric cam surface on a shaft connected to the vacuum adjustment knob **32**. The eccentric cam of the vacuum adjustment mechanism selectively blocks and thereby adjusts the stroke length of the pump actuator arm.

FIG. 5 is a perspective view of the breast cup **18** prior to engagement with the actuator arm **34** of the breast pump. The breast cup **18** includes a flange top **36** at the end of a nipple tunnel **46** that includes an over-molded disk having an attached barb **38** that engages with a keyhole or teardrop shaped detent opening **40** in the actuator arm **34**. FIG. 6 shows the breast cup **18** with the barb **38** engaged in the detent opening **40**. The barb **38** and detent opening **40** are configured such that the barb securely engages with the detent opening when the breast cup is received within the breast pump, and the barb releases from the detent opening when the beast cup is removed from the breast pump. The breast cup **18** also includes a bellows structure **42**, which is shown in FIG. 5 in its outward position. The bellows structure **42** is also shown in the outward position in Figs. 6, 8, 9A, 16, 17 and 19. During the inward stroke of the pump mechanism, the actuator arm **34** pushes the flange top **36** to its inward position, which causes the bellows structure **42** to reduce the volume of the vacuum chamber formed by the nipple tunnel and thereby create positive pressure within the vacuum chamber. The bellows structure **42** is shown in the inward position in Figs. 9B, 18 and 20. During the outward stroke, the actuator arm **34** pulls the flange top **36** back into its outward position, which causes the bellows structure to increase the volume of the vacuum chamber and thereby create negative pressure or suction within the vacuum chamber. The resiliency of the bellows structure **42** resists the inward stroke and assists in the outward stroke, aiding in the balanced operation of the pump. In normal use mode, with the breast cup producing vacuum, the outward force of the natural resiliency of the bellows structure largely offsets the inward force of vacuum created within the breast cup, resulting in balance in the pump operation.

The vacuum chamber of the breast cup **18** is formed by the nipple tunnel **46** having side walls that are sufficiently thick to prevent the side walls from collapsing from the high vacuum generated during the reciprocal action of the bellows structure **42**. That is, the nipple tunnel **46** is sufficiently rigid to support the reciprocal action of the bellows structure **42** without further support from a support ring or other structure within the pump housing. This is a significant improvement over the Gen-1 breast cup design, which requires a separate support ring for additional support.

The breast cup **18** also includes a funnel shaped breast interface section **48**, which spreads the breast contact surface and the associated compressive force (pressure) over a significantly larger portion of the breast and breast cup. The breast cup also includes an outer flange area **50**, that together with the interface section, form an air-tight seal with the woman's breast. Spreading out the breast contact surface area reduces the possibility of undesired restriction of milk flow due to compression of milk ducts in the breast. The breast cup **18** is held within the pump housing with a catch rib **53** located toward the end of the exterior wall of the nipple tunnel proximate to the bellows structure **42**. A pair of detent tabs located on the exterior wall of the nipple tunnel "click into place" to provide the user with tangible, audible feedback indicating that the breast cup is fully inserted into the housing. One detent tab **52a** is shown in Fig. 5 and an opposing detent tab is located on the opposite side of the nipple tunnel **46**. Both detent tabs **52a** and **52b** are shown in FIGS. 15 and 16.

FIG. 7 is a perspective view of the breast cup **18** showing the nipple tunnel **46**, breast interface section **48**, outer flange area **50**, and the outlet **24** that receives the one-way valve. FIG. 8 is a side view of the breast cup **18**. FIG. 9A is a cut-away side view of the breast cup **18** showing the flange top **36** in the outward position. FIG. 9B is a similar view showing the breast cup **18** with the flange top **36** in the inward position. During the inward pump stroke, the actuator arm of the breast pump pushes the flange top **36** from the outward position shown in FIG. 9A to the inward position shown in FIG. 9B, which creates positive pressure inside the vacuum chamber formed by the breast cup and the user's breast. During the inward stroke, the one-way valve located in the outlet **24** vents the positive pressure, which expels milk from the breast cup through the outlet. During the outward pump stroke, the actuator arm of the breast pump pulls the flange top **36** from the inward position shown in FIG. 9B to the outward position shown in FIG. 9A, which creates negative pressure (suction) inside the vacuum chamber. During the outward stroke, the one-way valve located in the outlet **24** seals the outlet, which causes the negative pressure (suction) to be sustained within the vacuum chamber to create a milking action promoting the expression of milk from the user's breast. As noted previously, the bellows structure **42** resiliently resists the inward stroke and assists the outward stroke such that, when the breast cup is operating in its normal

mode cyclically creating and sustaining suction during the outward stroke and expelling milk through the outlet vented by the one-way valve during the inward stroke, the amount of force applied by the pump mechanism to the flange top **36** is substantially the same during the inward and outward pump strokes.

FIGS. 10 and 11 are perspective views of the internal configuration of the breast pump **10**. These views show the outer housing **16**, the power switch control knob **30**, and the vacuum adjustment knob **32** located on the exterior of the pump. On the interior of the housing, the breast pump includes a pump mechanism **50** powered by a power source **52**, in this embodiment a single AA battery. The pump mechanism **50** includes a motor **54** and a drive train **56**, which are shown more clearly in the assembled view of FIG. 12 and the exploded views of FIGS. 13 and 14. The drive train **56**, which translates the rotary motion of the motor **54** to reciprocating linear motion of the actuator arm **34**, is supported by a motor plate **60** that is attached to the pump housing by a number of shock absorbing bushings for noise reduction. The motor plate **60** supports the motor and includes gear supports **62**, **64** and **66** along with slide channels or slots **68** and **70** for receiving the cam follower **72** and actuator arm **34**, respectively. The motor **54** drives a pinion gear **80**, which engages a drive gear **82** supported by the first gear support **62**, which engages a translation gear **84** supported by the second gear support **64**, which engages a cam gear **86** supported by the third gear support **66**.

The face of the cam gear **86** contains a cam track **90** (shown in FIGS. 24 and 25) that engages a cam follower pin **92** on the cam follower **72** to translate rotary motion of the cam gear into linear motion of the cam follower. The cam follower **72** engages the actuator arm **34** by way of a coil spring **94**, which is sufficiently rigid to support the force required to drive the actuator arm when the actuator arm is unconstrained. The cam follower **72** includes a boss **73** that interfaces with the spring **94**, which is captured within a spring channel **95** (shown in FIG. 14) of the actuator arm **34**. The coil spring **94** compresses to allow the cam follower **72** to move through its range of motion when movement of the actuator arm **34** is constrained. In particular, movement of the actuator arm **34** may be selectively constrained by the cam shaft **96** (shown in FIG. 13) driven by the vacuum adjustment knob **32**, which controls the stroke of the actuator

arm. The cam shaft **96** has an eccentric cam surface (or may contain multiple flat contact surfaces of varying radius relative to the center of the cam shaft) that blocks a variable amount of the available travel of the actuator arm **34** as the vacuum adjustment knob **32** is rotated.

In addition to providing vacuum adjustment, placement of the coil spring **94** in the drive train linkage between the actuator arm **34** and the cam follower **72** allows the cam follower to continue to reciprocate through its full path of motion even when the actuator arm **34** is manually blocked by another obstruction, for example when the actuator arm is jammed or held down by a person's hand. The coil spring **94** therefore provides stress relief to the drive train and motor, which cannot be manually jammed by blocking the actuator arm. This is a beneficial design feature that avoids potential damage to the pump from jamming the actuator arm, such as stalling and a potential over-current condition that could cause overheating of the motor, stripping of the gears, breaking of the gear supports, bending or breaking of the motor plate, and so forth. The coil spring **94** may also be selected to limit the maximum vacuum that the pump can generate, for example to a maximum limit of 250 mm Hg, which provides a beneficial safeguard against over stressing the mother's breast during pump operation.

Fig. 15 is an end view of the breast cup **18** and Fig. 16 is a bottom view of the breast cup showing the bellows structure **42**, the nipple tunnel **46**, the breast interface section **48**, the outer flange area **50**, the detent tabs **52a-b**, the outlet **24** that receives the one-way valve, the flange top **36**, and the barb **38**. FIG. 17 is a perspective view of the breast cup **18** with the flange top **36** and barb **38** in the outward position. This view also shows the one-way valve **20** in its operative position in the outlet **24**. FIG. 18 is a perspective view of the breast cup **18** with the flange top **36** in the inward position. FIG. 19 is a perspective view of the breast pump **10** with the breast cup **18** installed showing the actuator arm **34** and flange top **36** in the outward position. FIG. 20 is a perspective view of the breast pump **10** with the breast cup **18** installed showing the actuator arm **34** and flange top **36** in the inward position.

FIG. 21 is a perspective view of the breast pump **10** with the valve **20**, stem **26** and collection bag **28** assembled in their operative positions. The collection bag includes an elongated neck **27** that receives the stem **26**. The stem as received within

the neck of the collection bag extends into an opening in the pump enclosure, where the neck of the collection bag is captured in place between the top portion of the stem and the pump enclosure. The enclosure holds the top portion of the stem against the outlet of the breast cup to provide a leak-free milk transfer path from the outlet **24** of the breast cup to the container portion of the collection bag. As shown in FIG. 1, the stem **26** as received within the elongated neck of the collection bag passes between the bottom of the brassier and the user's chest, such that the container portion or pouch of the collection bag is suspended below and supported by the brassier. The wave shape across the transverse dimension of the stem **26** allows the milk to be transported along the exterior of the stem past the bottom of the brassier even though the stem and the neck of the collection bag are captured between the bottom of the brassier and the user's chest sufficiently firmly to support the container portion of the milk collection bag below the brassier without the aid of hands or other support devices. The collection bag **28** also includes seams **29** that extend from the neck **27** into the container portion of the bag. These seams prevent the collection bag from spilling milk when the collection bag holding milk is laid on its side with the stem **26** removed from the bag. This milk collection system has proven to be very successful in the Gen-1 design, and has therefore been retained in the Gen-2 design with some helpful improvements.

FIG. 22 is another perspective view of the breast pump **10** with the valve **20**, stem **26** and collection bag **28** assembled in their operative positions. In FIGS. 21 and 22, the removable cover plate **65** (shown in FIG. 23) that attaches to the outer housing **16** is transparent or removed to reveal the top of the breast cup **18** and its interface with the actuator arm **34**. The cover plate **65** may be transparent to allow the user to view the inside of the pump in the area of engagement between the actuator arm and the breast cup when the cover plate is installed. Because the silicon breast cup is also substantially transparent, the user can observe the condition of the nipple and milk flow through the cover plate or window **65**, which may also be removable to provide physical access to the area of engagement between the actuator arm and the breast cup. This helps the user observe and adjust the interface between the barb **38** and the detent opening **40** in the actuator arm **34**, if necessary, to ensure that the actuator arm is properly engaged with the breast cup. The inner housing **19** of the breast pump may

include an additional transparent window on the top of the breast pump enclosure adjacent to the power switch and vacuum control knob allowing the user to view the interface between her breast and the nipple channel of the breast cup from above to aid in proper placement of the breast pump on the breast. If desired, the entire breast pump enclosure may be manufactured from a transparent material to maximize visibility of the internal pump components and to aid in proper placement of the breast pump on the breast.

FIG. 23 is a perspective view of a particular embodiment of the breast pump **10** disassembled showing with the major components and accessories. The accessories of the breast pump include the breast cup **18**, the one-way valve **20**, the stem **26** and the collection bag **28**. The components of the drive train include the motor plate **60**, the pinion gear **80**, which attaches to the drive shaft of the motor **54**, the drive gear **82**, the translation gear **84**, and the cam gear **86**. The gear posts of the motor plate **60** may be cast in the material of the motor plate or they may be inserts, such as stainless steel pins. The cam gear **86** drives the cam follower **72** by way of the cam follower pin **92** (shown in FIGS. 13 and 14), which rides in the cam slot **90** (shown on FIGS. 24 and 25). In this embodiment, the cam follower pin **92** is covered by a sleeve **112**, which may be made from NYLON® impregnated with TEFLON® or another suitable material to provide a self-lubricating surface, to reduce friction between the cam slot and the cam follower pin and extend the life of the cam gear. The cam follower **72** is coupled to the actuator arm **34** by way of the coil spring **94**. The hood **33** covers the actuator arm **34** for sound proofing and sealing out liquid or other contaminants. The motor plate **60** is mounted to the pump enclosure by bushings **25** for noise reduction.

The adjustment components of the breast cup include the vacuum control knob **32**, which drives the eccentric cam shaft **96**. The cam shaft selectively blocks a portion of the stroke of the actuator arm **34** to provide vacuum adjustment, while the coil spring **94** in the linkage between the actuator arm and the cam follower **72** allows the cam follower to move through its full range of motion regardless of the whether a portion of the stroke of the actuator arm is blocked by the cam shaft. A water-tight gasket **110** seals the interface between the vacuum control knob **32** and the housing of the breast pump. The power control knob **30** operates a three-position power control switch **116**,

which is secured to the housing by screws **112**. A water-tight gasket **114** seals the interface between the power control knob **30** and the housing of the breast pump.

The electrical components of the breast cup include the motor **54**, the battery **52**, and the wiring **118** for electrically connecting the motor the to the battery by way of the switch **116**. The battery is electrically connected by way of a spring-type battery terminal **97** that fits into a socket in the pump housing and a leaf-type battery terminal **21** that is supported by a c-channel **120** that fits into a socket in the housing.

The components of the breast pump housing include the inner housing **19** that receives the breast cup **18**, the dome-shaped outer housing **16** that faces the inner surface of the breast cup of the user's brassier, and the removable battery cover **23**. The outer housing **16** includes a removable (and transparent, if desired) cover plate or window **65**. The inner housing **19** may also include a transparent window at the top of the housing below the vacuum control knob **32** and power control knob **30**.

FIG. 24 is a front view and FIG. 25 is a perspective view of the cam gear **86** of the breast pump showing the cam track **90**, which has a rounded carotid shape to produce the desired pump operating curve. As noted previously, the shape of the cam track **90** can be precisely selected to produce an operating curve with desired characteristics including a desired suck-release ratio or duty cycle. FIG. 26 is an illustrative operating curve **100** for a breast pump with a duty cycle of approximately one-half, and FIG. 27 is an illustrative operating curve **102** for a breast pump with a duty cycle of approximately two-thirds. The operating curve **100** has a suck-release ratio of approximately 1:1 (i.e. suck time = x, release time = x), whereas the operating curve **102** has a suck-release ratio of approximately 2:1 (i.e. suck time = 2y, release time = y), as indicated in the figures. Referring to FIGS. 24 and 25, the shape of the operating curve **100**, **102** is controlled by the shape of the cam track **90** and can be adjusted by changing the shape of the cam track within the operating capability of the motor and gear train. The dynamic properties of the gear train and the bellows structure of the breast cup also affect the performance of the breast pump.

Referring to FIGS. 26 and 27 with further reference to the breast cup shown in FIGS. 8, 9A-B and 15-18 and the shape of the cam track shown in FIGS. 24 and 25, the performance of the breast pump is generally optimized by designing the breast cup with

a high degree of balance in the drive train so that the bellows structure **42** of the breast cup **18** requires about the same amount of force during the inward stroke as during the outward stroke during normal operating conditions. Up to 250 mm Hg of negative pressure is generated on the outward stroke (when the one-way valve is closed) while only a small level of positive pressure is required on the inward stroke (when the one-way valve is open) to evacuate the expressed milk through the one-way valve and into the collection bag. On the other hand, the silicon of the bellows structure resists the inward stroke and assists in the outward stroke as the bellows resiliently returns to its original shape. That is, the bellows structure acts like a spring that is charged during the inward stroke and discharged during the outward stroke. Given this configuration, the performance of the breast pump is generally optimized when the bellows structure requires about the same maximum amount of force during the inward stroke as during the outward stroke under normal operating conditions, which results in minimum peak power consumption and a relatively steady current profile for the motor.

Although precise power optimization is not required for the pump to operate acceptably, taking the pumping dynamics into account allows the engineer to select among the available design parameters to obtain an efficient pump design that meets the basic design criteria of the breast pump. The design objectives include a maximum suction close to but not more than 250 mm Hg, and maximum suction in the range of 210 to 240 mm Hg is expected to produce acceptable results. An operating profile with a duty cycle of about two-thirds is considered to be desirable because this profile is generally consistent with the measured suck-release profile of a live nursing baby, and operating profiles with duty cycles in the one-half to two-thirds range are expected to produce acceptable results. The pump should operate at about 60 cycles per second to be roughly consistent with a nursing baby, and cycle rates in the range of 45 to 65 cycles are expected to produce acceptable results. Experience with the Gen-2 design confirm that the embodiments described in this application meet these design criteria and perform acceptably on live nursing adult women.

More specifically, these design objectives can be achieved using the breast cup profile shown in FIGS. 8, 9A-B and 15-18 manufactured from 50 durometer silicon, the shape of the cam track shown in FIGS. 25 and 26 producing a linear stroke of the

actuator arm in the range of approximately 7.5-8.5 mm, and a motor driven by a single 1.5 Volt AA battery. For this particular embodiment of the breast pump, the motor may be rated for 2.4 Volts DC and 7,700 rpm (e.g., Mabuchi FF-180SH motor). The operating speed of the motor is a function of the load applied to the motor and can be further controlled by adjusting the applied voltage through the range of about 1.0 to 1.5 Volts, for example through the use of a resistive voltage divider or voltage limiting diodes. Vacuum adjustment can be controlled with a cam shaft that selectively blocks and thereby controls the stroke of the actuator arm in the range of about 6 to 8 mm. The coil spring in the drive train between the cam follower and the actuator arm should be selected to limit the suction that can be developed by the breast cup to be no greater than about 250 mm Hg.

The operating noise of the pump can be mitigated by using a relatively soft material, such as a 50 durometer urethane, for the drive gear. As shown in FIG. 28, the mesh between the pinion gear and the drive gear may also be replaced by a belt drive if further noise mitigation is desired. The other gears may also be 50 durometer urethane, or they may be manufactured from NYLON® or another suitable material. Manufacturing the gears from a self lubricating material, such as NYLON® impregnated with TEFLON® is also desirable. The gear teeth should be shaped to minimize chatter in the drive train, as shown in the applicable figures, and the gears can be machine cut, injection molded, or manufactured with another suitable process. The housing can be made of any material suitable for injection molding the desired shape exhibiting acceptable strength and durability, such as LEXAN®.

The motor plate may be manufactured from a similar material, such as LEXAN®, and the gear support posts may be cast as part of the motor plate or they may be metal inserts, such as stainless steel pins. The bushings at the attachment points between the motor plate and the housing can be made of rubber or a synthetic material such as NEOPRENE® or any other material suitable for this purpose. It is important that the motor plate be sufficiently rigid to prevent bending in a manner that constricts the slide channels or slots where the cam follower and actuator arm slide, as this could result in binding. To prevent binding, the slide channels may be reinforced with metal inserts, such as stainless steel, to provide increased rigidity. The actuator arm and cam

follower may be ULTEM®, NYLON® or another suitable material, and a self lubricating material, such as NYLON impregnated with TEFLON®, is also desirable for these components. The pin of the cam follower may be cast as part of the cam follower. The cam follower pin may be covered by a sleeve made from a suitable material, such as stainless steel, or the may be a metal insert, such as a stainless steel pin. The cam follower pin may carry a sleeve made of NYLON impregnated with TEFLON® or similar material to reduce friction between the cam follower pin and the cam slot of the cam gear during normal operation of the pump.

FIG. 28 shows an assembled perspective view of a modified drive train **104** for the breast pump that includes a belt drive **106** between the motor-driven gear and the main drive gear. The belt drive further mitigated noise produced by the drive train.

In view of the foregoing, it will be appreciated that present invention provides significant improvements in breast pumps. It should be understood that the foregoing relates only to the exemplary embodiments of the present invention, and that numerous changes may be made therein without departing from the spirit and scope of the invention as defined by the following claims.

CLAIMS

1. A breast pump comprising:

a housing supporting a pump mechanism operative for reciprocal movement through an inward pump stroke and an outward pump stroke;

a breast cup configured to be supported by the housing in engagement with the pump mechanism comprising an interface section configured to form an air-tight seal with an adult human breast received against the interface section;

the breast cup and the breast creating a vacuum chamber configured to reduce in volume when compressed during the inward pump stroke and to increase in volume when expanded during the outward pump stroke;

the breast cup further comprising an outlet for expelling breast milk expressed from the breast;

a one-way valve operative to vent the vacuum chamber to allow the milk to pass through the outlet when the vacuum chamber is compressed during the inward pump stroke to create positive pressure within the vacuum chamber, the one-way valve further operative for sealing the vacuum chamber when the vacuum chamber is expanded during the outward pump stroke to create negative pressure within the vacuum chamber, thereby creating a milking action for causing milk to be expressed from the breast; and

wherein the pump mechanism comprises a balanced drive system configured to apply force to compress the vacuum chamber during the inward pump stroke and to apply force to expand the vacuum chamber during the outward pump stroke.

2. The breast pump of claim 1, wherein the housing and breast cup are sized and configured to be supported between the adult human breast and a breast cup of a brassier while the breast pump is actively pumping milk from the breast and expelling the milk through the outlet.

3. A breast pump of claim 2, wherein the housing and breast cup are sized and configured to be supported by the brassier without the aid of hands or other support devices.

4. The breast pump of claim 3, wherein the housing is configured to receive an electric battery for delivering electric power to the pump mechanism.

5. The breast pump of claim 4, wherein the housing is configured to receive an electric power cord for delivering electric power to the pump mechanism.

6. The breast pump of claim 1, wherein the vacuum chamber comprises a resilient bellows structure that resists the force applied by the pump mechanism during the inward stroke and assists the force applied by the pump mechanism during the outward.

7. The breast pump of claim 6, wherein the force applied by the pump mechanism in normal operation during the inward stroke is within eighty percent of the force applied by the pump mechanism during the outward stroke.

8. The breast pump of claim 1, wherein the one way valve is removably received within the outlet of the breast cup.

9. The breast pump of claim 1, wherein the breast cup is removably received within the housing.

10. The breast pump of claim 1, further comprising a motor and cam gear for translating rotary motion of the motor to linear reciprocating motion of an actuator arm that removably engages with the breast cup, pushes a bellows structure to compress the vacuum chamber during the inward pump stroke and pulls the bellows structure to expand the vacuum chamber during the outward pump stroke.

11. The breast pump of claim 10, further comprising a vacuum adjustment mechanism operative to selectively block a portion of the motion of the actuator arm to adjust the length of the inward and outward pump strokes to adjust the amount of negative pressure generated by the vacuum chamber.

12. The breast pump of claim 11, further comprising a spring linkage in a drive train between the cam gear and the actuator arm permitting the vacuum adjustment mechanism to selectively block a portion of the motion of the actuator arm without blocking rotation of the cam gear.

13. The breast pump of claim 12, wherein the vacuum adjustment mechanism comprises a cam shaft having an eccentric cam surface that selectively blocks a varying amount of the motion of the actuator arm in response to rotation of the cam shaft.

14. The breast pump of claim 1, wherein the housing comprises a transparent window facilitating viewing a nipple of a user's breast when the breast is received against the interface section of the breast cup.

15. The breast pump of claim 1, further comprising a milk collection container for collection milk expelled from the breast cup.

16. The breast pump of claim 15, wherein the milk collection container comprises a milk collection bag comprising an elongated neck and a container portion in fluid communication with the neck.

17. The breast pump of claim 16, further comprising a milk conduit having a coupling end in fluid communication with the outlet of the breast cup and a stem section received within the elongated neck of the collection bag, wherein the brassier supports the housing, the breast interface flange, the milk conduit, and the milk collection bag without the aid of hands or other support devices.

18. The breast pump of claim 17, wherein the milk conduit received within the elongated neck of the collection bag is configured to pass between a lower edge of the brassier and the body of a user wearing the brassier.

19. The breast pump of claim 18, wherein the stem section of the milk conduit defines an elongated dimension and a narrow dimension, and the stem section defines an open wave shape across the narrow dimension.

20. The breast pump of claim 16, wherein the container portion of the milk collection bag comprises first and second side panels and the milk collection bag comprises one or more seams sealing the first and second side panels together within part of the container portion of the milk collection bag to prevent milk contained within the container portion from leaking through the elongated neck when the milk collection bag is laid down horizontally on the first or second side panel without the milk conduit received within the elongated neck.

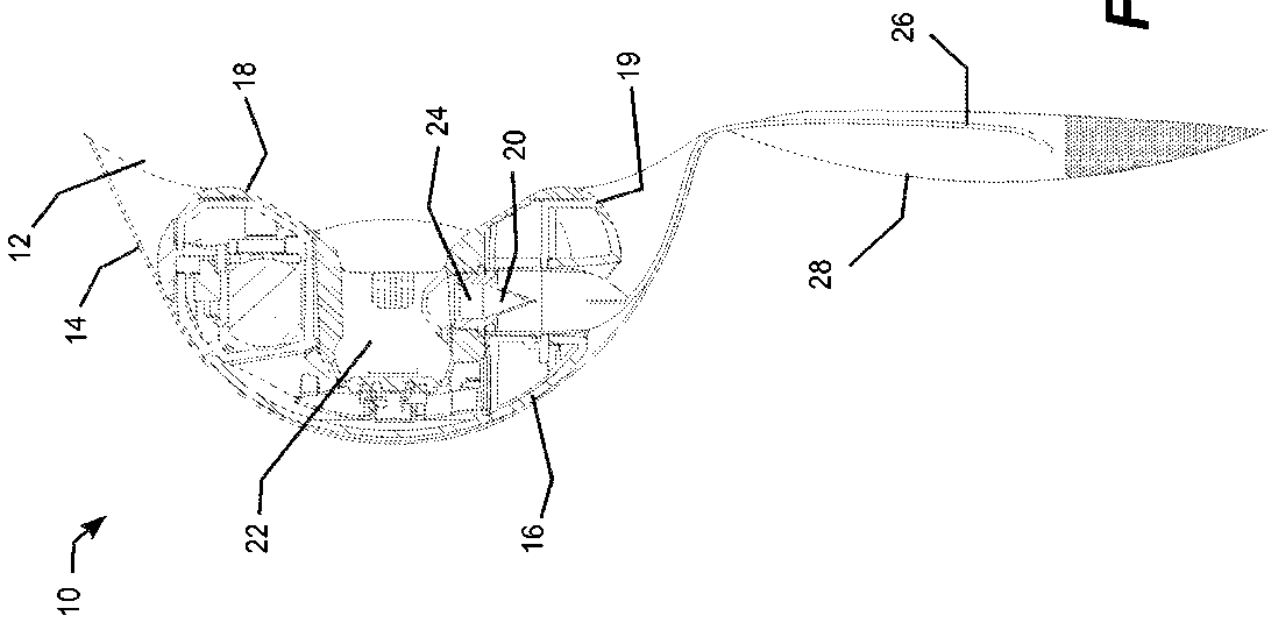


FIG. 1

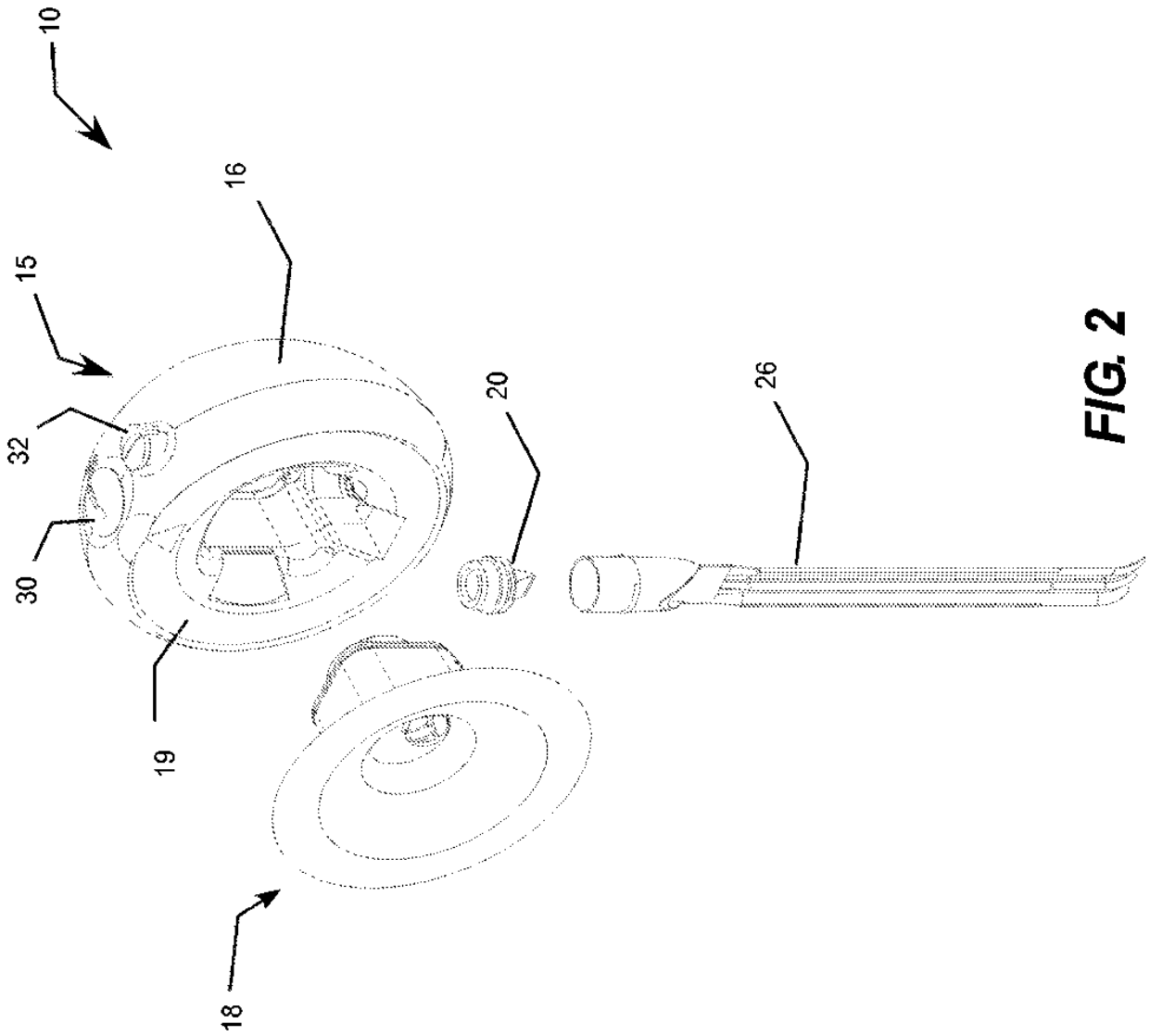


FIG. 2

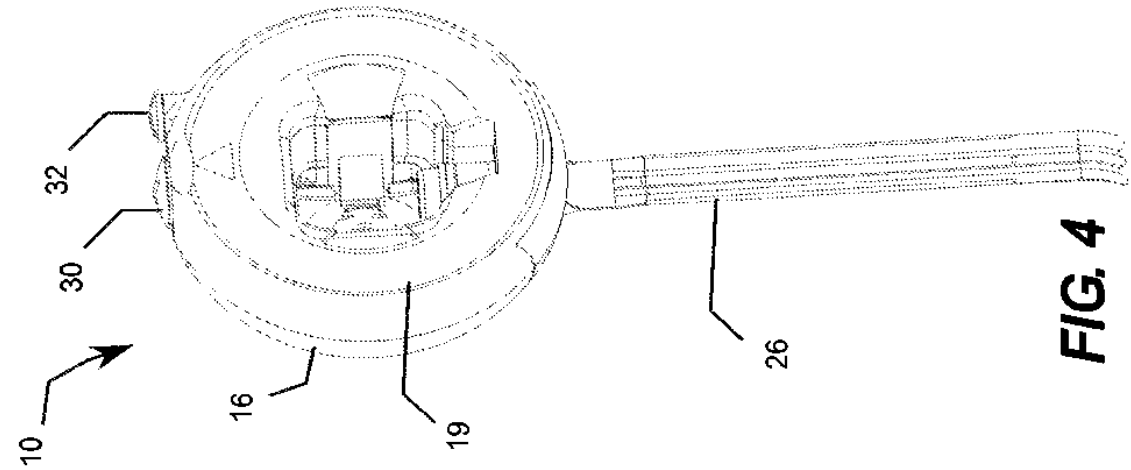


FIG. 4

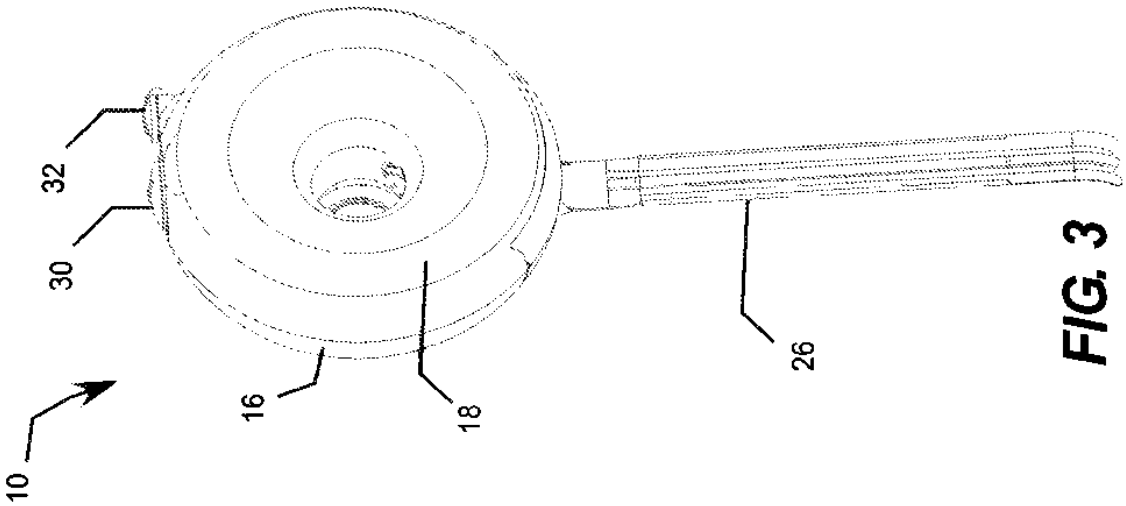


FIG. 3

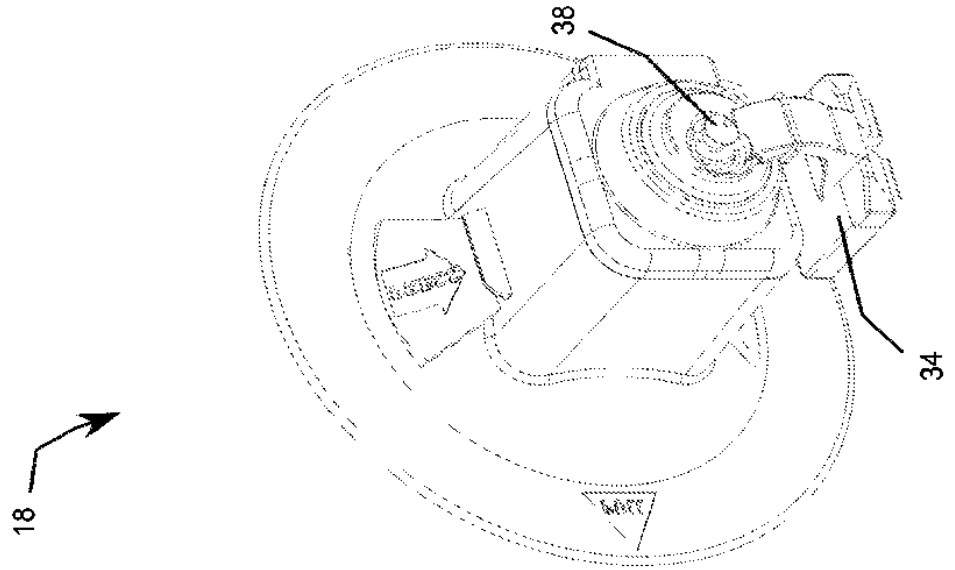


FIG. 6

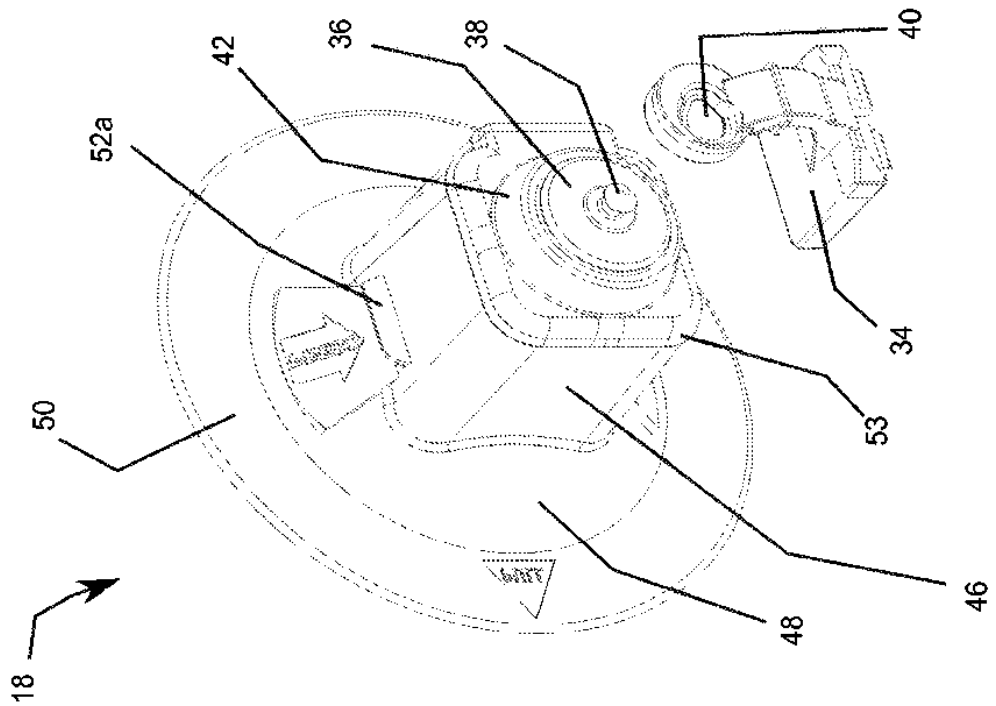


FIG. 5

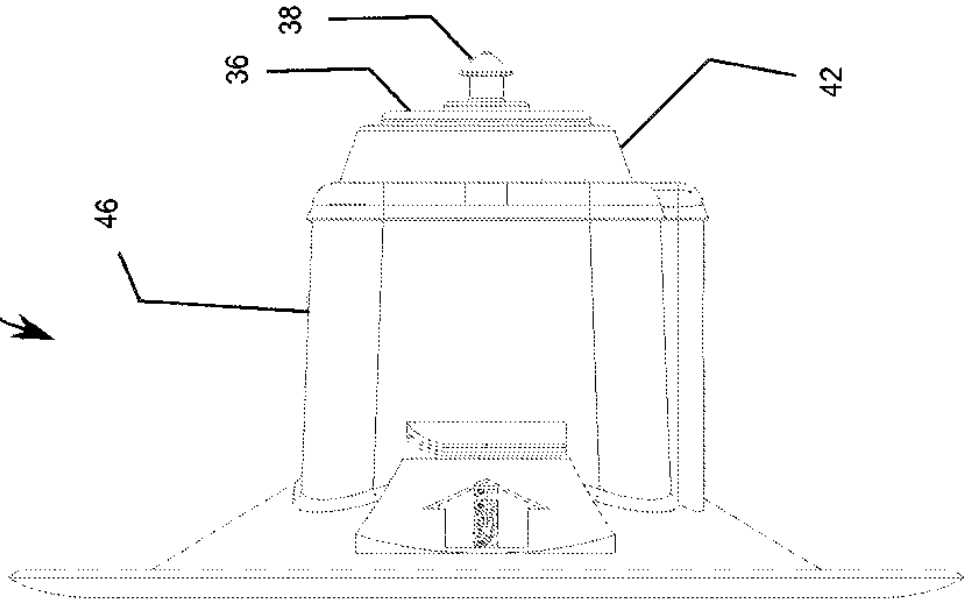


FIG. 8

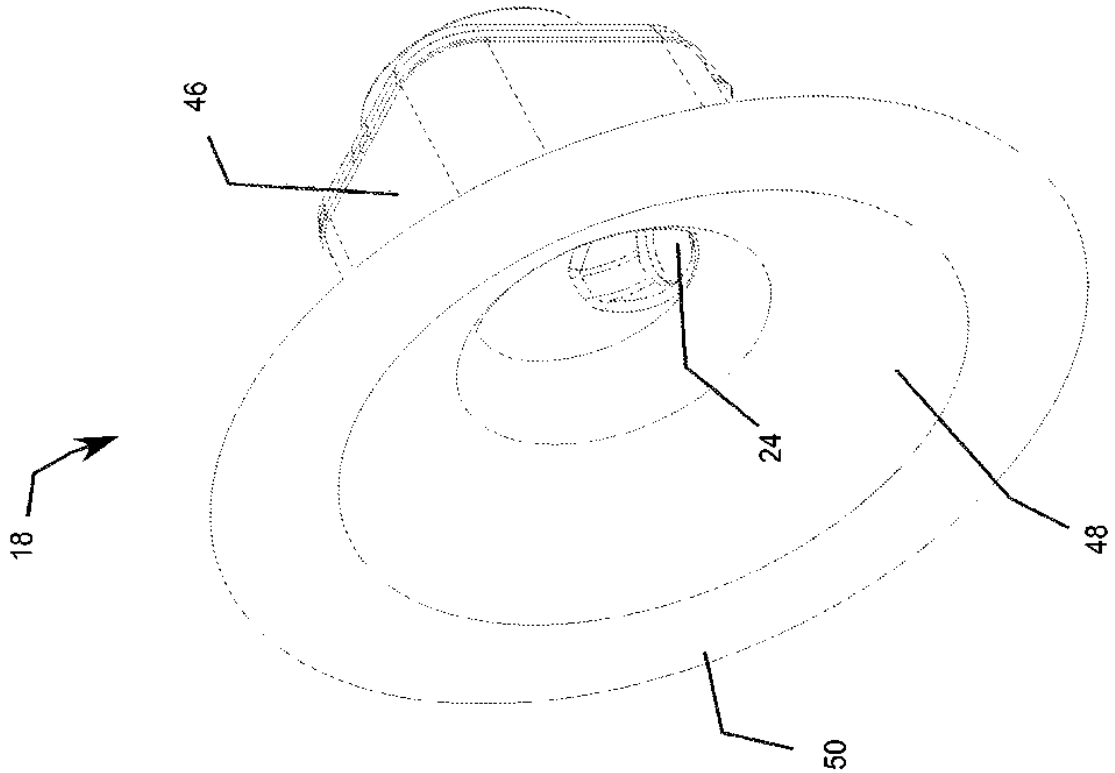


FIG. 7

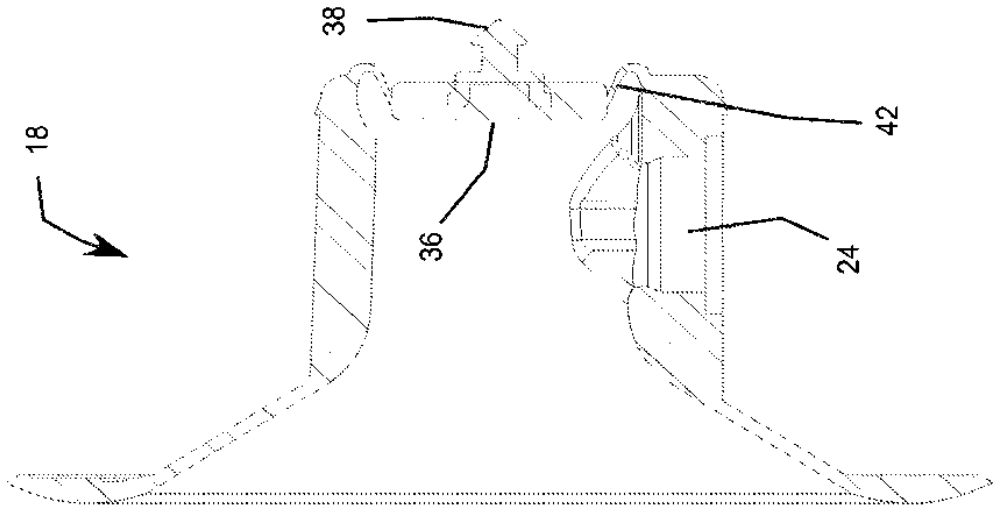


FIG. 9B

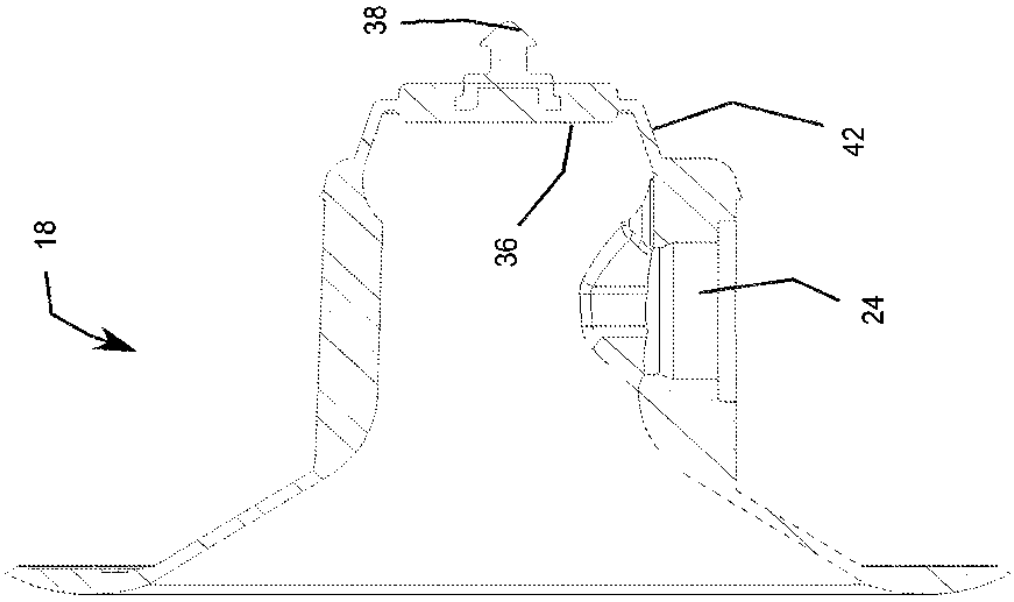


FIG. 9A

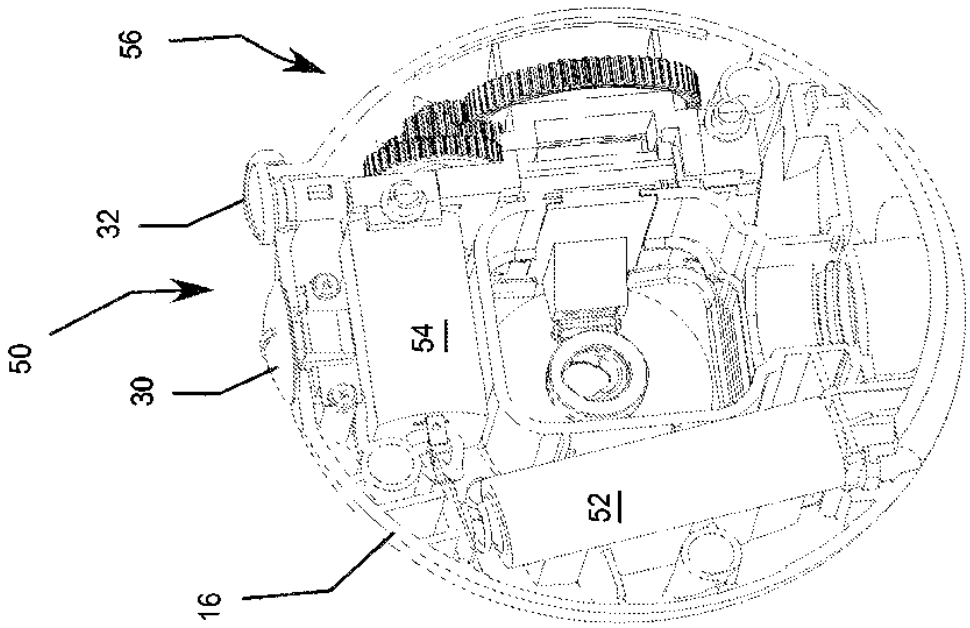


FIG. 11

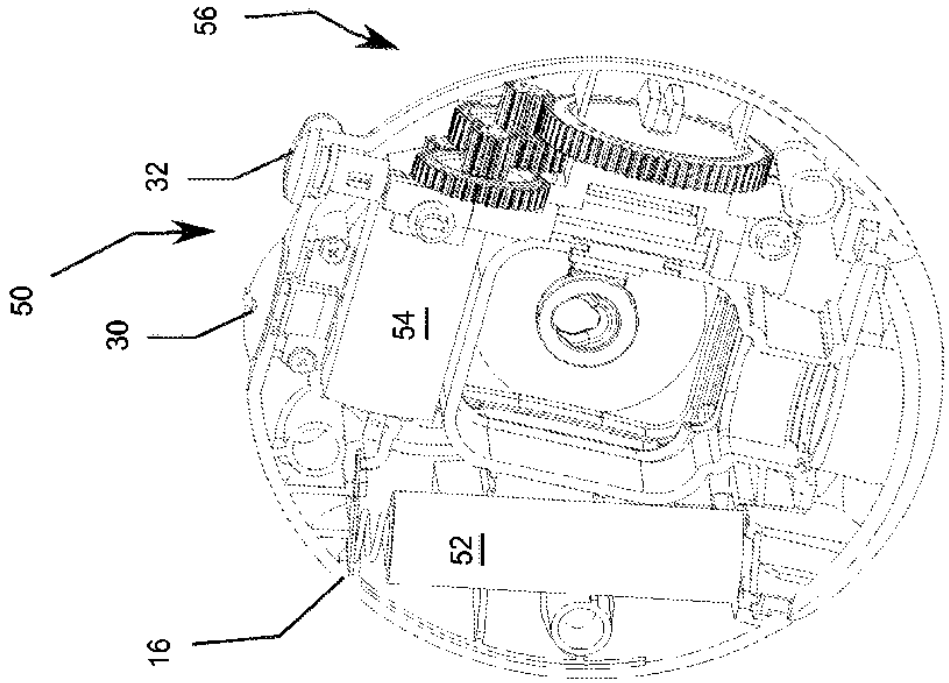


FIG. 10

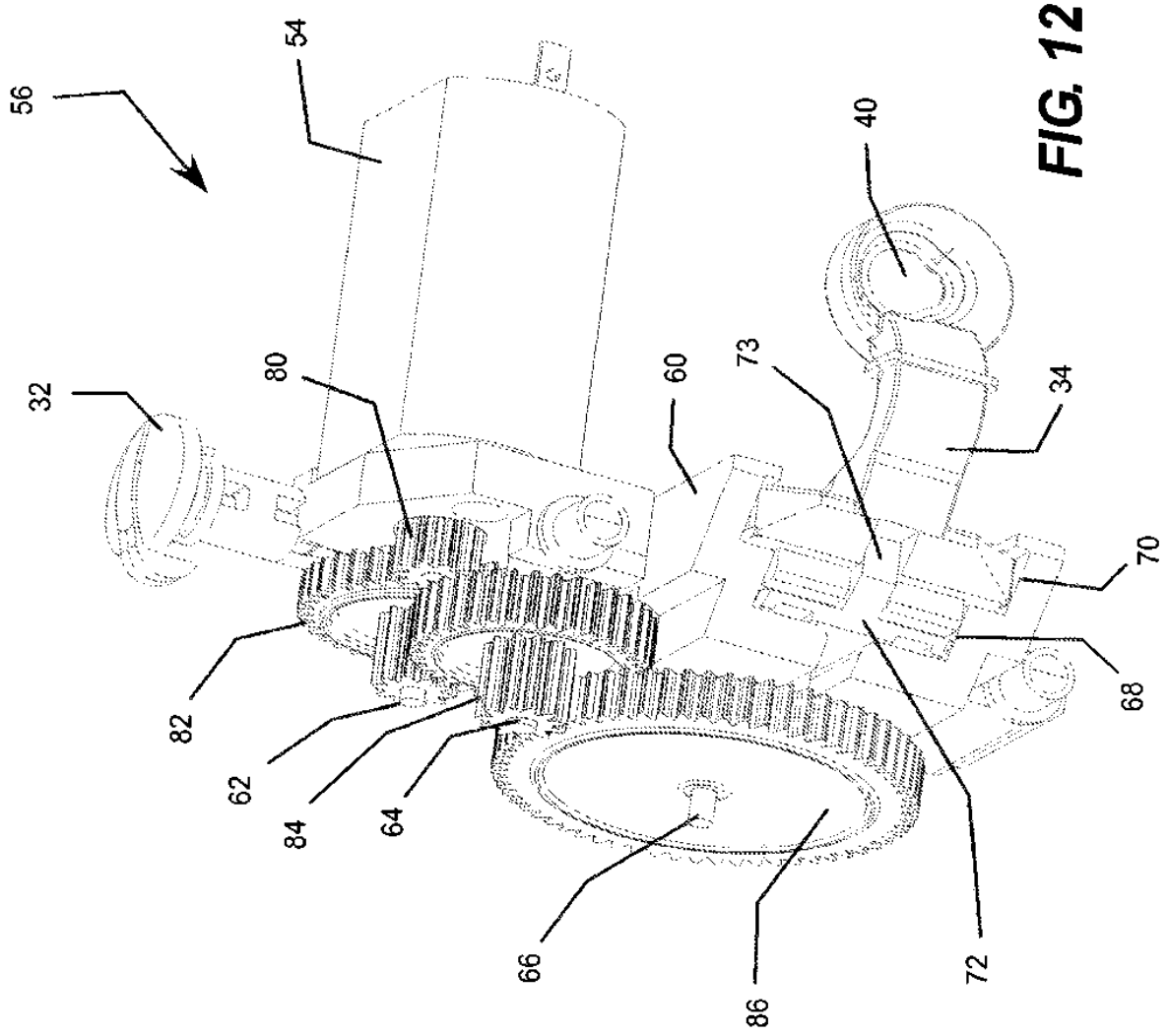


FIG. 12

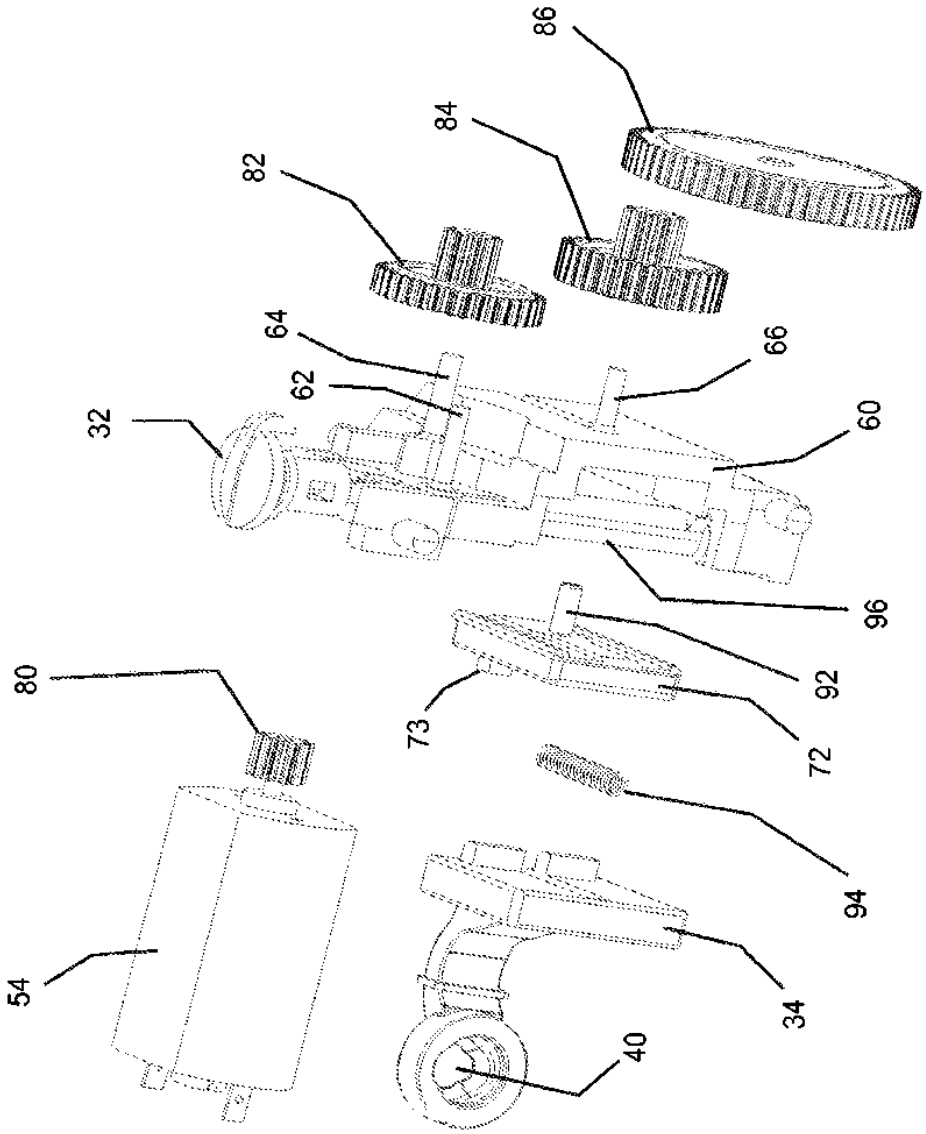


FIG. 13

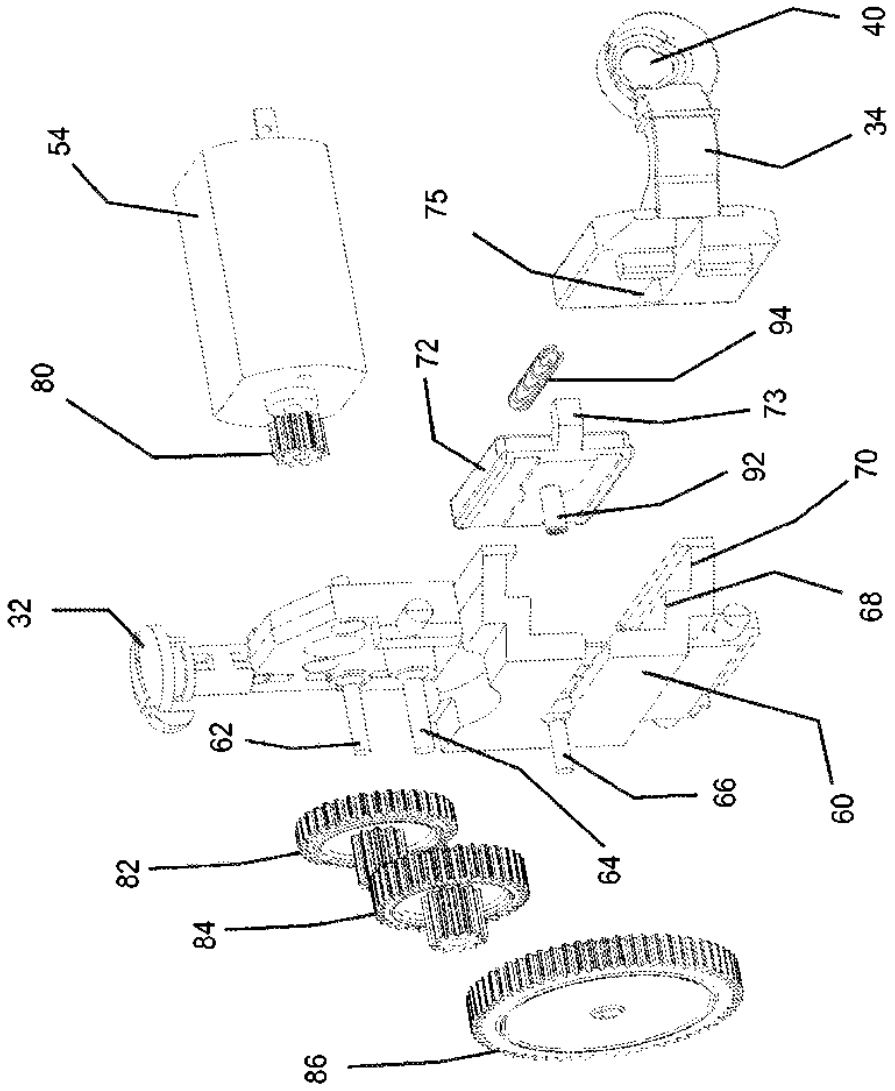


FIG. 14

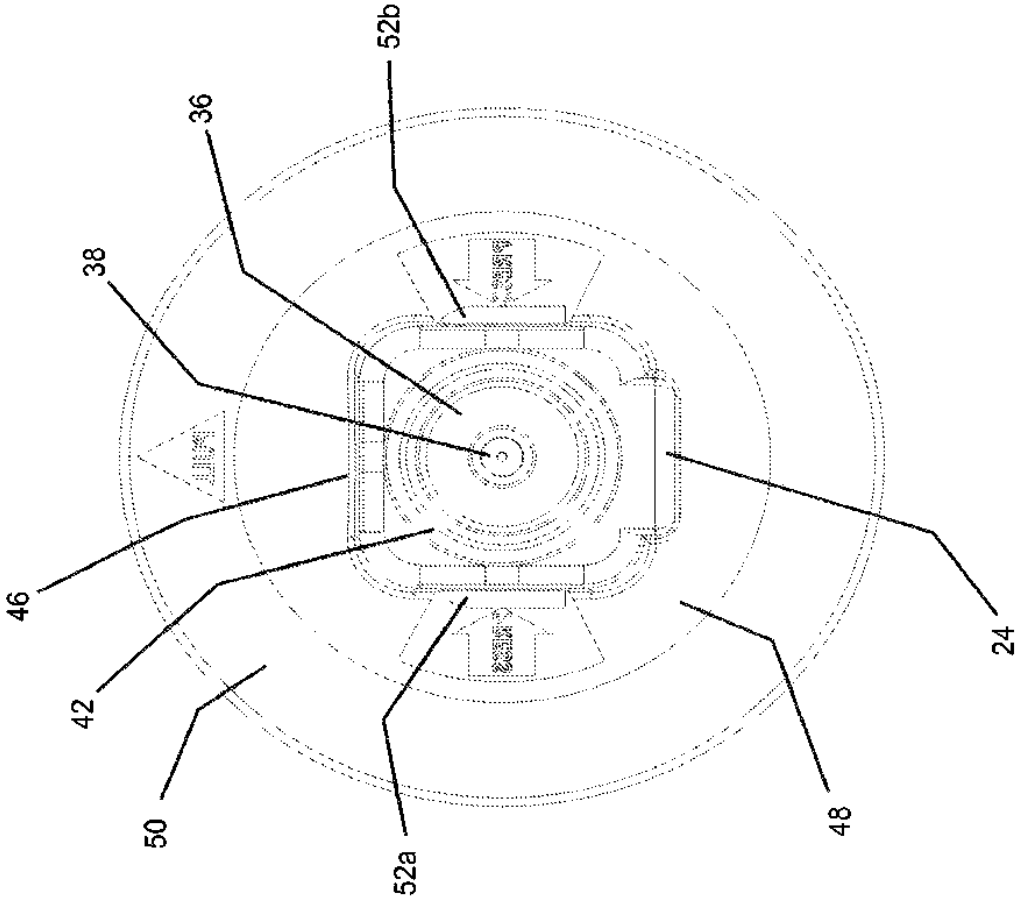


FIG. 15

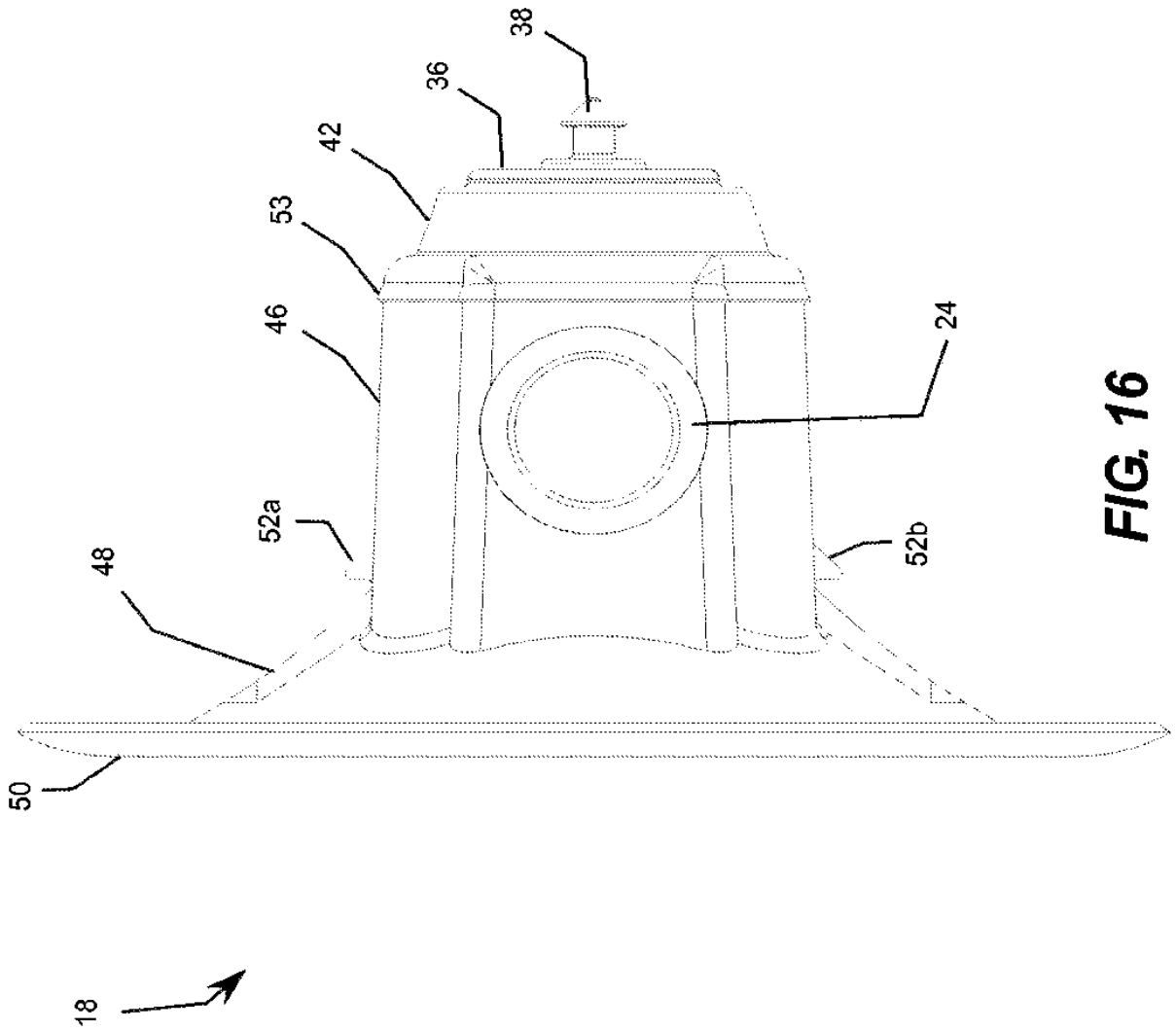


FIG. 16

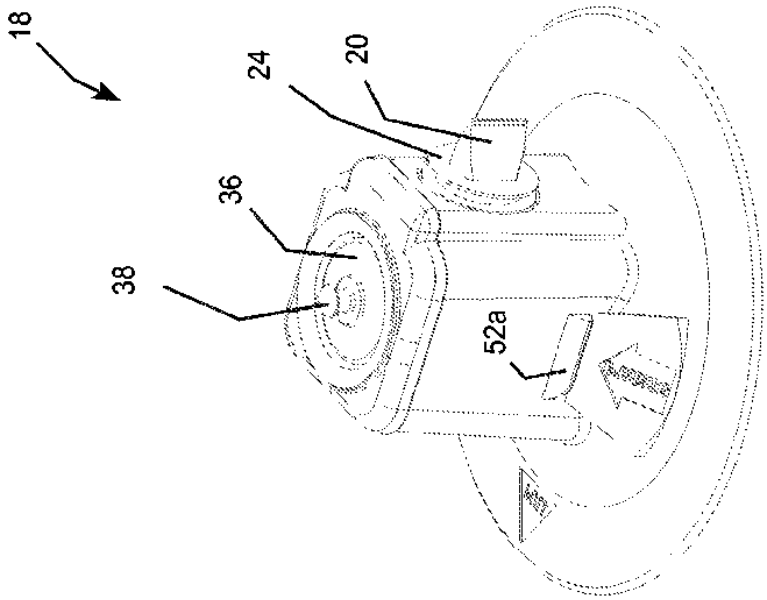


FIG. 18

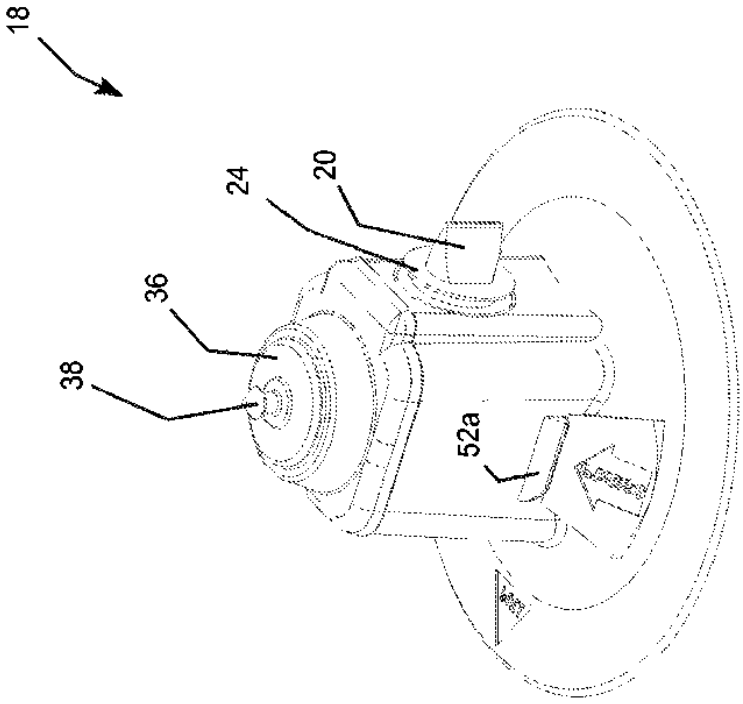


FIG. 17

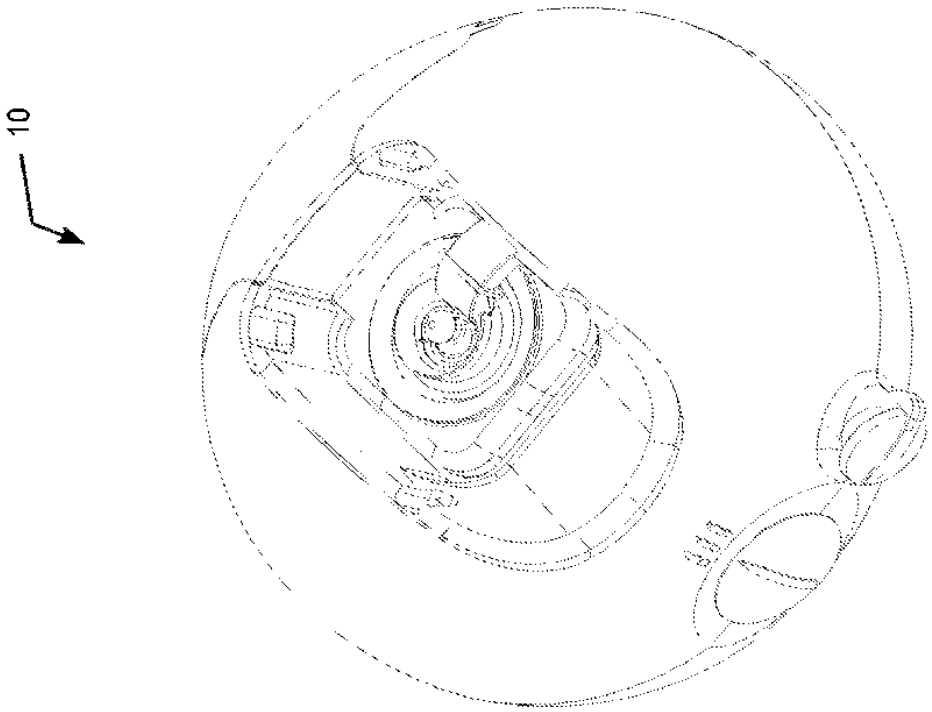


FIG. 20

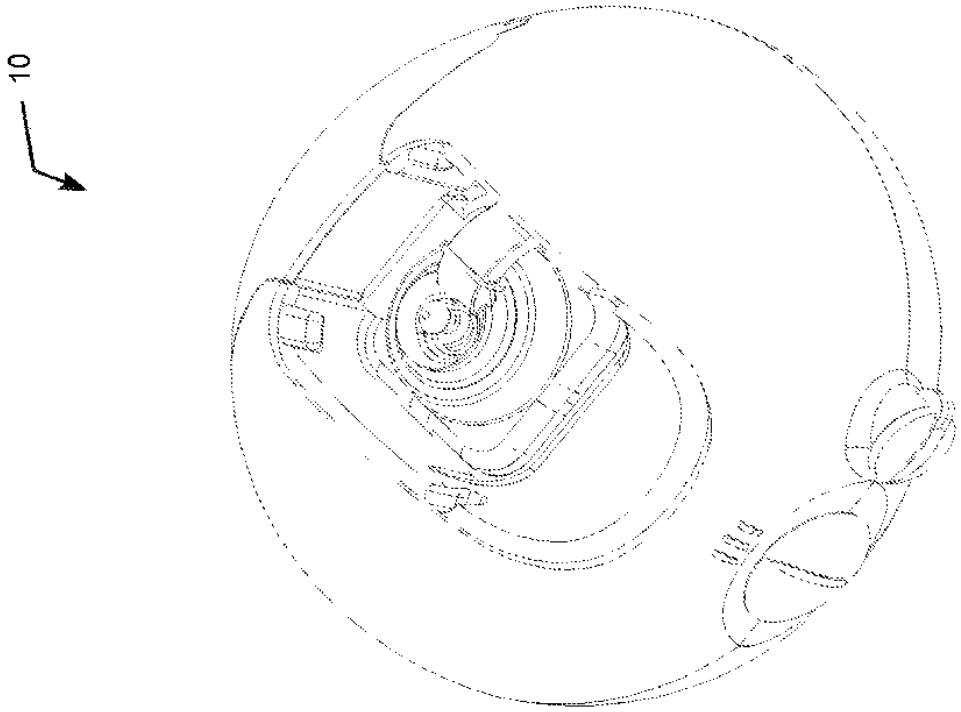


FIG. 19

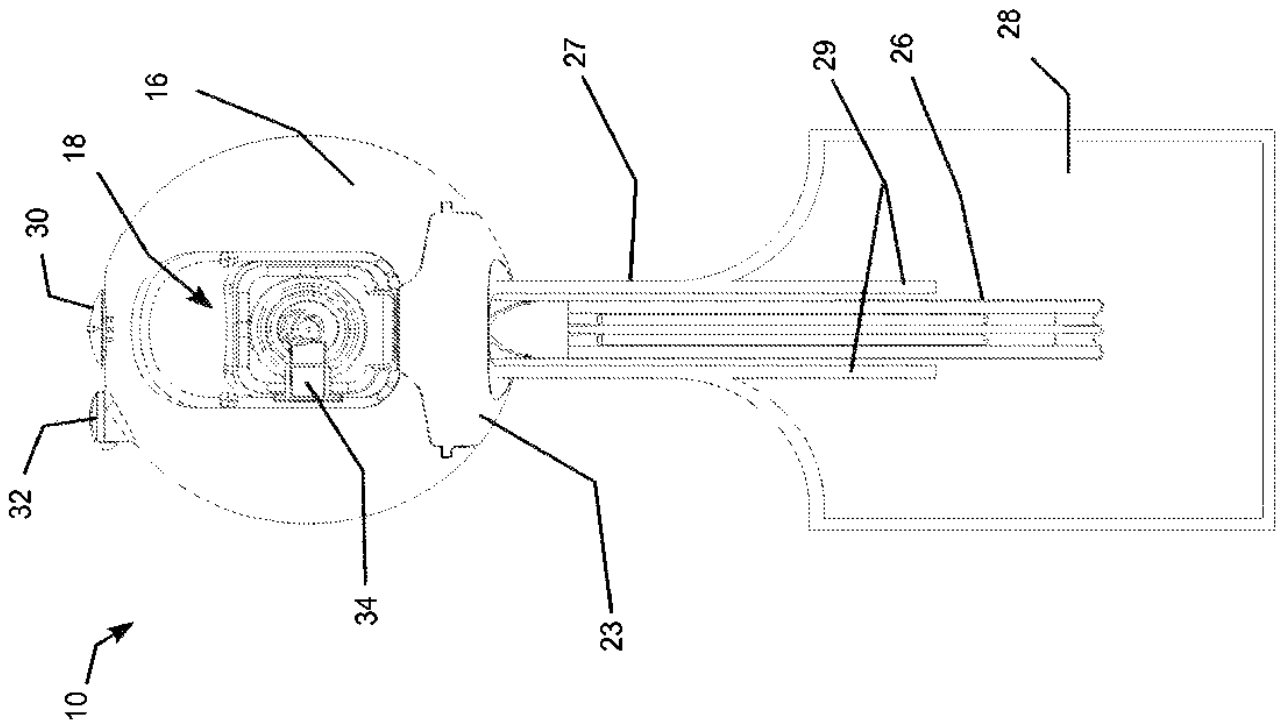


FIG. 21

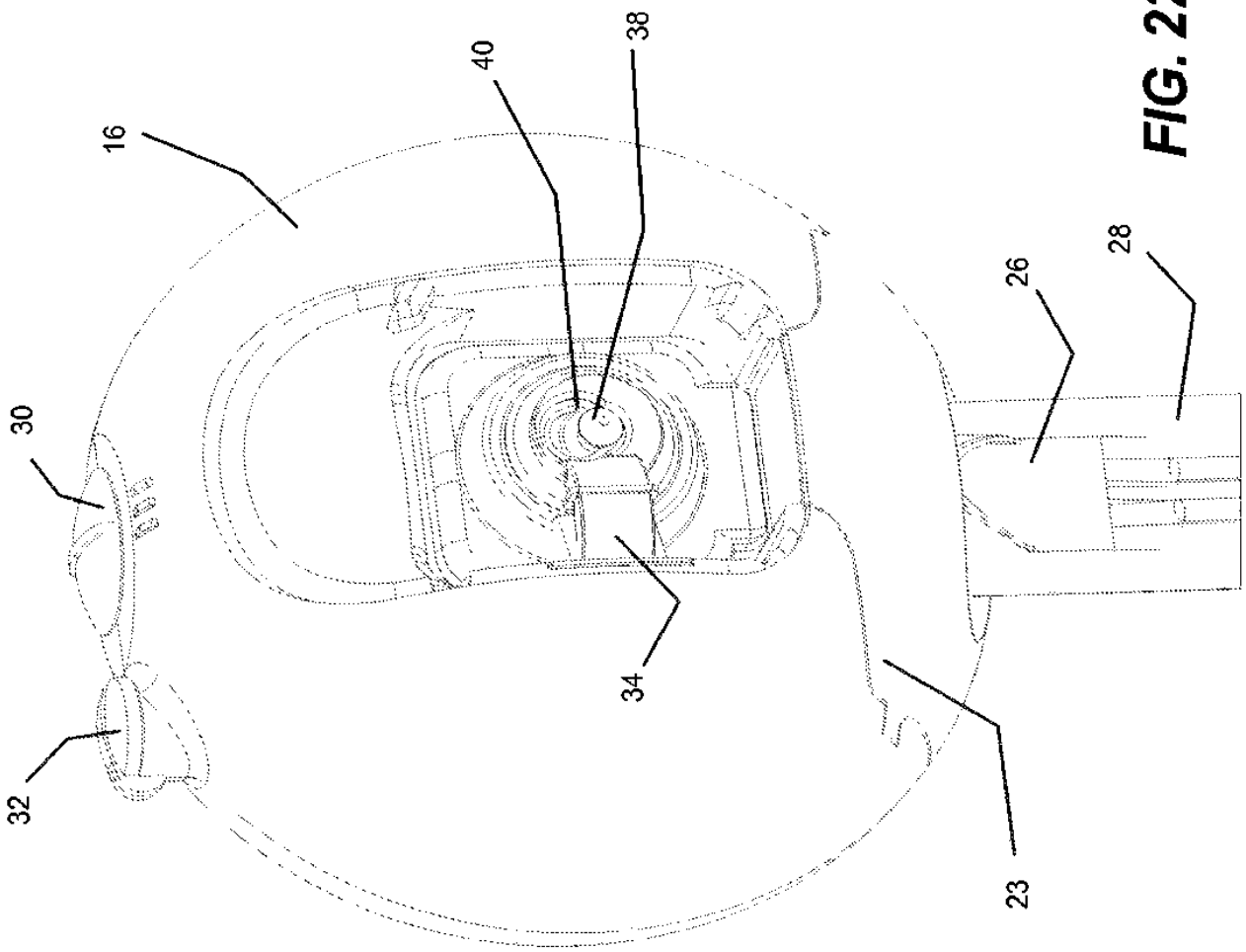


FIG. 22

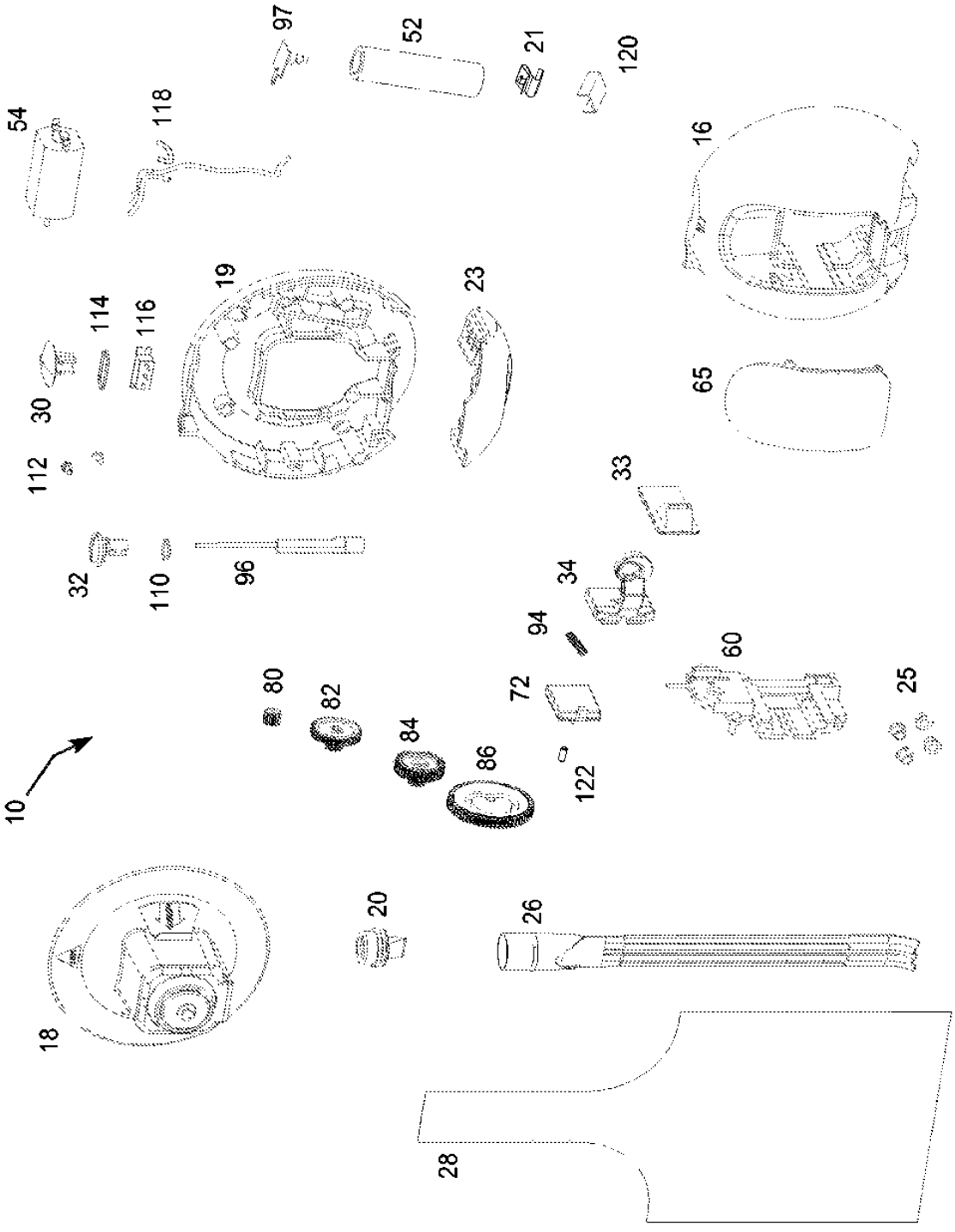

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FIG. 23

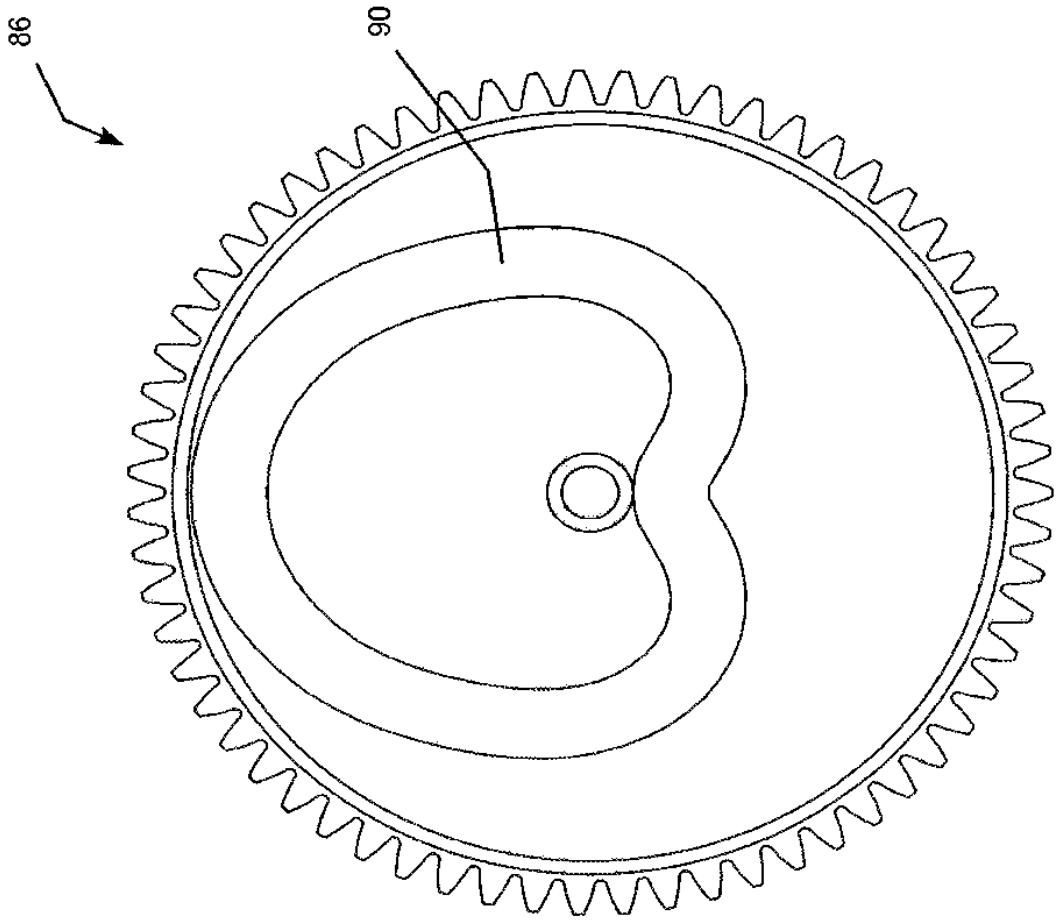


FIG. 24

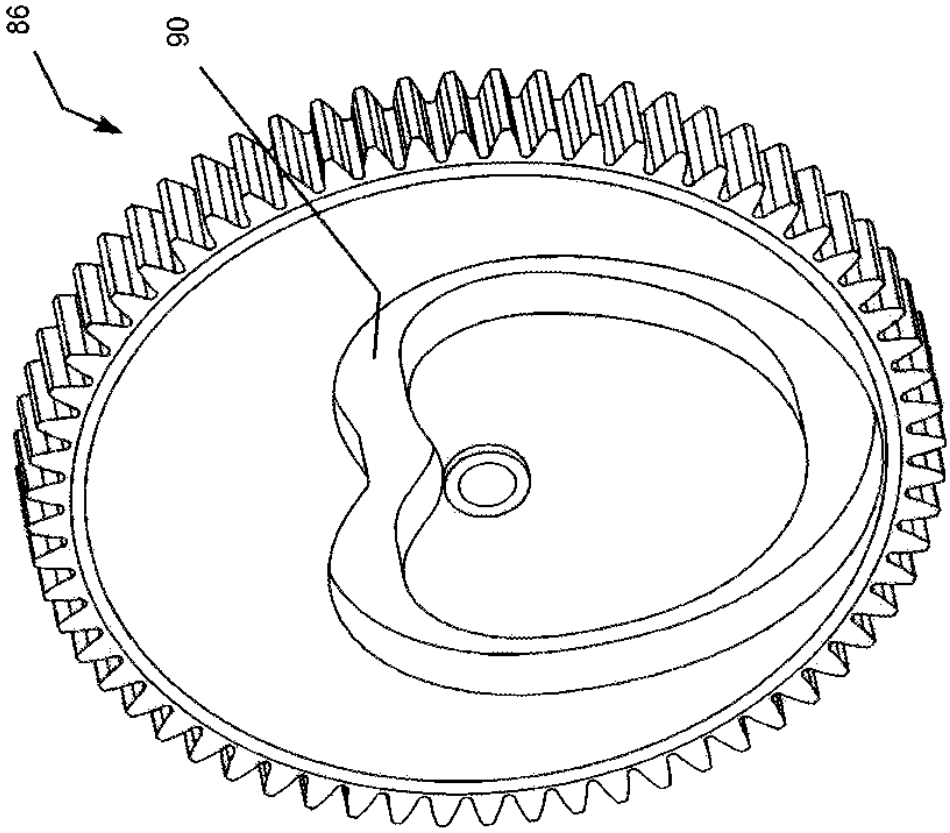


FIG. 25

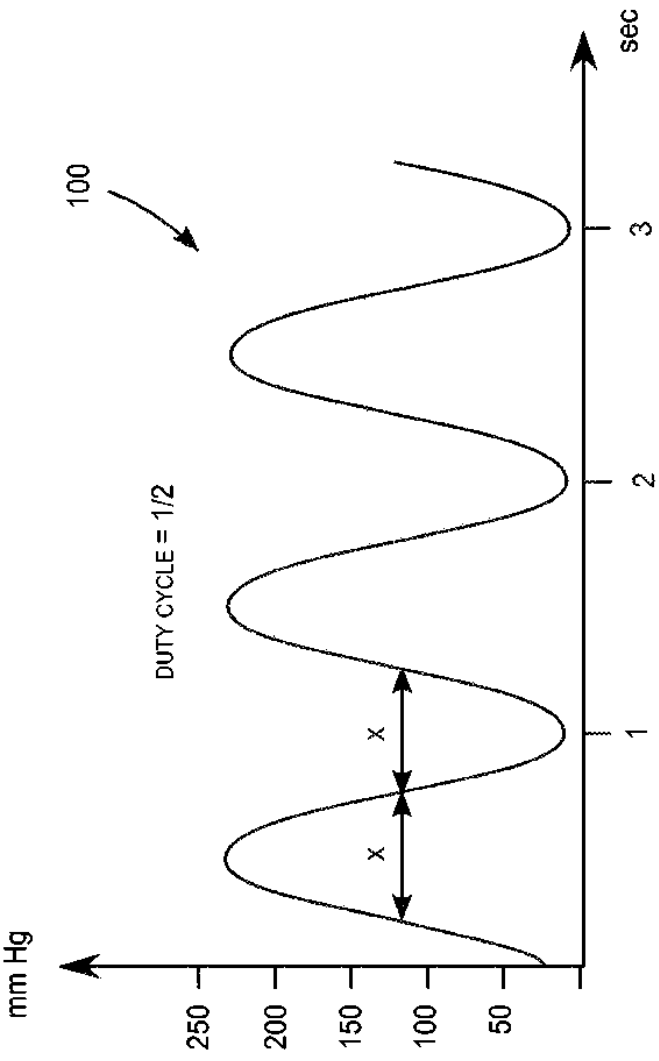


FIG. 26

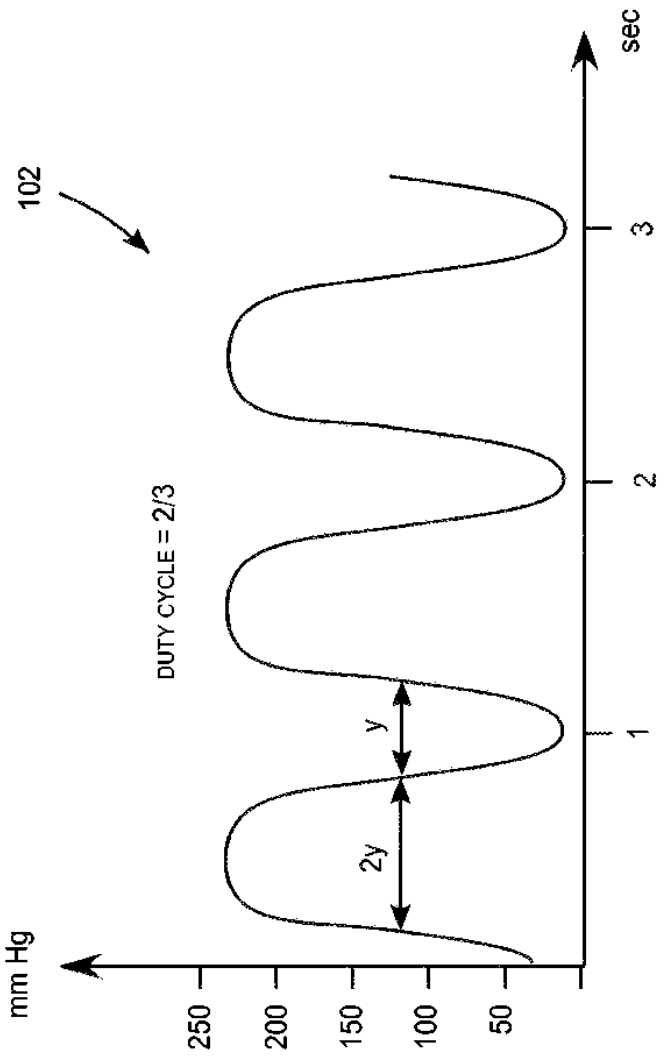


FIG. 27

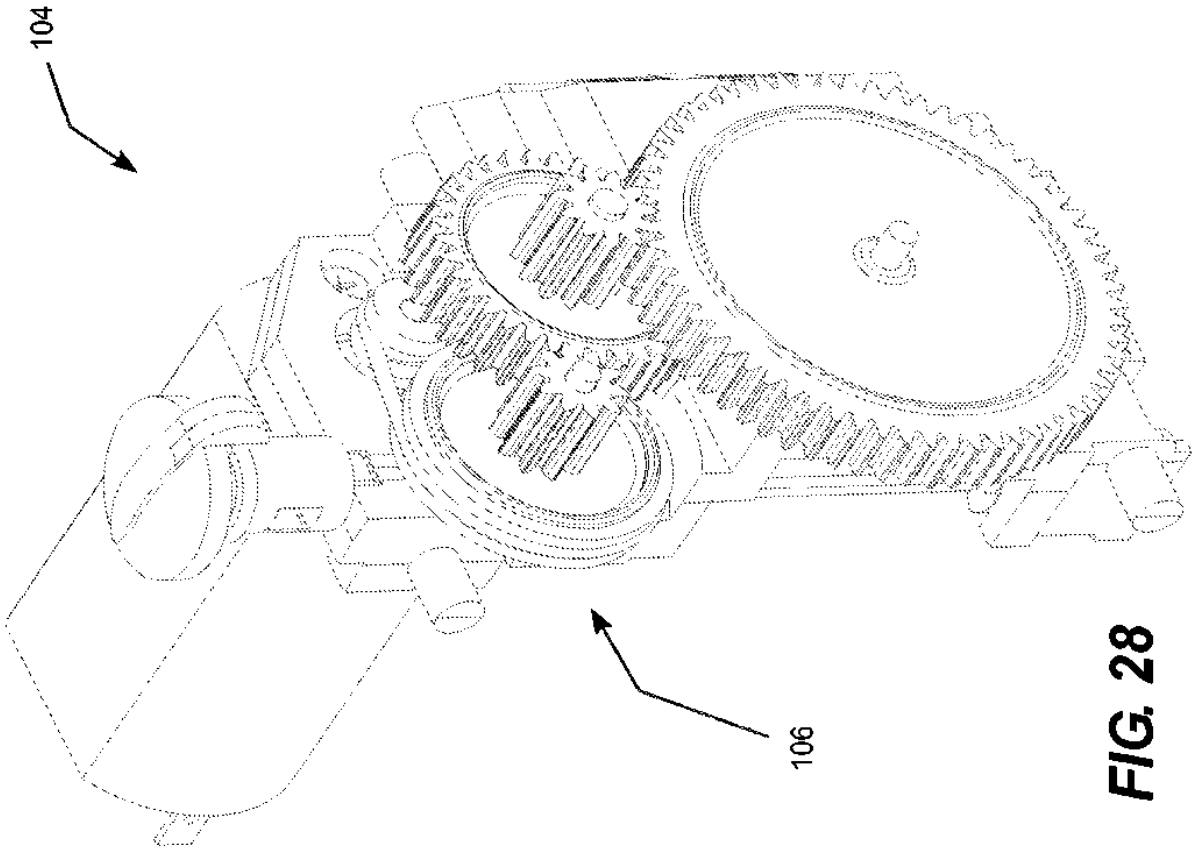


FIG. 28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/062422

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/193731 A1 (MYERS KENNETH E [US] ET AL) 19 December 2002 (2002-12-19) cited in the application paragraph [0062]; figures 6,11a,20a	1
A	US 2004/127845 A1 (RENZ CHARLES J [US] ET AL) 1 July 2004 (2004-07-01) paragraph [0129]; figure 12	1
A	US 4 857 051 A (LARSSON KARL O A H [CH]) 15 August 1989 (1989-08-15) column 5, line 44 - column 6, line 34; figure 2	1

☐ 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
27 August 2008	04/09/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, Angeliki

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/062422

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002193731 A1	19-12-2002	NONE	
US 2004127845 A1	01-07-2004	NONE	
US 4857051 A	15-08-1989	NONE	

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

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(30) Priority Data:
60/298,895 19 June 2001 (19.06.2001) US

(71) Applicant *(for all designated States except US)*: **WHISPER WEAR, INC.** [US/US]; 2221 Newmarket Pkwy., Ste. 136, Marietta, GA 30067 (US).

(72) Inventors; and

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(74) Agent: **FISHER, Stanley, P.**; Reed Smith LLP, 3110 Fairview Park Drive, Suite 1400, Falls Church, VA 22042 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

..... *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 02/102437 A2

(54) Title: SYSTEM FOR A PORTABLE HANDS-FREE BREAST PUMP AND METHOD OF USING THE SAME

(57) Abstract: A portable, hands-free and user friendly breast pump for facilitating breast-feeding, incorporates a dome-shaped housing having a servomotor mechanism; a hat-shaped flange having a chamber portion, a brim portion and an outlet, the chamber portion being formed so as to be placed over a nipple on a breast so as to define a chamber between the flange and the breast, and the brim portion being formed to surround the nipple and thereby form a suction seal therebetween; and a one-way venting element formed to operatively communicate with the chamber so as to vent pumped milk from the chamber via the outlet. The housing, the flange and the venting element are connected into an integral device held against the breast and underneath clothing so as to keep the integral device hidden. Breast milk is collected via a plastic collection bag that connects directly with the pump underneath clothing such that the milk is isolated from any contaminants in the air and may be easily stored immediately after being collected.

SYSTEM FOR A PORTABLE HANDS-FREE BREAST PUMP AND METHOD OF USING THE SAME

BACKGROUND OF THE INVENTION

Field of the Invention

[1] The invention generally relates to a portable, hands-free, and visually friendly breast pump system and method for collecting milk from a breast of a nursing mother which may be hidden from view when in use. In particular, the invention may be hidden underneath the clothing of a nursing mother, which provides privacy and avoids any attention and the awkwardness experienced by the nursing mother using existing breast pumps.

Description of the Related Art

[2] Breastfeeding is the best source of nutrition for a baby, and it also offers health benefits to the nursing mother. Often, the nursing mother needs to use a breast pump to collect milk. A variety of breast pumps are available. The basic types of breast pumps include manual (hand operated) pumps and electric pumps. The electric pumps may be battery and/or AC powered. Further, the electric pumps may be self-cycling or require some manual user control. U.S. Pat. No. 6,213,840 combines a manual hand pump with a breast pump support bra which supports the weight of the breast. While most hand pumps are inexpensive and portable, they are typically uncomfortable, inefficient, and difficult to clean.

[3] Some electric pumps are not battery-operated such that the nursing mother has to be near a power outlet. Other electric pumps, such as the diaphragm pump disclosed in U.S. Pat. Nos. 6,257,847 and 6,090,065, are assembled from many parts (hoses, gaskets, valves, etc.) which are difficult to clean, wash and carry. Figure 27 illustrates such a prior art system from the '065 patent having many parts which makes it cumbersome and difficult to use. In particular, in such a traditional breast pump, the milk has to pass through a plurality of components, such as a funnel P20, a cylindrical guiding means P22, a cap assembly P30, a reservoir P40, an inlet P62 connected to the suction assembly, etc., just to get to a container.

[4] The website at http://www.epinions.com/kifm-Health-Nursing_and_Feeding-Breast_Pumps-All/tk_~PR001.1.5 lists many commercially available breast pumps. Most of the electric breast pumps, such as Hollister's Purely Yours™ Kit, are

cumbersome and noisy, and thus very stressful for the nursing mother to use. In addition, while the nursing mother is using these breast pumps to collect milk, she cannot take care of the baby or do anything else.

[5] Even more, these pumps share the disadvantage that the mother's breast is exposed during use (lack of privacy) and that their motors are noisy. The breast pump vest described in U.S. Pat. No. 5,571,084, although covering most of the breast, is heavy and inconvenient to wear.

[6] Currently, there are no portable and user-friendly breast pumps capable of achieving private, quiet, easy, efficient, and effective breast-feeding.

SUMMARY OF THE INVENTION

[7] It is a purpose of this invention to provide a portable and hands-free breast pump system that facilitates hands-free, private, quiet, easy, efficient, and effective breast-pumping.

[8] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump hidden from view beneath clothing.

[9] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump while nursing a baby or doing something else at the same time.

[10] It is another purpose of this invention to provide a breast pump that has very few parts, and is easy to assemble and clean.

[11] It is another purpose of this invention to provide a breast pump that is cost-effective and easy to transport.

[12] It is another purpose of this invention to provide a breast pump with a vacuum chamber which also functions as a part of the vacuum mechanism.

[13] It is still another purpose of this invention to reduce the contamination of the milk during the processing, such as collection and storage, by a breast pump system.

[14] It is still another purpose of this invention to accurately emulate the suckling action of a baby when breast-feeding so as to facilitate the numerous benefits of breast-feeding to the mother and to the baby.

BRIEF DESCRIPTION OF THE DRAWINGS

[15] The foregoing and additional features and characteristics of the present invention will become more apparent from the following detailed description considered with reference to the accompanying drawings in which like reference numerals designate like elements and wherein:

Figure 1A is a perspective view showing the front side of the breast pump according to a preferred embodiment of the invention; and Figure 1B is a perspective view showing the rear side of the breast pump according to the first embodiment of the invention.

Figure 2 is a rear view of a top housing cover of the breast pump according to the first embodiment of the invention shown in Figure 1.

Figure 3 is side view showing the breast pump according to a second embodiment of the invention.

Figure 4 shows the details of the slide button according to the second embodiment of the invention.

Figure 5 is an exploded view showing the breast pump of the first embodiment of the invention.

Figure 6 is an exploded view showing the breast pump of the second embodiment in conjunction with a one-way valve and a splint.

Figure 7 is an enlarged inset view of a positive connect pin of the breast pump according to the second embodiment of the present invention.

Figure 8A shows an adapter for connecting a positive contacting pin to an external power supply of the invention, while Figure 8B shows an example of a tethered drive configuration of the present invention.

Figure 9 is an enlarged inset view showing the connection between the external power supply of Figure 8A and a positive contacting pin.

Figures 10A and 10B show cross-sectional views of different embodiments of the flange of the invention.

Figures 11A-C show a rear-piston lever-arm system of the breast pump according to the second embodiment that communicates with the servomotor mechanism so as to move linearly.

Figure 12 shows a second embodiment of a rear-piston lever-arm system in conjunction with a servomotor mechanism of the breast pump according to the first embodiment.

Figure 13 show a third embodiment of the rear-piston lever-arm system in conjunction with another embodiment of the servomotor mechanism according to the invention.

Figure 14 is an exploded view showing the servomotor mechanism illustrated in Figure 13.

Figure 15 shows a second embodiment of the linear movement mechanism according to the present invention.

Figure 16 shows a third embodiment of the linear movement mechanism according to the present invention.

Figure 17 shows a one-way valve for use with the breast pump of the invention.

Figure 18A shows a splint for use with the breast pump of the invention, while Figure 18B shows an outer sleeve according to the present invention.

Figures 19A and 19B show a collection bag for use with the breast pump of the invention.

Figures 20A and 20B show cross-sectional views of the pump along with splint and the bag bent to conform with the contour of the user's breast and body.

Figures 21A-C depict the actual suckling profiles of a seven-month-old baby boy.

Figures 22A and 22 B depict the suckling profiles of the present invention.

Figure 23 depict the suckling profiles of a conventional, mass-retail double pump set.

Figures 24A and 24B depict the suckling profiles of a conventional high-end double pump set.

Figures 25A and 25B depict the suckling profiles of a conventional battery powered portable pump.

Figure 26 shows a carrying case for a breast pump system according to the present invention.

Figure 27 is an exploded view showing the breast pump of the prior art (U.S. Pat. No. 6,090,065).

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[16] With reference to the figures, like reference characters will be used to indicate like elements throughout the several embodiments and views thereof. In particular, referring to Figures 1A and 1B, the breast pump 10 of the invention is embodied as a volume-displacement-type pump. Figure 1A is a perspective view of a preferred embodiment of the present invention showing the front side of the breast pump 10 with a dome-shaped housing shell 12. The housing shell 12 gives a natural appearance of the shape of a breast when the pump 10 is concealed underneath the user's clothing. Figure 1B is a perspective view showing the rear side of the breast pump 10.

[17] The pumping action generated by the breast pump 10 depends upon a cycle rate and a vacuum level which are controlled via an adjusting means 14. In one implementation, a user may use one finger to slide button 16 in an axial direction along the groove 18 so as to adjust the vacuum level (or range). Figure 2 depicts the open top housing cover 12a of breast pump showing the rear side of the slide button 16 shown in Figure 1.

[18] In a second embodiment shown in Figure 3, the slide button 16 is configured to slide in a circumferential direction along the groove 18 so as to adjust the pumping action to continuously vary the vacuum level. A push button 20 is used to control the cycling rate by incrementally increasing the rate with each push of the button 20 up to the fastest cycling rate designed into the pump. A further push of the button 20 then rolls the increment back to the slowest cycling rate for a continuous loop operation. Figure 4 depicts that the slide button 16 is connected to an electrical contacting base

21 with an arm 16a so as to slide the electrical contacting base 21 and vary the vacuum level.

[19] Referring to Figure 5, each breast pump 10 includes a housing shell 12, a central deck 22 with a servomotor mechanism 24 integrated therewith, and a straw-hat shaped breast "flange" 30 having a flange top 35. The servomotor mechanism 24 is a servomotor mechanism powered by at least one power source 26, such as two AA batteries. The central deck 22 includes a pump seat 28 for receiving the servomotor mechanism 24, two battery seats 32, 32' for receiving the batteries 26, and a tunnel 34 extending toward the housing shell 12 for guiding and receiving a piston cylinder 25 of a rear-piston lever-arm system 100 (See Figures 11A - 11C). A central deck cover 22' is used to fixedly encase the servomotor mechanism 24 and the two batteries 26 in the central deck 22.

[20] A second embodiment of the breast pump 10 as shown in Figure 6 is designed for a breast larger than that to which the first embodiment shown in Figure 5 is applied. Therefore, the central deck 22 of this second embodiment of the breast pump has a larger space that allows the two batteries 26 to be positioned parallel to one another. In addition, the central deck 22 of the second embodiment incorporates other parts for other parts, such as motor cover 40, rather than the fewer integral pieces as in the first embodiment.

[21] Specifically, the breast pump 10 of the second embodiment includes the housing shell 12, the cycling rate button 20, the vacuum level slide button 16, the central deck 22, the flange 30, the servomotor mechanism 24, and the batteries 26. In addition, the second embodiment includes a flange support 36 placed between the flange top 35 and the piston cylinder 25, a servomotor cover 40, a battery cover 38, a printed circuit assembly("PCA")/microprocessor 90, a PCA compartment 41, a DC power jack pin 42 (positive), a DC power jack tab 43 (negative), a battery contact 52, and a pair of screws 49 (Figure 6).

[22] The first embodiment of the breast pump uses traditional positive and negative contact plates with springs for receiving each battery. In the second embodiment of the breast pump, one positive contact pin 42 (Figure 7 inset view) is used instead. Both of these configurations would be known in the art for purposes of connecting to batteries held in small compartments.

[23] The second embodiment of the breast pump (Figure 6) has an additional flange support 36 designed to protect against any overshooting of the strokes towards the

flange top 35. The flange support 36 is fixed in place with the control deck 22, such as via a rotating lock mechanism, and then fitted around the exterior of the vacuum chamber 60 so as to have an interference fit at least around the base of the flange 30 (i.e., the 'bellows' area of the flange which creates the air displacement). The flange support 36 is an individual part of the unit assembly designed to be attached onto the flange 30. The flange support 36 not only holds the flange 30 in place during the pumping action (prevents over-pressure on the flange top 35) but also supports the vacuum chamber 60 from collapsing.

[24] Unlike most other breast pumps which have their pump mechanisms situated outside of their breast interface elements or even at a remote distance from the breast interface element, the servomotor mechanism 24 of the invention is integrated inside the pump 10. The servomotor mechanism 24 is designed to be lightweight (for example, 0.4 oz. making each entire pump 10 weigh only 2.4 oz. without batteries or 4.2 oz. with batteries) such that it sits directly inside the pump 10 and is supported by the housing without any additional components. The pump 10 in turn is exclusively supported by the bra and the negative pressure created between the breast and the flange 30 by the servomotor mechanism 24 and the lever arm system 100. In variations of the present invention, the servomotor mechanism 24 may be substituted with an external driving mechanism, such as an electrical motor or a tethered manual pumping device, to provide the negative pressure for pumping. The implementations of such substitute devices would have those devices modularized such that they could be substituted for one another and be easy to replace.

[25] In a third embodiment of the breast pump, power for the external servomotor mechanism 24 is located outside the housing. As shown in Figure 8A, an adapter 46 is used to connect a positive contacting pin to the external power supply 26 via a wire 26a. Figure 9 shows an inset view of how the adapter 46 is attached to the positive contacting pin 44. This embodiment has the advantage of a longer-lasting power supply that can be used, for example, in an institutional setting (i.e., a hospital) or even a home setting where a more limited range of mobility is acceptable or even desired.

[26] Alternatively, as shown in Figure 8B, the servomotor mechanism 24 may be replaced by a servomechanism 24' that may be just a mechanical or pneumatic linkage 101 connected to the lever arm 21 for implementing the pumping action of the vacuum chamber 60. The linkage 101 is connected to a remote control 103 that acts as the user's control for pumping via a linkage element 103. For example, in a

mechanical implementation, the linkage element 103 is a wire in a sleeve similar to that used in bicycle handbrake controls, while the control 103 is a hand- or foot-pedal that the user manipulates to move the lever arm 21 in the pump 10. Alternatively, in a pneumatic implementation, the linkage element 103 is a flexible pipe that feeds air or fluid into the linkage 101. The control 102 is also a hand- or foot-pedal that controls the flow of control air/fluid to the linkage 101 to then operate the pumping motion of the lever arm 21. The specific details for implementing either of the above-discussed alternative embodiments would be within the knowledge of those skilled in the art.

[27] Various components of the system are formed from resiliently plastic or other resin-type materials to accomplish various purposes. For example, in order that the splint 110 be flexible so as to conform with the shape of the user's breast, and so that the overall structure of the pump 10 is lightweight, including but not limited to the housing shell 12, the housing cover 12a, the lever arm 21 and the central deck 22, these various parts are formed from plastic. Other components in the system would be formed from materials appropriate to their function as would be understood by those skilled in the art. Other materials for the various components may also be used as would be known in the art so long as the selection of such materials is not inconsistent with the structure, operation and purpose of each such component and of the present invention as a whole.

[28] In the general operation and use of the present invention, as shown in Figures 20B, the pump 10 contacts the breast only with the breast flange 30, and the dome-shaped housing shell 12 does not contact the breast. A vacuum chamber 60 is defined between the breast flange 30 and the breast, and is completely isolated from the working components of the breast pump 10; the servomotor mechanism 24 is only in contact with the exterior surface of the breast flange 30. This allows the vacuum chamber 60 to be maintained at a negative air pressure while keeping the breast milk from contacting any other parts of the breast pump 10. The invention significantly reduces the number of parts that can come in contact with the milk so as to make the system easy to clean and sanitary. Further, the invention eliminates the potential of the milk co-mingling with any room air contaminants.

[29] The breast flange 30 is made from silicone or other soft elastic material for interfacing directly with a breast and situated on the breast with an inlet hole 50 (See Figures 5, 10A and 10B). The inlet hole 50 is designed for seating a nipple and areola in a vacuum chamber 60 which is defined between the breast pump 10 and the breast. The soft breast flange 30 allows the wearer to pump milk quickly and painlessly by

mimicking the baby's suckling movements when the servomotor mechanism 24 moves the flange 30, thereby triggering the female body's natural reaction to produce milk.

[30] A health benefit for the user or mother derived from the invention is that, as the nerves in the nipple and areola are stimulated by the action of the invention, the pituitary gland receives a signal to release prolactin and oxytocin into mother's blood stream. Prolactin relaxes the mother and stimulates the alveoli to produce more milk. Oxytocin causes the alveoli to contract and squeezes milk into the ducts. In contrast, the traditional hard funnel breast pumps (See Figure 27) simply pull the nipple into the rigid shaft to obtain milk. The hard shaft of the funnel is rigid and unyielding so that the suction concentrates on the nipple and creates a stinging sensation.

[31] Varying thicknesses in the silicone flange 30 helps the breast pump 10 to attach to the breast and be compressed towards the nipple by the rear-piston lever-arm system 100 shown in Figures 6, 11A-11C and 13. Pumping sessions become faster by using the soft flange 30 since the milk is being removed in a more natural way than with a traditional hard funnel. As such, the milk is also better extracted from the breast to avoid any decrease of milk production due to the remaining breast milk in the breast. The milk residuals reduce hormone stimulation for milking.

[32] As shown in Figure 10A, the flange 30 includes an outlet 62 through which the milk drawn from the breast flows out of the flange 30. As will be discussed further herein, the milk is then directed away from the breast pump 10 and stored. In a variation of the flange 30, as shown in Figure 10B, the outlet 62 is funnel-shaped so as to direct the milk flow out of the flange 30 and prevent the milk from flowing back towards the breast.

[33] In at least one of the embodiments of the invention, the nipple is well seated at the back of the breast pump 10 (inside the chamber 60), where only air is directly in contact with the nipple. When the nipple is placed inside the flange 30, the nipple rests within the vacuum chamber 60 with the surface of the surrounding area of the breast in contact with the surface of the flange 30. Air compression and suction is then controllably generated to occur by virtue of the cap-shaped piston cylinder 25 being cyclically pushed toward the breast so as to physically push on the top 35 of the flange 30 (see Figure 11A), and then released. The top 35 is formed with a relatively thin and soft side wall which has an accordion-style, contour-shape with alternating convex and concave edges formed on its surface for transferring and converting the contact pressure from the cap-shaped piston cylinder 25 to air compression and

suction on the nipple. In order to strengthen the top 35 and to help in uniformly compressing the vacuum chamber 60, the top 35 may be formed with a circular, reinforcing plate 35a fixedly imbedded therein. The reinforcing plate 35a is formed with a dome-shaped alignment stub or nipple 35b on a top center portion of the plate that aligns with the alignment dome 25b of the piston cylinder 25 so as to center the vacuum chamber 60 within the piston cylinder 25. This centered alignment is especially important in keeping the vacuum chamber 60 from floating or misaligning within the piston cylinder 25 during the pumping operation.

[34] In a first embodiment of the rear-piston lever-arm system 100, as shown in the exploded view of Figure 11A, the top of the piston cylinder 25 is shaped like a yo-yo or a doughnut without a hole. The lever arm 21 has a protrusion 21a on the top that contacts with the alignment dome 25b of the piston cylinder 25. The lever arm 21 is a projecting handle used to adjust or operate the piston cylinder 25. In particular, the rear piston lever-arm system 100 mechanically communicates with the servomotor mechanism 24 so as to be activated by the mechanism and thereby pivotally move the lever arm 21 which then linearly moves the piston cylinder 25 along a line generally parallel with the centerline of the pump 10. Such a linear movement is depicted, wherein the start or "upstroke" position of the piston cylinder's linear movement is shown in Figure 11B.

[35] Figure 11C shows the lever arm 21 pivoted forward thereby linearly pushing the piston cylinder toward the flange 30 in a "downstroke" motion. The lever arm 21 pushes the protrusion 21a against the alignment dome 25b of the piston cylinder 25 to move the piston cylinder 25 toward the nipple. As mentioned, the nipple is insulated by the vacuum chamber 60 of the flange 30 from direct contact with other components such as the piston cylinder 25. The motion of the piston cylinder 25 is controlled by the level arm 21 which sets the default position of the piston cylinder 25 within the tunnel 34 such that the piston cylinder 25 rests away from the breast when the pump is not in action. During operation, in the "upstroke" motion, the lever arm 21 pivots back thereby releasing the piston cylinder 25 and the top 35 of the flange 30. The movement of the piston cylinder 25 is rather short, delicate and efficient in comparison with the pumping action of other breast pumps.

[36] The servomotor mechanism 24 activates the rear-piston lever-arm system 100 embodied in the lever arm 21 and the piston cylinder 25 to create the "downstroke" action inward (toward the breast). This downstroke action displaces the air in the flange 30 which exits via a one-way valve 140 (See Figure 17) that is inserted into the

outlet 62, thereby releasing the vacuum and actively stimulating the breast for further expression of milk. In addition, milk expressed by the breast flows out also through the one-way valve 140 and into a collection bag 300 (as will be explained further herein). The "upstroke" action not only moves the lever arm 21 and the piston cylinder 25 back into their start positions, but also generates the vacuum pressure against the breast. The upstroke and downstroke action of the system 100 alternatingly generates and releases the volume displacement vacuum in the chamber 60, and in particular in the flange 30. Among the features of this construction, the "upstroke" passively maintains or creates the vacuum via the vacuum chamber 60 of the flange 30 elastically returning to its normal state, and not by any energy expended by the servomotor mechanism 24. However, in other embodiments, the protrusion 21a may be linked to piston cylinder 25 and the top 35 so as to actively generate both the "upstroke" and "downstroke" motions of the vacuum chamber 60.

[37] In order to further simulate the suckling motion of an infant, the preferred suckling time to releasing time is , for example, approximately 3:1 in a cycle of a second. Namely, the suckling stage takes 3/4 second, and the releasing stage takes 1/4 second for each cycle. However, other cycling ratios may be used based on individual user preferences or breastfeeding requirements. The combination of the servomotor mechanism 24, the lever arm 21 and the piston cylinder 25 provides precision control of the air compression inside the chamber 60 which allows the precise controlling of the cycle rate and the vacuum level.

[38] In a second embodiment of the rear-piston lever-arm system 100, as shown in Figure 12, the lever arm 21 is formed to surround the side wall of the cylinder piston 25 and connect to the piston via a protrusion 25c formed on the side wall. When the lever arm 21 pivots, it rotatively pushes on the protrusion 25c (rather than push on the top 35 of the piston cylinder 25) thereby linearly moving the cylinder piston 25. Otherwise, the operation and effects of this second embodiment are the same as those of the first embodiment.

[39] As shown throughout the drawings, the present invention includes various embodiments for the servomotor mechanism 24. Figures 11A-C depict using a first embodiment of servomotor mechanism 24, while Figures 5 and 12 illustrate a second embodiment of the servomotor mechanism 24 that is used with the rear piston 25 and the modified lever arm 21. Figures 6 and 13 shows a third (preferred) embodiment of the servomotor mechanism 24 applied to a third variation of the lever arm 21.

[40] Figure 14 illustrates an exploded view of the third embodiment of the servomotor mechanism 24 so as to provide an example of the internal structure for a servomotor mechanism that would be applicable to the present invention. That embodiment is implemented via a structure that includes a potentiometer 201, an output gear 202, cluster gears 203-206, a DC motor 207, an arm 208, a motor housing 209, a screw 210, a rotary pot contact 211, a power contact 212, a gear train motor shaft 213, a front cover 214, a rear cover 215, and a pinion gear 216. Essentially, a servomotor mechanism for the present invention is implemented via mechanical or electromechanical system that pivotally moves a lever arm that then linearly moves a piston (in this case, a cylindrical piston 25) that then creates the pumping motion in the flange 30. The electric motor structure of the third embodiment (even of the first and second embodiments) as described above is one such system. Otherwise, given this disclosure of the invention, one of skill in the art should be able to devise other structures for a servomotor mechanism that would serve the purposes of the present invention and within the scope and intent of the claims.

[41] Figures 15 and 16 illustrate other systems for providing the above-mentioned linear movements for the cylindrical piston 25, and thus the pumping operation of the flange 30. For example, Figure 15 shows a lead screw mechanism with a rotary motor. The motor 240 oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The rotation of a lead screw 250 pushes a plunger 260 so as to push the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 rotates the lead screw 250 away from the breast so as to move the plunger 260 away from the breast. This allows the flange 30 to return to its natural state so as to create a negative pressure in the vacuum chamber 60.

[42] In Figure 16, the lead screw 250 is substituted with a rack and pinion 270, wherein the motor 240 again oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The linear movement of the rack and pinion 270 pushes the plunger 260 pushing the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 linearly moves the rack and pinion 270 away from the breast so as to move the plunger 260 away from the breast. Again, this allows the flange 30 to return to its natural state and create a negative pressure in the vacuum chamber 60.

[43] The one-way valve 140 shown in Figure 17 is used in conjunction with the outlet 62 of the flange 30. The valve is generally implemented as a one-piece element that is inserted into the outlet 62. Alternatively, the one-way valve may be constructed as an integral part of the flange 30. Its main function is to help maintain the vacuum in the chamber 60 during operation and to help draw the expressed milk away from the chamber 60 in the flange 30 so as to flow to a collection bag 300. However, other embodiments as those of skill in the art would understand may be accomplished used to implement the one-way valve 140.

[44] The splint 110 shown in Figure 18A guides the milk from the pump to a collection bag 300. The splint 110 has a cup 115 and a wave-form portion 117. The cup 115 and the wave-form portion 117 of the splint 110 are inserted into the neck of the collection bag 300, extending downward to ensure the neck walls do not collapse due to the pressure from the bra at the point where the collection bag exits at the bottom edge of the bra (as will be discussed further hereinbelow). The cup 115 is formed to pressure fit into the outlet 70 of the housing shell 12 when inserted using an upward sliding force. The cup 115 is intended to have at least a liquid-tight fit within the outlet 70 while guiding the milk out of in the chamber 60. Preferably, the cup 115 has an air-tight fit when positioned in the outlet 70. Such a pressure fit is intended to hold the bag 300 tightly to the cup 115 so as to avoid any milk spillage and any air contaminants therebetween. At the bottom of the cup 115, there are holes 116 through which the milk is intended to flow out of the cup 115 and onto the wave-form portion 117 of the splint 110. In a preferred embodiment, the cup 115 has an extruded rim which will contact the outer edge of the neck of a collection bag 300 so as to further seal the neck. The splint may be formed integrally with the bag by incorporating the extruded tube in the construction of the collection bags. In such a case, a hot-pressed tear-off line is set between the end of the splint and the end of the bag neck.

[45] Also, in another variation as shown in Figure 18B, an outer sleeve 111 is used to surround the neck 310 of the bag 300. The outer sleeve serves to protect the neck of the bag 300 as it extends from the pump to the body 305 of the bag 300. In this implementation, the neck 310 of the bag connects directly to the one-way valve 140 with the sleeve 111 surrounding the connection. In one form, the outer sleeve 111 is C-shaped in cross-section and also formed of a resiliently plastic material, which allows the sleeve to have some flexibility. Other cross-sectional shapes or configurations as would be understood by one of skill in the art to perform the same function as the C-shaped sleeve may be used.

[46] When viewed along its longitudinal axis, the wave-form portion 117 has a substantially sinusoidal contour, wherein the peaks and valleys of the sinusoidal contour form channels along which the milk flows downward to the collection bag 300. The use of the wave form portion 117 enjoys several benefits over using a conventional tube form. First, it avoids any obstruction caused by air bubbles stuck in a tube. Second, a splint having a wave-form portion is more easily bent than a tube so as to conform with the contour of the breast and the bra to in order to reach the collection bag or a bottle. Third, the wave-form portion is easier to clean and keep sanitized than a tube. Plastic tubing needs to be cleaned each use. If washed, it has to be hung to allow it to drain and dry thoroughly. In contrast, the wave-form splint dries out more easily than a tube form. Lastly, a wave-form structure confronts less air resistance than a tube when it is inserted into either a regular container or the collection bag 300. As will be discussed further hereinbelow, the sub-assembly of the one-way valve 140 and the splint 110 provides further support for the vacuum chamber 60 so as to prevent it from collapsing.

[47] As shown in Figures 19A and 19B, the collection bag 300 is made of plastic and substantially deflated so as to be maintained in a substantially vacuum state for receiving the splint 110 and the milk. In one embodiment, the collection bag 300 is made by hot-pressing two thin plastic sheets to form a square bag body 305 with sealed edges 301, 301', 302, 303, 303' and a neck 310 with sealed edges 311 and 311'. Meanwhile, each perforation line 312 is punched with holes for easily separating the bags with a slight force. At the same time, graduations are printed on the surface of one plastic sheet to indicate ounces or milliliters. The sequentially hot-pressed bags are rolled into one roll to reduce storage space and make them easy to transport. Alternatively, the bags may be made using other conventional methods for fabricating plastic bags known in the art. Also, the bags may be formed into other shapes or with additional features (i.e., resealable tops, adhesive surfaces) or using other different materials that have the same manufacturing, sanitary and liquid-proof characteristics.

[48] The sealed edges 311 and 311' of the neck extend into the bag body 305 so that the splint 110, including the cup 115, can be fully inserted inside the neck 310 to completely seal the splint inside the collection bag 300 thereby avoiding any milk spillage outside of the collection bag 300 during use. After the collection bag 300 is filled, a user can remove the splint 110 and roll the neck 310 so as to seal the bag. Further, adhesive tape or an adhesive surface formed on the neck 310 or the body 305 may be used to fixedly secure the rolled neck to the body of the bag.

[49] In another embodiment, an additional pair of sealed edges 306, 306' in a V-shape are hot-pressed next to the neck 310 to provide additional pressure on the neck after the neck has been pressed from the top-down to expel any residual milk in the neck of the bag. In addition, the sealed edges 311, 311' include lower extensions that promote the sealing of the neck 310 when the neck is pressed, so as to function as a simple, one-way valve to prevent milk spillage after the neck is press-sealed. The neck of the collection bag with the sealed edges in a V-shape effectively becomes spill-proof after being pressed shut. This structure of the bag 300 solves the common problem encountered by mothers that use conventional plastic collection bags when they pump for breast milk. The plastic collection bags of the prior art have not been able to provide any effective means for sealing closed so as to allow the mother to put down the bags without spilling.

[50] In a further embodiment of the invention, an additional tear notch 304 is hot-pressed at a corner of the bag so that a user may tear off the bag at the line to release the milk into another container to feed a baby. Additional tear notches are hot-pressed at the neck of the bag so that a user may alter the length of the neck by tearing off the bag at any one of the notches.

[51] In a preferred implementation, each bag 300 is a freezer grade bag made of FDA rated plastic and intended only for single use so as to keep the milk from contamination caused by any residuals of old milk and eliminate laborious cleaning. The preferred dimensions of the bag body are 4.25 inches by 3 inches, and the dimension of the neck is 5.0 inches in length. The capacity of each bag is 4-8 ounces, which is the average production amount for a nursing mother. However, other dimensions may be used as one of skill in the art would understand.

[52] Like breastfeeding, pumping is a learned skill. Most mothers are able to express only a few drops of milk when they first try a breast pump. Sometimes if mothers don't see milk immediately after beginning pumping, they start to pump harder or increase the suction with the mistaken idea that more pressure will "pull" the milk out. Doing this can cause discomfort and anxiety and actually discourage the let-down response. The invention is simple and easy to use so that the mother will intuitively become efficient at pumping without much practice and knowledge of how the breast works. In addition, many working mothers have no option but to pump in their offices or in a restroom. The privacy of using a conventional breast pump and the effect of the ambient air on the safety of the breast milk are at issue.

[53] As generally illustrated in Figures 20A and 20B, a user just inserts a one-way valve 140 (if made as a separate component) into the hole in the flange 30 as a cap on the splint/bag. Otherwise, if the valve 140 is manufactured to be an integral part of the flange 30, then the user just then proceeds with inserting the "splint" 110 (the wave-shape guiding means) into neck 310 of a disposable collection bag 300. The splint 110 serves to keep the neck 310 of the bag fluid-passable as it passes underneath the bottom edge of the bra. The sub-assembly is inserted into the outlet 70 of the housing 12 at the bottom of the flange 30 and the breast pump 10. With the sub-assembly in place, the cup 115 of the splint 110 fixedly connects to the outlet of the one-way valve 140.

[54] There is no need for the mother to undress herself in order to use the breast pump of the invention. In contrast, all the prior art requires a user to undress herself so as to use the pump.

[55] After inserting the splint 110 into the housing shell 12, the user can insert the entire pump 10 with the sub-assembly of the splint 110 and collection bag 300 underneath her clothing and against the her breast. The inlet hole 50 is positioned over the breast so as to cover and surround the nipple and thereby catch the expressed breast milk. Alternatively, the user can insert the pump 10 underneath the clothing first, then insert the sub-assembly of the splint 110 and the collection bag 300.

[56] In at least one embodiment, the insertion of the sub-assembly may be designed to act as an activation switch for the operation of the pump 10. Alternatively, either the slide button 16 or the push button 20 may be used as the activation switch, or a combination of the slide button 16 or the push button 20 in conjunction with the insertion of the sub-assembly. In an even further embodiment, the servomotor mechanism 24 may be activated by an initial movement of the switch 16 resulting from the insertion of the sub-assembly.

[57] When a collection bag is filled or when the user is finished using the pump 10, the splint 110 along with the bag 300 is removed from the pump 10, but with the one-way valve 140 left in place to keep the outlet 70 plugged thereby prevent any milk from dripping out of the outlet 70. Upon removal of the sub-assembly, in one embodiment, contact between the sub-assembly and a switch of the servomotor mechanism 24 is severed which turns off the pump 10. As mentioned, the vacuum chamber 60 is air-tight and isolated from outside air turbulence. Such a design not only maintains the privacy of the user but keeps the pump from contacting any outside air contaminants.

[58] With respect to the adjusting means 14 (See Figure1A, 1B and 3), the pumping rate is controlled via a microprocessor 90 which reads the user inputs from the switch slide button 16 and the push button 20 for the vacuum level and the cycling rate, respectively, so as to power the servomotor mechanism 24 accordingly. The servomotor mechanism 24 in turn activates the rear-piston lever-arm system 100 to create a stroke action toward and away from the breast in accordance with the desired settings. When the appropriate time has passed, the microprocessor 90 will reverse the motor system to allow the flange 30 to return to its natural state. As noted above, the stroke action is programmed to mimic the natural suck-hold-release-relax cycling of a nursing baby according to the age of the baby. The present invention applies mimicking the baby's suckling movements to trigger a nursing mother's natural reaction to produce milk. The pumping rate in the present invention may be controlled and/or programmed to mimic both the nutritive and non-nutritive suckling actions of the a baby, which have distinctly different cycling characteristics.

[59] According to a controlled study of a seven-month-old baby boy, the suck-hold-release-relax cycle starts with a series of non-nutritive sucks at low vacuum levels with a high suckling rate as the suckling pulses depicted in Figure 21A. The non-nutritive suckling rate typically is higher than nutritive suckling; in this example, the non-nutritive suckling exceeded 100 cycles/min while nutritive suckling was 30 - 60 cycles/min. The peak vacuum level of each suck increases until reaching a threshold for milk expression (the first and second nutritive sucks) then holds longer on the threshold (152 mmHg, in this case) than non-nutritive sucks with no plateau but mere a peak. The plateaus exhibit distinct flatness to hold the threshold vacuum level of each cycle. The holding period (in the plateau) is about 2-3 times of the relax period (drop from the plateau).

[60] Figure 21B shows a second example illustrating a steady-state post-ejection reflex action. Essentially, the baby has achieved a rhythm in suckling. Figure 21C illustrates the threshold vacuum level decreasing with the cycle rate increasing. In this example, the baby is finishing feeding and/or tiring. Overall, the study reveals that the holding and releasing timing of a baby suckling is not symmetrical. Depending on the baby, there may be rapid transitions between holding and releasing periods. In the present invention, the microprocessor 90 is programmed to mimic the natural suck-hold-release-relax cycling of a nursing baby along the lines of the results of the study.

[61] The microprocessor 90 may be programmed to suggest or control the vacuum level and the cycle rate. In one preferred embodiment, the microprocessor 90 is programmed with artificial intelligence so as to mimic the natural suck-hold-release-relax cycling of a nursing baby as discussed. Each stroke of the breast pump of the present invention has a definite holding period, which is about 2 - 3 times the relaxation period. As depicted in Figures 22A and 22B, the cycle profile is designed to be consistent regardless of the maximum vacuum level or the cycle rate settings.

[62] In particular, the suction level starts at a minimum at the beginning for a new nursing mother, and then some quick, short pulses at the start of the pumping to especially stimulate and imitate more closely the way a baby initiates breastfeeding. Once the milk is flowing freely, long steadier strokes are initiated so as to be effective and less tiring. Since each woman has a different comfort level, the level may then be gradually increased to what is comfortable for her. The pumping mechanism supports a cycle rate up to 80 cycles per minute, which is higher than most of the other portable breast pumps (25-60 cycles/minute). However, the preferred cycle rates range from 35-60 cycles per minute which balances the efficiency and the comfort of the user. The most preferred cycle rate (45 cycles/minute) takes less than one-quarter second to fully vacuum the chamber 60 and incurs minimum noise.

[63] This stroke action creates a vacuum on the order of 200 mmHg in the flange 30 while the one-way valve 140 seals off the opening. As shown in Figures 22A and 22B, when the maximum vacuum level is set at 136 mmHg, the matching cycle rate is 39 cycles/min. when the maximum vacuum level is set at 204 mmHg, the matching cycle rate is 36 cycles/min. Vacuum control circuitry is provided for allowing manual adjustment of the level of vacuum generated by the electric pump means. This is accomplished by controlling the stroke length of the servomotor mechanism. In another embodiment of the invention, some residual vacuum is programmed in the stroke profile.

[64] In another variation of the invention, a flow sensor may be connected with the adjusting means 14 to monitor the suckling results of the stroke actions.

[65] In contrast, the commercially available products simply operate under mathematics profiles rather than a natural baby suckling profile as the present invention. For example, the characteristics of one inexpensive, mass-produced double pump set allows manual control as well as residual vacuum as shown in Figure 23. However, it operates with excessive tissue stress due to its slow vacuum rise profile. In addition, it operates terribly inefficient at 7 cycles/minute, which takes 8 seconds to

reach the full vacuum level of 220 mmHg. Other conventional high-end double pump sets operate according to the profiles such as those shown in Figures 24A and 24B which are within appropriate vacuum levels (180-200 mmHg) at an appropriate cycle rate range of 47-53 cycles/ min. Nevertheless, such systems have no holding periods, but instead release their vacuums immediately upon reaching full vacuum. One popular battery powered portable pump as shown in Figures 25A and 25B operates with appropriate holding periods (1-1.4 seconds) and releasing periods (0.9 second), but dragging along a slowly increasing profile from vacuum levels 100 to 270 mmHg at inefficient cycle rate range of 27-29 cycles/ min. Such a profile yields long periods of stress on the breast to reach a excessively high vacuum level of 270 mmHg.

[66] Studies and experience have shown that young breastfed babies usually need to nurse every 2-3 hours, and that it is best to pump on the same schedule. The more the breasts are stimulated, the more milk is produced. A good time for many mothers to pump is about one hour after the baby's first morning feeding. Most women tend to have more milk earlier in the day. The length of time spent pumping varies with each woman and with each day. When pumping one side at a time, alternating breasts several times during expression is more stimulating and can result in a higher volume of milk. Pumping at one side of the breast and nursing on the other side has the advantage of using the body's natural response to let down the milk for the baby.

[67] The microprocessor 90 of the present invention may be programmed to suggest or control the timing for pumping. For example, using two pumps 10 simultaneously can cut the total pumping time in half. Double pumping may also result in better stimulation of prolactin due to its sense of balance provided to a nursing mother. In a double pump arrangement, the adjusting mechanism 14 of each pump may be linked by hardwire connection or by wireless link to coordinate or synchronize their strokes via the microprocessor 90.

[68] A commercial implementation of the portable breast pump system of the invention as shown would include two breast pumps 10, a pair of valves 140 and splints 110, and a roll of collection bags. All of those components would be stored in a soft sided black shoulder bag 400 (Figure 26) having two storage compartments, the upper compartment 403 includes a working surface for storage of the pumps on its breast pump holders 409, 409', the accessories, and complete instructions; and the lower compartment 405 includes heat-insulating side walls and at least one cooling element 407. The cooling element 407 is formed with concave seats for receiving collection bottles or bags. The closeness of the walls hold the collection bags next to

the cooling element surfaces. The portable breast pump system of the invention would weigh only about 2 lbs., rather than the 8 - 10 lbs. of other commercially available portable breast pump system, or even then 25-40 lbs. of those used in hospitals. The cooler is available from Rubbermaid® (Blue ICE Model No. 1056). The shoulder bag 400 may be manufactured by companies such as California Innovation® with synthetic fabric surfaces which are easy to wipe clean. The aggregate weight of the cooler and the shoulder bag is approximately 2.5 lbs.

[69] Parts of the pump such as the collection bags 300 are sterilized to FDA's hygienic standard for rubber articles before the first use, while other parts that come into contact with the mother's skin or the milk will need to be sterilized before first use. After initial use, only the flange 30, the valve 140 and the splint 110 need to be washed in warm, soapy water, rinsed with hot water and drained on a clean towel. However, periodic boiling for sterilization may be desirable, depending on the individual needs of the baby.

[70] In summary, the breast pump of the present invention provides several unique features. As noted above, various parts of the system are made of plastic materials so as to be lightweight, easy to clean/maintain and easily conform with the contour of the user's breast (Figures 20A and 20B). Working moms can thus easily pump their milk and save it for the babysitter or daycare. The breast pump of the invention has very few parts so as to be easily assembled and cleaned. The overall system of the present invention also results in a breast pump smaller than commercially available breast pumps such as Hollister's Purely Yours™ Kit, i.e. about 1/4 size of other portable (the shoulder bag actually is 70% smaller) and Medela's Pump in Style system.

[71] The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However, the invention which is intended to be protected is not limited to the particular embodiments disclosed. The embodiments described herein are illustrative rather than restrictive. Variations and changes may be made by others, and equivalents employed, without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the spirit and scope of the present invention as defined in the claims, be embraced thereby.

WHAT IS CLAIMED IS:

1. A portable, hands-free and visually friendly breast pump for facilitating breast-pumping, comprising:

a dome-shaped housing having a servomotor mechanism;

a hat-shaped flange having a chamber portion, a brim portion and an outlet, the chamber portion being formed so as to be placed over a nipple on a breast so as to define a chamber between the flange and the breast, and the brim portion being formed to surround the nipple and thereby form a suction seal therebetween; and

a one-way venting element formed to operatively communicate with the chamber so as to vent pumped milk from the chamber via the outlet, wherein

the servomotor mechanism is operatively connected to the chamber portion of the flange so as to induce a pumping motion onto the chamber portion and create vacuum in the chamber to thereby pump milk from the breast, the chamber being sealed via the vacuum except at the outlet, and

the housing, the flange and the venting element are connected into an integral device held against the breast and underneath clothing so as to keep the integral device hidden.

2. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a guiding means operatively connected to the one-way venting element for guiding the pumped milk into a container.

3. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the outlet of the flange has the funnel shape.

4. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a flange support for preventing overshooting of strokes towards the flange, said flange support is fixed in place by fitting snuggly around a base of the flange.

5. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the hat-shaped flange is integrally formed from an elastic material.

6. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the dome-shaped housing further includes therein a portable power supply.

7. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism of the housing flange is operatively connected to the chamber portion of the flange so as to impart an alternating stroking action onto the chamber portion, whereby the chamber portion generates an air displacement and vacuum alternating motion that mimics suckling movement of a baby.

8. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the guide means includes a flexible guide element that extends from the integral device to a container and that is flexibly positionable so as to operatively connect the integral device to the container whereby the integral device, the guide element and the container are maintained against the breast and under the clothes.

9. A portable, hands-free and visually friendly breast pump system according to claim 8, wherein the guide element includes an elongated, flexible splint having a wave-form shape in a transverse direction of the splint.

10. A portable, hands-free and visually friendly breast pump system according to claim 9, wherein the guide means further include a cup head to be connected to the outlet, said cup head is connected with the wave-form splint with at least one hole at the bottom of the cup head for the milk to leak through to the wave-form splint.

11. A portable, hands-free and visually friendly breast pump system according to claim 10, wherein the cup fits snugly into the outlet under an upward sliding force so as to be air-tight while guiding the milk out of in the chamber.

12. A portable, hands-free and visually friendly breast pump system according to claim 2, wherein the container is a collection bag.

13. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag is formed from a thin, synthetic, leak-proof material.

14. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the container is a collection bag having a neck for snugly receiving the guiding means so as to allow leakproof flow of milk via the guiding means into the bag while maintaining operative contact with the guiding means.

15. A portable, hands-free and visually friendly breast pump system according to claim 14, wherein the neck of the collection bag has two sealed edges in a V-shape to make the neck spell-proof after being pressed.

16. A portable, hands-free and visually friendly breast pump system according to claim 11, wherein the container is a collection bag having a neck, and the cup has an extruded rim for covering on an edge of the neck thereby sealing the neck and going against pressure created by any clothing covering the breast pump.

17. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag is printed with a graduation scale to show the amount of milk collected in the bag.

18. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a control means for controlling operation of the servomotor mechanism.

19. A portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means includes means for controlling at least one of a cycle rate and a vacuum level of the servomotor mechanism.

20. A portable, hands-free and visually friendly breast pump according to claim 19, wherein the control means includes at least one variable switch on the housing.

21. A portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means includes a microprocessor.

22. A portable, hands-free and visually friendly breast pump according to claim 21, wherein the microprocessor controls the pump to mimic the natural suck-hold-release-relax cycling and force of a nursing baby.

23. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism is formed from one of an electric motor and a tethered hand pump device.

24. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism is located outside the housing.

25. A portable, hands-free and visually friendly breast pump according to claim 24, wherein the servomotor mechanism is connected to the housing with an adapter.

26. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism includes an electric motor, a lever arm operatively connected to the electric motor, and a rear piston operatively positioned to move linearly by the lever arm so as to press on a top of the flange toward the breast thereby pressing the air out of the chamber to create the vacuum on withdrawal.

27. A collection bag for collecting and storing breast milk obtained through a portable breast pump system, comprising:

a collection chamber; and

a receiving neck connected to the collection chamber for receiving breast milk to be stored in the collection chamber.

28. A collection bag according to claim 27, wherein the collection bag is formed from a thin, synthetic, leak-proof material.

29. A collection bag according to claim 27, wherein the neck is formed for snugly receiving a guiding element through which breast milk flows to be collected.

30. A collection bag according to claim 27, wherein the neck is formed for self-sealing after the breast milk has been collected.

31. A collection bag according to claim 27, wherein the collection chamber is printed with a graduation scale to show the amount of milk collected in the bag.

32. A collection bag according to claim 27, wherein a plurality of collection bags are formed together in a roll adjacent one of the plurality of collection bags being formed with perforations therebetween so as to facilitate separation of individual collection bags.

33. A carrying case for transporting a portable breast pump system, comprising:

a first storage compartment having a flat horizontal panel therein so as to provide a portable working surface for a user to manipulate components of the breast pump system; and

a second storage compartment having insulated walls and a cooling element for storing containers of the collected breast milk.

34. A carrying case according to claim 33, wherein the second storage compartment has concave seats for receiving the containers.

35. A miniature servomotor mechanism for a portable breast pump system, comprising:

a pump element for generating a cyclical pumping motion;

a lever arm operatively connected to the pump element;

a piston operatively positioned to move linearly by the lever arm so as to impart an alternating stroking action via the lever arm; and

an elastic chamber portion of the portable breast pump system operatively connected to the piston, wherein the alternating stroking action of the piston generates a displacement and vacuum alternating motion in the chamber portion.

36. A miniature servomotor mechanism according to claim 35, wherein the pump element is formed from one of an electric motor and a tethered hand pump device.

37. A portable, hands-free and visually friendly breast pump according to claim 36, wherein the servomotor mechanism is located outside the housing.

38. A miniature servomotor mechanism according to claim 35, further comprising: a power supply including at least one battery.

39. A method for stimulating milk expression by mimicking a baby's suckling movements with a breast pump on a breast of a nursing mother to trigger the nursing mother's natural reaction to produce milk.

40. A method according to claim 39, wherein the baby's suckling movements include at least one non-nutritive suck and at least one nutritive suck.

41. A method according to claim 40, wherein the non-nutritive suck incurs at a vacuum level lower than a threshold suckling level of the nutritive suck.

42. A method according to claim 40, wherein the non-nutritive suck occurs at a cycle rate exceeding 60 cycles/min.

43. A method according to claim 41, wherein threshold vacuum level of the nutritive suck is 70-220 mmHg.

44. A method according to claim 41, wherein the threshold suckling level of the nutritive suck remains consistent for at least twice as long as a releasing time from the threshold vacuum level.

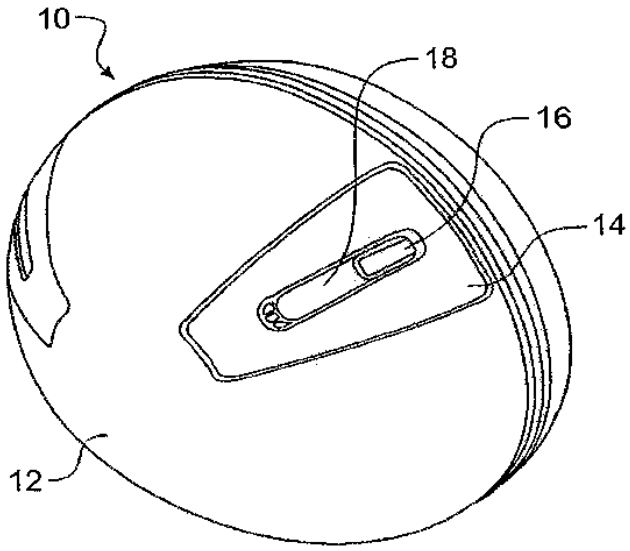


FIG. 1A

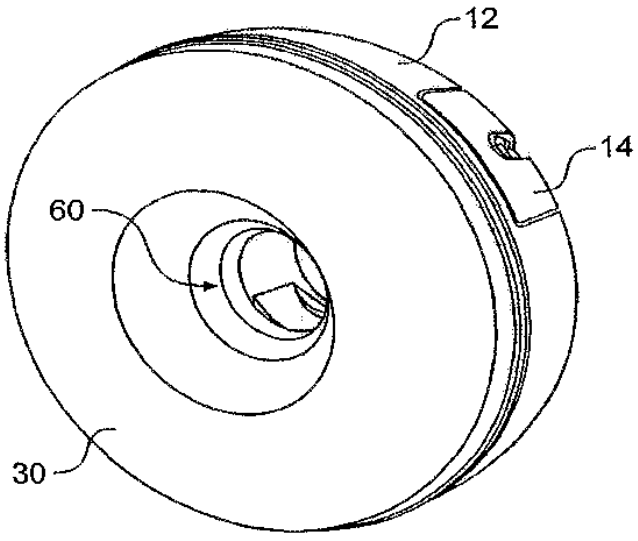


FIG. 1B

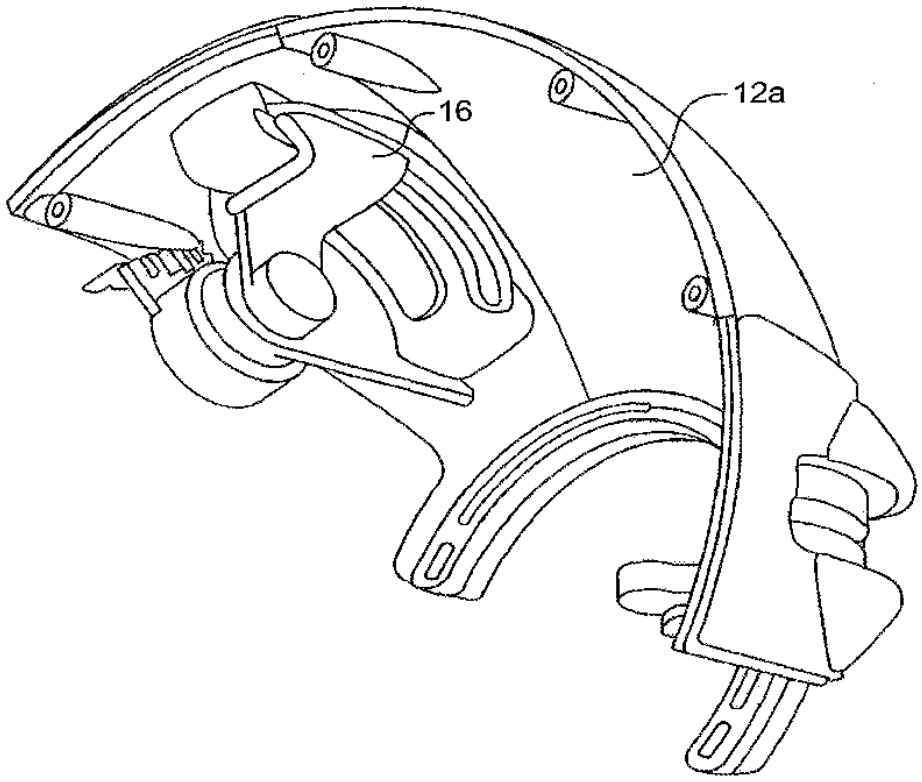


FIG. 2

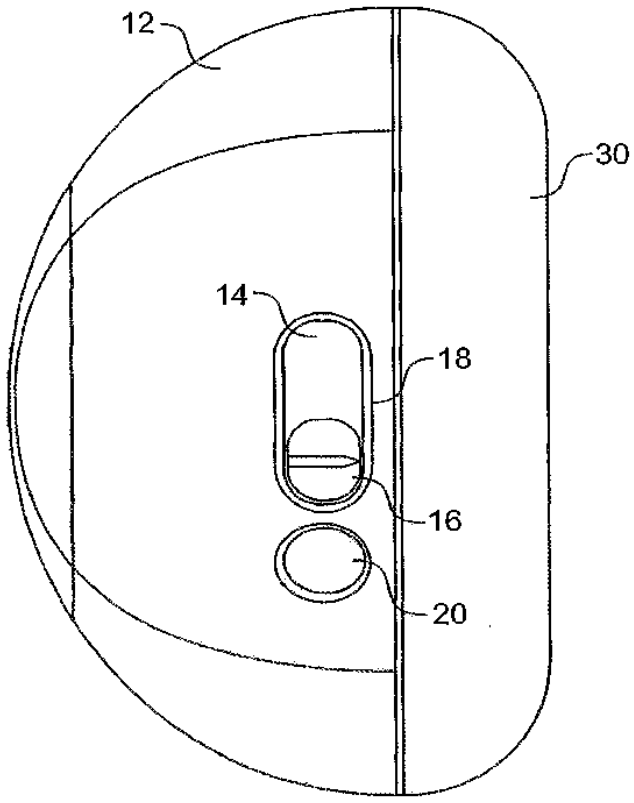


FIG. 3

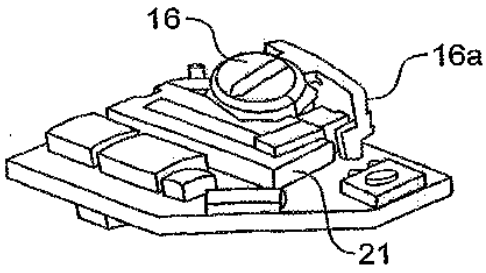


FIG. 4

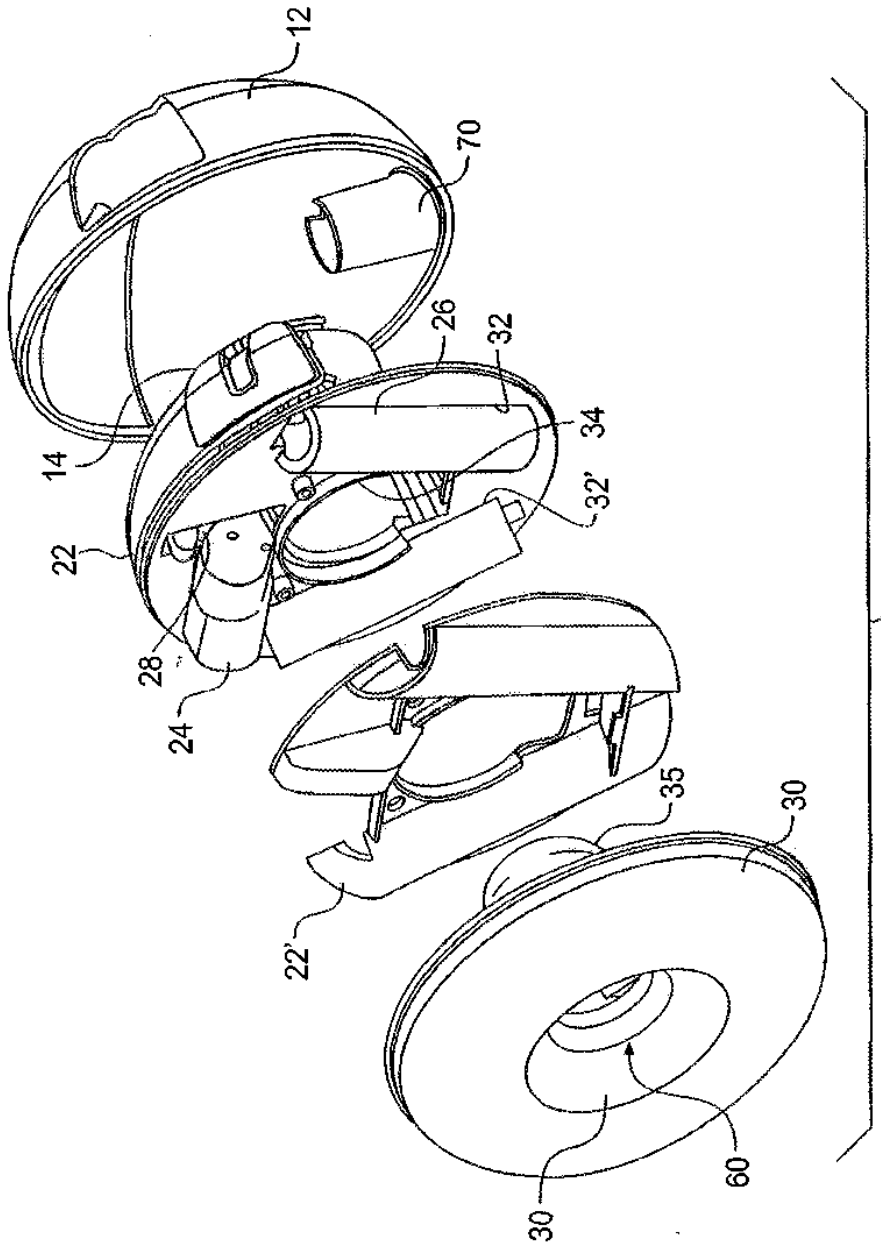


FIG. 5

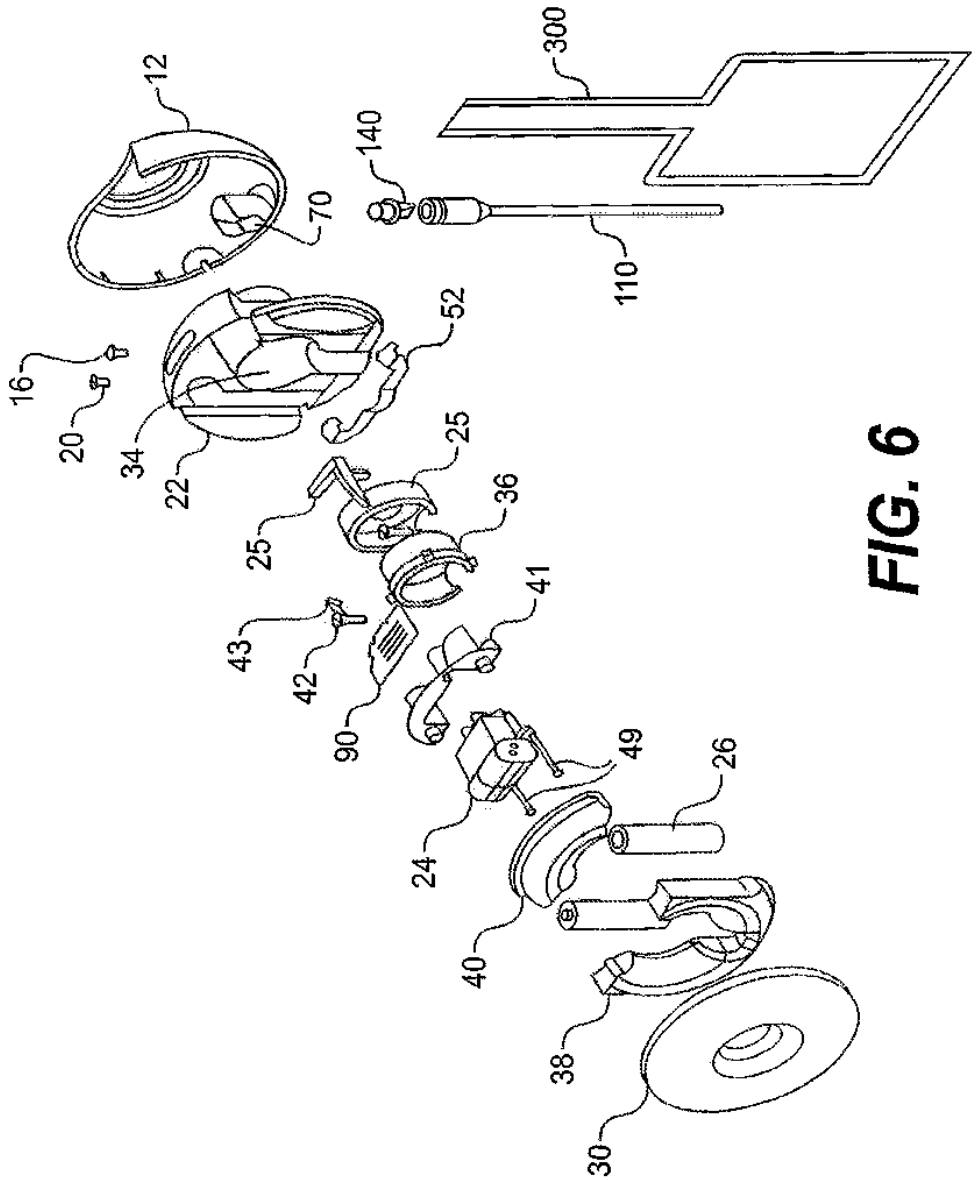


FIG. 6

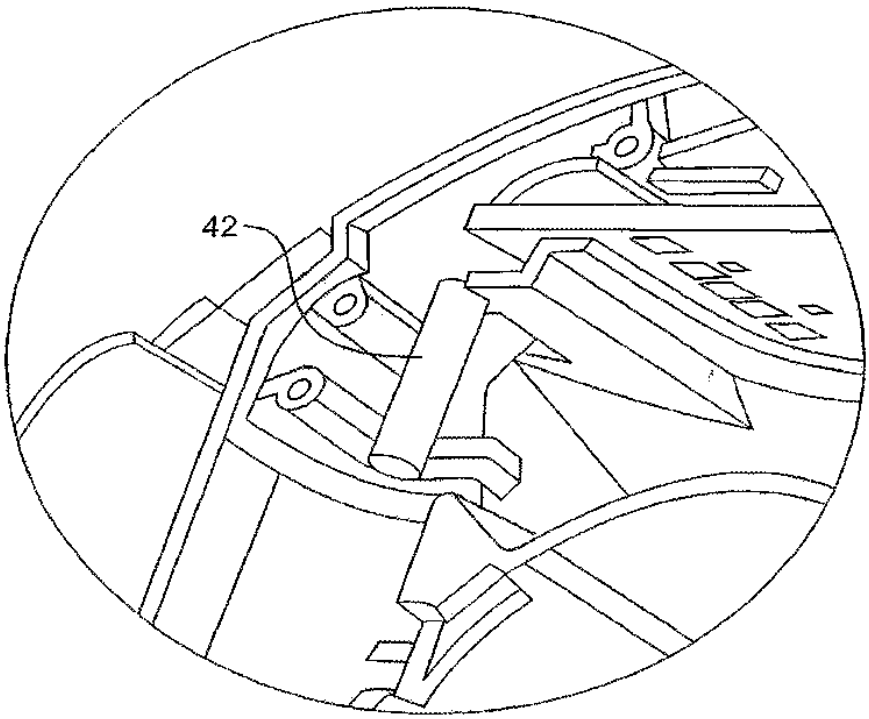


FIG. 7

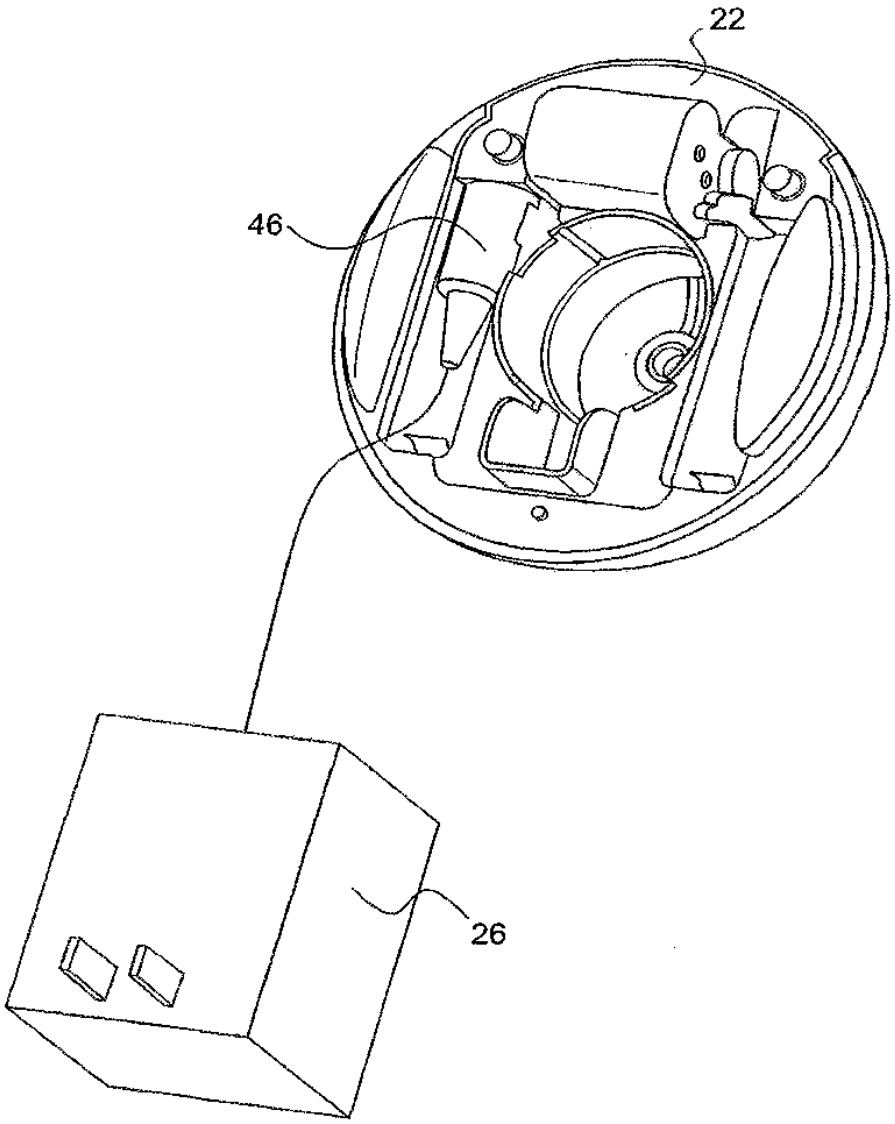


FIG. 8A

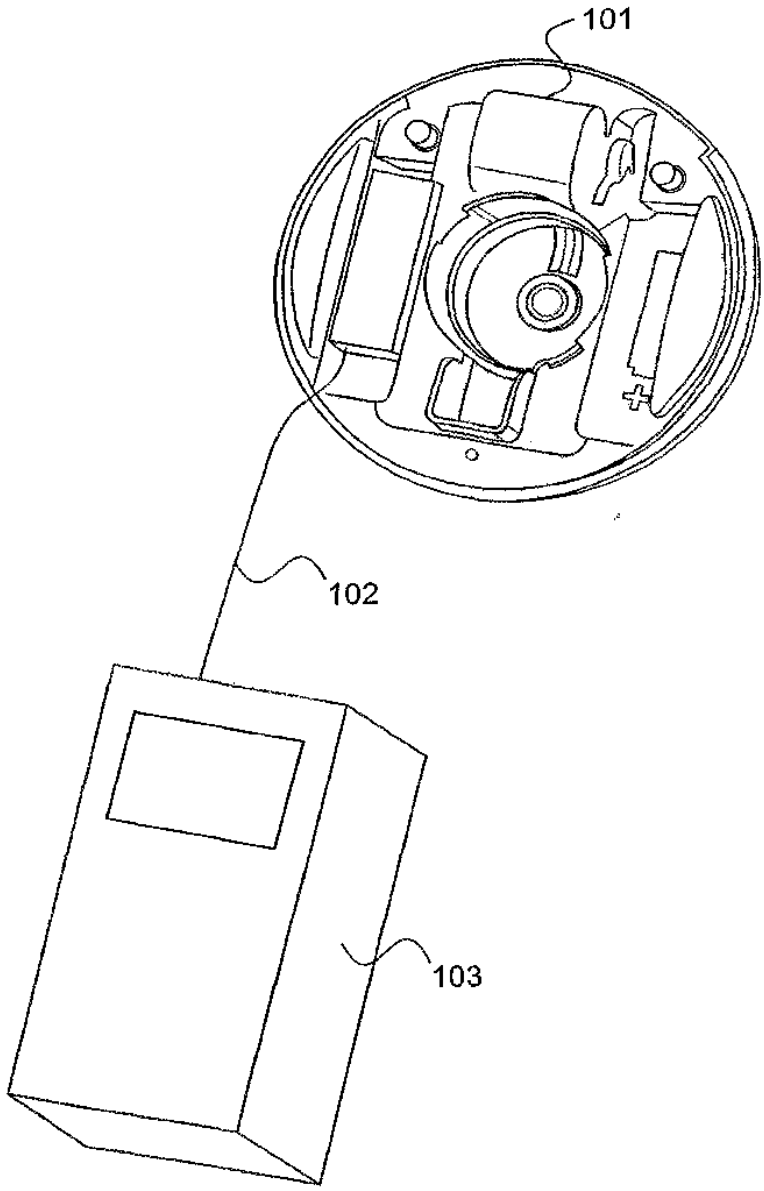


FIG. 8B

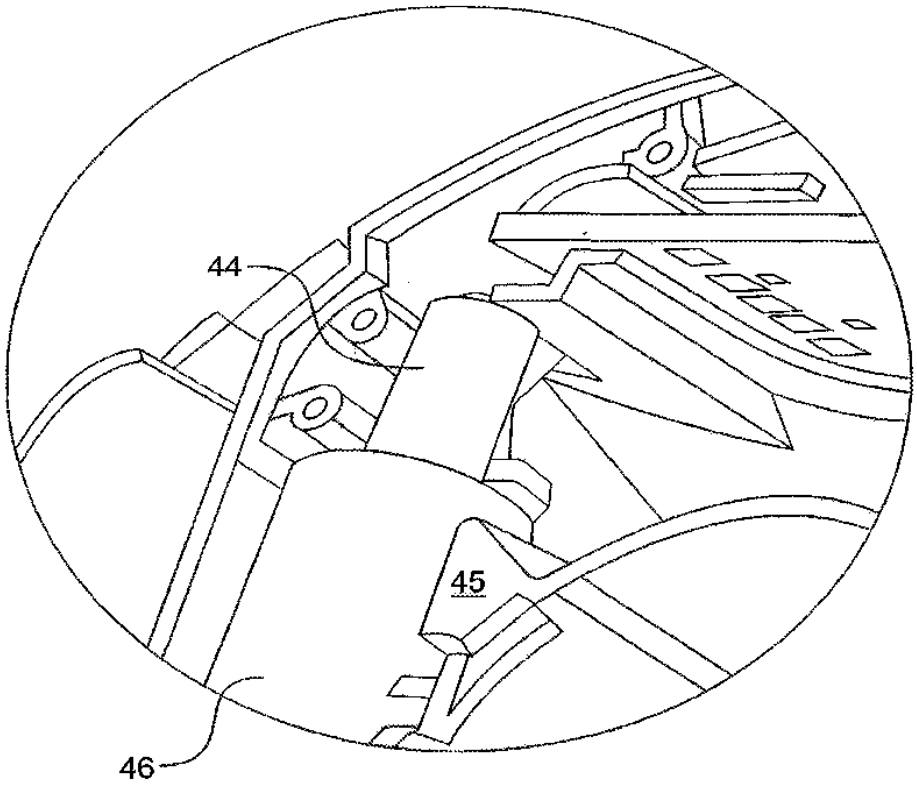


FIG. 9

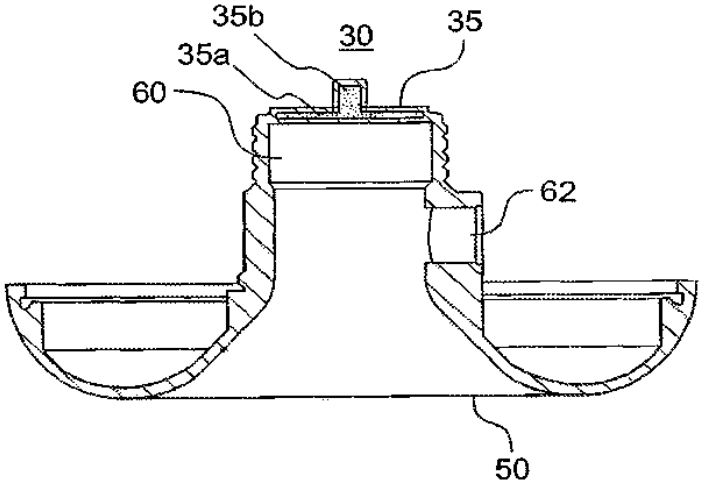


FIG. 10A

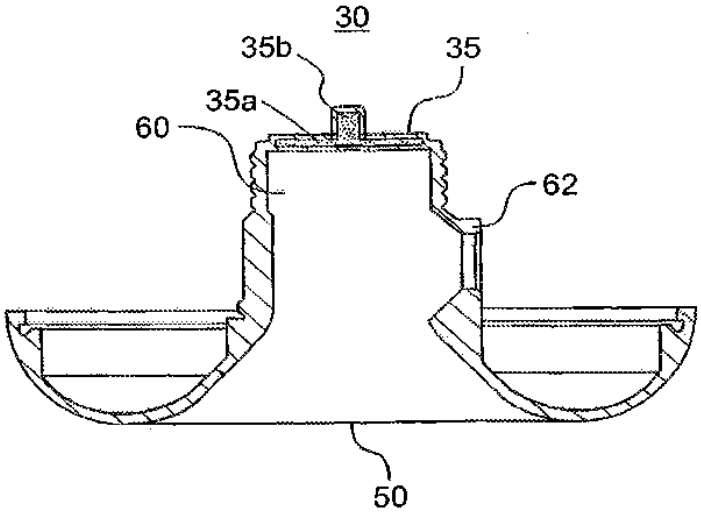


FIG. 10B

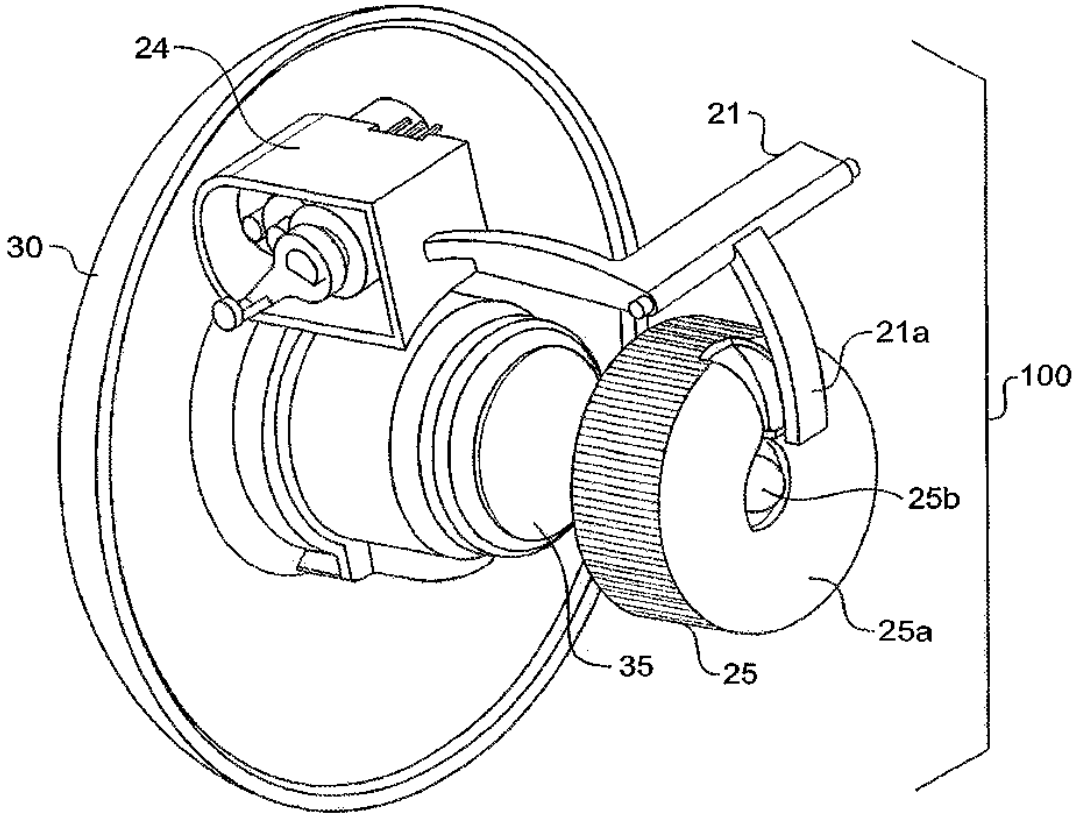


FIG. 11A

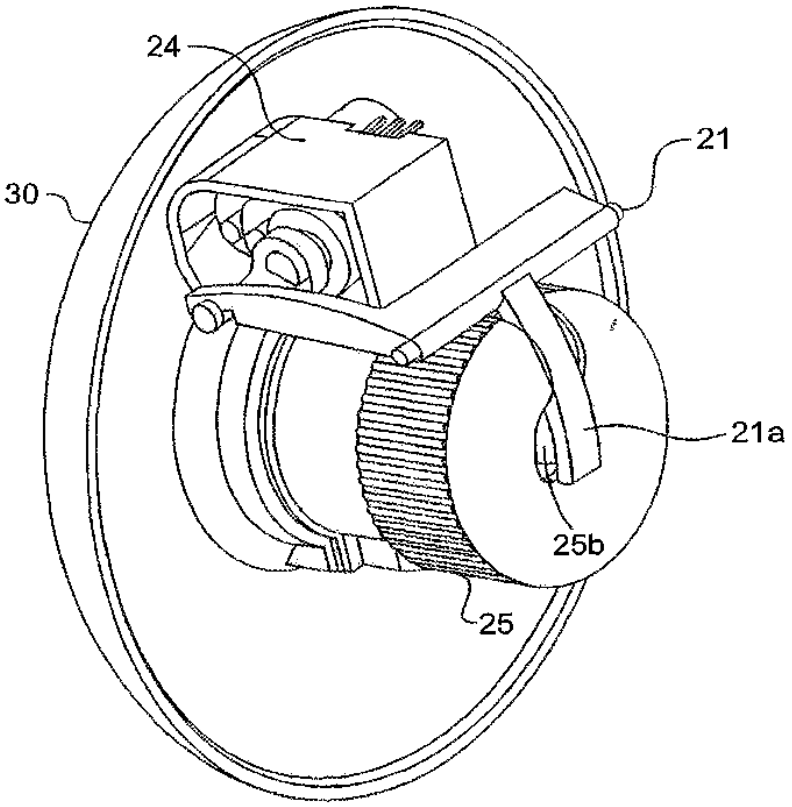


FIG. 11B

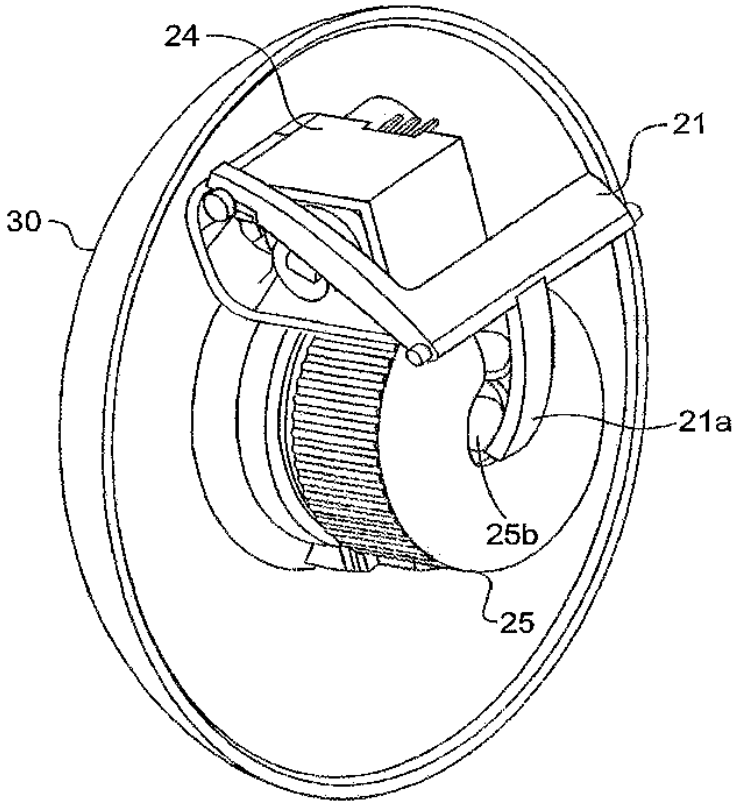


FIG. 11C

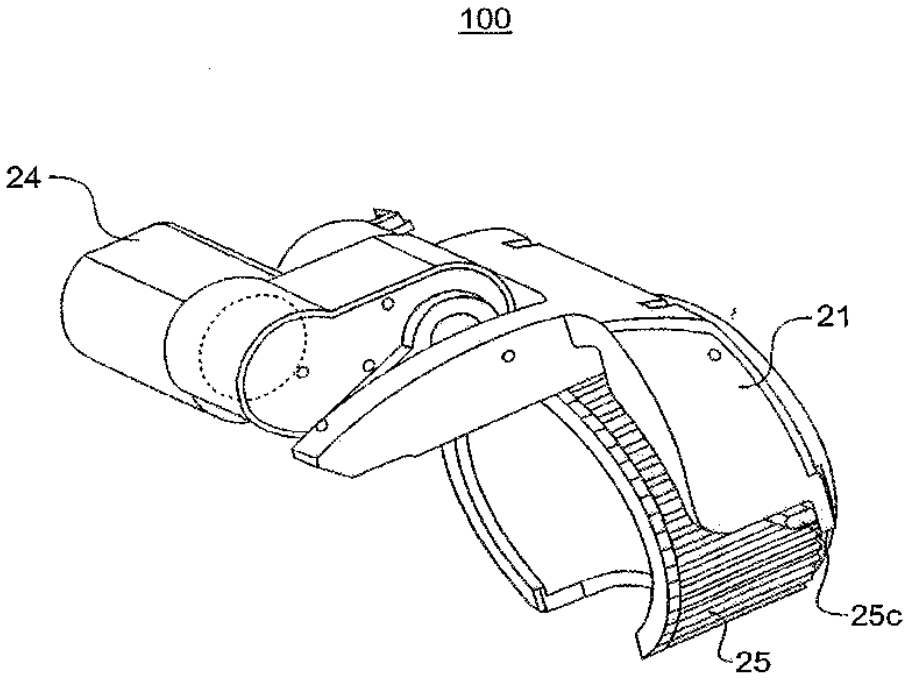


FIG. 12

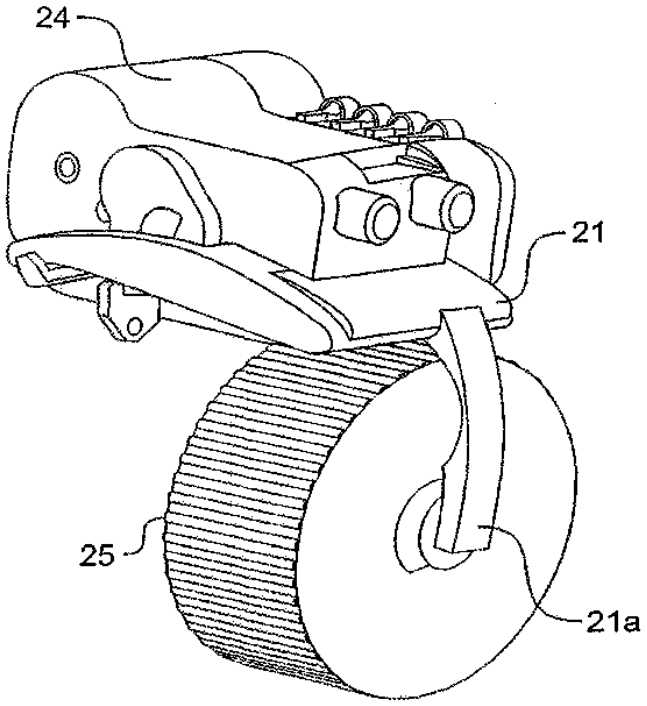


FIG. 13

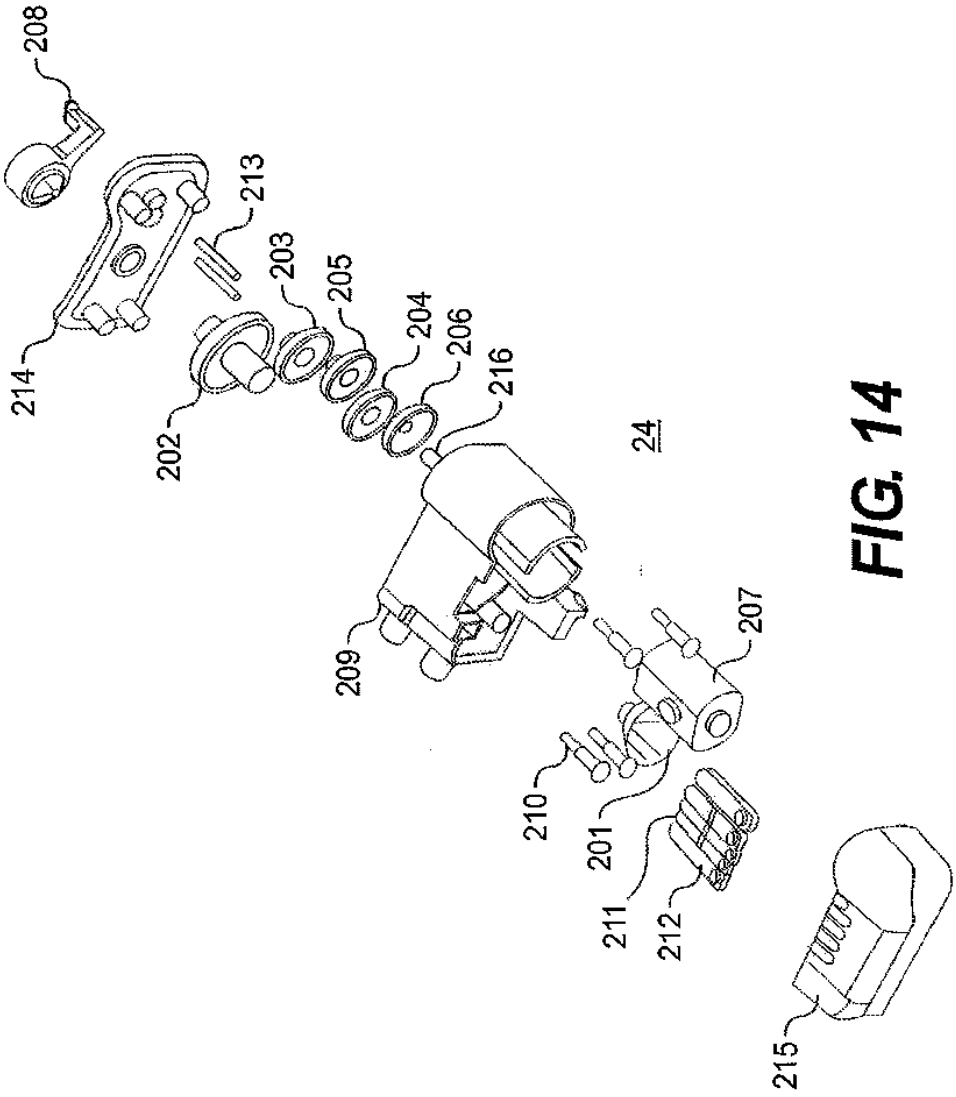

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FIG. 14

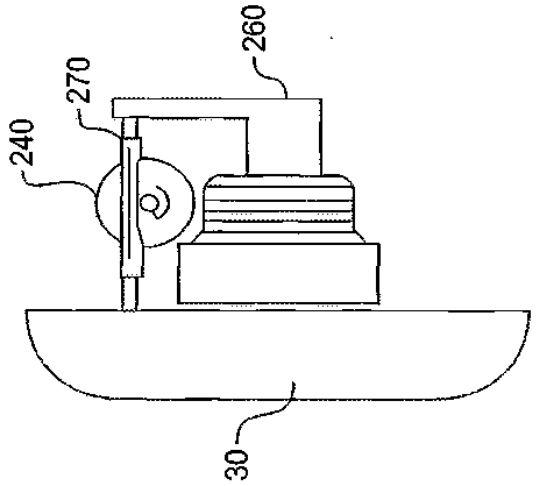


FIG. 16

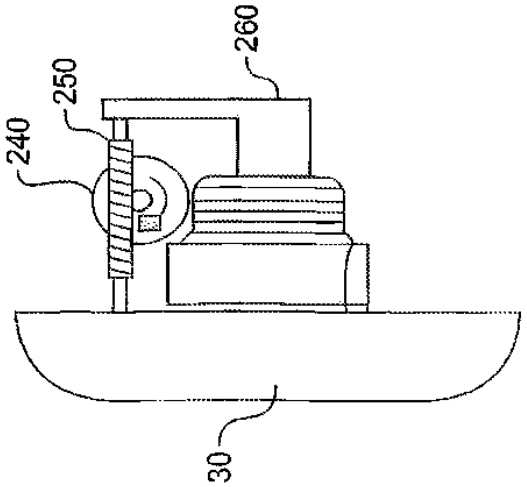


FIG. 15

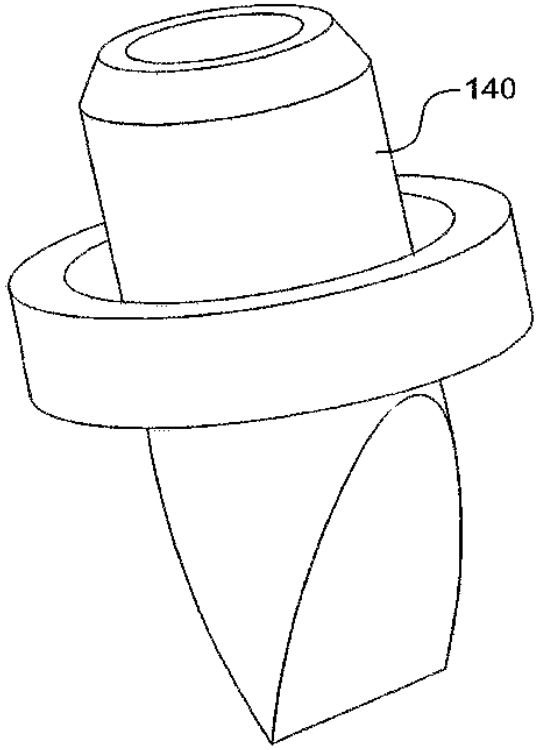


FIG. 17

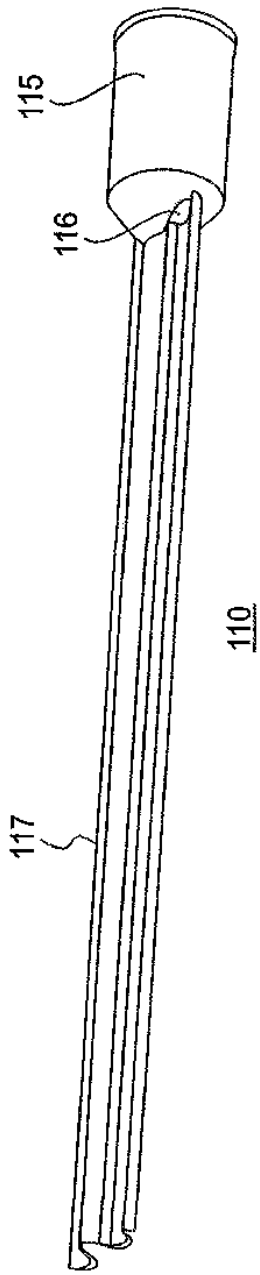


FIG. 18A

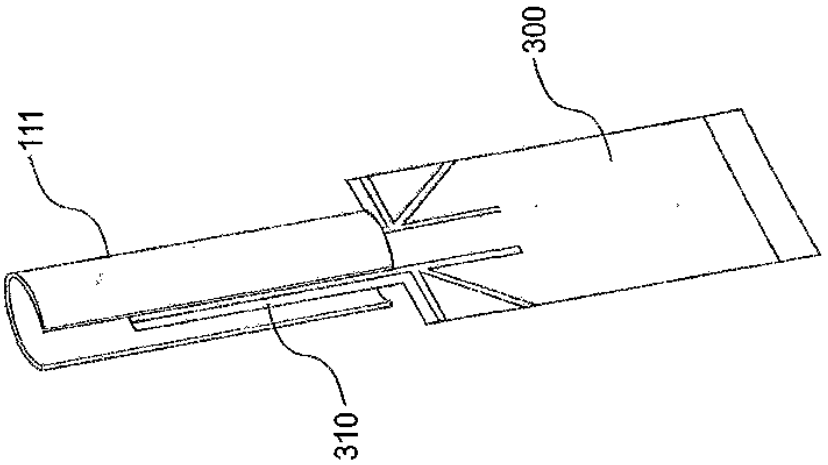


FIG. 18B

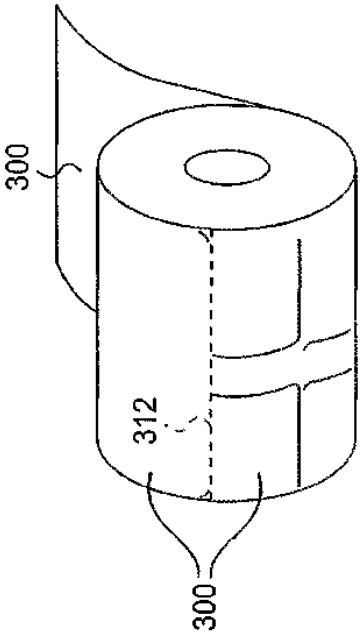


FIG. 19B

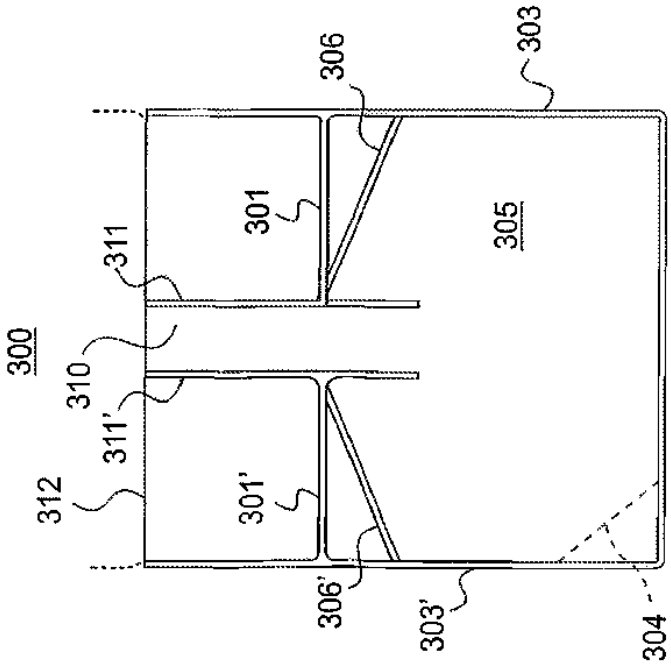


FIG. 19A

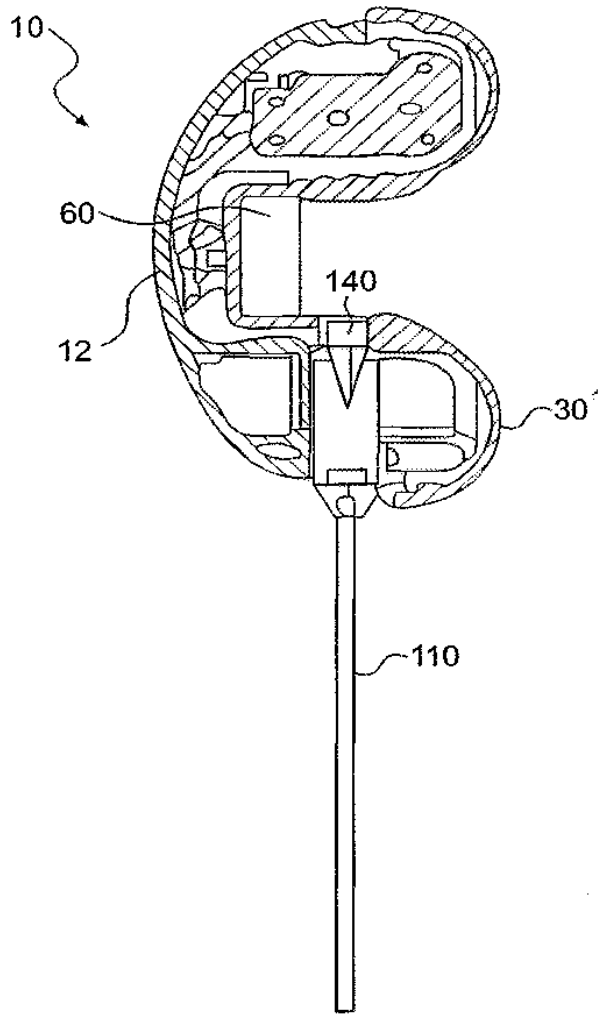


FIG. 20A

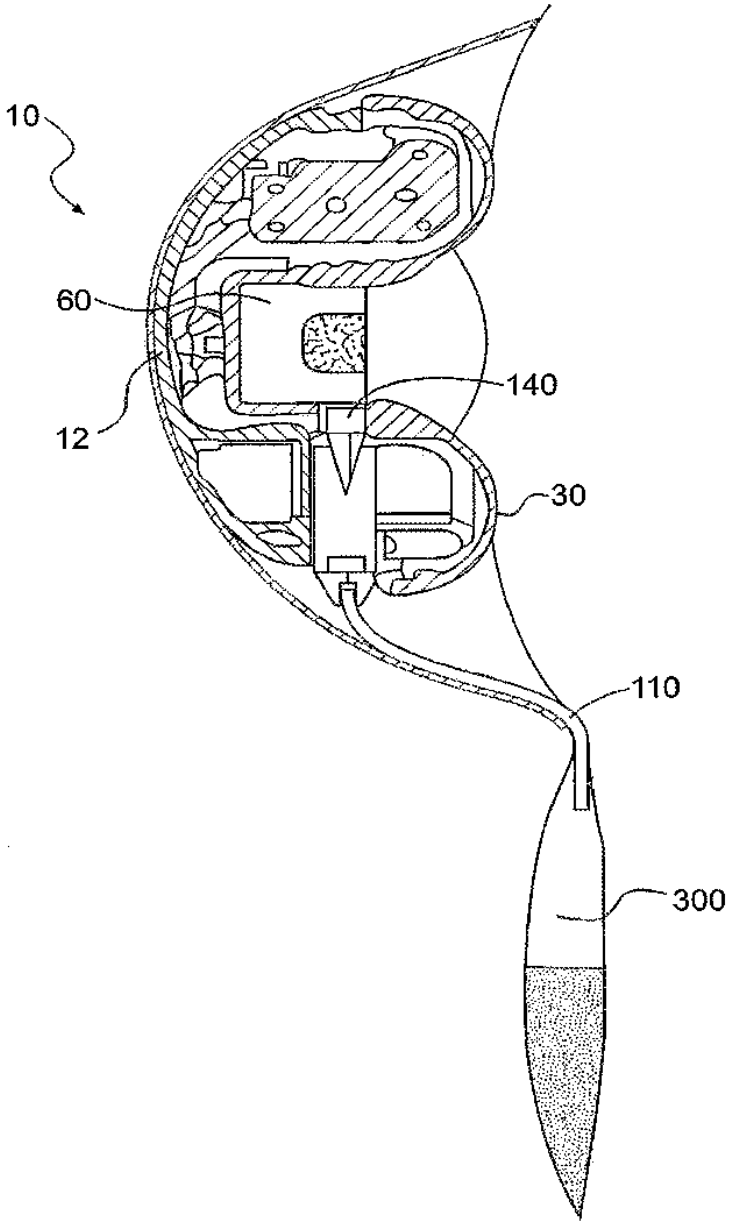


FIG. 20B

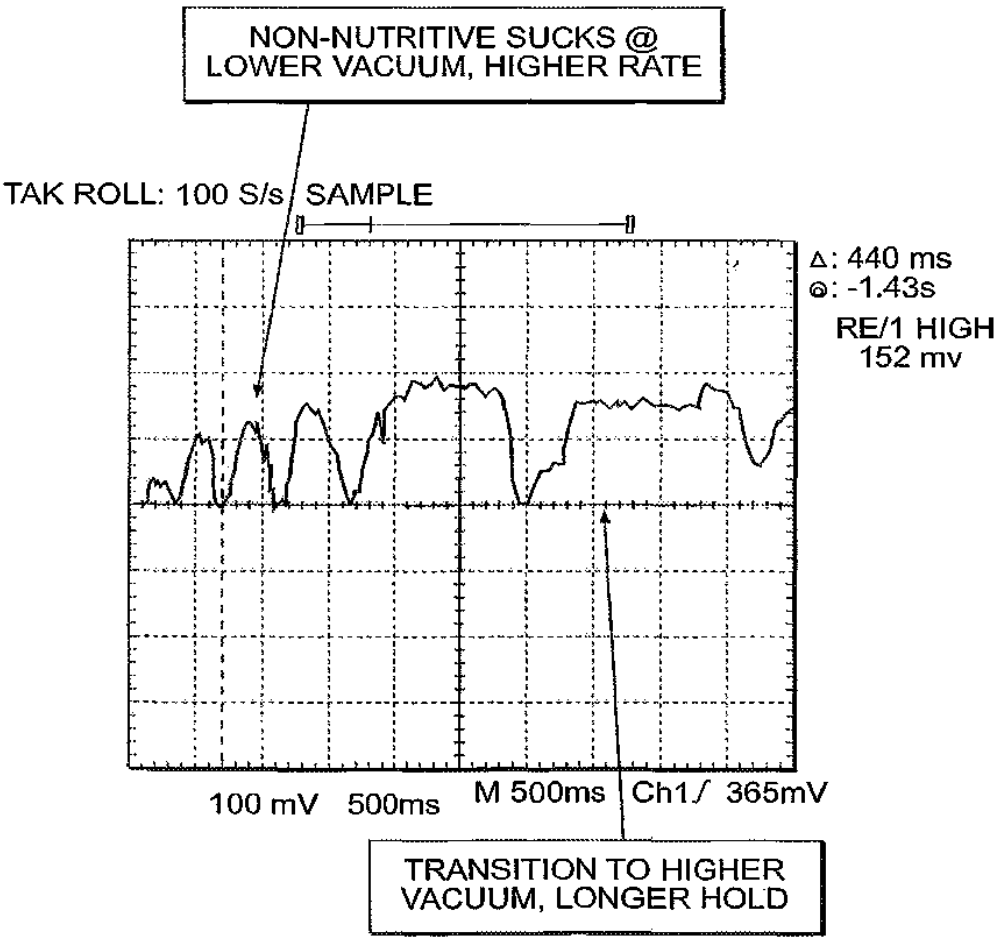

NON-NUTRITIVE SUCKS @
LOWER VACUUM, HIGHER RATE
TAK ROLL: 100 S/s SAMPLE
Δ: 440 ms
@: -1.43s
RE/1 HIGH
152 mv
100 mV 500ms
M 500ms Ch1 365mV
TRANSITION TO HIGHER
VACUUM, LONGER HOLD

FIG. 21A

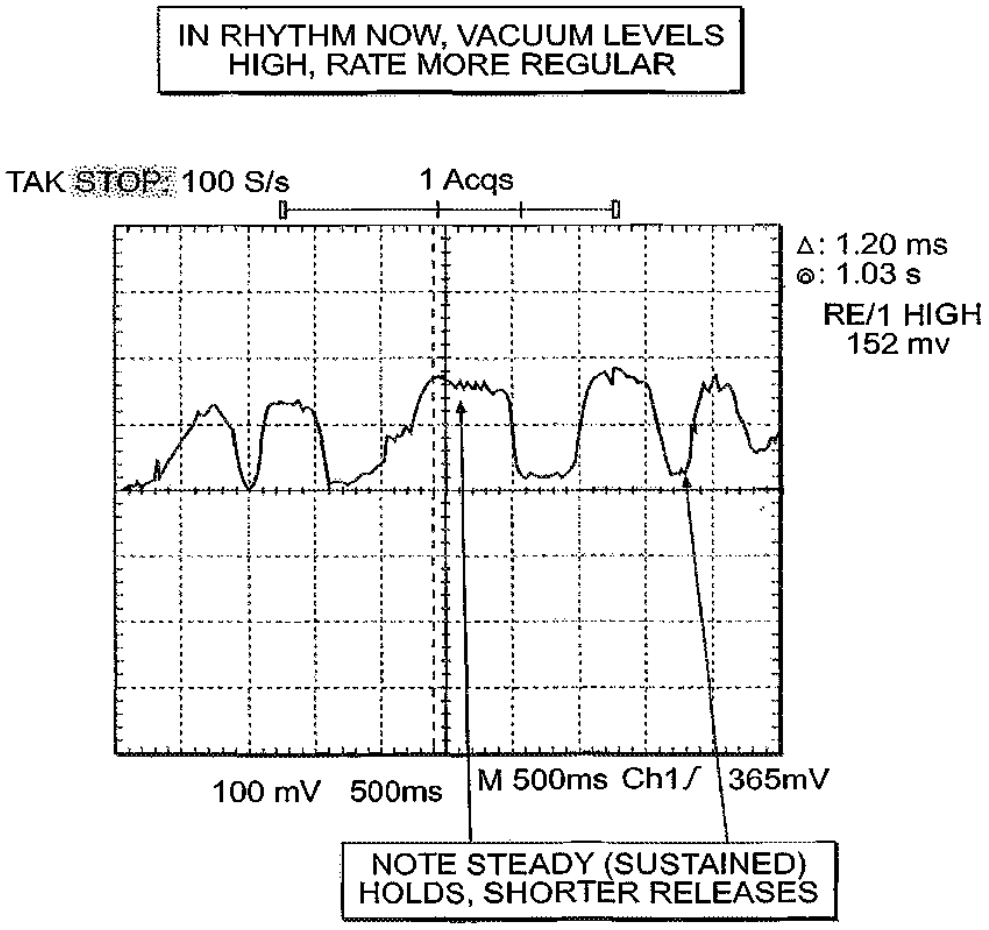

IN RHYTHM NOW, VACUUM LEVELS HIGH, RATE MORE REGULAR
TAK STOP: 100 S/s
1 Acqs
Δ: 1.20 ms
@: 1.03 s
RE/1 HIGH
152 mv
100 mV 500ms
M 500ms Ch1 365mV
NOTE STEADY (SUSTAINED) HOLDS, SHORTER RELEASES

FIG. 21B

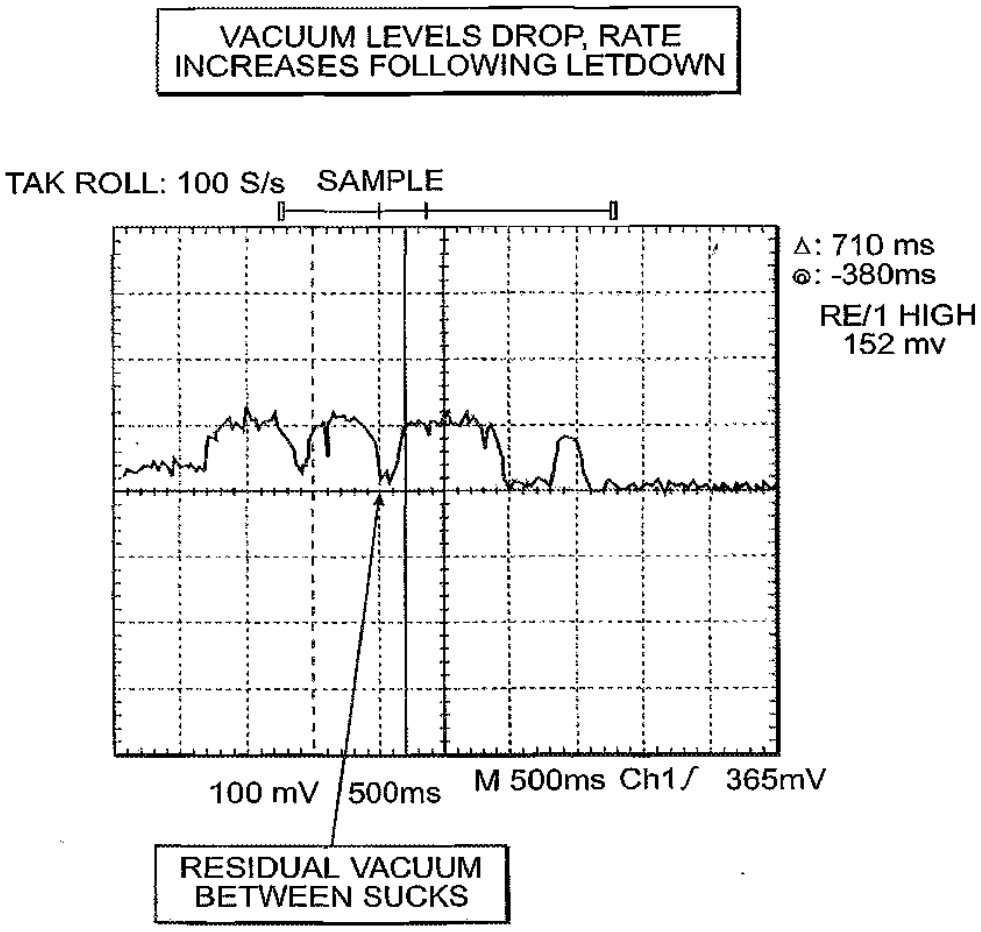
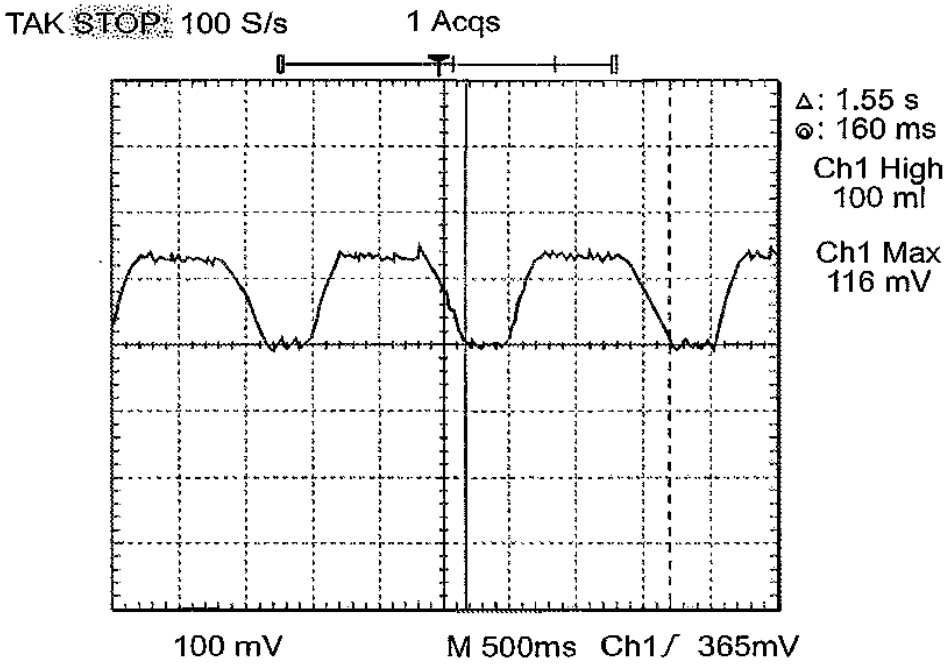
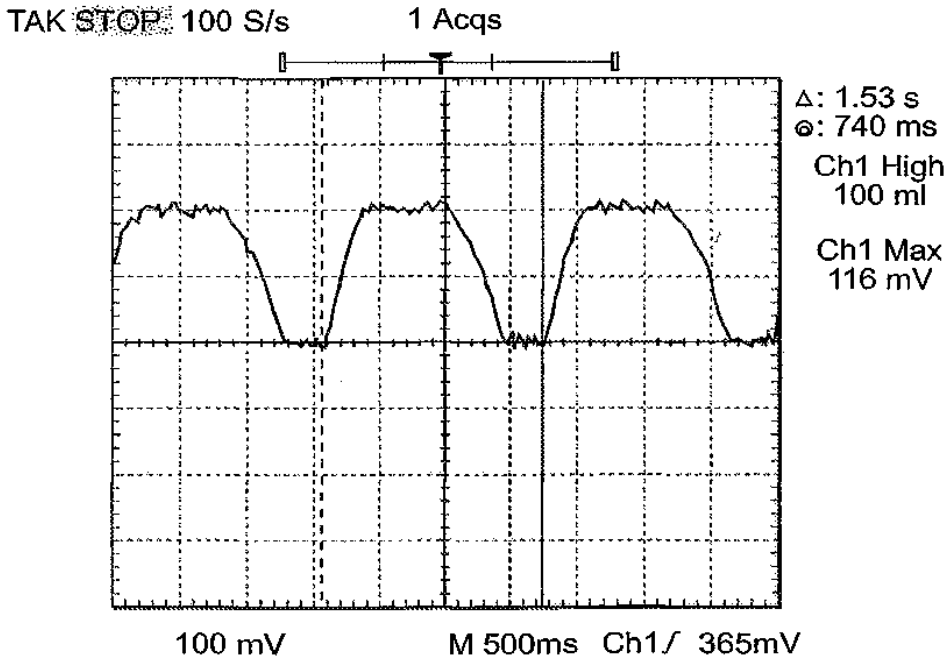

VACUUM LEVELS DROP, RATE INCREASES FOLLOWING LETDOWN
TAK ROLL: 100 S/s SAMPLE
Δ: 710 ms
@: -380ms
RE/1 HIGH
152 mv
100 mV
500ms
M 500ms Ch1 365mV
RESIDUAL VACUUM BETWEEN SUCKS

FIG. 21C



Max Vacuum (mmHg):	136
Rate (cyc/min):	39

FIG. 22A



Max Vacuum (mmHg):	204
Rate (cyc/min):	36

FIG. 22B

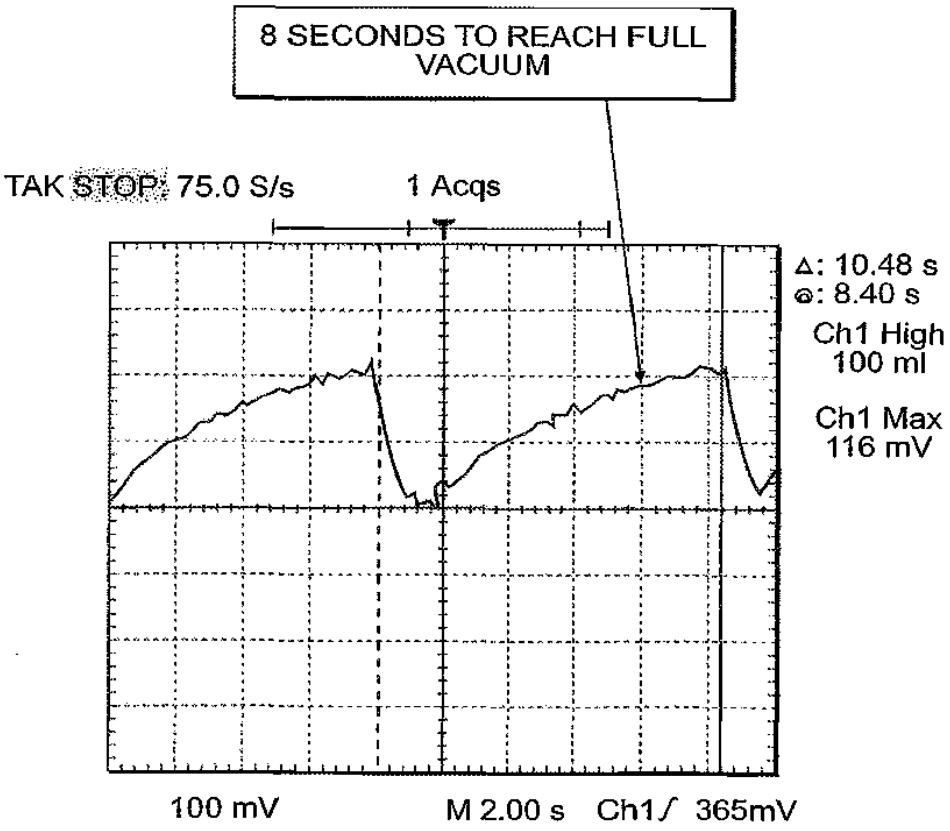


FIG. 23
PRIOR ART

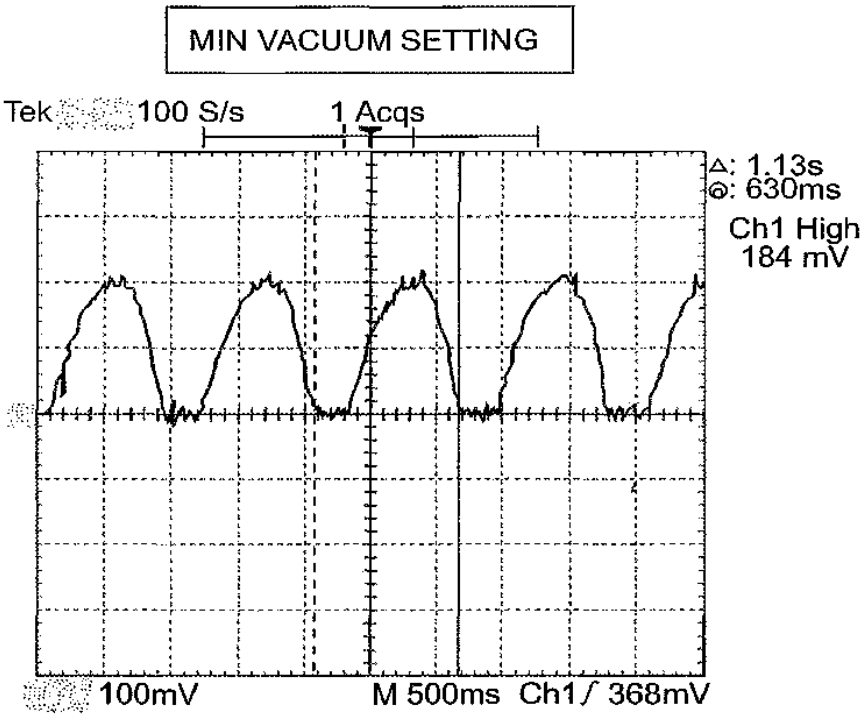


FIG. 24A
PRIOR ART

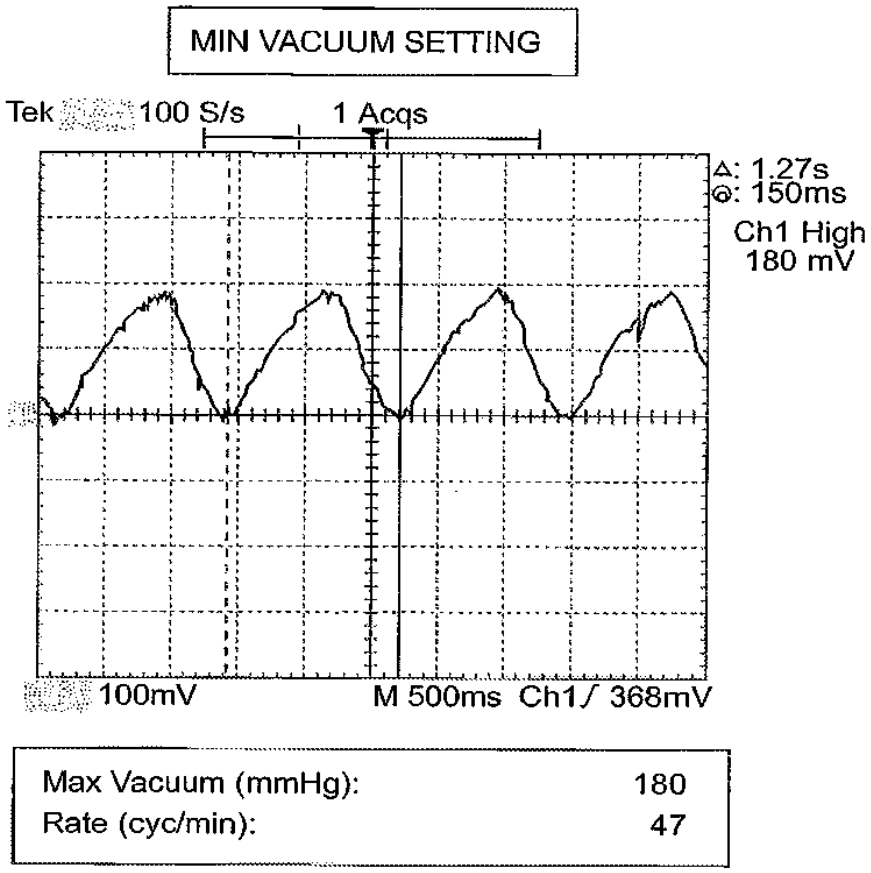
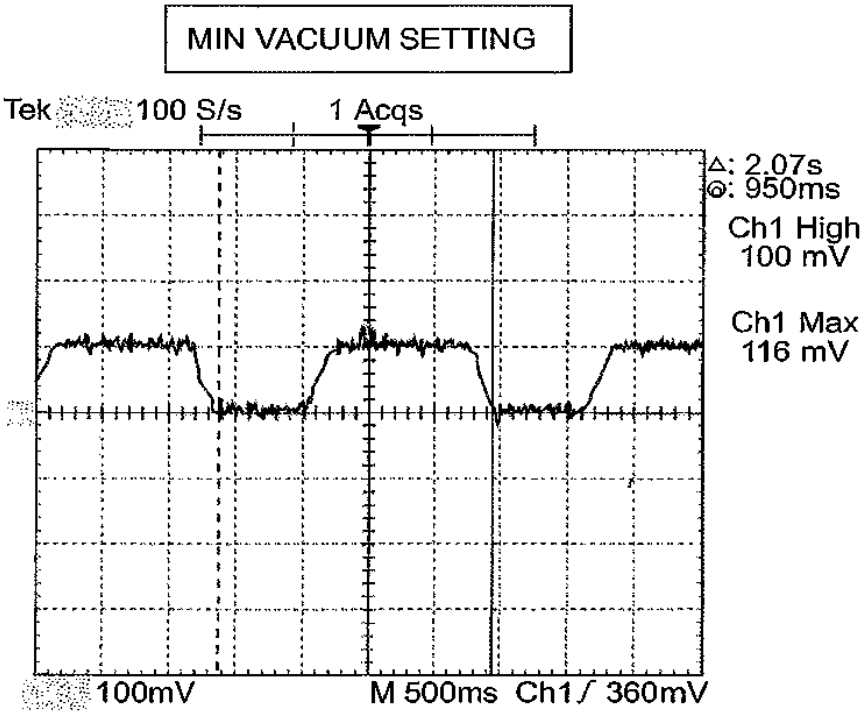


FIG. 24B
PRIOR ART

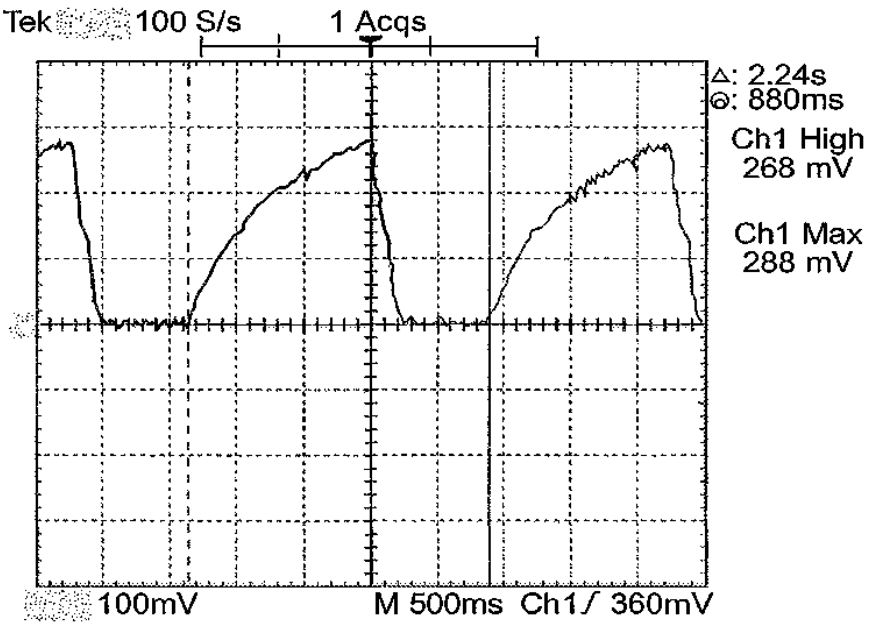


Max Vacuum (mmHg):	100
Rate (cyc/min):	29
>100 mmHg Hold (sec):	1
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Min
Cycles:	N/A

FIG. 25A
PRIOR ART

MAX VACUUM SETTING



Max Vacuum (mmHg):	270
Rate (cyc/min):	271
>100 mmHg Hold (sec):	1.4
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Max
Cycles:	N/A

FIG. 25B
PRIOR ART

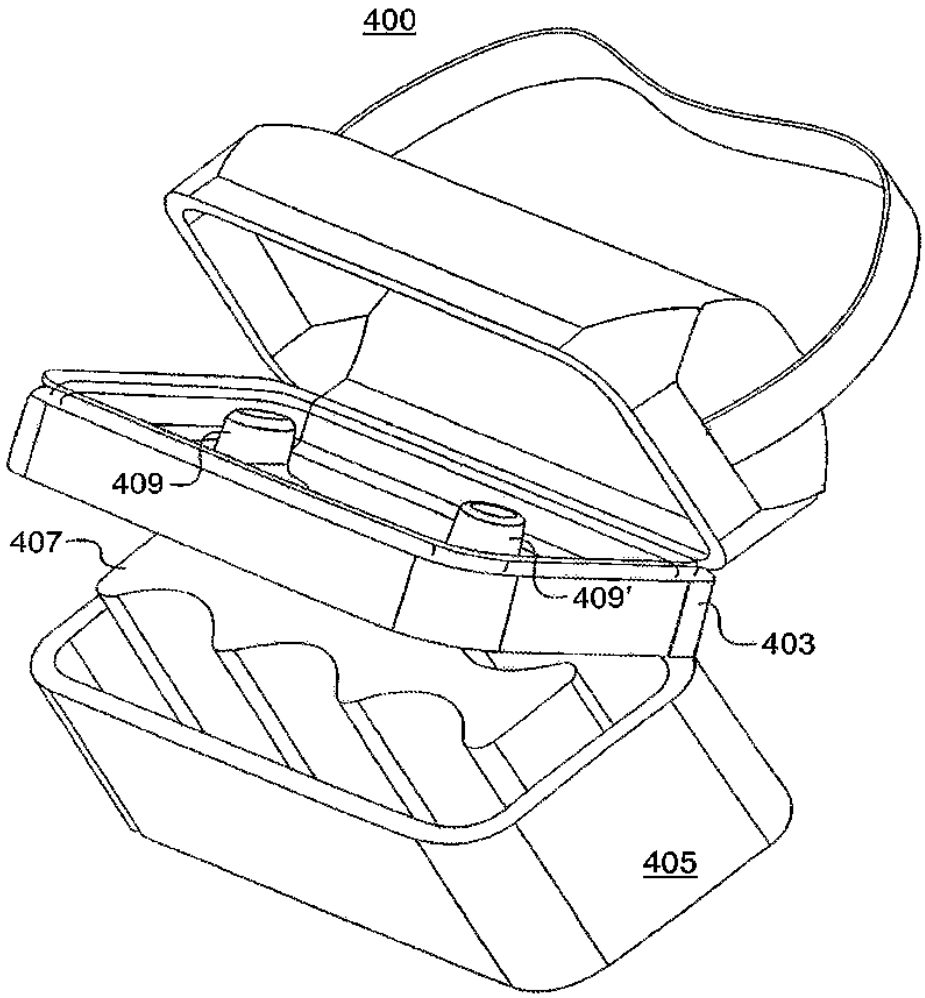


FIG. 26

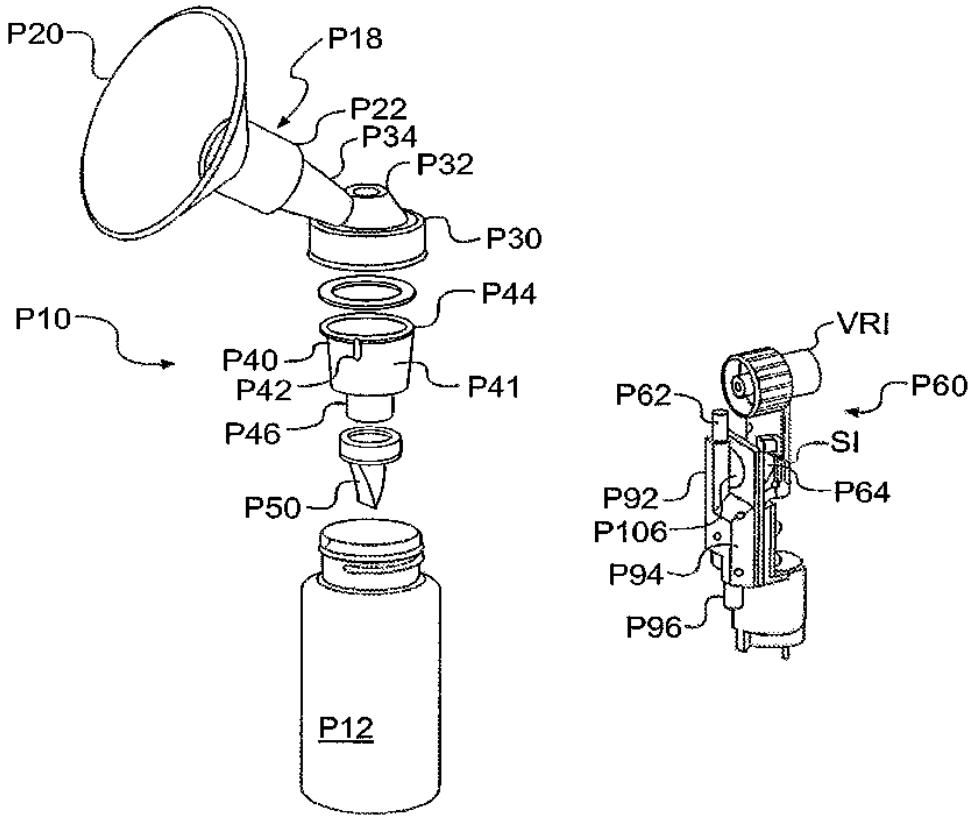


FIG. 27
PRIOR ART

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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(54) Title: BREASTSHIELD UNIT

(54) Bezeichnung: BRUSTHAUBENEINHEIT

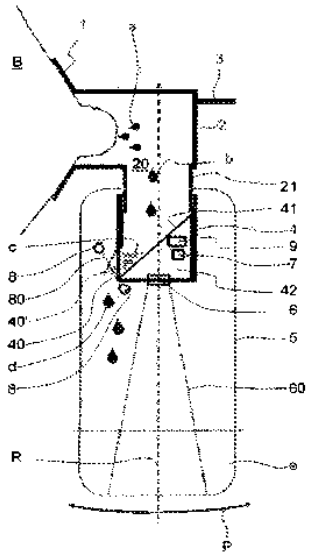


FIG. 1

(57) Abstract: A breastshield unit of a breast pump for expressing human breastmilk has a breastshield (1) to be placed onto a mother's breast, a milk collection container (5) for receiving expressed breastmilk, an adapter (2) for connecting the breastshield (1) to the milk collection container (5), and a valve head (4). A milk channel extends from the breastshield (1) through the adapter (2) and the valve head (4) into the milk collection container (5). The valve head (4) has a valve (40) which closes and opens the milk channel during the expressing action, wherein a fill level sensor (6) for measuring a fill level of the milk collection container (5) is arranged in the valve head (4). The breastshield unit according to the invention allows a fill level to be measured without structurally modifying the breastshield and milk collection container. It also permits data exchange with external information memories and/or information processors.

(57) Zusammenfassung: Eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) auf. Ein Milchkanal erstreckt sich von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5). Der Ventilkopf (4) weist ein Ventil (40) auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5). Die erfindungsgemässe Brusthaubeneinheit ermöglicht eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglicht zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

WO 2018/054758 A1

[Fortsetzung auf der nächsten Seite]

Veröffentlicht:
— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

TITEL

BRUSTHAUBENEINHEIT

TECHNISCHES GEBIET

Die vorliegende Erfindung betrifft eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie einen Ventilkopf einer derartigen Brusthaubeneinheit.

STAND DER TECHNIK

Zum Abpumpen von menschlicher Muttermilch wird auf die Mutterbrust eine Brusthaube aufgesetzt, welche mit einer Vakuumpumpe verbunden ist, um die Brust mit einem zyklisch variierenden Unterdruck zu beaufschlagen. Die abgepumpte Milch gelangt durch einen Milchkanal von der Brusthaube in einen Milchsammelbehälter. Um das Totvolumen beim Abpumpen möglichst klein zu halten, ist ein Milchkanal von der Brusthaube zum Milchsammelbehälter üblicherweise mit einem Rückschlagventil versehen, welches sich für den Einlass der abgepumpten Milch in den Milchsammelbehälter öffnet. Dieses Rückschlagventil ist vorzugsweise an einem Adapter angeordnet, welcher die Brusthaube mit dem Milchsammelbehälter und üblicherweise auch die Brusthaube mit der Vakuumpumpe oder mit einem zur Vakuumpumpe führenden Vakuumschlauch verbindet. Das Rückschlagventil kann auf einem Ventilkopf angeordnet sein, welcher fest oder lösbar mit dem Adapter, auch Kopplungsteil genannt, verbunden ist.

Eine derartige Vorrichtung ist beispielsweise aus WO 2014/161099 A1 bekannt. Die dort beschriebene Brusthaubeneinheit weist einen Durchflusssensor auf, welcher die Veränderung einer Ventilklappe des Rückschlagventils detektiert, so dass Rückschlüsse auf den Durchfluss der Milch von der Brusthaube in den Milchsammelbehälter gezogen werden können.

US 2016/0082166 A1 offenbart einen Adapter mit einem Sensor zur Detektion der Milchproduktion, wobei der Sensor über eine drahtlose Verbindung mit einem mobilen Datenempfänger oder mit der Milchpumpe kommuniziert.

WO 2006/003655 A1 zeigt ein Brusthütchen, welches während dem Stillen eines Babys auf die Mutterbrust aufgesetzt wird. Dieses Brusthütchen ist mit einem Sensor versehen, welches das aus der Brust austretende Milchvolumen misst.

WO 2009/081313 A1 offenbart eine Brusthaube mit mindestens einem Sensor zur Optimierung und Personalisierung des Pumpvorgangs.

Diese Brusthaubeneinheiten sind relativ aufwändig und deshalb kostenintensiv aufgebaut. Da die Brusthauben und Milchsammelbehälter oft jedoch nur einmal oder wenige Male verwendet werden können oder dürfen, sollten sie möglichst kostensparend gefertigt werden können und/oder sie sollten einfach zu reinigen sein.

DARSTELLUNG DER ERFINDUNG

Es ist deshalb eine Aufgabe der Erfindung, eine möglichst kostengünstige Brusthaubeneinheit zu schaffen, welche aber dennoch eine Erfassung der abgepumpten Milchmenge erlaubt.

Diese Aufgabe lösen eine Brusthaubeneinheit sowie ein Ventilkopf mit den Merkmalen des Patentanspruchs 1 bzw. 15.

Die erfindungsgemässe Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube zur Auflage an eine Mutterbrust, einen Milchsammelbehälter zur Aufnahme von abgepumpter Muttermilch, einen Adapter zur Verbindung der Brusthaube mit dem Milchsammelbehälter sowie einen Ventilkopf auf. Ein Milchkanal erstreckt sich von der Brusthaube durch den Adapter und durch den Ventilkopf in den Milchsammelbehälter. Der Ventilkopf weist ein Ventil auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf ein

Füllstandsensor angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters.

Da der Füllstandsensor im Ventilkopf angeordnet ist, lassen sich die Brusthaube, der Adapter und der Milchsammelbehälter kostengünstig ausbilden. Es lassen sich insbesondere Standardteile verwenden. Vorteilhaft ist ferner, dass sich der Ventilkopf so ausbilden lässt, dass er in bereits vorhandenen Brusthaubeneinheiten als Zubehörteil verwendet werden kann. Ein Redesign bekannter Brusthaubeneinheiten erübrigt sich dadurch.

Vorzugsweise ist der Milchsammelbehälter steif oder halbsteif ausgebildet. Vorzugsweise ist er eine Milchflasche, welche nach dem Entfernen des Ventilkopfes, des Adapters und der Brusthaube mit einem Deckel luftdicht verschliessbar ist. Vorzugsweise lässt sich dieselbe Flasche gemeinsam mit einem im Gebrauch aufzusetzenden Sauger als Saugflasche zur Verabreichung der Muttermilch an einen Säugling verwenden.

Durch die Messung des Füllstandes im Milchsammelbehälter wird ein genaues Mass über die tatsächlich zur Verfügung stehende Muttermilch erhalten. Die Messung wird vorzugsweise während des Abpumpens durchgeführt. Die Angabe zum Füllstand wird vorzugsweise während des Abpumpens zeitnah aktualisiert.

Die Messdaten lassen sich als Rohdaten oder als mittels einer im Ventilkopf integrierten Elektronikeinheit bereits ausgewertete Daten an eine Auswerteeinheit und/oder eine Steuerung und/oder eine Anzeige der Brustpumpe weiterleiten. In einer einfachen Ausführungsform zeigt die Brustpumpe diese Daten lediglich an. In anderen Ausführungsformen werden die Daten zusätzlich oder alternativ zur aktuellen oder späteren Steuerung der Pumpe verwendet, z.B. um automatisch von einem Stimulations- in einen Expressionsmodus oder umgekehrt zu schalten. In weiteren Ausführungsformen werden die Daten alternativ oder zusätzlich zur automatischen Veränderung der Pumpparameter oder der Muster der Vakuumkurven verwendet, wobei auch dies je nach Ausführungsform für den aktuellen und/oder für einen späteren Pumpvorgang durchgeführt wird.

Die Rohdaten und/oder die ausgewerteten Daten lassen sich auch an andere Empfänger

senden, beispielsweise an ein Smart Device wie einem Smartphone oder an ein anderes persönliches Gerät der Mutter. Dies erleichtert ihr die Erfassung der Füllstandmenge, auch wenn sie den Milchsammelbehälter nicht sehen kann. Zudem lassen sich die Daten direkt dem Internet, beispielsweise einer Cloud, zuführen, um auch Dritten zur Verfügung zu stehen.

Dank der Messung der Füllstandmenge lässt sich das abgepumpte Milchvolumen bestimmen. Durch Ableitung des Volumensignals lässt sich auch der Milchfluss detektieren.

Vorzugsweise ist der Füllstandsensor ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter befindlichen abgepumpten Muttermilch, d.h. des im Behälter befindlichen Milchsees. Auf diese Weise lässt sich der Füllstand auf einfache Weise messen, ohne dass der Behälter selber mit einem Füllstandsensor versehen werden muss und ohne dass die Milch mit mechanischen Mitteln kontaktiert werden muss.

Als Füllstandsensor eignet sich insbesondere ein Laufzeitverfahren-Sensor, auch TOF Sensor genannt (Time of flight Sensor). Es hat sich gezeigt, dass sich derartige TOF Sensoren zur Füllstandmessung von Milch eignen, obwohl sie beispielsweise für eine Füllstandmessung von Wasser ungeeignet sind.

Der Distanzsensor, insbesondere der TOF Sensor, erlaubt eine Distanzmessung vom Sensor bis zur Füllstandhöhe innerhalb des Milchsammelbehälters. Sofern die Geometrie des Milchsammelbehälters bekannt ist, vorzugsweise wenn zusätzlich der Lagewinkel des Milchsammelbehälters im dreidimensionalen Raum bekannt ist, lässt sich damit der Füllstand und somit das Milchvolumen berechnen.

Wird ein TOF Sensor verwendet, so ist eine optische Verbindung vom Sensor zum gegenüberliegenden Boden des Milchsammelbehälters notwendig. Vorzugsweise ist der TOF Sensor so positioniert, dass er sich auf einer Längsmittelachse des Milchsammelbehälters befindet. Vorzugsweise bildet diese Längsmittelachse eine Rotationssymmetrieachse des Milchsammelbehälters.

In einer einfachen Ausführungsform ist im Ventilkopf lediglich der Füllstandsensor angeordnet, welcher als Parameter den Füllstand der Milch im Behälter misst. Vorzugsweise ist im Ventilkopf jedoch mindestens ein zusätzlicher Sensor, vorzugsweise sind zwei oder mehrere zusätzliche Sensoren zum Messen von weiteren Parametern vorhanden.

Ein derartiger zusätzlicher Sensor ist beispielweise ein Durchflusssensor, welcher den Durchfluss durch das Ventil misst. Dieser Durchflusssensor ist beispielsweise ein optischer Sensor, welcher eine Auslenkung einer Ventilklappe des Ventils detektiert. Vorzugsweise ist der Sensor eine Lichtschranke, welche die Position der Ventilklappe detektiert. Vorzugsweise ist auf der Ventilklappe hierfür ein vorstehender Flügel angeordnet, welcher den Lichtpfad der Lichtschranke durchdringt. Ein derartiger Durchflusssensor ist beispielsweise in WO 2014/161099 offenbart.

Diese zusätzliche Messung des Durchflusses ermöglicht eine Korrektur der Füllstandmessung durch den Füllstandsensor insbesondere wenn sich erst kleine Milchvolumen im Milchsammelbehälter befinden. Auch lässt sich dieser Durchflusssensor während Bewegungen des Milchsammelbehälters verwenden, um die Messungen des während dieses Zeitraums ungenauen Füllstandsensors zu korrigieren oder ganz zu ersetzen. Des Weiteren lässt sich dieser Durchflusssensor als Kontrollmittel einsetzen, welches feststellt, ob sich das Ventil überhaupt geöffnet hat bzw. wie oft und/oder wann es sich öffnet. Diese Angaben lassen sich zur Steuerung des Füllstandsensors verwenden. Beispielsweise erübrigt sich eine Füllstandmessung, wenn sich das Ventil nicht geöffnet hat und somit keine neue Milch in den Milchsammelbehälter gelangt ist.

Alternativ oder zusätzlich ist als weiterer Sensor vorzugsweise ein Positionssensor vorhanden, welcher die Lage des Milchsammelbehälters im dreidimensionalen Raum und somit seine Kipplage im dreidimensionalen Raum detektiert. Als Positionssensor eignet sich insbesondere ein Beschleunigungssensor. Die Daten des Positionssensors werden vorzugsweise verwendet, um die Signale des Füllstandsensors in Kipplagen des Milchsammelbehälters zu kompensieren. Der Positionssensor wird vorzugsweise zusätzlich dazu verwendet, um festzustellen, ob der Milchsammelbehälter überhaupt in einer Position ist, um eine sinnvolle Füllstandmessung zu gewährleisten.

Der Füllstandsensor und mindestens der Positionssensor, vorzugsweise auch alle anderen weiteren Sensoren, sind vorzugsweise zueinander lagefixiert im Ventilkopf angeordnet.

Die Signale, auch Rohdaten genannt, des Füllstandsensors und falls vorhanden, des mindestens einen weiteren Sensors, werden vorzugsweise direkt an externe Einheiten weitergeleitet, wie beispielsweise an eine Auswerte- und Steuereinheit der Brustpumpe oder an eine andere externe Auswerteeinheit.

Vorzugsweise ist jedoch im Ventilkopf eine Elektronikeinheit zur Verarbeitung der Signale des Füllstandsensors angeordnet. Vorzugsweise verarbeitet diese interne Elektronikeinheit auch die Signale des mindestens einen weiteren Sensors, falls vorhanden.

Vorzugsweise ist die Elektronikeinheit zum Datenaustausch mit mindestens einer der folgenden Einheiten ausgebildet: Brustpumpe, informationstechnisch aufgerüstetes „Smart Device" wie Smartphone; externe Datenverarbeitungseinheit wie Personal Computer; Cloud; Internet, Internetzugangseinheit.

Zur einfachen Verwendung des Ventilkopfes ist dieser vorzugsweise nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet. Dies erleichtert zudem die Reinigung und ermöglicht eine mehrfache Wiederverwendung des Ventilkopfes.

In einer Ausführungsform ist der Ventilkopf ein integraler Bestandteil des Adapters. In diesem Fall kann der gesamte Adapter als Ventilkopf ausgebildet sein, d.h. die weiteren Sensoren können über den Adapter verteilt angeordnet sein und müssen sich nicht benachbart zum Anschluss an den Milchsammelbehälter befinden.

In einer anderen Ausführungsform ist der Ventilkopf lösbar mit dem Adapter und/oder dem Milchsammelbehälter verbindbar. Diese Ausführungsform eignet sich insbesondere als Nachrüstset.

Vorzugsweise sind der Füllstandsensor und falls vorhanden der mindestens eine weitere Sensor sowie falls ebenfalls vorhanden die Elektronikeinheit gegen Eindringen von

Flüssigkeit geschützt. Vorzugsweise ist der Ventilkopf spülmaschinenfest ausgebildet.

Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

Eine bevorzugte Ausführungsform der Erfindung ist im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine schematische Darstellung einer erfindungsgemässen Brusthaubeneinheit bei Anlage auf einer Mutterbrust und

Figur 2 eine schematische Darstellung der Brusthaubeneinheit gemäss Figur 1 in Kommunikation mit externen Einheiten.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

In Figur 1 ist eine erfindungsgemässe Brusthaubeneinheit dargestellt. Sie weist eine Brusthaube 1 zur Aufnahme einer Mutterbrust B, insbesondere der Brustwarze, auf. Die Brusthaube 1 ist fest oder vorzugsweise lösbar mit einem Adapter 2, auch Kopplungsteil genannt, verbunden. Der Adapter 2 kann direkt mit einer manuell oder elektromotorisch betriebenen Brustpumpe verbunden sein. Vorzugsweise ist er, wie hier dargestellt, über eine Vakuumleitung 3, insbesondere über einen Silikonschlauch, mit der Brustpumpe verbunden. Die Brustpumpe ist in Figur 2 dargestellt und dort mit dem Bezugszeichen 30 versehen.

Der Adapter weist einen Innenraum 20 auf, welcher einen Teil eines Milchkanals von der Brusthaube 1 zu einem Milchsammelbehälter 5 bildet. Der Milchsammelbehälter 5 ist an einem Anschlussstutzen 21 des Adapters 2 lösbar befestigt.

Am Adapter 2 ist ein Ventilkopf 4 fest oder lösbar angeordnet, wobei der Ventilkopf 4 vorzugsweise lagefixiert zum Adapter 2 ist. Beispielsweise ist der Ventilkopf 4 gemeinsam einstückig mit dem Adapter 2 ausgebildet oder über eine Steck- oder Schraubverbindung mit ihm verbindbar.

Der Adapter 2 und der Ventilkopf 4 sind vorzugsweise aus einem steifen Kunststoff gefertigt. Der Milchsammelbehälter 5 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise besteht auch der Milchsammelbehälter 5 aus Kunststoff. Er kann durchsichtig, halbdurchsichtig oder opak ausgebildet sein.

Der Ventilkopf 4 ragt vorzugsweise in den Milchsammelbehälter 5 hinein. Der Ventilkopf 4 weist ein Rückschlagventil auf. In diesem Ausführungsbeispiel weist das Ventil eine einseitig angelenkte Ventilklappe 40 auf. Das Bezugszeichen 40' bezeichnet die Ventilklappe in geöffneter Stellung, das Bezugszeichen 40 in geschlossener Position.

Der Weg der abgepumpten Milch ist in Figur 1 durch einzelne Milchtropfen dargestellt. Die aus der Mutterbrust B austretende Milch ist mit dem Bezugszeichen a bezeichnet, die in den Ventilkopf 4 fliessende, üblicherweise fallende Milch mit b, die sich vor der geschlossenen Ventilklappe 40 sammelnde Milch mit c und die schliesslich in den Milchsammelbehälter 5 gelangende Milch mit d. Der Milchsee im Milchsammelbehälter 5, also die bereits gesammelte Milch, ist mit dem Bezugszeichen e versehen. Je nach Ausführungsform öffnet die Ventilklappe 40 aufgrund der herrschenden Druckverhältnisse bei jedem Saugzyklus oder erst, wenn sich genügend Milch c vor der Klappe angesammelt hat, um diese zu öffnen. Andere Arten, das Ventil zu öffnen, sind auch möglich.

Im Bereich der Ventilklappe 40 ist vorzugsweise ein Durchflusssensor 8, hier ein als Lichtschranke ausgebildeter optischer Sensor vorhanden. In der schematischen Darstellung gemäss Figur 1 erscheint er innerhalb des Milchsammelbehälters 5 zu schweben. Er ist jedoch ebenfalls am Ventilkopf 4 befestigt.

Der Durchflusssensor 8 misst den Öffnungswinkel der Ventilklappe 40. Der Erfassungsbereich des Durchflusssensors 8, d.h. der Lichtpfad, ist in Figur 1 mit dem Bezugszeichen 80 versehen. Der Öffnungswinkel der Ventilklappe 40 ist in etwa

proportional zur „abfliessenden" Milchmenge d. Um die Messgenauigkeit zu optimieren, wird der Öffnungswinkel der Ventilklappe 40 vorzugsweise mit mindestens 30 Messungen/sec abgetastet. Dieses Messsignal wird, wie eingangs erwähnt, zur Korrektur der Messung des nachfolgend beschriebenen Füllstandsensors verwendet, insbesondere bei kleinen Füllhöhen. Zudem lässt sich mittels dieses Sensors feststellen, ob und wann sich die Ventilklappe 40 geöffnet hat.

In einem von vom Milchkanal getrennten Elektronikbereich 42 des Ventilkopfes 4 ist ein Füllstandsensor 6 angeordnet. Der Elektronikbereich 42 ist vorzugsweise als geschlossene Kammer ausgebildet. Die Trennung vom restlichen Ventilkopf kann beispielsweise über eine Trennwand 41 erfolgen. Ist diese schräg ausgebildet, erleichtert sie zudem den Milchfluss zur Ventilklappe 40.

Der Füllstandsensor 6 weist einen Erfassungsbereich 60 auf, welcher zum gegenüberliegenden Boden des Milchsammelbehälters 5 hin gerichtet ist. Der Füllstandsensor 6 ist deshalb vorzugsweise an der unteren Stirnfläche des Ventilkopfes 4 angeordnet. Bevorzugterweise befindet sich der Füllstandsensor 6 auf der Längsmittelachse des Milchsammelbehälters 5, welche vorzugsweise gleichzeitig die Rotationssymmetrieachse R des Milchsammelbehälters 5 bildet. Der Füllstandsensor 6 ist vorzugsweise ein Distanzsensor, bevorzugt ein optischer Distanzsensor und noch bevorzugter ein TOF Sensor (Time of flight Sensor).

Der TOF Sensor misst eine Distanz von der Sensoroberfläche bis zur Milchoberfläche. Diese Distanz wird, unter Einbezug der Flaschengeometrie, von einem Mikrokontroller einer Elektronikeinheit 9 in Volumen umgerechnet. Die Abstrahlung und somit der Erfassungsbereich 60 des TOF Sensors ist üblicherweise konisch oder kollimiert.

Im Elektronikbereich 42 ist vorzugsweise zudem ein Positionssensor 7, hier ein Bewegungssensor, angeordnet. Dieser Positionssensor 7 misst die Bewegung oder Kipplage des Ventilkopfes 4 und somit des mit diesem über den Adapter 2 verbundenen Milchsammelbehälters 5. Die Signale oder Daten werden an die oben genannte Elektronikeinheit 9, insbesondere demselben Mikrokontroller, geliefert. Sie dienen der Kompensation der Signale des Füllstandsensors 6 bei Kipplagen des

Milchsammelbehälters 5 und erhöhen somit die Genauigkeit der Messung. Die Kipplage ist in Figur 1 mit einem Doppelpfeil und dem Bezugszeichen P bezeichnet.

Der Füllstandsensor 6 sowie der Positionssensor 7 sind zueinander lagefixiert angeordnet; d.h. gerät der eine Sensor in eine Kipplage und/oder wird er bewegt, so gilt gleiches für den anderen Sensor. Vorzugsweise gilt gleiches auch für den Durchflusssensor 8. Der Milchsammelbehälter 5 ist ebenfalls lagefixiert zum Füllstandsensor 6 und, falls vorhanden, zum Positionssensor 7 angeordnet. Dies erfolgt über die entsprechende Verbindung mit dem Adapter 2 und der entsprechenden Verbindung zwischen Adapter 2 und Ventilkopf 4.

Die oben genannte Elektronikeinheit 9 ist vorzugsweise ebenfalls im Elektronikbereich 42 des Ventilkopfes 4 angeordnet. Vorzugsweise verfügt sie über eine im Ventilkopf 4 integrierte Energieversorgung, insbesondere einen Energiespeicher. Vorzugsweise führen keine Kabel oder Steckverbindungen nach aussen. Der Datentransfer von der Elektronikeinheit 9 nach aussen und falls vorhanden, auch von aussen zur Elektronikeinheit 9, findet vorzugsweise drahtlos statt. Die Energieübertragung erfolgt vorzugsweise ebenfalls drahtlos. Der Elektronikbereich 42 ist vorzugsweise flüssigkeitsdicht nach aussen abgeschottet.

In Figur 2 sind verschiedene Kommunikationswege 90 der erfindungsgemässen Brusthaubeneinheit mit externen Informationsspeicher- und/oder Informationsverarbeitungs-Einheiten dargestellt. Die Messwerte geben der Mutter, Stillberaterinnen oder anderen Experten Auskunft über die abgepumpte Milchmenge. Da die Mutter den Milchsammelbehälter 5 während des Abpumpens nicht unbedingt sehen kann, wird es ihr ermöglicht, diese Füllstandmenge auf einem Display der Brustpumpe 30, auf einem Smart Device SD, wie beispielsweise ihr Smartphone oder ihr Tablet, oder auf einem anderen geeigneten Gerät anzeigen lassen. Zudem können diese Daten ohne weiteres Zutun der Mutter über eine Internetzugangseinheit I dem Internet zur Verfügung gestellt werden. Sie können beispielsweise in eine dafür geeignete Cloud C gespeichert werden oder einer anderen Einheit OD, wie zum Beispiel einem Personal Computer, übermittelt werden. Diese gemessenen Füllstandmengenverläufe lassen sich zur zeitgleichen oder späteren Optimierung von Abpumpparametern oder Messalgorithmen

einsetzen. Abpumpparameter sind beispielsweise Vakuumhöhe und Pumpfrequenz, Dauer eines Stimulationsprogramms (let-down) der Pumpe vor einem automatischen oder manuellen Wechsel auf den expressiven, d.h. normalen Abpumpvorgang und ähnliches.

Die erfindungsgemässe Brusthaubeneinheit und der erfindungsgemässe Ventilkopf ermöglichen eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglichen zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

BEZUGSZEICHENLISTE

1	Brusthaube
2	Adapter
20	Innenraum
21	Anschlussstutzen
3	Vakuumleitung
30	Brustpumpe
4	Ventilkopf
40	Ventilklappe
40'	Ventilklappe in geöffneter Stellung
41	Trennwand
42	Elektronikbereich
5	Milchsammelbehälter
6	Füllstandsensor
60	Erfassungsbereich des Füllstandsensors
7	Positionssensor
8	Durchflusssensor
80	Erfassungsbereich des Durchflusssensors
9	Elektronikeinheit
90	Kommunikationsweg
B	Mutterbrust
a	aus der Mutterbrust austretende Milch
b	in den Ventilkopf fallende Milch
c	im Ventilkopf sich sammelnde Milch
d	aus dem Ventilkopf austretende Milch
e	im Milchsammelbehälter gesammelte Milch
P	Drehposition des Milchsammelbehälters im Raum
I	Internetzugangseinheit
SD	Smart Device
C	Cloud
OD	Andere Einheiten
R	Rotationsachse

PATENTANSPRÜCHE

1. Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) aufweist, wobei sich ein Milchkanal von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5) erstreckt und wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, dadurch gekennzeichnet, dass im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

2. Brusthaubeneinheit nach Anspruch 1, wobei der Füllstandsensor (6) ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter (5) befindlichen abgepumpten Muttermilch, vorzugsweise ein Laufzeitverfahen-Sensor (Time of flight Sensor), ist.

3. Brusthaubeneinheit nach einem der Ansprüche 1 bis 2, wobei im Ventilkopf (4) mindestens ein weiterer Sensor (7, 8) angeordnet ist.

4. Brusthaubeneinheit nach Anspruch 3, wobei einer des mindestens einen weiteren Sensors ein Durchflusssensor (8) ist, welcher den Durchfluss durch das Ventil (40) misst.

5. Brusthaubeneinheit nach Anspruch 4, wobei der Durchflusssensor (8) ein optischer Sensor ist, welcher eine Auslenkung einer Ventilklappe (40) des Ventils detektiert.

6. Brusthaubeneinheit nach einem der Ansprüche 1 bis 5, wobei einer des mindestens einen weiteren Sensors ein Positionssensor (7) ist, welcher die Position des Milchsammelbehälters (5) im dreidimensionalen Raum und somit

seine Schräglage im dreidimensionalen Raum detektiert.

7. Brusthaubeneinheit nach Anspruch 6, wobei der Positionssensor (7) ein Beschleunigungssensor ist.

8. Brusthaubeneinheit nach einem der Ansprüche 6 oder 7, wobei der Füllstandsensor (6) und der Positionssensor (7) zueinander lagefixiert im Ventilkopf (4) angeordnet sind.

9. Brusthaubeneinheit nach einem der Ansprüche 1 bis 8, wobei im Ventilkopf (4) eine Elektronikeinheit (9) zur Verarbeitung von Signalen des Füllstandsensors (6) angeordnet ist.

10. Brusthaubeneinheit nach Anspruch 9 und mindestens einem der Ansprüche 4 bis 8, wobei die Elektronikeinheit (9) zur Verarbeitung von Signalen des mindestens einen weiteren Sensors (7, 8) ausgebildet ist.

11. Brusthaubeneinheit nach einem der Ansprüche 9 oder 10, wobei die Elektronikeinheit (9) zum Datenaustausch (91, 92, 93, 94, 95, 96, 97) mit mindestens einer der folgenden Einheiten ausgebildet ist: Brustpumpe (30), informationstechnisch aufgerüstetes „Smart Device" (SD) wie Smartphone, externe Datenverarbeitungseinheit wie Computer (OD), Cloud (C), Internet, Internetzugangseinheit (I).

12. Brusthaubeneinheit nach einem der Ansprüche 1 bis 11, wobei der Ventilkopf (4) nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet ist.

13. Brusthaubeneinheit nach einem der Ansprüche 1 bis 12, wobei der Ventilkopf (4) integraler Bestandteil des Adapters (2) ist.

14. Brusthaubeneinheit nach einem der Ansprüche 1 bis 13, wobei der Ventilkopf (4) lösbar mit dem Adapter (2) und/oder dem Milchsammelbehälter (5) verbindbar

ist.

15. Ventilkopf einer Brusthaubeneinheit nach einem der Ansprüche 1 bis 14, wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, und wobei im Ventilkopf ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

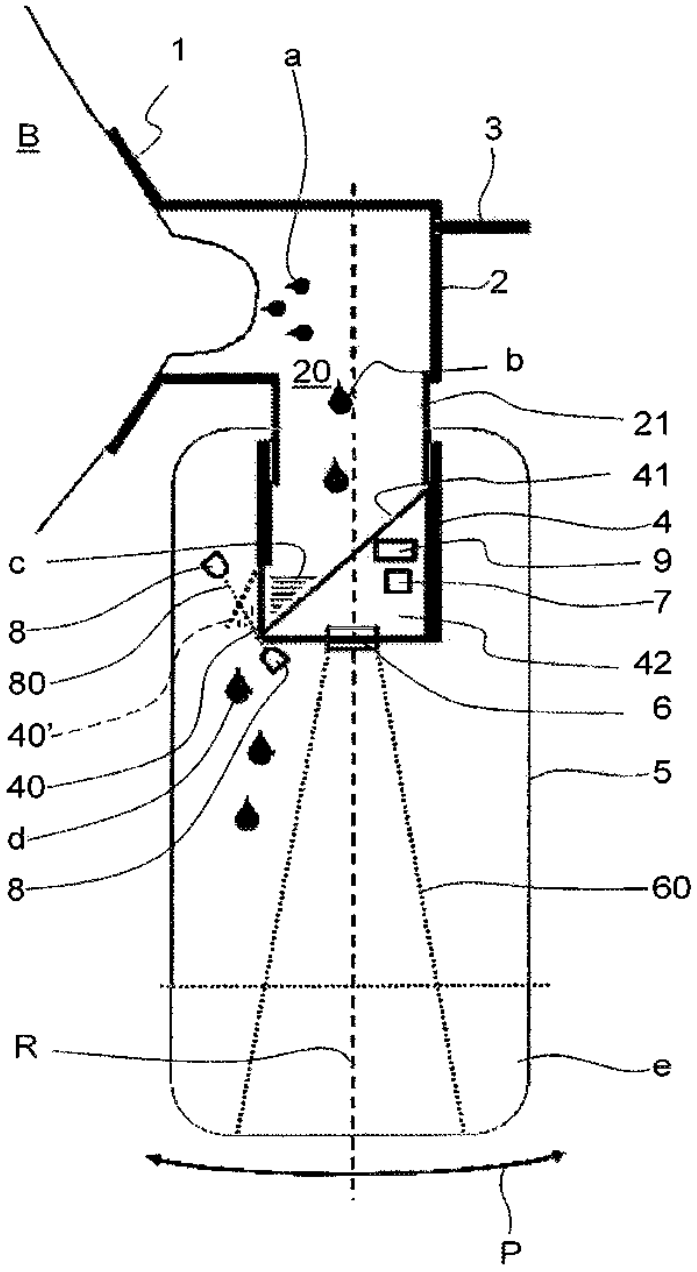


FIG. 1

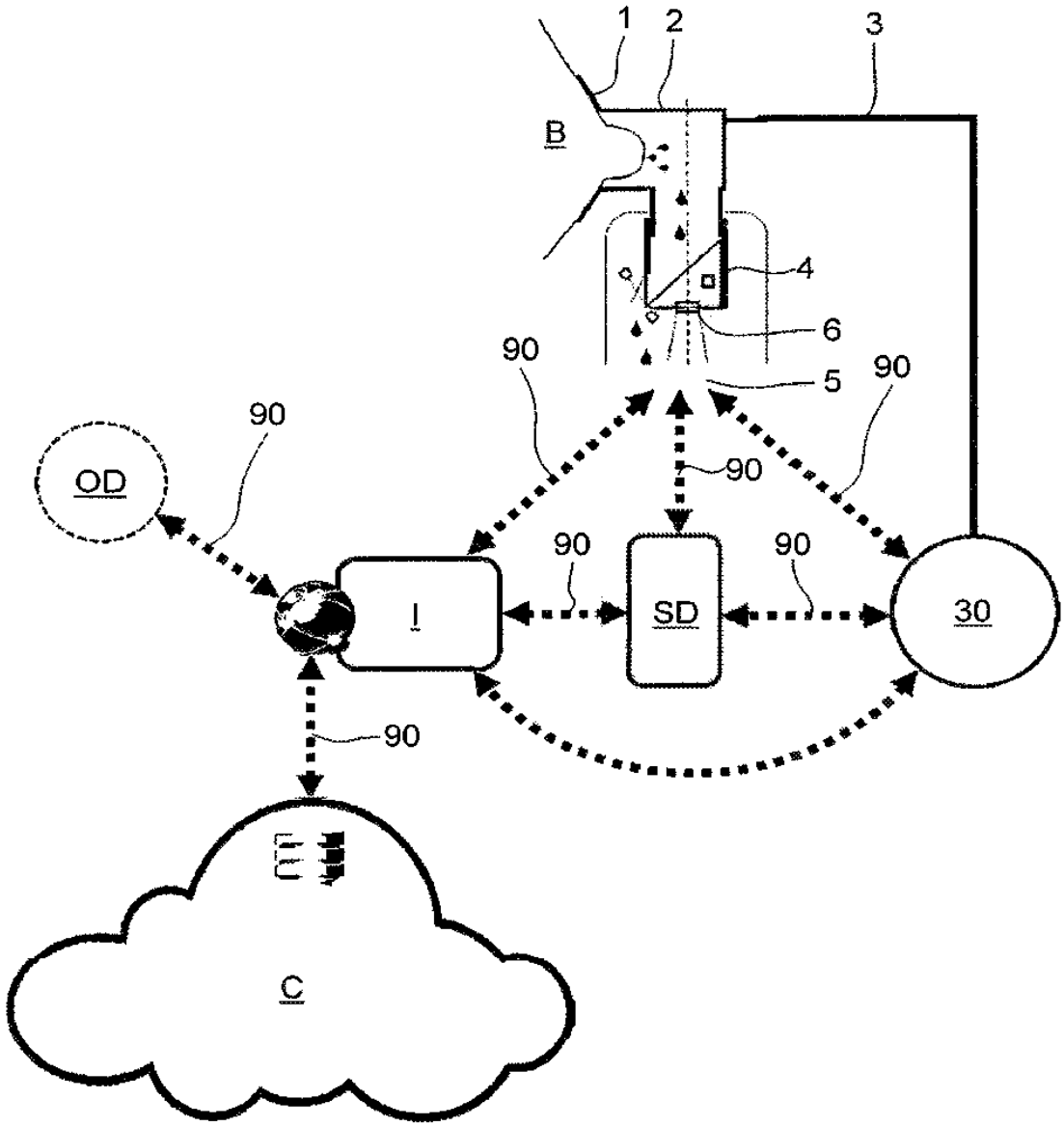


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/073155

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2016/082165 A1 (ALVAREZ JEFFERY B [US] ET AL) 24 March 2016 (2016-03-24) paragraphs [0107] - [0120], [0151] - [0152] figures 1, 11c-e, h, j 25	1,3,4, 6-15 2
X	US 2016/220743 A1 (GUTHRIE GABRIELLE V [US] ET AL) 4 August 2016 (2016-08-04) paragraphs [0063] - [0071] figures 5-8, 10-12	1,3,4,15
X	US 2015/038945 A1 (MCCABE JILL C [US]) 5 February 2015 (2015-02-05) paragraphs [0015] - [0024] figures 1, 2	1,13-15

-/--

[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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 November 2017	28/11/2017

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

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/073155

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/082166 A1 (GUTHRIE GABRIELLE V [US] ET AL) 24 March 2016 (2016-03-24) cited in the application paragraphs [0025], [0037] - [0038] figures 1-3, 5	1,9-15
X	WO 2014/161099 A1 (MEDELA HOLDING AG [CH]) 9 October 2014 (2014-10-09) cited in the application page 6, line 10 - page 9, line 10 figures 1, 6-9	1,3-5,9, 15
Y	EP 0 266 590 A2 (BRAUN MELSUNGEN AG [DE]) 11 May 1988 (1988-05-11) page 3, lines 29-40	2

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/073155

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US 2016220743 A1	04-08-2016	US 2016220743 A1	04-08-2016
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		US 2016038662 A1	11-02-2016
		WO 2014161099 A1	09-10-2014
EP 0266590 A2	11-05-1988	DE 3637771 C1	10-12-1987
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		ES 2021672 B3	16-11-1991
		GR 3002145 T3	30-12-1992
		JP H0459915 B2	24-09-1992
		JP S63132666 A	04-06-1988
		US 4832689 A	23-05-1989

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/073155

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X Y	US 2016/082165 A1 (ALVAREZ JEFFERY B [US] ET AL) 24. März 2016 (2016-03-24) Absätze [0107] - [0120], [0151] - [0152] Abbildungen 1, 11c-e, h, j 25 -----	1,3,4, 6-15 2
X	US 2016/220743 A1 (GUTHRIE GABRIELLE V [US] ET AL) 4. August 2016 (2016-08-04) Absätze [0063] - [0071] Abbildungen 5-8, 10-12 -----	1,3,4,15
X	US 2015/038945 A1 (MCCABE JILL C [US]) 5. Februar 2015 (2015-02-05) Absätze [0015] - [0024] Abbildungen 1, 2 ----- -/--	1,13-15

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
15. November 2017	28/11/2017

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/073155

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2016/082166 A1 (GUTHRIE GABRIELLE V [US] ET AL) 24. März 2016 (2016-03-24) in der Anmeldung erwähnt Absätze [0025], [0037] - [0038] Abbildungen 1-3, 5	1,9-15
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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2017/073155

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(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
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(43)公表日　平成28年3月24日(2016.3.24)

(51)Int.Cl.		F I		テーマコード（参考）
A61M 1/06	***(2006.01)***	A61M	1/06	4C077

審査請求 未請求　予備審査請求 未請求　（全 26 頁）

(21)出願番号	特願2015-560666 (P2015-560666)
(86)(22)出願日	平成26年3月5日 (2014.3.5)
(85)翻訳文提出日	平成27年9月30日 (2015.9.30)
(86)国際出願番号	PCT/EP2014/054197
(87)国際公開番号	WO2014/135553
(87)国際公開日	平成26年9月12日 (2014.9.12)
(31)優先権主張番号	61/772,597
(32)優先日	平成25年3月5日 (2013.3.5)
(33)優先権主張国	米国 (US)
(31)優先権主張番号	13157739.7
(32)優先日	平成25年3月5日 (2013.3.5)
(33)優先権主張国	欧州特許庁 (EP)

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特許業務法人M&Sパートナーズ

最終頁に続く

(54)【発明の名称】搾乳器のライナー及び乳房インターフェース

(57)【要約】
乳房インターフェース７０に使用するライナー１００である。当該ライナーは、乳房接触面１１８を画成する前壁部１１２と、乳房接触面に設けられた開口１１６ｂとを含み、乳房接触面１１８は、使用時に、女性の乳房に当接する一方で、乳房の乳首は、開口１１６ｂを通り少なくとも部分的に突出する前部セクション１１０と、前部セクション１１０に接続され、後端開口を有する管状壁部１７１を含む後部セクション１７０とを含み、前部セクション１１０及び後部セクション１７０は共に、乳房接触面１１８における開口１１６ｂから管状壁部１７１における後端開口まで延在し、後方方向において下方向に傾斜する乳用通路１９０を画成する。

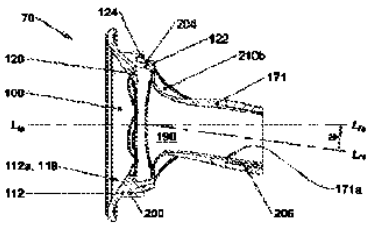


Fig. 7A

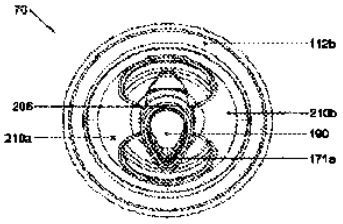


Fig. 7B

【特許請求の範囲】
【請求項１】
乳房インターフェースにおける使用のためのライナーであって、
乳房接触面を画成する前壁部と、前記乳房接触面に設けられた開口とを含み、前記乳房接触面は、使用時に、女性の乳房に当接する一方で、前記乳房の乳首は、前記開口を通り少なくとも部分的に突出する、前部セクションと、
前記前部セクションに接続され、後端開口を有する管状壁部を含む後部セクションと、
を含み、
前記前部セクション及び前記後部セクションは共に、前記乳房接触面における前記開口から前記管状壁部における前記後端開口まで延在する乳用通路を少なくとも部分的に画成し、
前記ライナーは、前記前部セクションの長手軸が実質的に水平に延在する使用姿勢に関連付けられる一方で、前記後部セクションの前記管状壁部は、前記乳用通路を部分的に境界付け、また、前記使用姿勢において、後方方向において見た場合に、前記長手軸に対して下方向に傾斜する下部内側表面部分を有し、前記後部セクションの前記管状壁部は、ティアドロップ形状の横断面を有し、前記ティアドロップ形状の横断面の細い部分は、溝を画定し、前記溝の底部は、前記下部内側表面部分によって画成される、ライナー。
【請求項２】
前記前部セクションの前記長手軸は、前記乳房接触面における前記開口の平面に実質的に垂直に延在する、請求項１に記載のライナー。
【請求項３】
前記下部内側表面部分は、前記後部セクションの前記管状壁部の実質的に全長に亘って延在する、請求項１又は２に記載のライナー。
【請求項４】
前記下部内側表面部分は、実質的に一定の傾斜角度で、前記前部セクションの前記長手軸に対して下方向に傾斜する、請求項１乃至３の何れか一項に記載のライナー。
【請求項５】
前記使用姿勢において、前記下部内側表面部分は、前記前部セクションの前記長手軸に対して１０～４５度の範囲内の平均下方向傾斜角度を有する、請求項１乃至４の何れか一項に記載のライナー。
【請求項６】
前記ライナーの前記前部セクションは、前記ライナーの前部円周エッジと後部円周エッジの径方向位置間の径方向位置において、前記前壁部の背面に接続し、前記前壁部の前記背面から、後方方向に延在する環状基部壁部を含み、前記前壁部は、環状の（乳）逆流バリアを形成するように、前記環状基部壁部を越えて径方向内側に延在する、請求項１乃至５の何れか一項に記載のライナー。
【請求項７】
前記前部セクションと前記後部セクションとの間に、前記後部セクションが前記前部セクションに中間セクションを介して接続されるように配置され、後部のテーパする漏斗状壁部を含む、前記中間セクションを更に含む、請求項１乃至６の何れか一項に記載のライナー。
【請求項８】
搾乳器用の乳房インターフェースであって、
ライナーの少なくとも一部を受容するライナー支持フレーム内部空間を画成し、前部リングと、後部リングと、前記前部リング及び前記後部リングを、前記前部リング及び前記後部リングが軸方向において離間されているように、相互接続する少なくとも１つのアームと、を含む、ライナー支持フレームと、
請求項１乃至７の何れか一項に記載のライナーと、
を含み、
前記ライナーの前記前部セクションは、前記ライナー支持フレームの前記前部リングに

係合する一方で、前記ライナーの前記後部セクションの前記管状壁部は、前記ライナー支持フレームの前記後部リングによって、嵌るように受容される、乳房インターフェース。
【請求項９】
前記ライナーの前記後部セクションの前記管状壁部の後端には、前記ライナー支持フレームの前記後部リングの内径よりも大きい外径を有し、また、前記乳房インターフェースの組み立てられた状態では、端部において、前記後部リングに当接する第１の環状フランジが設けられ、
前記後部リングは、前記ライナーの前記フランジが付いた後端の通過を容易とするように、互いに対して再配置可能である少なくとも２つの相補形の円周後部リング部分を含む分割後部リングである、請求項８に記載の乳房インターフェース。
【請求項１０】
請求項８又は９に記載の乳房インターフェースを含む搾乳器。
【発明の詳細な説明】
【技術分野】
【０００１】
本開示は、搾乳器に使用する乳房インターフェースに関し、当該乳房インターフェースは、フレキシブルライナーと、概して剛性であるライナー支持フレームとを含む。
【背景技術】
【０００２】
搾乳器は、当技術分野においてよく知られている。搾乳器は、通常、乳房にフィットする乳房インターフェース又は乳房シールドと、乳房インターフェース内に真空（負圧）を発生させるために乳房インターフェースと接続可能である真空ポンプとを含む。真空によって、乳房インターフェースは、乳房に引っ張られ、乳を搾り出すために乳房をマッサージする。搾り出された乳は、乳房インターフェースから集乳器に流れる。集乳器は、搾乳器に取り外し可能に接続される。
【０００３】
米国特許出願公開第２００９／０１７１２７０号は、搾乳器の付属装置について開示している。付属装置は、長手軸を有する漏斗形適用部と、適用部に隣接し、固定部によって接合される接続部とを有する。適用部は、適用部の長手軸が、固定部の回転軸に対し１８０°から逸れる角度位置に配置されるように、固定部に対してピボット可能に構成される。
【０００４】
米国特許出願公開第２００６／０１１６６３２号には、通路を形成する乳房シールドを含むリクライニング搾乳システムが開示されている。通路の一端に隣接する材料が、女性の乳首の周りの乳房にフィットするように成形されるフランジを形成する。通路のもう一端から延在する材料は、管を形成する。乳房の乳輪に平行な平面が、管の軸に垂直な平面から実質的に傾斜されて、管の偏差角が規定される。
【０００５】
米国特許出願公開第２００５／０２２２５３６号は、搾乳器の乳房シールドについて開示している。乳房シールドの第１の端は、広い横断面を有し、概して断面形状は円形である。第１の端は更に、円周フランジを含む。乳首トンネルが第１の端へと開き、第２の及び下流の端に向かって長手方向に延在する。乳房シールドの本体全体は、概して円筒形であり、乳房シールドは、その長手方向の長さに沿って湾曲していてもよい。
【０００６】
米国特許第６，９７４，４３９号は、乳房にフィットするカップアセンブリを有する少なくとも１つのエキスプレッサを含む搾乳デバイスについて開示している。カップアセンブリは、ベル状のハウジングと、比較的柔らかいドーナツ型パッドと、フレキシブルライナーとを含む。ライナーは、乳の入口開口付近では相対的に細い部分を、細い部分とカップアセンブリの出口端との間では広い部分とを有する。
【発明の概要】

【発明が解決しようとする課題】
【０００７】
従来の乳房インターフェースに関連付けられる問題は、それを使用する女性が、自身の乳房から搾り出された乳が確実に集乳器に向かい、その中に流れるように、前傾になる必要がある点である。１回の搾乳セッションには時間がかかり、特には３０分以上にも及ぶため、前傾姿勢は不快となる。
【０００８】
本開示は、上記問題を解決する又は少なくとも軽減するライナー及び当該ライナーを含む乳房インターフェースを提供することを目的とする。
【課題を解決するための手段】
【０００９】
このために、本開示の第１の態様は、乳房インターフェースに使用するライナーに関する。当該ライナーは、乳房接触面を画成する前壁部と、乳房接触面に設けられた開口とを含む前部セクションを含む。乳房接触面は、使用時に、女性の乳房に当接する一方で、乳房の乳首は、開口を通り少なくとも部分的に突出する。ライナーは更に、前部セクションに接続され、ライナーから乳を放出するための後端開口を有する管状壁部を含む後部セクションを含む。前部及び後部セクションは共に、乳房接触面における開口から管状壁部における後端開口まで延在する乳用通路を少なくとも部分的に画成する。更に、ライナーは、通常は、乳房接触面における開口の平面に実質的に垂直に延在する前部セクションの長手軸が実質的に水平に延在する使用姿勢に関連付けられる一方で、後部セクションの管状壁部は、乳用通路を部分的に境界付け、また、使用姿勢において、後方方向において見た場合に、長手軸に対して下方向に傾斜する下部内側表面部分を有する。後部セクションの管状壁部は、ティアドロップ形状の横断面を有する。ティアドロップ形状の横断面の細い部分は、溝を画定し、溝の底部は、下部内側表面部分によって画成される。
【００１０】
使用時、ここに開示されるライナーは、当該ライナーの前部セクションの乳房接触面が女性の乳房に接触するように、その使用姿勢に保持される。ライナーの前部セクションの長手軸は、実質的に水平に延在するが、後部セクションの管状壁部の下部内側表面部分は、それに対して下方向に傾斜する。したがって、乳房から搾り出された乳は、乳用通路を通り、管状壁部の後端開口に向かって自然に導かれ、後部開口に、動作上、接続される集乳器内に放出される。重力の作用による乳のライナーを通る自然な流れは、乳を搾り出す女性が前傾する必要をなくす。
【００１１】
ライナーの好適な実施形態では、下部内側表面は、後部セクションの管状壁部の実質的に全長に亘って延在する。下部内側表面部分は、好適には、実質的に一定の傾斜角度（φ）で、前部セクションの長手軸に対して下方向に傾斜する。使用姿勢において、下部内側表面部分は、前部セクションの長手軸に対して、好適には、１０～４５度の範囲内の平均下方向傾斜角度を有する。
【００１２】
本開示の第２の態様は、乳房インターフェースに関する。当該乳房インターフェースは、ライナーの少なくとも一部も受容するライナー支持フレーム内部空間を画成するライナー支持フレームを含む。ライナー支持フレームは、前部リングと、後部リングと、前部リング及び後部リングを、前部リング及び後部リングが軸方向において離間されているように、相互接続する少なくとも１つのアームとを含む。当該乳房インターフェースは更に、本開示の第１の態様によるライナーも含み、ライナーの前部セクションは、ライナー支持フレームの前部リングに係合する一方で、ライナーの後部セクションの管状壁部は、ライナー支持フレームの後部リングによって、嵌るように受容される。
【００１３】
特に好都合に組み立て可能な乳房インターフェースを詳細に説明すると、ライナーの後部セクションの管状壁部の後端には、ライナー支持フレームの後部リングの内径よりも大

きい外径を有し、また、乳房インターフェースの組み立てられた状態では、端部において、後部リングに当接する第１の環状フランジが設けられる。また、後部リングは、ライナーのフランジが付いた後端の通過を容易とするように、互いに対して再配置可能である少なくとも２つの相補形の円周後部リング部分を含む分割後部リングである。

【００１４】

本開示の第３の態様は、本開示の第２の態様による乳房インターフェースを含む搾乳器に関する。

【００１５】

本発明のこれらの及び他の特徴及び利点は、本発明を例示するものであって限定することを意図していない添付図面と共に参照することによって、本発明の特定の実施形態の以下の詳細な説明からより深く理解できよう。

【図面の簡単な説明】

【００１６】

【図１Ａ】図１Ａは、女性の乳房に接触する乳房インターフェースの第１の例示的な実施形態を含む、本開示による搾乳器の一実施形態を概略的に示す斜視図である。

【図１Ｂ】図１Ｂは、女性の乳房に接触する乳房インターフェースの第１の例示的な実施形態を含む、本開示による搾乳器の一実施形態を概略的に示す部分的に分解された側断面図である。

【図２Ａ】図２Ａは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す斜視図である。

【図２Ｂ】図２Ｂは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す側面図である。

【図２Ｃ】図２Ｃは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す、図２Ｄと相互に垂直な側断面図である。

【図２Ｄ】図２Ｄは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す、図２Ｃと相互に垂直な側断面図である。

【図３Ａ】図３Ａは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す斜視図である。

【図３Ｂ】図３Ｂは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す側面図である。

【図３Ｃ】図３Ｃは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す正面図である。

【図３Ｄ】図３Ｄは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す背面図である。

【図４Ａ】図４Ａは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す斜視図である。

【図４Ｂ】図４Ｂは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す側面図である。

【図４Ｃ】図４Ｃは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す正面図である。

【図５Ａ】図５Ａは、ライナー支持フレームが２つの取り外し可能な相補形の半体を含む、本開示による乳房インターフェースの第２の例示的な実施形態を概略的に示す斜視図である。

【図５Ｂ】図５Ｂは、ライナー支持フレームが２つの取り外し可能な相補形の半体を含む、本開示による乳房インターフェースの第２の例示的な実施形態を概略的に示す斜視図である。

【図６Ａ】図６Ａは、ライナー支持フレームがヒンジを介して接続される２つの相補形の半体を含む、本開示による乳房インターフェースの第３の例示的な実施形態を概略的に示

す斜視図である。
【図６Ｂ】図６Ｂは、ライナー支持フレームがヒンジを介して接続される２つの相補形の半体を含む、本開示による乳房インターフェースの第３の例示的な実施形態を概略的に示す斜視図である。
【図７Ａ】図７Ａは、ライナーがティアドロップ形の内側断面形状を有する管状後部セクションを含む、本開示による乳房インターフェースの第４の例示的な実施形態を概略的に示す側断面図である。
【図７Ｂ】図７Ｂは、ライナーがティアドロップ形の内側断面形状を有する管状後部セクションを含む、本開示による乳房インターフェースの第４の例示的な実施形態を概略的に示す背面図である。
【発明を実施するための形態】
【００１７】
図１は、本開示による例示的な搾乳器１を、斜視図で概略的に示す。搾乳器１は、真空ポンプ１０と、連結器３０と、例えば哺乳瓶である集乳器５０と、第１の例示的な実施形態の乳房インターフェース７０とを含む。
【００１８】
連結器３０は、第１のチャネル３４を画成する第１の略垂直に延在する管状セグメント３２と、第１の管状セグメント３２から斜めに及び／又は外側に延在し、第１のチャネル３４と流体連通する第２のチャネル３８を画成する第２の管状セグメント３６とを含む。第１の管状セグメント３２の下端において、連結器３０は、集乳器５０とのねじ込み接続のための内側ねじ山を有するねじ込みソケット４０を含み、集乳器５０の上端には、相補形の外側ねじ山が設けられている。第１の管状セグメント３２の反対側の上端は、第１のチャネル３４及び第２のチャネル３８に真空を与える真空ポンプ１０に接続される。真空ポンプ１０は、図示される実施形態にあるように、手動の真空ポンプであっても、電気的真空ポンプであってもよく、真空ポンプ自体は、従来のデザインであり、本明細書では説明されない。第２の管状セグメント３６の外側端は更に、真空ポンプ１０と、集乳器５０と、乳房インターフェース７０とが連結器３０を介して空気圧連結する一方で、集乳器５０と乳房インターフェース７０との間で流体連通が可能であるように、乳房インターフェース７０の後端を、圧入式に受容する受容路４２を画成する。当然ながら、搾乳器１の様々な実施形態は、上記され、図示されたものとは異なる形状及び構造を有する連結器３０を含んでもよく、また、特に真空ポンプ１０及び集乳器５０を連結器３０に接続するために使用される接続の種類は、例えばねじ山、スナップ式等の任意の適切なタイプであってよい。
【００１９】
概念的に、乳房インターフェース７０は、２つのコンポーネント、即ち、フレキシブルライナー１００と、頑丈で比較的硬く、即ち、剛性のライナー支持フレーム２００とを含む。ライナー１００及びライナー支持フレーム２００は、通常は、２つの別個の構造コンポーネントとして形成され、これらは、使用時には、乳房インターフェース７０を形成するように合せて組み立てられる必要があり、また、コンポーネントのうちの片方を洗浄及び交換し易くするために、後に、分解されてもよい。しかし、ライナー１００及びライナー支持フレーム２００は、乳房インターフェース７０の構造部品の数を少なくするように、或いは、単一の構造コンポーネントとして一体に形成される（例えばコモールドされる）ことも考えられる。
【００２０】
以下、本開示による乳房インターフェース７０のライナー１００及びライナー支持フレーム２００の構造について説明される。まず、図１乃至図４に示される乳房インターフェース７０の第１の例示的な実施形態のライナー１００及びライナー支持フレーム２００について、幾つかの考えられる変形態様も考慮しながら、説明される。続いて、図５、図６及び図７をそれぞれ参照して、乳房インターフェース７０の特に有利な第２の、第３の及び第４の例示的な実施形態について説明される。

【００２１】
ここでは、特に図２及び図３を参照する。ライナー１００は、３つの、通常は、一体に形成されるセクション、即ち、前部セクション１１０、中間セクション１４０、及び、後部セクション１７０を含む。各セクションは、各セクションを画成する少なくとも１つの壁部を含む。
【００２２】
ライナー１００の前部セクション１１０は、後方向にテーパする略円錐又はカップ状の前壁部１１２を含み、当該前壁部１１２は、前部開口１１６ａを境界付ける前部の径方向外側の円周エッジ１１４ａと、中央後部開口１１６ｂを境界付ける後部の径方向内側の円周エッジ１１４ｂとの間で延在する。円周エッジ１１４ａ、１１４ｂの間で軸方向に、前壁部１１２の前面１１２ａは、略円錐状の乳房接触面１１８を画成する。
【００２３】
ライナー１００の前部セクション１１０は更に、環状基部壁部１２２を含む。環状基部壁部１２２は、前壁部１１２の背面１１２ｂに、前部円周エッジ１１４ａと後部円周エッジ１１４ｂの径方向位置間の径方向位置において、接続し、前壁部１１２の背面１１２ｂから、後方方向に延在する。したがって、これらの環状接合部に沿って、前壁部１１２は、環状（乳）逆流バリア１２０が形成されるように、基部壁部１２２を越えて径方向内側に延在すると見なされる。
【００２４】
前部セクション１１０は、環状リップ壁部１２４も含む。環状基部壁部１２２と同様に、環状リップ壁部１２４は、前壁部１１２の背面１１２ｂに、前部円周エッジ１１４ａと後部円周エッジ１１４ｂの径方向位置間の径方向位置において、接続し、前壁部１１２の背面１１２ｂから、後方方向に延在する。環状リップ壁部１２４及び環状基部壁部１２２は、互いに円周方向において平行に延在する。環状リップ壁部１２４は、径方向外側のリップ壁部１２４と径方向内側の基部壁部１２２との間に、環状溝１２６が画成されるように、より大きい動径座標において延在する。環状溝１２６は、ライナー支持フレーム２００の前部リング２０４（図２Ｃ及び図２Ｄを参照）を受容係合し、したがって、前部リング２０４の（略径方向の）幅に等しい又は当該幅よりも僅かに小さい（略径方向の）幅を有する。
【００２５】
使用中、ライナー１００の前部セクション１１０は、円錐状の前壁部１１２によって境界付けられる内部空間が乳房の容器として機能を果たすように、女性の乳房に置かれ、乳房は、この内部空間内に少なくとも部分的に受容される。乳房の乳輪及び乳首、又は、少なくとも乳首は、前壁部１１２にある中央後部開口１１６ｂを通り突出する一方で、乳房接触面１１８は、乳房がライナー１００のより奥に挿入又は吸い込まれないように、乳房の乳輪の周囲部分に当接する止め具として機能する。
【００２６】
ライナー１００の前部セクション１１０は、使用中にその形状を実質的に維持するように構成される。即ち、前部セクション１１０は、著しく変形することを意図していない。しかし、ライナー１００の上記された中間セクション１４０は、動作中に乳房の乳首上に左右対称に凹むように構成される。中間セクション１４０は、前部セクション１１０（の基部壁部１２２）の後端に接続される。ライナー１００の中間セクション１４０が、制御されたやり方で、確実に左右対称に凹むのを促進するように、ライナー１００の前部セクション１１０の環状溝１２６と、その中に受容されるライナー支持フレーム２００の前部リング２０４とは、異なる円周形状を有する。形状の違いは、乳房インターフェース７０の組立ての際に、前部リング２０４は環状溝１２６に挿入され、前部セクション１１０（したがって、そこに接続されている中間セクション１４０）は、第１の径方向に沿って伸張され／広げられ、第１の径方向に実質的に垂直な第２の径方向に沿って圧縮される／狭くされるような違いであることが好適である。
【００２７】

一実施形態では、例えば環状溝１２６は、円形の円周形状を有する一方で、ライナー支持フレーム２００の前部リング２０４は、楕円形状を有する。前部リング２０４の楕円形状は、長軸及び短軸の観点から説明される。これらの軸は共に、乳房インターフェース７０のコンテキストでは、径方向に延在する軸である。これは、乳房インターフェース７０の長手軸Ｌに垂直に延在するからである。長軸は、円形溝の直径よりも僅かに大きい長さを有する一方で、短軸は、円形溝の直径よりも僅かに小さい長さを有する。したがって、ライナー１００の前部セクション１１０は、環状溝１２６内に前部リング２０４が挿入されると、圧縮応力が掛けられる。つまり、前部セクション１１０は、楕円形の前部リング２０４の長軸に沿って伸張され、前部リング２０４の短軸に沿って圧縮される。前部セクション１１０、したがって、そこに接続される中間セクション１４０のこの圧縮応力は、短軸に沿った中間セクションの左右対称の圧潰を促進する。

【００２８】

環状溝１２６と楕円形前部リング２０４とを含む乳房インターフェース７０の上記実施形態の欠点は、ライナー１００の中間セクション１４０の特定の壁剛性分布との前部リング２０４の短軸及び／又は長軸の回転位置ずれの影響を受けやすい点である。以下において明確にされるように、ライナー１００の中間セクション１４０は、その壁部に、細長い、比較的剛性の部分１４６（例えばリブ）を含む。リブ１４６は、中間セクション１４０の両側の壁部１４２、１４４上に延在し、ライナーの内部１８０が排気された時に、ライナー１００の制御された左右対称の圧潰を促進する。このようなリブ１４６を含む…実施形態では、中間セクション１４０のリブは、２つの特徴、即ち、壁剛性分布と、円形の環状溝１２６と楕円形の前部リング２０４との形状差異とである２つの特徴が、左右両側の圧潰をもたらす際に、互いに協働し、強化するように、前部リング２０４の長軸と回転位置合わせされることが好適である。しかし、乳房インターフェース７０の組立ての際、ライナー支持フレーム２００の前部リング２０４の主軸及び短軸は、例えば前部リングの短軸がリブと回転位置合わせされるように、ライナー１００の中間セクション１４０の壁剛性分布と容易に位置ずれし、これは、２つの特徴が、互いの意図された効果を妨害してしまう。

【００２９】

可能な位置ずれの問題を防止するために、乳房インターフェース７０の好適な実施形態は、その前部セクション１１０がｘ個の対称軸（を有する円周形状）を有する環状溝１２６を含むライナー１００と、ｙ個の対称軸（を有する円周形状）を有する環状前部リング２０４を含むライナー支持フレーム２００とを特徴とする。このとき、ｘ＜ｙである。このような好適な実施形態では、壁剛性分布に関連する非対称性と、ライナーの制御された左右両側の圧潰を促進する環状溝１２６と前部リング２０４との形状差異とは共に、製造時にライナー１００に組み込まれ、これは、組立て時におけるユーザによるライナー１００とライナー支持フレーム２００との可能な回転位置ずれの問題を未然に防ぐ。１つの好適な実施形態では、例えばライナー１００は、例えば楕円形（２つの対称軸）又は長円形（１つの対称軸）である非円形の環状溝１２６を含む前部セクションを有し、ライナー支持フレーム２００は、当該溝に挿入するための円形の前部リング２０４（無限の対称軸）を有する。図３に、このようなライナー実施形態１００が示される。図３Ｄの背面図には、楕円形の環状溝１２６の長軸A_{maj}及び短軸A_{min}と、中間セクション１４０の壁部１４２、１４４に延在する２つの向かい合うリブ１４６とが特定されている。図面から分かるように、楕円形の環状溝１２６の短軸A_{min}は、リブ１４６が離間されている方向と回転位置合わせされ、これにより、ライナー支持フレーム２００の前部リング２０４のライナー１００の前部セクション１１０の環状溝１２６内への挿入が、ライナーに短軸A_{min}に沿って圧縮応力を掛け、長軸A_{maj}に沿ったライナーの圧潰を促進する。別の実施形態では、ライナーは、長方形で、非正方形の溝（２つの対称軸）を含む前部セクションを有し、ライナー支持フレームは、正方形の前部リング（４つの対称軸）を有してもよい。

【００３０】

一般に、ユーザが、操作時に、乳房、具体的には、乳首を観察できることが望ましい。このために、ライナー１００は、透明である一方で、ライナー支持フレーム２００は、以下により詳細に説明されるように、ライナー支持フレーム内部空間２０２の視覚検査を可能とするようにアクセス窓２１２を画成するアーム２１０ａ、２１０ｂを有する開放フレーム構造体を含んでもよい。しかし、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂが、偶然に、ライナー１００の中間セクション１４０の壁部の圧潰しない部分に、回転位置合わせされた場合、アーム２１０ａ、２１０ｂは、壁部のこれらの圧潰しない部分を介した乳房の良好な視界を妨げる。圧潰しない壁部分が、アクセス窓２１２の前に、明白に位置決めされるように、ユーザが乳房インターフェース７０を組み立てるのに役立つように、ライナー１００、特にその前部セクション１１０には、少なくとも１つのマーク１２８が設けられていてもよい。マーク１２８は、組立ての際に、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂと回転位置合わせされる。当然ながら、マーク１２８は、マーク１２８のアーム２１０ａ、２１０ｂとの回転位置合わせが、アクセス窓２１２を介する壁部の圧潰しない部分の望ましい視認性がもたらされるように位置付けられるべきである。一実施形態では、ライナー１００上のマーク１２８の数は、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂの数と一致してもよく、これにより、各マーク１２８は、対応するアーム２１０ａ、２１０ｂと位置合わせされる。マーク１２８は、ライナー１００の外側にエンボス加工された矢じり、又は、マークが位置合わせされる必要のあるアーム２１０ａ、２１０ｂの（接線方向）幅と略等しい（接線方向）幅を有する隆起された表面部分といった様々な形態であってよい。

【００３１】

原則的に、前壁部１１２によって画成される中央後部開口１１６ｂは、任意の適切な円周形状を有してよい。一実施形態では、例えば中央後部開口１１６ｂは円形である。しかし、円形の中央後部開口は、幾つかの欠点を有する。１つのそのような欠点は、操作中、搾乳器１は、女性の乳房に真空を印加することがあるという事実に関連する。この真空は、乳房の皮膚、特に、皮膚が中央後部開口１１６ｂの円形の円周エッジ１１４ｂに接触する場所の発赤を引き起こす。乳房に付いた円周エッジ１１４ｂの赤みを帯びた跡は、白癬といった真菌感染症の兆候として誤って受け取られてしまうことがある。円形の中央後部開口のもう１つの欠点は、逆流バリア１２０及び基部壁部１２２によって画成されるアンダーカットが著しい場合がある点である。これは、製造時のモールドからのライナー１００の取り外しと、使用後のライナーの適切な洗浄との両方を妨げる。

【００３２】

これらの欠点を解決する又は少なくとも軽減するために、ライナー１００の好適な実施形態は、非円形の形状を有する中央後部開口１１６ｂを画成する前壁部１１２を含む。中央後部開口部１１６ｂは、例えば図３Ｃに明らかに示されるように、５枚の花びらを有する花といった花の形状を有する。例えば図３Ｃに示されるものとは花びらの数が異なる及び／又は花びらの形状が異なる様々な花の形状、又は、星形といった全く異なる形状が使用されてもよい。中央後部開口１１６ｂの円周エッジ１１４ｂの形状の径方向における変動によって、非円形の開口は、概して、乳房に赤みを帯びた円形の跡が付くことを阻止し、アンダーカットをよりアクセスし易くすることによって、アンダーカットを洗浄し易くする。中央後部開口１１６ｂの非円形の形状は、外観があまり機械的でなく、搾乳器１を使用する女性に装飾的及び魅力的に見えるという追加のメリットを提供する。

【００３３】

ライナー１００の中間セクション１４０は、２つの壁部、即ち、（ｉ）Ｓ字形曲線を有する接続壁部１４２と、（ｉｉ）後部のテーパする漏斗状壁部１４４とを含む。Ｓ字形曲線を有する接続壁部は、前部セクション１１０の基部壁部１２２（の後端）を、中間セクション１４０の漏斗状壁部１４４の広い前端に接続する。

【００３４】

中間セクション１４０によって境界付けられる内部空間１８０は、圧力チャンバを画成する。使用時、搾乳器１の真空ポンプ１０は、圧力チャンバ１８０に真空を印加し、これ

により、ライナー１００の中間セクション１４０が、交互に、（ｉ）乳房の乳首上に圧潰し、（ｉｉ）その弛緩形状を再確立する又はその弛緩形状に戻るように広がる。

【００３５】

Ｓ字形曲線を有する接続壁部１４２は、圧力チャンバ１８０が真空の影響を受ける時の中間セクション１４０の圧潰と、真空が除去された場合のその弛緩形状の再確立との両方を容易にする働きをする。Ｓ字形曲線を有する接続壁部は、その名称の由来が、その長手方向の断面形状（弛緩状態における）にある。当該長手方向の断面形状は、図２Ｃにおいて最もよく見えるように、Ｓ字形曲線、即ち、二重曲げ又は二重ひだを規定する。Ｓ字形曲線は、ライナー１００の前部セクション１１０の基部壁部１２２（の後端）にすぐ隣に配置され、ライナー１００の長手軸Ｌの周りに回転対称である。Ｓ字形曲線を有する接続壁部１４２は、事実上、圧力チャンバ１８０が真空の影響を受ける時に、ライナー１００の中間セクション１４０が容易に変形し、したがって、内側に圧潰することを可能とする余分の壁部材料を提供する。更に、Ｓ字形曲線を有する接続壁部１４２は、圧力チャンバ１８０内の真空が取り消されると、その弛緩形状に戻るように変形するように構成される。

【００３６】

ライナー１００の中間セクション１４０は、後部から前部にかけて生じる、乳首へのその安全で、繰り返し可能で、左右両側での蠕動性の圧潰を確実とするように構成されることが好適である。このような圧潰を確実とすることに役立つように、中間セクション１４０の一方又は両方の壁部１４２、１４４は、長手軸Ｌの周りに２回転対称を有する剛性分布を有する。このために、壁部１４２、１４４は、例えば、対応する壁部１４２、１４４に沿って又は対応する壁部１４２、１４４内で、略径方向／長手方向に延在する例えば壁部の比較的剛性部分である細長いリブ１４６を含む。一実施形態では、このようなリブ１４６は、壁部の比較的厚い部分によって形成され、これは、ライナー１００が、単一の均質材料、又は、少なくとも、ライナー１００の壁部全体に亘って一様である弾性係数を有する材料から製造できるという利点を提供する。別の実施形態では、リブ１４６は、相互に異なる弾性係数を有する少なくとも２つの構成材料を使用して実現されてもよい。このような実施形態では、リブ１４６は、第１の構成材料で作られる一方で、Ｓ字形曲線を有する壁部１４２及び／又は漏斗状壁部１４４の隣接する又は周囲の部分は、第１の構成材料の弾性係数よりも小さい弾性係数を有する第２の構成材料で作られる。

【００３７】

図３に示されるライナー１００の実施形態では、ライナーの中間セクション１４０は、Ｓ字形曲線を有する接続壁部１４２と漏斗状壁部１４４との両方の壁部の比較的厚い部分によって画成される２つの（接線方向に）広く、（長手方向に）細長いリブ１４６を含む。リブ１４６は、中間セクション１４０の直径方向において両側に位置付けられる。使用時、真空が圧力チャンバ１８０に印加されると、壁部１４２、１４４のリブ付き部分は、その直径方向において両側にあるリブなし部分よりも多くの圧潰に対する抵抗を提供し、これにより、リブなし部分の互いに向かう左右両側の圧潰の方が好まれる。

【００３８】

ライナー１００の後部セクション１７０は、略軸方向に延在する管状又はパイプ状壁部を含み、ライナーの中間セクション１４０の漏斗状壁部１４４によって画成される漏斗の延長部を形成すると見なされる。したがって、中間セクション１４０の漏斗状壁部１４４の後端は、後部セクション１７０の管状壁部の前端に接続される。

【００３９】

ライナー１００の後部セクション１７０の管状壁部は、原則的に、任意の内側及び／又は外側横断面を有する。例えば図２乃至図４に示されるライナー１００の第１の例示的な実施形態は、略円形の内側及び／又は外側横断面を有する後部セクション１７０を有する。或いは、後部セクション１７０の管状壁部は、図７に示される第４の例示的な実施形態にあるように、例えば略ティアドロップ形の内側及び／又は外側横断面を有してもよい。１つの対称軸を有し、（長円形とは異なり）曲線の広い部分がその狭い部分に合流すると

ころで排他的に凸状ではない滑らかな平面閉曲線によって画成されるティアドロップ形状は、操作時のライナー１００の上記の左右両側の圧潰を支援する。ティアドロップ形状の内側断面を含む管状後部セクション１７０を有するライナー１００の一実施形態では、ティアドロップ形状の細い部分が、乳房から搾り出された乳を集乳器５０へ導く乳用の溝の機能を果たす。このような実施形態では、ティアドロップ形状の横断面の細い部分の（ティアドロップの対称軸に沿って測定される）長さは、ティアドロップ形状の横断面の細い部分によって画成される乳用の溝が、後方への軸方向において深くなる、即ち、下方向に傾斜するように、後部セクション１７０の後方への軸方向において増加する。

【００４０】

後部セクション１７０は更に、１つ以上の外部の、概して環状のフランジを含む。フランジは、管状壁部と一体に形成され、そこから径方向外側に延在する。第１のフランジ１７２は、管状壁部の後端に設けられる。第２のフランジ１７４は、第１のフランジ１７２の前に設けられ、第１のフランジ１７２から、又は、少なくとも管状壁部の後端から、軸方向に離間される。両フランジ１７２、１７４は、以下に説明されるライナー支持フレーム２００の後部リング２０６の内径よりも大きい外径を有する。第１のフランジ１７２及び第２のフランジ１７４の両方を含む実施形態において、それらの間の軸方向の間隔は、通常、ライナー支持フレーム２００の後部リング２０６の軸方向の長さと一致する。第２のフランジ１７４は、通常、第１のフランジ１７２よりも幾分（軸方向において）広く、及び／又は、（径方向において）高い。以下、「シーリングリップ」及び「フィンガグリップリング」とそれぞれ呼ばれる第１のフランジ１７２及び第２のフランジ１７４の機能は、乳房インター－フェー－ス７０の組立てについて説明される以下において明らかにされる。

【００４１】

ライナー１００は、例えば熱可塑性エラストマー、ゴム、ラテックス又は液状シリコーンゴム（ＬＳＲ）といったフレキシブルで、好適には弾性を有する材料から一体部品として製造される。一実施形態では、ライナー１００は、射出成形を介して製造される。この処理では、ライナーは、その弛緩状態で固定又は硬化される。ライナー材料は透明であってよく、これにより、女性が、使用時に、ライナー１００の中で何が起きているのかを視覚的に観察することができる。

【００４２】

次に、ライナー支持フレーム２００の構造の説明に移る。図４Ａ乃至図４Ｃは、それぞれ、図２Ａ乃至図２Ｄに示される乳房インターフェース７０の第１の例示的な実施形態のライナー支持フレーム２００を、斜視図（図４Ａ）、側面図（図４Ｂ）及び正面図（図４Ｃ）で概略的に示す。

【００４３】

その名称が示すように、ライナー支持フレーム２００は、ライナー１００に機械的な支持を提供する働きをする。このために、ライナー支持フレーム２００は、ライナー支持フレーム内部空間２０２を画成し、その中に、乳房インターフェース７０の組み立てられた状態において、ライナー１００が（外部から）ライナー支持フレーム２００によって係合され、嵌めこまれるように、ライナー１００の少なくとも一部を受容することができる。図２Ａ乃至図２Ｄを参照されたい。その支持機能を果たすために、ライナー支持フレーム２００は、その構造が実質的に剛性であり、操作時に、大きく変形することなく、ライナー１００によってそこにかかる任意の力に耐えることができるように（ライナー１００に比べて）比較的硬い材料から作られる。ライナー支持フレーム２００は、例えば射出成形されたプラスチックといった任意の適切な材料から製造されてもよい。

【００４４】

ライナー支持フレーム２００は、透明であってもよいし、透明又は非透明のライナー１００と組み合わせて使用されてもよいが、透明なライナー１００と不透明なライナー支持フレーム２００との組み合わせが、ユーザ機能性を最大にし、２つの部品間のコントラストを最適にする。このコントラストによって、ユーザが乳房インターフェース７０を組立

て、組立ての正確さを確認する能力を高める。

【００４５】

ライナー支持フレーム２００は、２つの軸方向に離間されたリング、即ち、前部リング２０４と後部リング２０６とを含む。なお、明確にするために、本テキストにおいて使用される「リング」との用語は、広く解釈されるべきである。当該用語は、典型的には円形であるが、非円形（例えば多角形）であってもよいその円周形状に関係なく、任意の連続的又は不連続的／分割された環状要素を包含することを意図している。２つのリング２０４、２０６は、少なくとも１つの比較的硬く、略軸方向に延在するアーム又はストラットによって相互に接続される。図４Ａ乃至図４Ｃの第１の例示的な実施形態では、ライナー支持フレーム２００は、２つの硬いが、弾力のあるアーム２１０ａ、２１０ｂを含む。これらのアームは、構造上同一である。前部リング２０４は、通常、後部リング２０６よりも大きい内径及び外径を有する。したがって、複数のアーム２１０ａ、２１０ｂを有する実施形態では、２つのリング２０４、２０６を相互接続するアーム２１０ａ、２１０ｂは、前部リング２０４から、後方方向において、後部リング２０６に合流すると見なされる。後部リング２０６の内径は、ライナー１００の管状後部セクション１７０の外径に合せられる。即ち、当該外径に略等しい。後部リング２０６は、連結器３０との真空気密接続を可能とするように、管状後部セクション１７０を嵌めるように受容する（図２Ａ乃至図２Ｄを参照）。

【００４６】

図４Ａ乃至図４Ｃの第１の例示的な実施形態において見られるように、ライナー１００の前部セクション１１０における環状溝１２６に受容されるように構成される前部リング２０４は、単一の部品で、連続的又は閉リングである（前部リングが分割されている図５及び図６の第２及び第３の例示的な実施形態と比較されたい）。前部リング２０４の略軸方向の長さは、乳房インターフェース７０の組み立てられた状態において、前部リング２０４の後端（アーム２１０ａ、２１０ｂとの接合部は無視する）が、壁部１２２、１２４のうちの少なくとも一方、即ち、リップ壁部１２４の後端及び基部壁部１２２の後端のうちの少なくとも一方と実質的に同一平面にあるように、環状溝１２６を画成する壁部１２２、１２４の少なくとも一方の略軸方向の長さに一致することが好適である。図示される実施形態では、図２Ｄの側断面図において最もよく見えるように、前部リング２０４の後端は、基部壁部１２２の後端と同一平面に位置する。組立ての際、これらの後端の面一性は、前部リング２０４の環状溝１２６への挿入が完了したことを知らせる合図をユーザに提供する。

【００４７】

ライナー１００の管状後部セクション１７０に嵌るように、また、場合により、締め付けるように構成される後部リング２０６は、後部リング２０６自体が後部セクションの２つのフランジ１７２、１７４の間で軸方向にぴったりと受容可能であるように（図２Ａ乃至図２Ｄを参照）、分割された又は二重不連続リングであることが好適である。つまり、後部リング２０６は、後部リングを少なくとも２つの実質的に剛性の相補形の円周部分に分割する少なくとも２つの円周不連続部を含む。相補形の円周部分は、後部リング２０６の断面開口／通路領域が、一時的に拡大されるように、移動可能であり、したがって、互いに対し再配置可能であり、任意選択的に、互いから取り外すことも可能である。図４Ａ乃至図４Ｃの第１の例示的な実施形態では、例えば後部リング２０６は、当該リングを２つの別個の相補形の半体２０６ａ、２０６ｂに分割する実際の割れ目又はスリットの形態の２つの円周不連続部を有する。図５及び図６の第２及び第３の実施形態を参照するに、これらの実施形態は共に、分割された後部リング２０６を同様に含む。図６の実施形態を考慮すると、相補形の後部リング部分を接続する、図６におけるフォイルヒンジ２０１といったヒンジが、概して円周不連続部を形成すると見なされる。これは、ヒンジは、後部リング２０６の円周形状の画成に貢献する場合であっても、その（内）周に沿って、後部リングの実質的な剛性の不連続部を表すからである。即ち、ヒンジは、２つの実質的に剛性の相補形の円周後部リング部分を、それらの空間的再配置を可能とするために、意図的

に接続するに過ぎないからである。

【００４８】

図４Ａ乃至図４Ｃの第１の例示的な実施形態において見られるように、各相補形の後部リング部分２０６ａ、２０６ｂは、様々なアーム２１０ａ、２１０ｂを介して、前部リング２０４に接続される。ライナー支持フレーム２００は、比較的硬いが、この分割後部リング構造は、後部リングの相補形の円周部分２０６ａ、２０６ｂが（各アーム２１０ａ、２１０ｂによって加えられる適度な径方向内側へのバネ作用に逆らって）径方向／接線方向に離れることを可能とすること（これにより、各アーム２１０ａ、２１０ｂは、径方向外側に動く）によって、乳房インターフェース７０の組立てを容易にし、これにより、ライナー１００の管状後部セクション１７０を、円周部分の間で、軸方向に通す作業を簡単にする。これは、特に、ライナー１００の管状後部セクション１７０の後部端にフランジ又はシーリングリップ１７２を含む実施形態において、言えることである。

【００４９】

分割後部リング２０６における上記された少なくとも２つの円周不連続部は、当該リングを２つの相補形の部分２０６ａ、２０６ｂに分ける対応する割れ目２０８によって形成される。割れ目２０８は、図示される実施形態において見られるように、同一の形状を有してよいが、これは必須ではない。２つの相補形の円周後部リング部分２０６ａ、２０６ｂ間の割れ目２０８の形状は、基本的には任意の形状を有してもよい。一実施形態では、割れ目の形状は、真っ直ぐ又は線形である。しかし、真っ直ぐな割れ目形状は、後部リング２０６の相補形の円周部分２０６ａ、２０６ｂ間の相対的な軸方向の移動を容易にしてしまうという欠点があり、これは、ライナー支持フレーム２００における望ましくない機械的応力につながる。このような比較的軸方向の移動は、特に、乳房インターフェース７０の搾乳器１への接続の際に生じる。即ち、乳房インターフェース７０の後端が、連結器３０の受容路４２内に押し込まれる時に生じる。真っ直ぐな割れ目形状のもう１つの欠点は、後部リング２０６が、偶然に壊れたかのように見える点である。これらの欠点を解決するために、割れ目の形状は、図示される実施形態に示されるように、略Ｃ字形である。滑らかなＣ字形の割れ目形状は、相補形の後部リング部分２０６ａ、２０６ｂの正しい相対的な軸方向の位置合わせを維持するのに役立ち、後部リング２０６が誤って壊れていると見られないように、意図する通りに見える。

【００５０】

後部リング２０６の（径方向）内面は滑らかである。しかし、滑らかな内面は、例えばシリコーン製のライナー１００の後部セクション１７０と後部リング２０６との間の摩擦を促進することが分かっており、これは、乳房インターフェース７０の組立てを複雑にする可能性がある。ライナー１００の後部セクション１７０と後部リング２０６の内面との間の摩擦を減少させるために、内面には、例えばマット仕上げを有するように表面テクスチャが施される。表面テクスチャは、スパーク（sparked）仕上げであってもよい。

【００５１】

合わせて、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂも、ライナー支持フレーム２００のライナー支持フレーム内部空間２０２を完全に接線方向又は円周方向において包囲しないことが好適である。ライナー支持フレーム内部空間２０２を共に完全に包囲するアーム２１０ａ、２１０ｂは、乳房インターフェース７０の組立て及び組立て分解を妨げる場合があり、また、使用中におけるユーザのライナー１００の視野を遮る可能性がある。当該視野は、特にライナーの圧潰の過程に関する情報、また、透明のライナーを使用する実施形態では、乳首の配置及び乳の流れに関する情報を提供する。したがって、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂのうちの少なくとも一方が、少なくとも１つのアクセス窓２１２を画成することが好適である。より具体的には、２つの接線方向の隣接するアーム２１０ａ、２１０ｂは共に、それらの間に（接線方向に）アクセス窓１２１を画成し、当該アクセス窓２１２は、ライナー支持フレーム内部空間２０２への手動及び視覚的アクセスを可能にする。図４Ａ乃至図４Ｃに示されるライナー支持フレーム２００の実施形態は、ライナー支持フレーム２００の両側に２つのこのようなア

クセス窓を有する。組立ての際に、１つのアクセス窓２１２は、ライナー支持フレーム内部空間２０２の視覚的な観察のために使用され、もう１つのアクセス窓２１２は、そこへの手動アクセスのために使用される。

【００５２】

ライナー支持フレーム２００のロバスト性を高めるために、各アーム２１０ａ、２１０ｂと前部リング２０４との接合部又は接続部は、各アームと後部リング２０６との接合部よりも（接線方向に）広いことが好適である。したがって、アーム２１０ａ、２１０ｂの（接線方向の）幅は、後方方向にテーパする。これに加えて又は代えて、前部リング２０４における接合部は、例えば前部リング２０４の半径の少なくとも半分である曲率半径である比較的大きい曲率半径２１６を規定することが好適である。このような大きい半径は、アーム２１０ａ、２１０ｂの屈曲に対する剛性を増加させ、したがって、使用時に、乳房インターフェース７０が垂れた感じがあまりしない。

【００５３】

ライナー支持フレーム２００のアーム２１０ａ、２１０ｂが、その後部リング２０６に接合する場所において、段部２２０が画成されることが好適である。段部２２０は、角度の比較的急激な変化によって特徴付けられる。段部２２０は、乳房インターフェース７０の後部の搾乳器１の連結器３０内の受容路４２への挿入の際に、連結器の外面に対抗して付勢される止め部として働く。段部２２０があることによって、ユーザが、乳房インターフェースの後部を、連結器にある受容路４２内に、段部２２０が連結器に当接する点まで付勢することを促し、これにより、乳房インターフェース７０と連結器３０との間に適切な真空シールが実現され、また、乳房インターフェース７０の分割後部リング２０６が、定位置に固定され、ライナー支持フレーム２００にその剛性の一部が提供される。

【００５４】

ライナー支持フレーム２００のアーム２１０ａ、２１０ｂ各々には、ライナー１００の後部セクション１７０にある第２のフランジ１７４と協働するフランジ相互作用部材２２２が設けられている。フランジ相互作用部材２２２は、それが設けられているアーム２１０ａ、２１０ｂの内面から内側に突出する。長手方向の側断面図（図２Ｃを参照）において見られるように、フランジ相互作用部材２２２は、概して鋸歯状であり、後方方向において見た場合に、径方向内側に傾斜する傾斜面２２４と、実質的に径方向に延在する後部止め面２２６とを含む。止め面２２６は、当該止め面２２６と後部リング２０６の前端との間に軸方向の間隙２２８があるように、後部リング２０６の前端の隣にあるが、当該前端から軸方向に離間されて配置される。ライナー支持フレームのアーム２１０ａ、２１０ｂと後部リング２０６との間の接合部が、段部２２０を画成する実施形態では、フランジ相互作用部材２２２の止め面２２６は、段部２２０の内側に面する。

【００５５】

フランジ相互作用部材２２２は、乳房インターフェース７０の第１の例示的な実施形態の組立て処理の説明から明らかとなるように、幾つかの目的を果たす。

【００５６】

乳房インターフェース７０が、ライナー１００と、ライナー支持フレーム２００とを別個の構造コンポーネントとして含む場合、図２乃至図４の乳房インターフェースは、次の通りに組み立てられる。ユーザは、ライナー１００上に設けられるマーク１２８が、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂと回転位置合わせされるように、ライナーの管状後部セクション１７０を、ライナー支持フレーム２００の前部リング２０４を通して軸方向に挿入する。ユーザは、ライナー支持フレーム２００に設けられたアクセス窓２１２のうちの１つ以上を介して指を入れ、ライナー１００の後部セクション１７０に設けられた第２のフランジ又はフィンガグリップリング１７４を掴む。第２のフランジ１７４を掴みつつ、ユーザは、ライナー１００を後方に押す又は引っ張る。その際に、第２のフランジ１７４は、アーム２１０ａ、２１０ｂの内面に設けられたフランジ相互作用部材２２２に接触する。その結果、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂは、ライナー１００が更に後方に動かされるのにつれて、径方向に離れるように徐々

に広がるようにされる。アーム２１０ａ、２１０ｂの広がりは、ライナー支持フレーム２００の分割後部リング２０６の相補形の円周部分２０６ａ、２０６ｂの広がりを引き起こし、これは、相補形の円周部分間で、第１のフランジ１７２を通過し易くする。第２のフランジ１７４が、フランジ相互作用部材２２２の止め面２２６の軸方向の位置に到達すると、第２のフランジは、止め面２２６と後部リング２０６の前端との間の軸方向の間隙２２８内に嵌り込む。同時に、２つのアーム２１０ａ、２１０ｂは、相補形の円周後部リング部分２０６ａ、２０６ｂが、第１のフランジ１７２と第２のフランジ１７４との間に延在するライナー１００の管状後部セクション１７０の一部分に嵌合係合するように、再び弛緩し、互いに向かって動く。これは、少なくとも後端において、ライナー１００のライナー支持フレーム２００への挿入が完了したという視覚的確認をユーザに提供するだけでなく、シーリングリップ１７２及びフィンガグリップリング１７４、従って、ライナー１００も、更なる軸方向の移動に対して係止する。組立てを完了するために、ユーザは、ライナー支持フレーム２００の前部リング２０４が、ライナー１００の前部セクション１１０における環状溝１２６にきっちりと受容されたことを確認し、また、必要に応じて、好適には、前部リング２０４が、環状溝１２６を画成する壁部１２２、１２４の少なくとも一方の後端と同一平面であるように、前部リング２０４の環状溝１２６への適切な配置を確実にしてもよい。

【００５７】

乳房インターフェース７０自体が組み立てられると、その後部、具体的には、ライナー１００の管状後部セクション１７０とライナー支持フレーム２００の後部リング２０６とは、搾乳器１の連結器３０によって提供される受容路４２内に挿入される。受容路４２は、適切な真空シーリングが実現されるように、乳房インターフェース７０の後部が圧入受容されるような寸法にされることが好適である。

【００５８】

乳房インターフェース７０と連結器３０との間の第１の真空シールが、シーリングリップ１７２と、受容路４２の内面との間に形成される。このために、シーリングリップ１７２の外径は、受容路４２の内径よりも僅かに大きいことが好適である。ライナー材料の柔軟性によって、シーリングリップ１７２は、乳房インターフェース７０の後部の受容路４２への挿入時に変形する。これにより、シーリングリップ１７２の外周と、受容路４２の内周との間の形状における差異が調整され、効果的な真空シールが生成される。第２の真空シールが、分割後部リング２０６の外面と、受容路４２の内面との間に形成される。この第２の真空シールを実現するために、２つの、通常、剛性であるコンポーネント４２、２０６の表面は、実質的に形状が同一である必要があり、例えば同じ直径、テーパ等を有さなければならない。シーリングリップ１７２及びフィンガグリップリング１７４が、それらの間で軸方向において後部リング２０６に係合するにつれて、第３の真空シールが、フィンガグリップリング１７４との協働によってシーリングリップ１７２によって形成されてもよい。

【００５９】

図１乃至図４を参照して、乳房インターフェース７０の第１の例示的な実施形態について説明した。次に、幾つかの特定の及び有利な変形態様を示す幾つかの更なる例示的な実施形態に注目する。

【００６０】

なお、図１乃至図４の第１の例示的な実施形態のライナー支持フレーム２００は、単一部品コンポーネントであるが、代替実施形態のライナー支持フレーム２００は、複数の取り外し可能に接続可能な部品を含んでもよい。

【００６１】

一実施形態（図示せず）では、例えば前部リングと後部リングとを相互接続する少なくとも１つのアームは、実質的にアームの全軸方向長さに亘って、ライナー支持フレームの長手軸に対し１２０°～１８０°の範囲の角度に対応する。このような広い、「ハーフパイプ」アームは、追加のアームを不必要にする十分な剛性を有するクレードル状のライナ

一容器を提供する。このような実施形態では、前部リング２０４及び／又は後部リング２０６は、２つの取り外し可能に接続可能な相補形の円周部分を含む。各リングについて、相補形の円周部分のうちの一方は、ハーフパイプアームと一体にされ、もう一方は、例えばクリップの形で、ハーフパイプアームに取り外し可能に接続可能である。後者のリング部分の分離された状態では、ライナー１００の前者のアームが取り付けられた部分への挿入が容易にされる一方で、両部分の閉じた状態では、ライナーは、両部分間の適切な位置にしっかりと保持される。

【００６２】

図５の第２の例示的な実施形態といった後者の実施形態を更に詳細に説明するために、ライナー支持フレーム２００全体が、２つの取り外し可能に接続可能な部分又は半体２００ａ、２００ｂに分割されてもよい。図示されるように、この実施形態では、前部リング２０４及び後部リング２０６が共に分割され、各リング２０４、２０６は、第１のアーム２１０ａに固定して接続される１つの部分２０４ａ、２０６ａと、第２のアーム２１０ｂに固定して接続されるもう１つの相補形の部分２０４ｂ、２０６ｂとを有する。乳房インターフェース７０の組立ての際に、２つのフレーム部分又は半体２００ａ、２００ｂは、具体的には、（ｉ）前部リング部分２０４ａ、２０６ｂを、ライナー１００の環状溝１２６内に位置付けることによって、また、（ｉｉ）その後部リング部分２０６ａ、２０６ｂの後端を、シーリングリップ１７２に接して、場合により、シーリングリップ１７２により画成される環状溝１７３（図６Ａ参照）内に位置付けることによって、順々に、ライナー１００と係合される。続いて、乳房インターフェース７０は、搾乳器１の連結器３０によって提供される受容路４２内に圧入される。

【００６３】

図５の２パートライナー支持フレーム２００は、乳房インターフェース７０の組立ての際に、シーリングリップ１７２を、後部リング２０６を通して挿入するためにユーザがかなりの力を加える必要をなくすが、ライナー支持フレーム２００のマルチパートデザインは、フレームの様々な部品が一緒に保持されず、気が付かないうちに紛失する可能性があるという欠点を有する。この問題を回避するために、ライナー支持フレームの２つの相補形の半体２００ａ、２００ｂは、取り外し可能に接続可能であるようには作られず、その代わりに、図６の第３の例示的な実施形態にあるように、例えばフォイルヒンジ２０１によって、ヒンジを介して接続されてもよい。

【００６４】

図７Ａ及び図７Ｂは、本開示による乳房インターフェース７０の第４の実施形態を、側断面図（図７Ａ）及び後面斜視図（図７Ｂ）で概略的に示す。

【００６５】

図１乃至図４の乳房インターフェース７０の第１の例示的な実施形態に関連付けられる問題は、それを使用する女性が、自身の乳房から搾り出された乳が確実に集乳器５０に向かい、その中へと流れるように、前傾になる必要がある点である。１回の搾乳セッションには時間がかかり、特には３０分以上にも及ぶため、前傾姿勢は不快となる。

【００６６】

不快感の問題を解決するために、乳房インターフェース７０、及び、具体的にはそのライナー１００は、上部側又は頂部側及び下部側又は底部側を有する使用姿勢（use orientation）と関連付けられる。更に、ライナー１００の前部セクション１１０は、乳房接触面１１８（図２Ｃも参照）における開口１１６ｂの平面に実質的に垂直に延在する、また、上記の使用姿勢において、実質的に水平に延在する長手軸L_{fs}に関連付けられる。即ち、使用時、前部セクション１１０の乳房接触面１１８が、女性の乳房に接触すると、前部セクション１１０の長手軸L_{fs}は、実質的に水平に延在する。ライナー１００の構造は更に、ライナー１００の中間セクション１４０の後方にテーパする漏斗状壁部１４４及び／又は後部セクション１７０の管状壁部１７１が、乳房接触面１１８における（乳首を受容する）開口１１６ｂから、管状壁部１７１の後端（乳放出）開口にまで延在し、また、上記の使用姿勢において、前部セクション１１０の長手軸L_{fs}に対して下方向に傾斜

する細長い内側下部／底部表面部分１７１ａによって少なくとも部分的に境界付けられる乳用の導管１９０を画成するように、適応される。後部セクション１７０（の底部表面部分１７１ａ）の下方向への傾斜によって、乳房から搾り出された乳は、重力の作用によって、後部セクション１７０の管状壁部１７１を通り、その後端開口に向かって、自然に流れる。したがって、女性が、使用時に前傾する必要はない。

【００６７】

この解決策によれば、乳房インターフェース７０の長手軸Ｌは、乳房インターフェース７０の当該長手軸Ｌが２つの真っ直ぐで位置合わせされないセクションを含むように（下方向の）キンク又は屈曲を含むことが好適である（図７Ａを参照）。長手軸の第１のセクションL_{fs}は、ライナー１００の前部セクション１１０とライナー支持フレーム２００の前部リング２０４とに関連付けられ、長手軸の第２のセクションL_{rs}は、ライナー１００の後部セクション１７０と、ライナー支持フレーム２００の少なくとも１つのアーム２１０ａ、２１０ｂ及び後部リング２０６とに関連付けられる。乳房インターフェース７０の長手軸Ｌの２つのセクションL_{fs}、L_{rs}は、約１０～４５度の範囲内の角度φを含むことが好適である。後部セクション１７０の少なくとも管状壁部１７１の断面形状は、円形であるが、円形である必要はない。図示される実施形態では、例えば後部セクション１７０の管状壁部１７１は、上記され、かつ、図７Ｂに示されるように、（逆さまにされた）ティアドロップ形状の内側断面形状を有する。したがって、管状壁部１７１は、「下方向に傾斜する溝」を有する乳用の導管１９０である長手方向の部分を画成し、その底部は、細長い底部表面部分１７１ａによって形成される。

【００６８】

本明細書に開示される乳房インターフェースの例示的な実施形態が、部分的に添付図面を参照して、上で説明されたが、当然ながら、本開示は、これらの実施形態に限定されない。開示された実施形態の変形態様が、当業者によって、図面、開示及び添付の特許請求の範囲の検討から、乳房インターフェースを実施する際に、理解及び実現されてもよい。本明細書全体を通して「１つの実施形態」、「一実施形態」等との言及は、実施形態に関連して説明される特定の特徴、構造又は特性が、乳房インターフェースの少なくとも１つの実施形態に含まれてもよいことを意味する。したがって、本明細書全体に亘って様々な場所において出現する「１つの実施形態では」又は「一実施形態では」との表現は、必ずしもすべて同じ実施形態を指しているわけではない。なお、１つ以上の実施形態の特定の特徴、構造又は特性は、明示的には説明されていないが新しい実施形態を形成するために、任意の適切な態様で組み合わされてもよい。同様に、１つ以上の実施形態の特定の特徴、構造又は特性は、明示的には説明されていないが新しい実施形態を形成するために、明示的に説明されている実施形態から取り除かれてもよい。例えば図７の第４の例示的な実施形態を参照して説明されたライナーの「下方向に傾斜する後部セクション」という特徴は、新しい実施形態を形成するために、説明されたどの他の実施形態に組み込まれてもよい。同様に、他の実施形態を参照して説明された特徴も、明示的には説明されていないが新しい実施形態を形成するために、第４の実施形態に含めることも考えられる。

【００６９】

要素のリスト

１　搾乳器
１０　真空ポンプ
３０　連結器
３２　第１の管状セグメント
３４　第１のチャネル
３６　第２の管状セグメント
３８　第２のチャネル
４０　第１の管状セグメントの下端におけるねじ込みソケット
４２　乳房インターフェースの後端を受容するための受容路
５０　集乳器

７０　乳房インターフェース
１００　ライナー
１１０　前部セクション
１１２　円錐状前壁部
１１２ａ　前壁部の前面
１１２ｂ　前壁部の背面
１１４ａ　径方向外側の円周エッジ
１１４ｂ　径方向内側の円周エッジ
１１６ａ　前部開口
１１６ｂ　後部開口
１１８　乳房接触面
１２０　逆流バリア
１２２　基部壁部
１２４　リップ壁部
１２６　基部壁部とリップ壁部との間の環状溝
１２８　回転位置合わせマーク
１４０　中間セクション
１４２　Ｓ字形曲線を有する接続壁部
１４４　後部のテーパする漏斗状壁部
１４６　長手方向リブ
１７０　後部セクション
１７１　管状壁部
１７１ａ　下部内側表面部分
１７２　第１のフランジ／シーリングリップ
１７３　前方向に曲げられた第１のフランジによって画成される環状溝
１７４　第２のフランジ／フィンガグリップリング
１８０　内部圧力チャンバ
１９０　乳用通路
２００　ライナー支持フレーム
２００ａ　ライナー支持フレームの第１の相補形の部分
２００ｂ　ライナー支持フレームの第２の相補形の部分
２０１　（フォイル）ヒンジ
２０２　ライナー支持フレーム内部空間
２０４　前部リング
２０４ａ　第１の相補形の前部リング部分
２０４ｂ　第２の相補形の前部リング部分
２０６　分割後部リング
２０６ａ　第１の相補形の後部リング部分
２０６ｂ　第２の相補形の後部リング部分
２０８　リング半体間の割れ目
２１０ａ　第１のアーム
２１０ｂ　第２のアーム
２１２　第１のアームと第２のアームとの間のアクセス窓
２１４　アームと前部リングとの接合部
２１６　アームと前部リングとの接合部における大きい半径
２１８　アームと後部リングとの接合部
２２０　段部
２２２　フランジ相互作用部材
２２４　傾斜面
２２６　止め面

２２８　止め面と後部リングの前端との間の軸方向間隙
A_{maj}　楕円形環状溝の長軸
A_{min}　楕円形環状溝の短軸
L　乳房インターフェースの長手軸
L_{fs}　ライナーの前部セクション／フレームの前部リングの長手軸
L_{rs}　ライナーの後部セクション／フレームのアーム及び後部リングの長手軸
R　径方向
φ　長手軸セクションL_{fs}、L_{rs}によって挟まれる角度

【図１Ａ】

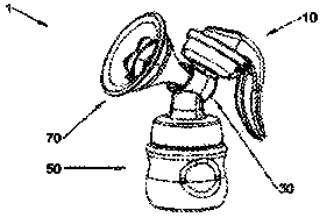


Fig. 1A

【図１Ｂ】

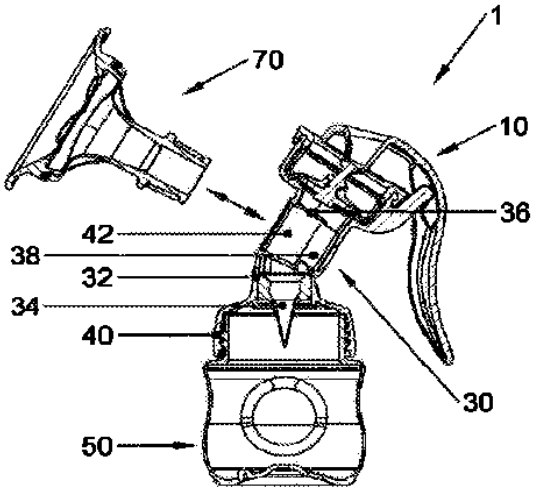


Fig. 1B

【図２Ａ】

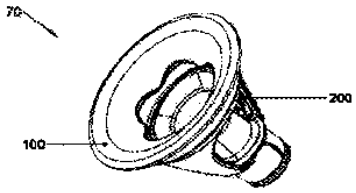


Fig. 2A

【図２Ｂ】

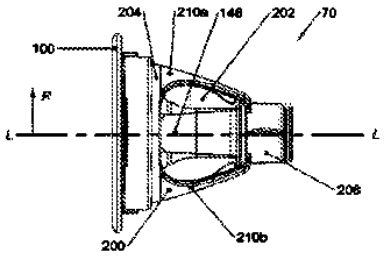


Fig. 2B

【図２Ｃ】

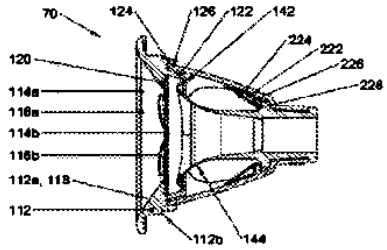


Fig. 2C

【図２Ｄ】

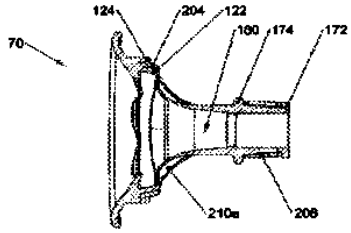


Fig. 2D

【図３Ａ】

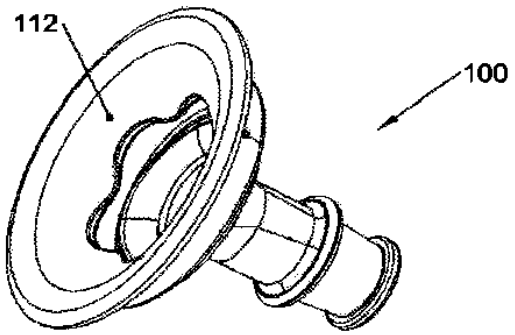


Fig. 3A

【図３Ｂ】

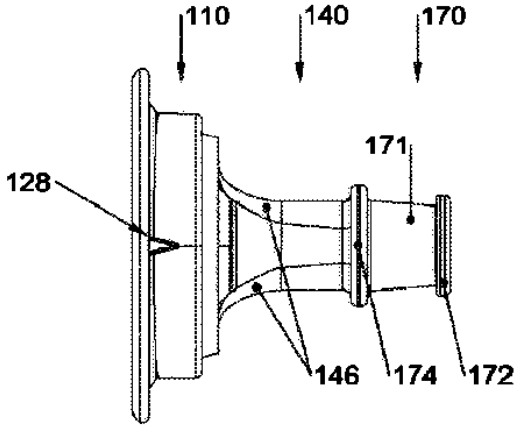


Fig. 3B

【図３Ｃ】

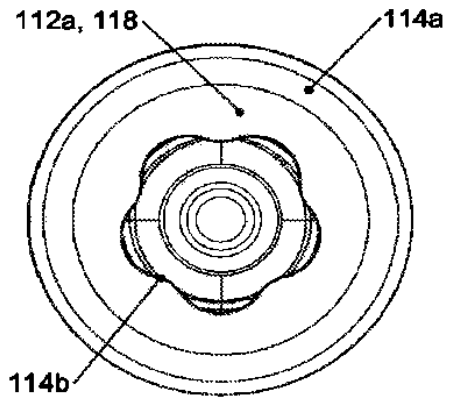


Fig. 3C

【図３Ｄ】

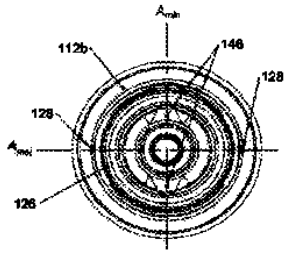


Fig. 3D

【図４Ａ】

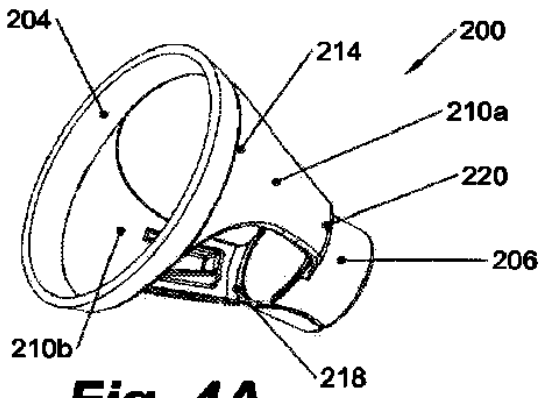


Fig. 4A

【図４Ｂ】

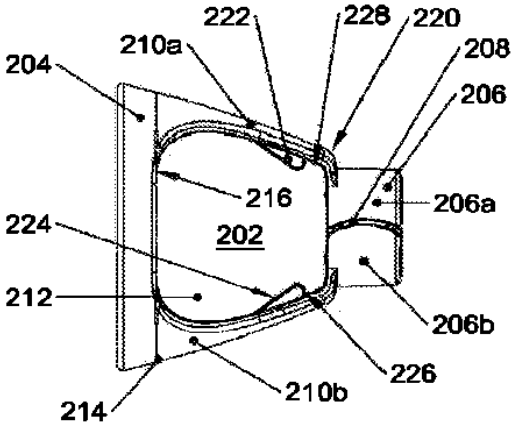


Fig. 4B

【図４Ｃ】

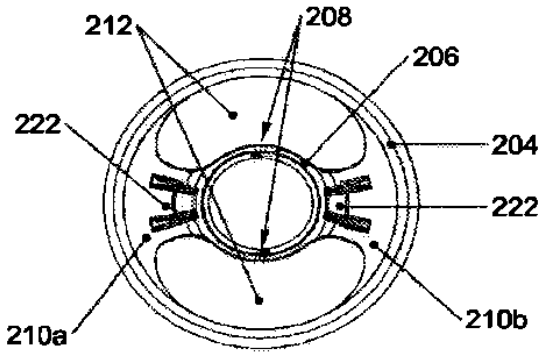


Fig. 4C

【図５Ａ】

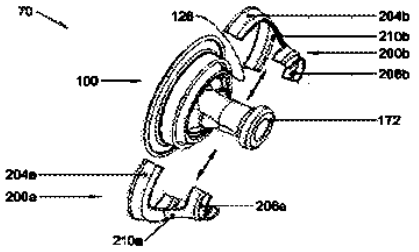


Fig. 5A

【図５Ｂ】

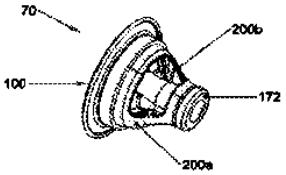


Fig. 5B

【図６Ａ】

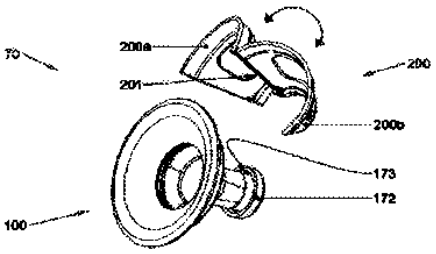


Fig. 6A

【図６Ｂ】

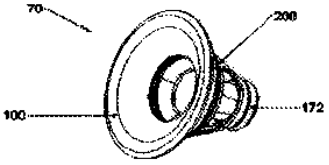


Fig. 6B

【図７Ａ】

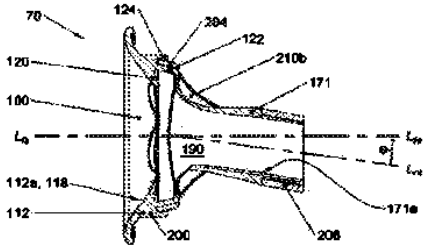


Fig. 7A

【図７Ｂ】

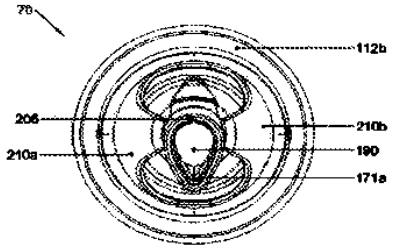


Fig. 7B

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/054197

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/171270 A1 (ROEHRIG PETER [AT]) 2 July 2009 (2009-07-02) abstract; figures 1,4-5 paragraph [0035] -----	1-7
Y	US 6 974 439 B1 (MCKENDRY BRUCE [US]) 13 December 2005 (2005-12-13) abstract; figures 2,6 column 4, line 18 - column 5, line 13 -----	1-10
Y	US 6 673 037 B1 (SILVER BRIAN H [US]) 6 January 2004 (2004-01-06) figures 1-2 column 2, lines 1-18 column 3, lines 9-40 -----	1-10

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
16 May 2014	27/05/2014

Name and mailing address of the ISA/	Authorized officer
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page 1 of 2

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/116632 A1 (GILLAN JONATHAN C [US]) 1 June 2006 (2006-06-01) abstract; figure 3 paragraphs [0040] - [0044] -----	1-10
A	US 2005/222536 A1 (SILVER BRIAN H [US]) 6 October 2005 (2005-10-06) abstract; figure 8 paragraph [0041] -----	1-10

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/054197

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 2007209749 A1	02-08-2007
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		US 2009171270 A1	02-07-2009
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		WO 2005097230 A2	20-10-2005

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

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(81)指定国 AP(BW,GH,GM,KE,LR,LS,MW,MZ,NA,RW,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,RU,TJ,TM),EP(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),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,KM,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AO,AT,AU,AZ,BA,BB,BG,BH,BN,BR,BW,BY,BZ,CA,CH,CL,CN,CO,CR,CU,CZ,DE,DK,DM,DO,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,GT,HN,HR,HU,ID,IL,IN,IR,IS,JP,KE,KG,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LT,LU,LY,MA,MD,ME,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PA,PE,PG,PH,PL,PT,QA,RO,RS,RU,RW,SA,SC,SD,SE,SG,SK,SL,SM,ST,SV,SY,TH,TJ,TM,TN,TR,TT,TZ,UA,UG,US

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(71) Applicant: MEDELA, INC. [US/US]; 4610 Prime Parkway, McHenry, IL 60051 (US).

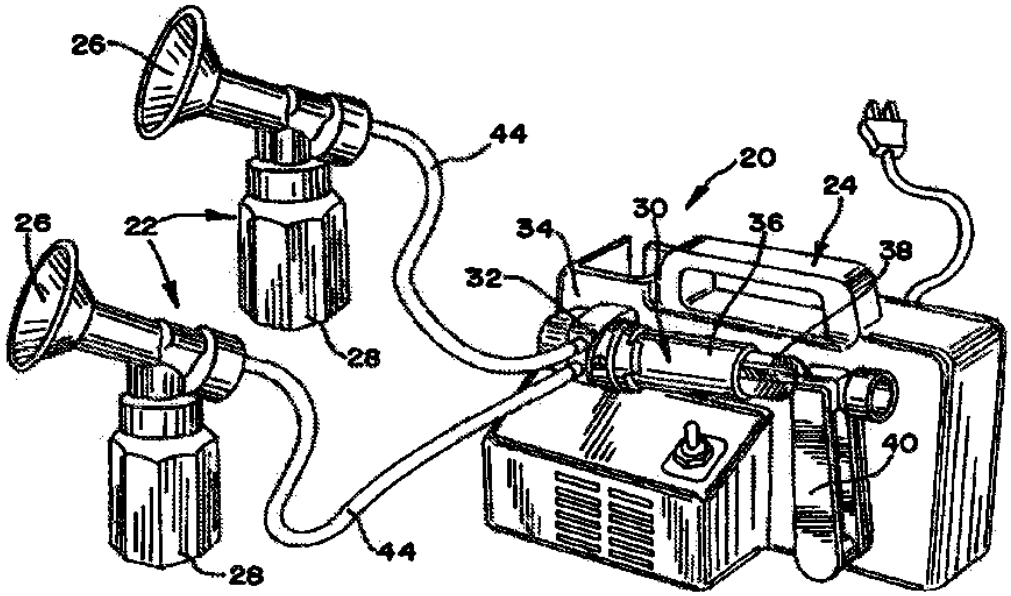
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(54) Title: IMPROVED BREAST PUMP ASSEMBLY AND METHOD OF USING SAME



(57) Abstract

An improved breast pump assembly (20) allows two breast pumps (22) to be connected to a motor drive unit (24) for simultaneous breast pumping. In a preferred embodiment, the improved breast pump assembly (20) can be adjusted for either single breast pumping or for double breast pumping, depending on the particular woman's needs.

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IMPROVED BREAST PUMP ASSEMBLY AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

The present invention is directed generally to breastmilk pumps and, more particularly, to an improved breast pump assembly for expressing mothers' milk, which may be used in a manually-driven mode as well as a motor-driven mode.

Breast pumps for extracting or expressing breastmilk from a woman's breasts for later use by an infant have been available for years. Typically, these breast pumps include a funnel-shaped hood, or shield, that is placed over the nipple and a substantial portion of the breast. A reduced pressure or vacuum is intermittently generated in the hood in a manner which causes milk to be expressed from the breast within the hood. The milk then typically flows from the hood to a storage container for later use.

Generally, two types of breast pumps have been marketed for use by nursing women: motor-driven pumps; and manually-operated pumps. In manually-operated breast pumps, the intermittent suction action is typically generated by means of a compressible bulb or, more frequently, a piston-type pump. The piston pump

generally includes a piston cylinder connected to the hood, and a piston slidably disposed within the piston cylinder and which is reciprocated by a hand-drivable piston rod. Motor-driven pumps typically either have a separate vacuum pump attached to the hood by tubing, or the motor is built into the hood assembly itself.

U.S. Patent No. 5,007,899 discloses a drive unit to which the piston pump of an otherwise manually-operated breast pump can be attached for motorized breast pumping. The present invention is the particular result of improvements to the breast pump assembly disclosed in U.S. Patent No. 5,007,899, and to the LACTINA breast pump assembly manufactured and sold by Medela, Inc. to which the foregoing patent relates.

SUMMARY OF THE INVENTION

The present invention provides an improved breast pump assembly which enables easy and effective vacuum connection of one or two breast hoods, or shields, to a piston pump, particularly where the piston pump is mounted to be driven by a motor drive unit. In a preferred embodiment of the present invention, the improved breast pump assembly can be readily adjusted through use of a selector element for either single breast pumping or for double breast pumping, depending on the particular woman's needs.

According to a first aspect of the present invention, the improved breast pump assembly includes at least one and preferably two breast pumps (i.e., shield, bottle, valving) each having a breast shield connected to an adapter device which is

attached to a piston pump. The breast shields are each connected to the adapter by means of an airline (tube) between the shield and the adapter. Each of the tubes includes a male connector at one end for insertion into a mating female receptacle formed in the adapter. The connector design provides for easy manipulation of the tube end to assure a good connection. The piston pump is preferably connected via the adapter (here, a piston cylinder holder) to a motor drive unit for reciprocating movement, but it will be seen that the inventive adapter is useful even in a manual mode of operation of the piston pump.

The present invention further provides an improved adapter for the piston pump. In a preferred embodiment of the invention, the adapter is provided with an easily-manipulated selector for connecting the vacuum generated by the piston pump to either or both of the breast pumps for single or double breast pumping. This enables quick and easy selection of one or both breast pumps by a simple single hand manipulation of the selector, leaving a hand free. It also enables shifting from one breast pump to the other by simply moving the selector.

These and other features and advantages of the present invention will be further understood upon consideration of the following detailed description of the present invention, taken in conjunction with the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing a preferred embodiment of an improved breast pump assembly of the present invention;

Fig. 2 is a side elevational view of the improved adapter, or cylinder holder, shown in Fig. 1, with the selector ring removed;

Fig. 3 is a front view of the cylinder holder taken along line 3-3 of Fig. 2, with a flap-valve removed for clarity;

Figs. 3A and 3B are a front and a side view of a flap valve;

Fig. 4 is a rear view of the cylinder holder taken along line 4-4 of Fig. 2;

Fig. 5 is a top view of the cylinder holder taken along line 5-5 of Fig. 2;

Fig. 6 is an elevational view of the cylinder holder taken along line 6-6 of Fig. 3;

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 5;

Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 5;

Fig. 9 is a cross-sectional view taken along line 9-9 of Fig. 3;

Fig. 10 is an enlarged view of detail 10 shown in Fig. 7;

Fig. 11 is an enlarged view of detail 11 shown in Fig. 9;

Fig. 12 is an enlarged view of detail 12 shown in Fig. 9;

Fig. 13 is a plan view of a selector ring used with the cylinder holder shown in Figs. 1-12 and 19-21;

Fig. 14 is a view of the selector ring taken along line 14-14 of Fig. 13;

Fig. 15 is a view of the selector ring taken along line 15-15 of Fig. 13;

Fig. 16 is a view of the selector ring taken along line 16-16 of Fig. 13;

Fig. 17 is a cross-sectional view taken along line 17-17 of Fig. 13;

Fig. 18 is a cross-sectional view taken along line 18-18 of Fig. 13;

Fig. 19 is a view identical to that shown in Fig. 9, but with the addition of the selector ring in place;

Fig. 20 is a view identical to that shown in Fig. 7, but with the addition of the selector ring, which is set to the double breast pumping position;

Fig. 21 is a view identical to that shown in Fig. 20, with the selector ring set to a single breast pumping position;

Fig. 22 is a perspective view of a male connector for connecting the tubing of a breast pump to the cylinder holder;

Fig. 23 is an elevational view of the male connector shown in Fig. 22;

Fig. 24 is an elevational view looking at the left-hand side of Fig. 23;

Fig. 25 is an elevational view looking at the right-hand side of Fig. 23;

Fig. 26 is an end view of the bottom of the male connector shown in Fig. 23; and

Fig. 27 is an end view of the top of the male connector shown in Fig. 23.

DETAILED DESCRIPTION OF A PRESENTLY PREFERRED EMBODIMENT

A. General Organization of Elements

As shown in Fig. 1, this embodiment of the improved breast pump assembly 20 of the present invention includes two breast pump units 22 and a motor drive unit 24. The breast pump units 22 have a hood assembly 26, and a container 28, such as a bottle, for collecting and storing the breast milk, which is connected to the lower portion of the hood assembly 26. The breast pumps 22 are adapted to be used with a piston pump 30. The piston cylinder of the piston pump 30 is connectable to the breast hood assembly 26 to operate the breast pump 22 in a manually-driven mode (i.e., the piston pump is reciprocated by hand). Details of this type of breast pump and the piston pump can be gleaned from U.S. Patents No. 4,929,229 and 4,857,051.

The motor drive unit 24 is adapted to receive and hold the piston pump 30 of one of the breast pumps 22 when it is removed therefrom, and to mechanically drive the piston pump 30. The motor drive unit 24 is substantially as shown and described in U.S. Patent No. 5,007,899, the disclosure of which is hereby incorporated by reference. An improved adapter or cylinder holder 32 is attachable to the casing 34 of the motor drive unit 24, and is a subject of the present application.

The piston cylinder 36 of the piston pump 30 is received in the cylinder holder 32, and the piston rod 38 is releasably held at one end of an arm 40. Arm 40 is mounted at its other end to the casing 34 to a drive system for reciprocal movement of the piston rod 38. As will be described in detail below, the cylinder holder 32 includes two ports 42 (see Fig. 2) for

variously connecting the vacuum tubes 44 to the hood assemblies 26 of the respective breast pumps 22.

In brief, the motor drive 24 reciprocally moves the piston rod 38 in piston cylinder 36. The rearward stroke of the piston rod 38 generates a vacuum (negative pressure) transmitted through the cylinder holder 32 and the tubes 44 to one or both of the breast pumps 22.

B. The Adapter/Cylinder Holder

Turning once again to the drawings, Figs. 2-21 depict various views of a preferred embodiment of the cylinder holder 32 of the present invention. As perhaps best shown in Figs. 2-9, the improved cylinder holder 32 includes a cap portion 46 which is match-threaded at 48 for substantially airtight attachment to the forward end of piston cylinder 36. Figs. 4, 9, 11 and 19 show that the inside of the cap portion 46 has a seal ring 47 disposed therearound for sealing engagement with the inner edge of piston cylinder 36.

Inside of the cap portion 46 is a vacuum chamber 58 that communicates with the piston cylinder 36 and, through the ports 42, with the breast pumps 22. The ports 42 are surrounded by non-circular female receptacles 52 (e.g., see Fig. 2), which are sized and shaped to snugly receive the mating male connectors 54 attached to the ends of the vacuum tubes 44, as described below and shown in Figs. 22-27. Further, the cylinder holder 32 includes a hollow post 56 which is received within a post hole (not shown) in the casing 34 to mount the cylinder holder 32 to the motor drive unit 24. A flange 51 is formed on the exterior sidewall of the cap portion 46. The flange 51 slides into an

enlarged slot (also not shown) when the post 56 is inserted in the post-hole and the cylinder holder 32 rotated into place (in a similar manner as described in U.S. Patent No. 5,007,899). Other means for mounting the cylinder holder to the casing can be readily employed, of course.

As shown in Figs. 2, 3 and 7, the vacuum chamber 58 communicates with three holes 60a, 60b and 60c disposed within a collar portion 53 formed on the forward extension of cylinder holder 32. These holes are the outlets for internal passages 59a, 59b and 59c, respectively. As shown in Figs. 7, 9 and 19-21, and as will be described in further detail hereinafter, the vacuum generated within the piston cylinder 36 is directed through the vacuum chamber 58, then through passage 59b to one or both of the passages 59a, 59c and ultimately to respective ports 42. Also, and again as described in more detail below, and as best shown in Figs. 7 and 10, the vacuum chamber 58 includes a leakage hole 63 that connects the vacuum chamber to atmosphere in single-pumping modes of operation. This serves to allow a predetermined amount of air to enter the vacuum chamber to compensate for the reduced air volume presented when single breast pumping, so that the vacuum pressure applied to the breast remains relatively constant whether single or double-pumping.

As shown in Figs. 7, 8, 20 and 21, passages 66a and 66c extend from passages 59a and 59c, respectively, to communicate with a respective port 42. (Two of the holes 64 which are depicted are non-functional in operation, but are part of the molding process.) The cylinder holder 32 includes a selector ring 70 for directing the vacuum to either or both of the ports

42 and then to breast pumps 22, as described in more detail hereafter.

With reference to Fig. 3, a flexible thin-disk 64 flap valve seal (Figs. 3A and 3B) is positioned over a plurality of holes 64, 65 (and 66a, 66c) formed in the forward end portion 62 of the cylinder holder. A central post 67 formed integral with the flap valve 64 is received within hole 61 to secure the flap valve in place. When the piston rod 38 is pushed into the piston cylinder 36 on its return stroke, the air present in the chamber 58 is forced through the vacuum chamber 58 and the holes 65 (see Fig. 4) past the flap seal. On the other hand, when the piston rod 38 is pulled from the piston cylinder 36, the flap seal is pulled tight over the holes 65, 66a and 66c to create a seal. Consequently, a vacuum is formed in the chamber 58 on the pulling stroke. Such a flap valve and its operation are described in U.S. Patent No. 4,929,229.

Figs. 13-21 depict the selector ring 70 in detail. The selector ring includes an upraised indicator lever 72, an internal vacuum flow channel 74 and a plurality of small recessed channels 76. Referring to Fig. 2, the selector ring is received in a snug but rotatable fit around the collar 53, with the internal channel 74 overlying the holes 60a, 60b and 60c. The selector ring 70 is shown in place in Figs. 19-21, for example. Markings (not depicted) provided on cowl 57 of the cylinder holder serve to orient the selector ring 70 in use. The middle marker corresponds to the "double breast pumping" setting for the breast pump assembly 20, and the side markers correspond, respectively, to the "single breast pumping" setting for either

the left or the right breast pump 22 shown in Fig. 1. To select the desired breast pumping function of the breast pumping assembly 20, the indicator 72 of the selector 70 is rotated to the corresponding marker. A bead 49 is formed around the collar 53 to help keep the selector ring 70 in place on the collar 53.

As best shown in Fig. 20, when the selector 70 is rotated on the collar 53 of cylinder holder 32 such that the indicator 72 is set to the "double pumping" marker, the vacuum flow channel 74 communicates with the passage 59b (which communicates with the vacuum chamber 58) and both of the passages 59a and 59c (which in turn are connected to the respective ports 42 via passages 66a and 66c). As can be understood, the vacuum generated in the piston cylinder 36 is drawn through the vacuum chamber 58 and through the passage 59b, which in turn draws vacuum through the channels 59a, 59c then through channels 66a, 66c to the ports 42. Thus, the vacuum is transmitted through the vacuum tubes 44 to the breast hoods 26 of each of the breast pumps 22. In addition, in the position shown in Fig. 20, the selector 70 blocks the leakage hole 63 in the double-pumping mode to prevent a reduction in vacuum pressure by air intake through hole 63.

As shown in Fig. 21, when the selector 70 is rotated to a marker for "single breast pumping" (by either the left or right breast pump 22), the vacuum flow channel 74 communicates with only the vacuum chamber 58 via passage 59b and one of the passages 59a, 59c. In Fig. 21, the selector 70 covers the hole 60c, preventing a vacuum connection between the vacuum chamber 58 and the passages 59c, 66c. Thus, the vacuum is transmitted

through only one port 42 and vacuum tube 44 to the respective breast pump 22 (in Fig. 21, via passages 59a, 66a).

Moreover, in the "single breast pumping" setting, one of the recess channels 76 formed in the selector 70 serves to uncover the leakage hole 63 to allow outside air to flow into the vacuum chamber 58, thereby reducing the vacuum pressure, in a predetermined manner, which otherwise would be generated by the piston pump 30. This is desirable to compensate for the reduced air volume in the system presented by only a single breast pump, so as to maintain substantially the same vacuum pressure to the breast pumps 22 whether one or both are being used. The recessed channels 76 also cooperate with elongated bosses 77 (Figs. 5 and 6, for example) formed on the exterior of the collar 53 to position the selector ring 70 and hold it in place. A stop 79 is additionally provided to prevent over-rotation of the selector ring 70 when the stop hits recess 78 (see Fig. 15).

C. The Vacuum Connection

As shown in Figs. 22-27, the vacuum tubes 44 terminate in male connectors 54, which are insertable into mating female receptacles 52 formed on the cylinder holder 32. This arrangement serves to provide an easily manipulated secure connection of the vacuum tubes 44 to the ports 42 on the cylinder holder 32.

The male connectors 54 include necked-in middle portion 80 and a port connector end 82. The middle portion 80 includes a number of ridges 84 for gripping the connector 54 and inserting or removing it into the corresponding female receptacle 52. Additionally, the male connectors 54 each include a sealing

surface 86 for sealing the vacuum tubes 44 to the interior sidewalls of the receptacles 52. Moreover, a stop 88 is provided on each of the male connectors 54 to limit the engagement depth of the connectors 54 within the female receptacles 52.

D. Method of Breast Pumping

The present invention also provides an improved method for breast pumping that utilizes the above-described breast pump assembly 20. A woman desiring to express breastmilk removes the piston pump 30 from her manually-operated breast pump. The piston pump 30 is attached to an adapter, such as the aforedescribed cylinder holder 32, and mounted on a motor drive unit 24 that reciprocally moves the piston rod 38 within the piston cylinder 36 of the piston pump 30 to generate a vacuum. Two separate breast pumps 22 are attached, in a preferred embodiment, via separate vacuum tubes 44 to the piston pump 30. The cylinder holder is provided with a vacuum selector, such as selector ring 70, that allows the operator to quickly and easily select either or both of the breast pumps 22 for breast pumping, and to switch from one breast to the other. The woman then supports either or both of the breast pumps 22 on her breasts, depending on the mode of breast pumping that she desires, and activates the motor drive unit 24 for breast pumping. While it is conceivable that the foregoing method could be practiced without the use of the motor drive, i.e. manually, difficulties would be presented in maintaining the two breast pumps in place while also handling the piston pump.

It should be appreciated that the improved breast pump assembly 20 of the present invention may be modified or

configured as appropriate for the desired application. The embodiment described above is to be considered in all respects only as illustrative and not restrictive. Changes may be made without departing from the spirit of the invention. All changes which come within the literal meaning as well as the range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. An improved breast pump assembly comprising:

a motor drive unit for reciprocally moving a piston rod within the interior of a piston cylinder to generate a vacuum, said piston cylinder having an output end and an end through which said piston rod extends in use,

a cylinder holder connected to said output end of said piston cylinder, said cylinder holder being adapted to be mounted to said motor drive unit for reciprocal movement of said piston rod, said cylinder holder having two ports which communicate with said piston cylinder interior;

two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective one of said two ports and at the other end to a respective breast hood; and

a selector on said cylinder holder, said selector being operable to connect a vacuum generated within said piston cylinder interior to one or both of said two ports.

2. The assembly of claim 1 wherein the selector is rotatably connected to the cylinder holder.

3. The assembly of claim 1 wherein the cylinder holder further comprises a non-circular cross-section female receptacle disposed around each of said two ports, and each said tube has a mating cross-section male connector at one end.

4. The assembly of claim 1 wherein the cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and a vacuum chamber formed within said cylinder holder, which vacuum chamber is in communication with said piston cylinder interior, said leakage hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and means for engaging and disengaging said leakage hole with ambient atmosphere.

5. The assembly of claim 4 wherein said leakage hole is disengaged by said selector when said selector connects the vacuum to both of said breast pumping units, and further wherein said leakage hole is engaged when said selector connects the vacuum to either one but not both of said breast pumping units.

6. A breast pump assembly for pumping a single breast as well as two breasts simultaneously, comprising:

a source of intermittent vacuum,

two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood; and

a connector device for selectively connecting said vacuum source to said breast pumping units such that intermittent vacuum can thereby be generated in each said breast hood to

effect the expression of milk from a breast, said connector device having an internal chamber in communication with said vacuum source and a pair of ports in communication with said internal chamber, each said port being adapted to receive another end of a respective tube therein to place said breast hood in communication with said vacuum source, and a selector on said connector device, said selector being operable to connect and disconnect either port as well as both ports simultaneously to said internal chamber to effect single and double pumping.

7. The assembly of claim 6 wherein said connector device is in the form of a cylinder holder which is received on an output end of a piston cylinder of a piston pump, said piston pump being used to generate said intermittent vacuum through reciprocation of a piston rod within the interior of said piston cylinder to generate a vacuum, said piston cylinder having an end through which said piston rod extends in use.

8. The assembly of claim 7 further including a motor drive unit for reciprocally moving said piston rod within said piston cylinder to generate a vacuum, said cylinder holder being adapted to be mounted on said motor drive, said motor drive having means to reciprocate said piston rod within said piston cylinder.

9. The assembly of claim 8 wherein said selector is rotatably carried on said cylinder holder.

10. The assembly of claim 9 wherein said cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and a vacuum chamber formed within said cylinder holder, which vacuum chamber is in communication with said piston cylinder interior, said leakage

hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and means for engaging and disengaging said leakage hole with ambient atmosphere.

11. The assembly of claim 10 wherein said leakage hole is disengaged by said selector when said selector connects the vacuum to both of said breast pumping units, and further wherein said leakage hole is engaged when said selector connects the vacuum to either one but not both of said breast pumping units.

12. An improved breast pump assembly comprising:

a source of intermittent vacuum,

at least one breast pumping unit including a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood; and

a connector device for connecting said vacuum source to said breast pumping unit such that intermittent vacuum can thereby be generated in said breast hood to effect the expression of milk from a breast, said connector device having an internal pathway in communication with said vacuum source and a port in communication with said internal chamber, said port having sidewalls and being formed as a female receptacle of non-circular axial cross-section, and

a male connector on another end of said tube which male connector has a non-circular axial cross-section matched to that of said female receptacle such that said male connector is adapted to be snugly received within said female receptacle in a substantially airtight engagement with said sidewalls.

13. The improved breast pump assembly of claim 12 wherein two breast pumping units are provided, said connecting device having two ports formed thereon for receiving a respective male connector of said breast pumping units, and further including a selector on said connector device, said selector being operable to connect and disconnect either port as well as connect both ports simultaneously to said internal chamber to effect single and double pumping.

14. The improved breast pump assembly of claim 13 wherein said connector device is in the form of a cylinder holder which is received on an output end of a piston cylinder of a piston pump, said piston pump further having a piston rod which is received through another end of said piston cylinder to drive a piston head to generate said intermittent vacuum through reciprocation of said piston rod within the interior of said piston cylinder, said piston cylinder having an end through which said piston rod extends in use.

15. The improved breast pump assembly of claim 14 further including a motor drive unit for reciprocally moving said piston rod within said piston cylinder to generate a vacuum, said cylinder holder being adapted to be mounted on said motor drive, said motor drive having means to reciprocate said piston rod within said piston cylinder with said piston cylinder received

in said cylinder holder and said cylinder holder mounted on said motor drive.

16. The improved breast pump assembly of claim 13 wherein said selector is a ring which is rotatably mounted on said cylinder holder, and said cylinder holder has a first hole extending therethrough which is in communication with one of said ports, a second hole extending therethrough which is in communication with the other of said ports, and a third hole extending therethrough which is in communication with said internal pathway, said selector ring having a cavity formed therein which overlies said three holes in a first position to place both said first and second holes in communication with said vacuum source via said third hole, said selector ring when rotated from said first position selectively covering one of said first and second holes in a second position such that only one of said first and second holes is placed in communication with said vacuum source.

17. The improved breast pump assembly of claim 16 wherein said cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and said internal pathway, said leakage hole being adapted to reduce the vacuum pressure generated when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and wherein said selector ring selectively covers and uncovers said leakage hole when said selector ring is rotated to engage and disengage said leakage hole with ambient atmosphere.

18. The breast pump assembly of claim 6 wherein said selector is rotatably mounted on said connector device, and said connector device has a first hole extending therethrough which is in communication with one of said ports, a second hole extending therethrough which is in communication with the other of said ports, and a third hole extending therethrough which is in communication with said internal pathway, said selector having a base with a cavity formed therein, said base having a substantially airtight engagement with said connector device in the vicinity of said cavity such that said cavity forms an air channel which overlies said three holes in a first position to place both said first and second holes in communication with said vacuum source via said third hole, said selector when rotated from said first position selectively covering one of said first and second holes in a second position such that only the other of said first and second holes is placed in communication with said vacuum source.

19. The breast pump assembly of claim 18 wherein said connector device further comprises a leakage hole formed in said connector device and extending between ambient atmosphere and said vacuum chamber, said leakage hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and wherein said selector selectively covers and uncovers said leakage hole when said selector is

rotated to engage and disengage said leakage hole with ambient atmosphere.

20. A method for pumping a single breast as well as two breasts simultaneously, comprising the steps of:

providing a source of intermittent vacuum,

providing two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood;

providing a connector device for selectively connecting said vacuum source to said breast pumping units such that intermittent vacuum can thereby be generated in each said breast hood to effect the expression of milk from a breast, said connector device having an internal chamber in communication with said vacuum source and a pair of ports in communication with said internal chamber, each said port being adapted to receive another end of a respective tube therein to place said breast hood in communication with said vacuum source, and a selector on said connector device, and

operating said selector to connect and disconnect either port as well as connecting both ports simultaneously to said internal chamber to effect single and double pumping.

FIG. 1

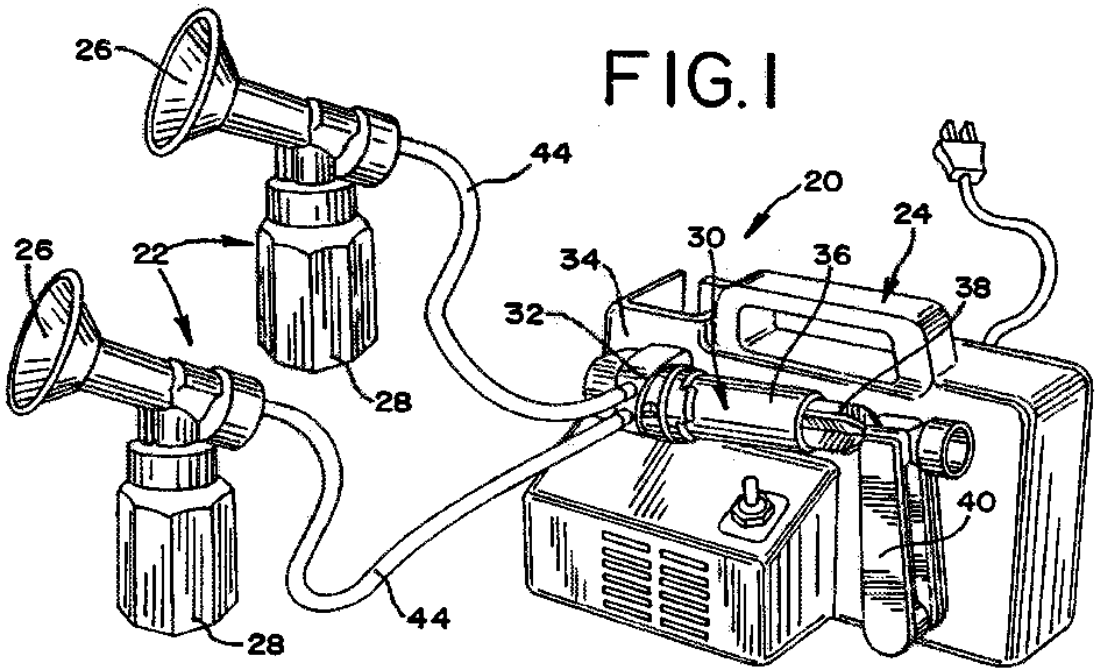


FIG. 2

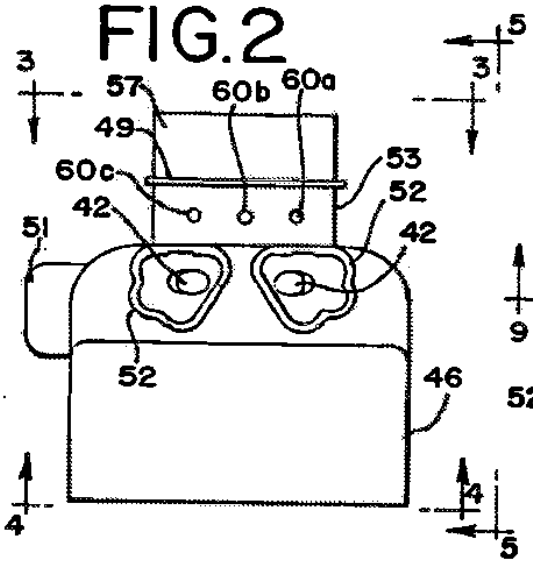


FIG. 3

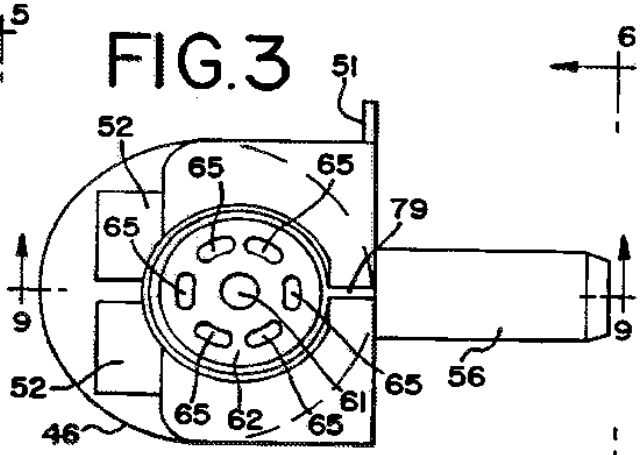


FIG. 3A

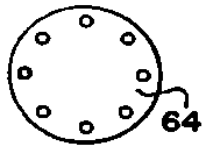


FIG. 3B

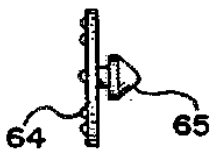
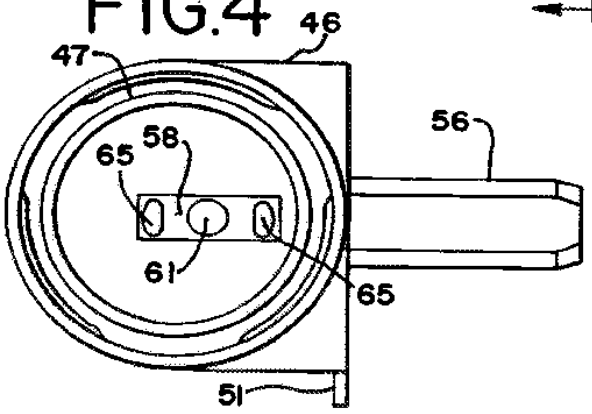


FIG. 4



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FIG.5

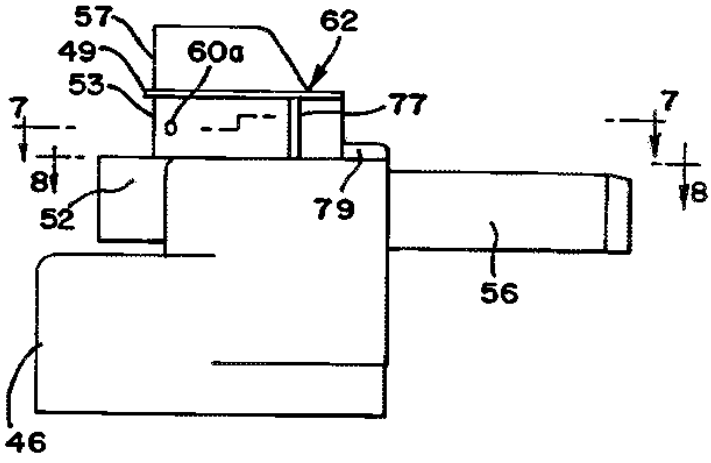


FIG.6

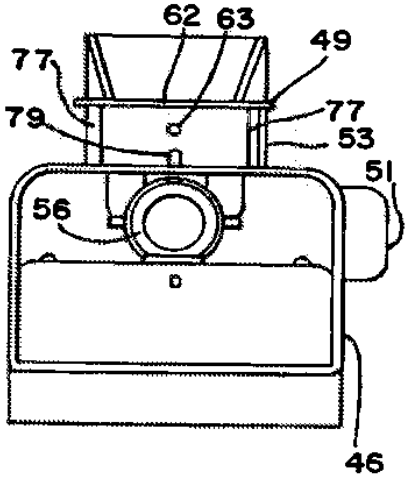


FIG.7

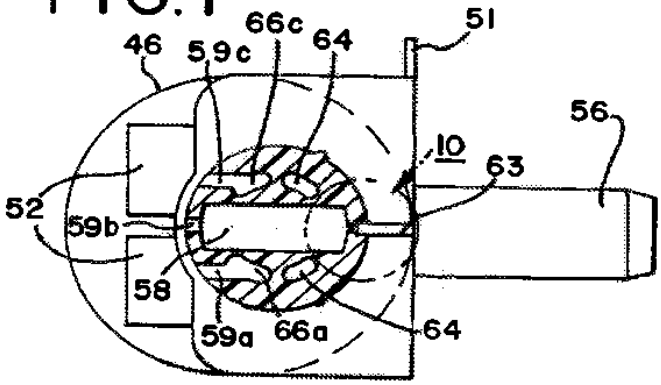
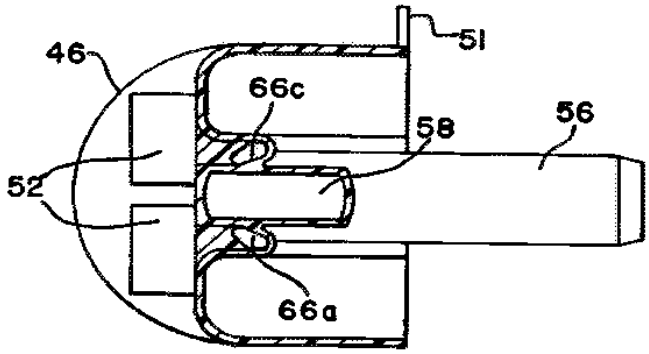


FIG.8



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FIG.9

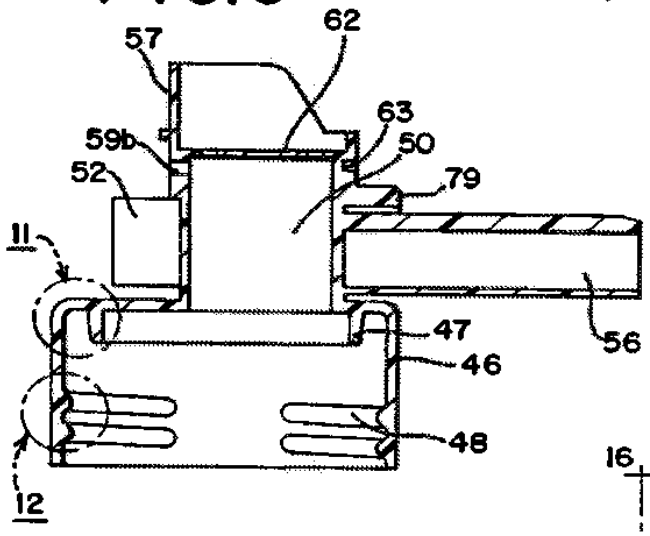


FIG.10

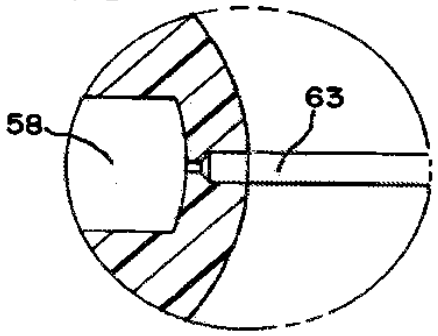


FIG.13

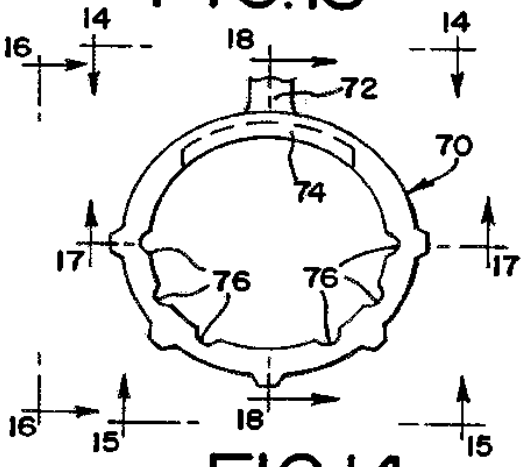


FIG.11

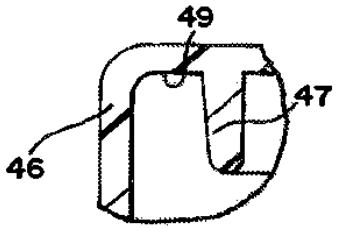


FIG.12



FIG.14

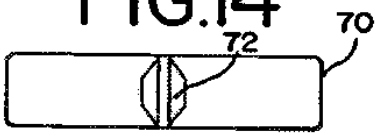


FIG.15



FIG.16

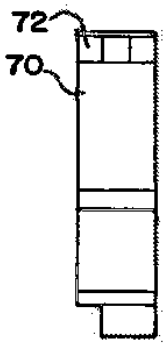


FIG.18

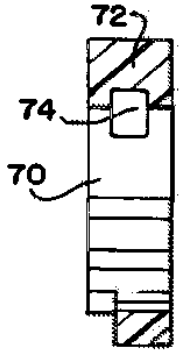
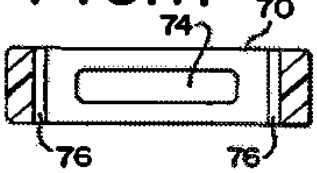


FIG.17



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FIG.19

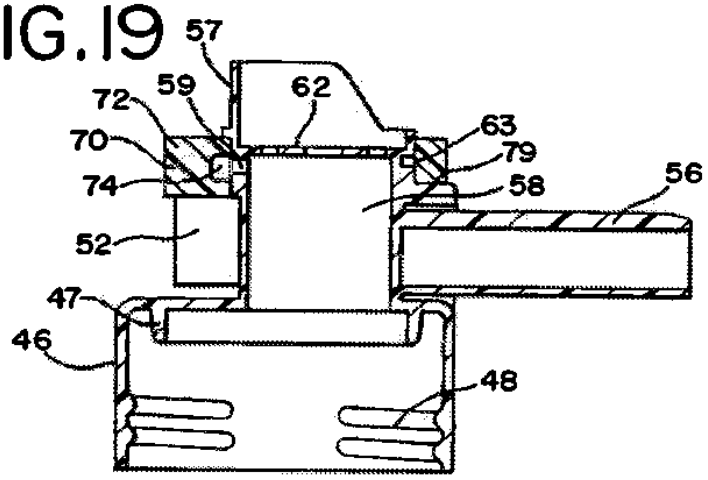


FIG.20

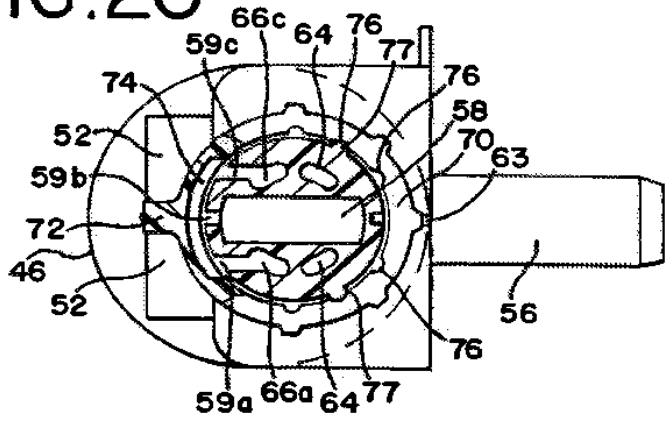
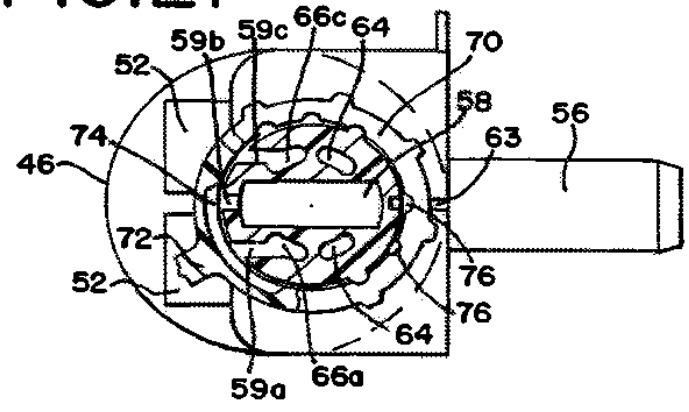


FIG.21



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FIG. 22

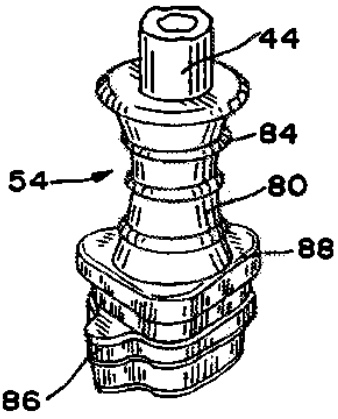


FIG. 23

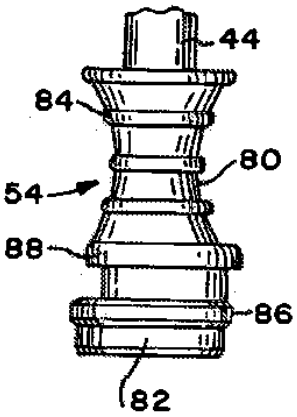


FIG. 24

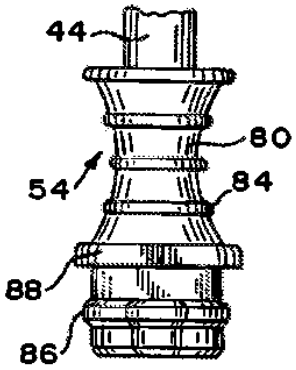


FIG. 25

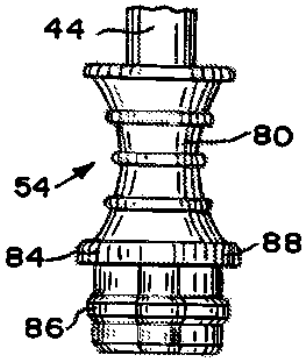


FIG. 27

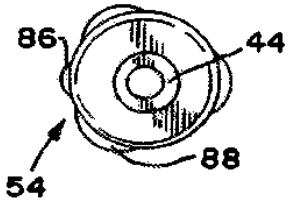
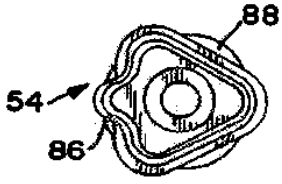


FIG. 26



INTERNATIONAL SEARCH REPORT

Inte. onal application No.
PCT/US96/01911

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/06; A61F 5/44
US CL : 604/74, 75, 76, 152, 154, 346
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)

U.S. : 604/74, 75, 76, 152, 154, 346

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,007,899 (LARSSON) 16 April 1991, Note the entire reference.	1-20
Y	US, A, 4,857,051 (LARSSON) 15 Agust 1989, Note the entire reference.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 25 APRIL 1996	Date of mailing of the international search report 12 JUN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer for A. T. NGUYEN Telephone No. (703) 308-2154

Form PCT/ISA/210 (second sheet)(July 1992)*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued

prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Document **US1** (10,195,321 B2) is submitted herewith as the English-language counterpart of document **FP2** (JP 2016508804 A).

Copies of documents **FP1-FP4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: March 26, 2024

1101 K Street, NW
10th Floor
Washington, D.C. 20005
202-371-2600

21575601.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-10195321-B2	02-05-2019	TATTERFIELD et al.	
	002	US-10335525-B2	07-02-2019	FELBER; Armin et al.	
	003	US-11806454-B2	11-07-2023	DE BECDELIEVRE; Thibault et al.	
	004	US-20060106334-A1	05-18-2006	JORDAN; Alan, et al.	
	005	US-20080171970-A1	07-17-2008	LUZBETAK; Mark A. et al.	
	006	US-20120136325-A1	05-31-2012	ALLEN; Julie et al.	
	007	US-20160174728-A1	06-23-2016	KARP et al.	
	008	US-20160304004-A1	10-20-2016	SANDBOTHE et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-109621041-A	04-16-2019	BINHAI CHANGZHENG ENTERPRISE MAN CO LTD [CN]		☐
	002	JP-2016508804-A	03-24-2016	KONINKLIJKE PHILIPS N.V. [NL]		☐
	003	WO-2018229504-A1	12-20-2018	CHIARO TECH LIMITED [GB]		☐
	004	WO-9625187-A1	08-22-1996	MEDELA INC [US]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
		None	

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	17/181,057
				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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.

☐ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-03-26
Name/Print	Yangbeini Wang	Registration Number	800,005

21575616.1

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20 December 2018 (20.12.2018)

WIPO | PCT

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

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15 June 2018 (15.06.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

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1709564.7	15 June 2017 (15.06.2017)	GB
1709561.3	15 June 2017 (15.06.2017)	GB
1809036.5	01 June 2018 (01.06.2018)	GB

(71) Applicant: **CHIARO TECHNOLOGY LIMITED** [GB/GB]; 63 - 66 Hatton Garden, London EC1N 8LE (GB).

(72) Inventors: **O'TOOLE, Jonathan**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **ROLLO, Adam**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **CARR, Andrew**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **LEVY, Benjamin**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **COGGINS, Jack**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **ROSS, Clare**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **POOLE, Rebecca**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **PESTANA, Nestor**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB).

(74) Agent: **ORIGIN LIMITED**; Twisden Works, Twisden Road, London NW5 1DN (GB).

(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, JO, 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,

(54) Title: BREAST PUMP SYSTEM

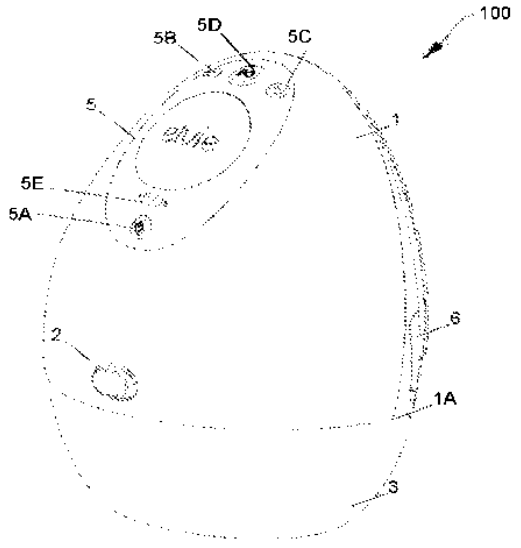


FIGURE 1

(57) 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.

[Continued on next page]

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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))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed

breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the

product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided

at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as

well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system **100** includes a housing **1** shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing **1** in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

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

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

5

SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2…IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2...IRn.

By comparing the emitted radiation intensities IE1; IE2...IEn with the received radiation intensities IR1; IR2...IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2...IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6gm and may, with material and design improvements, weigh less than 6gm.

In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In

this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore

connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. **Elvie Breast Pump: General Usability Feature Cluster**

B. **Elvie Piezo Air Pump Feature Cluster**

C. **Elvie Milk Container Feature Cluster**

D. **Elvie IR System Feature Cluster**

E. **Elvie Bra Clip Feature Cluster**

F. **Other Features, outside the breast pump context**

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing,

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

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

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

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

CLAIMS

1. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

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

3. The wearable breast pump system of Claim 1 or 2, in which the piezo air-pump is positioned at or close to the base of the housing.

4. The wearable breast pump system of any preceding Claim, 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 or 5, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. The wearable breast pump system of any preceding Claim, 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 any preceding Claim, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. The wearable breast pump system of any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, in which the piezo air-pump weighs less than 10gm.

13. The wearable breast pump system of any preceding Claim, 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 any preceding Claim, in which the piezo air-pump is fed by air that passes through an air filter.

15. The wearable breast pump system of any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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 any preceding Claim, 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.

Independents

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

69. 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.

70. A bra adjuster system 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.

71. A wearable device including multiple piezo pumps mounted together either in series or in parallel.

72. A wearable medical device including a piezo pump and a heat sink attached together.

Breast shield

73. The system of any preceding Claim in which the only parts of the system that come into contact with milk in normal use are a breast shield and a milk container.

74. The system of any preceding Claim in which milk only flows through a breast shield and then directly into a milk container.

75. The system of any preceding Claim in which a breast shield and a milk container are each pressed or pushed into engagement with the housing.

76. The system of any preceding Claim in which a breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

77. The system of any preceding Claim in which there are two user-removable parts, namely a breast shield and milk container, and each is insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

78. The system of any preceding Claim in which a 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.

79. The system of any preceding Claim in which a breast shield slides into the housing using guide members.

80. The system of any preceding Claim in which the housing is configured to slide onto a breast shield, when the breast shield has been placed onto a breast, using guide members.

81. The system of any preceding Claim in which a breast shield latches into position against the housing.

82. The system of any preceding Claim in which a 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.

83. The system of any preceding Claim in which a breast shield latches into position against the housing using magnets.

84. The system of any preceding Claim in which a 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.

85. The system of any preceding Claim in which a breast shield includes a nipple tunnel that includes on its lower surface an opening through which expressed milk flows directly into the milk container.

86. The system of any preceding Claim in which no other parts are removable from the breast shield, apart from the flexible diaphragm.

Milk container

87. The system of any preceding Claim in which a milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

88. The system of any preceding Claim in which a milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

89. The system of any preceding Claim in which a milk container mechanically or magnetically latches to the housing.

90. The system of any preceding Claim in which a milk container is released by the user pressing a button on the housing.

91. The system of any preceding Claim in which a milk container includes a removable cap and a removable valve that is seated on the lid.

92. The system of any preceding Claim in which in normal use, the milk container is positioned entirely within a bra.

93. The system of any preceding Claim in which no parts are removable from the milk container, apart from a cap and a valve.

94. The system of any preceding Claim in which all parts that are user-removable in normal use are attached to either a breast shield or a milk container.

95. The system of any preceding Claim in which 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.

Pump

96. The system of any preceding Claim in which a 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.

97. The system of any preceding Claim which also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements

98. The system of any preceding Claim in which a control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.

99. The system of any preceding Claim in which a 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.

100. The system of any preceding Claim in which an air pressure sensor detects pressure created by the pumping mechanism.

101. The system of any preceding Claim in which an air pressure sensor is a piezo air pressure sensor.

102. The system of any preceding Claim in which an air pressure sensor measures the negative air pressure during a normal milk expression session.

103. The system of any preceding Claim in which an 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.

104. The system of any preceding Claim in which an 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

105. The system of any preceding Claim in which an 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.

106. The system of any preceding Claim in which the operation of a pumping mechanism is varied by altering the duty or pump cycle.

107. The system of any preceding Claim in which the operation of a pumping mechanism is varied by altering the voltage applied to the pumping mechanism.

Piezo air-pump

108. The system of any preceding Claim in which a pumping mechanism is a piezo air pump.

109. The system of any preceding Claim in which a piezo air pump forms part of a closed or closed loop system.

110. The system of any preceding Claim in which a 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.

111. The system of any preceding Claim in which a piezo air pump is positioned at or close to the base of the housing.

112. The system of any preceding Claim in which there are two or more piezo air pumps.

113. The system of any preceding Claim in which there are two or more piezo air pumps mounted in a series arrangement.

114. The system of any preceding Claim in which there are two or more piezo air pumps mounted in a parallel arrangement.

115. The system of any preceding Claim in which a piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

116. The system of any preceding Claim in which a piezo air pump weighs less than 25gm, or less than 10gm.

117. The system of any preceding Claim in which 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.

118. The system of any preceding Claim in which 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.

119. The system of any preceding Claim in which a 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.

Diaphragm

120. The system of any preceding Claim in which a closed system is separated from a 'milk' side by a flexible diaphragm.

121. The system of any preceding Claim in which a deformable diaphragm is removably mounted against a part of a breast shield.

122. The system of any preceding Claim in which a deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

123. The system of any preceding Claim in which a deformable diaphragm is not physically connected to the piezo air-pump.

124. The system of any preceding Claim in which an 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.

125. The system of any preceding Claim in which a deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

126. The system of any preceding Claim in which an edge of a flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

127. The system of any preceding Claim 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 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.

Flow measurement and indication

128. The system of any preceding Claim in which 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 a milk container above its base is increasing above a threshold rate of increase

129. The system of any preceding Claim in which a haptic and/or visual indicator that indicates if the pump is operating correctly to pump milk, is a row of LEDs that changes appearance as the quantity of milk increases.

130. The system of any preceding Claim in which a haptic and/or visual indicator provides an indication of an estimation of the milk flow rate.

131. The system of any preceding Claim in which a visual indicator provides a colour-coded indication of an estimation of the milk flow rate.

132. The system of any preceding Claim in which a visual indicator provides an indication of how much of the container has been filled with milk.

133. The system of any preceding Claim in which a milk flow or quantity 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.

134. The system of any preceding Claim in which a milk flow or quantity 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.

135. The system of any preceding Claim in which a sub-system measures or infers the quantity and/or the height of the liquid in a milk container.

136. The system of any preceding Claim in which a sub-system measures or infers the quantity and/or the height of the liquid in a milk 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.

137. The system of any preceding Claim in which a 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 a milk container.

138. The system of any preceding Claim in which a sub-system measures or infers the angle the top surface of the liquid in a milk container makes with respect to a baseline, such as the horizontal.

139. The system of any preceding Claim in which a haptic and/or visual indicator indicates if the amount of milk in a milk container has reached a preset quantity or level.

140. The system of any preceding Claim in which a haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.

141. The system of any preceding Claim in which, 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.

142. The system of any preceding Claim in which, 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.

143. The system of any preceding Claim in which, 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.

144. The system of any preceding Claim in which, 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.

145. The system of any preceding Claim in which 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.

146. The system of any preceding Claim in which a sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.

147. The system of any preceding Claim in which, if the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.

148. The system of any preceding Claim in which a sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.

149. The system of any preceding Claim in which a sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.

150. The system of any preceding Claim in which one or more visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.

151. The system of any preceding Claim in which a 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.

152. The system of any preceding Claim in which 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.

153. The system of any preceding Claim in which a 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.

154. The system of any preceding Claim in which, where the expressed milk quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.

155. The system of any preceding Claim in which, where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.

156. The system of any preceding Claim in which milk-flow data is captured and stored.

157. The system of any preceding Claim in which, if milk-flow falls below a threshold, then a notification is provided to the mother.

158. A method of expressing and collecting milk, comprising the step of using a system as defined in any preceding Claim.

FIGURE 1

FIGURE 2

FIGURE 3

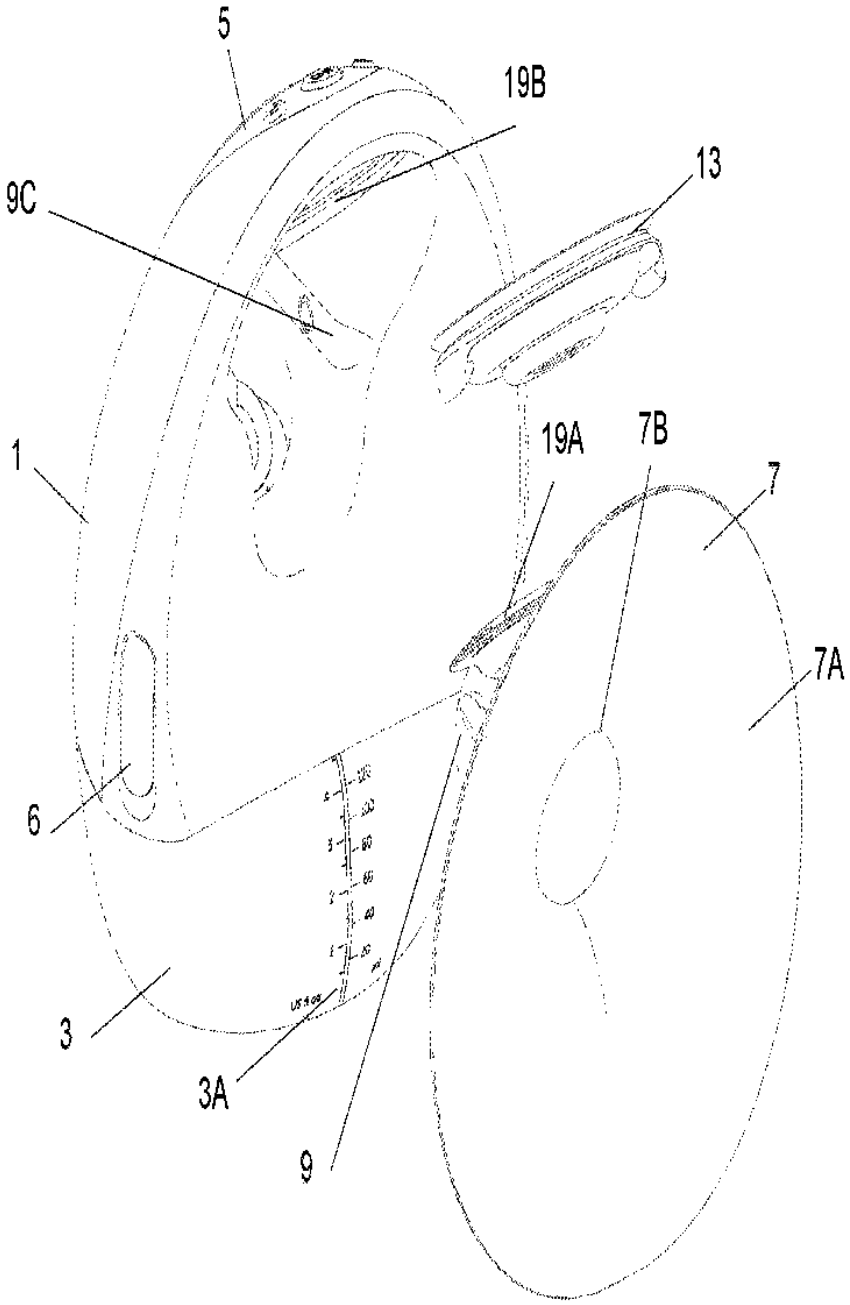


FIGURE 4

FIGURE 5

FIGURE 6

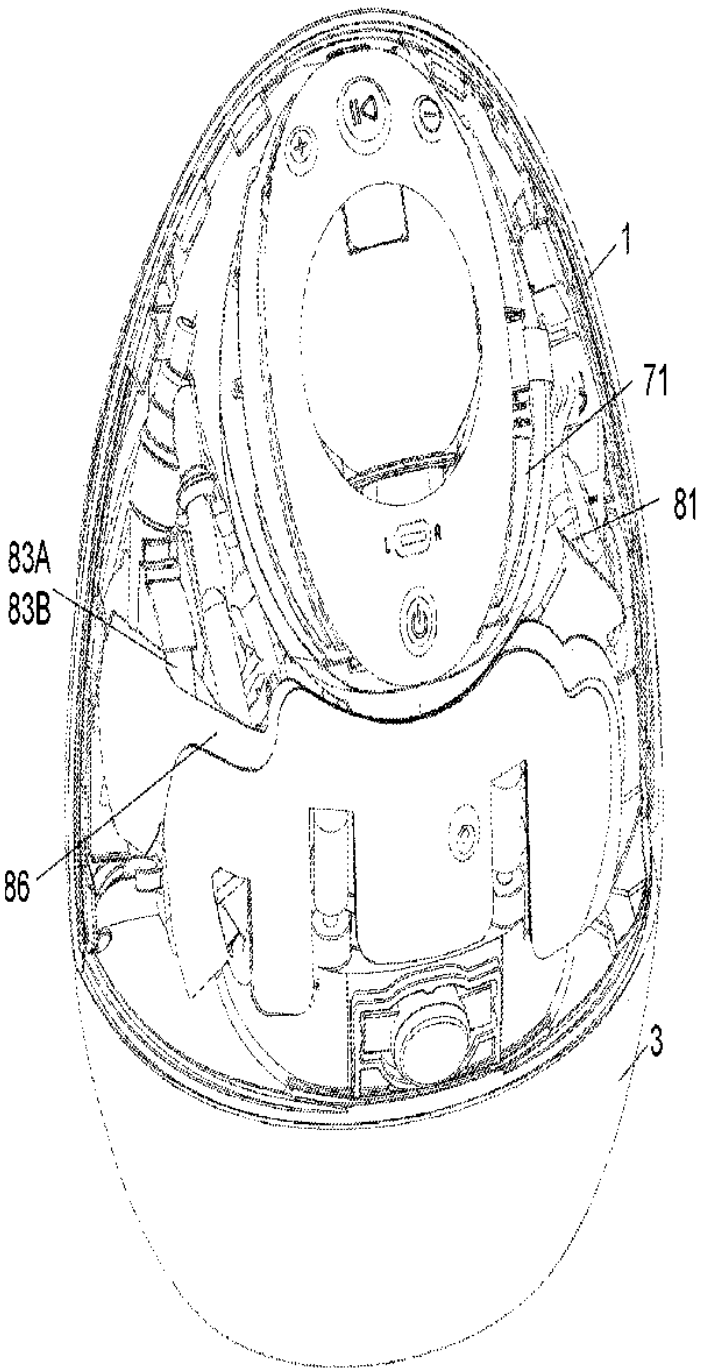


FIGURE 7

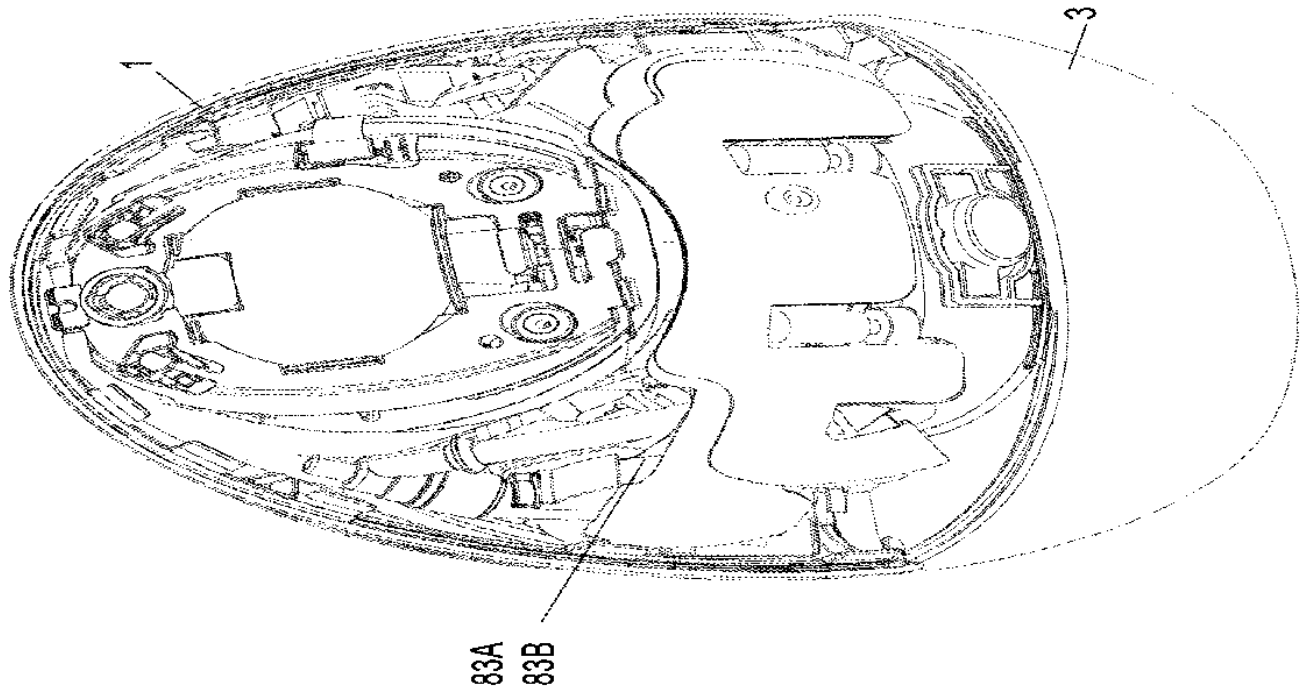


FIGURE 8

1272

FIGURE 9

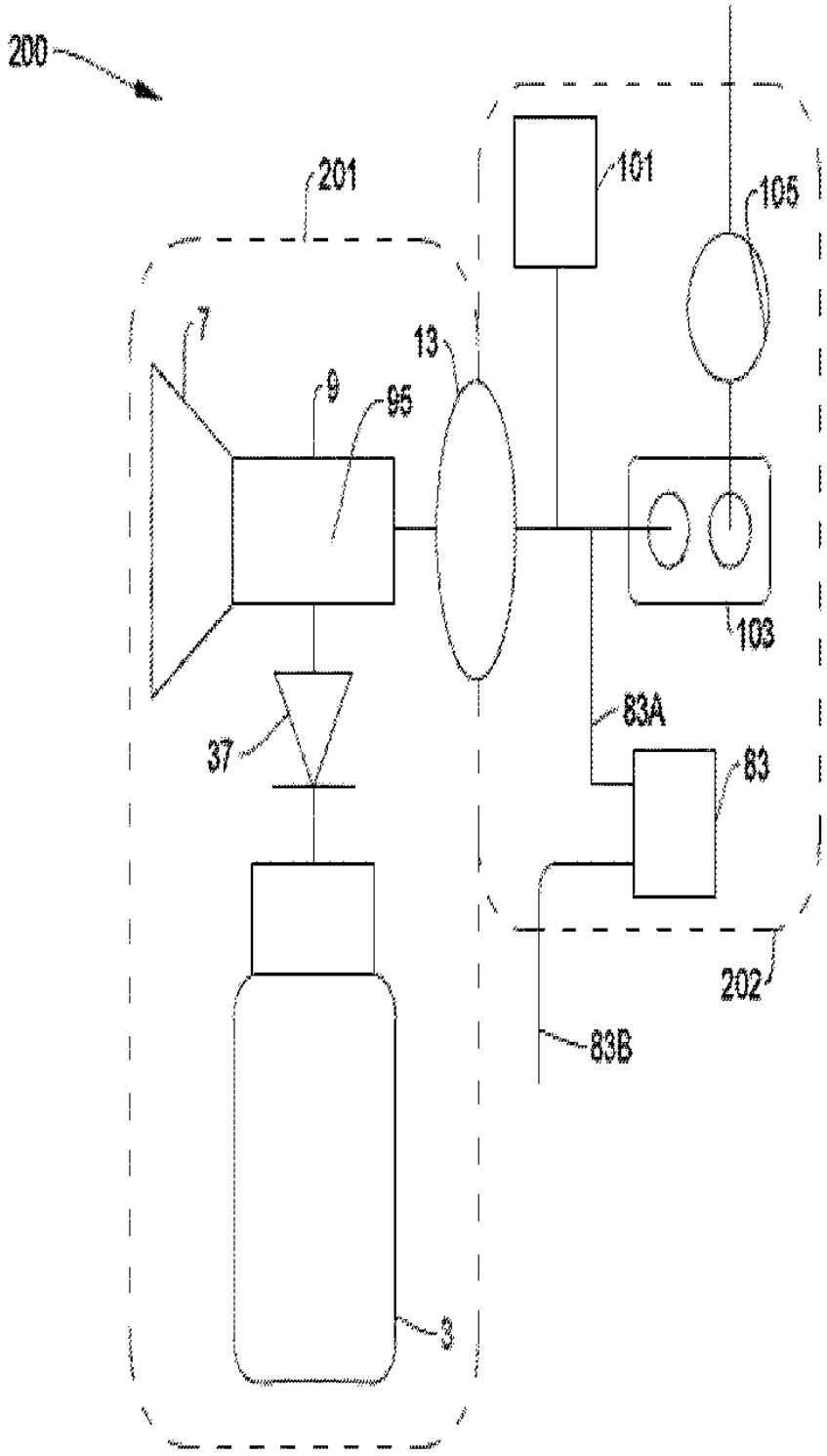


FIGURE 10

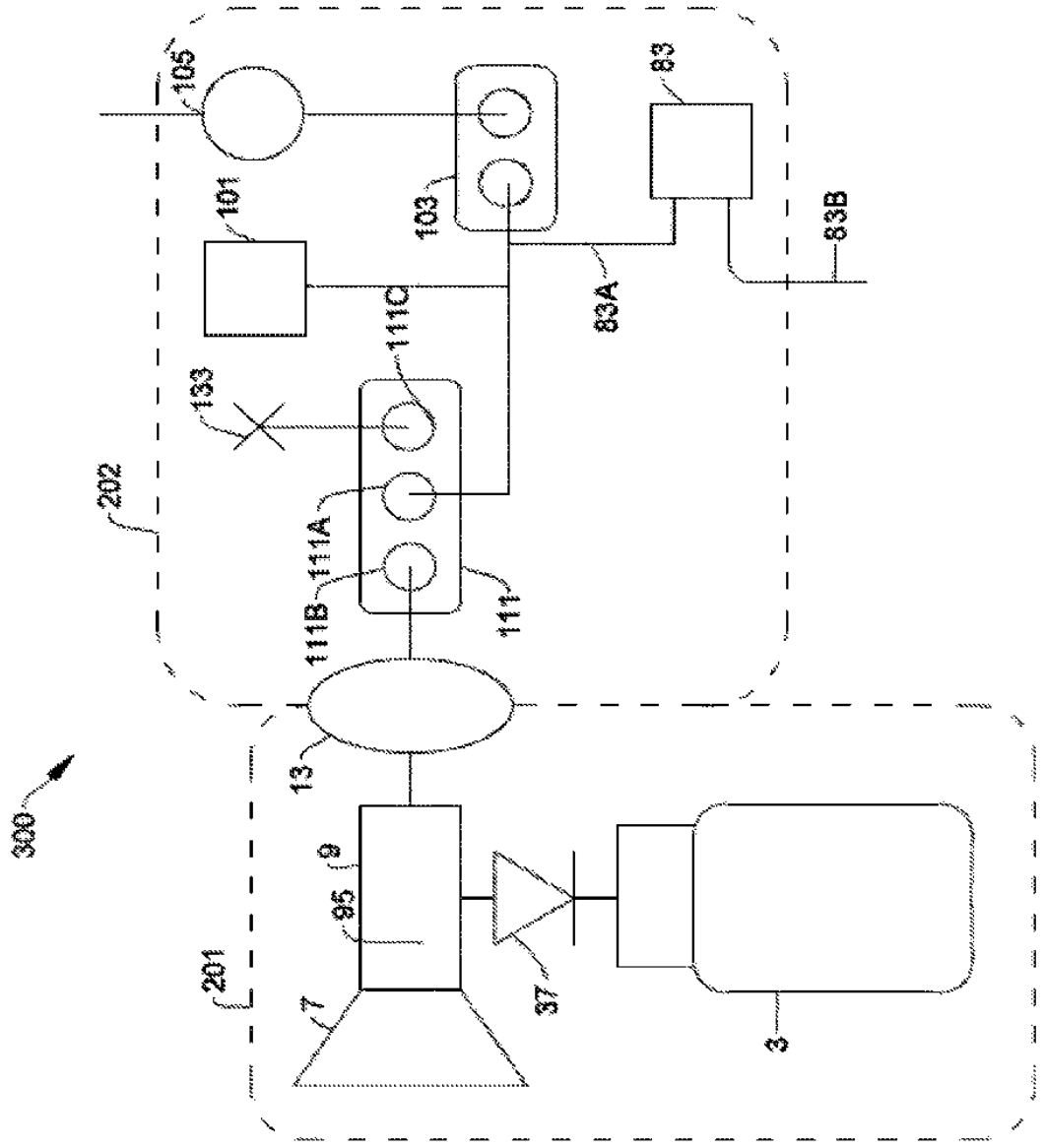

300
202
201
105
101
103
83
83B
83A
111C
133
111A
111B
111
13
9
95
7
37
3

FIGURE 11

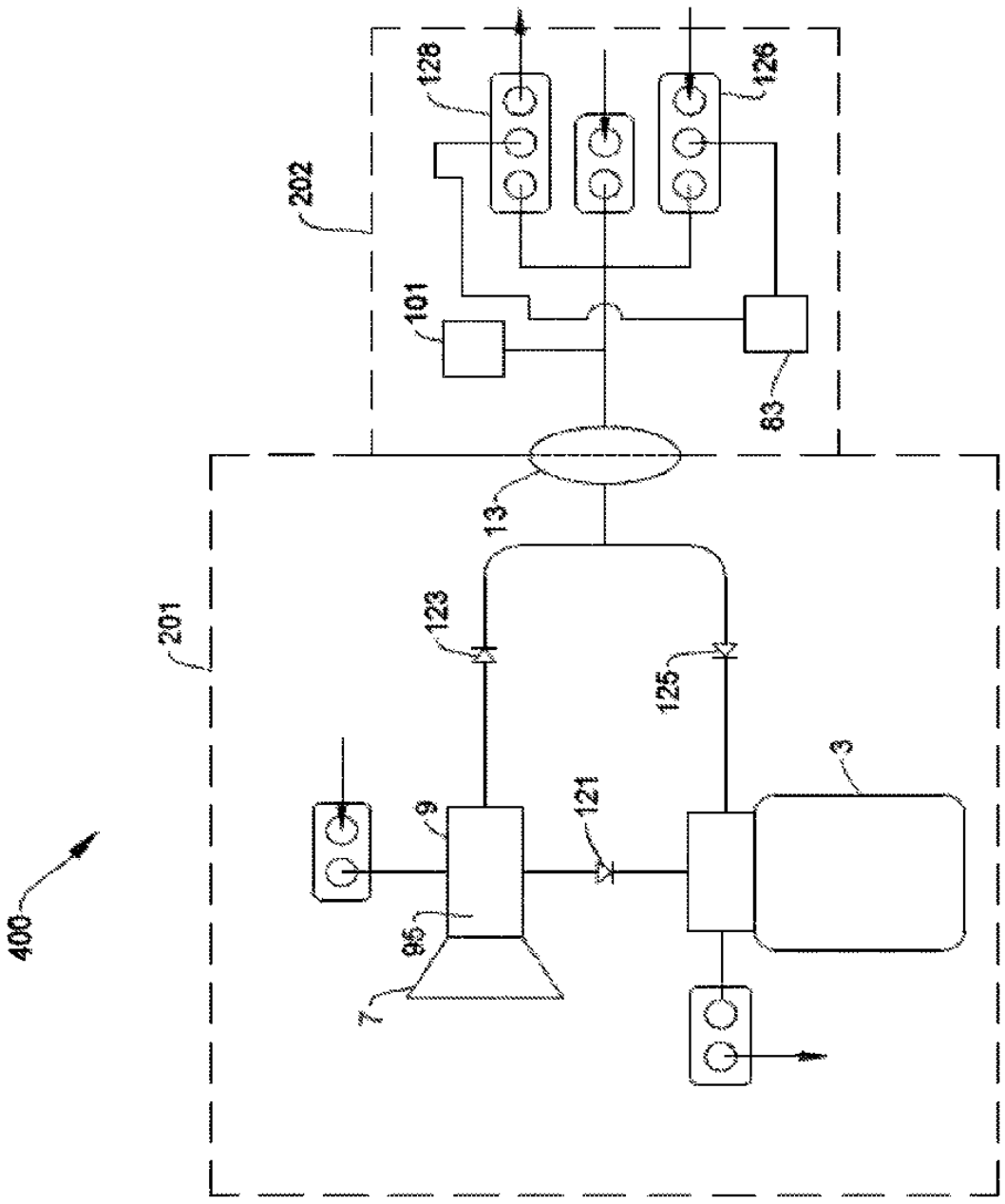


FIGURE 12

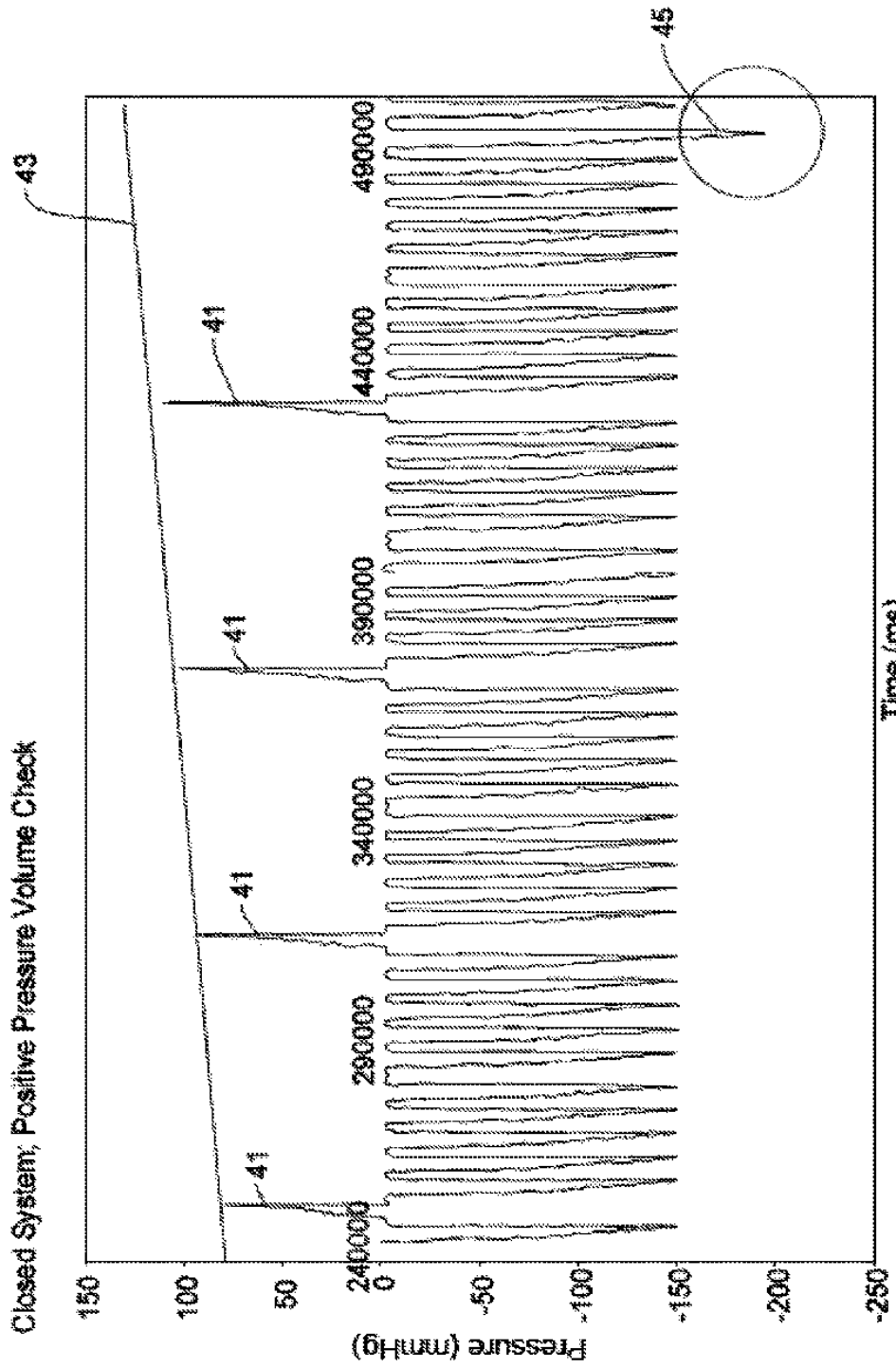

Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

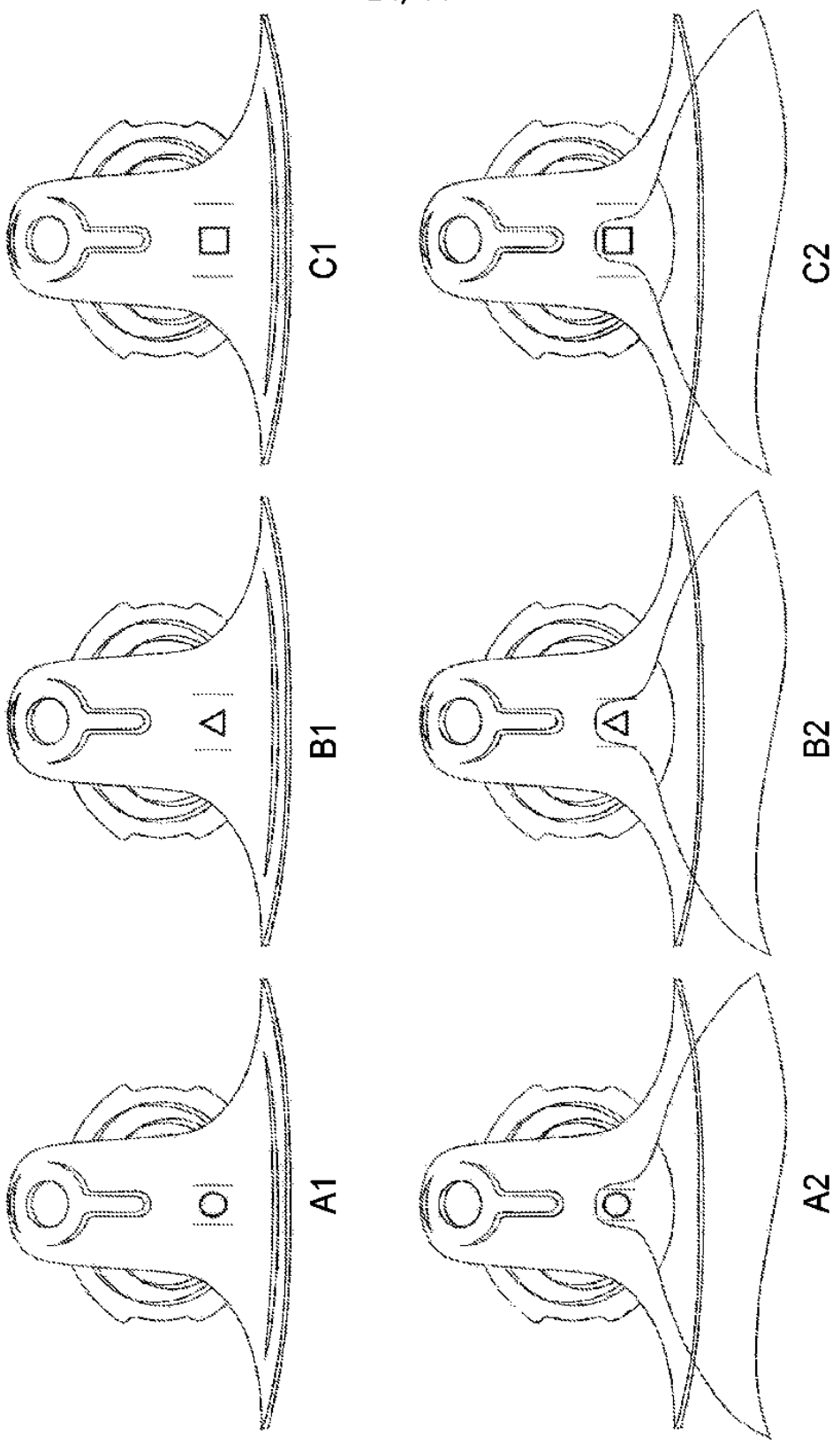


FIGURE 14

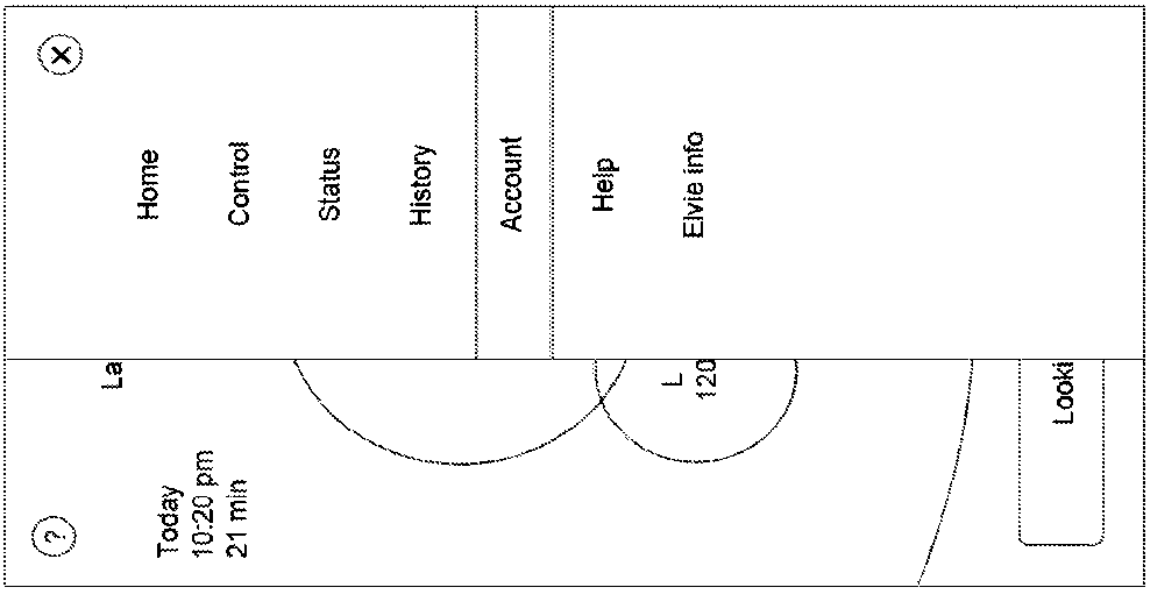

Home
Control
Status
History
Account
Help
Elvie info
La
Today
10:20 pm
21 min
L
120
Looki

FIGURE 15

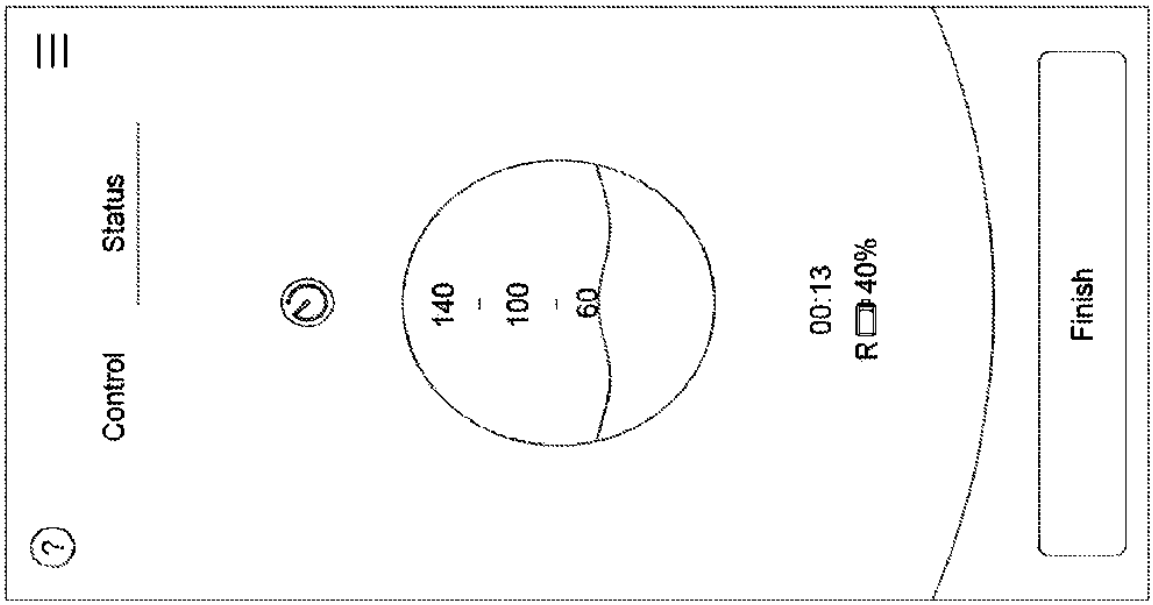


FIGURE 16

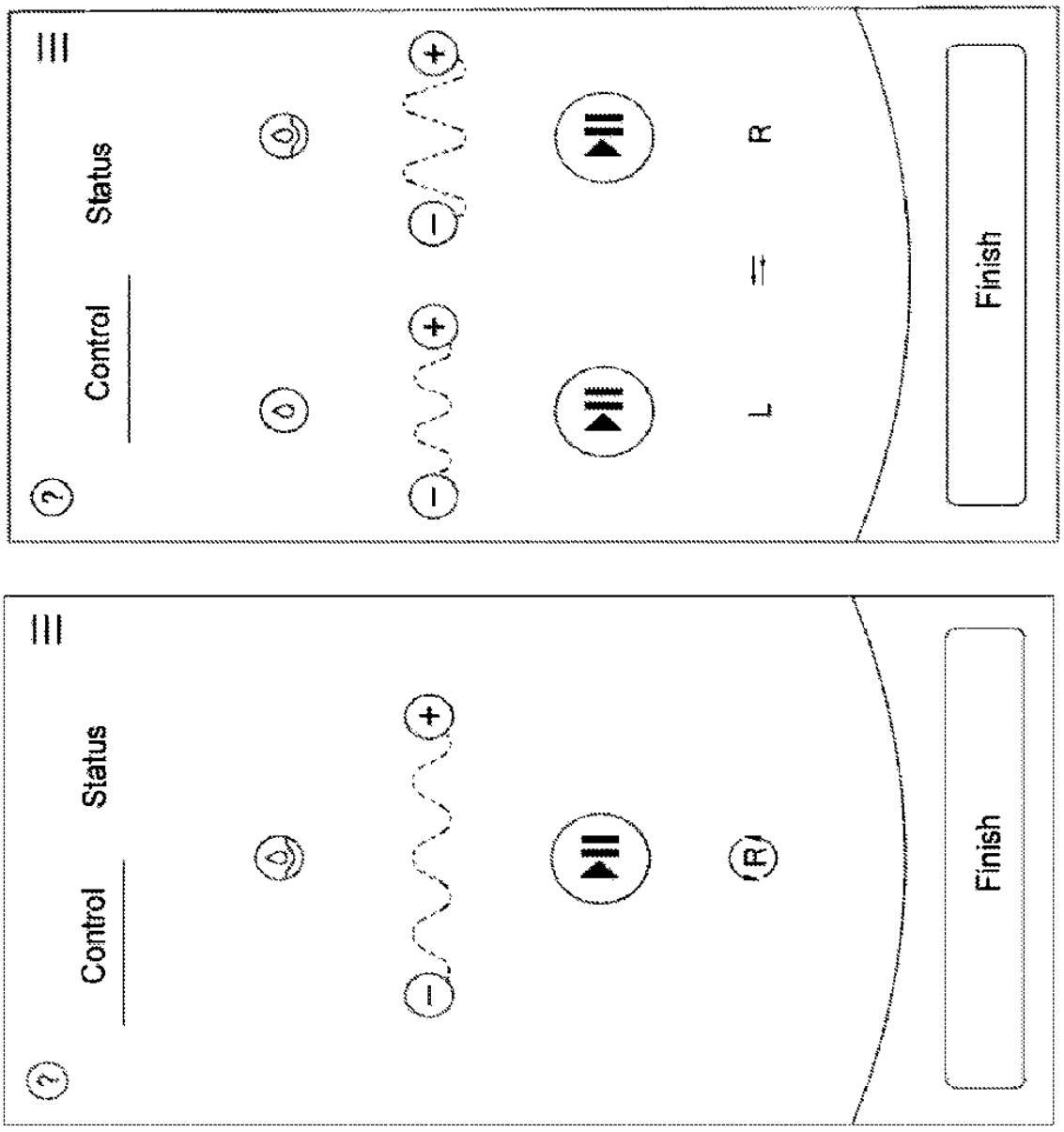


FIGURE 17

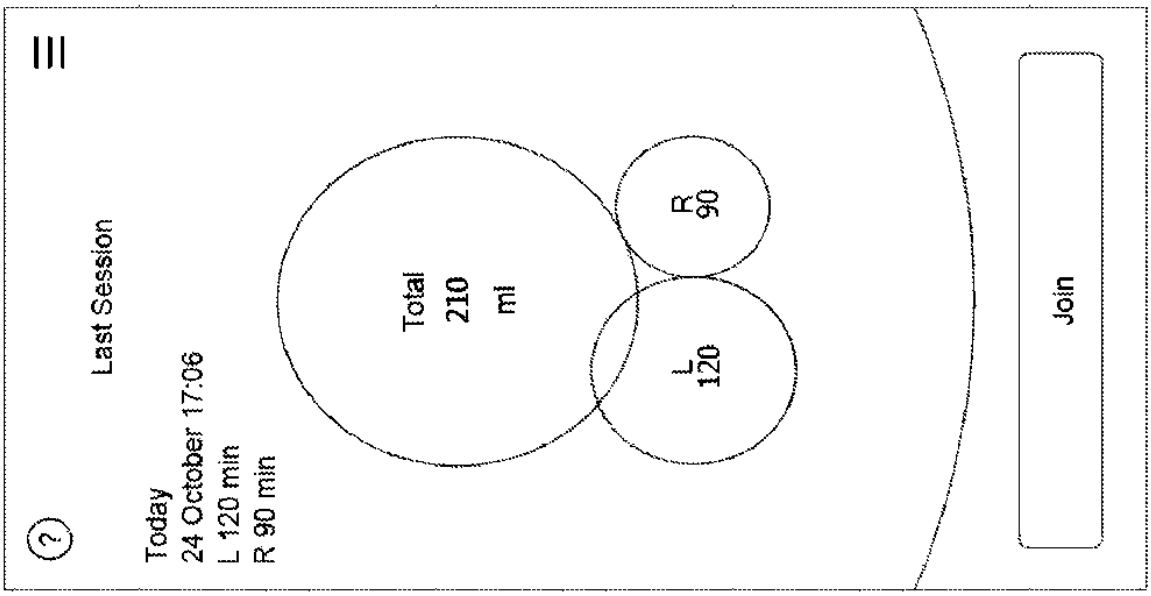

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
mi
R
90
L
120
Join

FIGURE 18

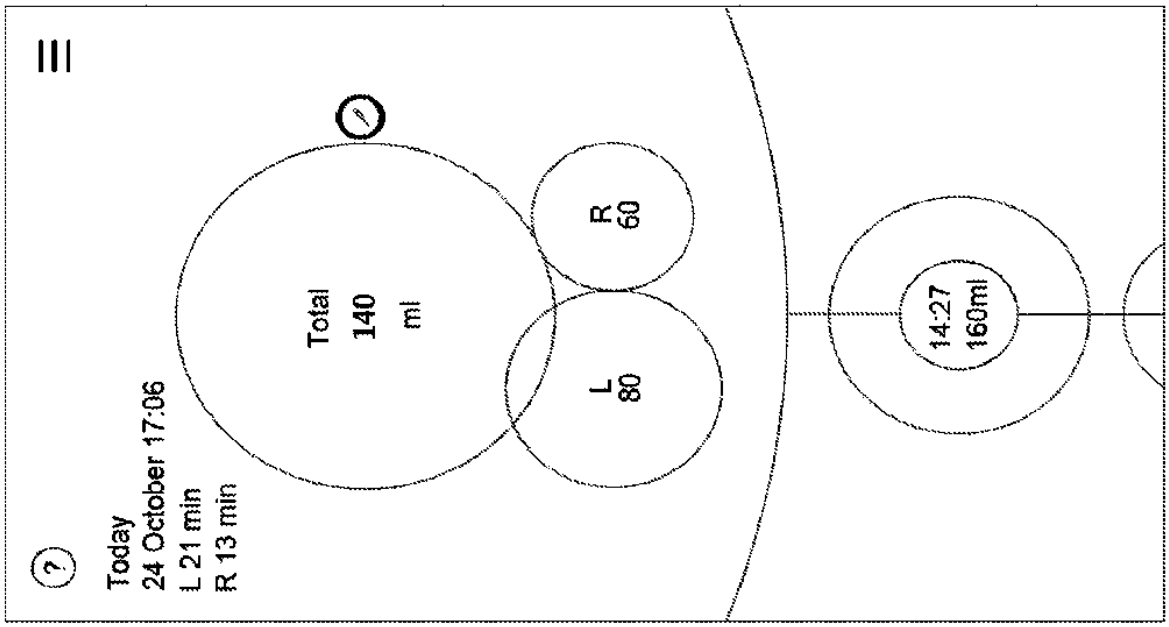

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

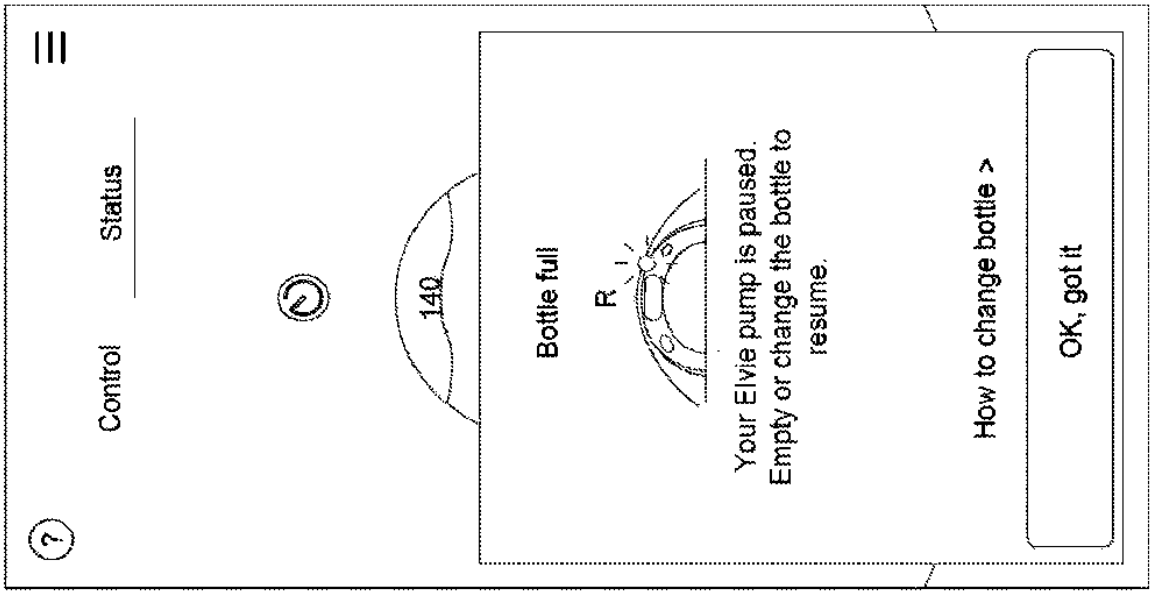

Control
Status
140
Bottle full
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

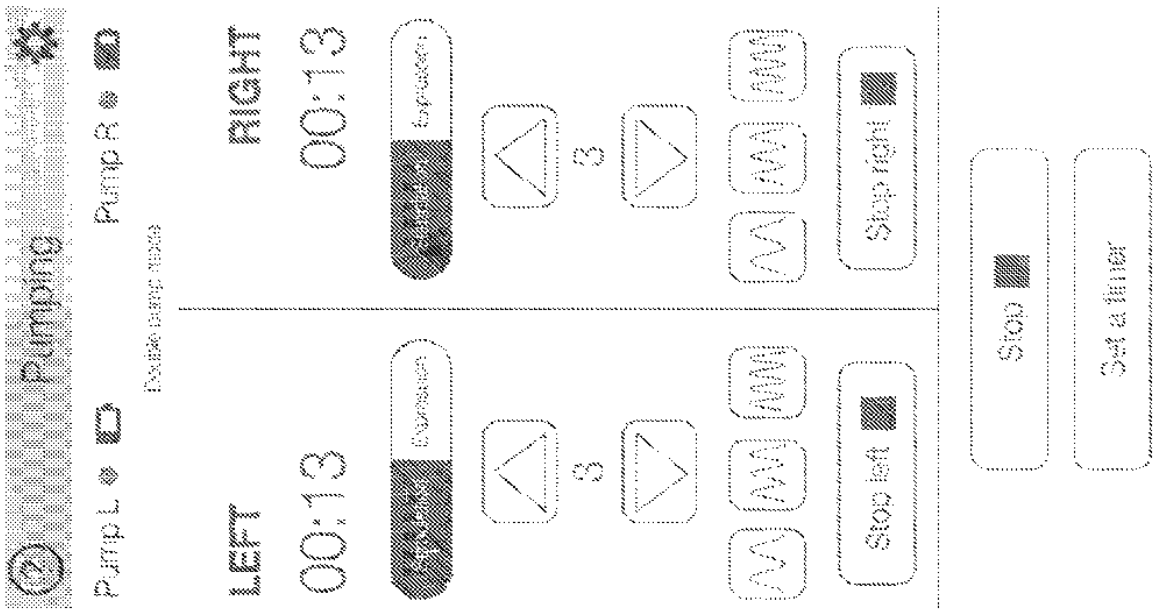

Pumping
Pump L
Pump R
LEFT
00:13
Expand
3
Stop left
RIGHT
00:13
Expand
3
Stop right
Stop
Set a timer

FIGURE 21

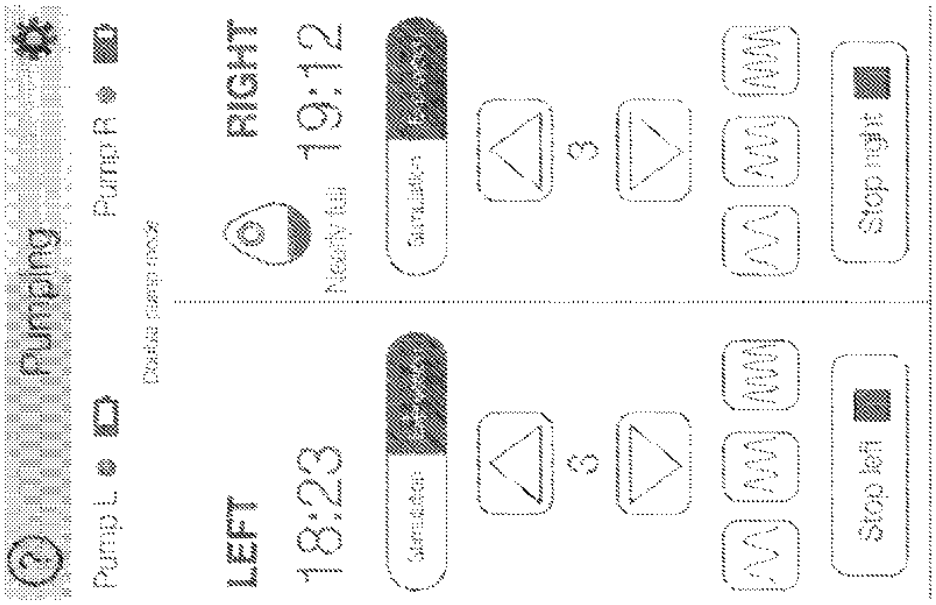

Pumping
Pump L
Pump R
Pump Stopped
LEFT
18:23
Nearly full
Stimulation
RIGHT
19:12
Nearly full
Stimulation
Stop left
Stop right
Stop
Set a timer

FIGURE 22

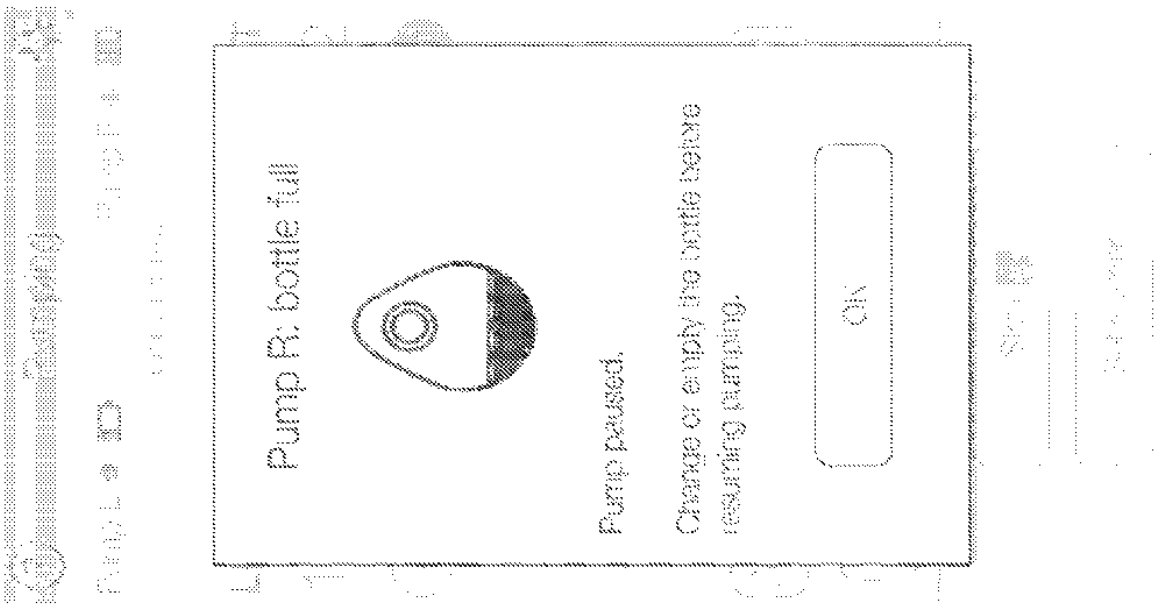


FIGURE 23

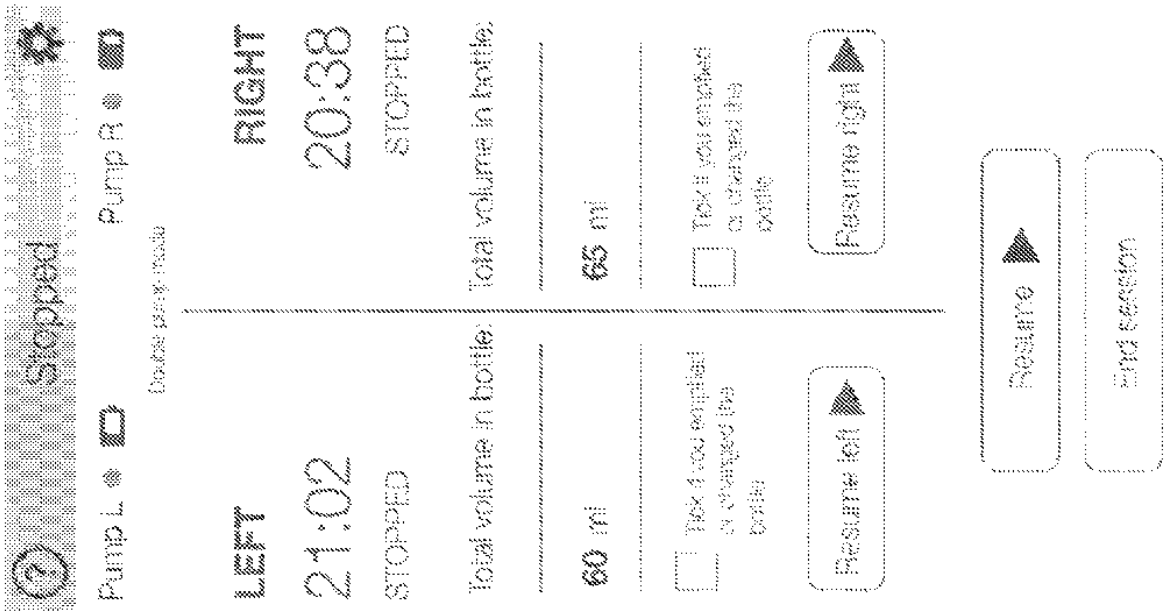

Stopped
Pump L
Pump R
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle
60 ml
Tick if you emptied a unmeasured bottle
Resume left
Total volume in bottle
65 ml
Tick if you emptied a unmeasured bottle
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
Pump R
Disable pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 16s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

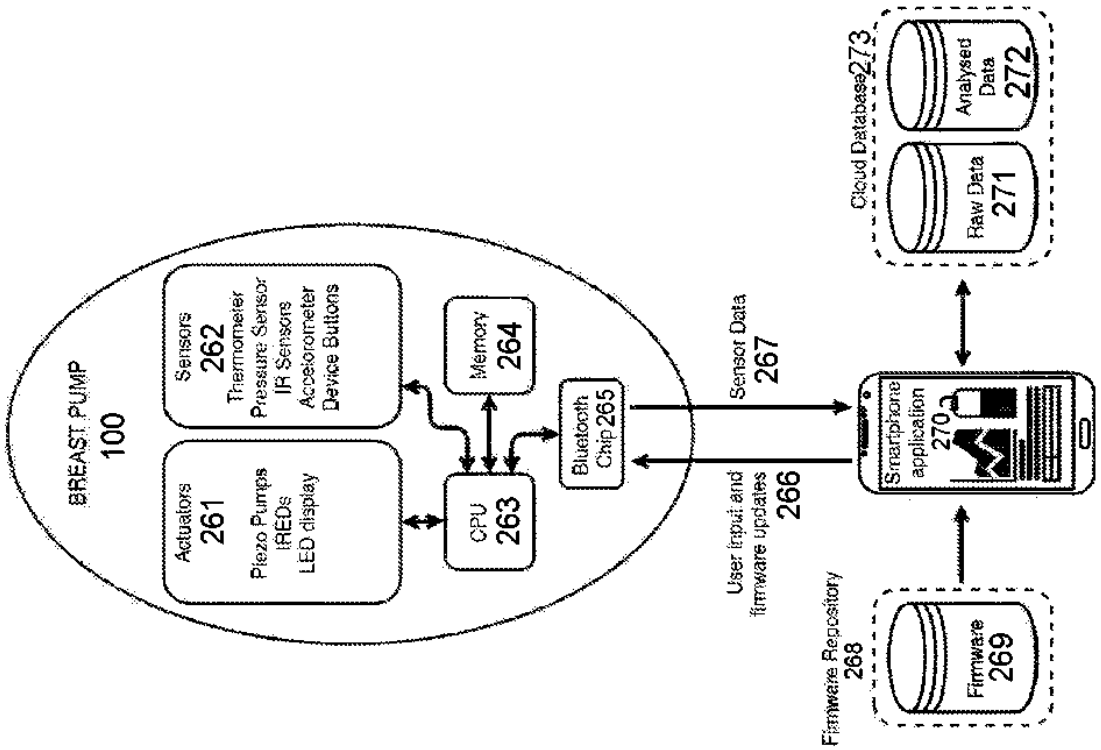

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data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

FIGURE 26

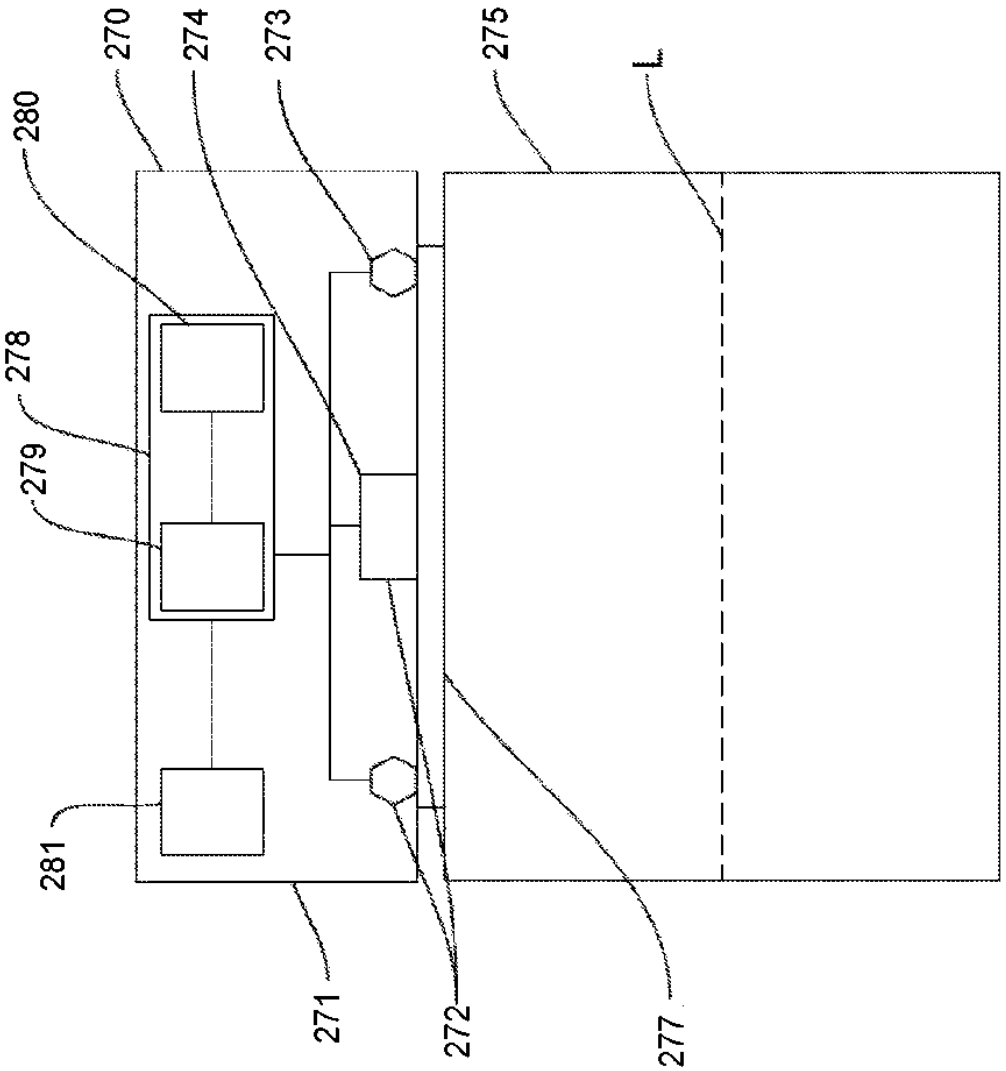


FIGURE 27

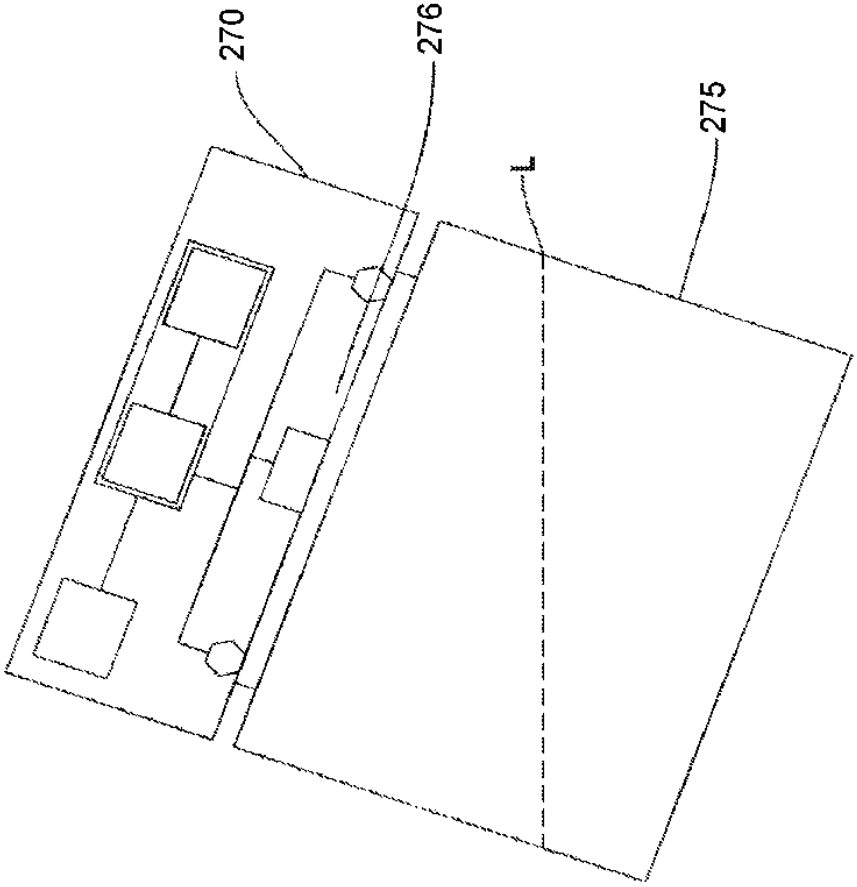


FIGURE 28

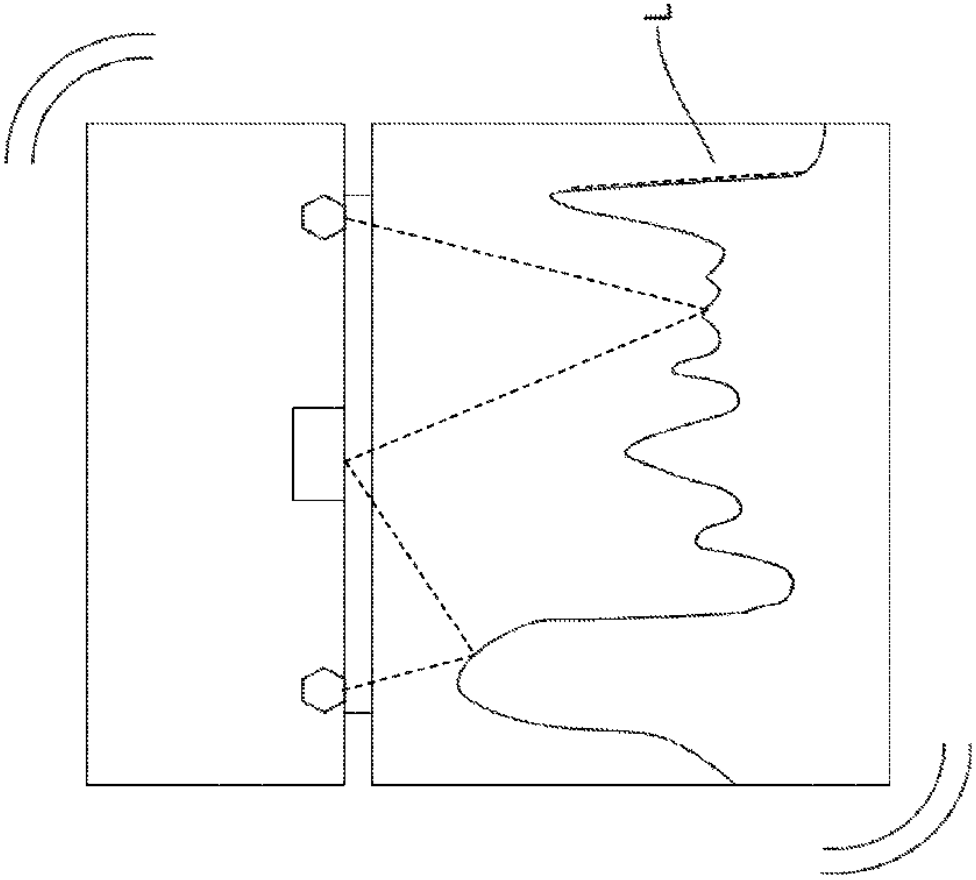


FIGURE 29

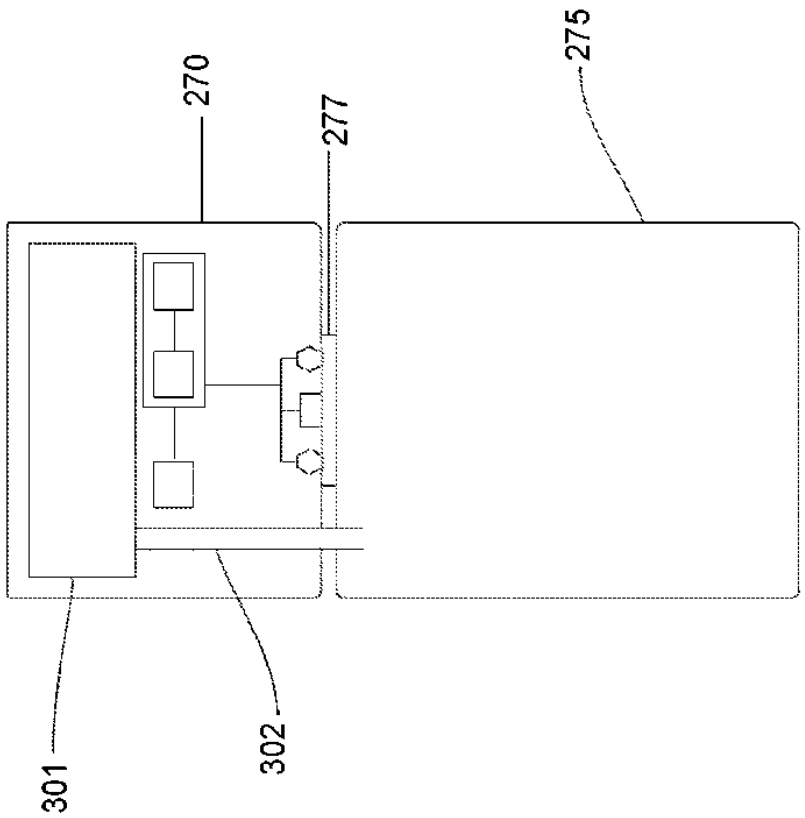


FIGURE 30

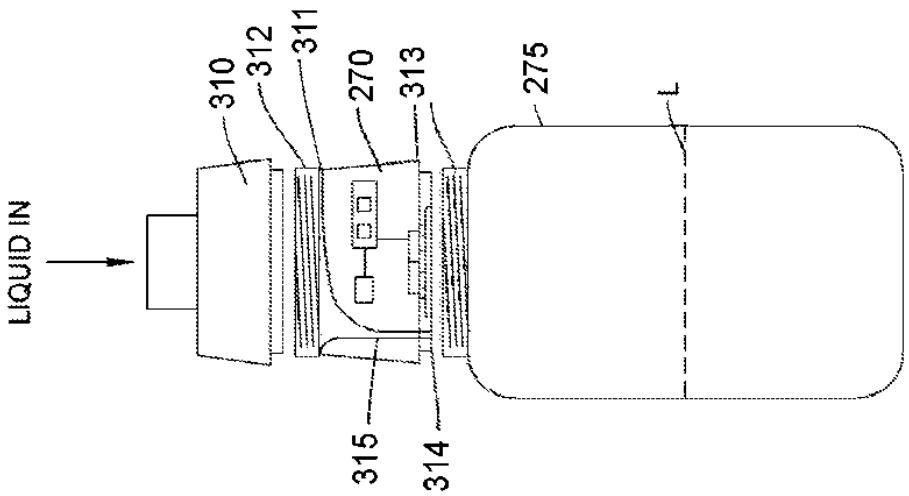


FIGURE 31

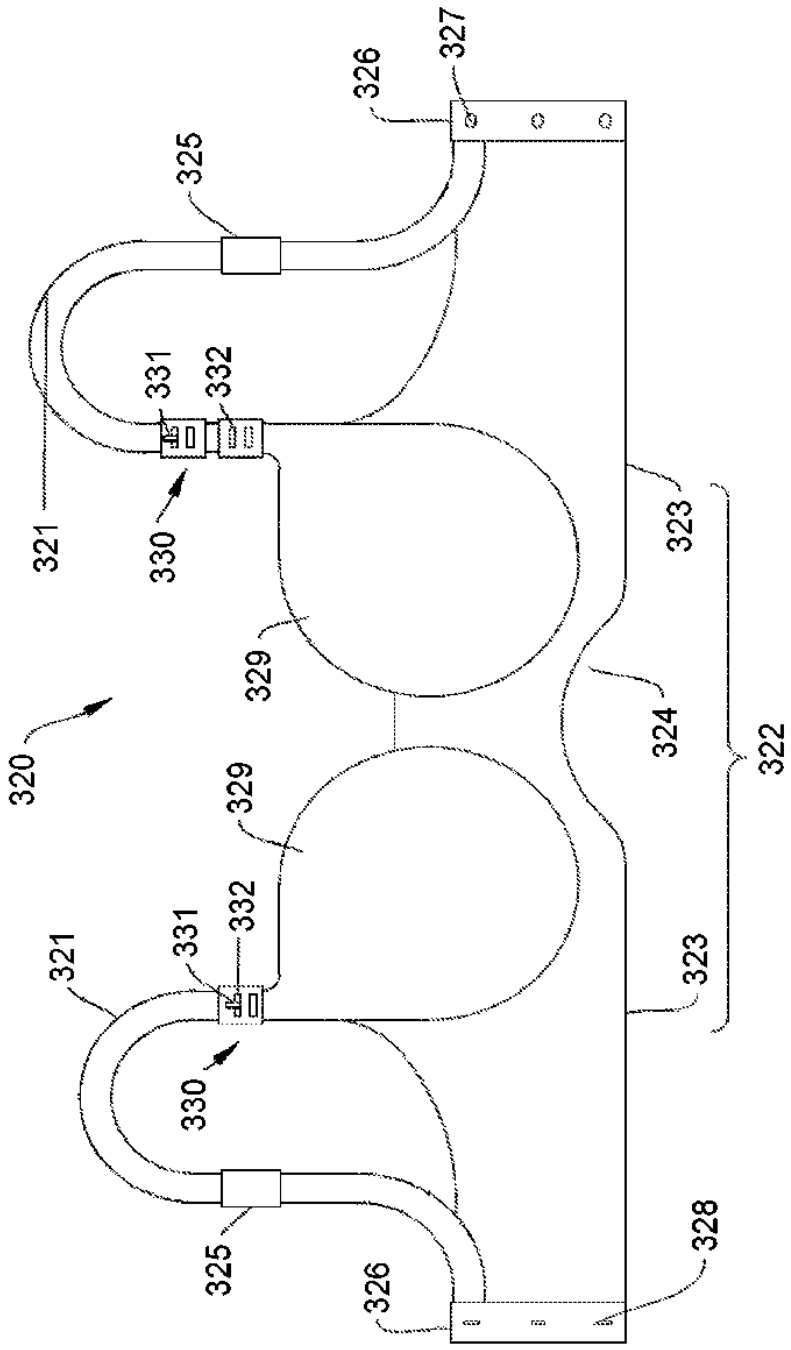


FIGURE 32

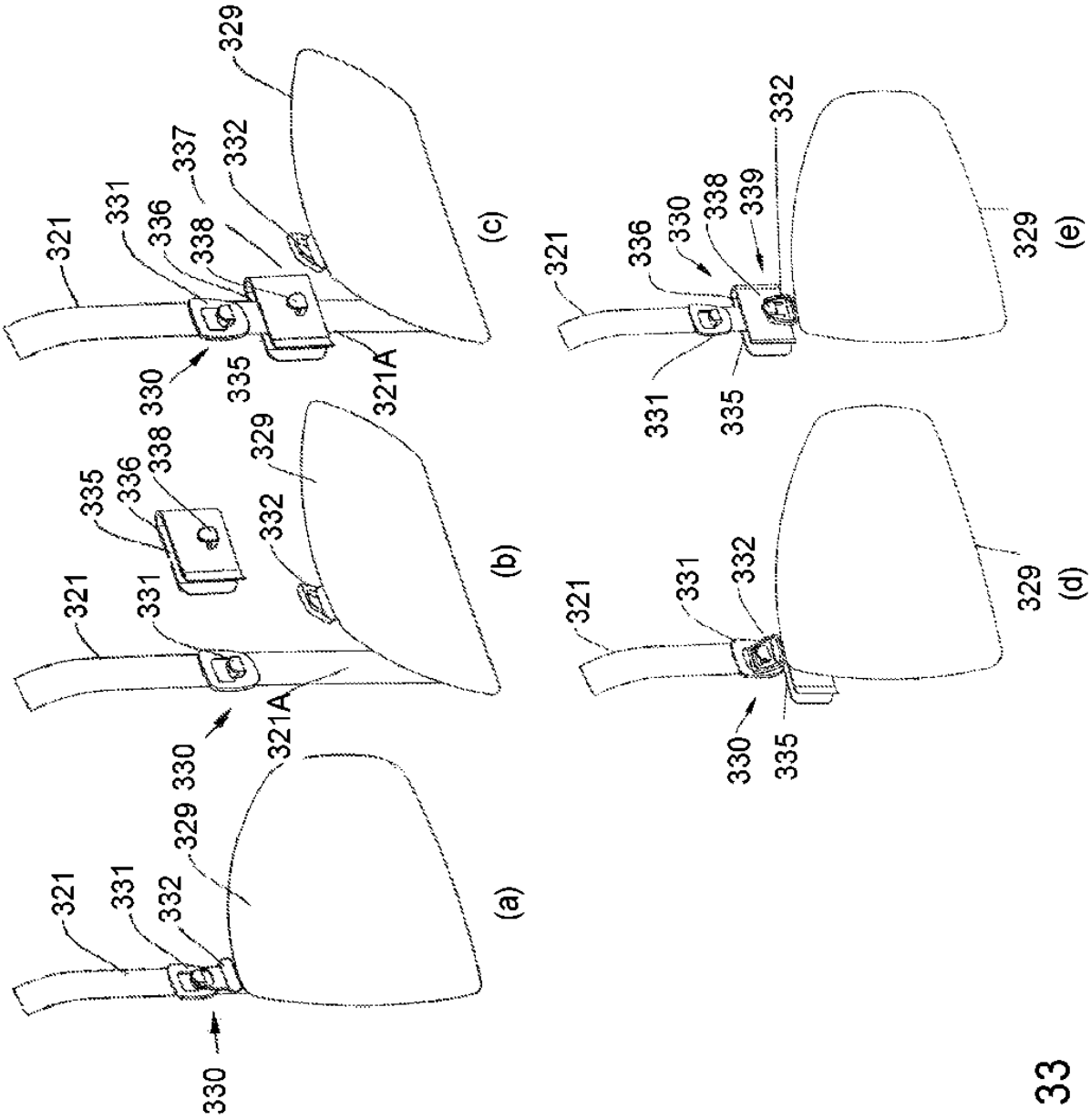

321
331
332
329
330
(a)
321
331
335
336
338
329
332
321A
330
(b)
321
331
336
338
337
332
329
335
321A
330
(c)
321
331
332
329
330
335
(d)
321
336
330
338
339
332
329
331
335
(e)

FIGURE 33

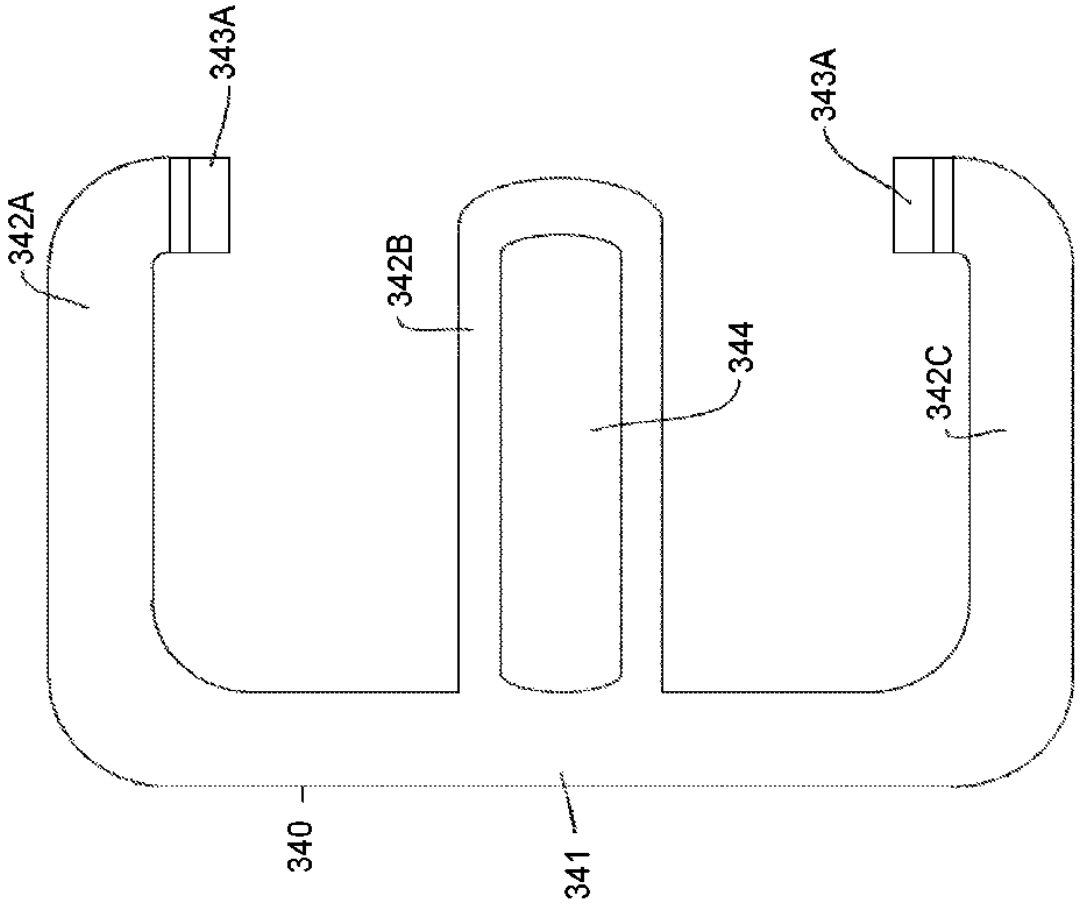


FIGURE 34

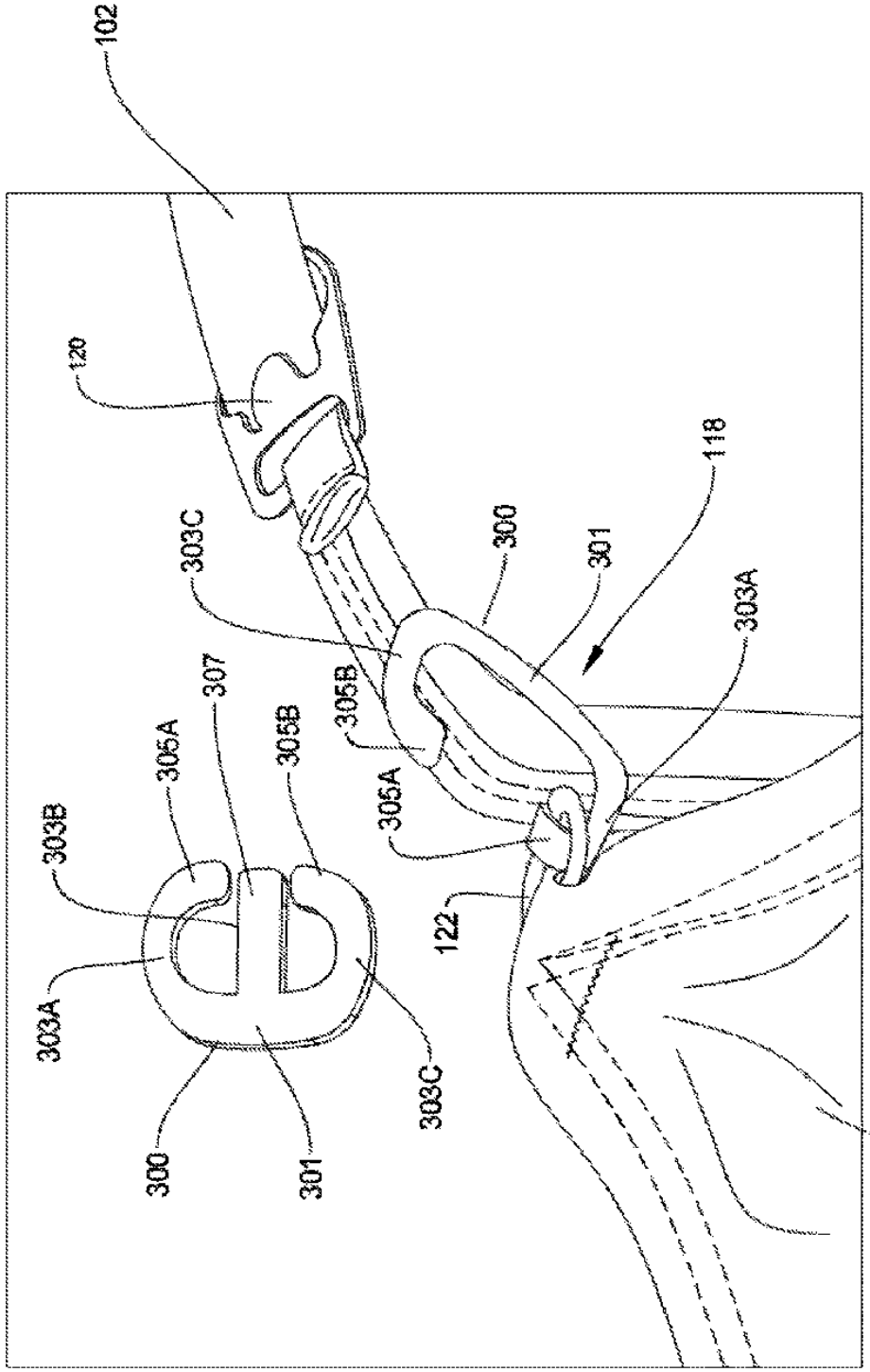

102
120
303C
300
301
118
303A
307
305B
305A
305B
305A
303B
122
303A
303C
300
301
116

FIGURE 35

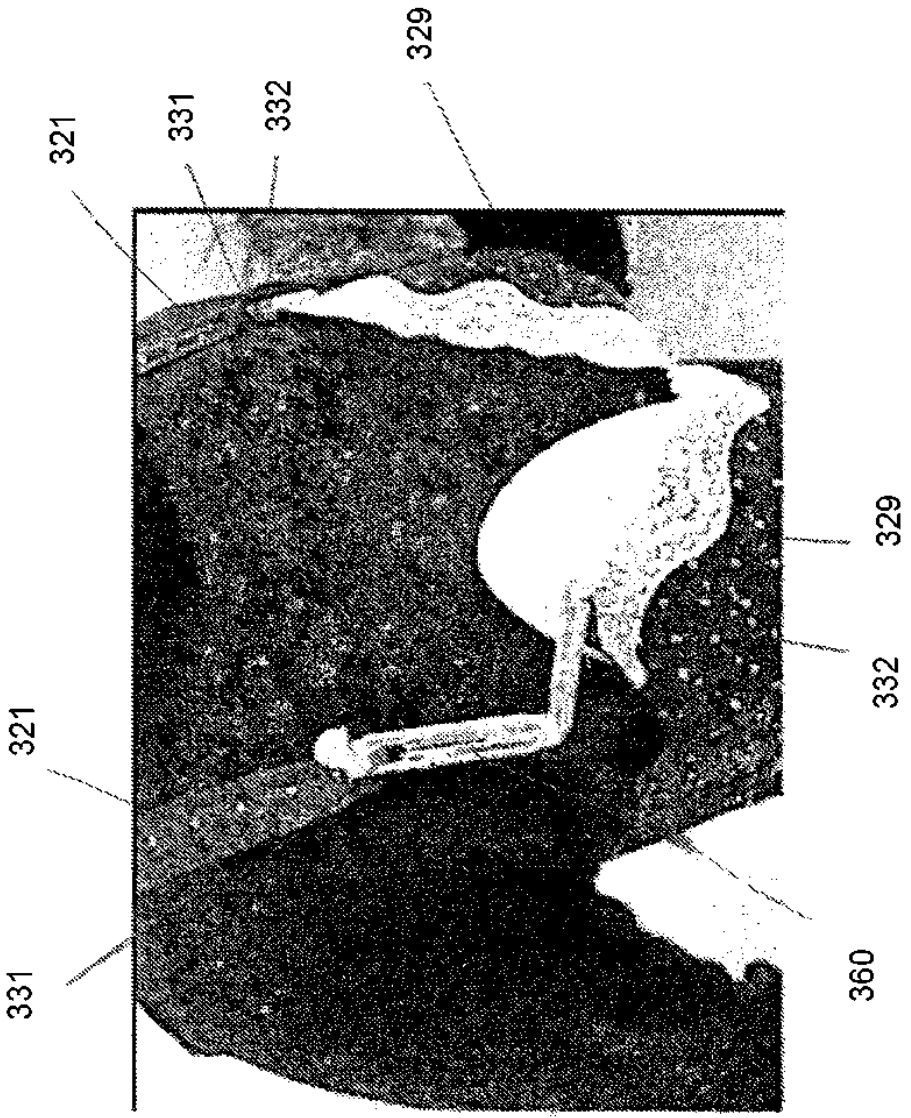


FIGURE 36

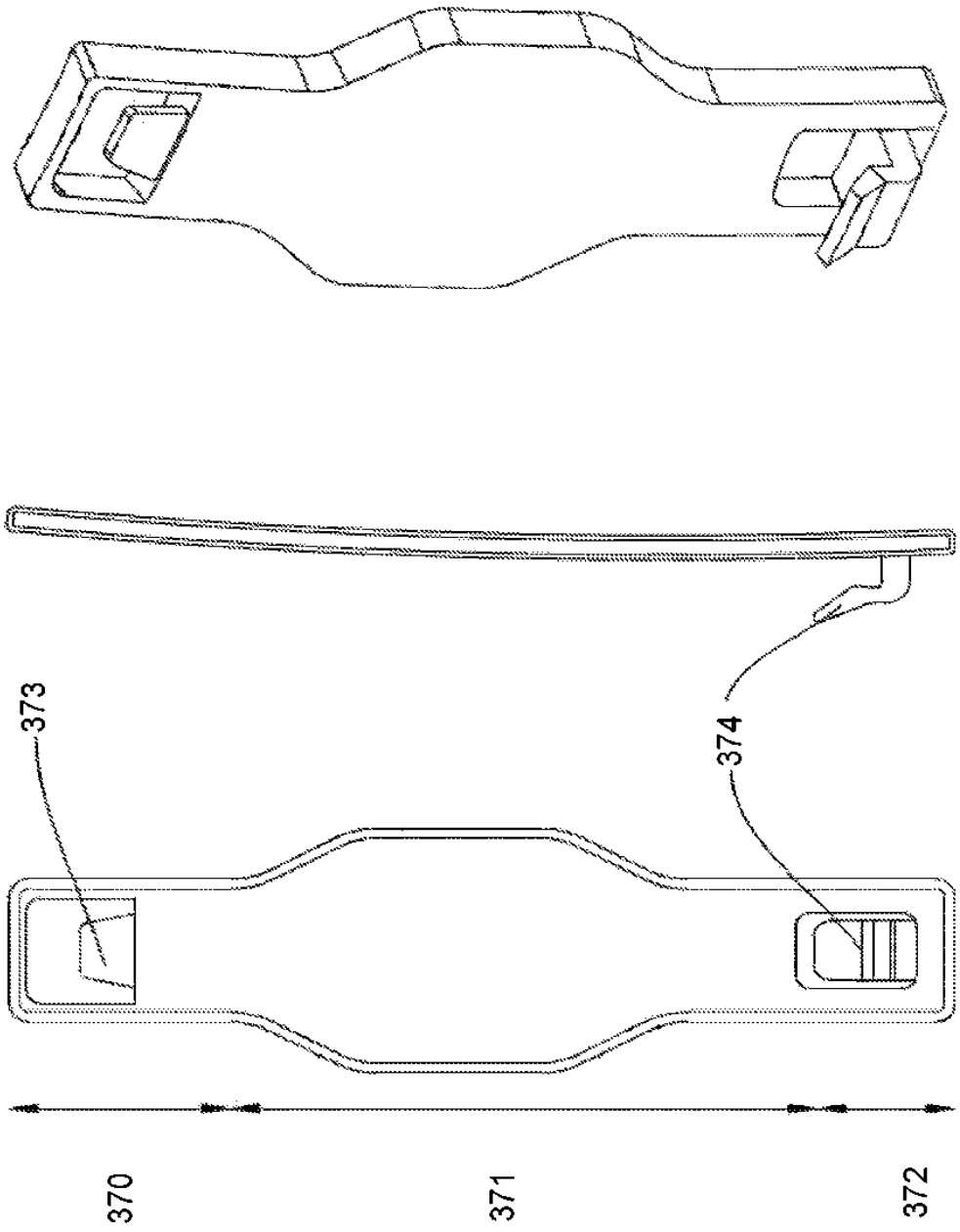


FIGURE 37

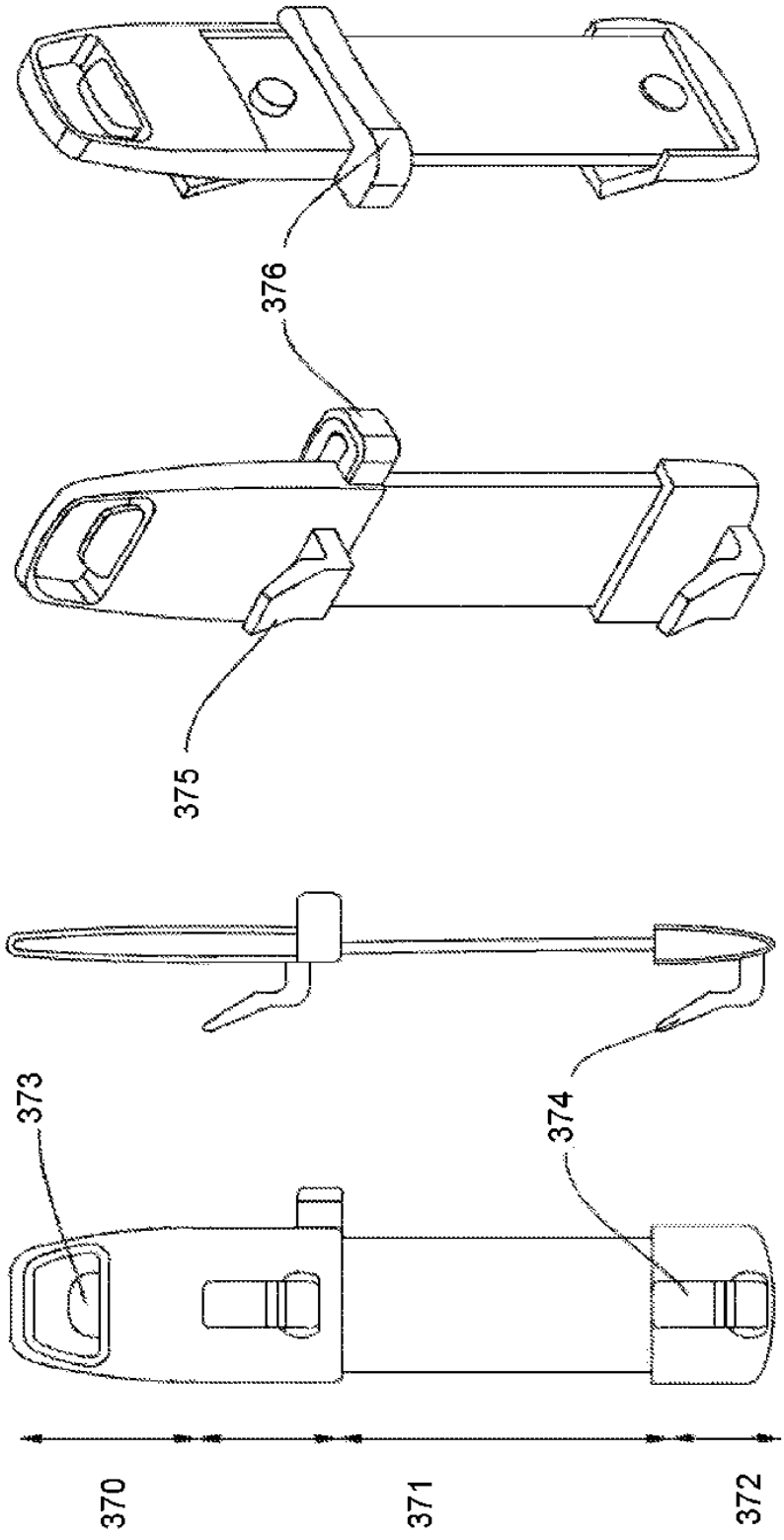


FIGURE 38

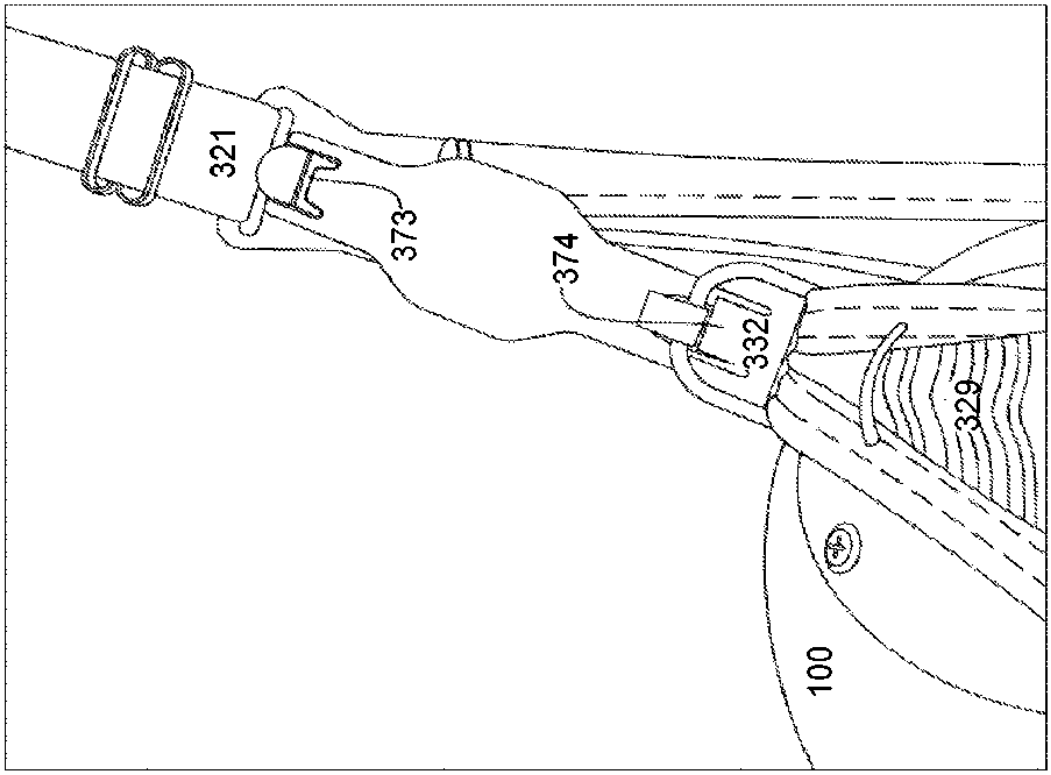


FIGURE 39

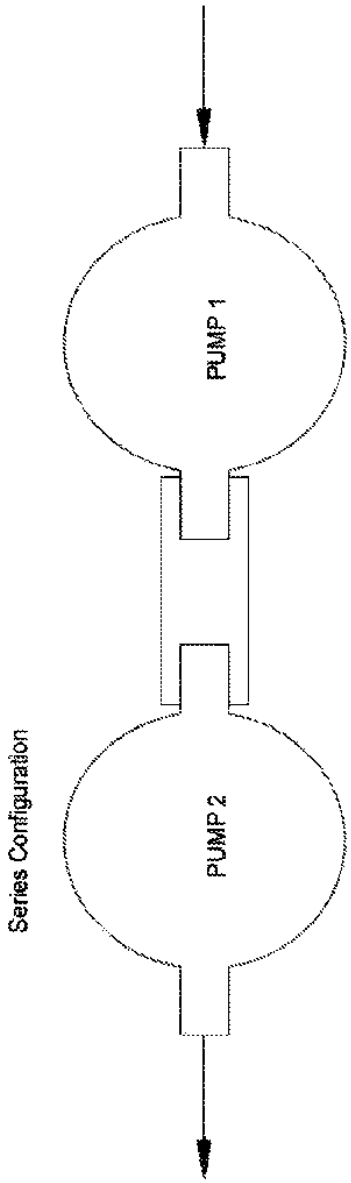


FIGURE 40

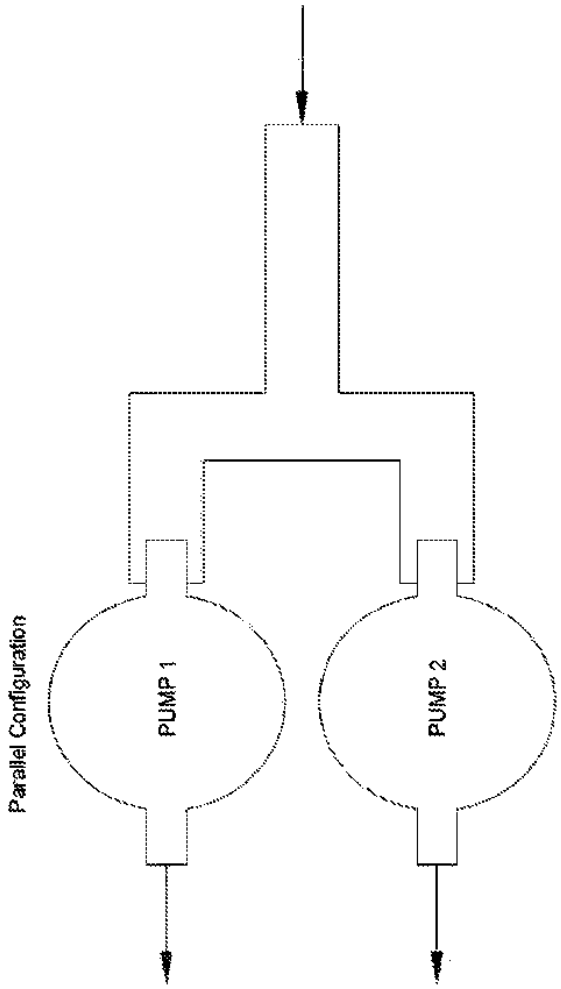


FIGURE 41

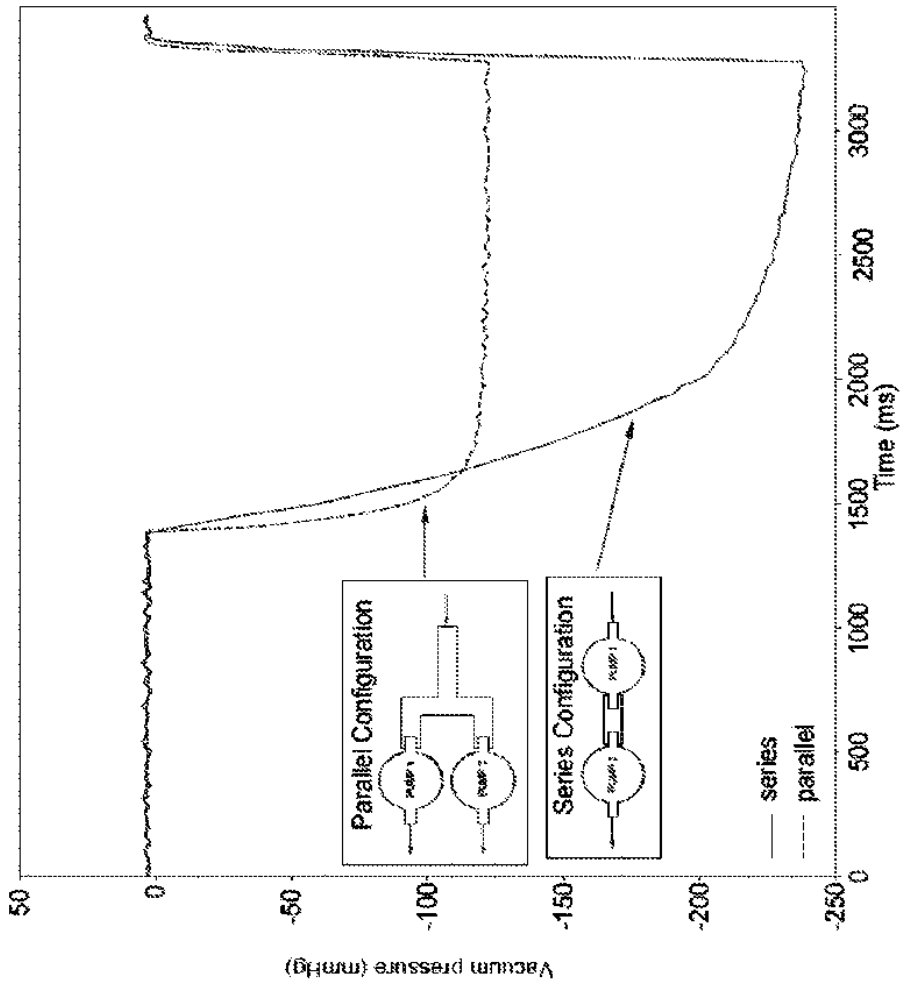

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

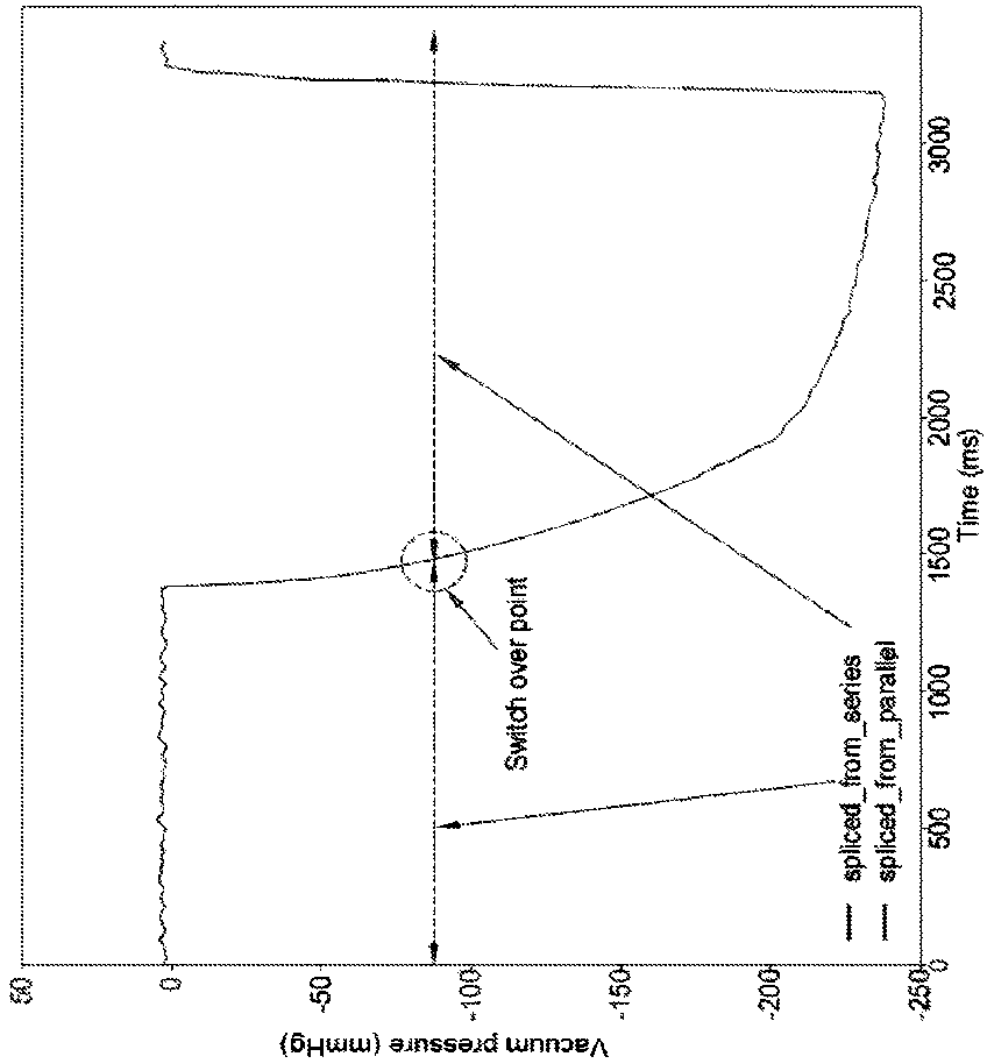

Vacuum pressure (mmHg)
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

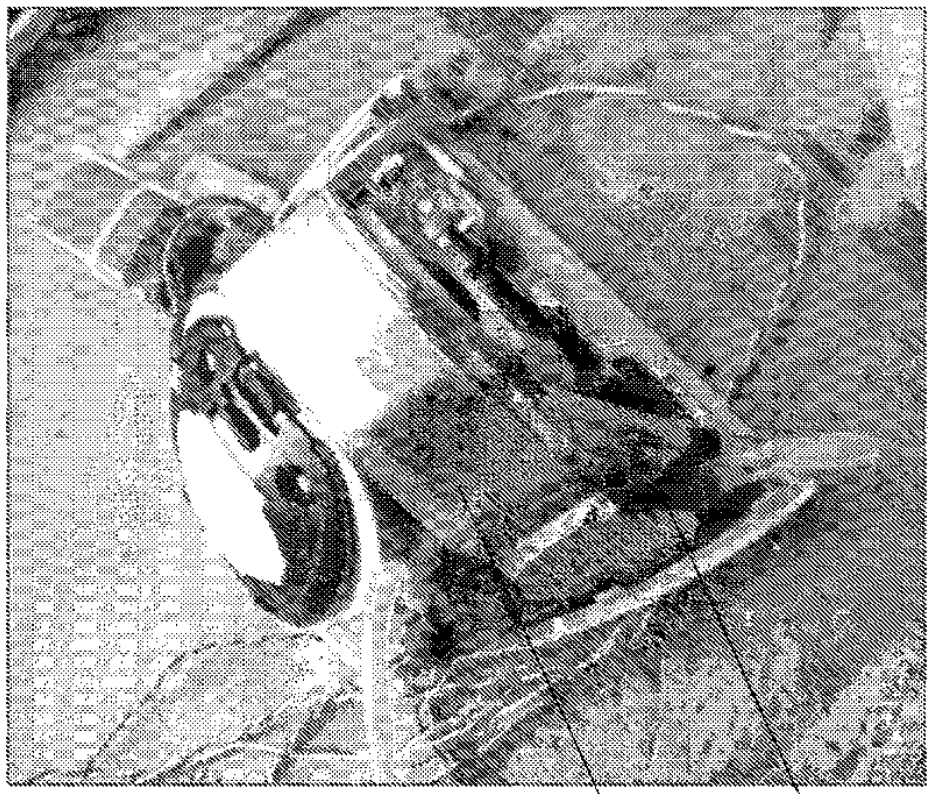


FIGURE 44

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

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	JP 2016 010524 A (MURATA MANUFACTURING CO) 21 January 2016 (2016-01-21) abstract figures 1-5,8	1-6, 11-14, 108-119, 158
X	US 2013/023821 A1 (KHALIL GAMAL [CH] ET AL) 24 January 2013 (2013-01-24) cited in the application page 3, paragraph 51-53 page 4, paragraph 66 - paragraph 69 figures 3-5,9-11	1-6, 11-14, 108-119, 158

-/--

[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" 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
25 September 2018	04/12/2018

Name and mailing address of the ISA/	Authorized officer
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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2018/051659

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.: 31-72(completely); 73-158(partially)
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:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 11-14, 108-119(completely); 158(partially)

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/095599 A1 (KONDO DAISUKE [JP] ET AL) 6 April 2017 (2017-04-06) page 3, paragraph 55 - paragraph 57 page 7, paragraph 146 - page 8, paragraph 175 figures 1,15,16 -----	1,2,4-6, 108, 112-114, 158
A	US 2016/271305 A1 (KURIHARA KIYOSHI [JP] ET AL) 22 September 2016 (2016-09-22) page 3, paragraph 51 - paragraph 56 page 4, paragraph 61 page 6, paragraph 91 - paragraph 93 figures 1,2,6 -----	1,2,14, 118,158

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2018/051659

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		JP WO2015115516 A1	23-03-2017
		US 2016271305 A1	22-09-2016
		WO 2015115516 A1	06-08-2015

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 11-14, 108-119(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the piezo air-pump; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump.

1.1. claims: 2(completely); 158(partially)

A wearable breast pump system as in claim 1, configured as a self-contained wearable device with an internal rechargeable battery; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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2. claims: 7-10, 120-127(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the diaphragm.

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3. claims: 15, 27, 28, 30, 87-95(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the milk container; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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4. claims: 16, 29, 73-86(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the breast shield; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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5. claims: 17-19, 21, 23, 128-157(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features related to flow measurement and indication; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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6. claims: 22(completely); 158(partially)

A wearable breast pump system as in claim 1, in which the centre of gravity with an empty milk container attached to te housing is at or below (i) the half-way height line of the housing or (ii) the horizontal line passing through a nipple tunnel or filling point on a breast shield (so that

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

the device that is not top-heavy for a woman using the pump); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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7. claims: 24(completely); 158(partially)

A wearable breast pump system as in claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote sensor; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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8. claims: 20, 25, 26, 96-107(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the pump (control); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 31-72(completely); 73-158(partially)

The present application contains 158 claims, of which 44 are independent.

There is no clear distinction between several of the 44 independent claims because of overlapping scope. Various independent claims directed to subject-matter that does not (completely) overlap do not meet the requirements of unity of invention (Rule 13 PCT).

According to what can be understood from the description, it seems that a protection is sought after for several a spects of a breast pump system:

- wearability (including a housing shaped at least in part to fit inside a bra)
- technical features of the breast shield
- technical features of the milk container
- technical features of the pump and its control to improve user comfort
- the pump is specifically a piezo air-pump (possibly two piezo air-pumps in series or in parallel), and details thereof
- a separate deformable diaphragm to generate negative air pressure inside the breast shield, the diaphragm as such separating the (piezo) air-pump from the breast shield such that the (piezo) air-pump forms part of a closed loop system
- a flow measurement and milk volume indication means

The 44 independent claims are either directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

Moreover, from the 114 dependent claims, 85 claims are dependent on any of the 41 independent claims directed to a "system" (as well as on any of the other dependent claims). They too are directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

There are thus so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

The non-compliance with the s ubstantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19 and 9.25).

The search was based on the subject-matter that is expected to be claimed later in the procedure, and the corresponding independent claim 1. Moreover, independent claim 158, directed to a method of expressing and collecting milk, comprising the step of using a system as defined in claim 1, has also been searched. Independent claims 31-72 and independent claim 158 when referring to any of the independent

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

claims 31-72 were not searched. Claims 73-157 when being dependent on any of claims 31-72 were also not searched.
Since the claims dependent on
claim 1 are not complying with unity of invention (Rule 13 PCT) (see non unity reasoning), the extent of the search was further limited to the technical features as claimed in claim 1 in combination with the first and second invention for which protection is sought, namely dependent claim 2 and the dependent claims further specifying details concerning the piezo air-pump (claims 3-6, 11-14, 108-119).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

A hidden on the milk collecting device inside of the breast pump main machine

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Abstract

The invention claims a hidden on the milk collecting device inside of the breast pump main machine, comprising a three-way, air bag and a duckbill valve, the tee comprising a pressure end, milk sucking end and milk-flowing end, whole-embedded under the breast pump main machine end, breast pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end. the milk collecting device is integrated at the lower end of the breast pump main machine, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the connectable device can host computer and the breast milk storage bottle connection as a whole so as to bear on the lower functional efficiency, so that volume of the breast can be made thinner and smaller.

Description

INVENTION-TITLE

technical field

The invention claims baby appliance field, especially claims a hidden on the milk collecting device inside of the breast pump main machine.

background technology

electric breast pump is used by nursing mothers, refers to instrument for extrusion (absorbing) the accumulation in the breast milk of the tool. the inner vacuum negative pressure pump changes inside air pressure changes, namely the circulation playing emulator allow suction breast milk of infant action.

the existing electric breast pump, mainly comprises the integrated pump and split type breast pump, the breast it is necessary to hand with hand supporting brassiere. the negative voltage output using split type breast pump breast milk collecting needed when the tee and bottle hung in front of the chest by air path hose connected to the breast pump main machine as breast, this line constraint exists and is difficult to assemble; and the integrated pump are integrated together, although the restriction of line, it makes the installation relatively simple, but the structure manner and appearance volume of them wearing and hidden.

summary of the invention

The purpose of the invention is to provide a hidden on the milk collecting device inside of the breast pump main machine, so as to solve the above background technology proposed in the prior art.

The technical solution to solve the technical problem is: a kind of hidden in the milk collecting device of breast pump main machine inside, comprising a tee, air bag and a duckbill valve, the tee comprising a pressure end, milk sucking end and milk-flowing end, the whole way to the breast pump main machine end, pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end.

As an improvement, the air bag is flat U shape, pressure end is set into flat U shape consistent with the air bag, the lower end of the breast pump main machine provided with a containing pressure end of U-shaped cavity.

As an improvement, said air bag is made of liquid silica gel material.

As an improvement, the inner top of the U-shaped cavity is provided with air bag cover, air bag cover is provided with a first air hole and a second air hole, the vacuum negative pressure device comprises a vacuum pump and the air release valve, a first air hole is connected with the vacuum pump, the second air hole connected with the air escape valve, air bag sealing connection on the air bag cover.

As an improvement, the air bag cover is provided with a deformation guide surface, deformation guide surface guiding the air bag under the vacuum negative pressure to the breast to form a flat shape.

As an improvement, the end sealing connected with a storage bottle, the milk bottle is jointed at the lower end of the breast pump main machine.

As an improvement, the duckbill valve is provided with a first valve and a second valve, the first valve comprises a first deformable wall at the two side part of the arc-shaped. two first deformation wall from up to down gradually close and form a first elongate-shaped incisions at the end, milk-flowing end and storage bottle connected the first valve, the second valve comprising a second deformable wall at the two side part of the arc-shaped, two second deformation wall from up to down gradually close and form second elongated-shaped incisions at the end, the second valve connecting the outside atmospheric pressure and storage bottle.

As an improvement, the duckbill valve made of food-grade material of liquid silica gel.

As an improvement, the outer side of said breast pump main machine set into the first curved surface, outer side of said storage bottle is set to the second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface.

As an improvement, the inner side face of said breast pump main machine and the inner side are coplanar in the storage bottle surface contact surface of the milk sucking end and the inner side of the breast pump main machine face.

Beneficial effect of this invention, the milk collecting device is integrated on the lower end part of the breast pump main machine, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the connectable device can host computer and the breast milk storage bottle connection as a whole so as to bear on the lower functional efficiency, so that volume of the breast can be made thinner and smaller.

Description

With reference to the accompanying drawings and embodiments, this invention can be further explained:

Picture 1 the assembling schematic hand hidden breast;

FIG. 2 is a hand perspective view hidden breast;

FIG. 3 is a left side view of FIG. 2;

FIG. 4 is a inside structure diagram of the breast pump main machine;

FIG. 5 is a structure diagram of a device;

FIG. 6 is a sectional diagram of the breast pump, air bag in the image in the natural state;

FIG. 7 is a sectional diagram of the breast pump, air bag is in negative pressure state in the image;

FIG. 8 is a breast pump work when the duckbill valve of the first valve open state diagram;

FIG. 9 is a breast pump work when the duckbill valve of the first valve closed state diagram;

FIG. 10 is a front view of the air bag;

FIG. 11 is a A-A sectional view in FIG. 10;

Picture 12 the three-dimensional structure schematic diagram of the duckbill valve;

FIG. 13 is a mammalian mother worn on free hand view of hidden-type breast pump;

FIG. 14 is a nursing mother worn on hand-free view of the hidden type pump.

Specific implementation methods

Referring to FIG. 3 to FIG. 1, the embodiment of a hand concealed breast pump, the breast pump main machine 1, a milk collecting device (3) and the milk bottle 2 and other components. breast pump main machine 1 is provided with a main control circuit board with a vacuum negative pressure device and connected with the vacuum negative pressure device 16, the main control circuit board 16 connected with

the breast pump main machine 1 the outer surface of the control panel 11. In FIG. 2, the control panel 11 set on the breast pump main machine top 1, on the one hand, it can convenient for nursing mothers to operation, on the other hand, it also can avoid worn inside the bra when the control panel 11 is pressed. The control panel 11 is provided with a breast pump power on/off key, suction the upshift operation key, suction downshift operation keys and lactation and milk mode switching key, and also equipped with suction gear, pump charging state indicating lamp. feeding mother combining actual condition to operate the control panel 11 sends an instruction to the main control circuit board 16, the main control circuit board 16 control the working state of the vacuum negative pressure device. When the host 1 is in the charging state, charging state indicating lamp for prompting. At the same time, pump main machine 1 is further provided with a wireless communication module for receiving electric signal of mobile terminal 18. electric signal in this embodiment, the mobile terminal is a mobile phone, and a wireless communication module 18 for analysis and the mobile phone communication protocol, receiving the mobile phone sends, and sends the electric signal to the main control circuit board 16, the wireless communication module 18 using the Bluetooth or WIFI communication mode. display a plurality of control options in the APP program on the mobile phone, the control option is basically consistent with the control option panel 11, to realize the adjustment of the pump working state. meanwhile, the APP program may further display residual electric suction-gear state and quantity information. to control the working state of the breast through the mobile terminal, greatly convenient the nursing mother in public places using a breast pump, the breast pump is hand hidden breast, nursing mother can wear well in advance, when needing to absorb milk, it only needs opening controlled by the mobile terminal, it is convenient and fast.

As shown in FIG. 4, the breast pump main machine 1 is further provided with a charging and discharging of the lithium battery 15 and charging interface 17, using an adapter can be convenient charging. located at the vacuum negative pressure device in the host unit 1 includes a vacuum pump 13 and the air release valve 14, pump lower end of the main machine 1 is provided with a U-shaped cavity 12, the milk collecting device 3 provided in the U-shaped cavity 12, milk collecting device 3 one end sealing connected with the vacuum negative pressure device. the other end and the sealing connecting a storage bottle 2, a bottle 2 with the breast pump main machine 1 the lower end joint, breast pump main machine outer side of 1 set to first surface, the storage bottle 2 of outer side is disposed at the second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface; breast pump main machine 1 the inner side surface and the storage bottle 2 the inner side surface is set to be coplanar.

the breast pump main machine 1 the provided control panel 11, working condition of controlling and adjusting breast pump convenient for breast feeding mother. At the same time, highly integrated, a vacuum negative pressure device and a milk collecting device 3 are integrally installed on the inside of the breast pump main machine 1, compact structure, pipeline without any restriction. and combining the engineering, the breast pump main machine 1 the outer side is disposed at the bra and abutted surface matching the first curved surface, the outer side of the storage bottle 2 set to match the second curved surface jointed with the bra, first curved surface and second curved surface are connected to form the bra and abutted surface matched with the arc curved surface, nursing mothers can be easy and natural breast in brassiere; breast pump main machine 1 the inner side surface and the storage bottle 2 inner side face is set into plane to joint with one side of the breast. the reasonable layout at the same time to minimize volume of the whole breast. the whole appearance is exquisite, smooth, suitable for wearing and hidden, the nursing mother in public places simply hidden and elegant and decent movement of the breast.

As shown in FIG. 5 is the milk collecting device 3, 3 is hidden in the milk collecting device 1 inside of the breast pump main machine, specifically comprising a tee 32, air bag 31 and duckbill valve 33, tee joint 32 comprises an air pressure end, milk sucking end and flow nipple end. the tee 32 is embedded into the U-shaped cavity 12 lower end host 1, air bag 31 is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to host 1 by breast pump in side surface pointing to the breast, the abutting surface of the milk sucking end 1 with the breast pump main machine inner side face. ensure the inner side of the breast surface is completely flat, the nursing mother to

wear comfort. a duckbill valve 33 fixedly set on the milk-flowing end and end hermetically connected with the storage bottle 2, breast milk through the duckbill valve 33 into the storage bottle 2. the water storage bottle 2 via the screw tooth thread of bottle mouth is connected with the milk-flowing end, convenient for dismounting and cleaning. At the same time, the U-shaped cavity 12 of the inner top is provided with air bag cover, air bag cover is provided with a first air hole and a second air hole, first air hole is connected with the vacuum pump 13 through the tube, second air hole connected with the air escape valve 14 through the tube, the sealing air bag 31 connected on the air bag cover, the air bag 31 with the vacuum pump 13 and release valve 14.

the milk collecting device 3 integrated in the breast pump main machine 1 the lower end, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the milk collecting device 3 can be the host computer 1 with the storage bottle 2 connecting as a whole so as to bear on the functional effect, so that volume of the breast can be made thinner and smaller.

the air bag 31 made by liquid silica gel material of food grade materials, which has better elasticity and fatigue resistance, which is mainly used for isolating the air pressure and breast milk. The FIG. 10 and FIG. 11, the air bag 31 is flat U shape, pressure end is set into a flat U-shape of the air bag 31 the same. air bag 31 opposite the wide milk sucking end is provided, the thickness of the two wide surface is small, which is beneficial for reducing the whole breast thinness, convenient nursing mother wearing the bra and the breast pump inside. At the same time, air bag between two narrow surface 31 of large distance, which is good for increasing the whole volume of the air bag 31, further increases in the whole tee 32 the pressure difference change greatly, so as to provide sufficient pressure to the breast. air bag cover is provided with a deformation guide surface, deformation guide surface of the air bag 31 the two narrow surface is correspondingly provided, deformation guide surface guiding the air bag 31 under the vacuum negative pressure to the breast to form a flat shape. As shown in FIG. 7, when the air bag 31 is flat by negative pressure, air bag 31 integrally from the breast, so as to increase the gap 31 between the breast and the air bag, convenient emulsion from tee 32 to smoothly flow to flow nipple end. deformation guiding face may be provided to be jointed with the surface of the air bag 31 folded, the folded folding sides are vertical to the air bag 31, so as to realize the offset guide 31 of the air bag.

FIG. 6 two states of FIG. 7 respectively show the pump working when air bag 31. In FIG. 6, the air bag 31 is in the natural state, the release valve 14 is in the open state, the air bag 31 connected with the atmospheric pressure, way 32 does not form negative pressure, the whole breast is in playing state. the state mainly for convenient liquid smoothly flows into the storage bottle 2. In FIG. 7, the air bag 31 is in the negative pressure state, then the bleed valve 14 is in the closed state, air bag 31 only connected with the vacuum pump 13 and is completely vacuumed way so as to form negative pressure because of the reduced air bag 31 volume in 32. the whole breast is in the absorbing state of the emulsion in the breast.

a duckbill valve 33 set on the milk-flowing end, has the function of anti-reflux. As shown in FIG. 12, the duckbill valve 33 is provided with a first valve 331 and second valve 332, first valve 331 comprises a first deformable wall at the two side part of the arc-shaped 3311. two first deformation wall 3311 from top to bottom gradually close and elongate-shaped first notch 3312 and first valve 331 formed at the end connected with the flow nipple end and the milk bottle 2, the second valve 332 includes a second deformable wall at the two side part of the arc-shaped 3321, two second deformation wall 3321 from top to bottom gradually close and elongate-shaped second notch 3322 formed at the end. the second valve 332 connects with the external atmospheric pressure and the storage bottle 2. The duckbill valve 33 by liquid silica gel made of food-grade material, which has better leak tightness, anti-tear strength, elasticity, anti-yellowing property, thermal stability, heat aging resistance and compressive deformation. first deformable wall 3311 and second deforming wall 3321 wall thickness is 0.4~0.6mm, the deformation wall design of large and thin area, ensuring easy rebound and the stress is easily deformed.

by deformation of the first deformable wall 3311 and second deformation wall 3321 can easily realize the first

notch 3312 and the second notch 3322 of the opening and closing state of the switching. wherein the second valve 332 connected with the external atmospheric pressure, second deformable wall 3321 and not subject to negative pressure of extrusion, so it is in normally open state, so that the bottle 2 to maintain ventilation state, the milk liquid can continuously flow into the milk bottle 2 through first incision 3312, and first valve 331 following the switching of the vacuum negative pressure and the normal pressure to open or close. releasing the negative pressure when the tee 32, first notch 3312 opened and milk immediately flows into the storage bottle 2. the storage bottle 2 during the vibration, milk extruding first deformable wall 3311 and second deformable wall 3321 from the outside so that the first notch 3312 and the second notch 3322 is closed, liquid cannot flow out from the storage bottle 2, effectively preventing the leakage and the backflow of milk.

As a preferred embodiment, first valve 331 and second valve 332 are connected on the gasket 333, the first notch 3312 and second notch 3322 are pointing to the inner cavity of the storing bottle 2, sealing pad 333 periphery of the port is sealed and jointed with the storage bottle 2. When the milk bottle 2 threaded connection when the flow nipple end, port storage bottle 2 against the lower side of the sealing pad 333, at the same time, is screwed can provide pressure so that the sealing pad 333 of upper side surface and milk-flowing end tightly, which effectively guarantees the sealing of milk-flowing end and storage bottle 2 connection. At the same time, seal pad 333 formed in part of separated first pneumatic chamber and a second pneumatic chamber, end are respectively formed with inserted to the first air pressure cavity of the first connecting part and the second connecting part is inserted to the second air pressure cavity, first valve 331 set on the lower end of the first air pressure cavity, the second valve 332 set on the lower end of the second air pressure chamber, first atmospheric pressure cavity is connected with the milk flow end, the second air pressure cavity is connected with the outside atmospheric pressure. the first air pressure cavity and the first connecting part in interference fit connection, a second air pressure cavity is connected with the second connection part in interference fit connection, it can avoid the valve failure caused by large deformation of the upper end part of the first valve 331 and second valve 332.

FIG. 8 and FIG. 9 respectively show the breast pump when working duckbill valve first valve 331 of the state diagram 33. In FIG. 8, the air bag 31 is in the natural state, the tee 32 is normal pressure, first cut 3312 naturally in open state, collecting the milk of the milk of the flow through first valve 331 flow into the milk bottle 2. In FIG. 9, the air bag 31 is in the negative pressure state, is negative pressure tee 32, first notch 3312 under the compression of the negative pressure in the closed state, the suction of liquid milk to milk-flowing end and stays at the first valve 331 the front.

FIG. 13 and FIG. 14 are nursing mothers worn on free hand hidden effect schematic diagram of breast pump, the hand hidden type breast pump can be well hidden in the brassiere, which is greatly convenient for the nursing mother in public places of breast.

on the drawings embodiments of the invention has been described in detail, but the present invention is not limited to the above embodiment, in the technical field of common technician has the knowledge range, but also can under the premise of not departing from the spirit of making various changes.

Claims

1. A hidden on the milk collecting device inside of the breast pump main machine, wherein it comprises a tee, air bag and a duckbill valve, the tee comprises a pressure end, milk sucking end and milk-flowing end, whole-embedded under the breast pump main machine end, a breast pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end.
2. The hidden according to claim 1 the milk collecting device of breast pump main machine inside, wherein the air bag is flat U shape, pressure end is set into flat U shape consistent with the air bag, the lower end of the breast pump main machine provided with a containing pressure end of U-shaped cavity.

3. The hidden according to claim 2 the milk collecting device of breast pump main machine inside, wherein the air bag is made of liquid silica gel material.
4. The hidden according to claim 3 the milk collecting device inside of the breast pump main machine, wherein the top of the U-shaped cavity is provided with an air bag cover, air bag cover is provided with a first air hole and a second air hole, the vacuum negative pressure device comprises a vacuum pump and the air release valve, a first air hole is connected with the vacuum pump, the second air hole connected with the air escape valve, air bag sealing connection on the air bag cover.
5. The hidden according to claim 4 the milk collecting device of breast pump main machine inside, wherein the air bag cover is provided with a deformation guide surface, deformation guide surface guides the air bag under the vacuum negative pressure to the breast to form a flat shape.
6. The hidden according to claim 1 the milk collecting device of breast pump main machine inside, wherein the end sealing connected with milk storage bottle, the milk bottle is jointed at the lower end of the breast pump main machine.
7. The hidden according to claim 6 the milk collecting device of breast pump main machine inside, wherein the duckbill valve is provided with a first valve and a second valve, the first valve comprises a first deformable wall at the two side part of the arc-shaped. two first deformation wall from up to down gradually close and form a first elongate-shaped incisions at the end, milk-flowing end and storage bottle connected the first valve, the second valve comprising a second deformable wall at the two side part of the arc-shaped, two second deformation wall from up to down gradually close and form second elongated-shaped incisions at the end, the second valve connecting the outside atmospheric pressure and storage bottle.
8. The hidden according to claim 7 the milk collecting device of breast pump main machine inside, wherein the duckbill valve is liquid silica gel food-grade material.
9. any one of said hidden on the milk collecting device inside of the breast pump main machine, wherein the outer side of said breast pump main machine set to the first curved surface, outer side of the milk bottle is set to a second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface according to claim 6~8.
10. The hidden according to claim 9 the milk collecting device of breast pump main machine inside, wherein the inner side face of said breast pump main machine and the inner side are coplanar in the storage bottle surface contact surface of the milk sucking end and the inner side of the breast pump main machine face.

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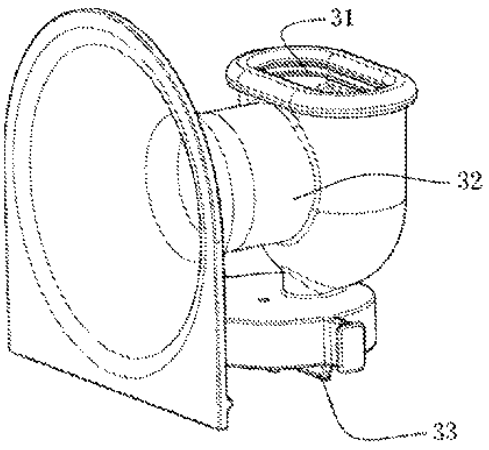
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(54)发明名称

一种隐藏在吸奶器主机内部的集奶装置

(57)摘要

本发明公开了一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。



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1.一种隐藏在吸奶器主机内部的集奶装置，其特征在于：包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

2.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

3.根据权利要求2所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊由液态硅胶材质制成。

4.根据权利要求3所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

5.根据权利要求4所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

6.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

7.根据权利要求6所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

8.根据权利要求7所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀由食品级材质的液态硅胶制成。

9.根据权利要求6～8任一项所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

10.根据权利要求9所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

一种隐藏在吸奶器主机内部的集奶装置

技术领域

[0001] 本发明涉及母婴电器领域，特别涉及一种隐藏在吸奶器主机内部的集奶装置。

背景技术

[0002] 电动吸奶器是供哺乳妈妈产后使用的仪器，是指用于挤(吸)出积聚在乳腺里的母乳的工具。通过内部真空负压泵改变内部气压变化，即循环“吸”“放”去仿效婴儿吸允母乳的动作。

[0003] 就现有的电动吸奶器，主要分为一体式吸奶器和分体式吸奶器，完成免手扶吸奶则需要配合免手扶文胸。使用分体式吸奶器采集母乳时需要将三通和奶瓶悬挂在胸前，用气路软管连接吸奶器主机做吸奶的负压输出，这就存在管线约束以及装配困难的问题；而一体式吸奶器将吸奶器集成于一体，虽然减去了管线的约束，使得装配相对简单，但他们的结构方式和外观体积不利于穿戴和隐藏。

发明内容

[0004] 本发明的目的在于提供一种隐藏在吸奶器主机内部的集奶装置，以解决上述背景技术中提出的问题。

[0005] 为解决上述技术问题所采用的技术方案：一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

[0006] 作为上述方案的改进，所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

[0007] 作为上述方案的改进，所述气囊由液态硅胶材质制成。

[0008] 作为上述方案的改进，在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

[0009] 作为上述方案的改进，所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

[0010] 作为上述方案的改进，所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

[0011] 作为上述方案的改进，所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

[0012] 作为上述方案的改进，所述鸭嘴阀由食品级材质的液态硅胶制成。

[0013] 作为上述方案的改进，所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

[0014] 作为上述方案的改进，所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

[0015] 有益效果：本发明中，集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

附图说明

[0016] 下面结合附图和实施例对本发明做进一步的说明：

[0017] 图1为免手扶隐藏式吸奶器的装配示意图；

[0018] 图2为免手扶隐藏式吸奶器的立体图；

[0019] 图3为图2的左侧视图；

[0020] 图4为吸奶器主机的内部结构示意图；

[0021] 图5为集奶装置的结构示意图；

[0022] 图6为吸奶器的剖面示意图，该图中气囊处于自然状态；

[0023] 图7为吸奶器的剖面示意图，该图中气囊处于负压贴合状态；

[0024] 图8为吸奶器工作时鸭嘴阀中的第一阀门打开的状态示意图；

[0025] 图9为吸奶器工作时鸭嘴阀中的第一阀门关闭的状态示意图；

[0026] 图10为气囊的正视图；

[0027] 图11为图10中A-A剖面示意图；

[0028] 图12为鸭嘴阀的立体结构示意图；

[0029] 图13为哺乳妈妈穿戴上免手扶隐藏式吸奶器的侧视图；

[0030] 图14为哺乳妈妈穿戴上免手扶隐藏式吸奶器的正视图。

具体实施方式

[0031] 参照图1至图3，为本实施例一种免手扶隐藏式吸奶器，该吸奶器由吸奶器主机1、集奶装置3以及储奶瓶2等零部件组成。吸奶器主机1内设置有真空负压装置以及与真空负压装置连接的主控电路板16，主控电路板16连接有设置于吸奶器主机1外表的控制面板11。图2中，控制面板11设置在吸奶器主机1的顶部，一方面可方便哺乳妈妈操作，另一方面也可避免穿戴在文胸内部时控制面板11受到挤压。该控制面板11上设置有吸奶器的开机/关机按键、吸力大小加档操作按键、吸力大小减档操作按键以及催乳和吸奶模式的切换按键，同时还设置有吸力档位提示灯，吸奶器充电状态提示灯等。哺乳妈妈结合实际情况对控制面板11进行操作，发送指令给主控电路板16，主控电路板16控制调节真空负压装置的工作状态。当吸奶器主机1处于充电转态时，充电状态提示灯予以提示。同时，吸奶器主机1内还设置有用于接收移动终端电信号的无线通讯模块18。本实施例中，移动终端为手机，无线通讯模块18用于解析与手机的通讯协议，接收手机发出的电信号，并将电信号发送至主控电路

板16，无线通讯模块18采用蓝牙或WIFI通信模式。手机上的APP程序中显示有多个控制选项，该控制选项基本与控制面板11上的选项相一致，用以实现吸奶器工作状态的调节。同时该APP程序中还可以显示吸力档位状态以及吸奶器的剩余电量等信息。通过移动终端对吸奶器的工作状态进行控制，极大方便了哺乳妈妈在公共场所使用吸奶器，由于该吸奶器为免手扶隐藏式吸奶器，哺乳妈妈可事先穿戴好，当需要吸奶时，只需通过移动终端控制开启即可，方便快捷。

[0032] 如图4所示，该吸奶器主机1内还设置有充放电的锂电池15和充电接口17，使用适配器可对其进行便捷充电。位于吸奶器主机1内的真空负压装置包括真空泵13和泄气阀14，吸奶器主机1的下端部设置有U形腔体12，集奶装置3设置在U形腔体12内，集奶装置3一端与真空负压装置密封连接，另一端与储奶瓶2密封连接，储奶瓶2与吸奶器主机1的下端对接，吸奶器主机1的外侧面设置成第一曲面，储奶瓶2的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面，吸奶器主机1的内侧面和储奶瓶2的内侧面设置成共面。

[0033] 通过在吸奶器主机1的外表设置控制面板11，方便哺乳妈妈控制和调节吸奶器的工作情况。同时，整机高度集成，真空负压装置和集奶装置3均集成安装于吸奶器主机1的内部，结构紧凑，无任何管线约束。并且，结合人体工程学，将吸奶器主机1的外侧面设置成与文胸贴合面匹配第一曲面，将储奶瓶2的外侧面设置成与文胸贴合面匹配第二曲面，第一曲面和第二曲面衔接形成与文胸贴合面匹配的弧形曲面，哺乳妈妈可轻松自然的将吸奶器放入哺乳文胸中；吸奶器主机1的内侧面以及储奶瓶2的内侧面设置成平面状以便与乳房一侧贴合。在布局合理的同时实现了整个吸奶器的体积最小化。该吸奶器整体外形精巧、圆滑，非常适合穿戴和隐藏，满足哺乳妈妈在公共场合实现简单隐蔽且动作优雅得体的吸奶。

[0034] 如图5所示为集奶装置3，该集奶装置3隐藏在吸奶器主机1内部，具体包括三通32、气囊31以及鸭嘴阀33，三通32包括气压端、吸奶端以及流奶端，整个三通32嵌入至吸奶器主机1下端部的U形腔体12内，气囊31设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机1的内侧面指向乳房，吸奶端的抵接面与吸奶器主机1的内侧面平齐，保证吸奶器的内侧面完全平整，增加哺乳妈妈穿戴的舒适度。鸭嘴阀33固定设置在流奶端，流奶端密封连接有储奶瓶2，吸奶器吸出的奶液经鸭嘴阀33流入至储奶瓶2。该储奶瓶2通过瓶口的螺牙螺接于流奶端，方便拆卸清洗。同时，在U形腔体12的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，第一气孔通过软管与真空泵13连通，第二气孔通过软管与泄气阀14连通，气囊31密封连接在气囊盖上，实现气囊31同时与真空泵13以及泄气阀14连通。

[0035] 集奶装置3集成在吸奶器主机1的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置3可将吸奶器主机1与储奶瓶2连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

[0036] 上述气囊31由食品级材质的液态硅胶材质制成，具有较优的弹性和耐疲劳性，其主要用于气压与母乳的隔离。如图10和图11所示，该气囊31呈扁平U形状，气压端设置成与气囊31相一致的扁平U形状。气囊31的宽面正对吸奶端设置，两个宽面之间的厚度较小，有利于减小整个吸奶器薄度，方便哺乳妈妈将吸奶器穿戴与文胸内部。同时，气囊31的两个窄

面之间的距离较大，有利于增加整个气囊31的体积，进而增大整个三通32内的气压差的变大幅度，以便提供充足的压力进行吸奶。气囊盖上设置有变形导向面，变形导向面与气囊31的两个窄面对应设置，变形导向面引导气囊31在真空负压下偏离于乳房贴合形成扁平状。如图7所示，当气囊31受负压贴合呈扁平状时，气囊31整体偏离于乳房，进而增加了乳房与气囊31之间的间隙，方便乳液从三通32内顺畅的流入至流奶端。变形导向面具体可设置成与气囊31表面贴合的折面，折面的对折处呈竖向偏离于气囊31设置，进而实现整个气囊31的偏离导向。

[0037] 图6和图7分别示出了吸奶器工作时气囊31的两种状态。图6中，气囊31处于自然状态，此时泄气阀14处于打开状态，气囊31与大气压相通，三通32内未形成负压，整个吸奶器处于“放”的状态，该状态主要是为了方便奶液顺利的流入至储奶瓶2中；图7中，气囊31处于负压贴合状态，此时泄气阀14处于关闭状态，气囊31仅与真空泵13连通且被完全抽真空，三通32内由于气囊31体积的缩小而形成负压，整个吸奶器处于“吸”的状态，实现乳房内乳液的吸出。

[0038] 鸭嘴阀33设置于流奶端，具有防逆流的作用。如图12所示，鸭嘴阀33上设置有第一阀门331和第二阀门332，第一阀门331包括位于其两侧部的呈弧形状的第一变形壁3311，两个第一变形壁3311由上至下逐渐靠拢且在末端形成细长状的第一切口3312，第一阀门331连通流奶端和储奶瓶2；第二阀门332包括位于其两侧部的呈弧形状的第二变形壁3321，两个第二变形壁3321由上至下逐渐靠拢且在末端形成细长状的第二切口3322，第二阀门332连通外界大气压和储奶瓶2。该鸭嘴阀33由食品级材质的液态硅胶制成，其有较优的密封性、抗撕裂强度、回弹性、抗变黄性、热稳定性、耐热老化性以及耐压缩变形的特点。第一变形壁3311和第二变形壁3321的壁厚为0.4~0.6mm，变形壁设计的面积大而薄，保证易回弹且受力易变形。

[0039] 通过第一变形壁3311和第二变形壁3321的变形可轻松实现第一切口3312和第二切口3322的打开和关闭状态的切换。其中，第二阀门332与外界大气压连通，第二变形壁3321并未受到负压的挤压，因此处于常开状态，进而使得储奶瓶2维持透气状态，奶液可以不断地经第一切口3312流入至储奶瓶2；而第一阀门331跟随真空负压与常压之间的切换而打开或关闭。当三通32解除负压时，第一切口3312打开，奶液立即流入至储奶瓶2。当储奶瓶2发生晃动时，奶液从外侧挤压第一变形壁3311和第二变形壁3321，进而使得第一切口3312和第二切口3322关闭，奶液无法从储奶瓶2中流出，有效了防止了奶液的外漏和逆流。

[0040] 作为优选，第一阀门331和第二阀门332共同连接在密封垫333上，第一切口3312和第二切口3322均指向储奶瓶2的内腔，密封垫333的周边与储奶瓶2的端口密封贴合。当储奶瓶2螺纹连接在流奶端时，储奶瓶2的端口紧抵在密封垫333的下侧面，同时，螺接的方式可提供压力使得密封垫333的上侧面与流奶端紧贴，有效保证了流奶端与储奶瓶2之间的密封连接。同时，密封垫333的中部形成相互隔开的第一气压腔和第二气压腔，流奶端分别形成有插入至第一气压腔的第一连接部以及插入至第二气压腔的第二连接部，第一阀门331设置在第一气压腔的下端，第二阀门332设置在第二气压腔的下端，第一气压腔与流奶端相通，第二气压腔与外界大气压相通。第一气压腔和第一连接部过盈配合连接，第二气压腔与第二连接部过盈配合连接，可避免因第一阀门331和第二阀门332上端部变形过大而导致的阀门失效。

[0041] 图8和图9分别示出了吸奶器工作时鸭嘴阀33中的第一阀门331的状态示意图。图8中，气囊31处于自然状态，三通32内为常压，第一切口3312自然处于打开状态，汇集在流奶端的奶液经第一阀门331流入至储奶瓶2；图9中，气囊31处于负压贴合状态，三通32内为负压，第一切口3312在负压的挤压下处于闭合状态，吸出来的奶液汇入至流奶端且停留在第一阀门331前端。

[0042] 图13和图14均为哺乳妈妈穿戴上免手扶隐藏式吸奶器的效果示意图，该免手扶隐藏式吸奶器的确能很好的隐藏于文胸内，大大方便了哺乳妈妈在公共场所随意的吸奶。

[0043] 上面结合附图对本发明的实施方式作了详细说明，但是本发明不限于上述实施方式，在所述技术领域普通技术人员所具备的知识范围内，还可以在不脱离本发明宗旨的前提下作出各种变化。

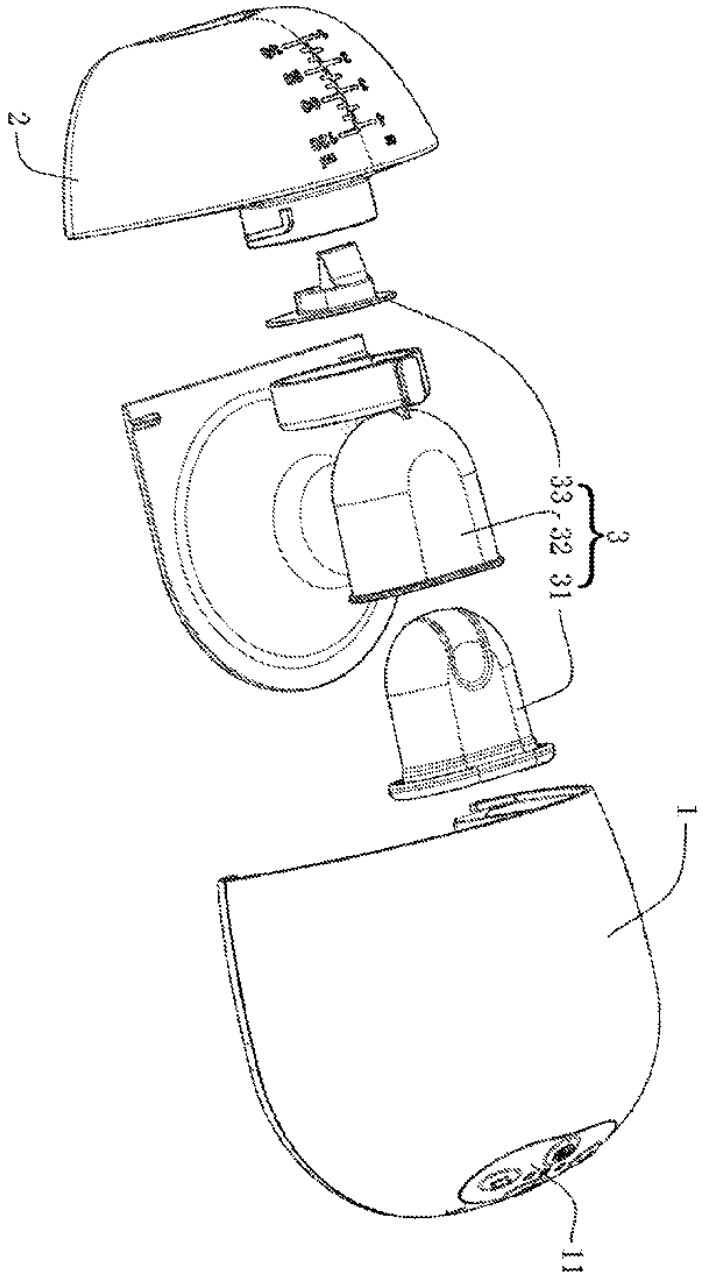


图1

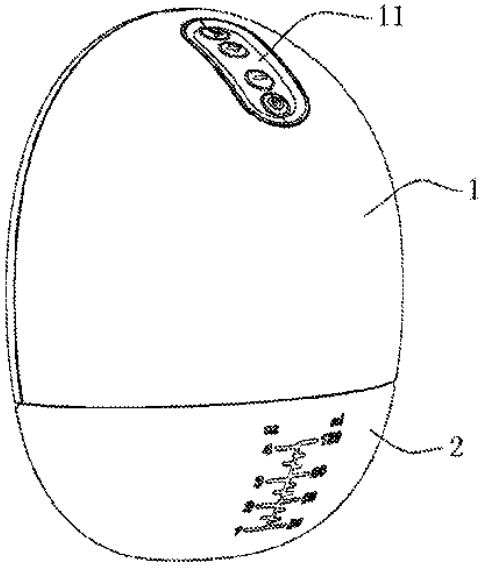


图2

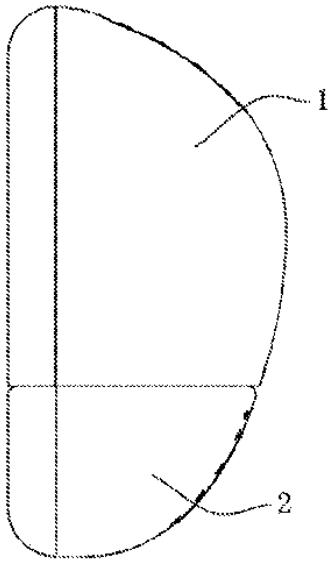


图3

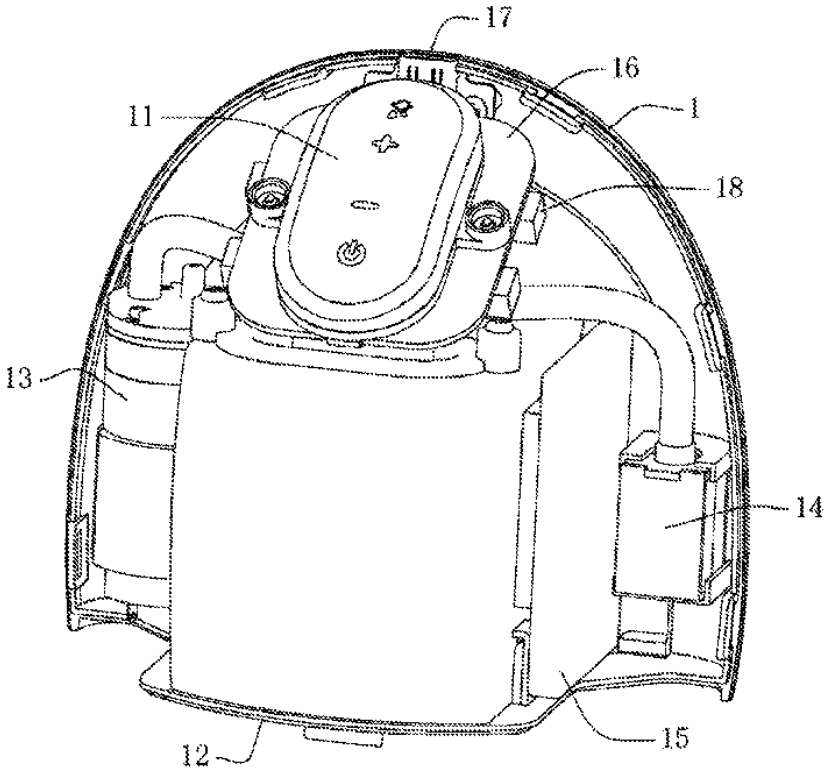


图4

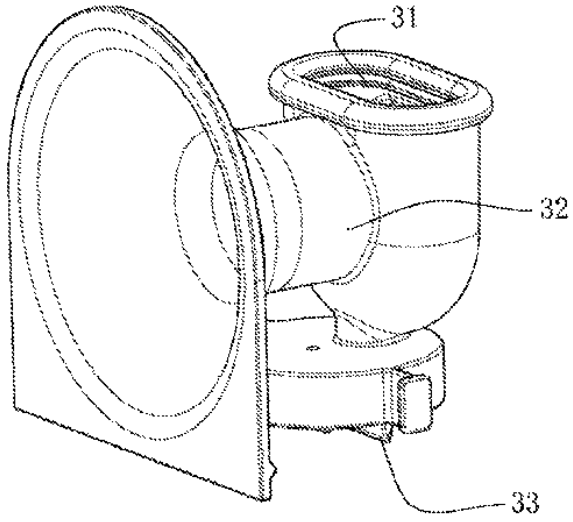


图5

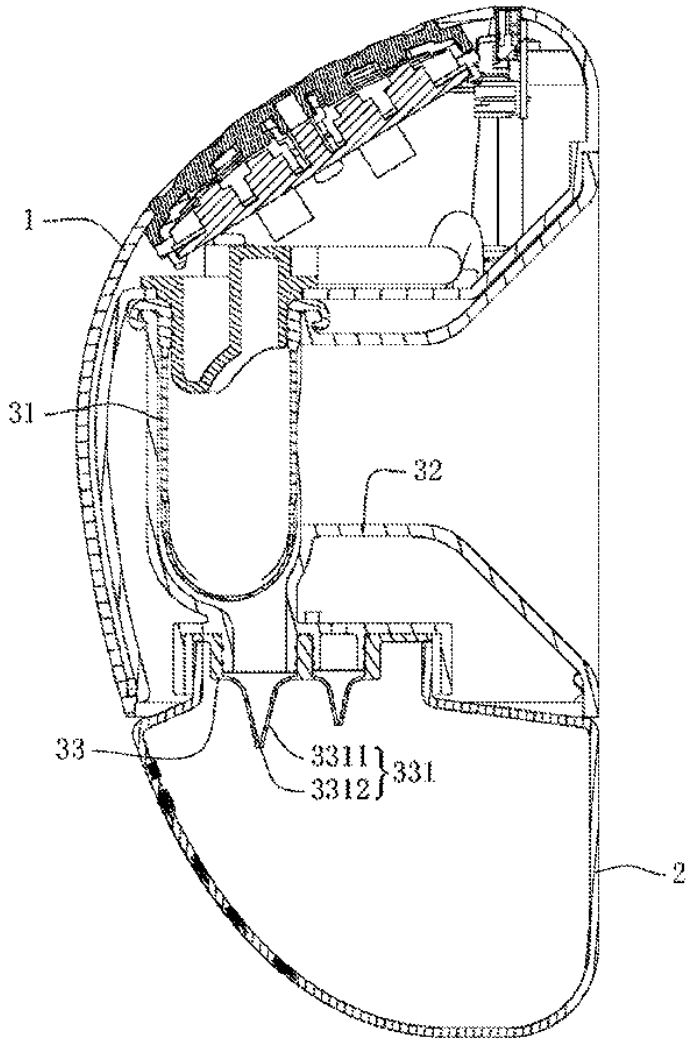


图6

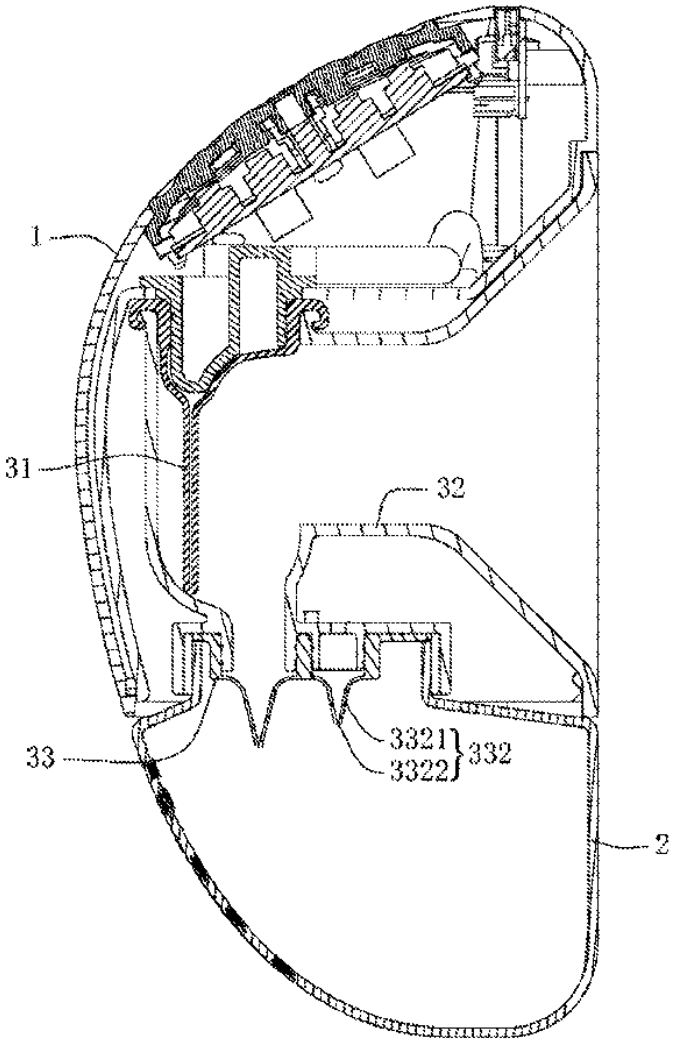


图7

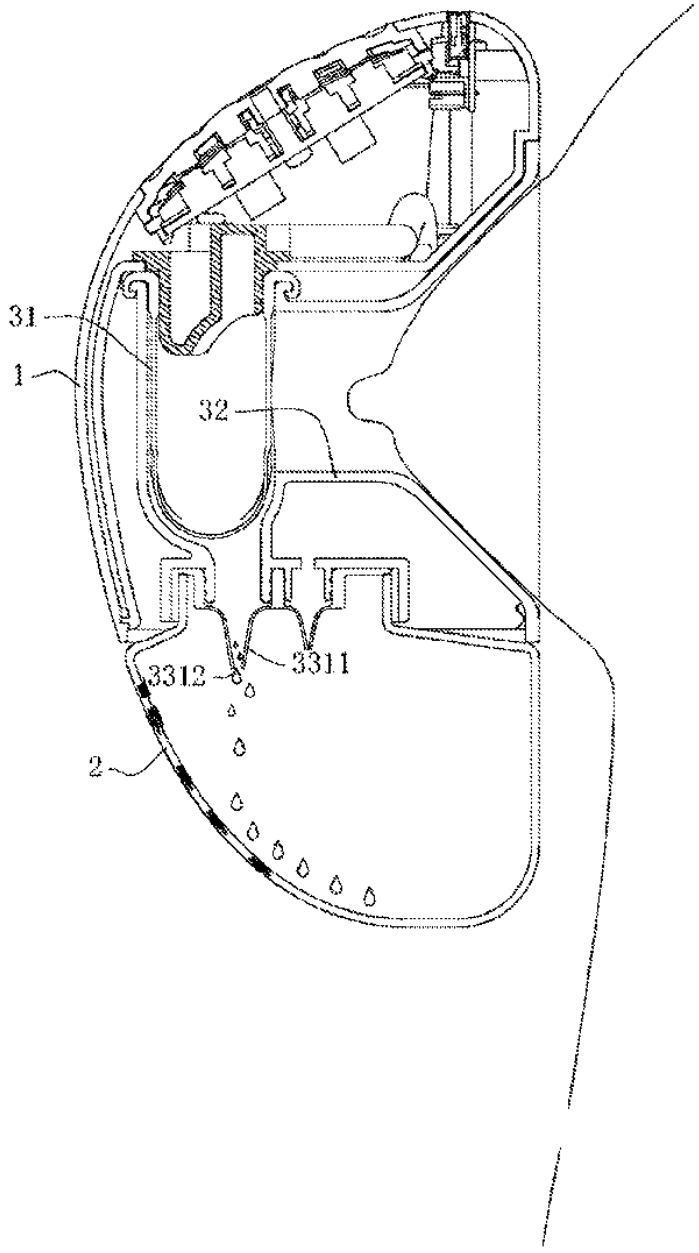


图8

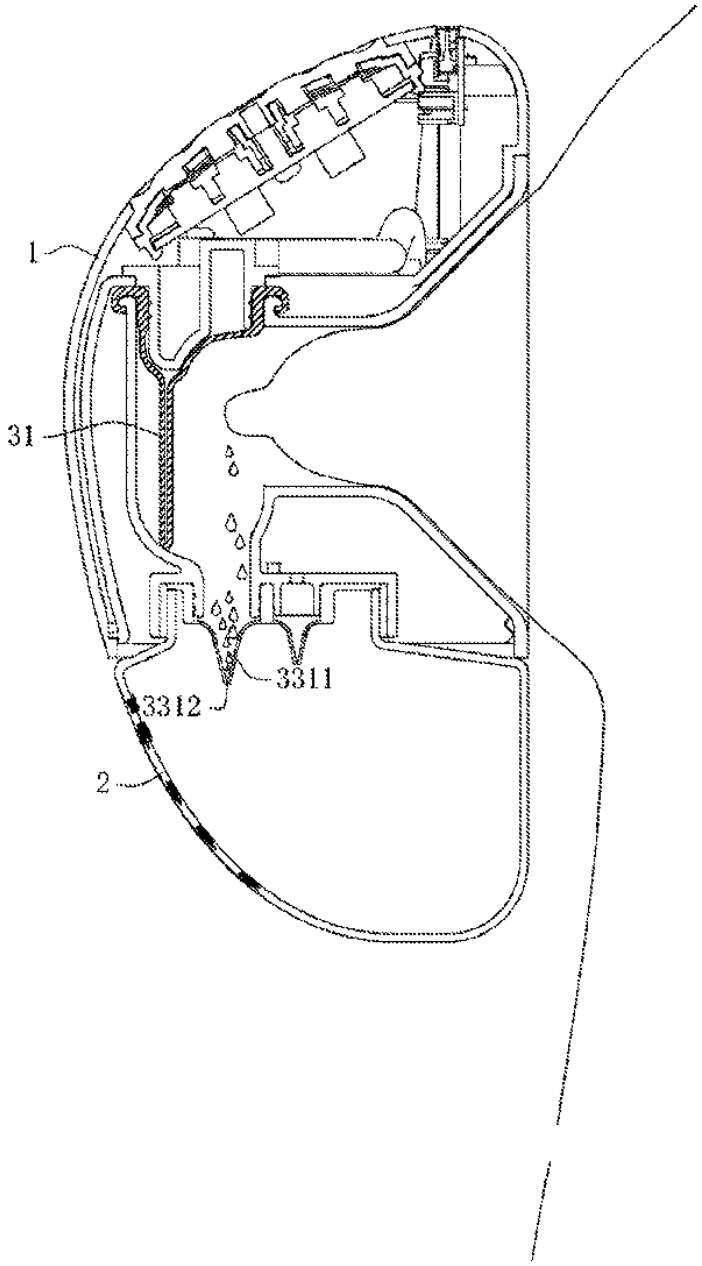


图9

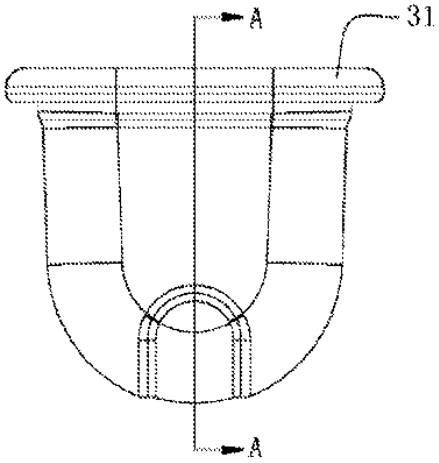


图10

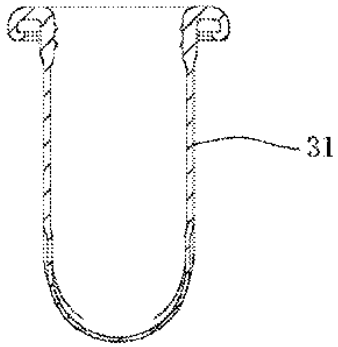


图11

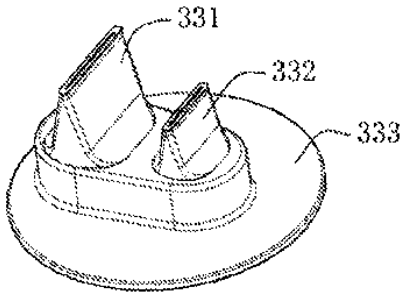


图12

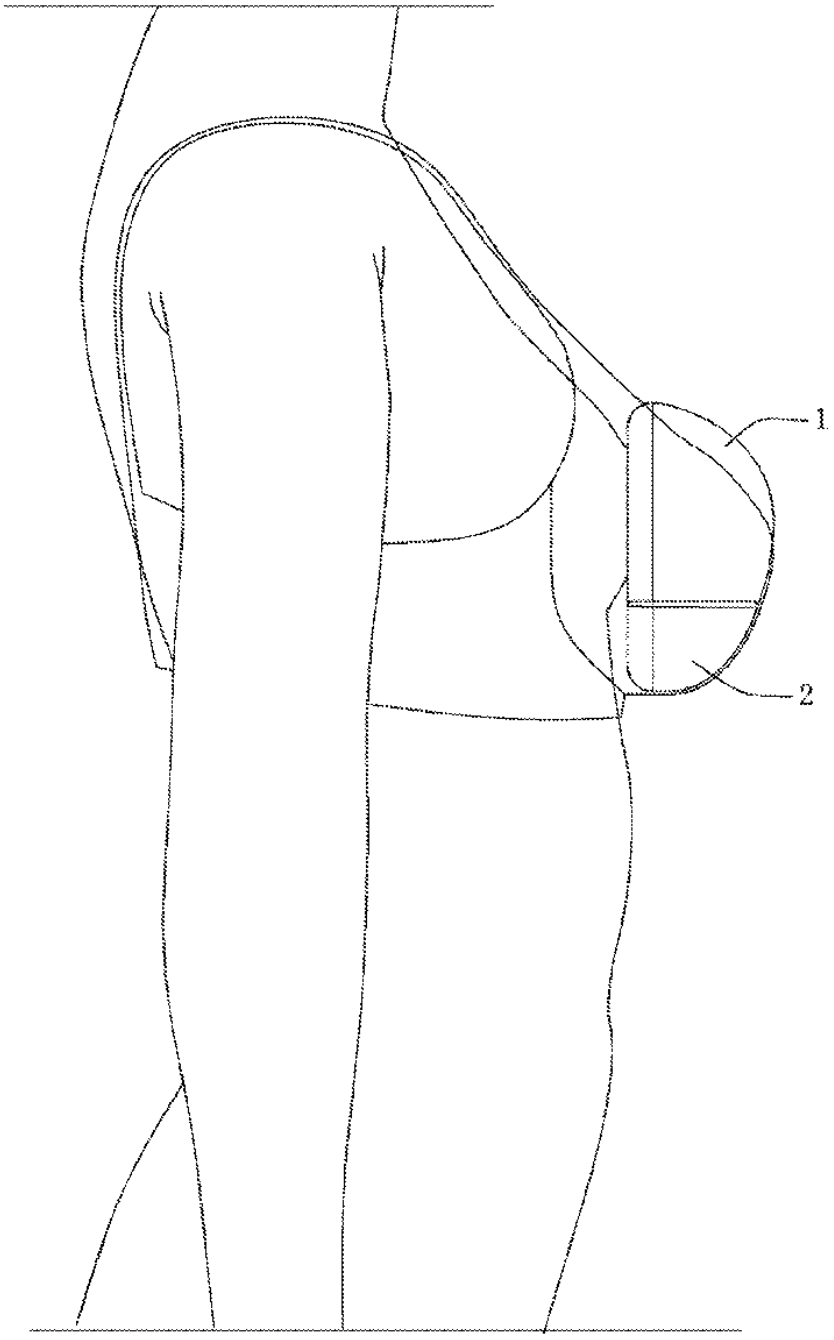


图13

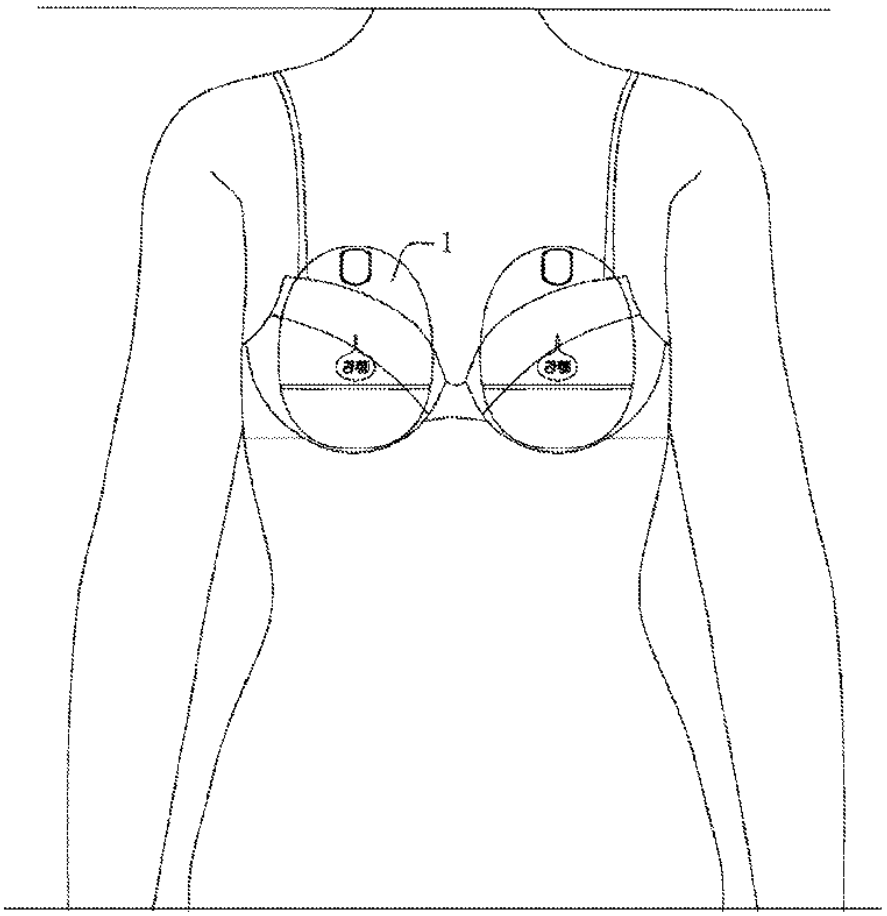


图14

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A61M 1/06(2006.01)

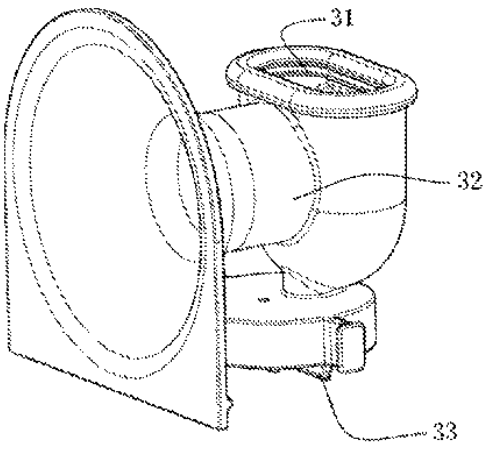
权利要求书1页 说明书5页 附图10页

(54)发明名称

一种隐藏在吸奶器主机内部的集奶装置

(57)摘要

本发明公开了一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。



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1.一种隐藏在吸奶器主机内部的集奶装置，其特征在于：包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

2.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

3.根据权利要求2所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊由液态硅胶材质制成。

4.根据权利要求3所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

5.根据权利要求4所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

6.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

7.根据权利要求6所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

8.根据权利要求7所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀由食品级材质的液态硅胶制成。

9.根据权利要求6～8任一项所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

10.根据权利要求9所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

一种隐藏在吸奶器主机内部的集奶装置

技术领域

[0001] 本发明涉及母婴电器领域，特别涉及一种隐藏在吸奶器主机内部的集奶装置。

背景技术

[0002] 电动吸奶器是供哺乳妈妈产后使用的仪器，是指用于挤(吸)出积聚在乳腺里的母乳的工具。通过内部真空负压泵改变内部气压变化，即循环“吸”“放”去仿效婴儿吸允母乳的动作。

[0003] 就现有的电动吸奶器，主要分为一体式吸奶器和分体式吸奶器，完成免手扶吸奶则需要配合免手扶文胸。使用分体式吸奶器采集母乳时需要将三通和奶瓶悬挂在胸前，用气路软管连接吸奶器主机做吸奶的负压输出，这就存在管线约束以及装配困难的问题；而一体式吸奶器将吸奶器集成于一体，虽然减去了管线的约束，使得装配相对简单，但他们的结构方式和外观体积不利于穿戴和隐藏。

发明内容

[0004] 本发明的目的在于提供一种隐藏在吸奶器主机内部的集奶装置，以解决上述背景技术中提出的问题。

[0005] 为解决上述技术问题所采用的技术方案：一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

[0006] 作为上述方案的改进，所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

[0007] 作为上述方案的改进，所述气囊由液态硅胶材质制成。

[0008] 作为上述方案的改进，在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

[0009] 作为上述方案的改进，所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

[0010] 作为上述方案的改进，所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

[0011] 作为上述方案的改进，所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

[0012] 作为上述方案的改进，所述鸭嘴阀由食品级材质的液态硅胶制成。

[0013] 作为上述方案的改进，所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

[0014] 作为上述方案的改进，所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

[0015] 有益效果：本发明中，集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

附图说明

[0016] 下面结合附图和实施例对本发明做进一步的说明：

[0017] 图1为免手扶隐藏式吸奶器的装配示意图；

[0018] 图2为免手扶隐藏式吸奶器的立体图；

[0019] 图3为图2的左侧视图；

[0020] 图4为吸奶器主机的内部结构示意图；

[0021] 图5为集奶装置的结构示意图；

[0022] 图6为吸奶器的剖面示意图，该图中气囊处于自然状态；

[0023] 图7为吸奶器的剖面示意图，该图中气囊处于负压贴合状态；

[0024] 图8为吸奶器工作时鸭嘴阀中的第一阀门打开的状态示意图；

[0025] 图9为吸奶器工作时鸭嘴阀中的第一阀门关闭的状态示意图；

[0026] 图10为气囊的正视图；

[0027] 图11为图10中A-A剖面示意图；

[0028] 图12为鸭嘴阀的立体结构示意图；

[0029] 图13为哺乳妈妈穿戴上免手扶隐藏式吸奶器的侧视图；

[0030] 图14为哺乳妈妈穿戴上免手扶隐藏式吸奶器的正视图。

具体实施方式

[0031] 参照图1至图3，为本实施例一种免手扶隐藏式吸奶器，该吸奶器由吸奶器主机1、集奶装置3以及储奶瓶2等零部件组成。吸奶器主机1内设置有真空负压装置以及与真空负压装置连接的主控电路板16，主控电路板16连接有设置于吸奶器主机1外表的控制面板11。图2中，控制面板11设置在吸奶器主机1的顶部，一方面可方便哺乳妈妈操作，另一方面也可避免穿戴在文胸内部时控制面板11受到挤压。该控制面板11上设置有吸奶器的开机/关机按键、吸力大小加档操作按键、吸力大小减档操作按键以及催乳和吸奶模式的切换按键，同时还设置有吸力档位提示灯，吸奶器充电状态提示灯等。哺乳妈妈结合实际情况对控制面板11进行操作，发送指令给主控电路板16，主控电路板16控制调节真空负压装置的工作状态。当吸奶器主机1处于充电转态时，充电状态提示灯予以提示。同时，吸奶器主机1内还设置有用于接收移动终端电信号的无线通讯模块18。本实施例中，移动终端为手机，无线通讯模块18用于解析与手机的通讯协议，接收手机发出的电信号，并将电信号发送至主控电路

板16，无线通讯模块18采用蓝牙或WIFI通信模式。手机上的APP程序中显示有多个控制选项，该控制选项基本与控制面板11上的选项相一致，用以实现吸奶器工作状态的调节。同时该APP程序中还可以显示吸力档位状态以及吸奶器的剩余电量等信息。通过移动终端对吸奶器的工作状态进行控制，极大方便了哺乳妈妈在公共场所使用吸奶器，由于该吸奶器为免手扶隐藏式吸奶器，哺乳妈妈可事先穿戴好，当需要吸奶时，只需通过移动终端控制开启即可，方便快捷。

[0032] 如图4所示，该吸奶器主机1内还设置有充放电的锂电池15和充电接口17，使用适配器可对其进行便捷充电。位于吸奶器主机1内的真空负压装置包括真空泵13和泄气阀14，吸奶器主机1的下端部设置有U形腔体12，集奶装置3设置在U形腔体12内，集奶装置3一端与真空负压装置密封连接，另一端与储奶瓶2密封连接，储奶瓶2与吸奶器主机1的下端对接，吸奶器主机1的外侧面设置成第一曲面，储奶瓶2的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面，吸奶器主机1的内侧面和储奶瓶2的内侧面设置成共面。

[0033] 通过在吸奶器主机1的外表设置控制面板11，方便哺乳妈妈控制和调节吸奶器的工作情况。同时，整机高度集成，真空负压装置和集奶装置3均集成安装于吸奶器主机1的内部，结构紧凑，无任何管线约束。并且，结合人体工程学，将吸奶器主机1的外侧面设置成与文胸贴合面匹配第一曲面，将储奶瓶2的外侧面设置成与文胸贴合面匹配第二曲面，第一曲面和第二曲面衔接形成与文胸贴合面匹配的弧形曲面，哺乳妈妈可轻松自然的将吸奶器放入哺乳文胸中：吸奶器主机1的内侧面以及储奶瓶2的内侧面设置成平面状以便与乳房一侧贴合。在布局合理的同时实现了整个吸奶器的体积最小化。该吸奶器整体外形精巧、圆滑，非常适合穿戴和隐藏，满足哺乳妈妈在公共场合实现简单隐蔽且动作优雅得体的吸奶。

[0034] 如图5所示为集奶装置3，该集奶装置3隐藏在吸奶器主机1内部，具体包括三通32、气囊31以及鸭嘴阀33，三通32包括气压端、吸奶端以及流奶端，整个三通32嵌入至吸奶器主机1下端部的U形腔体12内，气囊31设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机1的内侧面指向乳房，吸奶端的抵接面与吸奶器主机1的内侧面平齐，保证吸奶器的内侧面完全平整，增加哺乳妈妈穿戴的舒适度。鸭嘴阀33固定设置在流奶端，流奶端密封连接有储奶瓶2，吸奶器吸出的奶液经鸭嘴阀33流入至储奶瓶2。该储奶瓶2通过瓶口的螺牙螺接于流奶端，方便拆卸清洗。同时，在U形腔体12的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，第一气孔通过软管与真空泵13连通，第二气孔通过软管与泄气阀14连通，气囊31密封连接在气囊盖上，实现气囊31同时与真空泵13以及泄气阀14连通。

[0035] 集奶装置3集成在吸奶器主机1的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置3可将吸奶器主机1与储奶瓶2连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

[0036] 上述气囊31由食品级材质的液态硅胶材质制成，具有较优的弹性和耐疲劳性，其主要用于气压与母乳的隔离。如图10和图11所示，该气囊31呈扁平U形状，气压端设置成与气囊31相一致的扁平U形状。气囊31的宽面正对吸奶端设置，两个宽面之间的厚度较小，有利于减小整个吸奶器薄度，方便哺乳妈妈将吸奶器穿戴与文胸内部。同时，气囊31的两个窄

面之间的距离较大，有利于增加整个气囊31的体积，进而增大整个三通32内的气压差的变大幅度，以便提供充足的压力进行吸奶。气囊盖上设置有变形导向面，变形导向面与气囊31的两个窄面对应设置，变形导向面引导气囊31在真空负压下偏离于乳房贴合形成扁平状。如图7所示，当气囊31受负压贴合呈扁平状时，气囊31整体偏离于乳房，进而增加了乳房与气囊31之间的间隙，方便乳液从三通32内顺畅的流入至流奶端。变形导向面具体可设置成与气囊31表面贴合的折面，折面的对折处呈竖向偏离于气囊31设置，进而实现整个气囊31的偏离导向。

[0037] 图6和图7分别示出了吸奶器工作时气囊31的两种状态。图6中，气囊31处于自然状态，此时泄气阀14处于打开状态，气囊31与大气压相通，三通32内未形成负压，整个吸奶器处于“放”的状态，该状态主要是为了方便奶液顺利的流入至储奶瓶2中；图7中，气囊31处于负压贴合状态，此时泄气阀14处于关闭状态，气囊31仅与真空泵13连通且被完全抽真空，三通32内由于气囊31体积的缩小而形成负压，整个吸奶器处于“吸”的状态，实现乳房内乳液的吸出。

[0038] 鸭嘴阀33设置于流奶端，具有防逆流的作用。如图12所示，鸭嘴阀33上设置有第一阀门331和第二阀门332，第一阀门331包括位于其两侧部的呈弧形状的第一变形壁3311，两个第一变形壁3311由上至下逐渐靠拢且在末端形成细长状的第一切口3312，第一阀门331连通流奶端和储奶瓶2；第二阀门332包括位于其两侧部的呈弧形状的第二变形壁3321，两个第二变形壁3321由上至下逐渐靠拢且在末端形成细长状的第二切口3322，第二阀门332连通外界大气压和储奶瓶2。该鸭嘴阀33由食品级材质的液态硅胶制成，其有较优的密封性、抗撕裂强度、回弹性、抗变黄性、热稳定性、耐热老化性以及耐压缩变形的特点。第一变形壁3311和第二变形壁3321的壁厚为0.4~0.6mm，变形壁设计的面积大而薄，保证易回弹且受力易变形。

[0039] 通过第一变形壁3311和第二变形壁3321的变形可轻松实现第一切口3312和第二切口3322的打开和关闭状态的切换。其中，第二阀门332与外界大气压连通，第二变形壁3321并未受到负压的挤压，因此处于常开状态，进而使得储奶瓶2维持透气状态，奶液可以不断地经第一切口3312流入至储奶瓶2；而第一阀门331跟随真空负压与常压之间的切换而打开或关闭。当三通32解除负压时，第一切口3312打开，奶液立即流入至储奶瓶2。当储奶瓶2发生晃动时，奶液从外侧挤压第一变形壁3311和第二变形壁3321，进而使得第一切口3312和第二切口3322关闭，奶液无法从储奶瓶2中流出，有效了防止了奶液的外漏和逆流。

[0040] 作为优选，第一阀门331和第二阀门332共同连接在密封垫333上，第一切口3312和第二切口3322均指向储奶瓶2的内腔，密封垫333的周边与储奶瓶2的端口密封贴合。当储奶瓶2螺纹连接在流奶端时，储奶瓶2的端口紧抵在密封垫333的下侧面，同时，螺接的方式可提供压力使得密封垫333的上侧面与流奶端紧贴，有效保证了流奶端与储奶瓶2之间的密封连接。同时，密封垫333的中部形成相互隔开的第一气压腔和第二气压腔，流奶端分别形成有插入至第一气压腔的第一连接部以及插入至第二气压腔的第二连接部，第一阀门331设置在第一气压腔的下端，第二阀门332设置在第二气压腔的下端，第一气压腔与流奶端相通，第二气压腔与外界大气压相通。第一气压腔和第一连接部过盈配合连接，第二气压腔与第二连接部过盈配合连接，可避免因第一阀门331和第二阀门332上端部变形过大而导致的阀门失效。

[0041] 图8和图9分别示出了吸奶器工作时鸭嘴阀33中的第一阀门331的状态示意图。图8中，气囊31处于自然状态，三通32内为常压，第一切口3312自然处于打开状态，汇集在流奶端的奶液经第一阀门331流入至储奶瓶2；图9中，气囊31处于负压贴合状态，三通32内为负压，第一切口3312在负压的挤压下处于闭合状态，吸出来的奶液汇入至流奶端且停留在第一阀门331前端。

[0042] 图13和图14均为哺乳妈妈穿戴上免手扶隐藏式吸奶器的效果示意图，该免手扶隐藏式吸奶器的确能很好的隐藏于文胸内，大大方便了哺乳妈妈在公共场所随意的吸奶。

[0043] 上面结合附图对本发明的实施方式作了详细说明，但是本发明不限于上述实施方式，在所述技术领域普通技术人员所具备的知识范围内，还可以在不脱离本发明宗旨的前提下作出各种变化。

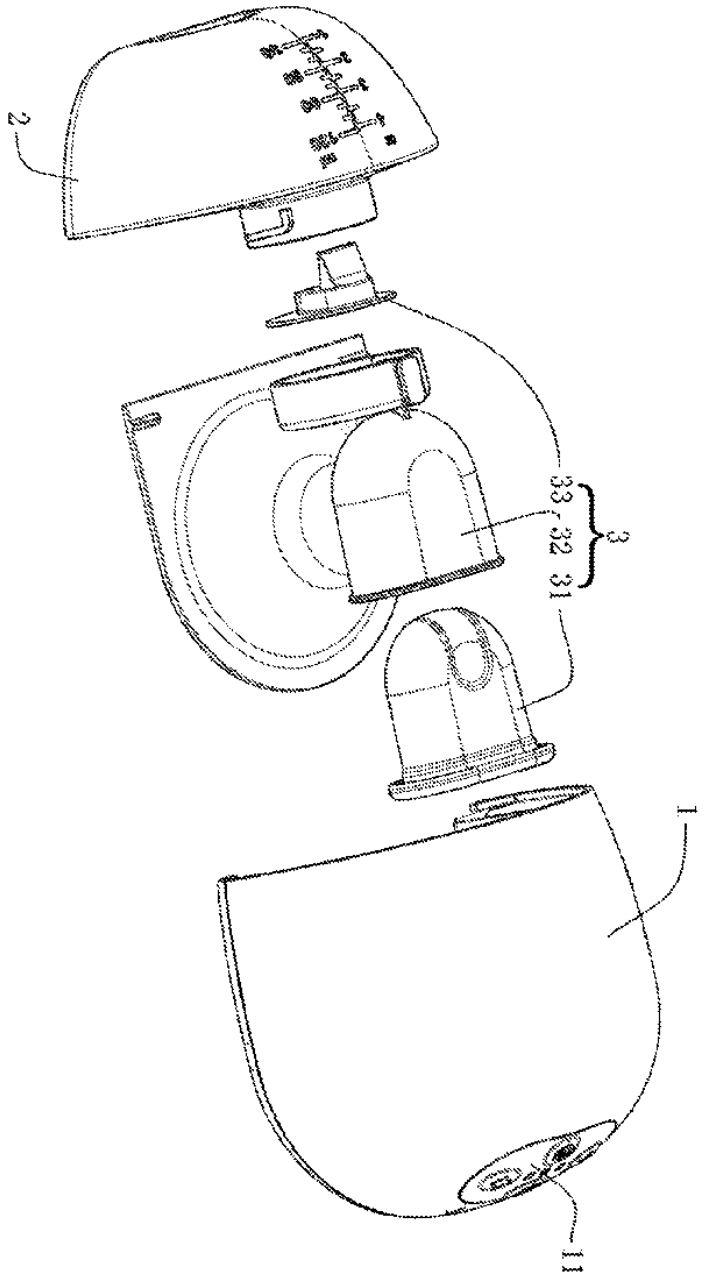


图1

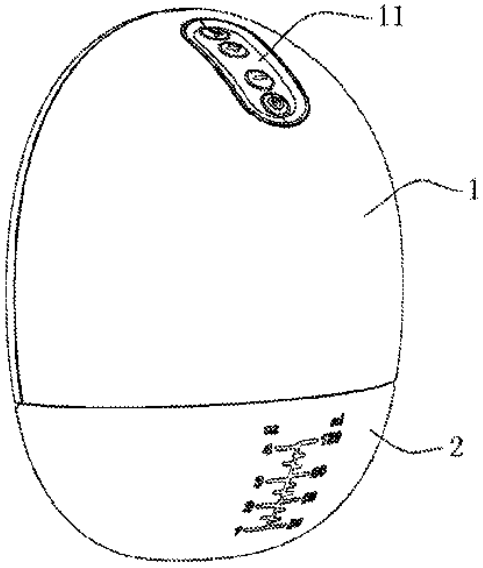


图2

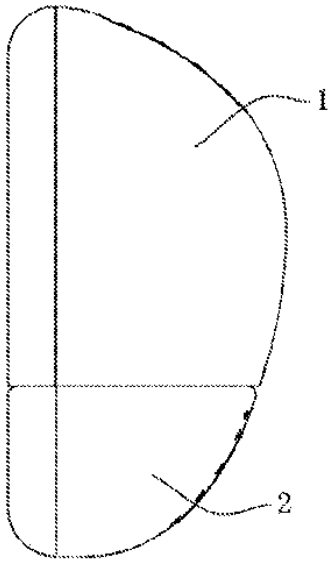


图3

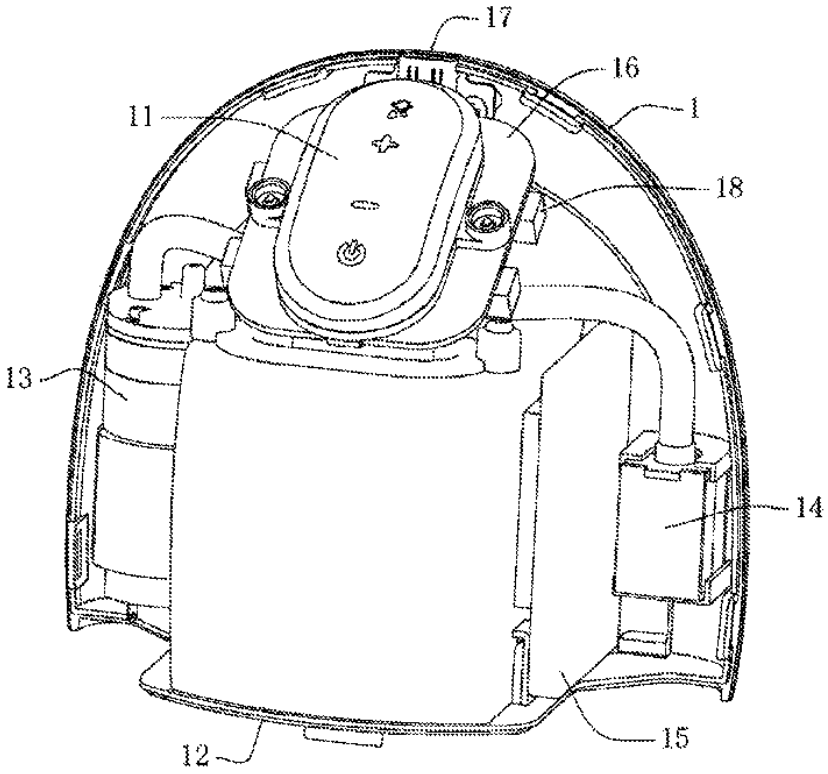


图4

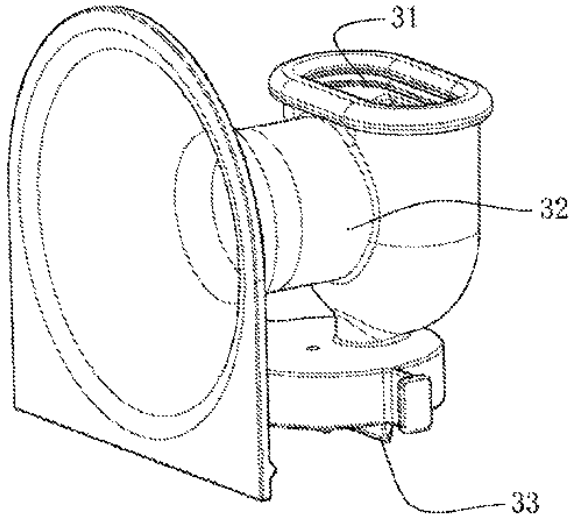


图5

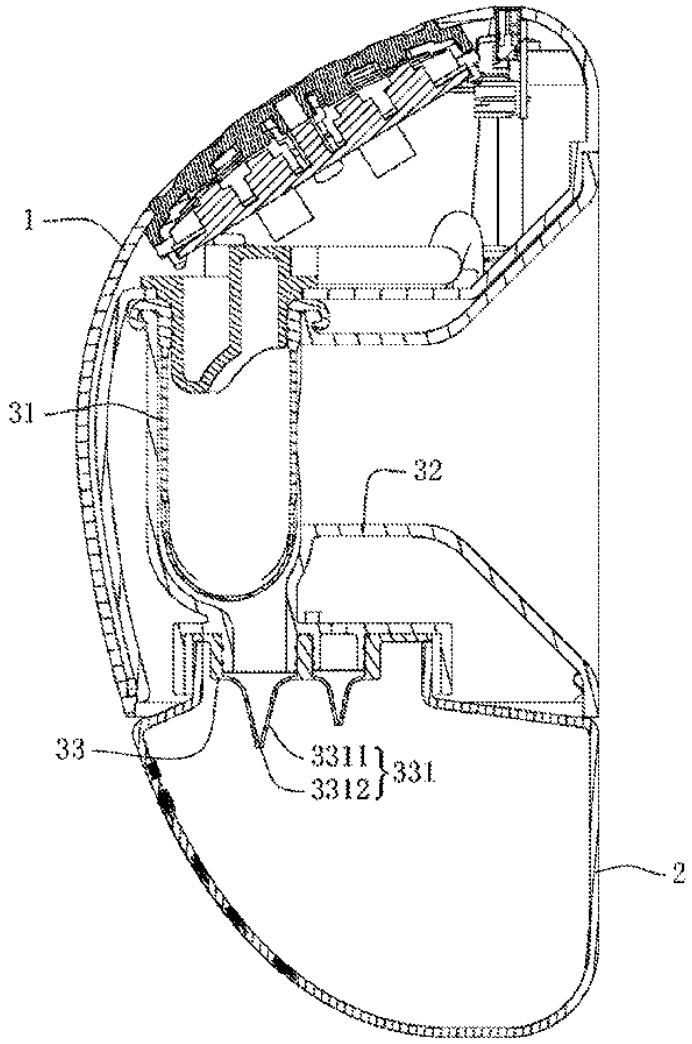


图6

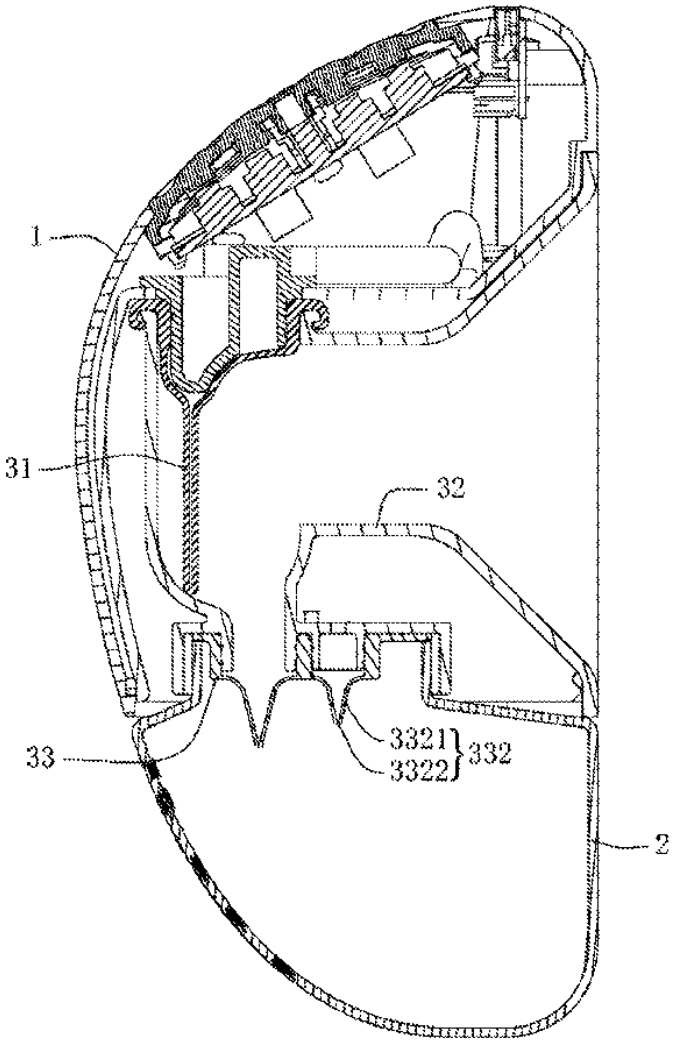


图7

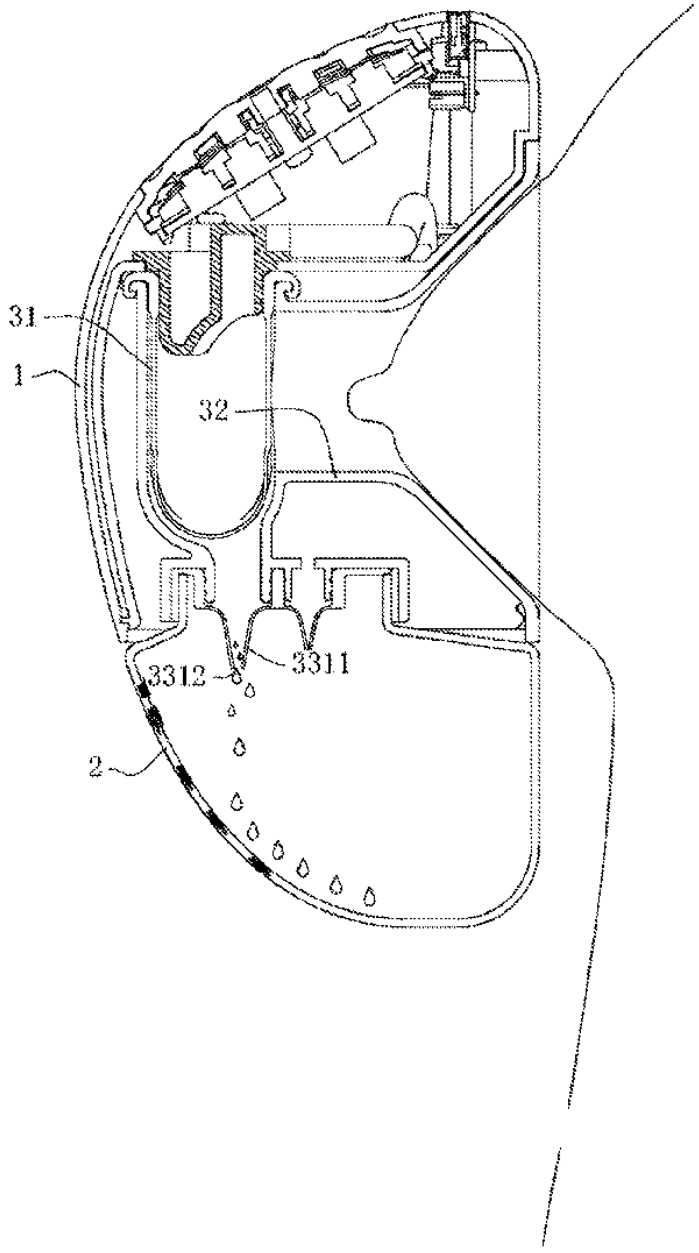


图8

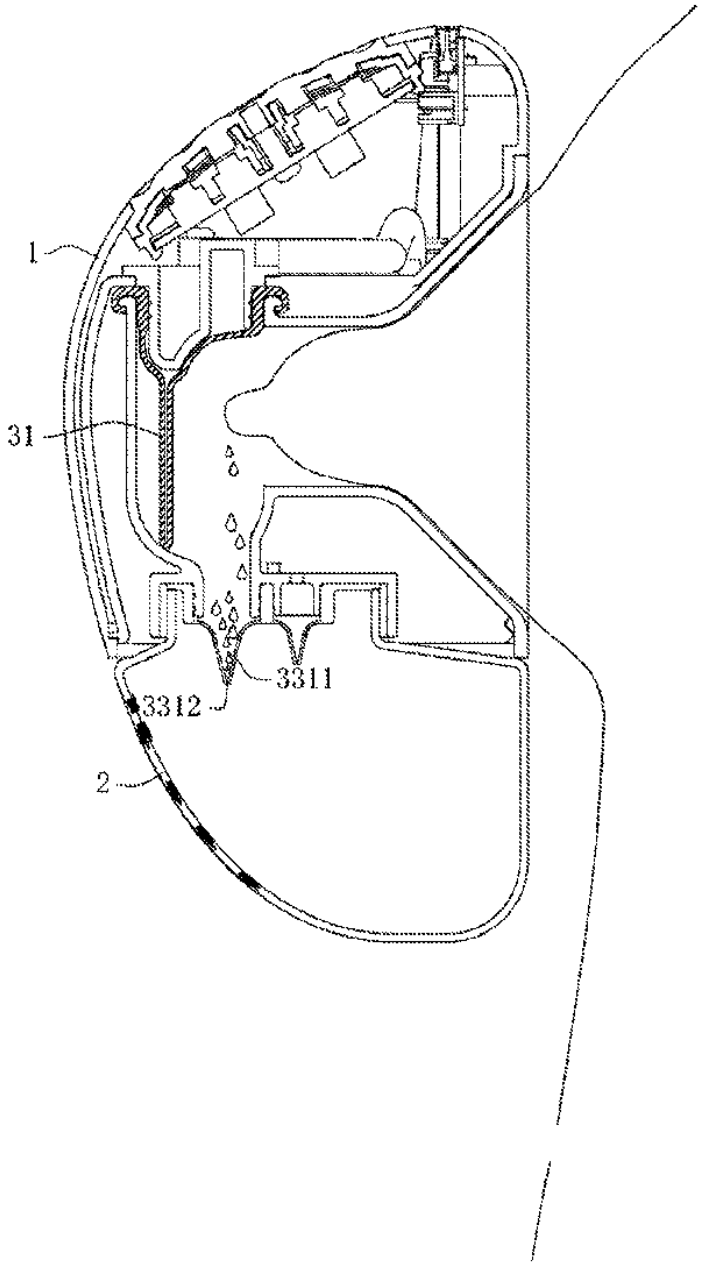


图9

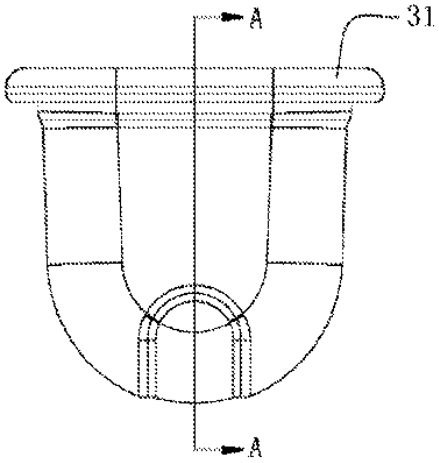


图10

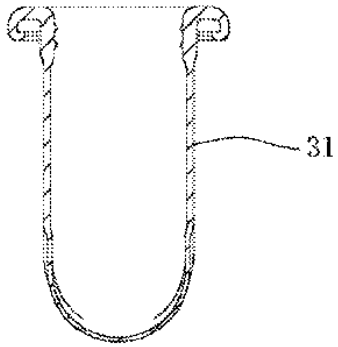


图11

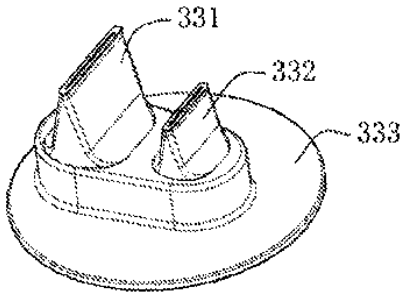


图12

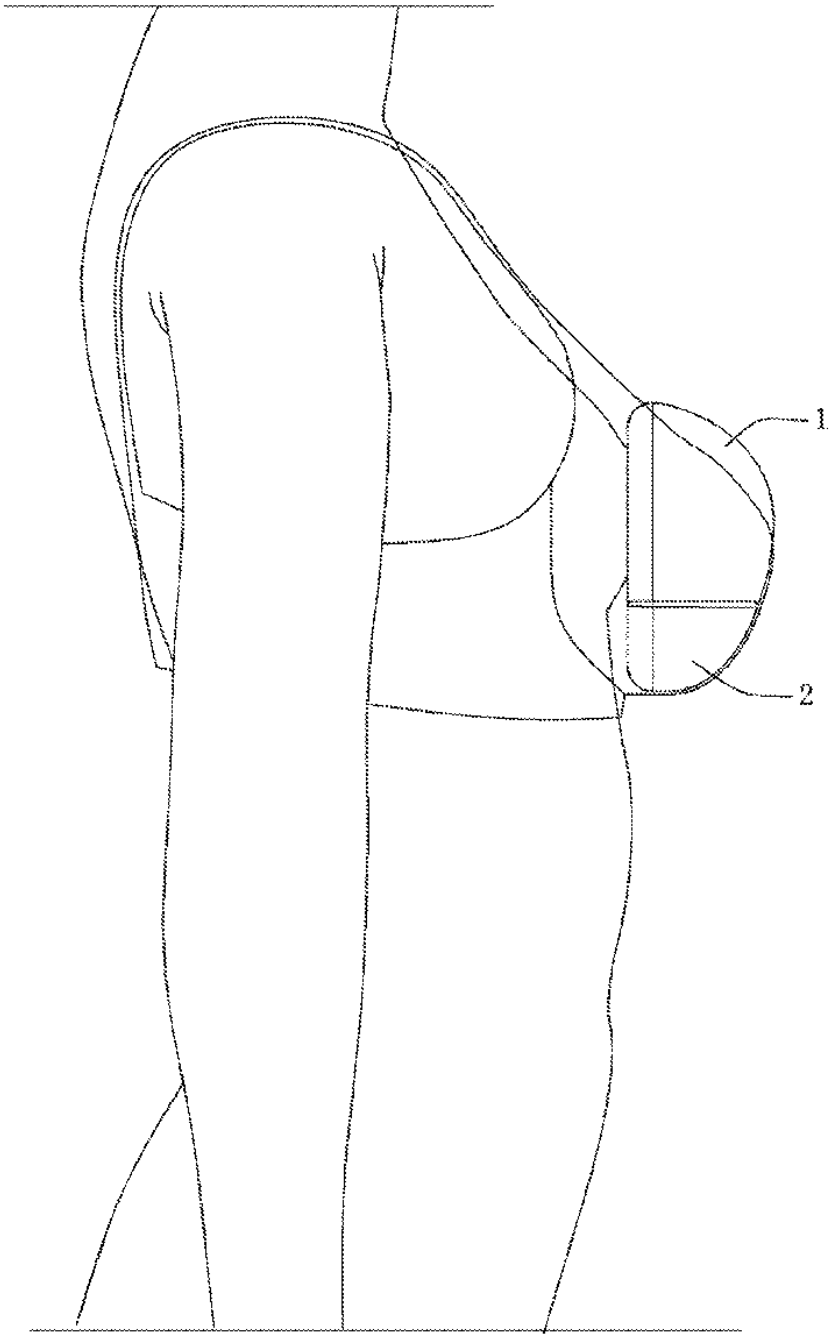


图13

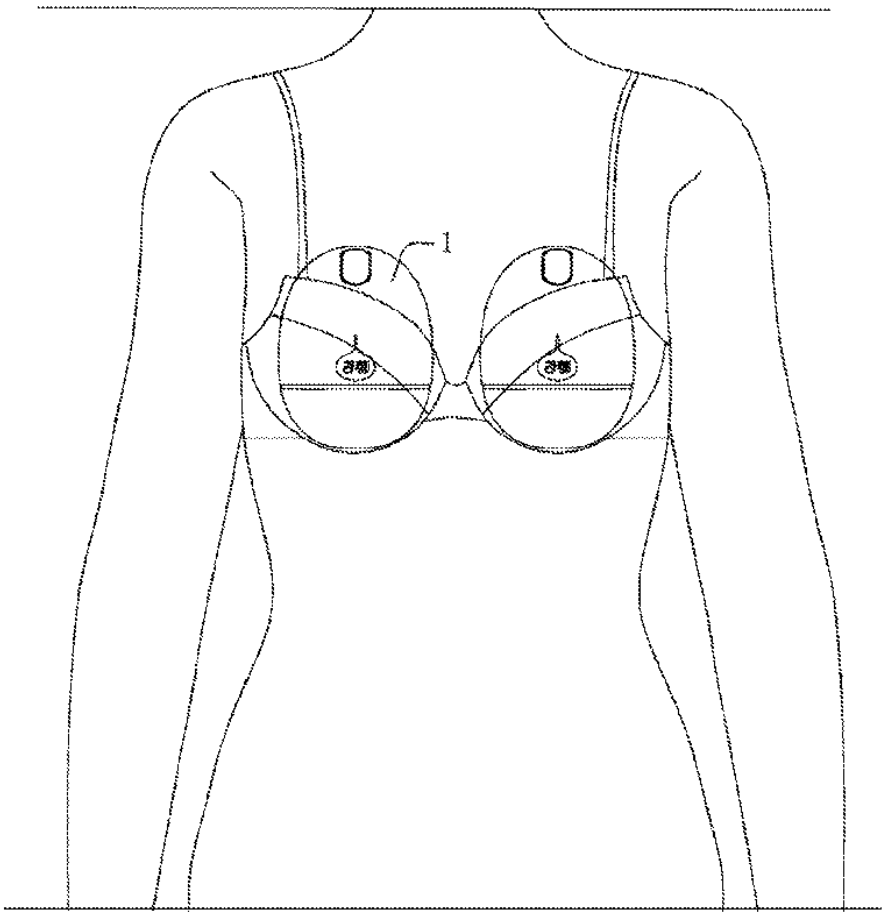


图14

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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):

  Copies of FP1-FP4.

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	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	March 26, 2024	Reg. No.	800,005

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/26/2024 05:04:13 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	64835546	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-03-26-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	167 KB
2024-03-26-sIDS-Pleading-4944-0120006.pdf	3	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-03-26-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	110 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_CN109621041A.pdf	41	Foreign Reference	855 KB
FOR_2_JP2016508804A.pdf	26	Foreign Reference	899 KB
FOR_3_WO9625187A1.pdf	29	Foreign Reference	635 KB

FOR_4_WO2018229504A1.pdf	198	Foreign Reference	2923 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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/30 (11-17)
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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

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. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. 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).

   a. ☑ 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.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☑ Other Amendment and Reply Under 37 C.F.R. § 1.116 filed on February 12, 2024.

   b. ☐ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☐ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ 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)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 19-0036.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

   d. ■ Payment by EFS-Web

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Yangbeini Wang #800,005/	Date	March 6, 2024
Name (Print/Type)	Yangbeini Wang	Registration No.	800,005

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Name (Print/Type)		Date	

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

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):
  Request for Continued Examination Transmittal (PTO/SB/30EFS)

Remarks

Online Credit Card Authorization for $2,420.00 to cover:

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	March 6, 2024	Reg. No.	800,005

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Typed or printed name		Date	

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/07/2024 06:43:16 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Kim Perry
PATENT CENTER #	64597343	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-03-07-EOT-4944-0120006.pdf	1	Extension of Time	238 KB
2024-03-07-Transmittal-Form-4944-0120006.pdf	1	Transmittal Letter	201 KB
2024-03-07-RCE-4944-0120006.pdf	1	Request for Continued Examination (RCE)	265 KB

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DOCUMENT	MESSAGE DIGEST(SHA-512)

2024-03-07-EOT-4944-0120006.pdf	6E0D3E9467891B0D673F8340A43625DA0FF54B3566AD15D5CD2D40AF73F53D7E774A95225B555D5A3E11C6C196AF2132BCA043740CCB42A80F31B18E98B13F69
2024-03-07-Transmittal-Form-4944-0120006.pdf	71FA5FE161B3FA7044FF914B88ABB74D7FE5E6E40C7F8F0BECE5F63FFDB477860BD9929E336A78A8C4101DDF1B032BC51F9F2FA6021B075CB68CE037631CE1FA
2024-03-07-RCE-4944-0120006.pdf	13EECAACB12EEF6F4DDF0E0230CE9C2BDC78670096174BC523B050AC50B6ACBCA158FB9E8825386E5A6D7C9F7B18BE36B76D3A6D9099EDFA00767D418473CAC3

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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/AIA/22 (12-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 4944.0120006
Application Number 17/181,057	Filed 02/22/2021
For BREAST PUMP SYSTEM	
Art Unit 3783	Examiner FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$220	$88	$44	$
☑	Two months (37 CFR 1.17(a)(2))	$640	$256	$128	$ 420
☐	Three months (37 CFR 1.17(a)(3))	$1,480	$592	$296	$
☐	Four months (37 CFR 1.17(a)(4))	$2,320	$928	$464	$
☐	Five months (37 CFR 1.17(a)(5))	$3,160	$1,264	$632	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via USPTO's patent electronic filing system (Patent Center or EFS-Web).

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I am the

☐ applicant.

☑ attorney or agent of record. Registration number 800,005.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Yangbeini Wang #800,005/	March 6, 2024
Signature	Date
Yangbeini Wang	(202) 371-2600
Typed or printed name	Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/07/2024 06:43:16 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Kim Perry
PATENT CENTER #	64597343	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 3007	**E202437I46249254**	**Kim Perry**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1252	EXTENSION FOR RESPONSE WITHIN SECOND MONTH	420.00	1	420.00
1820	REQUEST FOR CONTINUED EXAMINATION (RCE)- 2ND AND SUBSEQUENT REQUEST (SEE 37 CFR 1.114)	2000.00	1	2000.00
			TOTAL AMOUNT:	**$2,420.00**

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 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

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
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	177963

The entity status change request below filed through Patent Center on 03/07/2024 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/	Yangbeini Wang	800005

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 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/07/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

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

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

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

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

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.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 02/22/2024
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
02/22/2024	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):

e-office@sternekessler.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/181,057	**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 --

THE REPLY FILED 12 February 2024 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☑ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a)☑ will not be entered, or (b)☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Further search and consideration of the proposed amendments is required..
13. ☑ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: PTO-2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1,3-22,24-25 and 28-34.
    Claim(s) withdrawn from consideration:_____.

/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	

Continuation of 3. NOTE: The amendment presents limitations which were not previously considered and which change the scope of the claim. Further time in excess of that allowed under the AFCP pilot is required to determine if the amendments would place the application in condition for allowance.

AFCP 2.0 Decision

Application No.	Applicant(s)	
17/181,057	O'TOOLE et al.	
Examiner	**Art Unit**	**AIA (FITF) Status**
COURTNEY FREDRICKSON	3783	Yes

This is in response to the After Final Consideration Pilot request filed 12 February 2024.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☑ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

DO NOT ENTER: /C.B.F./

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Commissioner:

In reply to the Office Action dated **October 12, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2001/0044593 A1	11-22-2001	Lundy	
	US2	2009/0254028 A1	10-08-2009	Brittner	
	US3	2011/0144636 A1	06-16-2011	Alexander et al.	
	US4	2018/0154055 A1	06-07-2018	Alvarez et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	02/13/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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.

☒ 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	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-12-01
Name/Print	Yangbeini Wang	Registration Number	800,005

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 CFR1.14. 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./

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**02/12/2024 03:25:37 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	64286342	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 6

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-02-12-Request-AFCP-4944-0120006.pdf		2	After Final Consideration Program Request	203 KB
2024-02-12-Amendment-Reply-116-4944-0120006.pdf		12	-	251 KB
2024-02-12-Amendment-Reply-116-4944-0120006-A.NE.pdf	(1-1)	1	Response After Final Action	103 KB
2024-02-12-Amendment-Reply-116-4944-0120006-CLM.pdf	(2-6)	5	Claims	81 KB
2024-02-12-Amendment-Reply-116-4944-0120006-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	238 KB

2024-02-12-Transmittal-Form-4944-0120006.pdf	1	Transmittal Letter	165 KB
2024-02-12-EOT-4944-0120006.pdf	1	Extension of Time	222 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-02-12-Request-AFCP-4944-0120006.pdf	D77CA6632710E4D6C4BAF96E4B201FAC9201A7D1BE5590172 2C548EEF7A44E5172F2D0FE4119268BC23B63E881F232D6AD BF4A699B2ABC562256C0B4F78166AA
2024-02-12-Amendment-Reply-116-4944-0120006.pdf	B09A28F30EB9A77EFA69CF59FB44EDD922F5AFF0CBEDE407 A70E079F30AEE862A51619DF0FB80CB44E30AB75569714838 161B69A1EFABEF15894948F9A27C617
2024-02-12-Amendment-Reply-116-4944-0120006-A.NE.pdf	070F37E929CC4DFF45941210EA75A73FADAFE7276D8B04405 F79C0C39C891179FCB9D1407AB2F7FC60847E6E71D175A37C 7948158496814522OC4092118DCA04
2024-02-12-Amendment-Reply-116-4944-0120006-CLM.pdf	B943BE66F8AF7575B65011C291E486878F2BA405D8A95E22D C634B2A29DFE9AD158D35758F0BF3EEA81A562F7C5A8262B E64D8614699EF718F15FD0B298F9BD0
2024-02-12-Amendment-Reply-116-4944-0120006-REM.pdf	665A9D00775416E60C833D1A33427B539C8254CAF5D10CB09 A1584CF671BD05C3F786EB319DEFD4C9ECB3467B231587EC D2EDAF4E3DCC4FF54899D5DEF9D48A5
2024-02-12-Transmittal-Form-4944-0120006.pdf	04D1C32F382AFC6E1027203CD46D140DE1330FE8BC00286F5 7CD649A04C778E8955050E34A41586A708A4702B91CF9A60E 582D2CE35C66073C2836955659D064
2024-02-12-EOT-4944-0120006.pdf	29E841F0CC6976E66FDD602A587CDC7827CDA5FB3E3C357D 81FB68E3E9BC561EB1D24911DC40F63F15F39A9E37313A496 8EE4924C54B24C7E2D159BF5B7A30CC

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New Applications Under 35 U.S.C. 111

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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/AIA/22 (12-22)
Approved for use through 05/31/2024. OMB 0651-0031
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 4944.0120006

Application Number: 17/181,057

Filed: 02/22/2021

For: BREAST PUMP SYSTEM

Art Unit: 3783

Examiner: FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$220	$88	$44	$ 220
☐ Two months (37 CFR 1.17(a)(2))	$640	$256	$128	$
☐ Three months (37 CFR 1.17(a)(3))	$1,480	$592	$296	$
☐ Four months (37 CFR 1.17(a)(4))	$2,320	$928	$464	$
☐ Five months (37 CFR 1.17(a)(5))	$3,160	$1,264	$632	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via USPTO's patent electronic filing system (Patent Center or EFS-Web).

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I am the

☐ applicant.

☑ attorney or agent of record. Registration number 800,005.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Yangbeini Wang #800,005/ — Signature

February 8, 2024 — Date

Yangbeini Wang — Typed or printed name

(202) 371-2600 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** If filing this completed form by mail, send to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

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):

Certification and Request for Consideration Under the After Final Consideration Pilot Program 2.0

Remarks

Online Credit Card Authorization for $220.00 to cover the 1 Month Extension of Time Fee.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any over payment, to our Deposit Account No. 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	February 8, 2024	Reg. No.	800,005

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 and 1.14. 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.**

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PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**02/12/2024 03:25:37 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	64286342	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1005	**E20242BF27016926**	**Rolonda Lee**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1251	EXTENSION FOR RESPONSE WITHIN FIRST MONTH	220.00	1	220.00
			TOTAL AMOUNT:	**$220.00**

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 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.

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Commissioner:

In reply to the Office Action dated **October 12, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A breast pump device comprising:

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and ~~fit lines~~ guide lines, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the ~~fit lines~~ guide lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved and to visually define a correct spacing of the nipple from the side wall of the nipple tunnel.

2. (Canceled)

3. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously Presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously Presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously Presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently Amended) The breast pump device of claim 1, wherein the ~~fit lines~~ guide lines are configured to run parallel along one or more sides of the nipple tunnel.

17. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously Presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously Presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously Presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously Presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously Presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously Presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously Presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Currently Amended) The kit of claim 31, wherein the ~~fit lines~~ guide lines are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously Presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Previously Presented) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 3–22, 24, 25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 16, and 32 are amended. These changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider all outstanding rejections and that they be withdrawn.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that claim 28 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. Office Action 37. Upon entry of above amendment and based on the following remarks, Applicant respectfully submits that all pending claims are in condition for allowance.

Rejections under 35 U.S.C. § 103

Independent claim 1

Claims 1, 3, 6–8, 10, 11, 14, 16–18, 22, 24, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Applicant No. 2008/0275386 to Myers, in view of EP 2502640 to Cook et al., and in further view of U.S. Patent Applicant Publication No. 2002/0198489 to Silver et al.

Claims 1, 6–10, 14, 17, 18, 20, 22, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent Applicant Publication No. 2013/0023821 to Khalil et al. in view of Myers, in view of Cook, and further in view of Silver.

Without agreeing to the propriety of the rejections, claim 1 is amended and now recites, "wherein the guide lines are configured to be aligned with the outside of the nipple when a correct

nipple alignment is achieved and to visually define a correct spacing of the nipple from the side wall of the nipple tunnel." The applied references do not teach or suggest at least this feature of claim 1.

The Office acknowledges that Myers, Cook, and Khalil do not teach that the nipple tunnel comprises a guide line configured to define the spacing of the nipple from the side wall of the nipple tunnel, and only relies on Sliver for this feature. Office Action, 6–8 and 11–13.

Silver discloses a breastshield 1095 formed with a skeletal frame, and the skeletal frame comprises a series of stiffening longitudinally extending ribs 1160, 1164, and 1166, which allegedly correspond to the recited guide lines. Silver, FIG. 28; Office Action, 8. However, Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel.

The Office in response contends that the ribs of Silver is configured to define a corrected space of the nipple from the side of the nipple tunnel because if a user *feels* the ribs against the breast/nipple, it signals that the breast shield is improperly sized. Office Action, 3. The ribs of Silver, however, does not *visually* define a correct spacing of the nipple from the side wall of the nipple tunnel, as recited in amended claim 1.

In addition, claim 1 recites, "a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size." The person of skill in the art would have understood that on breast shields of different sizes, the guide lines that visually define a correct spacing of the nipple from the side wall of the nipple tunnel would be positioned differently, as shown in FIG. 14 of the present application (reproduced below). In contrast, the ribs of Silver, as the skeletal frame for structural support, would not be positioned differently on differently sized breast shields. Indeed, Silver does not discloses a plurality of interchangeable breast shields having different sizes, so Silver does not provide the motivation to position the ribs on different locations as a visual signal reflecting differently sized breast shields.

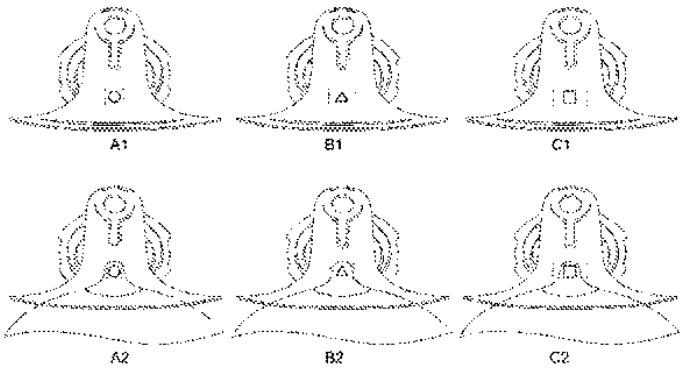


FIGURE 14

FIG. 14 of Present Application

Accordingly, amended claim 1 and its dependent claims would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1, 3, 6–10, 11, 14, 16–18, 20, 22, 24, 31, 32, and 34.

Dependent claims

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Myers in view of Cook in view of Silver and further in view of U.S. Patent Application Publication No. 2005/0228342 to Yuen.

Claim 5 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2018/0333523 to Chang et al.

Claims 12 and 13 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2016/0296682 to Phillips et al.

Claim 15 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver as applied and in further view of U.S. Patent Applicant Publication No. 2007/0228059 to Karsan.

Claim 19 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2012/0277636 to Blondheim et al.

Claims 20 and 21 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2014/0378895 to Barak.

Claim 25 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2016/0220743 to Guthrie et al.

Claim 29 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent No. 6,227,936 to Mendoza.

Claim 30 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2009/0281485 to Baker et al.

Claim 33 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver as applied and further in view of U.S. Patent No. 5,542,921 to Meyers ("Meyers '921").

Each of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 depends from and adds features to independent claim 1. The additionally applied references do not overcome the deficiencies of Myers, Cook, Silver, and Khalil as discussed above. Accordingly, claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33.

Double Patenting Rejection

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver.

- U.S. Applicant No. 17/203050 (U.S. Patent No. 11357893)
- U.S. Applicant No. 17/203079 (U.S. Patent No. 11376352)
- U.S. Applicant No. 17/203216 (U.S. Patent No. 11357894)
- U.S. Applicant No. 17/203259 (U.S. Patent No. 11324866)
- U.S. Applicant No. 17/203327 (U.S. Patent No. 11413380)

Claims 1, 3–22, 24, 25, and 28–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers and Cook, and Silver.

- U.S. Applicant No. 17/203109 (U.S. Patent No. 11260151)
- U.S. Applicant No. 17/203313 (U.S. Patent No. 11311654)

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 34–38.

- U.S. Applicant No. 17/203150
- U.S. Applicant No. 17/203179
- U.S. Applicant No. 17/203292
- U.S. Applicant No. 17/203355
- U.S. Applicant No. 17/203384
- U.S. Applicant No. 17/203397
- U.S. Applicant No. 17/203418

Applicant respectfully requests that the currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: February 8, 2024

1101 K Street NW, 10th Floor
Washington, D.C. 20005
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21115358.1

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
4944.0120006	17/181,057	02/22/2021
First Named Inventor:	**Title:**	
Jonathan O'TOOLE	BREAST PUMP SYSTEM	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) (a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)), or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. (There is no additional fee required to request consideration under AFCP 2.0.)
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Yangbeini Wang #800,005/	February 8, 2024
Name (Print/Typed) Yangbeini Wang	**Practitioner Registration No.** 800,005

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, see below.*

☐ * Total of ..... 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/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 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	02/12/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	PROGRAM SUPPORT SPECIALIST
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/FIKIRTE A GEREMEW/
*** 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.

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

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Commissioner:

In reply to the Office Action dated **October 12, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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.

Online Credit Card Payment Authorization in the Amount of $104.00 to Cover:
$104.00 - Information Disclosure Statement fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	December 1, 2023	Reg. No.	800,005

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.**

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UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**12/01/2023 03:27:11 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	63458258	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-12-01-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-12-01-sIDS-Pleading-4944-0120006.pdf	3	Transmittal Letter	98 KB
2023-12-01-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	146 KB

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-12-01-Transmittal-Form-sIDS-4944-0120006.pdf	42A213C30FDFC9CBAFB29ED3858F85EC0E4F8E03DB5F0B3B17526420960D0A10E35622FF1E94CCB48AF49461E1D59C957E5C1953F97A9A4A89F13088B96B97A2
2023-12-01-sIDS-Pleading-4944-0120006.pdf	DCBDAB7C8ABD72459EF6C4E63D1912880F3406BDEFED2DCDFE1C9698398A195661574BA2246B9AF3C9CBB38C89556F7455A4BDE36E527DEA63DF43123B48CE9D
2023-12-01-sIDS-Form-SB08-4944-0120006.pdf	1023928D0A85853F6ABAFCC5D3BED061D344D45646182E7BA0289541BC2BD007BAA366ACA822A5DDA55AD186186C18424C13C4D5A8D95D1385819AB3859814AF

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 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

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

> I hereby state that no item of information in this 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 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: December 1, 2023

1101 K Street, NW
10th Floor
Washington, D.C. 20005
Main: 202-371-2600
Direct: 202-772-8833

21279079.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2001/0044593 A1	11-22-2001	Lundy	
	US2	2009/0254028 A1	10-08-2009	Brittner	
	US3	2011/0144636 A1	06-16-2011	Alexander et al.	
	US4	2018/0154055 A1	06-07-2018	Alvarez et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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.

☒ 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	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-12-01
Name/Print	Yangbeini Wang	Registration Number	800,005

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 CFR1.14. 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.**

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	12/01/2023 03:27:11 PM Z ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	63458258	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1008	E2023B1F28228758	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	$104.00

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
10/12/2023	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):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	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 30June2023.

☐ 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) 1,3-22,24-25 and 28-34 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) 1,3-22,24-25 and 28-34 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 22February2021 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 June 30, 2023. As directed by the amendment: claims 1, 16, and 32 have been amended. Thus, claims 1, 3-22, 24, 25, and 238-34 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 March 30, 2023.

Response to Arguments

Applicant's arguments filed June 30, 2023 have been fully considered but they are not persuasive.

Applicant argues on pg. 8 of the Remarks that "*Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel or assist with correct nipple alignment. Furthermore, Silver does not disclose that ribs 1160, 1164, and 1166 are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved*". The examiner respectfully disagrees and notes that the claim is not directed towards guide lines which define a correct spacing of the nipple from the side of the nipple tunnel. The claims are merely drawn to fit lines which are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved. The examiner further notes that "correct nipple alignment" is

also not further defined. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the case of Silver, the longitudinal ribs (1160, 1164, and 1166 in fig. 28) are capable of being positioned so that the ribs are alongside the outside of the nipple when the shield is fitted onto a breast when the nipple is "correctly" aligned with this correct alignment being the nipple received in the nipple tunnel. Additionally, the ribs of Silver are fully configured to define a correct spacing of the nipple from the side of the nipple tunnel and to signify to a user that the shield is sized for a nipple of the user. As seen in fig. 28, the ribs are shown to be positioned interior to the shield (see dotted lines in fig. 28). A user would be able to see (Myers discloses the shield is transparent, paragraph 65) and feel the ribs to ascertain if the shield is too small. For example, if a user feels the ribs against the breast/nipple, this could signal to a user that the shield is improperly sized for their nipples. For this reason, the rejection is maintained.

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 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.

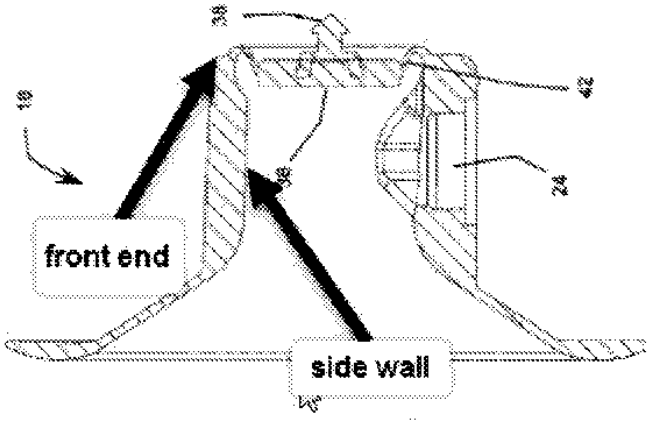
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640) and in further view of Silver (US 20020198489).

Regarding claim 1, Myers discloses a breast pump device comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

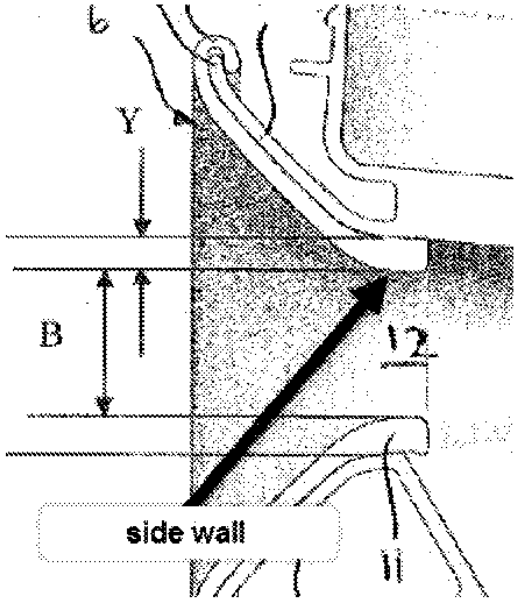


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each of the plurality of interchangeable breast shields having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises fit lines, wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different

wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved

(longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Silver discloses the fit lines are configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1166 and 1164 are longitudinal lines).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches the fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1164 and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple, see response to arguments above).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is

a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

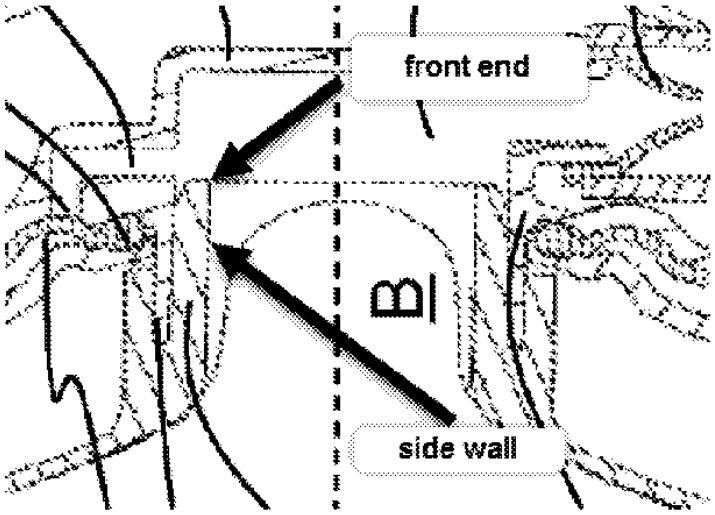
Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 6-10, 14, 17-18, 20-22, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook and in further view of Silver.

Regarding claim 1, Khalil discloses a breast pump device comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



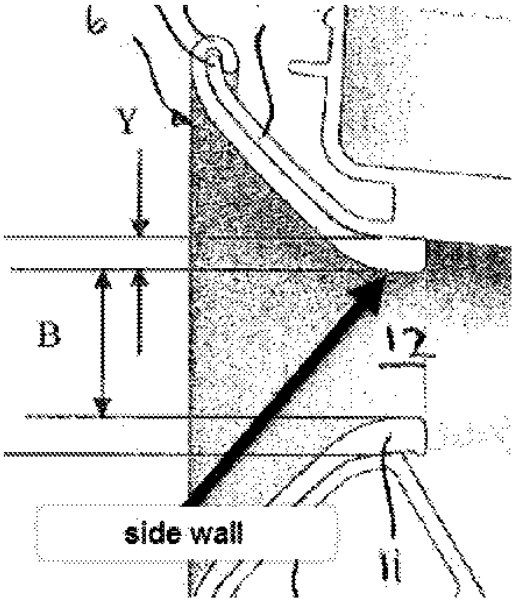
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises fit lines, wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill

before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



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 shield to be of a plurality

of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 16, in the modified device of Khalil, Silver discloses the fit lines are configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1166 and 1164 are longitudinal lines).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which

expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches the fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1164 and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple, see response to arguments above).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be

made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a

corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a

piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a

lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). 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 be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of

modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook, Silver, and the teachings below (see table).

- **17203050 (US Patent 11357893)**
- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of

interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to

provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches

that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**
- **17203384**
- **17203397**

- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Primary Examiner, Art Unit 3783

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	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 SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf
Updated search	10/06/2023	cbf

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

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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	01/12/2022	10/17/2022	03/24/2023	10/06/2023					
	1	✓	✓	✓	✓					
	2	✓	-	-	-					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	✓	✓	✓	✓					
	13	✓	✓	✓	✓					
	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
	16	✓	✓	✓	✓					
	17	✓	✓	✓	✓					
	18	✓	✓	✓	✓					
	19	✓	✓	✓	✓					
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	22	✓	✓	✓	✓					
	23	-	-	-	-					
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	25	✓	✓	✓	✓					
	26	-	-	-	-					
	27	-	-	-	-					
	28	✓	✓	✓	✓					
	29	✓	✓	✓	✓					
	30	✓	✓	✓	✓					
	31	✓	✓	✓	✓					
	32	✓	✓	✓	✓					
	33	✓	✓	✓	✓					
	34		✓	✓	✓					

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

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Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2003/0069536 A1	04-10-2003	Greter et al.	
	US2	2007/0054651 A1	03-08-2007	Farmer et al.	
	US3	2014/0227112 A1	08-14-2014	Felber	
	US4	2019/0365966 A1	12-05-2019	Bächler et al.	
	US5	2020/0016307 A1	01-16-2020	Edelman et al.	
	US6	2020/0300237 A1	09-24-2020	Marbet et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5](if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	EP 3482782 A1	05-15-2019	MEDELA HOLDING AG		

Examiner Signature		Date Considered	

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

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

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☐ See attached certification statement.

☒ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2023-05-15
Name/Print	Yangbeini Wang	Registration Number	800,005

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 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	US1	2002/0062103 A1	05-23-2002	Larsson et al.	
	US2	2008/0009815 A1	01-10-2008	Grabenkort et al.	
	US3	2015/0314053 A1	11-05-2015	Furrer et al.	

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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☒ 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	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-04-20
Name/Print	Richard D. Coller III	Registration Number	60,390

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 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	US1	US20040024351A1	02-05-2004	GRETER; Andy et al.	
	US2	US20050228342A1	10-13-2005	YUEN; Yat Keung William	
	US3	US2015/0157775A1	06-11-2015	HU	
	US4	US20170173232A1	06-22-2017	CHANG; John Y. et al.	
	US5	US20180021491A1	01-25-2018	RIGERT; Mario et al.	
	US6	US20190209748A1	07-11-2019	ANALYTIS et al.	
	US7	US20210093761A1	04-01-2021	HWANG et al.	
	US8	US20230111110A1	04-13-2023	DE BECDELIEVRE et al.	
	US9	US20230143842A1	05-11-2023	O'TOOLE et al.	
	US10	US20230158215A1	05-25-2023	O'TOOLE et al.	
	US11	US4,673,388A	06-16-1987	SCHLENSOG et al.	
	US12	US9498565B2	11-22-2016	NOWROOZI et al.	
	US13	US11260151B2	03-01-2022	O'TOOLE; Jonathan et al.	
	US14	US11311654B2	04-26-2022	O'TOOLE; Jonathan et al.	
	US15	US11324866B2	05-10-2022	O'TOOLE; Jonathan et al.	
	US16	US11357894B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US17	US11357893B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US18	US11376352B2	07-05-2022	O'TOOLE; Jonathan et al.	
	US19	US11413380B2	08-16-2022	O'TOOLE; Jonathan et al.	

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	NPL1	Amended Complaint in Shenzhen Root Technology Co., Ltd. v. Chiaro Technology, Ltd., WDWA-2-23-cv-00631, filed June 2, 2023; 24 pages.	

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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Signature	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-06-22
Name/Print	Yangbeini Wang	Registration Number	800,005

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR "20120277636" OR "20130023821" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR					

		"8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936" "20090281485" "20120165729"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/03/24 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM
L34	1	1 AND (correct WITH nipple WITH align$6)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/06 02:29 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: O'TOOLE *et al.*	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Amendment and Reply Under 37 C.F.R. § 1.111

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop Amendment

Commissioner:

In reply to the Office Action dated **March 30, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A breast pump device comprising:

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and ~~a guide line~~ fit lines, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the ~~guide line is~~ fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved ~~define the spacing of the nipple from the side wall of the nipple tunnel~~.

2. (Canceled)

3. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously Presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously Presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously Presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently Amended) The breast pump device of claim 1, wherein the ~~guide line is~~ fit lines are configured to run parallel along one or more sides of the nipple tunnel.

17. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously Presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously Presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously Presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously Presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously Presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously Presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously Presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Currently Amended) The kit of claim 31, wherein ~~each of the plurality of interchangeable breast shields comprises~~ the fit lines ~~in a nipple tunnel of that breast shield that~~ are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously Presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Previously Presented) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 3–22, 24, 25, and 28–34 are pending in the application. Claims 1 is an independent claim. Claims 1, 16, and 32 are amended. These changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

Applicant thanks Examiner Fredrickson for indicating that claim 28 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. Office Action, 28.

Claim Objections

Claim 1 is objected to for informalities. Office Action, 3.

Without agreeing to the propriety of the objection, relevant language of claim 1 is deleted. Therefore, the objection is now moot. Applicant respectfully requests that the objection be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 3–22, 24, 25, and 28–34 are rejected under 35 U.S.C. § 112(b) as allegedly being indefinite. Office Action, 3–4.

Without agreeing to the propriety of the rejections, relevant language of claim 1 is deleted, thereby rendering the rejection of claim 1 moot, and claim 1 is amended to recite, "the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and *fit lines*," thereby providing antecedent basis for claim 32. Accordingly, Applicant respectfully requests that the § 112 rejections of claims 1, 3–22, 24, 25, and 28–34 be withdrawn.

Rejections under 35 U.S.C. § 103

Independent claim 1

Claims 1, 3, 6–8, 10, 11, 14, 16–18, 22, 24, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Applicant No. 2008/0275386 to Myers, in view of EP 2502640 to Cook et al., and in further view of U.S. Patent Applicant Publication No. 2002/0198489 to Silver et al. Office Action, 5–10.

Claims 1, 6–10, 14, 17, 18, 20, 22, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent Applicant Publication No. 2013/0023821 to Khalil et al. in view of Myers, in view of Cook, and further in view of Silver. Office Action, 11–16.

Without agreeing to the propriety of the rejections, claim 1 is amended and now recites, "wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved." The applied references do not teach or suggest at least this feature of claim 1.

The Office acknowledges that Myers, Cook, and Khalil do not teach that the nipple tunnel comprises a guide line configured to define the spacing of the nipple from the side wall of the nipple tunnel, and only relies on Sliver for this feature. Office Action, 6–8 and 12–14.

Silver discloses a breastshield 1095 formed with a skeletal frame, and the skeletal frame comprises a series of stiffening longitudinally extending ribs 1160, 1164, and 1166. Silver, ¶¶ [0200]-[0201] and FIG. 28. The Office interprets ribs 1160, 1164, and 1166 to allegedly correspond to the recited guide line. Office Action, 8. However, Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel or assist with correct nipple alignment. Furthermore, Silver does not disclose that ribs 1160, 1164, and 1166 are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as recited in amended claim 1.

Accordingly, amended claim 1 and its dependent claims would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1, 3, 6–10, 11, 14, 16–18, 20, 22, 24, 31, 32, and 34.

Dependent claims

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Myers in view of Cook, in view of Silver, as applied to claim 1 above, in view of U.S. Patent Applicant Publication No. 2016/0296682 to Phillips et al., and further in view of U.S. Patent Applicant Publication No. 2005/0228342 to Yuen. Office Action, 10–11.

Claim 5 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2018/0333523 to Chang et al. Office Action, 16–17.

Claims 12 and 13 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of Phillips. Office Action, 17–18.

Claim 15 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2007/0228059 to Karsan. Office Action, 18–19.

Claim 19 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2012/0277636 to Blondheim et al. Office Action, 19–20.

Claims 20 and 21 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2014/0378895 to Barak. Office Action, 20–21.

Claim 25 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2016/0220743 to Guthrie et al. Office Action, 21–22.

Claim 29 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent No. 6,227,936 to Mendoza. Office Action, 22–23.

Claim 30 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2009/0281485 to Baker et al. Office Action, 23–24.

Claim 33 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent No. 5,542,921 to Meyers et al. Office Action, 24.

Each of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 depends from and adds features to independent claim 1. The additionally applied references do not overcome the deficiencies of Myers, Cook, Silver, and Khalil as discussed above. Accordingly, claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33.

Double Patenting Rejection

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 26–30.

- U.S. Applicant No. 17/203050 (U.S. Patent No. 11357893)
- U.S. Applicant No. 17/203079 (U.S. Patent No. 11376352)
- U.S. Applicant No. 17/203216 (U.S. Patent No. 11357894)
- U.S. Applicant No. 17/203259 (U.S. Patent No. 11324866)
- U.S. Applicant No. 17/203327 (U.S. Patent No. 11413380)

Claims 1, 3–22, 24, 25, and 28–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 30–34.

- U.S. Applicant No. 17/203109 (U.S. Patent No. 11260151)
- U.S. Applicant No. 17/203313 (U.S. Patent No. 11311654)

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 34–38.

- U.S. Applicant No. 17/203150
- U.S. Applicant No. 17/203179
- U.S. Applicant No. 17/203292
- U.S. Applicant No. 17/203355
- U.S. Applicant No. 17/203384
- U.S. Applicant No. 17/203397
- U.S. Applicant No. 17/203418

Applicant respectfully requests that the currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw all presently outstanding objections and rejections. A full and complete reply has been made to the outstanding Office Action and, as such, the present application is in

condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: June 30, 2023

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

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	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	June 30, 2023	Reg. No.	800,005

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/30/2023 10:56:14 AM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	62369354	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2023-06-30-Transmittal-Form-4944-0120006.PDF		1	Transmittal Letter	162 KB
2023-06-30-Amendment-Reply-111-4944-0120006.PDF		12	-	153 KB
2023-06-30-Amendment-Reply-111-4944-0120006-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	117 KB
2023-06-30-Amendment-Reply-111-4944-0120006-CLM.pdf	(2-6)	5	Claims	81 KB

2023-06-30-Amendment-Reply-111-4944-0120006-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	140 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-06-30-Transmittal-Form-4944-0120006.PDF	4152C7FF2F44E9494452F5C72E161884957F7855894618E34BFC024FD2B6A9C7DC5F03F8E33494C7A544AA198E23D101209FBD08F9C7FC9B9F2E1AC351A27373
2023-06-30-Amendment-Reply-111-4944-0120006.PDF	D9CE5CF94EE165AC04CF761F0987FA9EC7279B9DC53D90506B81B1323A99D85543D36FEB4C768ABBF8136607C8C76FD402EFB2CD151C33BD68F1E42DFE985583
2023-06-30-Amendment-Reply-111-4944-0120006-A....pdf	49C07B0B4B1416D30B214F3A9E192E7C478AC100841BC15FA2738B9FF0EBCE4F9D66E5ECB4DAEF3F12B90FD2AD8C07DD88B08537806175CFC2E1B4D142401206
2023-06-30-Amendment-Reply-111-4944-0120006-CLM.pdf	406F2101C60741B14BA57E750378F3AE1F3CE962D3B0261335F94C99CEC9D70D43B0CB93AF1334D0D9BDFA9CA68FD002EC48065FAFFE9C93B9817B94B2B194E1
2023-06-30-Amendment-Reply-111-4944-0120006-REM.pdf	A4CEF82F872A82584B06C05286A7463418D928BE04C6943A621E90C78D14D35CF9F6DE18256FF63FEA23398DFE430AA64CEC6789702264B164647C771BF271F6

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 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)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/30/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LISA R WRIGHT/
*** 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.	

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	US20040024351A1	02-05-2004	GRETER; Andy et al.	
	US2	US20050228342A1	10-13-2005	YUEN; Yat Keung William	
	US3	US2015/0157775A1	06-11-2015	HU	
	US4	US20170173232A1	06-22-2017	CHANG; John Y. et al.	
	US5	US20180021491A1	01-25-2018	RIGERT; Mario et al.	
	US6	US20190209748A1	07-11-2019	ANALYTIS et al.	
	US7	US20210093761A1	04-01-2021	HWANG et al.	
	US8	US20230111110A1	04-13-2023	DE BECDELIEVRE et al.	
	US9	US20230143842A1	05-11-2023	O'TOOLE et al.	
	US10	US20230158215A1	05-25-2023	O'TOOLE et al.	
	US11	US4,673,388A	06-16-1987	SCHLENSOG et al.	
	US12	US9498565B2	11-22-2016	NOWROOZI et al.	
	US13	US11260151B2	03-01-2022	O'TOOLE; Jonathan et al.	
	US14	US11311654B2	04-26-2022	O'TOOLE; Jonathan et al.	
	US15	US11324866B2	05-10-2022	O'TOOLE; Jonathan et al.	
	US16	US11357894B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US17	US11357893B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US18	US11376352B2	07-05-2022	O'TOOLE; Jonathan et al.	
	US19	US11413380B2	08-16-2022	O'TOOLE; Jonathan et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Amended Complaint in Shenzhen Root Technology Co., Ltd. v. Chiaro Technology, Ltd., WDWA-2-23-cv-00631, filed June 2, 2023; 24 pages.	

Examiner Signature		Date Considered	

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Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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.

☒ 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	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-06-22
Name/Print	Yangbeini Wang	Registration Number	800,005

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/22/2023 05:46:14 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baition
PATENT CENTER #	62321111	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1005	E20236LH47176578	Jon Baition

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	**$104.00**

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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

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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

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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):

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Remarks

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	June 22, 2023	Reg. No.	800,005

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Typed or printed name		Date	

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/22/2023 05:46:14 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62321111	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-06-22-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-06-22-sIDS-Pleading-4944-0120006.pdf	2	Transmittal Letter	99 KB
2023-06-22-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	149 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_1_Amended-Complaint.pdf	24	Non Patent Literature	304 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-06-22-Transmittal-Form-sIDS-4944-0120006.pdf	B32E6BCCDC2633E53E463D7E0EE4E65F5EB2ED92B259C64F25FBA0FCC0A40F3ECB0B3002BAA3FC0E62D178B83602A75704EEE33D219FB78C11C9CCD74DCD6460
2023-06-22-sIDS-Pleading-4944-0120006.pdf	B21766329C44FDD244CB6049CDBDAA67FDBCC95797C467E162F6C50BDAEFA939EE988961AEE7EEA7992C0E826D1E30F1CC3C15391B465491DBA05950F497D8D8
2023-06-22-sIDS-Form-SB08-4944-0120006.pdf	D574E7D735F0C271DE3D94EC290C816EE17C1DD95203DA85B00427BFF1C390FB02662F6D22E21BDEC12E94D47A753FDDF54F5189A972936FD883437CAFAB4CEA
NPL_1_Amended-Complaint.pdf	0689BD6CB3C7261D12519D347B8C0BA90106F9A82F5EDFF2CFCA991A41F5DD6062586413A5BB4A3635FD59FFEF8835335CB14B154E8924BE9E35D7074B78F5D7

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

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New International Application Filed with the USPTO as a Receiving Office

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

Copy of document **NPL1** is submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: June 22, 2023

1100 New York Avenue, N.W.
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(202) 371-2600

20347793.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2003/0069536 A1	04-10-2003	Greter et al.	
	US2	2007/0054651 A1	03-08-2007	Farmer et al.	
	US3	2014/0227112 A1	08-14-2014	Felber	
	US4	2019/0365966 A1	12-05-2019	Bächler et al.	
	US5	2020/0016307 A1	01-16-2020	Edelman et al.	
	US6	2020/0300237 A1	09-24-2020	Marbet et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	EP 3482782 A1	05-15-2019	MEDELA HOLDING AG		

Examiner Signature		Date Considered	

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature		Date Considered	

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Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				*Complete if Known*	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

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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.

☒ 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	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2023-05-15
Name/Print	Yangbeini Wang	Registration Number	800,005

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	05/15/2023 03:27:41 PM ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62088330	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1008	E20235EF29268657	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
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National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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
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- ☐ Petition to Convert to a Provisional Application
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- ☐ After Allowance Communication to TC
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- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	May 15, 2023	Reg. No.	800,005

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

(11) EP 3 482 782 A1

(12) EUROPÄISCHE PATENTANMELDUNG

(43) Veröffentlichungstag:
15.05.2019 Patentblatt 2019/20

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

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(22) Anmeldetag: **14.11.2017**

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(54) MEDIZINISCHE SAUGPUMPE

(57) Eine motorbetriebene medizinische Saugpumpe weist ein Pumpaggregat zur Erzeugung eines Unterdrucks, einen Pumpaggregatträger (3) zur Halterung des Pumpaggregats (7) und eine Aufnahme (35) zur Aufnahme eines Energiespeichers (7) auf. Das im Pumpaggregatträger (3) angeordnete Pumpaggregat (7) definiert eine erste Längsachse (L_1) und die Aufnahme (35) definiert eine zweite Längsachse (L_2). Der Pumpaggregatträger (3) bildet die Aufnahme (35). Die zweite Längsachse (L_2) verläuft in einem Winkel zur ersten Längsachse (L_1). Diese Saugpumpe ist klein und kompakt und weist eine gute Schalldämpfung auf.

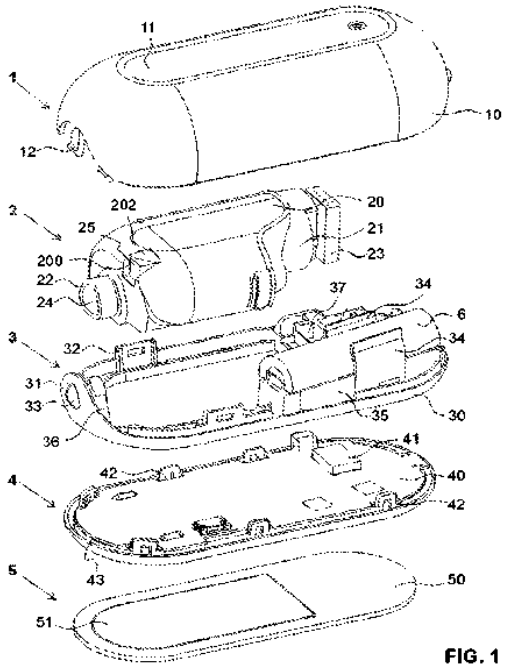


FIG. 1

EP 3 482 782 A1

Printed by Jouve, 75001 PARIS (FR)

Beschreibung

TECHNISCHES GEBIET

[0001] Die vorliegende Erfindung betrifft eine medizinische Saugpumpe, insbesondere eine motorbetriebene medizinische Saugpumpe. Derartige Saugpumpen sind insbesondere Brustpumpen zum Abpumpen von menschlicher Muttermilch oder Drainagepumpen zum Absaugen von Körperflüssigkeiten, wie beispielsweise für die Thoraxdrainage oder für die Wunddrainage.

STAND DER TECHNIK

[0002] Medizinische Saugpumpen, auch Vakuumpumpen genannt, sind für die verschiedensten Anwendungen bekannt. Beispielsweise werden sie als Brustpumpen zum Abpumpen von menschlicher Muttermilch oder als Drainagepumpen zum Absaugen von Körperflüssigkeiten verwendet. Derartige Saugpumpen weisen als Pumpaggregat Kolbenpumpen oder Membranpumpen auf. Die Verwendung einer Pumpmembran hat den Vorteil, dass die Saugpumpe als Ganzes relativ klein und leicht und im Gebrauch tragbar ausgebildet werden kann. Ein sehr kleines und trotzdem die hohen Anforderungen an eine Brustpumpe erfüllendes motorbetriebenes Pumpaggregat ist aus WO 2006/032156 A1 bekannt. Tragbare Saugpumpen weisen üblicherweise auch einen Energiespeicher zum Betreiben eines Motors des Pumpaggregats auf. Die Grösse des Energiespeichers und des Pumpaggregat bestimmen somit im Wesentlichen die Grösse des Pumpengehäuses.

[0003] Eine weitere Anforderung an derartige Saugpumpen ist die Schalldämpfung. Das Pumpaggregat ist oft relativ laut und rhythmisch wiederkehrende Geräusche stören den Benützer. Es ist deshalb bekannt, das Pumpaggregat in eine schalldämmende bzw. schalldämpfende Umgebung einzubetten. In diesem Text wird Schalldämmung und Schalldämpfung gleichwertig behandelt und jeweils als Schalldämpfung bezeichnet.

[0004] WO 2017/157691 A1 offenbart eine medizinische Saugpumpe mit einer elastischen Lagerung des Pumpaggregats innerhalb eines Pumpengehäuses.

[0005] In WO 2015/109934 A1 ist das Pumpaggregat in einem geschlossenen inneren Gehäuse angeordnet und eine Batterie ist parallel zum inneren Gehäuse in einem äusseren Pumpengehäuse angeordnet.

[0006] In WO 2017/140562 A1 ist das Pumpaggregat mittels Federn in einem äusseren Pumpengehäuse befestigt.

DARSTELLUNG DER ERFINDUNG

[0007] Es ist deshalb eine Aufgabe der Erfindung, eine medizinische Saugpumpe zu schaffen, welche möglichst kompakt, jedoch robust ausgebildet ist.

[0008] Diese Aufgabe löst eine motorbetriebene medizinische Saugpumpe mit den Merkmalen des Patentanspruchs 1.

[0009] Die erfindungsgemässe motorbetriebene medizinische Saugpumpe weist ein Pumpaggregat zur Erzeugung eines Unterdrucks, einen Pumpaggregatträger zur Halterung des Pumpaggregats und eine Aufnahme zur Aufnahme eines Energiespeichers auf, wobei das im Pumpaggregatträger angeordnete Pumpaggregat eine erste Längsachse definiert und die Aufnahme eine zweite Längsachse definiert. Erfindungsgemäss bildet der Pumpaggregatträger die Aufnahme und die zweite Längsachse verläuft in einem Winkel zur ersten Längsachse.

[0010] Da der Pumpaggregatträger die Aufnahme für den Energiespeicher bildet und dank der winkligen Anordnung von Pumpaggregat und Energiespeicher sind praktisch keine Leerräume vorhanden und die Grösse der Saugpumpe insgesamt ist minimiert. Da Pumpaggregat und Energiespeicher von demselben Pumpaggregatträger gehalten sind, ist die Vorrichtung insgesamt relativ steif ausgebildet. Dies erhöht nicht nur die Robustheit der Vorrichtung sondern dies minimiert auch Schwingungen beim Betrieb des Pumpaggregats und reduziert somit die Geräuschbildung bzw. -weiterleitung.

[0011] In bevorzugten Ausführungsformen ist der Pumpaggregatträger im Wesentlichen als Rahmen ausgebildet. Der Rahmen kann eine beliebige Form aufweisen. Vorzugsweise weist er jedoch eine im Wesentlichen längliche abgerundete Grundform, insbesondere eine elliptische oder ovale Grundform, auf. Die Ausbildung als Rahmen ermöglicht eine Leichtbauweise und erhöht zudem die Steifigkeit. Zudem ist ein Minimum an Material notwendig, was die Herstellungskosten entsprechend minimiert. Der Rahmen ist vorzugsweise einstückig ausgebildet. Vorzugsweise ist er im Spritzgussverfahren aus Kunststoff hergestellt.

[0012] Vorzugsweise umfasst die Saugpumpe ein erstes Pumpgengehäuseteil und ein zweites Pumpengehäuseteil, wobei der Pumpaggregatträger zwischen dem ersten und dem zweiten Pumpengehäuseteil gehalten ist. Dadurch wird er in seiner Lage fixiert und seine Steifigkeit wird erhöht.

[0013] In bevorzugten Ausführungsformen bildet der Pumpaggregatträger einen Teil des Pumpengehäuses. Er bildet vorzugsweise ein von aussen sichtbares Verbindungsteil zwischen dem ersten und dem zweiten Pumpengehäuseteil. Dies erleichtert den Zusammenbau der einzelnen Bauteile und eine weitere Lagerung des Pumpaggregatträgers inner-

halb des Pumpengehäuses lässt sich dadurch vermeiden.

[0014] Vorzugsweise ist der gesamte Pumpaggregatträger einstückig ausgebildet.

[0015] In bevorzugten Ausführungsformen sind mindestens zwei elastische Lager zur Lagerung des Pumpaggregats im Pumpaggregatträger vorhanden. Dadurch lässt sich die Übertragung von Vibrationen und Körperschall vom Pumpaggregat auf den Pumpaggregatträger und somit auf das Pumpengehäuse minimieren bzw. vermeiden. Zudem ist das Pumpaggregat dadurch definiert gehalten und trotzdem flexibel aufgehängt, so dass die Geräuschentwicklung reduziert und/oder gedämpft wird. Vorzugsweise ist eine Zweipunktlagerung vorhanden. Es ist jedoch auch möglich, eine Drei- oder Mehrpunktlagerung einzusetzen. Die Lager sind vorzugsweise aus einem Elastomer gebildet.

[0016] Vorzugsweise bildet mindestens ein erstes dieser Lager einen Vakuumanschluss. Mindestens ein zweites dieser Lager, welches vorzugsweise das Gegenlager zum ersten Lager bildet, ist vorzugsweise an einem motorseitigen Ende des Pumpaggregats und in Verlängerung einer Motorachse des Pumpaggregats, d.h. in der Flucht der Motorachse, angeordnet.

[0017] Vorzugsweise sind genau zwei Lager vorhanden, welche entlang der ersten Längsachse an gegenüberliegenden Enden des Pumpaggregats angeordnet sind. Vorzugsweise sind diese zwei Lager bezüglich der ersten Längsachse versetzt zueinander angeordnet. Die Verwendung von genau zwei elastischen Lagern und/oder die genannte Anordnung der Lager minimiert die Grösse der Saugpumpe insgesamt und führt zudem dazu, dass sich Vibrationen und Körperschall nicht oder nur begrenzt ausbreiten können.

[0018] Die Schalldämpfung ist optimiert, wenn das Pumpaggregat in einem Schalldämpfungsgehäuse angeordnet ist und das Schalldämpfungsgehäuse im Pumpaggregatträger gehalten ist.

[0019] Vorzugsweise ist eine Lufteinlassöffnung vorhanden, welche von einem Schalldämpfungselement überdeckt ist. Vorzugsweise ist die Lufteinlassöffnung im Schalldämpfungsgehäuse angeordnet, welches Zischgeräusche beim Einsaugen der Umgebungsluft minimiert. Das Schalldämpfungselement besteht vorzugsweise aus Schaumstoff oder aus einem anderen geeigneten porösen oder luftdurchlässigen Material. Das Pumpengehäuse ist vorzugsweise auf bekannte Art und Weise undicht ausgebildet, so dass über mehrere Stellen ein Luftaustausch vom Innenraum des Pumpgengehäuses in die Umgebung und umgekehrt stattfinden kann.

[0020] Vorzugsweise weist das Schalldämpfungsgehäuse ein Etui mit einer Aufnahmeöffnung zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel auf, wobei der Deckel gebogen ausgebildet ist. Dies erleichtert den Zusammenbau der Vorrichtung und ermöglicht eine möglichst platzsparende Ausbildung des Schalldämpfungsgehäuses. Das Etui ist vorzugsweise aus einem steifen oder halbsteifen Material, insbesondere aus einem Kunststoff, und der Deckel ist vorzugsweise aus einem weichen Material gefertigt.

[0021] Vorzugsweise ist das Schalldämpfungsgehäuse mittels der mindestens zwei elastischen Lager im Pumpaggregatträger gelagert. Vorzugsweise lagern die mindestens zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses. D.h. dieselben Lager weisen Doppelfunktionen auf. vorzugsweise weist jedes Lager auf zwei gegenüberliegenden Seiten entsprechende Flächen oder Ausbildungen auf. Dadurch reduziert sich die Anzahl der benötigten Lager. Die Lagerung ist genau definiert und optimiert. Zudem benötigt sie wenig Platz und ein Minimum an Bauteilen. Die Schalldämpfung ist verbessert, der Zusammenbau erleichtert und die Herstellungskosten minimiert.

[0022] Vorzugsweise ist das erste Lager ein Lagermodul in Form eines elastischen Einsatzelements, welches im Schalldämpfungsgehäuse gehalten ist und dieses durchsetzt. Das gesamte Einsatzelement ist vorzugsweise weich und einstückig hergestellt, beispielsweise aus Silikon oder TPE (thermoplastisches Elastomer). Das Einsatzelement dient als zweiseitiges Lager und verschliesst zudem das Schalldämpfungsgehäuse.

[0023] Vorzugsweise ist das zweite Lager ein Deckel oder ein Lagermodul in Form eines Teils eines Deckels des Schalldämpfungsgehäuses, wobei der gesamte Deckel elastisch ausgebildet ist. Vorzugsweise besteht er aus einem weichen Material, wie z.B. Silikon oder TPE. Durch Wahl der Form des Deckels lässt sich die Steifigkeit der Lagerstelle definieren. Der Deckel an sich kann das zweite Lager bilden oder zumindest Teile dieses Lagers bilden.

[0024] Einzelne Elemente lassen sich auch ohne die winklige Anordnung von Pumpaggregat und Energiespeicher bzw. ohne die Anordnung dieser zwei Bauteile auf einem gemeinsamen Pumpaggregatträger zu anderen erfindungsgemässen Saugpumpen zusammensetzen. Beispiele hierfür sind nachfolgend angegeben, welche als separate Erfindungen ebenfalls beansprucht sind. Die oben genannten bevorzugten Ausführungsformen, insbesondere die Merkmale der abhängigen Patentansprüche, lassen sich auch entsprechend mit diesen Beispielen ohne Verwendung aller Merkmale des Patentanspruchs 1 kombinieren.

[0025] In einer bevorzugten, ebenfalls als Erfindung beanspruchten Ausführungsform weist eine medizinische Saugpumpe ein Pumpengehäuse, ein im Pumpengehäuse angeordnetes Pumpaggregat zur Erzeugung eines Unterdrucks und mindestens ein erstes elastisches Lager und ein zweites elastisches Lager zur Lagerung des Pumpaggregats im Pumpengehäuse auf. Das erste elastische Lager befindet sich an einem ersten Ende des Pumpaggregats und das zweite elastische Lager befindet sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats. Dabei bildet das erste elastische Lager einen Vakuumanschluss. Diese Anordnung ist äusserst platzsparend und vermindert in optimaler Weise Vibrationen.

[0026] In einer anderen, ebenfalls als Erfindung beanspruchten Ausführungsform weist eine medizinische Saugpumpe ein Pumpaggregat, ein Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und ein Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses auf. Das Schalldämpfungsgehäuse weist ein Etui zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel auf. Der Deckel ist elastisch ausgebildet und er weist ein elastisches Lager zur Lagerung des Schalldämpfungsgehäuses im Pumpengehäuse auf. Diese Ausbildung ermöglicht einen einfachen Zusammenbau der Vorrichtung, da das Pumpaggregat lediglich in das Etui eingeschoben werden muss. Der elastische, insbesondere weiche Deckel verhindert auf optimale Weise Vibrationen und die Verbreitung von Körperschall.

[0027] In bevorzugten Ausführungsformen sind diese zwei Varianten miteinander kombiniert. D.h. das erste Lager bildet den Vakuumanschluss und das zweite Lager den Deckel.

[0028] In einer weiteren bevorzugten Ausführungsform, welche ebenfalls als separate Erfindung beansprucht wird, weist eine medizinische Saugpumpe ein Pumpaggregat, ein Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und ein Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses auf. Mindestens ein erstes und ein zweites elastisches Lager sind vorhanden, wobei mindestens eines dieser zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse lagert und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses lagert. Vorzugsweise lagern beide elastischen Lager sowohl das Schalldämpfungsgehäuse bezüglich des Pumpengehäuses wie auch das Pumpaggregat bezüglich des Schalldämpfungsgehäuses. Das heisst, vorzugsweise sind beide elastischen Lager als Module ausgebildet, welche auf zwei gegenüberliegenden Seiten Lagerstellen bilden. Wie oben bereits erwähnt, ist hier die Lagerung sowie die Schalldämpfung optimiert und eine äusserst kompakte Bauweise ermöglicht. Diese Ausführungsform lässt sich beispielsweise erreichen, indem der Deckel und/oder der Vakuumanschluss als Lager ausgebildet sind und jeweils an den entsprechenden Stellen oder gesamthaft weich bzw. flexibel ausgebildet sind.

[0029] Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

[0030] Bevorzugte Ausführungsformen der Erfindung werden im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine Explosionsdarstellung einer erfindungsgemässen Saugpumpe in einer ersten Ausführungsform;

Figur 2 einen ersten Querschnitt durch die Saugpumpe gemäss Figur 1;

Figur 3 einen zweiten Querschnitt durch die Saugpumpe gemäss Figur 1;

Figur 4 eine Explosionsdarstellung eines Schalldämpfungsgehäuses mit einem Pumpaggregat der Saugpumpe gemäss Figur 1;

Figur 5 eine perspektivische Darstellung eines Teils der Saugpumpe gemäss Figur 1 ohne Schalldämpfungselement;

Figur 6 eine perspektivische Darstellung eines Teils der Saugpumpe gemäss Figur 1 mit Schalldämpfungselement;

Figur 7 eine perspektivische Darstellung eines ersten Lagermoduls der Saugpumpe gemäss Figur 1;

Figur 8 eine Ansicht des ersten Lagermoduls gemäss Figur 7 von oben;

Figur 9a einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer ersten Variante;

Figur 9b einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer zweiten Variante;

Figur 9c einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer dritten Variante;

Figur 10 eine perspektivische Darstellung eines zweiten Lagermoduls der Saugpumpe gemäss Figur 1;

Figur 11 eine Ansicht des zweiten Lagermoduls gemäss Figur 10 von oben;

Figur 12a einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer ersten Variante;

Figur 12b einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer zweiten Variante;

Figur 12c einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer dritten Variante und

Figur 12d einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer vierten Variante.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

[0031] In Figur 1 ist ein bevorzugtes Ausführungsbeispiel einer erfindungsgemässen Saugpumpe dargestellt. Es handelt sich um eine Brustpumpe zum Abpumpen von menschlicher Muttermilch.

[0032] Die Saugpumpe weist ein erstes Pumpengehäuseteil 1, ein Schalldämpfungsgehäuse 2, einen Pumpaggregatträger 3, ein zweites Pumpengehäuseteil 4 sowie eine Abdeckung 5 auf. Im zusammengesetzten Zustand der Saugpumpe befindet sich das Schalldämpfungsgehäuse 2 innerhalb eines Pumpengehäuses, welches im Wesentlichen durch das erste Pumpengehäuseteil 1, das zweite Pumpengehäuseteil 4 und den dazwischen angeordneten und zwischen diesen zwei Teilen 1, 4 eingeklemmten Pumpaggregatträger 3 gebildet ist. Der Pumpaggregatträger 3 ist somit vorzugsweise von aussen als umlaufender Streifen erkennbar.

[0033] Das erste Pumpengehäuseteil 1 bildet den Boden der Saugpumpe. Es weist einen schalenförmigen Grundkörper 10 auf, dessen Unterseite, welche hier nach oben gerichtet ist, nahezu flach ausgebildet ist und eine Auflagefläche 11 bildet. Im Längsschnitt ist der Grundkörper 10 oval ausgebildet. Am Umfang des Grundkörpers 10 verteilt sind erste Verbindungselemente 12, vorzugsweise Schnappelemente oder andere bekannte Verbindungsmittel, angeordnet.

[0034] Das zweite Pumpengehäuseteil 4 weist eine im Wesentlichen ovale Grundplatte 40 und eine umlaufende Rinne 43 zur Aufnahme des Pumpaggregatträgers 3 auf. Auf der Grundplatte 40 sind die in Saugpumpen üblichen elektronischen Bauteile angeordnet. Sie sind hier lediglich schematisch dargestellt. Eine Steuer- und Elektronikeinheit ist mit dem Bezugszeichen 41 versehen. Über dem Umfang des zweiten Pumpengehäuseteils 4 verteilt sind zweite Verbindungselemente 42 angeordnet, die in den Rahmen 30 eingreifen.

[0035] Die Abdeckung 5 bildet zusammen mit dem zweiten Pumpengehäuseteil 4 das obere Teil des Pumpengehäuses, auch wenn diese Bauteile in dieser Darstellung unten angeordnet sind. Die Abdeckung 5 lässt sich auf dem zweiten Pumpengehäuseteil 4 befestigen. Sie weist vorzugsweise eine planparallele steife und ovale Deckplatte 50 mit einem Anzeige- und Betätigungsfenster 51 auf. Mittels des Anzeige- und Betätigungsfensters 51 lassen sich beispielsweise Benutzereingaben eingeben und die Funktionsweise der Saugpumpe optisch darstellen.

[0036] Der Pumpaggregatträger 3 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise ist er aus einem Kunststoff gefertigt und vorzugsweise ist er einstückig. Er weist einen ovalen Rahmen 30 auf. An einer schmalen Stirnseite geht der Rahmen 30 in eine erhöhte Stirnwand 31 über, welche eine Durchgangsöffnung 33 aufweist. Die Rückseite der Stirnwand 31 ist mit einer ersten Lageraufnahme 36 versehen, welche die Durchgangsöffnung 33 umgibt. Verteilt über dem Umfang des Rahmens 30 sind dritte Verbindungselemente 32 vorhanden, die in das erste Pumpengehäuseteil 1 eingreifen, um das Pumpengehäuse zusammenzuhalten.

[0037] An dem der Durchgangsöffnung 33 gegenüberliegenden Ende des Rahmens 30 ist eine Energiespeicheraufnahme 35 angeordnet. Sie ist entsprechend der Form eines Energiespeichers 6 geformt. Der Energiespeicher 6 ist in diesem Beispiel eine zylinderförmige, wieder aufladbare Batterie. Andere Formen und Arten von Energiespeichern lassen sich auch verwenden. Die Energiespeicheraufnahme 35 ist als ein in der Figur 1 nach oben offener Kasten ausgebildet, wobei auf zwei gegenüberliegenden Seiten je ein Klammerelement 34 nach oben ragt. All diese Elemente sind vorzugsweise einstückig gemeinsam mit dem Rahmen 30 ausgebildet.

[0038] Benachbart zur Energiespeicheraufnahme 35 ist eine zweite Lageraufnahme 37 ausgebildet. Auch diese ist in diesem Beispiel als rechteckförmiger, nach oben offen ausgebildeter Kasten einstückig am Rahmen 30 angeformt. Das hintere, der Durchgangsöffnung 33 entgegengesetzte Ende des Rahmens 30 ist als Stromanschluss 38 ausgebildet. Dies ist in den Figuren 2 und 3 gut erkennbar.

[0039] Das Schalldämpfungsgehäuse 2 weist ein Etui 20 zur Aufnahme eines Pumpaggregats 7 auf. Das Etui 20 ist vorzugsweise steif oder halbsteif ausgebildet, insbesondere besteht es aus Kunststoff. Vorzugsweise weist es eine zur Pumpgehäuseform passende ovale abgerundete Form auf, wobei das Etui 20 im Bereich seiner Öffnung abgeschrägt ist. Die Abschrägung ist vorzugsweise geschwungen, so dass das Etui stufenförmig und auf einer Seite länger ausgebildet

ist als auf der anderen Seite. Dies ist in Figur 1 gut erkennbar.

[0040] Dieser stufenförmige Rand ist mittels eines Deckels 21 geschlossen. Der Deckel 21 weist einen entsprechend geschwungen ausgebildeten, d.h. gebogenen Verschlusskörper 210 auf. Dieser geht vorzugsweise einstückig in einen annähernd zylinderförmigen Übergangsbereich 211 über. Der Durchmesser dieses Übergangsbereichs 211 entspricht vorzugsweise annähernd dem Durchmesser des längeren Bereichs des Etuis 20. Dem Übergangsbereich 211 folgt ein Verbindungsstift 212, an welchem sich ein zweites Lagermodul 23 anschliesst. Dies ist in den Figuren 2 und 3 gut erkennbar. Ein erstes Lagermodul 22 befindet sich am gegenüberliegenden Ende des Etuis 20 und wird weiter unten im Text ausführlicher beschrieben.

[0041] Das zweite Lagermodul 23 kann auf den Verbindungsstift 212 aufgesteckt sein. Vorzugsweise ist es jedoch einstückig mit diesem und dem gesamten restlichen Deckel 21 ausgebildet. Vorzugsweise ist der Deckel 21 mit dem zweiten Lager 23 elastisch ausgebildet. Insbesondere ist er weich. Vorzugsweise ist er aus einem Elastomer oder aus Silikon gefertigt.

[0042] Das Etui 20 weist im Bereich des ersten Lagermoduls 22 eine Ausnehmung 200 auf, welche im oberen Bereich ein Fenster 202 aufweist. In dieser Ausnehmung 200 ist ein Schalldämpfungselement 25, hier ein Schaumstoffwürfel, angeordnet.

[0043] In Figur 2 ist die Anordnung des Schalldämpfungsgehäuses 2 sowie des Energiespeichers 6 innerhalb des Rahmens 30 des Pumpaggregatträgers 3 gut erkennbar. Das Schalldämpfungsgehäuse 2, genauer das Etui 20, ist mittels des ersten Lagermoduls 22 in der ersten Lageraufnahme 36 gelagert. Das zweite Lagermodul 23 befindet sich in der zweiten Lageraufnahme 37 des Pumpaggregatträgers 3, so dass das Schalldämpfungsgehäuse 2 auch an diesem gegenüberliegenden Ende im Pumpaggregatträger 3 gelagert ist. Somit ist eine Zweipunktlagerung vorhanden.

[0044] Eine Durchgangsöffnung des ersten Lagermoduls 22, welche hier einen Vakuumanschluss 24 bildet, fluchtet mit der Durchgangsöffnung 33 des Pumpaggregatträgers 3, wie dies in Figur 3 gut erkennbar ist. Diese Durchgangsöffnung 33 bildet somit eine Aufnahme für einen Stecker eines Saugschlauchs, welcher zu einer Brusthaube zum Anlegen an die Mutterbrust führt. Stecker, Saugschlauch und Brusthaube sind hier nicht dargestellt. Sie sind jedoch aus dem Stand der Technik hinlänglich bekannt.

[0045] Wie in Figur 2 erkennbar ist, definiert das Etui 20 eine erste Längsachse L_1, welche mit der Längsmittelachse des Vakuumanschlusses 24 fluchtet. Der Energiespeicher 6 definiert einen zweite Längsachse L_2, welche in einem Winkel zu dieser ersten Längsachse L_1 verläuft. Das zweite Lagermodul 23 definiert mit seiner Längsmittelachse eine dritte Längsachse L_3, welche parallel versetzt zur ersten Längsachse L_1 verläuft.

[0046] Wie in den Figuren 2 und 3 gut erkennbar ist, ist der Platz innerhalb des Pumpaggregatträgers durch die Abschrägung des Etuis 20 sowie durch die schräge Anordnung des Energiespeichers 6 optimal genutzt und Leerräume sind weitgehend vermieden. Das Pumpengehäuse kann insgesamt sehr klein und kompakt ausgebildet werden. Es ist schallgedämpft und trotzdem steif und robust.

[0047] Die Anordnung des Pumpaggregats 7 innerhalb des Schalldämpfungsgehäuses 2 ist in Figur 3 dargestellt. Eine passende Explosionsdarstellung dazu findet sich in Figur 4.

[0048] Vorzugsweise entspricht das Pumpaggregat 7 im Wesentlichen dem in WO 2006/032156 A1 beschriebenen Pumpaggregat. Es lassen sich jedoch auch andere Formen und Ausgestaltungen in der erfindungsgemässen Vorrichtung verwenden. Vorzugsweise umfasst das Pumpaggregat jedoch einen Elektromotor sowie eine Pumpeinheit, insbesondere eine Membranpumpe, vorzugsweise eine Pumpkammer mit einer Pumpmembran.

[0049] Der Elektromotor ist in den Figuren mit dem Bezugszeichen 70 versehen, die Pumpeinheit mit dem Bezugszeichen 71. Die dritte Längsachse L_3 des zweiten Lagermoduls 23 bildet die Flucht einer nicht dargestellten Motorachse des Elektromotors 70. Der Elektromotor 70 ist somit benachbart zum zweiten Lagermodul 23 angeordnet.

[0050] Die Pumpeinheit 71 weist eine Entlüftungsöffnung 710, eine Vakuumöffnung 711 sowie eine Belüftungsöffnung 712 auf. Dies ist in Figur 3 gut erkennbar.

[0051] Die Belüftungsöffnung 712 schliesst sich im zusammengebauten Zustand der Vorrichtung an eine Lufteinlassöffnung 201 an, welche sich in der Ausnehmung des Schalldämpfungsgehäuses 2 befindet. Diese Lufteinlassöffnung 201 ist in Figur 5 gut erkennbar. Sie ist vom Schalldämpfungselement 25 überdeckt, wie dies in Figur 6 dargestellt ist. Ein Fenster 202 ist aus spritzgusstechnischen Gründen im Etui 20 vorhanden.

[0052] Die Entlüftungsöffnung 710 führt in das Innere des Schalldämpfungsgehäuses 2, genauer des Etuis 20. Luft, welche über diese Entlüftungsöffnung 710 aus der Pumpeinheit 71 entweicht, verlässt das Schalldämpfungsgehäuse 2 über undichte Stellen wie beispielsweise über ein Aufnahmeelement 26 einer Steckverbindung mit einem Einsteckelement 213 des Deckels 21.

[0053] Die Vakuumöffnung 711 fluchtet mit einem Verbindungskanal 222 des ersten Lagermoduls 22, wie dies in Figur 4 erkennbar ist. Der Verbindungskanal 222 weist im Innern des ersten Lagermoduls 22 einen abgewinkelten, d.h. nicht geradlinigen Verlauf auf und endet im Vakuumanschluss 24, genauer in der darin vorhandenen Anschlussöffnung 225. Diese Anschlussöffnung 225 ist in Figur 7 gut erkennbar.

[0054] Das Pumpaggregat 7 ist mittels des ersten Lagermoduls 22 vakuumseitig im Schalldämpfungsgehäuse 2 gelagert und mittels des zweiten Lagermoduls 23, genauer des Deckels 21, motorseitig im Schalldämpfungsgehäuse 2

gelagert. Der Deckel 21 ist hierfür lediglich auf dem Etui 20 aufzustecken und mit den bereits erwähnten Einsteckelementen 213 in die entsprechenden Aufnahmeelemente 26 einzustecken.

[0055] Das erste Lagermodul 22 ist nicht wie in Figur 4 dargestellt dem Etui 20 vorgelagert, sondern es befindet sich innerhalb des Etuis 20. Es lässt sich hierfür einfach über die gebogene Öffnung einschieben und durch eine stirnseitige Durchgangsöffnung 27 des Etuis 20 teilweise durchschieben. Ein Anschlusskörper 221 ragt aus der Öffnung heraus, ein Hals 226 ist freigestellt und ein Grundkörper 220 dichtet gegenüber dem Innenraum des Etuis 20 an dessen Innenseite. Diese Teile sind in den Figuren 7 und 8 gut erkennbar. Zur Befestigung des Grundkörpers 220 im Etui 20 dient vorzugsweise ein Klemmelement 223 in der Form einer federnden Zunge. Diese Zunge 223 dichtet ebenfalls gegenüber dem Innenraum des Etuis 20.

[0056] Der Grundkörper 220 weist einen Belüftungskanal 224 auf, welcher die Verbindung zwischen der Belüftungsöffnung 712 der Pumpeinheit 71 und der Lufteinlassöffnung 201 des Etuis 20 schafft.

[0057] Das gesamte erste Lagermodul 22 ist einstückig und vorzugsweise elastisch, insbesondere weich ausgebildet. Es bildet somit an zwei gegenüberliegenden Seiten Lagerstellen aus: auf einer ersten Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregatträger 3 und somit dem Pumpengehäuse und auf einer gegenüberliegenden Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregat 7, genauer der Pumpeinheit 71.

[0058] Auch der Deckel mit dem zweiten Lagermodul 23 ist einstückig und vorzugsweise elastisch, insbesondere weich ausgebildet. Auch dieses bildet somit an zwei gegenüberliegenden Seiten Lagerstellen aus: auf einer ersten Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregatträger 3 und somit dem Pumpengehäuse und auf einer gegenüberliegenden Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregat 7, genauer dem Elektromotor 70. Da der Pumpaggregatträger 3 Teil des äusseren Pumpengehäuses ist, erübrigt sich eine weitere Lagerung.

[0059] Die Schalldämpfung bzw. die Vibrationsdämpfung lässt sich weiterhin optimieren, indem die Anschlussöffnung 225 entsprechend gewählt wird. Bewährt haben sich Formen, wie sie in den Figuren 9a bis 9c dargestellt sind. Es ist der Hals 226 des ersten Lagermoduls 22 im Querschnitt gezeigt sowie die sich darin befindliche Anschlussöffnung 225. Die Querschnitte des Halses 226 sowie die Formen der Anschlussöffnung 225 lassen sich beliebig miteinander kombinieren. In Figur 9a ist der Hals 226 kreuzförmig und die Anschlussöffnung 225 ist rund. In Figur 9b sind der Hals 226 und die Anschlussöffnung 225 oval und in Figur 9c sind sie rund. Die Kombination gemäss Figur 9b ist am meisten bevorzugt.

[0060] In den Figuren 10 bis 12d ist der Deckel 21 mit dem zweiten Lagermodul 23 dargestellt. Er weist wie bereits beschrieben den gebogenen Verschlusskörper 210, den Übergangsbereich 211, den Verbindungsstift 212 und das zweite Lagermodul 23 auf. Das zweite Lagermodul 23 weist vorzugsweise einen quaderförmigen Rahmen mit darin verlaufenden Verbindungsstreben auf. Dadurch ist er elastisch und passt sich seiner zugehörigen zweiten Lageraufnahme 37 optimal an.

[0061] Im Übergangsbereich 211 sind vorzugsweise Kabeldurchführungen 214 in Form von Durchgangsöffnungen vorhanden, um den Elektromotor 70 über die Grundplatte 40 mit der Steuer- und Elektronikeinheit 41 zu verbinden. Am gebogenen Verschlusskörper 210 sind die Einsteckelemente 213 angeformt.

[0062] Die Schalldämpfung und die Lagerung lassen sich durch die Formgebung des Verbindungsstifts 212 zusätzlich optimieren. In den Figuren 12a bis 12 sind bevorzugte Varianten dargestellt. Vorzugsweise ist der Verbindungsstift 212 vollflächig, also massiv ausgebildet. Vorzugsweise ist er relativ steif.

[0063] In Figur 12a ist sein Querschnitt kreuzförmig, in Figur 12b rund, in Figur 12c rechteckig und in Figur 12d oval. Vorzugsweise ist er kreuzförmig.

[0064] Die erfindungsgemässe Saugpumpe ist klein und kompakt und weist eine gute Schalldämpfung auf.

BEZUGSZEICHENLISTE

[0065]

1	erstes Pumpengehäuseteil	30	Rahmen
10	schalenförmiger Grundkörper	31	Stirnwand
11	Auflagefläche	32	drittes Verbindungselement
12	erstes Verbindungselement	33	Durchgangsöffnung
		34	Klammerelement
2	Schalldämpfungsgehäuse	35	Energiespeicheraufnahme
20	Etui	36	erste Lageraufnahme
200	Ausnehmung	37	zweite Lageraufnahme
201	Lufteinlassöffnung	38	Stromanschluss
202	Fenster		

(fortgesetzt)

21	Deckel	4	zweites Pumpengehäuseteil
210	gebogener Verschlusskörper	40	Grundplatte
211	Übergangsbereich	41	Steuer- und Elektronikeinheit
212	Verbindungsstift	42	zweites Verbindungselement
213	Einsteckelement	43	Rinne
214	Kabeldurchführungen		
22	erstes Lagermodul	5	Abdeckung
220	Grundkörper	50	Deckplatte
221	Anschlusskörper	51	Anzeige- und Betätigungsfenster
222	Verbindungskanal		
223	Klemmelement		
224	Belüftungskanal	6	Energiespeicher
225	Anschlussöffnung		
226	Hals	7	Pumpaggregat
23	zweites Lagermodul	70	Elektromotor
24	Vakuumanschluss	71	Pumpeinheit
25	Schalldämpfungselement	710	Entlüftungsöffnung
26	Aufnahmeelement	711	Vakuumöffnung
27	Durchgangsöffnung	712	Belüftungsöffnung
3	Pumpaggregatträger	L_1	erste Längsachse
L_2	zweite Längsachse		
L_3	dritte Längsachse		

Patentansprüche

1. Motorbetriebene medizinische Saugpumpe mit einem Pumpaggregat zur Erzeugung eines Unterdrucks, mit einem Pumpaggregatträger (3) zur Halterung des Pumpaggregats (7) und mit einer Aufnahme (35) zur Aufnahme eines Energiespeichers (7), wobei das im Pumpaggregatträger (3) angeordnete Pumpaggregat (7) eine erste Längsachse (L_1) definiert und die Aufnahme (35) eine zweite Längsachse (L_2) definiert, **dadurch gekennzeichnet, dass** der Pumpaggregatträger (3) die Aufnahme (35) bildet und dass die zweite Längsachse (L_2) in einem Winkel zur ersten Längsachse (L_1) verläuft.

2. Motorbetriebene medizinische Saugpumpe nach Anspruch 1, wobei der Pumpaggregatträger (3) im Wesentlichen als Rahmen (30) ausgebildet ist und eine im Wesentlichen längliche abgerundete Grundform, insbesondere einen elliptische oder ovale Grundform, aufweist.

3. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 oder 2, wobei sie ein Pumpengehäuse mit einem ersten Pumpengehäuseteil (1) und einem zweiten Pumpengehäuseteil (4) umfasst und wobei der Pumpaggregatträger (3) zwischen dem ersten und dem zweiten Pumpengehäuseteil (1, 4) gehalten ist.

4. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 3, wobei eine Lufteinlassöffnung (201) vorhanden ist, welche von einem Schalldämpfungselement (25) überdeckt ist.

5. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 4, wobei mindestens zwei elastische Lager (22, 23) vorhanden sind zur Lagerung des Pumpaggregats (7) im Pumpaggregatträger (3).

6. Motorbetriebene medizinische Saugpumpe nach Anspruch 5, wobei mindestens ein erstes dieser Lager (22) einen Vakuumanschluss (24) bildet und mindestens ein zweites dieser Lager (23) an einem motorseitigen Ende des Pumpaggregats (7) und in Verlängerung einer Motorachse des Pumpaggregats (7) angeordnet ist.

7. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 5 oder 6, wobei genau zwei Lager (22, 23) vorhanden sind, welche entlang der ersten Längsachse (L_1) an gegenüberliegenden Enden des Pumpaggregats

angeordnet sind.

8. Motorbetriebene medizinische Saugpumpe nach Anspruch 7, wobei die zwei Lager (22, 23) bezüglich der ersten Längsachse (L_1) versetzt zueinander angeordnet sind.

9. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 8, wobei das Pumpaggregat (7) in einem Schalldämpfungsgehäuse (2) angeordnet ist und das Schalldämpfungsgehäuse (2) im Pumpaggregatträger (3) gehalten ist.

10. Motorbetriebene medizinische Saugpumpe nach Anspruch 9, wobei das Schalldämpfungsgehäuse (2) ein Etui (20) mit einer Aufnahmeöffnung zur Aufnahme des Pumpaggregats (7) und einen das Etui (20) verschliessenden Deckel (21) aufweist, wobei der Deckel (21) gebogen ausgebildet ist.

11. Motorbetriebene medizinische Saugpumpe nach den Ansprüchen 5 und 9, wobei das Schalldämpfungsgehäuse (2) mittels der mindestens zwei elastischen Lager (22, 23) im Pumpaggregatträger (3) gelagert ist.

12. Motorbetriebene medizinische Saugpumpe nach Anspruch 11, wobei die mindestens zwei elastischen Lager (22, 23) einerseits das Schalldämpfungsgehäuse (2) im Pumpengehäuse (1, 3, 4) lagern und andererseits das Pumpaggregat (7) innerhalb des Schalldämpfungsgehäuses (2) lagern.

13. Motorbetriebene medizinische Saugpumpe nach Anspruch 12, wobei das erste Lager (22) ein elastisches Einsatzelement ist, welches im Schalldämpfungsgehäuse (2) gehalten ist und dieses durchsetzt.

14. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 12 oder 13, wobei das zweite Lager (23) Teil eines Deckels (21) des Schalldämpfungsgehäuses (2) ist, wobei der gesamte Deckel (21) elastisch ausgebildet ist.

15. Medizinische Saugpumpe mit einem Pumpengehäuse (1, 3, 4), mit einem im Pumpengehäuse (1, 3, 4) angeordneten Pumpaggregat (7) zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager (22) und einem zweiten elastischen Lager (23) zur Lagerung des Pumpaggregats (7) im Pumpengehäuse (1, 3, 4), wobei das erste elastische Lager (22) sich an einem ersten Ende des Pumpaggregats (7) befindet und das zweite elastische Lager (23) sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats (7) befindet, **dadurch gekennzeichnet, dass** das erste elastische Lager (22) einen Vakuumanschluss (24) bildet.

16. Medizinische Saugpumpe mit einem Pumpaggregat (7), einem Schalldämpfungsgehäuse (2) zur Aufnahme des Pumpaggregats (7) und mit einem Pumpengehäuse (1, 3, 4) zur Aufnahme des Schalldämpfungsgehäuses (2), **dadurch gekennzeichnet, dass** das Schalldämpfungsgehäuse (2) ein Etui (20) zur Aufnahme des Pumpaggregats (7) und einen das Etui (20) verschliessenden Deckel (21) aufweist, wobei der Deckel (21) elastisch ausgebildet ist und ein elastisches Lager (23) zur Lagerung des Schalldämpfungsgehäuses (2) im Pumpengehäuse (1, 3, 4) aufweist.

17. Medizinische Saugpumpe mit einem Pumpaggregat (7), einem Schalldämpfungsgehäuse (2) zur Aufnahme des Pumpaggregats (7) und mit einem Pumpengehäuse (1, 3, 4) zur Aufnahme des Schalldämpfungsgehäuses (2), **dadurch gekennzeichnet, dass** mindestens ein erstes und ein zweites elastisches Lager (22, 23) vorhanden sind, wobei mindestens eines dieser zwei elastischen Lager (22, 23) einerseits das Schalldämpfungsgehäuse (2) im Pumpengehäuse (1, 3, 4) lagert und andererseits das Pumpaggregat (7) innerhalb des Schalldämpfungsgehäuses (2) lagert.

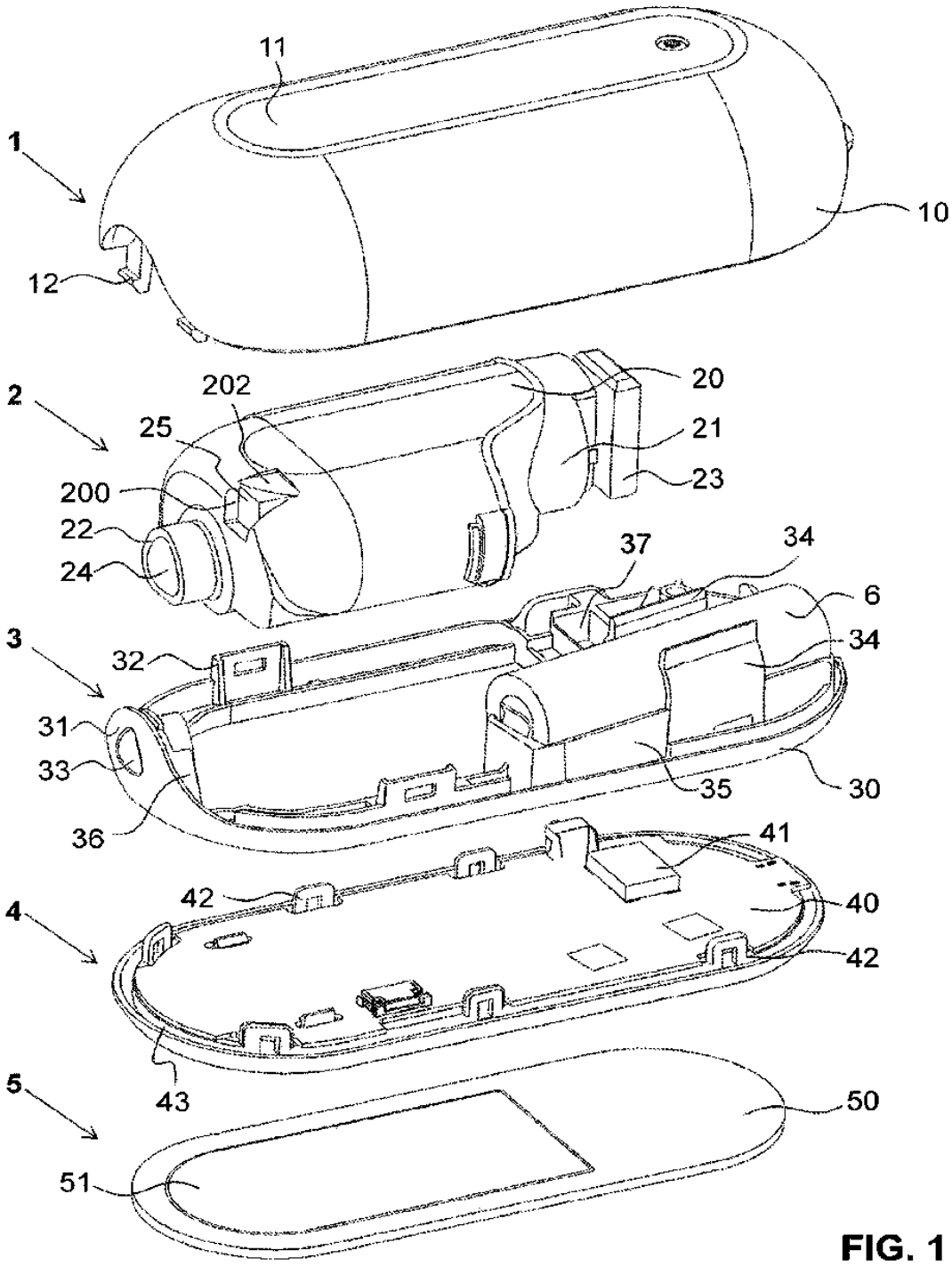

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FIG. 1

FIG. 2

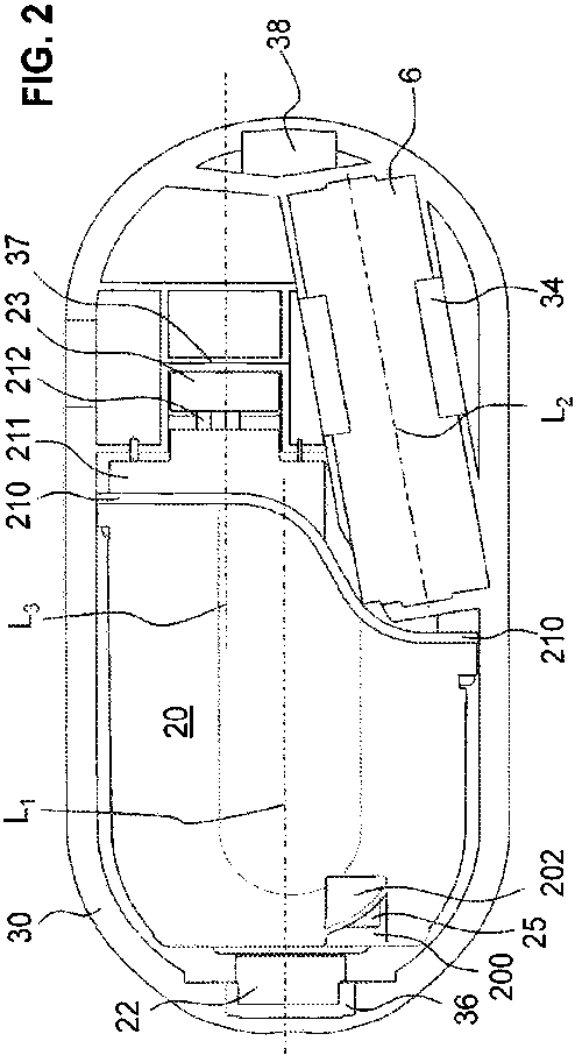
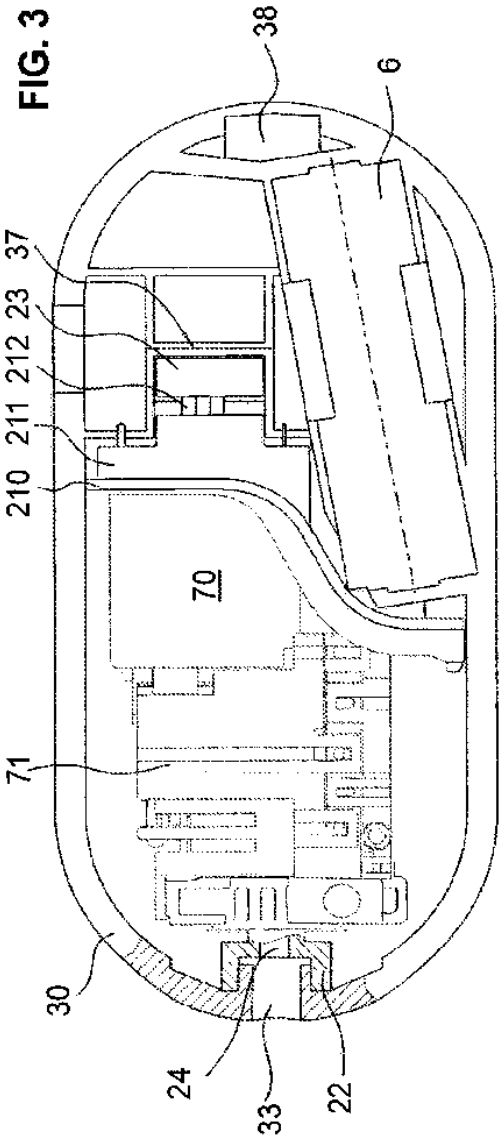

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FIG. 3


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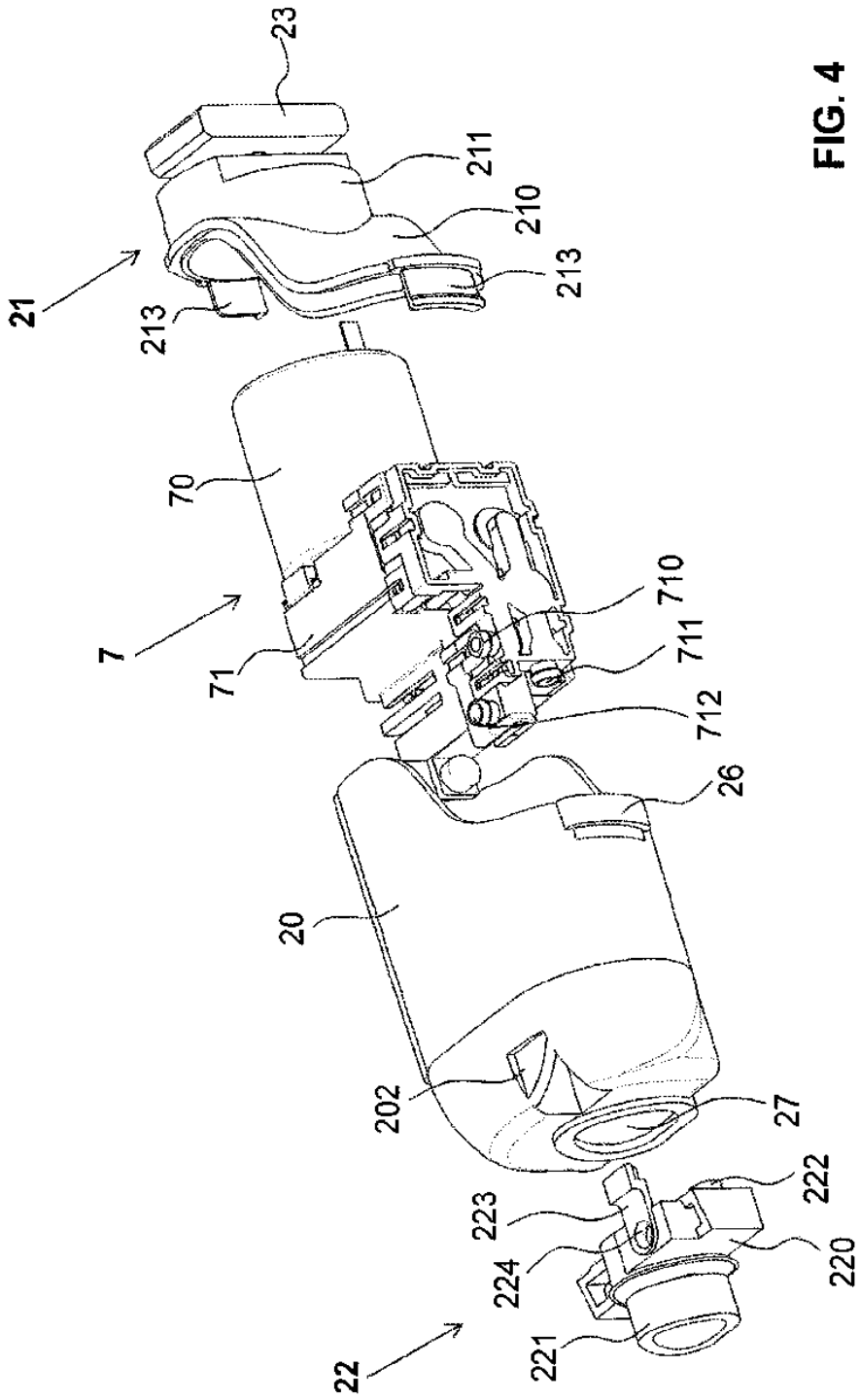

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FIG. 4

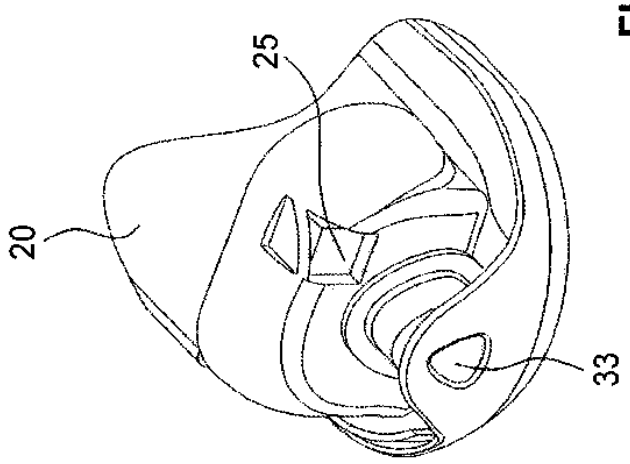


FIG. 6

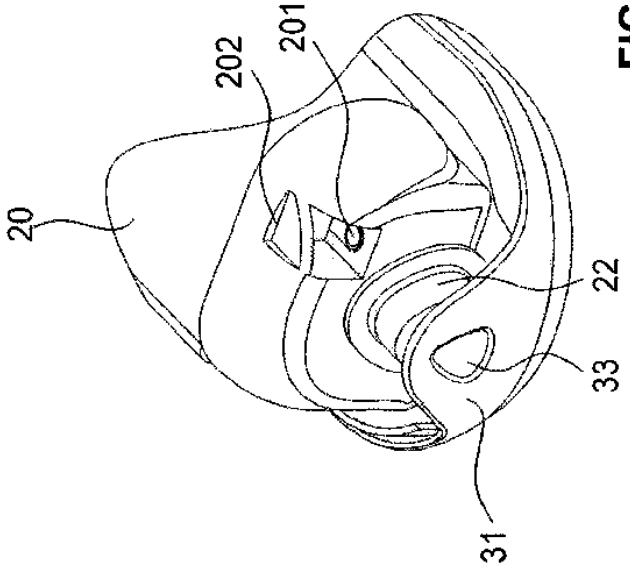


FIG. 5

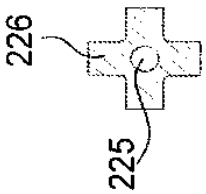


FIG. 9a

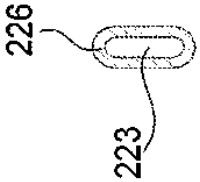


FIG. 9b

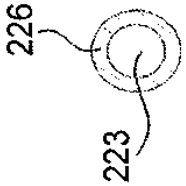


FIG. 9c

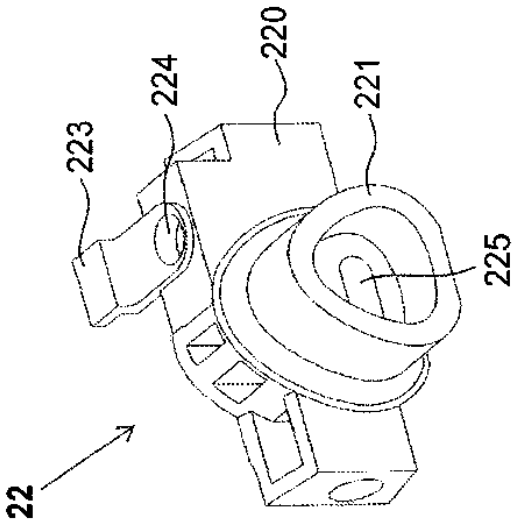


FIG. 7

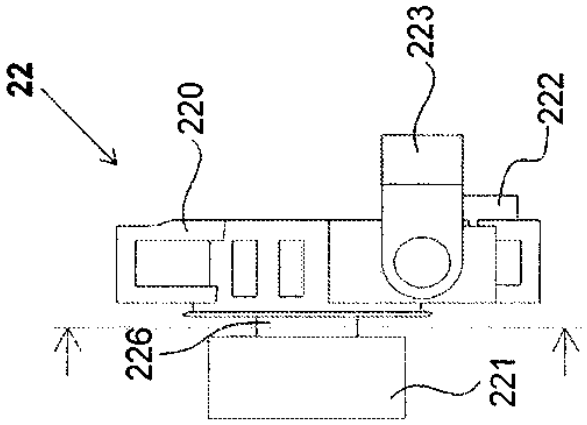


FIG. 8



FIG. 12a



FIG. 12b



FIG. 12c



FIG. 12d

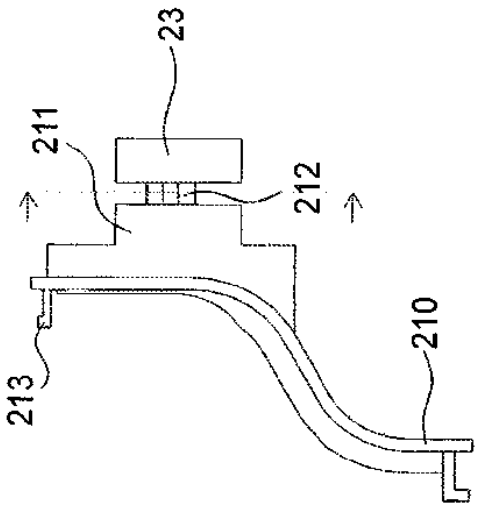


FIG. 11

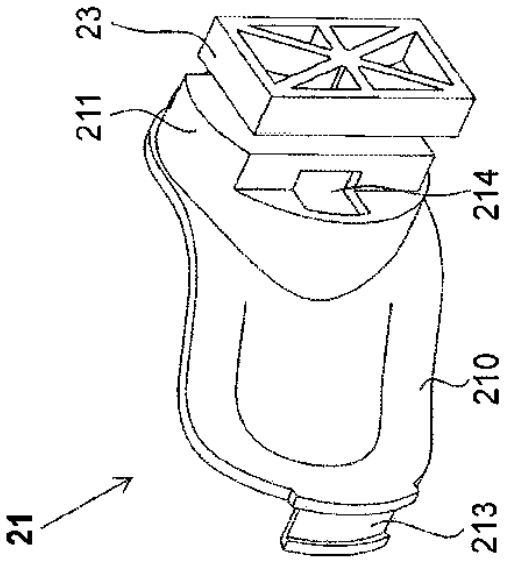


FIG. 10

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EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 17 20 1540

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (IPC)
X	WO 2017/139437 A1 (EXPLORAMED NC7 INC [US]) 17. August 2017 (2017-08-17) * Absätze [0080] - [0083]; Abbildungen 2,6A *	1-14	INV. A61M1/00
X	US 2015/025482 A1 (BEGIN MILES [US] ET AL) 22. Januar 2015 (2015-01-22) * Absätze [0044] - [0049]; Abbildung 2E *	1-14	
X	WO 2009/047524 A2 (TALLEY GROUP LTD [GB]; BYBORDI FARHAD [US]) 16. April 2009 (2009-04-16) * Seite 9, Zeilen 3-29; Abbildung 2B *	1-14	
X	WO 2016/103031 A1 (SMITH & NEPHEW [GB]) 30. Juni 2016 (2016-06-30) * Absätze [0155], [0211]; Abbildungen 13-14, 20 *	15	

RECHERCHIERTE SACHGEBIETE (IPC)

A61M

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
Den Haag	18. Juni 2018	Westsson, David

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
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Siehe Ergänzungsblatt B

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☐ Keine der weiteren Recherchengebühren wurde innerhalb der gesetzten Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für die Teile der Anmeldung erstellt, die sich auf die zuerst in den Patentansprüchen erwähnte Erfindung beziehen, nämlich Patentansprüche:

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1. Ansprüche: 1-14

Motorbetriebene medizinische Saugpumpe mit einem Pumpaggregat zur Erzeugung eines Unterdrucks, mit einem Pumpaggregatträger zur Halterung des Pumpaggregats und mit einer Aufnahme zur Aufnahme eines Energiespeichers, wobei das im Pumpaggregatträger angeordnete Pumpaggregat eine erste Längsachse (L) definiert und die Aufnahme eine zweite Längsachse (L2) definiert,dadurch gekennzeichnet, dassder Pumpaggregatträger die Aufnahme bildet und dass die zweite Längsachse (L2) in einem Winkel zur ersten Längsachse (L]) verläuft.

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2. Anspruch: 15

Medizinische Saugpumpe mit einem Pumpengehäuse, mit einem im Pumpengehäuse angeordneten Pumpaggregat zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager und einem zweiten elastischen Lager zur Lagerung des Pumpaggregats im Pumpengehäuse, wobei das erste elastische Lager sich an einem ersten Ende des Pumpaggregats befindet und das zweite elastische Lager sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats befindet,dadurch gekennzeichnet, dassdas erste elastische Lager einen Vakuumanschluss bildet.

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3. Anspruch: 15

Medizinische Saugpumpe mit einem Pumpengehäuse, mit einem im Pumpengehäuse angeordneten Pumpaggregat zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager und einem zweiten elastischen Lager zur Lagerung des Pumpaggregats im Pumpengehäuse, wobei das erste elastische Lager sich an einem ersten Ende des Pumpaggregats befindet und das zweite elastische Lager sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats befindet,dadurch gekennzeichnet, dassdas erste elastische Lager einen Vakuumanschluss bildet.

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4. Anspruch: 16

Medizinische Saugpumpe mit einem Pumpaggregat, einem Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und mit einem Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses,dadurch gekennzeichnet, dassdas Schalldämpfungsgehäuse ein Etui zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel aufweist, wobei der Deckel elastisch ausgebildet ist und ein

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Nummer der Anmeldung
EP 17 20 1540

Nach Auffassung der Recherchenabteilung entspricht die vorliegende europäische Patentanmeldung nicht den Anforderungen an die Einheitlichkeit der Erfindung und enthält mehrere Erfindungen oder Gruppen von Erfindungen, nämlich:

elastisches Lager zur Lagerung des Schalldämpfungsgehäuses im Pumpengehäuse aufweist.

---

5. Anspruch: 17

Medizinische Saugpumpe mit einem Pumpaggregat, einem Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und mit einem Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses,dadurch gekennzeichnet, dassmindestens ein erstes und ein zweites elastisches Lager vorhanden sind, wobei mindestens eines dieser zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse lagert und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses lagert.

ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR. EP 17 20 1540

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

18-06-2018

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
WO 2017139437 A1	17-08-2017	KEINE	
US 2015025482 A1	22-01-2015	US 2015025482 A1	22-01-2015
		US 2017348469 A1	07-12-2017
WO 2009047524 A2	16-04-2009	KEINE	
WO 2016103031 A1	30-06-2016	AU 2015370582 A1	15-06-2017
		AU 2015370583 A1	15-06-2017
		AU 2015370584 A1	15-06-2017
		AU 2015370586 A1	15-06-2017
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		CA 2971796 A1	30-06-2016
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		CA 2971799 A1	30-06-2016
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		CN 107708758 A	16-02-2018
		EP 3236902 A2	01-11-2017
		EP 3237030 A1	01-11-2017
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		SG 11201704250T A	28-07-2017
		SG 11201704253V A	28-07-2017
		SG 11201704254X A	28-07-2017
		SG 11201704255W A	28-07-2017
		US 2017368239 A1	28-12-2017
		US 2018133378 A1	17-05-2018
		WO 2016103031 A1	30-06-2016
		WO 2016103032 A1	30-06-2016
		WO 2016103033 A2	30-06-2016
		WO 2016103035 A2	30-06-2016

EPO FORM P0461

Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

IN DER BESCHREIBUNG AUFGEFÜHRTE DOKUMENTE

Diese Liste der vom Anmelder aufgeführten Dokumente wurde ausschließlich zur Information des Lesers aufgenommen und ist nicht Bestandteil des europäischen Patentdokumentes. Sie wurde mit größter Sorgfalt zusammengestellt; das EPA übernimmt jedoch keinerlei Haftung für etwaige Fehler oder Auslassungen.

In der Beschreibung aufgeführte Patentdokumente

- WO 2006032156 A1 **[0002] [0048]**
- WO 2017157691 A1 **[0004]**
- WO 2015109934 A1 **[0005]**
- WO 2017140562 A1 **[0006]**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

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This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

A concise explanation of the relevance of the non-English language document(s) appears below in accordance with 37 C.F.R. § 1.98(a)(3).

Document **US6** (2020/0300237 A1) is submitted herewith as the English-language counterpart of document **FP1** (EP 3482782 A1).

A copy of document **FP1** is submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: May 15, 2023

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20260440.1

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**05/15/2023 03:27:41 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62088330	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-05-15-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-05-15-sIDS-Pleading-4944-0120006.pdf	3	Transmittal Letter	100 KB
2023-05-15-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	147 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_EP3482782A1.pdf	21	Foreign Reference	442 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-05-15-Transmittal-Form-sIDS-4944-0120006.pdf	F0C4DDBAE8E49C2EC106418E9E2150D705E82025A01C7AF8F616FAB4E5FE746B9732D8F408D760356DD627385F01A15A981570FF9160D9DBD7A75D6FB33DD89F
2023-05-15-sIDS-Pleading-4944-0120006.pdf	A4CA1114BD069621DF3F359B9F2D4DDE9E6F2AC05793A27D00C7C014D4B9ACF67B9688923A566F1B01130FC6BD7FD83A96B9508EA333F1E16A25929D7BD57224
2023-05-15-sIDS-Form-SB08-4944-0120006.pdf	15FEC9EE4BCEC7CFB4164C440BA5A1569F55FE22487FE695BA511C59D69167C785AD43EC91D8A66DDC17706AAFEBF1057461A3E4ABF20865AAE3B7777FFEF740
FOR_1_EP3482782A1.pdf	0A4794FB75138AF6B1F20955E40340F7D8470ADA20062553DF4C0F08FF07D8C66A0E17A8A211AB8592F5D46EFC71AE7573646AD8E14ABA1BF7CA3E1FD42142A9

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 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.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2002/0062103 A1	05-23-2002	Larsson et al.	
	US2	2008/0009815 A1	01-10-2008	Grabenkort et al.	
	US3	2015/0314053 A1	11-05-2015	Furrer et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	2	of	3	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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.

☒ 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	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-04-20
Name/Print	Richard D. Coller III	Registration Number	60,390

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 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**04/20/2023 04:08:22 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	61955806	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Richard Coller

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-04-20-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	160 KB
2023-04-20-sIDS-Pleading-4944-0120006.pdf	2	Transmittal Letter	112 KB
2023-04-20-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	146 KB

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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-04-20-Transmittal-Form-sIDS-4944-0120006.pdf	D4933E5E447819C7BB67851D70E380B09815BAC1C0301E0281 D3BD955EE1185F7A1F2EE619BDF067358DCB869A6D26F37C0 F1375948880B64EBC0711C4BBB6A3
2023-04-20-sIDS-Pleading-4944-0120006.pdf	0A219C2D41BC79F1BE81840ACC1903037F0AC1762BA300976 84D680A64405A3D8C9D337B2F5B5E01F09751450DC05DBA19 17C7898287CCE81CEB4F52F477531C
2023-04-20-sIDS-Form-SB08-4944-0120006.pdf	E6481901DF45F7ECA7CF0FDF46AB3516A376C0C688D6F619E 63D010B23F07A84A300E0535383C9E38D48FD5CC4AE006FFD F815B8DCCE7B9229F91BF3368F831A

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

Total Number of Pages in This Submission

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.

Online Credit Card Payment Authorization in the Amount of $104.00 to Cover:
$104.00 - Information Disclosure Statement fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Richard D. Coller III/		
Printed name	Richard D. Coller III		
Date	April 20, 2023	Reg. No.	60,390

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:

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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.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
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Commissioner:

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Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

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The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Richard D. Coller III
Attorney for Applicant
Registration No. 60,390

Date: April 20, 2023

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

20127596.1

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	04/20/2023 04:08:22 PM ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	61955806	AUTHORIZED BY	Richard Coller
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1008	E20234JG10346942	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	$104.00

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
03/30/2023	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):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	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 26January2023.

☐ 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) 1,3-22,24-25 and 28-34 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) 1,3-22,24-25 and 28-34 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 22February2021 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 January 26, 2023 has been entered.

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 January 26, 2023. As directed by the amendment: claims 1, 16, and 34 have been amended. Thus, claims 1, 3-22, 24, 25, and 28-34 are presently pending in this application.

Applicant's amendments to the Specification, Drawings, and Claims have overcome each and every objection previously set forth in the Final Office Action mailed October 26, 2022.

Response to Arguments

Applicant's arguments, see pg. 8, filed January 26, 2023, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim should be amended to recite "to define a spacing..." in the second to last line to provide antecedent basis for the claim terminology. Appropriate correction is required.

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, 3-22, 24, 25, and 28-34 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 applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Regarding claim 1, the claim was amended to include a guide line which is configured to define the spacing of the nipple from the side of the wall of the nipple tunnel. It is unclear, in light of the specification, how a singular guide line would be able

to perform this function as it appears that two guide lines would be required to perform the function. With a singular guide line, the shield can be rotated 360° so that the guide line can be located anywhere relative to the nipple and would not be able to perform the function.

Further regarding claim 1, it is unclear how the guide line defines the spacing of the nipple from the side wall of the nipple tunnel. It appears that a spacing (even if the spacing is zero) would inherently exist in every combination of nipple and nipple tunnel. A review of Applicant's specification shows that the guide line(s) are configured to define the correct spacing of the nipple from the side wall of the nipple tunnel (paragraph 452 of the published application). For examination purposes, this interpretation was used.

Regarding claim 32, the claim is drawn to "fit lines" and is dependent on claim 1 which was amended to include a "guide line". It is unclear if the fit lines are a part of the guide line or if the fit lines are separate from the guide line. For examination purposes, the fit lines are considered the same/a part of the guide line of claim 1.

Claims 3-22, 24, 25, 28-31, 33, and 34 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 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.

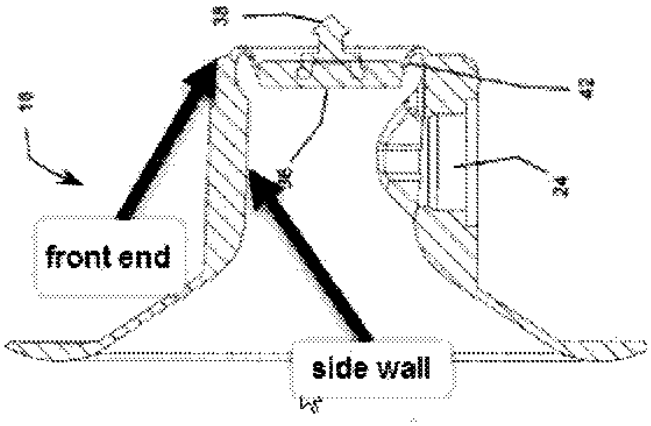
Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640) and in further view of Silver (US 20020198489).

Regarding claim 1, Myers discloses a breast pump device comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig.

5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

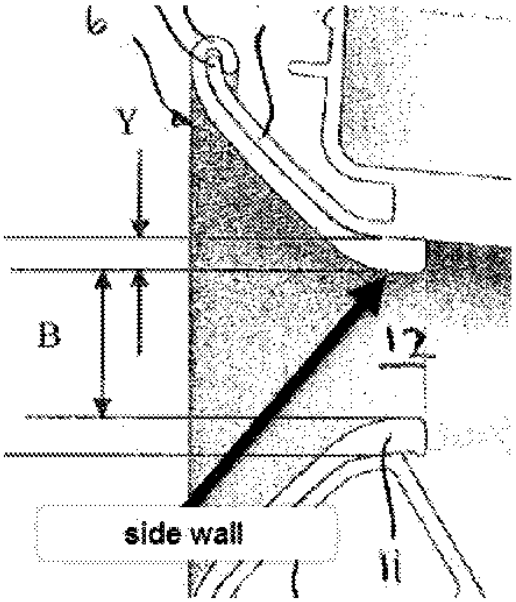


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each of the plurality of interchangeable breast shields having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple

tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in

fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Silver discloses the guide line configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1160 as longitudinal lines).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1160, 1164, and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

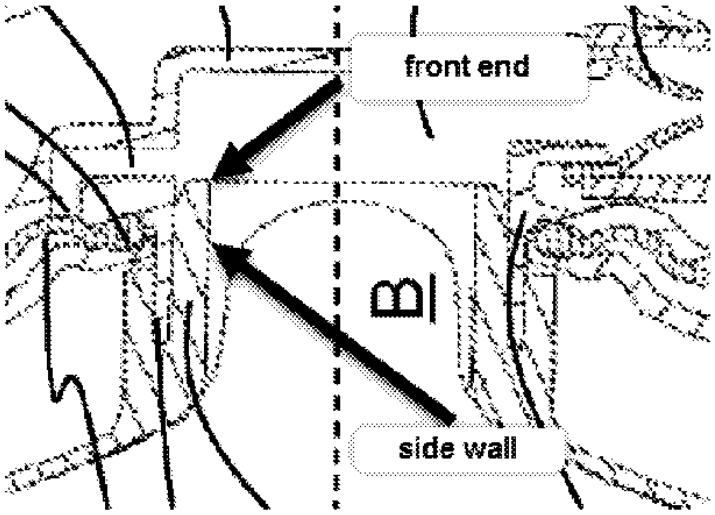
Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 6-10, 14, 17-18, 20-22, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook and in further view of Silver.

Regarding claim 1, Khalil discloses a breast pump device comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



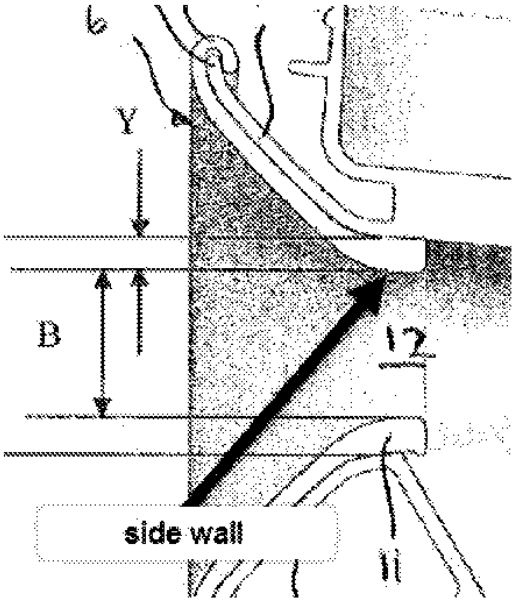
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill

before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



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 shield to be of a plurality

of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Khalil to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 16, in the modified device of Khalil, Silver discloses the guide line is configured to run parallel along one or more sides of the nipple tunnel (fig. 28).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Khalil teaches each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1160, 1164, and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be

made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a

corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a

piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a

lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). 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 be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of

modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook, Silver, and the teachings below (see table).

- **17203050 (US Patent 11357893)**
- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of

interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to

provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches

that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**
- **17203384**
- **17203397**

- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. 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 shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). 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 shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center,

visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	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-20020198489-A1	12-2002	Silver, Brian H.	A61M1/066	119/14.47
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	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 SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf

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

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	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	01/12/2022	10/17/2022	03/24/2023						
	1	✓	✓	✓						
	2	✓	-	-						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	✓						
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	25	✓	✓	✓						
	26	-	-	-						
	27	-	-	-						
	28	✓	✓	✓						
	29	✓	✓	✓						
	30	✓	✓	✓						
	31	✓	✓	✓						
	32	✓	✓	✓						
	33	✓	✓	✓						
	34		✓	✓						

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	1	494	4

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2012/0109083 A1	05-03-2012	Coulthard et al.	
	US2	2016/0135998 A1	05-19-2016	Riesinger	
	US3	2014/0142501 A1	05-22-2014	Clark et al.	
	US4	2018/0104396 A1	04-19-2018	Park	
	US5	10,864,306 B2	12-15-2020	Fujisaki	
	US6	5,406,063 A	04-11-1995	Jelen	
	US7	2005/0245860 A1	11-03-2005	Britto et al.	
	US8	2007/0236584 A1	10-11-2007	Frost-Ruebling et al.	
	US9	2018/0008758 A1	01-11-2018	Garbez et al.	
	US10	2008/0299517 A1	12-04-2008	Delaney, II	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2013-545519 A	12-26-2013	KCI Licensing, Inc.		X
	FP2	JP 2016-524490 A	08-18-2016	BSN Medical GmbH		X
	FP3	WO 2013/064852 A1	05-10-2013	Smith & Nephew PLC		
	FP4	JP 2014-532498 A	12-08-2014	Smith & Nephew PLC		X
	FP5	WO 2016/006458 A1	01-14-2016	Murata Manufacturing Co., Ltd.		X
	FP6	JP H 11-178917 A	07-06-1999	Hirose Electric Co., Ltd.		X
	FP7	JP 2000-350527 A	12-19-2000	Pigeon Corp.		X
	FP8	WO 2016/007561 A1	01-14-2016	Naya Health Inc.		
	FP9	WO 2016/025405 A1	02-18-2016	Barral et al.		
	FP10	WO 2004/108184 A2	12-16-2004	Playtex Products, Inc.		
	FP11	JP 2016-526396 A	09-05-2016	Koninklijke Philips NV		X

Examiner Signature		Date Considered	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP12	WO 2014/160614 A1	10-02-2014	Naia Health, Inc.		
	FP13	JP 2017-503552 A	02-02-2017	Nestec SA		X

Examiner Signature		Date Considered	

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				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	3	494	4	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	NPL1	International Search Report issued in International Application No. PCT/GB2021/050764, mailed July 6, 2021, 5 pages.	☐
	NPL2	Japanese Search Report issued in Japanese Application No. 2020-519188, mailed June 24, 2022, 20 pages.	☐
	NPL3	Extended European Search Report issued in European Application No. 22174446.9, mailed October 11, 2022; 26 pages.	☐

/COURTNEY B FREDRICKSON/ 03/24/2023

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Sheet	4	494	4

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Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

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.

☐ 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	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name/Print	Richard D. Coller III	Registration Number	60,390

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 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
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L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR					

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L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
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L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936" "20090281485" "20120165729"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/03/24 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	1	494	4

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2012/0109083 A1	05-03-2012	Coulthard et al.	
	US2	2016/0135998 A1	05-19-2016	Riesinger	
	US3	2014/0142501 A1	05-22-2014	Clark et al.	
	US4	2018/0104396 A1	04-19-2018	Park	
	US5	10,864,306 B2	12-15-2020	Fujisaki	
	US6	5,406,063 A	04-11-1995	Jelen	
	US7	2005/0245860 A1	11-03-2005	Britto et al.	
	US8	2007/0236584 A1	10-11-2007	Frost-Ruebling et al.	
	US9	2018/0008758 A1	01-11-2018	Garbez et al.	
	US10	2008/0299517 A1	12-04-2008	Delaney, II	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2013-545519 A	12-26-2013	KCI Licensing, Inc.		X
	FP2	JP 2016-524490 A	08-18-2016	BSN Medical GmbH		X
	FP3	WO 2013/064852 A1	05-10-2013	Smith & Nephew PLC		
	FP4	JP 2014-532498 A	12-08-2014	Smith & Nephew PLC		X
	FP5	WO 2016/006458 A1	01-14-2016	Murata Manufacturing Co., Ltd.		X
	FP6	JP H 11-178917 A	07-06-1999	Hirose Electric Co., Ltd.		X
	FP7	JP 2000-350527 A	12-19-2000	Pigeon Corp.		X
	FP8	WO 2016/007561 A1	01-14-2016	Naya Health Inc.		
	FP9	WO 2016/025405 A1	02-18-2016	Barral et al.		
	FP10	WO 2004/108184 A2	12-16-2004	Playtex Products, Inc.		
	FP11	JP 2016-526396 A	09-05-2016	Koninklijke Philips NV		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	494	4

Complete if Known	
Application Number	17/181,057
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Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP12	WO 2014/160614 A1	10-02-2014	Naia Health, Inc.		
	FP13	JP 2017-503552 A	02-02-2017	Nestec SA		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	3	494	4

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Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	NPL1	International Search Report issued in International Application No. PCT/GB2021/050764, mailed July 6, 2021, 5 pages.	☐
	NPL2	Japanese Search Report issued in Japanese Application No. 2020-519188, mailed June 24, 2022, 20 pages.	☐
	NPL3	Extended European Search Report issued in European Application No. 22174446.9, mailed October 11, 2022; 26 pages.	☐

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	4	494	4

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Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

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.

☐ 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	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name/Print	Richard D. Coller III	Registration Number	60,390

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 CFR1.14. 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.**

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	17/181,057	Filing Date	2021-02-22	Docket Number (if applicable)	4944.0120006	Art Unit	3783
First Named Inventor	Jonathan O'TOOLE			Examiner Name	FREDRICKSON, Courtney B.		

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 _____

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 190036

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	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name	Richard D. Coller III	Registration Number	60390

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.

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2013-545519
(P2013-545519A)
(43)公表日　平成25年12月26日(2013.12.26)

(51)Int.Cl.		F I		テーマコード（参考）
A61M 27/00	***(2006.01)***	A61M	27/00	4C066
A61M 31/00	***(2006.01)***	A61M	31/00	4C167

審査請求 未請求　予備審査請求 未請求　（全 37 頁）

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(86)(22)出願日　平成23年7月15日 (2011.7.15)
(85)翻訳文提出日　平成25年6月12日 (2013.6.12)
(86)国際出願番号　PCT/US2011/044187
(87)国際公開番号　WO2012/057881
(87)国際公開日　平成24年5月3日 (2012.5.3)
(31)優先権主張番号　61/407,194
(32)優先日　平成22年10月27日 (2010.10.27)
(33)優先権主張国　米国 (US)
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(32)優先日　平成23年2月22日 (2011.2.22)
(33)優先権主張国　米国 (US)
(31)優先権主張番号　61/418,730
(32)優先日　平成22年12月1日 (2010.12.1)
(33)優先権主張国　米国 (US)

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特許業務法人北青山インターナショナル
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最終頁に続く

(54)【発明の名称】無線ポンプを使用する減圧システム、ドレッシング、および方法

(57)【要約】
減圧ポンプに無線で電力を供給することを含む、患者の組織部位に減圧をもたらすためのシステム、方法、およびドレッシングが提供される。一例では、ＲＦＩＤアンテナを使用して、導管によって減圧ドレッシングに流体的に結合される減圧ポンプに電力を供給する。別の例では、減圧ドレッシングが、マイクロポンプと、マイクロポンプに電力を供給するために使用されるＲＦＩＤアンテナとを組み込む。他のシステム、方法、および装置が提供される。
【選択図】図１

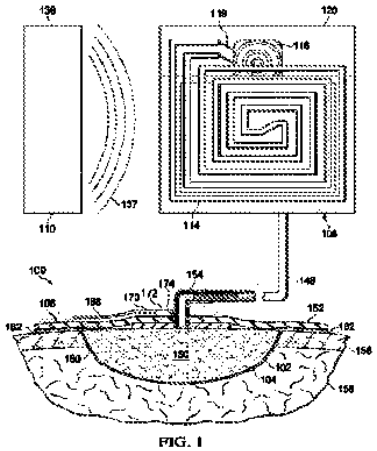


FIG. 1

【特許請求の範囲】
【請求項１】
減圧によって組織部位を治療するシステムにおいて、前記システムが：
前記組織部位に近接して配置される減圧ドレッシングと；
前記減圧ドレッシングに流体的に結合された無線減圧ポンプであって、
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含む無線減圧ポンプと；
ＲＦＩＤリーダを有するベースユニットと；
を含み、
前記ＲＦＩＤリーダが、前記ＲＦＩＤアンテナに電力をもたらし、前記マイクロポンプ装置に電力供給を行うように構成されることを特徴とする、システム。
【請求項２】
請求項１に記載のシステムにおいて、第１のポンプシール部材および第２のポンプシール部材をさらに含み、前記第１のポンプシール部材および前記第２のポンプシール部材が、少なくとも部分的に結合してポンプ用パウチを形成し、そこに前記マイクロポンプ装置が配置されていることを特徴とする、システム。
【請求項３】
請求項１または２に記載のシステムにおいて、前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、システム。
【請求項４】
請求項１～３のいずれか１項に記載のシステムにおいて、前記無線減圧ポンプが、前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置をさらに含むことを特徴とする、システム。
【請求項５】
請求項１～３のいずれか１項に記載のシステムにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記ベースユニットが、前記ＲＦＩＤリーダに結合された第２のプロセッサを含み、および
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成されることを特徴とする、システム。
【請求項６】
請求項１～３のいずれか１項に記載のシステムにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記ベースユニットが、前記ＲＦＩＤリーダに結合された第２のプロセッサを含み、
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成され、
前記第１のプロセッサおよび前記圧力感知装置が、前記圧力問合せ信号に応答して前記圧力メッセージ信号を準備するように構成され、
前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、前記圧力メッセージ信号を送信するように構成され、および
前記第２のプロセッサが、前記圧力メッセージ信号を受信し、制御信号を準備するように構成され、および前記第２のプロセッサおよびＲＦＩＤが、前記無線減圧ポンプに前記

制御信号を送信して、前記マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成されていることを特徴とする、システム。

【請求項７】

請求項１～３のいずれか１項に記載のシステムにおいて、

前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、

前記圧力感知装置が、圧力メッセージ信号を生成するように動作可能であり、および

前記第１のプロセッサが、前記圧力メッセージ信号を受信しかつ制御信号を生成して前記マイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能であることを特徴とする、システム。

【請求項８】

請求項１に記載のシステムにおいて、

前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置と；

第１の分配マニホールドと、

吸収層と、

ダイバータ層と、

ポンプシール部材と、

第２のポンプシール部材と

をさらに含み、

前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、ポンプシール部材および第２のポンプシール部材によって形成されたポンプ用パウチ内に配置され；

前記マイクロポンプ装置が圧電ポンプを含み；

前記減圧ドレッシングが；

前記組織部位に近接して配置されるインターフェース分配マニホールド、

ドレッシングシール部材、および

減圧インターフェース

を含み、および

前記ＲＦＩＤアンテナが前記ベースユニットから５センチメートル未満であることを特徴とする、システム。

【請求項９】

無線減圧ポンプにおいて；

第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と；

ＲＦＩＤアンテナと

前記ＲＦＩＤアンテナに結合された第１のプロセッサと；

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧および正圧を発生させるマイクロポンプ装置と；

前記第１のチャンバに流体的に結合された複数の膨張式支持部材と；

前記第２のチャンバを含む液溜めと

を含み、

前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合されてそこに正圧を排出する通気口と、前記第２のチャンバに流体的に結合されてそこに減圧を供給する流入口とを有することを特徴とする、無線減圧ポンプ。

【請求項１０】

請求項９に記載の無線減圧ポンプにおいて、前記第１のチャンバに流体的に結合された第１の圧力逃がし弁をさらに含み、前記第１の圧力逃がし弁が、第１の閾値圧力を上回る正圧を放出するように動作可能であることを特徴とする、無線減圧ポンプ。

【請求項１１】

請求項９または１０に記載の無線減圧ポンプにおいて、前記第１のチャンバおよび前記第２のチャンバが、ピラミッドの一部分の形状であることを特徴とする、無線減圧ポンプ

。
【請求項１２】
請求項９または１０乃至１１の何れか１項に記載の無線減圧ポンプにおいて、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、無線減圧ポンプ。
【請求項１３】
減圧によって患者の組織部位を治療するシステムの製造方法において、前記方法が：
前記組織部位に近接して配置される減圧ドレッシングを提供するステップと；
無線減圧ポンプを提供するステップであって、前記無線減圧ポンプが：
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含むステップと；
ＲＦＩＤリーダを有するベースユニットを提供するステップと
を含み、
前記ＲＦＩＤリーダが、前記ＲＦＩＤアンテナに電力をもたらし、前記マイクロポンプ装置に電力供給を行うように構成されていることを特徴とする、方法。
【請求項１４】
請求項１３に記載の製造方法において、第１のポンプシール部材および第２のポンプシール部材をさらに含み、前記第１のポンプシール部材および第２のポンプシールが、少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成することを特徴とする、方法。
【請求項１５】
請求項１３に記載の製造方法において、前記無線減圧ポンプを前記減圧ドレッシングに流体的に結合する減圧導管を設けるステップをさらに含むことを特徴とする、方法。
【請求項１６】
請求項１３に記載の製造方法において、圧力感知装置を提供するステップと、前記圧力感知装置を前記減圧ドレッシングに結合するステップとをさらに含むことを特徴とする、方法。
【請求項１７】
減圧によって患者の組織部位を治療する方法において、
前記組織部位に近接して減圧ドレッシングを配置するステップと；
無線減圧ポンプを提供するステップであって、前記無線減圧ポンプが：
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含むステップと；
前記無線減圧ポンプを前記減圧ドレッシングに流体的に結合するステップと；
ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと；
前記ベースユニットを作動させ、それにより、前記ＲＦＩＤリーダおよび前記第２のプロセッサが、前記無線減圧ポンプに作動信号を送信して、前記無線減圧ポンプを作動させるステップと
を含むことを特徴とする、方法。
【請求項１８】
請求項１７に記載の方法において、前記無線減圧ポンプが：
第１のポンプシール部材と；

第２のポンプシール部材であって、前記第１のポンプシール部材および第２のポンプシールが少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成する、第２のポンプシール部材と
をさらに含むことを特徴とする、方法。
【請求項１９】
請求項１７または１８に記載の方法において、前記マイクロポンプ装置が必要とする電力が全て前記ＲＦＩＤリーダによって供給されることを特徴とする、方法。
【請求項２０】
請求項１７または１８乃至１９の何れか１項に記載の方法において、前記ＲＦＩＤリーダを前記無線減圧ポンプの前記ＲＦＩＤアンテナから５センチメートル以内に配置するステップをさらに含むことを特徴とする、方法。
【請求項２１】
請求項１８に記載の方法において、
前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されておらず；
前記無線減圧ポンプが：
前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置、
第１の分配マニホールド、
吸収層、
ダイバータ層
をさらに含み、
前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、前記第１のポンプシール部材および前記第２のポンプシール部材によって形成された前記ポンプ用パウチ内に配置され、および
前記マイクロポンプ装置が圧電ポンプを含み；および
前記減圧ドレッシングが：
前記組織部位に近接して配置されるインターフェース分配マニホールド、
ドレッシングシール部材、および
減圧インターフェース
を含むことを特徴とする、方法。
【請求項２２】
減圧によって組織部位を治療する減圧システムにおいて、前記減圧システムが：
無線減圧ドレッシングであって：
前記組織部位に近接して配置されるインターフェース分配マニホールド、
前記インターフェース分配マニホールドから流体を受け取って保持する吸収部材、
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置であって、流入口および排出口を有するマイクロポンプ装置、
前記組織部位を覆って密閉空間を形成する第１のシール部材、および
前記マイクロポンプ装置の前記排出口を外部に流体的に結合する通気口；
を含み、前記マイクロポンプが前記密閉空間に流体的に結合されて、そこに減圧を供給する、無線減圧ドレッシングと；
ＲＦＩＤリーダを含むベースユニットであって、無線減圧ドレッシングにポンプ信号を供給して前記マイクロポンプ装置を付勢するように動作可能なベースユニットと
を含むことを特徴とする、減圧システム。
【請求項２３】
請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサは前記第１のプロセッサに結合され、前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、圧力問合せ信号を受信しかつ圧力メッセージ信

号を生成し、それを前記ベースユニットに送信するように動作可能であることを特徴とする、システム。

【請求項２４】

請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサが前記第１のプロセッサに結合され、前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してそれを前記ベースユニットに送信するように動作可能であり、前記ベースユニットが第２のプロセッサをさらに含み、前記第２のプロセッサが、前記圧力メッセージ信号を受信しかつポンプ制御信号を生成するように動作可能であることを特徴とする、システム。

【請求項２５】

請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサは前記第１のプロセッサに結合され、および前記第１のプロセッサは、前記第１の圧力センサから圧力メッセージ信号を受信しかつ制御信号を生成して前記マイクロポンプ装置を制御するように構成されることを特徴とする、システム。

【請求項２６】

請求項２２に記載されたシステムにおいて、前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されておらず、および前記減圧ドレッシングに供給される減圧のみが前記マイクロポンプ装置からのものであることを特徴とする、システム。

【請求項２７】

請求項２２または２３乃至２６の何れか１項に記載のシステムにおいて、前記無線減圧ドレッシングには導管もワイヤも結合されていないことを特徴とする、システム。

【請求項２８】

減圧によって患者の組織部位を治療する方法において、

前記組織部位に近接して無線減圧ドレッシングを配置するステップであって、前記無線減圧ドレッシングが：

前記組織部位に近接して配置されるインターフェース分配マニホールド、

前記インターフェース分配マニホールドから流体を受け取って保持する吸収部材、

ＲＦＩＤアンテナ、

前記ＲＦＩＤアンテナに結合された第１のプロセッサ、

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させ、かつ流入口および排出口を有するマイクロポンプ装置、

前記組織部位を覆いかつ密閉空間を形成する第１のシール部材、および

前記排出口を外部に流体的に結合する通気口

を含むステップと；

ＲＦＩＤリーダを含むベースユニットを提供するステップであって、前記ベースユニットが、前記無線減圧ドレッシングにポンプ信号を供給して前記マイクロポンプ装置を付勢するように構成されているステップと；

前記ベースユニットを作動して前記無線減圧ドレッシングに前記ポンプ信号を供給するステップと

を含むことを特徴とする、方法。

【請求項２９】

無線減圧ポンプにおいて、

ＲＦＩＤアンテナと；

前記ＲＦＩＤアンテナに結合された第１のプロセッサと；

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と

を含むことを特徴とする、無線減圧ポンプ。

【請求項３０】

請求項２９に記載の無線減圧ポンプにおいて、前記マイクロポンプ装置に流体的に結合された液溜めをさらに含むことを特徴とする、無線減圧ポンプ。
【請求項３１】
請求項２９または３０に記載の無線減圧ポンプにおいて、
第１のポンプシール部材と；
第２のポンプシール部材であって、前記第１のポンプシール部材および第２のポンプシールが、少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成する、第２のポンプシール部材と
をさらに含むことを特徴とする、無線減圧ポンプ。
【請求項３２】
請求項２９～３１のいずれか１項に記載の無線減圧ポンプにおいて、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、無線減圧ポンプ。
【請求項３３】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置をさらに含むことを特徴とする、無線減圧ポンプ。
【請求項３４】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み；
前記ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットをさらに含み；および
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成されていることを特徴とする、無線減圧ポンプ。
【請求項３５】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットをさらに含み、
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成され、
前記第１のプロセッサおよび前記圧力感知装置が、前記圧力問合せ信号に応答して前記圧力メッセージ信号を準備するように構成され、
前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、前記圧力メッセージ信号を送信するように構成され、および
前記第２のプロセッサが、前記圧力メッセージ信号を受信し、制御信号を準備するように構成され、および前記第２のプロセッサおよびＲＦＩＤが、前記無線減圧ポンプに前記制御信号を送信して、前記マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成されていることを特徴とする、無線減圧ポンプ。
【請求項３６】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記圧力感知装置が、圧力メッセージ信号を生成するように動作可能であり、および
前記第１のプロセッサが、前記圧力メッセージ信号を受信しかつ制御信号を生成して、前記マイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能であることを特徴とする、無線減圧ポンプ。

【請求項３７】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、前記無線減圧ポンプが：
第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と、
前記第１のチャンバに流体的に結合された第１の圧力逃がし弁であって、第１の閾値圧力を上回る正圧を放出するように動作可能である第１の圧力逃がし弁と、
前記第１のチャンバに流体的に結合された複数の膨張式支持部材と
をさらに含み、
前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合されて、そこに正圧を供給する通気口と、前記第２のチャンバに流体的に結合されて、そこに減圧を供給する流入口とを有し、
前記液溜めが前記第２のチャンバを含むことを特徴とする、無線減圧ポンプ。
【請求項３８】
請求項２９または３０に記載の無線減圧ポンプにおいて、前記無線減圧ポンプが：
ピラミッドの一部分の形状である第１のチャンバおよび第２のチャンバと；
前記第１のチャンバに流体的に結合された第１の圧力逃がし弁であって、第１の閾値圧力を上回る正圧を放出するように動作可能である第１の圧力逃がし弁と；
前記第１のチャンバに流体的に結合された複数の膨張式支持部材と；
をさらに含み、
前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合された通気口を有し；
前記液溜めが前記第２のチャンバを含むことを特徴とする、無線減圧ポンプ。
【請求項３９】
請求項２９または３０に記載の無線減圧ポンプにおいて、
前記無線減圧ポンプには前記ＲＦＩＤアンテナ以外の動力源が設置されておらず；
前記無線減圧ポンプが：
前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置、
第１の分配マニホールド、
吸収層、
ダイバータ層
をさらに含み、
前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、前記第１のポンプシール部材および前記第２のポンプシール部材によって形成された前記ポンプ用パウチ内に配置され；
前記マイクロポンプ装置が圧電ポンプを含み；
前記減圧ドレッシングが：
前記組織部位に近接して配置されているインターフェース分配マニホールド、
ドレッシングシール部材、および
減圧インターフェース
を含み；
前記ＲＦＩＤアンテナが、前記ベースユニットから約５センチメートル未満にあり；および
減圧導管が減圧インターフェースを前記無線減圧ポンプに流体的に結合していることを特徴とする、無線減圧ポンプ。
【発明の詳細な説明】
【技術分野】
【０００１】
関連出願の相互参照
本発明は、３５ＵＳＣ§１１９（ｅ）下において、２０１０年１０月２７日出願の米国仮特許出願第６１／４０７，１９４号（「Ｓｙｓｔｅｍ ａｎｄ Ｍｅｔｈｏｄｓ Ｆｏ

r Electrically Detecting The Presence of Exudate In Reduced－Pressure Dressings」（あらゆる目的のために本願明細書に援用する）［VAC.0975PRO1］；2010年12月1日出願の米国仮特許出願第61／418，730号（「Systems and Methods for Electrically Detecting the Presence of Exudate in Dressings」（あらゆる目的のために本願明細書に援用する）［VAC.0975PRO2］；2011年2月22日出願の米国仮特許出願第61／445，383号（「Interactive，Wireless Reduced－Pressure Dressings，Methods，and Systems」（あらゆる目的のために本願明細書に援用する）［VAC.0999PRO］；および2011年2月22日出願の米国仮特許出願第61／445，338号（「Reduced－Pressure Systems，Dressings，and Methods Employing a Wireless Pump」（あらゆる目的のために本願明細書に援用する）［VAC.1000PRO］の利益を主張する。

【0002】

本開示は、概して治療システムに関し、より詳細には、限定するものではないが、組織部位に減圧を行うポンプに無線で電力を供給することを含むシステム、ドレッシング、および方法に関する。

【背景技術】

【0003】

臨床試験および実習において、組織部位に近接して減圧をもたらすことによって、組織部位における新しい組織の増殖を増強および加速することが示されている。この現象の適用例は多数あるが、減圧を行うことは、創傷の治療においてかなり成功している。この治療（医学界では「陰圧閉鎖療法」、「減圧療法」、または「真空療法」と呼ばれることが多い）は、いくつもの利点を提供し、それら利点には、迅速な治癒、および肉芽組織の形成加速化が含まれ得る。一般に、減圧は、開放創に行われるとき、多孔質パッドまたは他のマニホールド装置を通して組織に行われる。多孔質パッドは、減圧を組織に分配し、および組織から引き出された流体を送る。減圧はまた、腹腔などの体洞から流体を除去するのにも使用し得る。

【発明の概要】

【0004】

例示的実施形態によれば、減圧によって組織部位を治療するシステムは、組織部位に近接して配置される減圧ドレッシングと、減圧ドレッシングに流体的に結合された無線減圧ポンプとを含む。無線減圧ポンプは、無線周波数認証（RFID：Radio Frequency Identification）アンテナと、RFIDアンテナに結合された第1のプロセッサと、電力を受信しかつ減圧を発生させるためにプロセッサに結合されたマイクロポンプ装置と、第1のポンプシール部材と、液溜めと、第2のポンプシール部材とを含む。第1のポンプシール部材および第2のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを形成する。このシステムは、RFIDリーダを有するベースユニットをさらに含む。RFIDリーダは、RFIDアンテナに電力をもたらし、マイクロポンプに電力供給を行うように構成される。

【0005】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療するシステムの製造方法は、組織部位に近接して配置される減圧ドレッシングを提供するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは、RFIDアンテナと、RFIDアンテナに結合された第1のプロセッサと、電力を受信しかつ減圧を発生させるために第1のプロセッサに結合されたマイクロポンプ装置と、第1のポンプシール部材と、液溜めと、第2のポンプシール部材とを含む。第1のポンプシール部材および第2のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを

形成する。この方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合するために減圧供給導管を設けるステップをさらに含み得る。この方法は、ＲＦＩＤリーダを有するベースユニットを提供するステップをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプに電力供給を行うように構成される。

【０００６】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して減圧ドレッシングを配置するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、電力を受信しかつ減圧を発生させるためにプロセッサに結合されたマイクロポンプ装置と、第１のポンプシール部材と、液溜めと、第２のポンプシール部材とを含む。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを形成する。この方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合するステップと、ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと、ベースユニットを作動させ、それにより、ＲＦＩＤリーダおよび第２のプロセッサが、無線減圧ポンプに作動信号を送信して、無線減圧ポンプを作動させるステップとをさらに含む。

【０００７】

別の例示的実施形態によれば、減圧によって組織部位を治療する減圧システムが、減圧ドレッシングを含む。減圧ドレッシングは、組織部位に近接して配置される第１の分配マニホールドと、第１の分配マニホールドから流体を受け取って保持する吸収層と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されて、そこから電力を受信しかつ減圧を発生させるマイクロポンプとを含む。マイクロポンプは流入口および排出口を有する。このシステムはまた、組織部位およびマイクロポンプの上側を覆って密閉空間を形成する第１のシール部材と、マイクロポンプの排出口を外部に流体的に結合する通気口とを含む。このシステムは、ＲＦＩＤリーダを含むベースユニットをさらに含む。ベースユニットは、減圧ドレッシングにポンプ信号を供給してマイクロポンプを付勢するように動作可能である。

【０００８】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法が、組織部位に近接して無線減圧ドレッシングを配置するステップを含む。無線減圧ドレッシングは、組織部位に近接して配置される第１の分配マニホールドと、第１の分配マニホールドから流体を受け取って保持する吸収層と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されて、そこから電力を受信しかつ減圧を発生させるマイクロポンプとを含む。マイクロポンプは、流入口および排出口と、組織部位およびマイクロポンプの上側を覆って密閉空間を形成する第１のシール部材と、マイクロポンプの排出口を外部に流体的に結合する通気口とを有する。この方法は、ＲＦＩＤリーダを含むベースユニットを提供するステップをさらに含む。ベースユニットは、無線減圧ドレッシングにポンプ信号を供給してマイクロポンプを付勢するように動作可能である。この方法はまた、ベースユニットを作動させて無線減圧ドレッシングにポンプ信号を供給するステップを含む。

【０００９】

例示的実施形態の他の特徴、および利点は、以下の図面および詳細な説明を参照することにより明らかとなる。

【図面の簡単な説明】

【００１０】

【図１】図１は、減圧によって組織部位を治療するシステムの例示的実施形態の一部分を断面で示す概略図である。

【図２】図２は、図１のシステムの一部として使用される無線減圧ポンプの例示的実施形態の概略的な分解斜視図である。

【図３】図３は、追加的な態様およびいくつかの代替例を示す図１のシステムの一部分を

断面で示す概略図である。
【図４】図４は、無線減圧ポンプの例示的実施形態の概略的な部分断面図である。
【図５】図５は、図１にあるような減圧によって組織部位を治療するシステムの一部として使用するマイクロポンプ装置の例示的一実施形態の概略的な断面図である。
【図６】図６は、無線減圧ポンプの例示的実施形態の概略的な斜視図である。
【図７】図７は、無線減圧ポンプの別の例示的実施形態の概略的な断面図である。
【図８】図８は、図７の無線減圧ポンプの概略的な斜視図である。
【図９】図９は、減圧によって組織部位を治療する減圧システムの例示的実施形態の一部分を斜視図で示す概略図である。
【図１０】図１０は、線１０－１０に沿って取った図９に示す減圧ドレッシングの概略的な断面図である。
【図１１】図１１は、図９～１０の減圧ドレッシングの概略的な分解斜視図である。
【図１２】図１２は、減圧によって組織部位を治療するシステムの例示的実施形態の概略的な断面図である。
【図１３】図１３は、減圧ドレッシングの別の例示的実施形態の概略的な分解斜視図である。
【発明を実施するための形態】
【００１１】
以下の例示的非限定的な実施形態の詳細な説明において、本明細書の一部をなす添付図面を参照する。これらの実施形態は、当業者が本発明を実施できるようにするのに十分な程度、詳細に説明し、および、本発明の趣旨または範囲から逸脱せずに、他の実施形態を使用し得ること、および論理的な構造上の、機械的な、電気的なおよび化学的な変更がなされ得ることが理解される。当業者が、本明細書で説明する実施形態を実施できるようにするのに必要ではない詳細を避けるために、説明では、当業者に公知の特定の情報を省略し得る。以下の詳細な説明は、限定的ととられるべきではなく、例示的実施形態の範囲は、添付の特許請求の範囲によってのみ定義される。
【００１２】
本明細書の例示的実施形態は、無線周波数認証（ＲＦＩＤ）または高性能タイプ（ｅｎｈａｎｃｅｄ　ｔｙｐｅ）の無線周波数認証（ＲＦＩＤ）技術を使用して、減圧ドレッシングにあるマイクロポンプ装置を付勢することを含む。ＲＦＩＤは、伝統的に、標的上にあるＲＦＩＤタグまたはラベルと、ＲＦＩＤタグを付勢してそこからの信号を読み取るＲＦＩＤリーダとを使用する。１つの一般的な例は料金タグである。ほとんどのＲＦＩＤタグは、情報を記憶しかつ処理する集積回路と、変調器と、復調器とを含む。ＲＦＩＤタグは、パッシブタグ、アクティブＲＦＩＤタグ、およびバッテリー付きパッシブタグとし得る。一般的に、パッシブタグは、バッテリーを使用せず、かつ、ＲＦＩＤリーダによって付勢されない限り、情報を送信しない。アクティブタグは搭載バッテリーを有して、自律的に（すなわち、ＲＦＩＤリーダによって付勢されずに）送信できる。バッテリー付きパッシブタグは、一般に、ＲＦＩＤリーダが存在することで起動される小型のバッテリーが搭載されている。ＲＦＩＤタグの性能を高めるために、減圧ドレッシングにマイクロコントローラおよびセンサが組み込まれてもよい。ＲＦＩＤタグ、マイクロコントローラおよびセンサは、感知機能、および任意選択的なコンピュータによる機能を可能にする。さらに、ＲＦＩＤタグおよびマイクロコントローラは、部分的にまたは完全にマイクロポンプに電力を供給する。
【００１３】
例示的一実施形態では、高性能ＲＦＩＤ技術は、ＷＩＳＰ（Ｗｉｒｅｌｅｓｓ　Ｉｄｅｎｔｉｆｉｃａｔｉｏｎ　ａｎｄ　Ｓｅｎｓｉｎｇ　Ｐｌａｔｆｏｒｍ）装置である。ＷＩＳＰは、ＲＦＩＤタグ（またはラベル）と似て、ＲＦＩＤリーダを用いてＷＩＳＰ装置に電力を供給しかつそれを読み取ることを含む。ＷＩＳＰ装置は、ＲＦＩＤリーダが発した無線信号から電力を得て、かつ感知機能を実行する（および任意選択的にコンピュータによる機能を実行する）。ＷＩＳＰ装置は、情報を備える無線信号をＲＦＩＤリーダに送

信する。ＷＩＳＰ装置はＲＦＩＤリーダから電力を受信する。ＷＩＳＰ装置は、エネルギーを得るタグまたはアンテナと、サンプリングセンサなどの、様々なタスクを実行できるマイクロコントローラ（またはプロセッサ）とを有する。ＷＩＳＰ装置はＲＦＩＤリーダにデータを報告する。例示的一実施形態では、ＷＩＳＰ装置は、電力源（ｐｏｗｅｒ ｈａｒｖｅｓｔｉｎｇ）回路を備える集積回路、復調器、変調器、マイクロコントローラ、センサを含み、かつエネルギーを蓄積するために１つ以上のコンデンサを含んでもよい。ＷＩＳＰ技術の一形態は、Ｉｎｔｅｌ Ｒｅｓｅａｒｃｈ Ｓｅａｔｔｌｅ（ｗｗｗ．ｓｅａｔｔｌｅ．ｉｎｔｅｌ－ｒｅｓｅａｒｃｈ．ｎｅｔ／ｗｉｓｐ／）によって開発された。本明細書では、ＲＦＩＤ装置はＷＩＳＰ装置も含む。

【００１４】

ここで図面、初めに図１～５を参照して、減圧によって組織部位１０２、例えば創傷１０４、または空洞を治療するシステム１００の例示的実施形態を説明する。システム１００は、組織部位１０２に近接して配置される減圧ドレッシング１０６；減圧ドレッシング１０６に流体的に結合された無線減圧ポンプ１０８；およびＲＦＩＤリーダ１１２を有するベースユニット１１０を含む。無線減圧ポンプ１０８は、第１のＲＦＩＤアンテナ１１４およびマイクロポンプ装置１１６を含む。ＲＦＩＤリーダ１１２は、第１のＲＦＩＤアンテナ１１４に電力をもたらすポンプ信号を発生させかつ送信するように構成される。第１のＲＦＩＤアンテナ１１４によって受信されたポンプ信号によって、マイクロポンプ装置１１６に電力を供給する。マイクロポンプ装置１１６に遠くから電力供給することによって、いくつもの潜在的利益が提供される。これら利益には、適用が容易であることが含まれ得る。さらに、無線減圧ポンプ１０８は、内蔵型の使い捨てユニットとし得る。図示のシステム１００の潜在的な変形例のいくつかを示すために、図面間でいくらかの違いがあることに留意されたい。

【００１５】

システム１００は、様々な異なるタイプの組織部位１０２で使用し得る。組織部位１０２は、骨組織、脂肪組織、筋組織、皮膚組織、脈管組織、結合組織、軟骨、腱、靭帯、体洞、または任意の他の組織を含む、任意のヒト、動物、または他の生物の体の組織とし得る。組織部位１０２の治療は、流体、例えば滲出液や腹水の除去を含み得る。

【００１６】

無線減圧ポンプ１０８は第１のＲＦＩＤアンテナ１１４を含み、このＲＦＩＤアンテナは、導線１１９によって第１のプロセッサ１１８に結合される。第１のプロセッサ１１８は、マイクロポンプ装置１１６、すなわちマイクロポンプに結合されて、電力を受信する。第１のプロセッサ１１８はマイクロポンプ装置１１６に組み込まれてもよい。第１のプロセッサ１１８およびマイクロポンプ装置１１６は、ポンプ用パウチ１２０内に配置され得る。

【００１７】

ポンプ用パウチ１２０は、第１のポンプシール部材１２２を第２のポンプシール部材１２４に結合するように形成し得る。ポンプ用パウチ１２０はまた、ポリマーからポンプ用パウチ１２０を注入成形するなど、他の技術によって形成してもよい。ポンプ用パウチ１２０の少なくとも一部分は、組織部位１０２から流体１２７を受け取って保持する液溜め１２６を含む。マイクロポンプ装置１１６は、圧電ポンプ、蠕動ポンプ、または最小限の所要電力で減圧を生じさせる他の小型ポンプとし得る。第１のプロセッサ１１８は、圧力感知装置１３８から圧力メッセージ信号を受信するように動作可能である。圧力メッセージ信号の受信に応答して、第１のプロセッサ１１８は制御信号を生成して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させる。圧力感知装置１３８は、変換器としてもよいし、または十分な減圧が存在すると作動される単純なスイッチとしてもよい。

【００１８】

主に図３を参照して説明すると、ベースユニット１１０は、ＲＦＩＤリーダ１１２に結合された第２のプロセッサ１２８を含む。コントロールパネル１３０（例えばユーザイン

ターフェース）、第１のディスプレイ１３２、および電源１３４（例えば、バッテリーまたは電気的接続）も第２のプロセッサ１２８に結合され得る。ベースユニット１１０はベースハウジング１３６を含み得る。第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、信号１３７、例えばポンプ信号や圧力問合せ信号を、第１のＲＦＩＤアンテナ１１４に送信するように構成される。

【００１９】

減圧ポンプ１０８の第１のＲＦＩＤアンテナ１１４は、第１のプロセッサ１１８に、導線１１９によってまたは無線結合（ｗｉｒｅｌｅｓｓ　ｃｏｕｐｌｉｎｇ）によって結合される。第１のプロセッサ１１８はマイクロポンプ装置１１６に結合されて、マイクロポンプ装置１１６に電力を供給しかつそれを制御する。第１のプロセッサ１１８に追加的な電力をもたらすために第１の電源１４０が含まれ得る。第１のプロセッサ１１８には圧力感知装置１３８が結合され得る。圧力感知装置１３８は、圧力感知ルーメン１６６（すなわち通気路１７４またはインターフェース分配マニホールド１５０）に流体的に結合されて、その内部の圧力を感知する。マイクロポンプ装置１１６は液溜め１２６に流体的に結合される。液溜め１２６は、減圧ルーメ１６４からすなわちインターフェース分配マニホールド１５０から流体１２７を受け取って保持する。

【００２０】

ベースユニット１１０によって送信されたポンプ信号は、第１のＲＦＩＤアンテナ１１４によって受信され、かつマイクロポンプ装置１１６を付勢して減圧を生じる。圧力問合せ信号は、第２のプロセッサ１２８およびＲＦＩＤリーダ１１２によって無線減圧ポンプ１０８の第１のプロセッサ１１８に送信される。それに応じて、無線減圧ポンプ１０８の第１のプロセッサ１１８および圧力感知装置１３８は、減圧ドレッシング１０６が受けている圧力を示す圧力メッセージ信号をベースユニット１１０に送信する。

【００２１】

第２のプロセッサ１２８は、無線減圧ポンプ１０８から圧力メッセージ信号を受信し、かつ制御信号を準備するように構成される。第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、制御信号を無線減圧ポンプ１０８に送信して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させるように構成される。別の例示的実施形態では、上述の通り、第１のプロセッサ１１８は、圧力感知装置１３８から圧力メッセージ信号を受信しかつ制御信号を生成して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させるように動作可能である。

【００２２】

ここで主に図２および図４を参照して説明すると、無線減圧ポンプ１０８は減圧を生成し、その減圧は組織部位１０２に供給される。無線減圧ポンプ１０８は、組織部位１０２から流体を受け取って保持する。減圧は、概して、治療を施されている組織部位における周囲圧力に達しない圧力を指す。ほとんどの場合、この減圧は、患者がいる場所の気圧に達しない。あるいは、減圧は、組織部位における静水圧未満とし得る。他に指定のない限り、本明細書で挙げられた圧力の値はゲージ圧である。供給される減圧は、一定であってもまたは変動しても（パターン化またはランダム）よく、連続的にまたは断続的に供給され得る。本明細書での使用に一致して、他に指定のない限り、減圧または真空圧の上昇は、一般に、絶対圧の相対的低下を指す。

【００２３】

無線減圧ポンプ１０８はシステム１００のために減圧をもたらす。無線減圧ポンプ１０８は、第１の分配マニホールド１４２、ダイバータ層１４４、および吸収層１４６を含み得る。通気口１７６を使用して、排気路をマイクロポンプ装置１１６から無線減圧ポンプ１０８の外部に流体的に結合する。第１の分配マニホールド１４２は、マイクロポンプ装置１１６によって生成された減圧を分配する働きをする。マイクロポンプ装置１１６と第１の分配マニホールド１４２との間に空気液体分離器１４３、例えば疎水性フィルタを配置して、マイクロポンプ装置１１６に液体が入らないようにする。吸収層１４６は、組織部位１０２から流体を受け取って保持する働きをする。吸収層１４６は、組織部位１０２

から滲出液などの液体を吸収することができる任意の材料から作製し得る。

【００２４】

吸収層１４６は超吸収繊維から作製し得る。超吸収繊維は、繊維への物理的または化学的な変化を伴って、液体を保持しても、または液体に結びついてもよい。非限定的な一例では、超吸収繊維は、Ｔｅｃｈｎｉｃａｌ Ａｂｓｏｒｂｅｎｔｓ，Ｌｔｄ．（Ｇｒｉｍｓｂｙ、Ｕｎｉｔｅｄ Ｋｉｎｇｄｏｍ）からのＳｕｐｅｒ Ａｂｓｏｒｂｅｎｔ Ｆｉｂｅｒ（ＳＡＦ）材を含み得る。吸収層１４６は、繊維が組織部位１０２からの液体を吸収する繊維性材料のシートまたはマットとし得る。繊維を含む吸収層１４６の構造は、織構造でもまたは不織構造でもよい。吸収層１４６の繊維は、液体と接触するとゲルとなってもよく、それにより、液体を捕捉する。繊維間の空間または空隙によって、吸収層１４６に行われる減圧が吸収層１４６内をおよびそこを通って伝達することができるようにし得る。例示的一実施形態では、吸収層１４６内の繊維の繊維密度は、１ミリメートル当たり約１．４グラムとし得る。

【００２５】

ダイバータ層１４４は、吸収層１４６および第１の分配マニホールド１４２に隣接して配置される。ダイバータ層１４４は、液不透過性材料から形成されるが、複数のアパーチャ１４５を含んでいる。複数のアパーチャ１４５によって、マイクロポンプ装置１１６からの減圧を、ダイバータ層１４４を通して所望の個所に伝達する。ダイバータ層１４４は、吸収層１４６に適用されるときの減圧のパターンを制御するのを助ける。減圧は、第１の分配マニホールド１４２によってダイバータ層１４４に分配される。アパーチャ１４５は、吸収層１４６の複数の部分に減圧を行うパターンで配置されて、吸収層１４６が組織部位１０２からより多くの流体を吸収するときに、組織部位１０２への減圧の伝達を継続する吸収層１４６の性能を高め得る。

【００２６】

複数のアパーチャ１４５は、ダイバータ層１４４の中心から離れてダイバータ層１４４の周辺部分を取り囲むパターンで位置決めして、減圧が、吸収層１４６の中心領域から離れて、吸収層１４６で行われるようにし得る。ダイバータ層１４４は、第１の分配マニホールド１４２と共に作用して、ダイバータ層１４４と併用されない吸収層１４６と比較すると吸収層１４６の吸収能力および吸収効率が確実に高まるようにする。吸収層１４６全体にわたって液体の分配を良好に行うことによって、ダイバータ層１４４はまた、無線減圧ポンプ１０８の有効容量を多くし、かつ治療時間を長くする。

【００２７】

ダイバータ層１４４は、隣接する吸収層の減圧伝達能力および貯蔵能力を高める任意の材料から作製し得る。例えば、ダイバータ層１４４は、液体および気体に対して実質的に不透過性でありかつアパーチャ１４５を通過するように減圧の流れをそらす材料から作製し得る。その代わりにまたはそれに加えて、ダイバータ層１４４が作製される材料は、予め定められた透湿度（ｍｏｉｓｔｕｒｅ ｖａｐｏｒ ｔｒａｎｓｆｅｒ ｒａｔｅ）を有してもよく、それはガス透過性と一致している。いずれの例でも、ダイバータ層１４４は、依然として、アパーチャのないガス透過性材料で可能な量よりも大量の液体または気体を伝達するアパーチャのパターンを含み得る。しかしながら、液体ではなく気体に対するダイバータ層１４４の透過性は、ドレッシングを通る減圧の伝達率を高めるが、依然として液体の流れをダイバータ層１４４の周囲またはその付近へ向けることができることを留意されたい。

【００２８】

第１の分配マニホールド１４２、ダイバータ層１４４、および吸収層１４６は、ポンプ用パウチ１２０内に配置され得る。無線減圧ポンプ１０８はまた、圧力感知のために減圧ドレッシング１０６に流体的に結合されかつ第１のプロセッサ１１８と通信する圧力感知装置１３８を含み得る。減圧導管１４８は、減圧ドレッシング１０６からの流体を無線減圧ポンプ１０８へ供給する。例示的一実施形態では、減圧導管１４８は吸収層１４６に直接配置される。別の例示的実施形態では、減圧導管１４８と吸収層１４６をインターフェ

ース（図示せず）が流体的に結合する。

【００２９】

ここで主に図１および図３を参照して説明すると、減圧ドレッシング１０６は組織部位１０２に配置される。組織部位１０２は、例えば、表皮１５６を通って皮下組織１５８に至る創傷１０４、または任意の他の組織部位とし得る。減圧ドレッシング１０６は、組織部位１０２に減圧をもたらしかつ組織部位１０２から流体を受け取る任意の装置とし得る。例えば、減圧ドレッシング１０６は、発泡体部材、複数の画成されたチャネルを備える構造、吸引管、または他の装置によって形成し得る。例示的一実施形態では、減圧ドレッシング１０６は、組織部位１０２に近接して配置されるインターフェース分配マニホールド１５０と、ドレッシングシール部材１５２と、減圧インターフェース１５４とを含み得る。

【００３０】

マニホールドは、一般的に、組織部位１０２に減圧を行う、流体を供給する、またはそこから流体を除去するのを支援するために設けられる物体または構造を指す。インターフェース分配マニホールド１５０は、一般に、流体を、インターフェース分配マニホールド１５０の周りの組織部位１０２にもたらしかつそこから除去するように分配させる複数の流路または流れ経路を含む。例示的一実施形態では、流路または流れ経路は相互に接続されて、組織部位１０２に提供されるまたはそこから除去される流体の分配を改善する。インターフェース分配マニホールド１５０はまた、組織部位１０２と接触して配置されかつ組織部位１０２に減圧を分配させることができる生体適合性材料とし得る。インターフェース分配マニホールドの例としては、限定はされないが、以下を含み得る：流路を形成するように配置された構造要素を有する装置、例えば、気泡質の発泡体、連続気泡発泡体、多孔性組織集合体、液体、ゲル、および流路を含むまたは硬化して流路を含む発泡体；発泡体；ガーゼ；フェルトのマット；または特定の生物学的適用に好適な任意の他の材料。

【００３１】

一実施形態では、インターフェース分配マニホールド１５０は多孔質発泡体であり、かつ流路の機能を果たす複数の連続気泡または細孔を含む。多孔質発泡体は、ポリウレタン製の連続気泡の網状発泡体、例えばＫｉｎｅｔｉｃ Ｃｏｎｃｅｐｔｓ，Ｉｎｃｏｒｐｏｒａｔｅｄ（Ｓａｎ Ａｎｔｏｎｉｏ、Ｔｅｘａｓ）から入手可能なＧｒａｎｕＦｏａｍ（登録商標）材とし得る。場合によっては、インターフェース分配マニホールド１５０はまた、薬剤、抗菌薬、成長因子、および様々な溶液などの流体を組織部位１０２に分配するためにも使用し得る。インターフェース分配マニホールド１５０にまたはインターフェース分配マニホールド１５０上に、吸収材料、ウィッキング材料、疎水性材料、および親水性材料などの他の層も含まれ得る。

【００３２】

例示的一実施形態では、インターフェース分配マニホールド１５０の全体または一部分は、減圧ドレッシング１０６の使用後に、患者の体に残ってもよい生体再吸収性（ｂｉｏｒｅｓｏｒｂａｂｌｅ）材料から構成し得る。好適な生体再吸収性材料は、限定はされないが、ポリ乳酸（ＰＬＡ）とポリグリコール酸（ＰＧＡ）とのポリマーブレンドを含み得る。ポリマーブレンドはまた、限定はされないが、ポリカーボネート、ポリフマレート、およびカプララクトンを含み得る。インターフェース分配マニホールド１５０は、新しい細胞増殖のための足場としての機能をさらに果たしてもよいし、または細胞増殖を促進するためにインターフェース分配マニホールド１５０と足場材料が一緒に使用されてもよい。足場は、細胞増殖または組織形成を増進させるまたは促進するのに使用される物体または構造であり、例えば、細胞増殖のテンプレートを提供する三次元の多孔質構造である。足場材料の例示的例は、リン酸カルシウム、コラーゲン、ＰＬＡ／ＰＧＡ、コーラルヒドロキシアパタイト（ｃｏｒａｌ ｈｙｄｒｏｘｙ ａｐａｔｉｔｅ）、カーボネート、または加工された同種移植片材料を含む。

【００３３】

インターフェース分配マニホールド１５０はドレッシングシール部材１５２によって覆

われる。ドレッシングシール部材１５２は、流体シールをもたらす任意の材料とし得る。流体シールは、特定の減圧源または関連のサブシステムによって与えられた減圧を所望の部位に維持するのに適切なシールである。ドレッシングシール部材１５２は、例えば、不透過性または半透過性のエラストマー性材料とし得る。エラストマー性材料は、エラストマーの特性を有する。一般的に、ゴムのような特性を有するポリマー材料を指す。より具体的には、ほとんどのエラストマーは、１００％超の極限伸びおよび相当の弾力性を有する。材料の弾力性は、弾性変形から回復する材料の能力を指す。エラストマーの例は、限定されるものではないが、天然ゴム、ポリイソプレン、スチレンブタジエンゴム、クロロプレンゴム、ポリブタジエン、ニトリルゴム、ブチルゴム、エチレンプロピレンゴム、エチレンプロピレンジエンモノマー、クロロスルホン化ポリエチレン、多硫化ゴム、ポリウレタン（ＰＵ）、ＥＶＡフィルム、コーポリエステル、およびシリコーンを含む。ドレッシングシール部材材料の追加的な具体例は、シリコーンドレープ、３Ｍ Ｔｅｇａｄｅｒｍ（登録商標）ドレープ、Ａｖｅｒｙ Ｄｅｎｎｉｓｏｎ Ｃｏｒｐｏｒａｔｉｏｎ（Ｐａｓａｄｅｎａ、Ｃａｌｉｆｏｒｎｉａ）から入手可能なポリウレタン（ＰＵ）ドレープを含む。ドレッシングシール部材１５２は、組織部位１０２の上側を覆う密閉空間１６０を形成し、そこに、マイクロポンプ装置１１６を含んでもよい。

【００３４】

取付装置１６２を使用して、ドレッシングシール部材１５２を患者の表皮１５６または別の層、例えばガスケットまたは追加的なシール部材に保持してもよい。取付装置１６２は多くの形態を取り得る。例えば、取付装置１６２は、医学的に容認できる感圧接着剤としてもよく、これは、ドレッシングシール部材１５２の周辺にまたは全てに延在する、または表皮１５６を覆う患者対面側面のドレッシングシール部材１５２の少なくとも一部分を覆う。

【００３５】

減圧インターフェース１５４を使用して、減圧導管１４８と減圧ドレッシング１０６の密閉空間１６０との間に流体連通をもたらし得る。減圧は、減圧導管１４８を通って減圧インターフェース１５４に、その後密閉空間１６０に供給され得る。例示的一実施形態では、減圧インターフェース１５４は、ＫＣＩ（Ｓａｎ Ａｎｔｏｎｉｏ、Ｔｅｘａｓ）から入手可能なＴ．Ｒ．Ａ．Ｃ．（登録商標）ＰａｄまたはＳｅｎｓａ Ｔ．Ｒ．Ａ．Ｃ．（登録商標）Ｐａｄである。減圧導管１４８は、図１に示すように一体型導管として形成されたまたは図３に示すように別個に形成された減圧ルーメン１６４および圧力感知ルーメン１６６を含んでもよい。

【００３６】

図１に示す例示的一実施形態では、圧力感知能力を減圧ドレッシング１０６に付加して、圧力感知装置１３８に追加してまたはその装置の代わりに機能するようにしてもよい。減圧ドレッシング１０６は、第２のＲＦＩＤアンテナ１６８、第３のプロセッサ１７０、および第２の圧力感知装置１７２を含み得る。第３のプロセッサ１７０は、第２のＲＦＩＤアンテナ１６８および第２の圧力感知装置１７２に結合されている。通気路１７４が密閉空間１６０と第２の圧力感知装置１７２との間に流体連通をもたらす。第３のプロセッサ１７０および第２の圧力感知装置１７２は、ベースユニット１１０から圧力問合せ信号を受信し、密閉空間１６０内の圧力を示す圧力メッセージ信号によって応答するように動作可能である。

【００３７】

例示的一実施形態では、無線減圧ポンプ１０８は無線式のパッシブな（すなわちバッテリーがない）装置である。そのようなものとして、無線減圧ポンプ１０８には、第１のＲＦＩＤアンテナ１１４によって供給される電力以外の動力源が設置されていない。一部の実施形態では、無線減圧ポンプ１０８は、電気エネルギーを蓄積するためのコンデンサを含み得る。別の例示的実施形態では、図３に示すような第１の電源１４０は、第１のＲＦＩＤアンテナ１１４によって供給される電力を増大するかまたはマイクロポンプ装置１１６を動作させるように設けてもよい。第１の電源１４０は、第１のＲＦＩＤアンテナ１１

４からの電力によって再充電されてもよい。

【００３８】

マイクロポンプ装置１１６は、圧電ポンプ、蠕動ポンプ、または他の小型ポンプなどの多数の形態を取り得る。ここで主に図５を参照して、無線減圧ポンプ１０８の一態様として使用するのに好適なマイクロポンプ装置１１６の例示的実施形態を説明する。マイクロポンプ装置１１６は、第１の端壁１８０、第２の端壁１８２、および環状側壁１８４によって画成された空洞１７８を含む。空洞１７８は、実質的に円形形状とし得るが、楕円形などの他の形状も可能である。例示的一実施形態では、空洞１７８は、約１０ｍｌの流体を保持してもよいし、またはより多くのまたはより少ない流体を保持してもよい。

【００３９】

空洞１７８はノード様流入口１８６を備え、そこは弁付きでもまたは弁付きでなくてもよい。空洞１７８はまた、弁付き排出口１９０を有してもよい。第１の端壁１８０はディスク１９２とし得る。ディスク１９２上には、アクチュエータ１９４、例えば圧電ディスク、磁歪装置、またはソレノイド作動装置がある。アクチュエータ１９４は駆動回路に電気的に結合され、この駆動回路はプロセッサによって制御される。駆動回路は、交流電気信号をアクチュエータ１９４に印加して、ディスク１９２に振動を誘起する。振動の周波数は、チャンバの固有周波数に適合するように調整できる。圧電ディスクは、厚さが１ｍｍ未満とし、および５００Ｈｚ超で、１０ｋＨｚ超、または２０ｋＨｚ超でも動作するように同調され得る。作動すると、アクチュエータ１９４は、図示の通りの空洞１７８の平面に実質的に垂直な方向において振動してもよく、それにより、空洞１７８内の流体に半径方向の圧力振動を生成する。１つ以上のマイクロポンプ装置１１６を並列にまたは直列に使用してもよい。

【００４０】

例示的一実施形態では、マイクロポンプ装置１１６は、空洞１７８に流体を有し、かつ第１の端壁１８０、第２の端壁１８２、および側壁１８４によって囲まれる実質的にシリンダー形状を有する。少なくとも２つのアパーチャ、例えば、流入口１８６および排出口１９０が、空洞１７８を形成する壁１８０、１８２、１８４を通って形成される。空洞１７８は半径ｒおよび高さｈを有し、およびｒ／ｈ＞１．２およびｈ^{2}／ｒ＞４×１０$^{-10}$ｍである。圧電ディスクであるアクチュエータ１９４は、端壁１８０、１８２の一方に、第１の端壁１８０および第２の端壁１８２の平面に対して実質的に垂直な方向の振動運動を生じる。端壁１８０、１８２の軸方向振動は、空洞１７８に流体圧力の半径方向の振動を発生させ、かつ減圧を生じるポンピングを可能にする。マイクロポンプ装置１１６は、音響ポンプのように、空洞１７８内に音響共振を生じる。流入口１８６を使用して流体を引き込み、および排出口１９０は通気口、例えば図４の通気口１７６に結合され、外部に排出する。他のマイクロポンプ装置を使用してもよい。マイクロポンプ装置１１６は、米国特許出願公開第２００９／０２４０１８５号明細書（米国特許出願第１２／３９８，９０４号；２００９年３月５日出願）（「Ｄｒｅｓｓｉｎｇ ａｎｄ Ｍｅｔｈｏｄ ｆｏｒ Ａｐｐｌｙｉｎｇ Ｒｅｄｕｃｅｄ Ｐｒｅｓｓｕｒｅ Ｔｏ ａｎｄ Ｃｏｌｌｅｃｔｉｎｇ Ａｎｄ Ｓｔｏｒｉｎｇ Ｆｌｕｉｄ ｆｒｏｍ ａ Ｔｉｓｓｕｅ Ｓｉｔｅ」）に示すマイクロポンプのタイプとし得る。この文献をあらゆる目的のために本願明細書に援用する。

【００４１】

ここで主に図１～３を参照して説明すると、例示的一実施形態によれば、システム１００の動作中、減圧ドレッシング１０６は組織部位１０２に適用される。特に、インターフェース分配マニホールド１５０は組織部位１０２に近接して配置される。その後、インターフェース分配マニホールド１５０および組織部位１０２がドレッシングシール部材１５２によって覆われて、密閉空間１６０を生成する。ドレッシングシール部材１５２の患者対面側面上の取付装置１６２は、患者の表皮１５６の一部分に流体シールをもたらすのを助け得る。減圧インターフェース１５４がまだ設置されていない場合には、例えばドレッシングシール部材１５２に小さなアパーチャの切り込みを入れ、アパーチャまたは孔を覆

ってまたはそこを通して減圧インターフェース１５４を固定するなどによって、減圧インターフェースを適用し得る。

【００４２】

その後、無線減圧ポンプ１０８が提供され、減圧導管１４８によって減圧インターフェース１５４に流体的に結合される。第１のＲＦＩＤアンテナ１１４をベースユニット１１０の動作範囲内に配置するように、無線減圧ポンプ１０８を位置決めする。例示的一実施形態では、第１のＲＦＩＤアンテナ１１４は、ベースユニット１１０のＲＦＩＤリーダ１１２から数ミリメートル内に配置する。別の例示的実施形態では、第１のＲＦＩＤアンテナ１１４は、ＲＦＩＤリーダ１１２から１０メートル離れた個所に配置してもよい。所与の範囲内の任意の距離を容易に使用し得る。

【００４３】

その後、ベースユニット１１０を使用者が作動させる。ベースユニット１１０は、無線減圧ポンプ１０８にポンプ信号１３７を送信する。ポンプ信号は第１のＲＦＩＤアンテナ１１４によって受信され、およびポンプ信号のエネルギーが第１のプロセッサ１１８に供給される。第１のプロセッサ１１８はマイクロポンプ装置１１６にエネルギーを供給する。マイクロポンプ１１６は減圧を生じ、それが、減圧導管１４８に流体的に結合されている液溜め１２６に供給される。それゆえ、減圧は、減圧導管１４８を通して減圧ドレッシング１０６に供給される。組織部位１０２からの流体がインターフェース分配マニホールド１５０、減圧インターフェース１５４、および減圧導管１４８を通って液溜め１２６まで流れる。

【００４４】

組織部位１０２における圧力が、圧力感知装置、例えば図３の圧力感知装置１３８または図１の第２の圧力感知装置１７２を使用して直接または間接的に監視され得る。第１の例示的例では、ベースユニット１１０の第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、ポンプ信号とは別にまたはポンプ信号と共に、無線減圧ポンプ１０８に圧力問合せ信号を送信する。圧力問合せ信号に応答して、第１のプロセッサ１１８および圧力感知装置１３８は圧力メッセージ信号を準備し、組織部位における圧力の測定値を通信し得る。その後、圧力メッセージ信号を、第１のプロセッサ１１８による別の処理に使用して、必要とされ得るときにマイクロポンプ１１６を作動または動作停止させるポンプ制御信号を発生させる。その代わりにまたはそれに加えて、第１のプロセッサ１１８は、第１のＲＦＩＤアンテナ１１４を介してＲＦＩＤリーダ１１２に圧力メッセージ信号を送信し得る。圧力メッセージ信号は、ＲＦＩＤリーダ１１２に達した後、第２のプロセッサ１２８に供給される。圧力メッセージ信号を使用して、第２のプロセッサ１２８はポンプ制御信号を準備し、そのポンプ制御信号は、ＲＦＩＤリーダ１１２によって無線減圧ポンプ１０８に送信されて、必要に応じマイクロポンプ１１６を動作停止または作動させる。

【００４５】

適切な時間間隔を経た後、圧力が所望の動作範囲外に留まっている場合、ベースユニット１１０または無線減圧ポンプ１０８によって警報信号が生成される。警報は、別個の可聴装置、視覚警報としてもよいし、またはマイクロポンプ１１６が異なる周波数範囲、例えば低周波数で機能して、警報のための可聴雑音を生成してもよい。

【００４６】

第２の例示的手法では、減圧ドレッシング１０６は、第３のプロセッサ１７０に結合される第２のＲＦＩＤアンテナ１６８を含み、その第３のプロセッサは、第２の圧力感知装置１７２に結合されている。第２の圧力感知装置１７２は、通気路１７４を介して密閉空間１６０内の圧力を受ける。ベースユニット１１０は、第２のＲＦＩＤアンテナ１６８に圧力問合せ信号を送信する。それに応答して、第２の圧力感知装置１７２および第３のプロセッサ１７０は圧力メッセージ信号を生成し、それが、第２のＲＦＩＤアンテナ１６８によってベースユニット１１０に送信される。上述の通り、その後、ベースユニット１１０はポンプ制御信号を生成して、それが無線減圧ポンプ１０８に送信され、マイクロポンプ１１６を作動させるまたはその動作を停止させる。あるいは、第３のプロセッサ１７０

は、圧力を見積もり、かつ、フィードバックまたは制御ループの一部としてポンプ制御信号を準備し得る。

【００４７】

ここで主に図４および図６を参照して、無線減圧ポンプ１０８の例示的実施形態を説明する。この例示的実施形態では、無線減圧ポンプ１０８は、ポール１９６上のベースユニット１１０に取り外し可能に固定され得る内蔵型の使い捨てパウチ設計とし得る。既に説明したように、ポンプ用パウチ１２０は、第１のポンプシール部材１２２および第２のポンプシール部材１２４によって形成される。ポンプ用パウチ１２０の外辺部は、第１のフランジ１２３および第２のフランジ１２５を含み得る。ポンプ用パウチ１２０は、所望の場合には多数の区画に分割または区分され得る。例えば、ある区画（明示せず）は、区画内にマイクロポンプ１１６を有して形成されてもよく、および別の区画は、吸収層１４６を含んで形成されてもよい。

【００４８】

ポンプ用パウチ１２０の例示的実施形態でのフランジ１２３、１２５は、溶接、ボンディング、またはそうでなければ第１のポンプシール部材１２２および第２のポンプシール部材１２４の取り付け部分によって形成され得る。第１のフランジ１２３は、１つ以上のポスト１９８を収容するための１つ以上のアパーチャ１２９を含み得る。ポスト１９８は、ポンプ用パウチ１２０をベースユニット１１０に隣接させて固定する。減圧導管１４８は、第２のフランジ１２５にあるアパーチャ１４９を通って入り込んでもよく、封止された締まり嵌めを提供するか、または封止接続をもたらすカップリングを有する。他の接続を使用してもよい。

【００４９】

図４から最もよく分かるように、第１のＲＦＩＤアンテナ１１４をベースユニット１１０の最も近くに配置して、第１のＲＦＩＤアンテナ１１４がベースユニット１１０のＲＦＩＤリーダ１１２に直接隣接するようにし得る。非限定的な一例では、第１のＲＦＩＤアンテナ１１４は、ＲＦＩＤリーダ１１２から２ミリメートルまたは１ミリメートル（１ｍｍ）またはそれより近くに位置決めされる。ＲＦＩＤリーダ１１２および第１のＲＦＩＤアンテナ１１４は実質的に適合されかつ位置合わせされ得る。別の例示的実施形態では、図１に提案するように、第１のＲＦＩＤアンテナ１１４が、遠くに配置されたベースユニット１１０の方へ外側に向くような状態で、無線減圧ポンプ１０８はポスト１９８に取り付けられ得る。例えば、ベースユニット１１０は中心のハブ領域に配置されてもよく、そこで、無線減圧ポンプ１０８は、１０メートル以上離れていてもよいベースユニット１１０を使用して監視されかつ電力供給される。

【００５０】

ここで主に図６を参照して説明すると、ベースユニット１１０は、コントロールパネル１３０および１つ以上のディスプレイ１３２を含んでもよい。ベースユニット１１０は、ベースハウジングまたはベース本体１３６を含み得る。ベースハウジングまたは本体１３６は、無線減圧ポンプ１０８が組織部位１０２からの流体で満たされるときに無線減圧ポンプ１０８の一部分に物理的な支持をもたらし得る棚部分１９９を含み得る。この点について、図６に示す無線減圧ポンプ１０８は、使用前の状態を示すことに留意されたい。図４および図６の実施形態では、無線減圧ポンプ１０８が流体を保持する容量に達したら、マイクロポンプ１１６は動作停止されてもよく、および使用者は無線減圧ポンプ１０８全体を廃棄してもよい。

【００５１】

ここで主に図７および図８を参照して、無線減圧ポンプ２００の別の例示的実施形態を説明する。無線減圧ポンプ２００を、組織部位を治療するシステム、例えば図１のシステムの一部として使用し得る。無線減圧ポンプ２００は複数の壁部材２０２を含み、第１のチャンバ２０４および第２のチャンバ２０６を形成する。複数の壁部材２０２の１つが、第１のチャンバ２０４を第２のチャンバ２０６から区分する区画壁２０８である。既に説明した図面のマイクロポンプ１１６と類似しているマイクロポンプ２１０が、第１のチャ

ンバ２０４内に配置され得る。マイクロポンプ１１６は、流体を受け取る（または前記別の方法では、減圧を排出する）流入口２１２が第２のチャンバ２０６に流体的に結合されるように構成される。マイクロポンプ２１０は、第１のチャンバ２０４に流体的に結合される排出口または通気口２１４を有する。マイクロポンプ２１０は、排出口または通気口２１４を通って第１のチャンバ２０４まで正圧を放出する。

【００５２】

第１のチャンバ２０４を形成する複数の壁部材２０２の１つの一部分は、アパーチャ２１６を含む。任意選択的な逃がし弁２１８がアパーチャ２１６に結合される。逃がし弁２１８は、圧力が第１の閾値圧力を上回るときに、第１のチャンバ２０４内の圧力が無線減圧ポンプ２００の外部に放出されるように構成される。第２のチャンバ２０６を構成する複数の壁部材２０２の少なくとも一部分は、膨張式支持部材、典型的には複数の膨張式支持部材２２０を含む。複数の膨張式支持部材２２０を示すが、単一の膨張式支持部材を使用して第２のチャンバ２０６を形成し得ることを理解されたい。

【００５３】

膨張式支持部材２２０は、複数のアパーチャ２２２を通してなど、第１のチャンバ２０４と流体連通している。それゆえ、第１のチャンバ２０４内の正圧が複数の膨張式支持部材２２０を満たす。複数の膨張式支持部材２２０が十分な流体で満たされると、複数の膨張式支持部材２２０は、相対的に剛性を得て、第２のチャンバ２０６に体積部を形成するのを助ける構造体を提供する。組織部位からの流体２２３は、減圧導管２２４を通って第２のチャンバ２０６の体積部に収容される。ピラミッド形状で示す無線減圧ポンプ２００は、他の形状、例えば、ボックス、シリンダー、または任意の他の形状をとるように形成してもよい。

【００５４】

既に説明した実施形態のように、マイクロポンプ２１０は、ＲＦＩＤアンテナ２２６に供給されたポンプ信号によって、全体的にまたは部分的に、電力供給される。ＲＦＩＤアンテナ２２６は第１のプロセッサ２２８に結合されている。第１のプロセッサ２２８は、導線２３０によってマイクロポンプ２１０に電気的に結合されており、この導線は複数の壁部材２０２の１つに含まれ得るが、図７では別個に示す。図８に示すように、複数の壁部材２０２の床部分２３２がプラットフォーム部材２３４内に含まれ得る。

【００５５】

ここで主に図７および図８を参照して説明すると、例示的一実施形態による動作では、減圧導管２２４は、減圧ドレッシング、例えば図１および図３の減圧ドレッシング１０６に結合される。ベースユニット、例えば図１のベースユニット１１０を使用して、無線減圧ポンプ２００のＲＦＩＤアンテナ２２６にポンプ信号またはポンプ作動信号を送信する。ＲＦＩＤアンテナ２２６によって受信されるポンプ信号が、第１のプロセッサ２２８に供給される。第１のプロセッサ２２８からマイクロポンプ２１０へ電力が供給され、マイクロポンプ２１０を付勢する。マイクロポンプ２１０が付勢されると、減圧が第２のチャンバ２０６に供給され、かつ正圧が第１のチャンバ２０４に供給される。圧力が第１のチャンバ２０４内で高まると、圧力が複数の膨張式支持部材２２０に充填されて、無線減圧ポンプ２００が、しぼんだ状態から膨張状態に変化する。流入口２１２をスペーサ部材（図示せず）が覆って、膨張式支持部材２２０が充填される前の始動中の気閉塞を防止する。

【００５６】

膨張式支持部材２２０が膨張すると、第２のチャンバ２０６の最大体積が達成される。それと同時に、第２のチャンバ２０６の減圧が減圧導管２２４に供給される。流体２２３（液体を含む）が第２のチャンバ２０６に注入される。

【００５７】

明示しないが、例えば図３の圧力感知装置１３８に類似した減圧感知装置が第２のチャンバ２０６の一部分に組み込まれて、第２のチャンバ２０６の圧力を測定し得ることを理解されたい。ここでも、明示しないが、例えば図３の圧力感知装置１３８に類似した減圧

感知装置が、減圧ポンプ２００に含まれてもよいことを理解されたい。減圧導管２２４はまた、分配マニホールドにおける圧力を測定するための減圧感知装置に流体的に結合される圧力感知ルーメンを有し得る。どちらの例でも、圧力感知装置は第１のプロセッサ２２８に結合されて、圧力メッセージ信号を発生させる。圧力メッセージ信号は、ベースユニットからの圧力問合せ信号に応答して、または第１のプロセッサ２２８によって自然発生して供給され得る。第１のプロセッサ２２８は圧力メッセージ信号を使用してポンプ制御信号を発生させ、それがマイクロポンプ２１０に供給され得る。あるいは、圧力メッセージ信号はベースユニットに送信され、そこで、ベースユニット内のプロセッサが、既に説明した実施形態と同様のポンプ制御信号を発生させ得る。

【００５８】

代替的な実施形態では、既に説明した無線減圧ポンプ１０８、２００が、ＲＦＩＤアンテナを有する代わりに、ポンプとベースとの間に導線またはソケットおよびプラグを有する。導線またはソケットおよびプラグは、電力および信号をやり取りするために互いに容易に差し込み得る。

【００５９】

ここで主に図９～１１を参照して、減圧によって組織部位３０２を治療する減圧システム３００の例示的実施形態を説明する。減圧システム３００は、無線減圧ドレッシング３０４およびベースユニット３０６を含む。ベースユニット３０６は電源コネクタ３０７を含んでもよい。無線減圧ドレッシング３０４は、ベースユニット３０６から電力を受信しかつ制御を受ける内蔵型の使い捨てドレッシングである。ベースユニット３０６は、無線減圧ドレッシング３０４に実質的に隣接し得る、例えば、１または２ミリメートル以内に、または１０メートルまでまたはそれ以上離れて、またはそれらの間のどこかにあり得る。一実施形態では、マイクロポンプ３１６は、吸収層または吸収部材３１０から分離していてもよく、使用後に、マイクロポンプ３１６を容易に分離し得る。そのため、マイクロポンプ３１６を修理および再使用してもよい。

【００６０】

無線減圧ドレッシング３０４は、組織部位３０２に近接して配置されるインターフェース分配マニホールド３０８を含む。無線減圧ドレッシング３０４はまた、吸収層３１０、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４を含んでもよい。ＲＦＩＤアンテナ３１２は第１のプロセッサ３１４に電気的に結合される。第１のプロセッサ３１４はマイクロポンプ３１６に電気的に結合される。インターフェース分配マニホールド３０８、吸収層３１０、ＲＦＩＤアンテナ３１２、第１のプロセッサ３１４、およびマイクロポンプ３１６は全て適所に保持され、かつ１つ以上のシール部材、例えばシール部材３２０によって密閉空間３１８内に固定される。追加的な層および構成要素を無線減圧ドレッシング３０４に含めてもよい。

【００６１】

図９～１１の例示的実施形態は、追加的な層および構成要素を含む。追加的な層および構成要素は、異なる順序で配置してもよい。シール層３２２を使用して、組織部位３０２の周りで無線減圧ドレッシング３０４を封止する。シール層３２２はアパーチャ３２３を備えて形成され、インターフェース分配マニホールド３０８に流体連通をもたらす。インターフェース分配マニホールド３０８および組織部位３０２と流体連通して第１の内部分配マニホールド３２４が位置決めされる。吸収層３１０は、第１の内部分配マニホールド３２４、インターフェース分配マニホールド３０８、および組織部位３０２と流体連通して位置決めされる。吸収層３１０に隣接してダイバータ層３２６が位置決めされる。ダイバータ層３２６に流体連通して第２の内部分配マニホールド３２８が位置決めされる。ダイバータ層３２６は、複数のアパーチャ３２７を備えて形成され、それらアパーチャは、多数のパターンおよび形態をとり得る。ダイバータ層３２６は、この特定の例示的実施形態では、正方形のパターンを形成する複数のアパーチャ３２７を備えて示す。正方形のパターンでは、角にあるアパーチャが他のアパーチャよりも大きい。第２の内部分配マニホールド３２８に隣接して気液分離装置３３０が位置決めされる。

【００６２】
マイクロポンプ３１６、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４は、気液分離装置３３０に隣接し得る。マイクロポンプ３１６の排出口３３４を覆ってチャコールフィルタ３３２または他の臭気除去装置を位置決めし得る。シール部材３２０は、アパーチャ３３６を備えて形成され、マイクロポンプ３１６の排出口３３４が無線減圧ドレッシング３０４の外部に排気できるようにする。排出口３３４およびアパーチャ３３６は共に通気口３３８を形成する。

【００６３】
マイクロポンプ３１６は、統合無線減圧ドレッシング３０４を組織部位３０２に維持できるようにするのに十分に小型かつ軽量なマイクロポンプとし得る。さらに、マイクロポンプ３１６は、統合減圧ドレッシング３０４が組織部位３０２を引っ張らないまたは他の方法で悪影響を与えないようなサイズおよび重量にし得る。例示的一実施形態では、マイクロポンプ３１６は、上述したものと同様の圧電アクチュエータを有するディスク型ポンプとし得る。米国特許出願公開第２００９／００８７３２３号明細書および米国特許出願公開第２００９／０２４０１８５号明細書（これらをあらゆる目的のために本願明細書に援用する）に示されているポンプも参照する。代替的な実施形態では、マイクロポンプ３１６は、様々な流体をくみ上げるために使用する蠕動ポンプとし得る。代替的なポンプ技術を用いてもよいこと、および回転ポンプ、リニアポンプ、または他の構成のポンプを用いてもよいことを理解されたい。

【００６４】
マイクロポンプ３１６は、創傷治療に治療力のある十分な減圧を生成する。例示的一実施形態では、マイクロポンプ３１６は、減圧治療を継続的に行うことができるように十分な流量特性、減圧特性、および動作寿命特性を有する。流量は約５～１０００ｍｌ／分の範囲、および減圧は約－５０～－２００ｍｍ Ｈｇ（－６．６～－２６．６ｋＰａ）の範囲とし得る。統合無線減圧ドレッシング３０４の構成、創傷のサイズ、または創傷のタイプに依存して、代替的な範囲を使用してもよいことを理解されたい。例示的一実施形態では、複数のポンプを単一のドレッシングに位置決めして、必要に応じて流量または真空レベルを上昇させて供給してもよい。

【００６５】
マイクロポンプ３１６はドレッシング内に配置されて、創傷の滲出液を収集するための導管および外部キャニスタの使用を回避する。マイクロポンプ３１６は、減圧ドレッシング３０４から空気を放出するまたは排気するための排出口３３４を含む。排出口３３４を使用する場合、排出口３３４は、シール部材３２０のアパーチャ３３６と流体連通しているか、またはその内部に位置決めされ得る。あるいは、シール部材３２０は、マイクロポンプ３１６の出口ポートの周りで封止され、マイクロポンプ３１６からのガスが、アパーチャ３３６を通って直接排気できるようにし得る。図９～１１の例示的実施形態では、マイクロポンプ３１６の排出口３３４は、気液分離装置３３０（または疎水性フィルタ）から離れる方向に向けられて、無線減圧ドレッシング３０４に空気を加えないようにする。一方向弁を含み得るシール部材３２０のアパーチャ３３６を通って空気は排出される。あるいは、空気または別のガスは、減圧を維持するシール部材３２０の能力が影響を受けない限り、シール部材３２０のガス透過性部分を通って排出され得る。

【００６６】
マイクロポンプ３１６が圧電ポンプであるとき、マイクロポンプ３１６に関連付けられた圧電アクチュエータは、ときには、異なる周波数で駆動されてブザーまたは振動性警告システムの機能を果たし得る。警告システムは、警報状況を使用者に警告し得る。例えば、警報状況は、ドレッシングに漏れが存在すること、センサによって測定された減圧が変化したこと、ドレッシングが、インジケータによって示され得るような最大容量の液体を吸収したこと、または１つ以上の層がもはや効率的に減圧を多岐的に分配（ｍａｎｉｆｏｌｄｉｎｇ）しないことを示し得る。

【００６７】

制御電子回路が第１のプロセッサ３１４の一部として物理的にまたは機能的に組み込まれ得る。制御電子回路は、マイクロポンプ３１６の動作を制御するために使用し得る。制御電子回路は、アナログでもまたはデジタルでもよく、およびマイクロポンプ３１６が動作する速度またはデューティサイクルを調整する調整器を備えて構成し得る。さらに、制御電子回路は、センサまたはスイッチ、例えば、圧力感知装置（図１２の３４０参照）からの感知信号を受信するコントローラを備えて構成し得る。センサは無線減圧ドレッシング３０４全体にわたって配置され、パラメータ、例えば圧力、温度、湿度、化学的性質、臭気、またはマイクロポンプ３１６の管理および制御に用い得る任意の他のパラメータを感知し得る。制御電子回路は、コンピュータプロセッサまたはプログラマブル・ゲート・アレイまたは他の制御装置を含んでもよい。制御電子回路は、本明細書で説明する機能を実行するデジタルまたはアナログ構成要素の任意の形態を含み得ることを理解されたい。制御電子回路は、第１のプロセッサ３１４としてもよいし、またはそれを含んでもよい。

【００６８】

制御電子回路は、いくつかの状態、例えば、（ｉ）低圧、（ｉｉ）過度の漏れ、（ｉｉｉ）吸収層レベル、および（ｉｖ）バッテリー状態（含まれる場合）に関して監視しかつ警報を発するように配置され得る。それゆえ、制御電子回路は、パラメータの各々を監視しかつスピーカ、バイブレータ、または照明装置、例えば発光ダイオード（ＬＥＤ）を使用して警報信号（例えば、高音のビープ音、振動、または光）を生成するエレクトロニクスを含み得る。それゆえ、制御電子回路は、医療専門家、患者、または家族の一員に、パラメータが所望の範囲外にあることを通知し得る。例えば、組織部位３０２における圧力が治療レベルを下回る場合、連続音調が生成され得る。別の例として、吸収層３１０が飽和する場合、連続的なビープ音が生成され得る。バッテリーが、ある電圧レベルよりも下がる場合、異なる可聴周波数が生成され得るか、またはＬＥＤが作動され得る。様々な異なる警報信号が、医療専門家に特定の行動をとるように通知するために確立され得る。

【００６９】

ＲＦＩＤアンテナ３１２を使用して、マイクロポンプ３１６および制御電子回路に電気出力をもたらす。バッテリー３４２はまた、ＲＦＩＤアンテナ３１２からの出力を増大するために蓄積エネルギーをもたらすように使用してもよい。バッテリー３４２は、任意のサイズおよび形状としてもよく、および任意の材料、例えばポリマーとし得る。バッテリー３４２は、必要な電力全体またはその一部分をもたらし得る。バッテリー３４２は、ＲＦＩＤアンテナ３１２からの電力によって再充電し得る。

【００７０】

例示的一実施形態では、バッテリー３４２は、制御電子回路によって監視される電圧レベルセンサを備えて構成してもよく、および制御電子回路は、低電力レベルが検出されると警報を発生し得る。バッテリー３４２は、マイクロポンプ３１６に直接接続され得る。あるいは、バッテリー３４２は、バッテリー３４２からの電力を使用してマイクロポンプ３１６を駆動させる制御電子回路または１つまたは複数のプロセッサに接続され得る。制御電子回路は、連続的な変調電力、例えばパルス幅変調（ＰＷＭ）信号を使用して、マイクロポンプ３１６を駆動し得る。

【００７１】

シール層３２２は、減圧ドレッシング３０４の構成要素に掛けるかそうでなければ覆うために使用されるシール部材３２０に、接着されるまたは他の方法で接続される。シール層３２２は、患者の創傷の周りの表皮と真空シールを形成するのに十分に強力な医療グレードの接着材料または他のシール装置を含み得る。シール層３２２は、気液分離装置３３０または他の層の幾何学的なパラメータよりもわずかに大きい、アパーチャ３２３を有する帯状体としてもよく、シール部材３２０が患者の組織部位３０２の周りの表皮と接触するようにする。シール部材３２０は、流体、例えば空気および液体に対し不透過性である。

【００７２】

別の例示的実施形態では、シール部材３２０はダイバータ層３２６に接着してもよく、

およびダイバータ層３２６はシール部材３２０に接着して、上部ドレッシング部分および下部ドレッシング部分を形成する。上部ドレッシング部分は、シール部材３２０、マイクロポンプ３１６および関連の構成要素、気液分離装置３３０、第２の内部分配マニホールド３２８、およびダイバータ層３２６を含み得る。下部ドレッシング部分は、吸収層３１０、第１の内部分配マニホールド３２４、シール層３２２、およびインターフェース分配マニホールド３０８を含み得る。無線減圧ドレッシング３０４は、無線減圧ドレッシングが流体を最大容量吸収したら、下部ドレッシング部分を交換できるように構成し得る。上部ドレッシング部分は、下部ドレッシング部分の交換後に再使用してもよい。これにより、マイクロポンプ３１６を複数回使用することができるようになるが、ドレッシングの使い捨て部分は交換してもよい。別の例示的実施形態では、マイクロポンプ３１６、第１のプロセッサ３１４、およびＲＦＩＤアンテナ３１２は、再使用するためにドレッシングから取り除き、およびドレッシングの残りの層を交換してもよい。さらに別の例示的実施形態では、吸収層３１０のみを交換してもよい。さらに別の例示的実施形態では、吸収層３１０およびインターフェース分配マニホールド３０８のみを交換してもよい。

【００７３】

チャコールフィルタ３３２を無線減圧ドレッシング３０４に用いて、組織部位３０２によって生じかつ無線減圧ドレッシング３０４から広まった臭気を低減させてもよい。チャコールフィルタ３３２は、弁またはマイクロポンプ３１６からの他の排出用の通気口の上方に配置されて、マイクロポンプ３１６からの排気を統合減圧ドレッシング３０４から放出される前にろ過し得る。あるいは、チャコールフィルタ３３２は、マイクロポンプ３１６の上方または下方に構成および配置してもよいことを理解されたい。別の例示的実施形態では、チャコールフィルタを使用するのではなく、チャコールを、統合減圧ドレッシング３０４に用いられる異なる層のいずれかまたは全てに組み込んでもよい。

【００７４】

例示的一実施形態によれば、動作中、図９～１１の減圧システム３００は、組織部位３０２に近接させてインターフェース分配マニホールド３０８を配置することによって適用される。アパーチャ３２３がインターフェース分配マニホールド３０８の上側になるように、インターフェース分配マニホールド３０８の上側にシール層３２２を配置する。第１の内部分配マニホールド３２４は、第１のインターフェース分配マニホールド３０８に、およびおそらくシール層３２２の一部分に隣接して配置される。吸収層３１０は第１の内部分配マニホールド３２４に隣接して配置される。ダイバータ層３２６は、そのように示される構成要素の全てを覆って配置され得る。その後、第２の内部分配マニホールド３２８は、気液分離装置３３０と共に、ダイバータ層３２６の一部分に隣接して配置され得る。マイクロポンプ３１６、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４が適用され得る。本明細書で述べた構成要素はまた、ドレッシング積層体として予め組み立てられ得る。

【００７５】

シール部材３２０を使用して、密閉空間３１８を形成するシールを生成する。ベースユニット３０６を使用して、既に述べたように、ＲＦＩＤアンテナ３１２にポンプ信号を送信し、ポンプ信号は第１のプロセッサ３１４によって受信され、かつマイクロポンプ３１６に電力を供給するために使用される。第１のプロセッサ３１４は、電力または１つ以上のバッテリー、例えば再充電可能なバッテリーを保持するために１つ以上のコンデンサをさらに含んでもよい。ポンプ信号は、マイクロポンプ３１６によって減圧が発生されるようにする。減圧は組織部位３０２に伝達されて、流体を除去するまたは減圧療法をもたらす。組織部位３０２から除去された流体は、減圧ドレッシング３０４内において吸収層３１０に伝達され、そこで、流体は保持されるかまたは実質的に保持される。図１２に関連して説明するように、圧力感知装置は無線減圧ドレッシング３０４の一部として含まれ、ベースユニット３０６に圧力メッセージ信号をもたらしてもよい。

【００７６】

ここで主に図１２を参照して、減圧システム３００の別の例示的実施形態を説明する。

既に述べたように、減圧システム３００は、無線減圧ドレッシング３０４およびベースユニット３０６を含む。図１２の減圧システム３００は、無線減圧ドレッシング３０４が含む構成要素数が少数であること、および無線減圧ドレッシング３０４が、第１のプロセッサ３１４に電気的に結合された圧力感知装置３４０を追加で含むことを除いて、図９～１１に示すシステムと類似している。さらに、任意選択的なバッテリー３４２が含まれる。バッテリー３４２は、ＲＦＩＤアンテナ３１２によってもたらされた電力を補い得るか、または主電源として使用されて、ＲＦＩＤアンテナ３１２によって再充電され得る。ＲＦＩＤアンテナ３１２は、ベースユニット３０６から電力を受信する。シール部材３２０は、取付装置３４６によって表皮３４４に固定されて示す。図９～１１で説明したドレッシングに含まれた構成要素には同じ参照符号を付し、ここでは必ずしもさらに説明をしない。

【００７７】

例示的実施形態によれば、動作中、図１２の減圧システム３００は、組織部位３０２に隣接してインターフェース分配マニホールド３０８をまず適用することによって使用され得る。吸収層３１０は、インターフェース分配マニホールド３０８と流体連通して配置され得る。気液分離装置３３０は吸収層３１０の上側に配置され得る。その後、ＲＦＩＤアンテナ３１２、圧力感知装置３４０、第１のプロセッサ３１４、マイクロポンプ３１６、およびバッテリー３４２が気液分離装置３３０上に配置される。あるいは、構成要素のいくつか、例えばマイクロポンプ３１６が、気液分離装置３３０に隣接し得る。シール部材３２０は、組織部位３０２の上側を覆って適用されて密閉空間３１８を形成し、かつ上述の構成要素を全て覆う。既に説明した構成要素は、全部または部分的に予め組み立てられ得る。ベースユニット３０６は、減圧ドレッシング３０４にポンプ信号またはポンプ作動信号を送信し、それによりマイクロポンプ３１６を作動させる。マイクロポンプ３１６は、密閉空間３１８から空気または他の流体を除去し、それにより、減圧による組織部位３０２の治療を開始する。

【００７８】

ベースユニット３０６からＲＦＩＤアンテナ３１２へポンプ作動信号またはポンプ信号を供給することに加え、ベースユニット３０６はまた、圧力問合せ信号を送信し得る。圧力問合せ信号を受信すると、ＲＦＩＤアンテナ３１２、第１のプロセッサ３１４、および圧力感知装置３４０が圧力メッセージ信号を発生させ、それが、ＲＦＩＤアンテナによってベースユニット３０６のＲＦＩＤリーダ（明示せず）に送信される。ベースユニット３０６はプロセッサ（明示せず）を含み、そのプロセッサは、圧力メッセージ信号を受信し、かつマイクロポンプ３１６を作動させるまたはその動作を停止させるポンプ制御信号を発生させ得る。減圧が所望の治療範囲内にあるとき、マイクロポンプ３１６は、動作が停止され得る。同様に、圧力が絶対尺度で大きすぎる場合、ベースユニット３０６は、より減圧をもたらすように、マイクロポンプ３１６を作動させるまたは継続させるポンプ信号を送信し得る。所望の圧力に達しない経過時間が十分すぎるほど過ぎたら、警報がベースユニット３０６によってトリガされ得る。無線減圧ドレッシング３０４はガルバニ電池（明示せず）を含んで、滲出液または他の体液が２つの電極を電気的に結合すると、フル表示メッセージ信号をもたらす。フル表示メッセージ信号は、ＲＦＩＤアンテナ３１２によってベースユニット３０６に送信され、ドレッシングが満杯であることを示す。

【００７９】

ここで主に図１３を参照して、無線減圧ポンプ４３０を含む減圧ドレッシング４００の別の例示的実施形態を説明する。減圧ドレッシング４００は分解図として示し、患者４０４の組織部位４０２、例えば創傷を覆う。減圧ドレッシング４００は、組織部位４０２に近接して配置されるインターフェース分配マニホールド４０６を含む。インターフェース分配マニホールド４０６は、任意のマニホールド材料、例えばＧｒａｎｕＦｏａｍ（登録商標）材、または既に説明した任意の他のマニホールド材料から形成され得る。

【００８０】

減圧ドレッシング４００は、下部ドレープまたはダイバータ４０８をさらに含む。下部

ドレープ４０８は、下側面（組織対面側面）に接着剤を有するポリエチレン材料とし、治療される組織部位４０２を取り囲んで患者４０４に付着し得る。下部ドレープ４０８は、アパーチャまたは穿孔を含み、インターフェース分配マニホールド４０６を通して組織部位４０２に減圧を伝えかつ組織部位４０２から創傷液（液体または気体）を引き出し得る。下部ドレープ４０８はまたシーリング４１０を含み、追加的な接着強度をもたらして、減圧を所望の治療レベルに維持し得る。最初はシーリング４１０を保護用剥離ライナー４１２が覆っている。下部ドレープ４０８が患者４０４に位置決めされる前に、保護用剥離ライナー４１２を下部ドレープ４０８の下側から取り外す。

【００８１】

減圧ドレッシング４００は、不織ファブリックとし得る吸収層４１４を含み、下部ドレープ４０８のアパーチャを通って引き込まれる創傷液を吸収する。吸収層４１４は、創傷液を吸収層４１４に逃がすおよび分配する２つのウィッキング層４１６と４１８との間に挟まれている。ウィッキング層４１６、４１８の高密度側は、吸収層４１４から外方に向いている。ウィッキング層４１６、４１８はそれらの間に吸収層４１４を挟み、流体貯蔵装置４２０を形成する。

【００８２】

減圧ドレッシング４００は、ポリエチレンで形成された無孔の閉鎖的バリアとし得る上部ドレープ４２２をさらに含む。上部ドレープ４２２の平滑側は、上部ウィッキング層４１６に対面している。上部ドレープ４２２は、アパーチャまたは開口部４２４を含む。アパーチャまたは開口部４２４は、吸収層４１４内に創傷液や滲出液を含ませるために液体から空気を分離する疎水性フィルタ４２６によって覆われ得る。疎水性フィルタ４２６は、同時に、疎水性フィルタ４２６に減圧が行われる結果、吸収層４１４からのガスの流れを可能にする。上部ドレープ４２２および疎水性フィルタ４２６は、流体貯蔵装置４２０を覆う減圧ドレッシング４００の最上層４２８を含む。剥離ライナー４１２を除く上述のドレッシングアセンブリの要素は全て、まとめて、減圧ドレッシング４００の「創傷ドレッシング」部分と呼ぶ。

【００８３】

減圧ドレッシング４００は、無線減圧ポンプ、またはポンプ部分４３０をさらに含む。ポンプ部分４３０は、上部ドレープ４２２の上部に位置決めされたマイクロポンプアセンブリ４３２を含み、疎水性フィルタ４２６、流体貯蔵装置４２０、およびインターフェース分配マニホールド４０６を通して空気を引き出す減圧をもたらす。マイクロポンプアセンブリ４３２は圧電ディスクポンプ４３４を含み、この圧電ディスクポンプは、予め定められた周波数で振動して、圧電ディスクポンプ４３４の入力側で所望の減圧を生成する。圧電ディスクポンプ４３４は、図１２のマイクロポンプ３１６に類似し得る。マイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４は、上部ドレープ４２２の下側で組織部位４０２から吸収層４１４に引き込まれた液体が少しでも圧電ディスクポンプ４３４の入力ポートに入ると、動作しないとし得る。疎水性フィルタ４２６は、創傷液や滲出液がマイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４に流入しないようにする。

【００８４】

減圧ドレッシング４００はまた、疎水性フィルタ４２６と圧電ディスクポンプ４３４の流入口との間に位置決めされたスペーサーリングまたはリングシール４３６を含み、マイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４に空気の流れのための空洞をもたらし得る。マイクロポンプアセンブリ４３２は、第１の発泡体クッション４３８と第２の発泡体クッション４４０との間に挟まれ得る。マイクロポンプアセンブリ４３２、第１のクッション４３８、および第２のクッション４４０は、外側プライ４４２と内側プライ４４４との間に挟まれ、かつ上部ドレープ４２２に取り外し可能に取り付けられる単一の複合パッケージを形成する。外側プライ４４２は、マイクロポンプアセンブリ４３２の排出用の排出経路をもたらすアパーチャまたは穿孔４４６を含む。

【００８５】

圧電ディスクポンプ４３４または他のマイクロポンプは、第１のプロセッサ４４８およ

び他の制御電子回路によって制御され得る。圧電ディスクポンプ４３４は、第１のパワーユニット４５０および第２のパワーユニット４５２によって電力供給され得る。パワーユニット４５０、４５２はバッテリーとし得る。別の代替的な実施形態では、第１のパワーユニット４５０または第２のパワーユニット４５２は、第１のプロセッサ４４８および圧電ディスクポンプ４３４に電力を供給するＲＦＩＤアンテナを含み得る。

【００８６】

実施形態によれば、減圧によって組織部位を治療するシステムは、組織部位に近接して配置される減圧ドレッシング；および減圧ドレッシングに流体的に結合された無線減圧ポンプを含む。無線減圧ポンプは、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。システムは、ＲＦＩＤリーダを有するベースユニットをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプ装置に電力供給を行うように構成される。システムは、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシール部材は、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能する。無線減圧ポンプは、組織部位における圧力を感知するために減圧ドレッシングおよび第１のプロセッサに流体的に結合された圧力感知装置をさらに含む。無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含む。ベースユニットは、ＲＦＩＤリーダに結合された第２のプロセッサをさらに含み、かつ、第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。

【００８７】

前段落で説明したシステムに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含み得る。ベースユニットは、ＲＦＩＤリーダに結合された第２のプロセッサを含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成し得る。第１のプロセッサおよび圧力感知装置は、圧力問合せ信号に応答して圧力メッセージ信号を準備するように構成し得る。第１のプロセッサおよびＲＦＩＤアンテナは、圧力メッセージ信号を送信するように構成し得る。および、第２のプロセッサは、圧力メッセージ信号を受信し、制御信号を準備するように構成し得る。第２のプロセッサおよびＲＦＩＤは、無線減圧ポンプに制御信号を送信して、マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成し得る。

【００８８】

前段落で説明したシステムに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含み得る。圧力感知装置は、圧力メッセージ信号を生成するように動作可能である。第１のプロセッサは、圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能である。

【００８９】

前段落で説明したシステムの別の実施形態では、システムは、減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置と；第１の分配マニホールドと、吸収層と、ダイバータ層と、ポンプシール部材と、第２のポンプシール部材とをさらに含み、第１の分配マニホールド、吸収層、およびダイバータ層が、ポンプシール部材および第２のポンプシール部材によって形成されるポンプ用パウチ内に配置され；マイクロポンプ装置が圧電ポンプを含む。減圧ドレッシングは、組織部位に近接して配置されるインターフェース分配マニホールドと、ドレッシングシール部材と、減圧インターフェースとを含む。一実施形態では、ＲＦＩＤアンテナは、ベースユニ

ットから５センチメートル未満のところにある。

【００９０】

別の例示的実施形態によれば、無線減圧ポンプは、第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と；ＲＦＩＤアンテナと；ＲＦＩＤアンテナに結合された第１のプロセッサと；第１のプロセッサに結合されてそこから電力を受信しかつ減圧および正圧を発生させるマイクロポンプ装置とを含む。マイクロポンプ装置は、第１のチャンバに流体的に結合されてそこに正圧を排出する通気口と、第２のチャンバに流体的に結合されてそこに減圧を供給する流入口とを有する。ポンプは、第１のチャンバに流体的に結合された複数の膨張式支持部材と；第２のチャンバを含む液溜めとをさらに含む。ポンプは、第１のチャンバに流体的に結合された第１の圧力逃がし弁をさらに含み得る。第１の圧力逃がし弁は、第１の閾値圧力を上回る正圧を放出するように動作可能である。第１のチャンバおよび第２のチャンバは、ピラミッドの一部分の形状とし得る。ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。

【００９１】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療するシステムの製造方法は、組織部位に近接して配置される減圧ドレッシングを提供するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは：ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。この方法は、ＲＦＩＤリーダを有するベースユニットを提供するステップをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプ装置に電力供給を行うように構成し得る。この製造方法は、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。この製造方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合する減圧導管を設けるステップをさらに含み得る。この製造方法は、圧力感知装置を提供するステップと、圧力感知装置を減圧ドレッシングに結合するステップとをさらに含む。

【００９２】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して減圧ドレッシングを配置するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは：ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。この方法はまた、無線減圧ポンプを減圧ドレッシングに流体的に結合するステップと；ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと；ベースユニットを作動させ、それにより、ＲＦＩＤリーダおよび第２のプロセッサが無線減圧ポンプに作動信号を送信して、無線減圧ポンプを作動させるステップとを含む。無線減圧ポンプは、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。マイクロポンプ装置が必要とする電力は全て、ＲＦＩＤリーダによって供給され得る。この方法は、無線減圧ポンプのＲＦＩＤアンテナから５センチメートル以内にＲＦＩＤリーダを配置するステップをさらに含み得る。

【００９３】

前段落の方法に関して、無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源が設置されておらず、および無線減圧ポンプは：減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置と、第１の分配マニホールドと、吸収層と、ダイバータ層とをさらに含む。第１の分配マニホールド、吸収層、およびダイバータ層は、第１のポンプシール部材および第２のポンプシール部材によって形成さ

れたポンプ用パウチ内に配置され得る。マイクロポンプ装置は圧電ポンプとし得る。減圧ドレッシングは：組織部位に近接して配置されるインターフェース分配マニホールドと、ドレッシングシール部材と、減圧インターフェースとを含み得る。

【００９４】

別の例示的実施形態によれば、減圧によって組織部位を治療する減圧システムは：組織部位に近接して配置されるインターフェース分配マニホールドと、インターフェース分配マニホールドから流体を受け取って保持する吸収部材と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置であって、流入口および排出口を有するマイクロポンプ装置と、組織部位を覆って密閉空間を形成する第１のシール部材と、マイクロポンプ装置の排出口を外部に流体的に結合する通気口とを含む無線減圧ドレッシングを含む。マイクロポンプは、密閉空間に流体的に結合され、そこに減圧を供給する。システムは、ＲＦＩＤリーダを含むベースユニットをさらに含む。ベースユニットは、ポンプ信号を無線減圧ドレッシングに供給して、マイクロポンプ装置を付勢するように動作可能である。システムは、第１のプロセッサに結合された無線減圧ドレッシングに第１の圧力センサをさらに含む。第１のプロセッサおよびＲＦＩＤアンテナは、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してベースユニットに送信するように動作可能である。

【００９５】

前段落で説明したシステムの別の実施形態では、システムは、第１のプロセッサに結合される無線減圧ドレッシングの第１の圧力センサをさらに含み得る。第１のプロセッサおよびＲＦＩＤアンテナは、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してベースユニットに送信するように動作可能である。ベースユニットは第２のプロセッサをさらに含む。第２のプロセッサは、圧力メッセージ信号を受信しかつポンプ制御信号を生成するように動作可能である。

【００９６】

前段落で説明したシステムの別の実施形態では、システムは、第１のプロセッサに結合される無線減圧ドレッシングに第１の圧力センサをさらに含んでもよく、および第１のプロセッサは、第１の圧力センサから圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を制御するように構成される。前段落で説明したシステムの別の実施形態では、無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。さらに、減圧ドレッシングに供給される減圧のみが、マイクロポンプ装置からのものとし得る。このシステムは、導管またはワイヤが無線減圧ドレッシングに結合されないように組み立てられ得る。

【００９７】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して無線減圧ドレッシングを配置するステップを含む。無線減圧ドレッシングは、組織部位に近接して配置されるインターフェース分配マニホールドと、インターフェース分配マニホールドから流体を受け取って保持する吸収部材と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させ、かつ流入口および排出口を有するマイクロポンプ装置と、組織部位を覆いかつ密閉空間を形成する第１のシール部材と、排出口を外部に流体的に結合する通気口とを含む。この方法は、ＲＦＩＤリーダを含むベースユニットを提供するステップであって、ベースユニットが、無線減圧ドレッシングにポンプ信号を供給してマイクロポンプ装置を付勢するように構成されているステップと；ベースユニットを作動させて無線減圧ドレッシングにポンプ信号を供給するステップとをさらに含む。

【００９８】

別の例示的実施形態によれば、無線減圧ポンプであって、無線減圧ポンプが、ＲＦＩＤアンテナと；ＲＦＩＤアンテナに結合された第１のプロセッサと；第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置とを含む。無線

減圧ポンプは、マイクロポンプ装置に流体的に結合された液溜めをさらに含み得る。無線減圧ポンプはまた、第１のポンプシール部材および第２のポンプシール部材をさらに含んでもよく、第１のポンプシール部材および第２のポンプシールは少なくとも部分的に結合してポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。無線減圧ポンプは、減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置をさらに含み得る。

【００９９】

前段落の無線減圧ポンプに関して、ポンプは、第１のプロセッサに結合された圧力感知装置と、ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットとをさらに含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。

【０１００】

前段落の無線減圧ポンプに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置と、ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットとをさらに含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。第１のプロセッサおよび圧力感知装置は、圧力問合せ信号に応答して圧力メッセージ信号を準備するように構成される。第１のプロセッサおよびＲＦＩＤアンテナは、圧力メッセージ信号を送信するように構成される。第２のプロセッサは、圧力メッセージ信号を受信し、制御信号を準備するように構成され、および第２のプロセッサおよびＲＦＩＤは、無線減圧ポンプに制御信号を送信し、マイクロポンプ装置を作動または動作停止させるための制御信号をもたらすように構成される。無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含んでもよく；圧力感知装置は、圧力メッセージ信号を生成するように動作可能であり、および第１のプロセッサは、圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能である。

【０１０１】

一般論として、患者の組織部位に減圧をもたらすシステム、方法、およびドレッシングは、減圧ポンプに無線で電力をもたらすことを含むと説明される。一例では、ＲＦＩＤアンテナを使用して、導管によって減圧ドレッシングに流体的に結合された減圧ポンプに電力供給する。別の例では、減圧ドレッシングは、マイクロポンプと、マイクロポンプに電力供給するのに使用されるＲＦＩＤアンテナとを含む。本明細書では他のシステム、方法、および装置が説明される。

【０１０２】

本発明およびその利点を、いくつかの例示的非限定的な実施形態に照らして説明したが、添付の特許請求の範囲によって定義された本発明の範囲から逸脱せずに、様々な変更、代用、交換、および修正をなすことができることを理解されたい。任意の一実施形態に関連して説明された任意の特徴はまた、任意の他の実施形態にも適用可能であることを理解されたい。

【０１０３】

上述の利益および利点は、一実施形態に関連し得ること、またはいくつかの実施形態に関連し得ることを理解されたい。「１つの」品目への言及は、１つ以上のそれら品目を指すことをさらに理解されたい。

【０１０４】

本明細書で説明した方法のステップは、任意の好適な順序で、または適切な場合には同時に実施し得る。

【０１０５】

適切な場合には、上述の実施形態のいずれかの態様を、説明の任意の他の実施形態の態

様と組み合わせて、類似のまたは異なる特性を有しかつ同じまたは異なる問題に対処する別の例を形成する。

【０１０６】

好ましい実施形態の上述の説明は例示にすぎず、当業者は様々な修正をなし得ることを理解されたい。上述の明細書、例およびデータは、本発明の例示的な実施形態の構造および使用の完全な説明を提供する。本発明の様々な実施形態を、ある程度詳細に、または１つ以上の個々の実施形態を参照して上記で説明したが、当業者は、特許請求の範囲から逸脱せずに、開示の実施形態に多数の修正をなすことができる。

【図１】

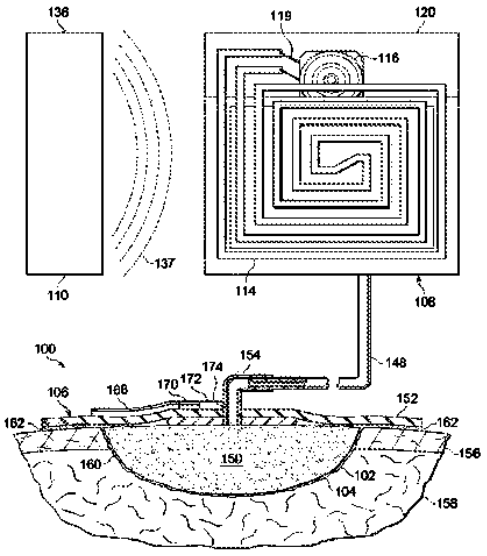


FIG. 1

【図２】

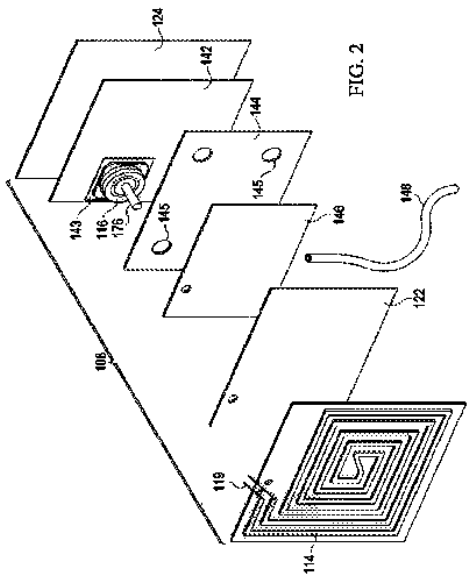


FIG. 2

【図３】

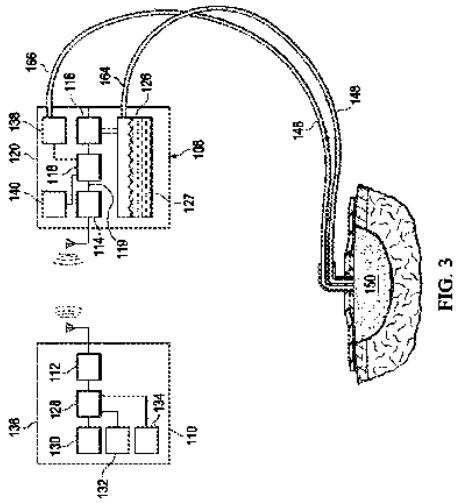


FIG. 3

【図４】

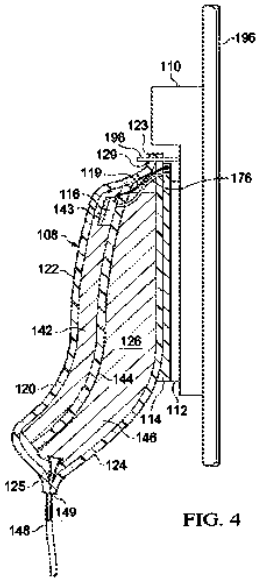


FIG. 4

【図５】

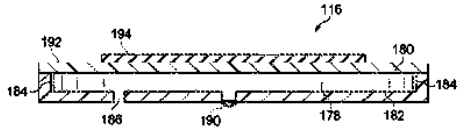


FIG. 5

【図６】

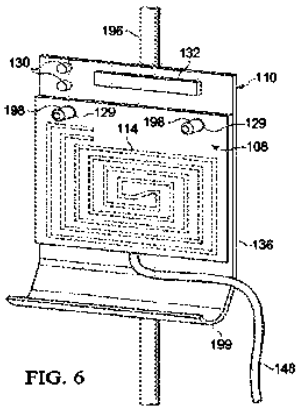


FIG. 6

【図７】

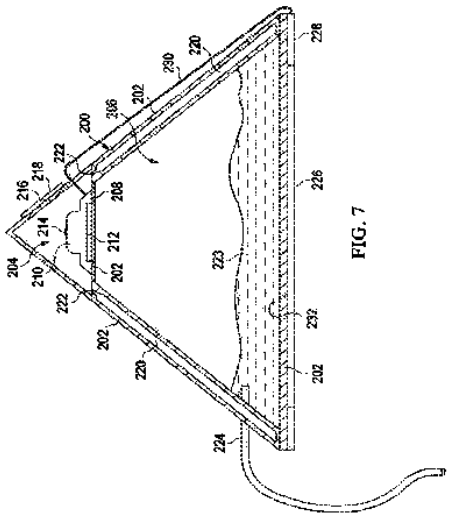


FIG. 7

【図８】

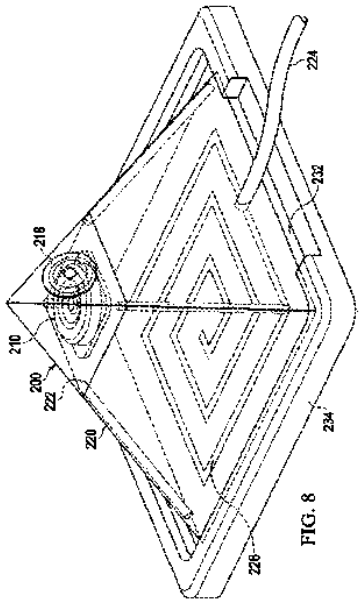


FIG. 8

【図９】

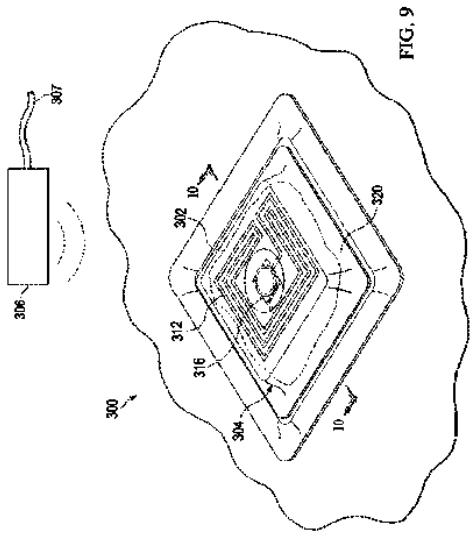


FIG. 9

【図１０】

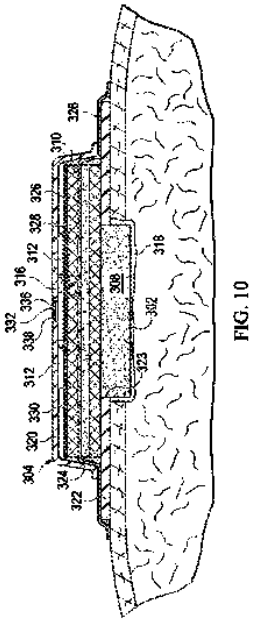


FIG. 10

【図１１】

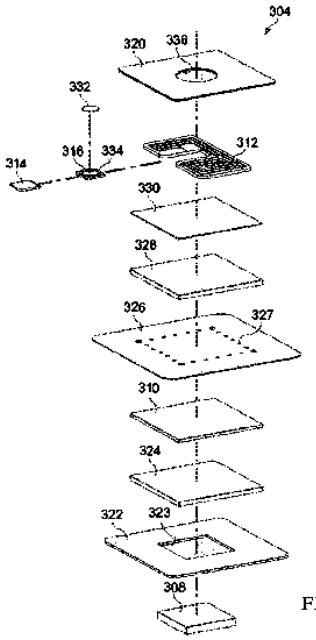


FIG. 11

【図１２】

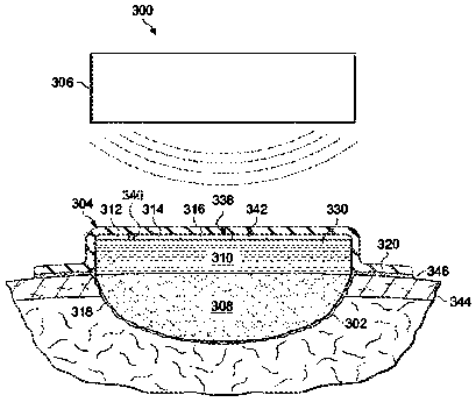


FIG. 12

【図１３】

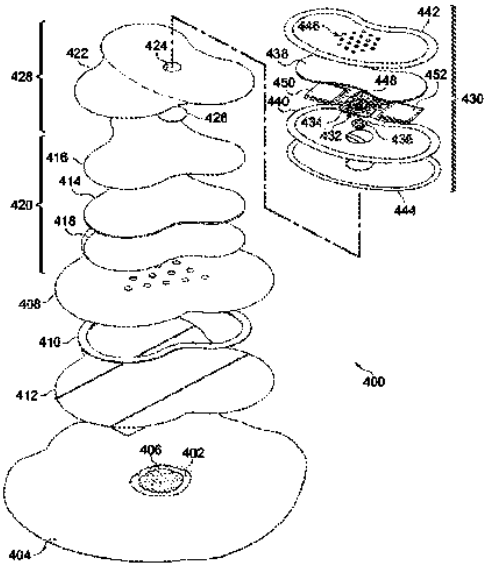


FIG. 13

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/044187

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/02 A61B17/08 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)
A61F 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 practical, 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	KR 2002 0032508 A (COSMOGENOME INC [KR]) 3 May 2002 (2002-05-03)	29-33,36
A	abstract; figure 3	1-28,34, 35,37-39
A	WO 2008/051924 A2 (ABBOTT DIABETES CARE INC [US]; STAFFORD GARY ASHLEY [US]) 2 May 2008 (2008-05-02) paragraphs [0006] - [0011]; figures 1-3	1-39
A	US 2009/227969 A1 (JAEB JONATHAN PAUL [US] ET AL) 10 September 2009 (2009-09-10) paragraphs [0006] - [0015]; figures 1-20	1-39

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 September 2011	24/10/2011

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	Mangin, Sophie

1

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/044187

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 2008051924 A2	02-05-2008	AU 2007309070 A1	02-05-2008
		CA 2667305 A1	02-05-2008
		CN 101528282 A	09-09-2009
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Form PCT/ISA/210 (patent family annex) (April 2005)

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(32)優先日 平成23年2月22日(2011.2.22)
(33)優先権主張国 米国(US)

(81)指定国 AP(BW,GH,GM,KE,LR,LS,MW,MZ,NA,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(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),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AO,AT,AU,AZ,BA,BB,BG,BH,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,IS,JP,KE,KG,KM,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LT,LU,LY,MA,MD,ME,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PE,PG,PH,PL,PT,RO,RS,RU,SC,SD,SE,SG,SK,SL,SM,ST,SV,SY,TH,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VC,VN,ZA,ZM,ZW

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Ｆターム(参考) 4C066 AA01 AA07 BB05 CC01 DD02
4C167 AA39 CC04 CC06 GG02 GG03 GG05 GG11 GG12 GG36 GG43

Patents JP 2013-545519 A

Pressure reducing system, dressing and method using wireless pump

Abstract

translated from Japanese

Systems, methods, and dressings are provided for providing reduced pressure to a patient's tissue site, including wirelessly powering a reduced pressure pump. In one example, an RFID antenna is used to power a vacuum pump that is fluidly coupled by a conduit to a vacuum dressing. In another example, a reduced pressure dressing incorporates a micropump and an RFID antenna that is used to power the micropump. Other systems, methods, and apparatus are provided.
[Selection] Figure 1

Images (13)



FIG. 5

Classifications

- A61M1/0023 Suction drainage systems

View 22 more classifications

JP2013545519A
Japan

Other languages: Japanese

Inventor: クルーサード、ヨナセード、グロエル、ジョン、ロック、クリストファー、グライアン、ストークス、ベンジャミン

Current Assignee : KCI Licensing Inc

Worldwide applications

2011 US IN CN WO AU JP CA BR EP CA AU EP JP WO TW TW
2013 US

Application JP2013536616A events

2010-10-27 Priority to US40710410P
2011-07-15 Application filed by KCI Licensing Inc
2013-12-26 Publication of JP2013545519A
2014-08-14 Publication of JP2013545519A5
2016-01-13 Application granted
2016-01-13 Publication of JP5843296B2
Status Expired - Fee Related
2031-07-15 Anticipated expiration

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External links: Espacenet, Global Dossier, Discuss

Claims (39)

Hide Dependent

translated from Japanese

In a system for treating a tissue site by decompression, the system includes:
A reduced pressure dressing positioned proximate to the tissue site,
A wireless vacuum pump fluidly coupled to the vacuum dressing.
RFID antenna
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a depressurization; and a wireless depressurization pump including a reservoir fluidly coupled to the micropump device;
A base unit having an RFID reader;
Including
The system, wherein the RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. The system of claim 1, further comprising a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal member are at least partially coupled. A system characterized in that a pump pouch is formed, on which the micropump device is arranged. 3. The system according to claim 1, wherein a power source other than the RFID antenna is not installed in the wireless decompression pump. 4. The system according to any one of claims 1-3, wherein the wireless vacuum pump is fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site. The system further comprising. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;
The base unit includes a second processor coupled to the RFID reader, and the second processor and the RFID reader transmit a pressure inquiry signal to the first processor of the wireless decompression pump and to it A system configured to receive a pressure message signal from the first processor in response. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;
The base unit includes a second processor coupled to the RFID reader.
The second processor and the RFID reader are configured to send a pressure inquiry signal to the first processor of the wireless decompression pump and receive a pressure message signal from the first processor in response thereto,
The first processor and the pressure sensing device are configured to prepare the pressure message signal in response to the pressure inquiry signal;
The first processor and the RFID antenna are configured to transmit the pressure message signal, and the second processor is configured to receive the pressure message signal

and prepare a control signal; and The system, wherein the second processor and RFID are configured to send the control signal to the wireless vacuum pump to provide a control signal to activate or deactivate the micropump device. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor,
The pressure sensing device is operable to generate a pressure message signal, and the first processor receives the pressure message signal and generates a control signal to activate the micropump device or A system characterized in that it is operable to stop operation. The system of claim 1, wherein
A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site;
A first distribution manifold;
An absorbent layer,
The diverter layer,
A pump seal member,
A second pump seal member,
The first distribution manifold, the absorbent layer, and the diverter layer are disposed within a pump pouch formed by a pump seal member and a second pump seal member;
The micropump device includes a piezoelectric pump;
Said reduced pressure dressing;
An interface distribution manifold disposed proximate to the tissue site;
A system comprising, a dressing seal member; and a vacuum interface, and wherein the RFID antenna is less than 5 centimeters from the base unit. In wireless vacuum pump
At least one wall member forming a first chamber and a second chamber;
An RFID antenna and a first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating reduced pressure and positive pressure,
A plurality of inflatable support members fluidly coupled to the first chamber;
A liquid reservoir containing the second chamber,
The micropump device is fluidly coupled to the first chamber and exhausts positive pressure thereto; and an inlet fluidly coupled to the second chamber and supplies reduced pressure thereto. A wireless decompression pump, comprising: 16. The wireless vacuum pump according to claim 9, further comprising a first pressure relief valve fluidly coupled to the first chamber, wherein the first pressure relief valve is a positive pressure above a first threshold pressure. A wireless vacuum pump, characterized in that it is operable to release pressure. The wireless decompression pump according to claim 9 or 10, wherein the first chamber and the second chamber are in the shape of a part of a pyramid. The wireless decompression pump according to any one of claims 9 and 10 to 11, wherein a power source other than the RFID antenna is not installed. In a method of manufacturing a system for treating a tissue site of a patient by decompression, the method comprises
Providing a reduced pressure dressing positioned proximate to the tissue site;
Providing a wireless vacuum pump, the wireless vacuum pump comprising:
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure; and a reservoir fluidly coupled to the micropump device;
Providing a base unit having an RFID reader,
A method wherein the RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. 14. The manufacturing method according to claim 13, further comprising a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal are at least partially coupled, Forming a pumping pouch in which the micropump device is arranged. 14. The method of claim 13, further comprising providing a vacuum conduit that fluidly couples the wireless vacuum pump to the vacuum dressing. 14. The method of claim 13, further comprising providing a pressure sensing device and coupling the pressure sensing device to the reduced pressure dressing. In a method of treating a tissue site of a patient by decompression,
Placing a reduced pressure dressing proximate to the tissue site,
Providing a wireless vacuum pump, the wireless vacuum pump comprising,
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure; and a reservoir fluidly coupled to the micropump device;
Fluidly coupling the wireless vacuum pump to the vacuum dressing;
Providing a base unit having an RFID reader and a second processor;
Activating the base unit, whereby the RFID reader and the second processor send an activation signal to the wireless decompression pump to activate the wireless decompression pump. Method. 18. The method of claim 17, wherein the wireless vacuum pump is:
A first pump seal member;
A second pump seal member, wherein the first pump seal member and the second pump seal are at least partially combined to form a pump pouch in which the micropump device is disposed; And a pump seal member. 19. A method according to claim 17 or 18, characterized in that all the power required by the micropump device is supplied by the RFID reader. 20. A method according to any of claims 17 or 18 to 19, further comprising the step of positioning the RFID reader within 5 centimeters of the RFID antenna of the wireless vacuum pump. The method of claim 18, wherein
No power source other than the RFID antenna is installed in the wireless decompression pump;
The wireless vacuum pump is:
A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site,
A first distribution manifold,
Absorption layer,
Further including a diverter layer,
The first distribution manifold, the absorbent layer, and the diverter layer are disposed in the pump pouch formed by the first pump seal member and the second pump seal member, and the micropump device Comprises a piezoelectric pump; and the vacuum dressing comprises:
An interface distribution manifold disposed proximate to the tissue site;
A method comprising: a dressing seal member; and a vacuum interface. In a decompression system for treating a tissue site by decompression, the decompression system includes:
Wireless decompression dressing,
An interface distribution manifold disposed proximate to the tissue site;
An absorbent member for receiving and holding fluid from the interface distribution manifold;
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure, the micropump device having an inlet and an outlet,
A first seal member that covers the tissue site and forms a sealed space, and a vent hole that fluidly couples the discharge port of the micropump device to the outside;
A wireless reduced pressure dressing, wherein the micropump is fluidly coupled to the enclosed space and supplies reduced pressure thereto,
A decompression system comprising a base unit including an RFID reader, the base unit operable to supply a pump signal to a wireless decompression dressing to energize the micropump device. 23. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, wherein the first pressure sensor is coupled to

the first processor, and the first processor and the RFID antenna are: A system operable to receive a pressure inquiry signal and generate a pressure message signal and send it to the base unit. 23. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, wherein the first pressure sensor is coupled to the first processor, and the first processor and the RFID antenna are: Operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit, the base unit further comprising a second processor, wherein the second processor comprises the pressure A system operable to receive a message signal and generate a pump control signal. 28. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, the first pressure sensor coupled to the first processor, and the first processor comprising the first processor. A system configured to receive a pressure message signal from a plurality of pressure sensors and generate a control signal to control the micropump device. 28. The system of claim 22, wherein the wireless decompression pump is not provided with a power source other than the RFID antenna, and only the decompression supplied to the decompression dressing is from the micropump device. A system characterized by being. 27. A system according to any one of claims 22 or 23 to 26, wherein no conduit or wire is coupled to the wireless vacuum dressing. In a method of treating a tissue site of a patient by decompression,

Placing a wireless vacuum dressing proximate to the tissue site, the wireless vacuum dressing comprising:

An interface distribution manifold disposed proximate to the tissue site,

An absorbent member for receiving and holding fluid from the interface distribution manifold,

RFID antenna,

A first processor coupled to the RFID antenna;

A micropump device coupled to the first processor for receiving power therefrom and generating a vacuum and having an inlet and an outlet,

A first sealing member that covers the tissue site and forms a sealed space, and a vent that fluidly couples the outlet to the outside,

Providing a base unit including an RFID reader, wherein the base unit is configured to provide a pump signal to the wireless decompression dressing to energize the micropump device;

Activating the base unit to provide the pump signal to the wireless decompression dressing. In wireless decompression pump,

With an RFID antenna;

A first processor coupled to the RFID antenna;

And a micropump device coupled to the first processor for receiving power therefrom and generating a vacuum. 30. The wireless vacuum pump according to claim 29, further comprising a reservoir fluidly coupled to the micropump device. The wireless decompression pump according to claim 29 or 30,

A first pump seal member;

A second pump seal member, wherein the first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump device is disposed. And a pump seal member. The wireless decompression pump according to any one of claims 29 to 31, wherein a power source other than the RFID antenna is not installed. 33. The wireless vacuum pump according to any one of claims 29 or 30 to 32, further comprising a pressure sensing device fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site. A wireless decompression pump characterized by that. A wireless decompression pump according to any one of claims 29 or 30 to 32.

The wireless vacuum pump further includes a pressure sensing device coupled to the first processor;

A base unit including a second processor coupled to the RFID reader, and the second processor and the RFID reader transmit a pressure interrogation signal to the first processor of the wireless vacuum pump and to it A wireless decompression pump configured to receive a pressure message signal from the first processor in response. A wireless decompression pump according to any one of claims 29 or 30 to 32,

The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;

A base unit including a second processor coupled to the RFID reader,

The second processor and the RFID reader are configured to send a pressure inquiry signal to the first processor of the wireless decompression pump and receive a pressure message signal from the first processor in response thereto;

The first processor and the pressure sensing device are configured to prepare the pressure message signal in response to the pressure inquiry signal;

The first processor and the RFID antenna are configured to transmit the pressure message signal, and the second processor is configured to receive the pressure message signal and prepare a control signal, and The wireless decompression, wherein the second processor and RFID are configured to send the control signal to the wireless decompression pump to provide a control signal to activate or deactivate the micropump device pump. A wireless decompression pump according to any one of claims 29 or 30 to 32,

The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;

The pressure sensing device is operable to generate a pressure message signal, and the first processor receives the pressure message signal and generates a control signal to activate the micropump device, or A wireless decompression pump, characterized in that it is operable to stop its operation. 33. The wireless vacuum pump according to any one of claims 29 or 30 to 32, wherein the wireless vacuum pump is:

At least one wall member forming a first chamber and a second chamber;

A first pressure relief valve fluidly coupled to the first chamber, the first pressure relief valve operable to release a positive pressure above a first threshold pressure,

A plurality of inflatable support members fluidly coupled to the first chamber,

The micropump device is fluidly coupled to the first chamber and has a vent for supplying positive pressure thereto, and a fluid fluidly coupled to the second chamber and for supplying reduced pressure thereto. And an entrance

The wireless pressure reducing pump, wherein the liquid reservoir includes the second chamber. 31. The wireless vacuum pump according to claim 29 or 30, wherein the wireless vacuum pump is:

A first chamber and a second chamber in the form of a portion of a pyramid,

A first pressure relief valve fluidly coupled to the first chamber, the first pressure relief valve operable to release a positive pressure above a first threshold pressure;

A plurality of inflatable support members fluidly coupled to the first chamber;

Further including

The micropump device has a vent fluidly coupled to the first chamber,

The wireless pressure reducing pump, wherein the liquid reservoir includes the second chamber. The wireless decompression pump according to claim 29 or 30,

No power source other than the RFID antenna is installed in the wireless decompression pump;

The wireless vacuum pump is:

A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site;

A first distribution manifold,

Absorption layer,

Further including a diverter layer,

The first distribution manifold, the absorbent layer, and the diverter layer are disposed within the pump pouch formed by the first pump seal member and the second pump seal member;

The micropump device includes a piezoelectric pump;

Said reduced pressure dressing:

An interface distribution manifold disposed proximate to the tissue site,

Including a dressing seal member, and a vacuum interface,

A wireless decompression pump, wherein the RFID antenna is less than about 5 centimeters from the base unit, and a decompression conduit fluidly couples a decompression interface to the wireless decompression pump

Description translated from Japanese

CROSS REFERENCE TO RELATED APPLICATIONS The present invention is incorporated under 35 USC §119 (e), US Provisional Patent Application No. 61 / 407,194, filed Oct. 27, 2010 ("System and Methods For Electrical The Presentation Of Excluded In Reduced-Pressure Dressing "(incorporated herein for all purposes) [VAC. 0975PRO1]; US Provisional Patent Application No. 61 / 418,730, filed Dec. 1, 2010 (" Systems and Methods for Electrically "), Detecting the Presence of Update in Dressing " (incorporated herein by reference for all purposes) [VAC 0975PRO2], US Provisional Patent Application No. 61 / 445,383, filed Feb. 22, 2011 ("Interactive, Wireless Reduced-Pressures, Methods, and Systems" (incorporated herein by reference for all purposes)), [VAC. 0999PRO]; and U.S. Provisional Patent Application No. 61 / 445,338, filed February 22, 2011 ("Reduce Pressure Systems, Dressings, and Methods Employing a Wireless Pump"), Insist on the benefits of [VAC.1000PRO].

The present disclosure relates generally to treatment systems, and more particularly, but not exclusively, to systems, dressings, and methods that include wirelessly powering a pump that applies a vacuum to a tissue site.

In clinical trials and practice, it has been shown to enhance and accelerate the growth of new tissue at a tissue site by providing a reduced pressure in proximity to the tissue site. Although there are many applications of this phenomenon, reducing the pressure has been quite successful in treating wounds. This treatment (often referred to in the medical community as "negative pressure closure therapy", "decompression therapy", or "vacuum therapy") offers a number of benefits, including rapid healing and granulation tissue Acceleration of formation may be included. In general, when reduced pressure is applied to an open wound, it is applied to the tissue through a porous pad or other manifold device. The porous pad distributes the vacuum to the tissue and delivers fluid drawn from the tissue. Reduced pressure can also be used to remove fluid from a body sinus such as the abdominal cavity.

According to an exemplary embodiment, a system for treating a tissue site with reduced pressure includes a reduced pressure dressing disposed proximate to the tissue site and a wireless reduced pressure pump fluidly coupled to the reduced pressure dressing. A wireless decompression pump includes a radio frequency identification (RFID) antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the processor for receiving power and generating decompression. , A first pump seal member, a liquid reservoir, and a second pump seal member. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The system further includes a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and power the micropump.

According to another exemplary embodiment, a method of manufacturing a system for treating a patient tissue site by decompression provides a decompression dressing disposed proximate to the tissue site, and provides a wireless decompression pump, including. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the first processor for receiving power and generating decompression, and a first pump seal. A member, a reservoir, and a second pump seal member. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The method may further include providing a vacuum supply conduit to fluidly couple the wireless vacuum pump to the vacuum dressing. The method further includes providing a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and power the micropump.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a decompression dressing proximate the tissue site and providing a wireless decompression pump. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the processor for receiving power and generating decompression, a first pump seal member, A liquid reservoir and a second pump seal member are included. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The method includes fluidly coupling a wireless vacuum pump to a vacuum dressing, providing a base unit having an RFID reader and a second processor, activating the base unit, thereby providing the RFID reader and the second The processor further sends an activation signal to the wireless vacuum pump to activate the wireless vacuum pump.

According to another exemplary embodiment, a reduced pressure system for treating a tissue site with reduced pressure includes a reduced pressure dressing. The reduced pressure dressing includes a first distribution manifold disposed proximate to a tissue site, an absorbent layer for receiving and retaining fluid from the first distribution manifold, an RFID antenna, and a first processor coupled to the RFID antenna. And a micropump coupled to the first processor for receiving power therefrom and generating a decompression. The micropump has an inlet and an outlet. The system also includes a first seal member that forms a sealed space over the tissue site and the top of the micropump, and a vent that fluidly couples the micropump outlet to the outside. The system further includes a base unit that includes an RFID reader. The base unit is operable to supply a pump signal to the decompression dressing to energize the micropump.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a wireless decompression dressing proximate to the tissue site. The wireless decompression dressing includes a first distribution manifold disposed proximate to the tissue site, an absorbent layer that receives and retains fluid from the first distribution manifold, an RFID antenna, and a first coupled to the RFID antenna. A processor and a micropump coupled to the first processor for receiving power therefrom and generating a vacuum. The micropump includes an inlet and an outlet, a first seal member that covers the tissue site and the upper side of the micropump to form a sealed space, and a vent that fluidly couples the outlet of the micropump to the outside. Have. The method further includes providing a base unit that includes an RFID reader. The base unit is operable to provide a pump signal to the wireless vacuum dressing to energize the micropump. The method also includes activating the base unit to provide a pump signal to the wireless vacuum dressing.

Other features and advantages of the exemplary embodiments will become apparent with reference to the drawings and detailed description that follow.

FIG. 1 is a schematic diagram illustrating, in cross section, a portion of an exemplary embodiment of a system for treating a tissue site with reduced pressure. 2 is a schematic exploded perspective view of an exemplary embodiment of a wireless vacuum pump used as part of the system of FIG. FIG. 3 is a schematic diagram illustrating a portion of the system of FIG. FIG. 4 is a schematic partial cross-sectional view of an exemplary embodiment of a wireless vacuum pump. FIG. 5 is a schematic cross-sectional view of an exemplary embodiment of a micropump device for use as part of a system for treating a tissue site with reduced pressure as in FIG. FIG. 6 is a schematic perspective view of an exemplary embodiment of a wireless vacuum pump. FIG. 7 is a schematic cross-sectional view of another exemplary embodiment of a wireless vacuum pump. FIG. 8 is a schematic perspective view of the wireless decompression pump of FIG. FIG. 9 is a schematic diagram illustrating, in perspective view, a portion of an exemplary embodiment of a reduced pressure system that treats a tissue site with reduced pressure. 10 is a schematic cross-sectional view of the vacuum dressing shown in FIG. 9 taken along line 10-10. FIG. 11 is a schematic exploded perspective view of the vacuum dressing of FIGS. FIG. 12 is a schematic cross-sectional view of an exemplary embodiment of a system for treating a tissue site with reduced pressure. FIG. 13 is a schematic exploded perspective view of another exemplary embodiment of a vacuum dressing.

In the following detailed description of exemplary, non-limiting embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and other embodiments may be used without departing from the spirit or scope of the invention. It is understood that mechanical, electrical and chemical changes can be made on the logical structure. To avoid details not necessary to enable one skilled in the art to implement the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is not to be taken in a limiting sense, and the scope of the exemplary embodiments is defined only by the appended claims.

Exemplary embodiments herein use radio frequency authentication (RFID) or enhanced type radio frequency authentication (RFID) technology to power a micropump device in a vacuum dressing. Including. RFID traditionally uses an RFID tag or label on the target and an RFID reader that activates the RFID tag and reads signals therefrom. One common example is a price tag. Most RFID tags include an integrated circuit that stores and processes information, a modulator, and a demodulator.

RFID tags can be passive tags, active RFID tags, and passive tags with batteries. In general, passive tags do not use batteries and do not transmit information unless activated by an RFID reader. An active tag has an on-board battery and can transmit autonomously (ie, not energized by an RFID reader). Generally, a passive tag with a battery is equipped with a small battery that is activated by the presence of an RFID reader. To enhance the performance of the RFID tag, a microcontroller and sensor may be incorporated into the reduced pressure dressing. RFID tags, microcontrollers and sensors allow for sensing functions and optional computer functions. In addition, RFID tags and microcontrollers partially or fully power the micropump.

In one exemplary embodiment, the high performance RFID technology is a WISP (Wireless Identification and Sensing Platform) device. WISP, similar to RFID tags (or labels), includes using an RFID reader to power and read the WISP device. The WISP device obtains power from the radio signal emitted by the RFID reader and performs a sensing function (and optionally performs a computer function). The WISP device transmits a wireless signal comprising information to the RFID reader. The WISP device receives power from the RFID reader. A WISP device has a tag or antenna to obtain energy and a microcontroller (or processor) that can perform various tasks, such as a sampling sensor. The WISP device reports data to the RFID reader. In one exemplary embodiment, a WISP device includes an integrated circuit with a power harvesting circuit, a demodulator, a modulator, a microcontroller, a sensor, and includes one or more capacitors to store energy. But you can. One form of WISP technology was developed by Intel Research Seattle (www.seattle.intel-research.net/wisp/). As used herein, RFID devices also include WISP devices.

Referring now to the drawings, and initially to FIGS. 1-5, an exemplary embodiment of a system 100 for treating a tissue site 102, eg, a wound 104, or cavity by reduced pressure will be described. The system 100 includes a base unit 110 having a reduced pressure dressing 106 disposed proximate to a tissue site 102, a wireless reduced pressure pump 108 fluidly coupled to the reduced pressure dressing 106, and an RFID reader 112. The wireless decompression pump 108 includes a first RFID antenna 114 and a micropump device 116. The RFID reader 112 is configured to generate and transmit a pump signal that provides power to the first RFID antenna 114. Power is supplied to the micropump device 116 by the pump signal received by the first RFID antenna 114. Powering the micropump device 116 from a distance provides a number of potential benefits. These benefits can include ease of application. Further, the wireless vacuum pump 108 can be a built-in disposable unit. It should be noted that there are some differences between the drawings to illustrate some of the potential variations of the illustrated system 100.

System 100 may be used with a variety of different types of tissue sites 102. The tissue site 102 can be any human, animal, or other, including bone tissue, adipose tissue, muscle tissue, skin tissue, vascular tissue, connective tissue, cartilage, tendon, ligament, body sinus, or any other tissue it can be the body tissue of any organism. Treatment of the tissue site 102 may include removal of fluids such as exudates and ascites.

The wireless decompression pump 108 includes a first RFID antenna 114 that is coupled to the first processor 118 by a conductor 119. The first processor 118 is coupled to the micropump device 116, i.e. the micropump, and receives power. The first processor 118 may be incorporated into the micropump device 116. The first processor 118 and the micropump device 116 may be disposed within the pump pouch 120.

The pump pouch 120 can be formed to couple the first pump seal member 122 to the second pump seal member 124. The pump pouch 120 may also be formed by other techniques, such as casting the pump pouch 120 from a polymer. At least a portion of the pump pouch 120 includes a reservoir 126 that receives and retains fluid 127 from the tissue site 102. The micropump device 116 can be a piezoelectric pump, a peristaltic pump, or other small pump that produces a vacuum with minimal power requirements. The first processor 118 is operable to receive a pressure message signal from the pressure sensing device 138. In response to receiving the pressure message signal, the first processor 118 generates a control signal to activate or deactivate the micropump device 116. The pressure sensing device 138 may be a transducer or a simple switch that is activated when sufficient vacuum is present.

Referring primarily to FIG. 3, the base unit 110 includes a second processor 128 coupled to the RFID reader 112. A control panel 130 (eg, a user interface), a first display 132, and a power source 134 (eg, a battery or electrical connection) may also be coupled to the second processor 128. Base unit 110 may include a base housing 136. The second processor 128 and RFID reader 112 are configured to transmit a signal 137, such as a pump signal or a pressure interrogation signal, to the first RFID antenna 114.

The first RFID antenna 114 of the vacuum pump 108 is coupled to the first processor 118 by a conductor 119 or by wireless coupling. The first processor 118 is coupled to the micropump device 116 to supply power to and control the micropump device 116. A first power supply 140 may be included to provide additional power to the first processor 118. A pressure sensing device 138 may be coupled to the first processor 118. Pressure sensing device 138 is fluidly coupled to pressure sensing lumen 166 (ie, air passage 174 or interface distribution manifold 150) to sense the pressure therein. Micropump device 116 is fluidly coupled to reservoir 126. Reservoir 126 receives and holds fluid 127 from vacuum lumen 164, ie, interface distribution manifold 150.

The pump signal transmitted by the base unit 110 is received by the first RFID antenna 114 and energizes the micropump device 116 to produce a reduced pressure. The pressure inquiry signal is transmitted by the second processor 128 and the RFID reader 112 to the first processor 118 of the wireless vacuum pump 108. In response, the first processor 118 and the pressure sensing device 138 of the wireless decompression pump 108 send a pressure message signal to the base unit 110 indicating the pressure that the decompression dressing 106 is experiencing.

The second processor 128 is configured to receive a pressure message signal from the wireless vacuum pump 106 and prepare a control signal. The second processor 128 and RFID reader 112 are configured to send a control signal to the wireless vacuum pump 106 to activate or deactivate the micropump device 116. In another exemplary embodiment, as described above, the first processor 118 receives the pressure message signal from the pressure sensing device 138 and generates a control signal to activate or deactivate the micropump device 116. It is possible to operate.

Referring now primarily to FIGS. 2 and 4, the wireless vacuum pump 108 generates a vacuum that is supplied to the tissue site 102. The wireless vacuum pump 108 receives and holds fluid from the tissue site 102. Depressurization generally refers to a pressure that does not reach ambient pressure at the tissue site being treated. In most cases, this reduced pressure does not reach the air pressure where the patient is. Alternatively, the reduced pressure can be less than the hydrostatic pressure at the tissue site. Unless otherwise specified, the pressure values listed herein are gauge pressures. The reduced pressure supplied can be constant or variable (patterned or random) and can be supplied continuously or intermittently. Consistent with the use herein, unless otherwise specified, an increase in vacuum or vacuum generally refers to a relative decrease in absolute pressure.

The wireless vacuum pump 108 provides vacuum for the system 100. The wireless vacuum pump 108 can include a first distribution manifold 142, a diverter layer 144, and an absorption layer 146. A vent 176 is used to fluidly couple the exhaust path from the micropump device 116 to the exterior of the wireless vacuum pump 108. The first distribution manifold 142 serves to distribute the reduced pressure generated by the micropump device 116. An air liquid separator 143, for example, a hydrophobic filter, is disposed between the micropump device 116 and the first distribution manifold 142 to prevent liquid from entering the micropump device 116. Absorbent layer 146 serves to receive and retain fluid from tissue site 102. The absorbent layer 146 can be made of any material that can absorb liquids such as exudates from the tissue site 102.

The absorbent layer 146 can be made from superabsorbent fibers. Superabsorbent fibers may hold liquids or bind to liquids with physical or chemical changes to the fibers. In one non-limiting example, superabsorbent fibers can be obtained from Technical Absorbents, Ltd. Super Absorbent Fiber (SAF) material from (Grimsby, United Kingdom) may be included. Absorbent layer 146 may be a sheet or mat of fibrous material in which the fibers absorb liquid from tissue site 102. The structure of the absorbent layer 146 containing fibers may be woven or non-woven. The fibers of the absorbent layer 146 may become a gel when in contact with the liquid, thereby

trapping the liquid. The spaces or voids between the fibers may allow the reduced pressure applied to the absorbent layer 146 to be transmitted through and through the absorbent layer 146. In one exemplary embodiment, the fiber density of the fibers in the absorbent layer 146 may be about 1 4 grams per millimeter.

The diverter layer 144 is disposed adjacent to the absorbent layer 146 and the first distribution manifold 142. The diverter layer 144 is formed from a liquid impervious material, but includes a plurality of apertures 145. A plurality of apertures 145 transmit the reduced pressure from the micropump device 116 through the diverter layer 144 to a desired location. The diverter layer 144 helps to control the pattern of vacuum when applied to the absorbent layer 146. The reduced pressure is distributed to the diverter layer 144 by the first distribution manifold 142. Apertures 145 are arranged in a pattern that reduces the pressure on multiple portions of absorbent layer 146 and continues to transmit the reduced pressure to tissue site 102 as absorbent layer 146 absorbs more fluid from tissue site 102. The performance of the absorption layer 146 can be improved.

The plurality of apertures 145 may be positioned in a pattern that surrounds the peripheral portion of the diverter layer 144 away from the center of the diverter layer 144 so that decompression is performed at the absorbent layer 146 away from the central region of the absorbent layer 146. . The diverter layer 144 works with the first distribution manifold 142 to ensure that the absorption capacity and absorption efficiency of the absorbent layer 146 is increased compared to the absorbent layer 146 not used with the diverter layer 144. By providing good liquid distribution throughout the absorbent layer 146, the diverter layer 144 also increases the effective capacity of the wireless vacuum pump 108 and increases the treatment time.

The diverter layer 144 can be made from any material that enhances the vacuum transfer capacity and storage capacity of the adjacent absorbent layer. For example, the diverter layer 144 may be made of a material that is substantially impermeable to liquids and gases and that diverts the reduced pressure flow through the aperture 145. Alternatively or additionally, the material from which the diverter layer 144 is made may have a predetermined moisture transfer rate, which is consistent with gas permeability. In either example, the diverter layer 144 may still include a pattern of apertures that transmit a greater amount of liquid or gas than is possible with an apertureless gas permeable material. However, it should be noted that the permeability of the diverter layer 144 to gas rather than liquid increases the transfer rate of vacuum through the dressing, but still allows the liquid flow to be directed around or near the diverter layer 144.

The first distribution manifold 142, the diverter layer 144, and the absorbent layer 146 can be disposed within the pump pouch 120. The wireless vacuum pump 108 may also include a pressure sensing device 138 that is fluidly coupled to the vacuum dressing 106 and communicates with the first processor 118 for pressure sensing. The decompression conduit 148 supplies fluid from the decompression dressing 106 to the wireless decompression pump 108. In one exemplary embodiment, the vacuum conduit 148 is disposed directly on the absorbent layer 146. In another exemplary embodiment, an interface (not shown) fluidly couples the vacuum conduit 148 and the absorbent layer 146.

Referring now primarily to FIGS. 1 and 3, the reduced pressure dressing 106 is disposed at the tissue site 102. The tissue site 102 can be, for example, the wound 104 through the epidermis 156 to the subcutaneous tissue 158, or any other tissue site. The reduced pressure dressing 106 can be any device that provides reduced pressure to the tissue site 102 and receives fluid from the tissue site 102. For example, the vacuum dressing 106 may be formed by a foam member, a structure with a plurality of defined channels, a suction tube, or other device. In one exemplary embodiment, the reduced pressure dressing 106 may include an interface distribution manifold 150, a dressing seal member 152, and a reduced pressure interface 154 disposed proximate to the tissue site 102.

A manifold generally refers to an object or structure that is provided to assist in reducing pressure, supplying fluid, or removing fluid therefrom. The interface distribution manifold 150 generally includes a plurality of channels or flow paths that allow fluid to be distributed to and removed from the tissue site 102 around the interface distribution manifold 150. In one exemplary embodiment, the flow paths or flow paths are interconnected to improve the distribution of fluid provided to or removed from the tissue site 102. The interface distribution manifold 150 may also be a biocompatible material that can be placed in contact with the tissue site 102 and allow the reduced pressure to be distributed to the tissue site 102. Examples of interface distribution manifolds may include, but are not limited to: devices having structural elements arranged to form a flow path, eg, cellular foam, open cell foam, porous tissue Aggregates, liquids, gels, and foams that contain or cure the flow path. foams, gauze, felt mats, or any other material suitable for a particular biological application.

In one embodiment, the interface distribution manifold 150 is a porous foam and includes a plurality of open cells or pores that serve as flow paths. The porous foam may be an open cell reticulated foam made of polyurethane, such as GranuFoam® material available from Kinetic Concepts, Incorporated (San Antonio, Texas). In some cases, interface distribution manifold 150 may also be used to distribute fluids such as drugs, antimicrobial agents, growth factors, and various solutions to tissue site 102. Other layers such as absorbent material, wicking material, hydrophobic material, and hydrophilic material may also be included in or on the interface distribution manifold 150.

In one exemplary embodiment, all or a portion of the interface distribution manifold 150 may be composed of a bioresorbable material that may remain on the patient's body after use of the reduced pressure dressing 106. Suitable bioresorbable materials can include, but are not limited to, polymer blends of polylactic acid (PLA) and polyglycolic acid (PGA). The polymer blend can also include, but is not limited to, polycarbonate, polyfumarate, and caprolactone. The interface distribution manifold 150 may further serve as a scaffold for new cell growth, or the interface distribution manifold 150 and scaffold material may be used together to promote cell growth. A scaffold is an object or structure used to enhance or promote cell growth or tissue formation, eg, a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA / PGA, coral hydroxyapatite, carbonate, or processed allograft material.

The interface distribution manifold 150 is covered by a dressing seal member 152. The dressing seal member 152 may be any material that provides a fluid seal. A fluid seal is a suitable seal to maintain the reduced pressure provided by a particular reduced pressure source or associated subsystem at the desired site. The dressing seal member 152 may be, for example, an impermeable or semi-permeable elastomeric material. Elastomeric materials have elastomeric properties. Generally refers to a polymer material having rubber-like properties. More specifically, most elastomers have an ultimate elongation of more than 100% and considerable elasticity. The elasticity of a material refers to the ability of the material to recover from elastic deformation. Examples of elastomers include, but are not limited to, natural rubber, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber , Polyurethane (PU), EVA film, co polyester, and silicone. Additional examples of dressing seal member materials include silicone drapes, 3M Tegaderm® drapes, polyurethane (PU) drapes available from Avery Dennison Corporation (Pasadena, Calif). The dressing seal member 152 may form a sealed space 160 that covers the upper side of the tissue site 102 and may include the micropump device 116 therein.

The attachment device 162 may be used to hold the dressing seal member 152 to the patient's epidermis 156 or another layer, such as a gasket or additional seal member. The attachment device 162 can take many forms. For example, the attachment device 162 may be a medically acceptable pressure sensitive adhesive that extends around or all around the dressing seal member 152 or covers the epidermis 156 on the patient facing side. Covering at least a portion of

A vacuum interface 154 may be used to provide fluid communication between the vacuum conduit 148 and the enclosed space 160 of the vacuum dressing 106. The reduced pressure can be supplied through the reduced pressure conduit 148 to the reduced pressure interface 154 and then to the enclosed space 160. In one exemplary embodiment, the vacuum interface 154 is a T.D. available from KCI (San Antonio, Texas). R. A. C. (Registered trademark) Pad or Sensa T. R. A. C. (Registered trademark) Pad. The decompression conduit 148 may include a decompression lumen 154 and a pressure sensing lumen 166 formed as an integral conduit as shown in FIG. 1 or separately formed as shown in FIG.

In the exemplary embodiment shown in FIG. 1, pressure sensing capability may be added to the reduced pressure dressing 106 to function in addition to or instead of the pressure sensing device 138. The reduced pressure dressing 106 may include a second RFID antenna 168, a third processor 170, and a second pressure sensing device 172. The third processor 170 is coupled to the second RFID antenna 168 and the second pressure sensing device 172. An air passage 174 provides fluid communication between the enclosed space 160 and the second pressure sensing device 172. Third processor 170 and second pressure sensing device 172 are operable to receive a pressure interrogation signal from base unit 110 and respond with a pressure message signal indicative of the pressure in enclosed space 160.

In one exemplary embodiment, the wireless vacuum pump 108 is a wireless passive (ie, no battery) device. As such, the wireless decompression pump 108 is not provided with a power source other than the power supplied by the first RFID antenna 114. In some embodiments, the wireless vacuum pump 108 may include a capacitor for storing electrical energy. In another exemplary embodiment, a first power supply 140 as shown in FIG. 3 may be provided to increase the power supplied by the first RFID antenna 114 or to operate the micropump device 116. . The first power supply 140 may be recharged with power from the first RFID antenna 114.

The micropump device 116 may take many forms, such as a piezoelectric pump, a peristaltic pump, or other small pump. Referring now primarily to FIG. 5, an exemplary embodiment of a micropump device 116 suitable for use as an aspect of the wireless vacuum pump 108 will be described. Micropump device 116 includes a cavity 178 defined by a first end wall 180, a second end wall 182, and an annular side wall 184. The cavity 178 may be substantially circular in shape, but other shapes such as an ellipse are possible. In an exemplary embodiment, the cavity 178 may hold about 10 ml of fluid, or may hold more or less fluid.

Cavity 178 includes a nozzle-like inlet 186, which may or may not be valved. The cavity 178 may also have a valved outlet 190. The first end wall 180 may be a disk 192. On the disk 192 is an actuator 194, such as a piezoelectric disk, a magnetostrictor, or a solenoid actuator. Actuator 194 is electrically coupled to a drive circuit, which is controlled by the processor. The drive circuit applies an alternating electrical signal to the actuator 194 to induce vibration in the disk 192. The frequency of vibration can be adjusted to match the natural frequency of the chamber. Piezoelectric discs can be tuned to be less than 1 mm thick and to operate above 500 Hz, above 10 kHz, or above 20 kHz. In operation, the actuator 194 may vibrate in a direction substantially perpendicular to the plane of the cavity 178 as shown, thereby creating a radial pressure oscillation in the fluid in the cavity 178. One or more micropump devices 116 may be used in parallel or in series.

In one exemplary embodiment, micropump device 116 has a substantially cylindrical shape with fluid in cavity 178 and surrounded by first end wall 180, second end wall 182, and side wall 184. At least two apertures, such as an inlet 186 and an outlet 190 are formed through the walls 180, 182, 184 that define the cavity 178. The cavity 178 has a radius r and a height h, and $r / h > 1.2$ and $h^2 / r > 4 \times 10^{-10}$ m. The actuator 194, which is a piezoelectric disk, causes an oscillating motion in a direction substantially perpendicular to the plane of the first end wall 180 and the second end wall 182 on one of the end walls 180, 182. The axial vibration of the end walls 180, 182 causes the cavity 178 to generate a radial vibration of fluid pressure and allows pumping to cause a vacuum. The micropump device 116 produces an acoustic resonance in the cavity 178, like an acoustic pump. Inlet 186 is used to draw fluid and outlet 190 is coupled to a vent, such as vent 176 in FIG. Other micropump devices may be used. The micropump device 116 is disclosed in U.S. Patent Application Publication No. 2009/0234185 (U.S. Patent Application No. 12 / 398,904; filed on March 5, 2009) ("Dressing and Method for Applying Reduced Pressure To and Collecting And." "Storing Fluid from Tissue Site"). This document is incorporated herein for all purposes

Referring now primarily to FIGS. 1-3, according to an exemplary embodiment, the reduced pressure dressing 106 is applied to the tissue site 102 during operation of the system 100. In particular, interface distribution manifold 150 is positioned proximate to tissue site 102. Thereafter, the interface distribution manifold 150 and the tissue site 102 are covered by a dressing seal member 152 to create a sealed space 160. The attachment device 162 on the patient facing side of the dressing seal member 152 may help provide a fluid seal to a portion of the patient's epidermis 156. If the decompression interface 154 is not yet installed, the decompression interface may be applied, for example, by making a small aperture cut in the dressing seal member 152 and securing the decompression interface 154 over or through the aperture or hole .

A wireless vacuum pump 108 is then provided and fluidly coupled to the vacuum interface 154 by a vacuum conduit 148. The wireless decompression pump 108 is positioned so that the first RFID antenna 114 is disposed within the operating range of the base unit 110. In an exemplary embodiment, the first RFID antenna 114 is located within a few millimeters from the RFID reader 112 of the base unit 110. In another exemplary embodiment, the first RFID antenna 114 may be located 10 meters away from the RFID reader 112. Any distance within a given range can easily be used.

Thereafter, the user operates the base unit 110. The base unit 110 transmits a pump signal 197 to the wireless decompression pump 108. The pump signal is received by the first RFID antenna 114 and the energy of the pump signal is supplied to the first processor 118. The first processor 118 supplies energy to the micropump device 116. The micropump 116 creates a vacuum that is fed to a sump 126 that is fluidly coupled to a vacuum conduit 148. Therefore, reduced pressure is supplied to the reduced pressure dressing 106 through the reduced pressure conduit 148. Fluid from the tissue site 102 flows through the interface distribution manifold 150, the vacuum interface 154, and the vacuum conduit 148 to the sump 126.

The pressure at the tissue site 102 may be monitored directly or indirectly using a pressure sensing device, such as the pressure sensing device 138 of FIG. 3 or the second pressure sensing device 172 of FIG. In the first illustrative example, the second processor 128 and RFID reader 112 of the base unit 110 send a pressure inquiry signal to the wireless vacuum pump 108 separately from or in conjunction with the pump signal. In response to the pressure interrogation signal, the first processor 118 and pressure sensing device 138 may prepare a pressure message signal and communicate pressure measurements at the tissue site. The pressure message signal is then used for further processing by the first processor 118 to generate a pump control signal that activates or deactivates the micropump 116 when it may be needed. Alternatively or additionally, the first processor 118 may send a pressure message signal to the RFID reader 112 via the first RFID antenna 114. The pressure message signal is provided to the second processor 128 after reaching the RFID reader 112. Using the pressure message signal, the second processor 128 prepares a pump control signal, which is sent by the RFID reader 112 to the wireless vacuum pump 108 to deactivate or deactivate the micropump 116 as needed. Operate.

After a suitable time interval, an alarm signal is generated by the base unit 110 or the wireless decompression pump 108 if the pressure remains outside the desired operating range. The alarm may be a separate audible device, a visual alarm, or the micropump 116 may function at a different frequency range, such as a low frequency, to generate audible noise for the alarm.

In a second exemplary approach, the reduced pressure dressing 106 includes a second RFID antenna 168 coupled to a third processor 170 that is coupled to a second pressure sensing device 172. . The second pressure sensing device 172 receives the pressure in the sealed space 160 via the ventilation path 174. The base unit 110 transmits a pressure inquiry signal to the second RFID antenna 168. In response, the second pressure sensing device 172 and the third processor 170 generate a pressure message signal that is transmitted by the second RFID antenna 168 to the base unit 110. As described above, the base unit 110 then generates a pump control signal that is sent to the wireless vacuum pump 108 to activate or deactivate the micropump 116. Alternatively, the third processor 170 may estimate the pressure and prepare a pump control signal as part of the feedback or control loop

An exemplary embodiment of the wireless vacuum pump 108 will now be described primarily with reference to FIGS. 4 and 6. In this exemplary embodiment, the wireless vacuum pump 108 may be a self-contained disposable pouch design that can be removably secured to the base unit 110 on the pole 196. As already described, the pump pouch 120 is formed by the first pump seal member 122 and the second pump seal member 124. The outer side of the pump pouch 120 may include a first flange 123 and a second flange 125. The pump pouch 120 can be divided or partitioned into multiple compartments if desired. For example, one compartment (not explicitly shown) may be formed with the micropump 116 in the compartment, and another compartment may be formed including the absorbent layer 146.

The flanges 123, 125 in the exemplary embodiment of the pump pouch 120 may be formed by welding, bonding, or otherwise attaching portions of the first pump seal member 122 and the second pump seal member 124. The first flange 123 may include one or more apertures 129 for receiving one or more posts 198. The post 198 fixes the pump pouch 120 adjacent to the base unit 110. The decompression conduit 148 may enter through an aperture 149 in the second flange 125 and has a coupling that provides a sealed interference fit or provides a sealed connection. Other connections may be used

As best seen in FIG. 4, the first RFID antenna 114 may be placed closest to the base unit 110 such that the first RFID antenna 114 is directly adjacent to the RFID reader 112 of the base unit 110. In one non-limiting example, the first RFID antenna 114 is positioned 2 millimeters or 1 millimeter (1 mm) or closer from the RFID reader 112. The RFID reader 112 and the first RFID antenna 114 can be substantially adapted and aligned. In another exemplary embodiment, as processed in FIG. 1, the wireless decompression pump 108 is a post 198 with the first RFID antenna 114 facing outwardly toward a remotely located base unit 110. Can be attached to. For example, the base unit 110 may be located in a central hub area, where the wireless vacuum pump 108 is monitored and powered using the base unit 110, which may be 10 meters or more away.

Referring now primarily to FIG. 6, the base unit 110 may include a control panel 130 and one or more displays 132. The base unit 110 may include a base housing or base body 136. Base housing or body 136 may include a shelf portion 199 that may provide physical support to a portion of wireless vacuum pump 108 when wireless vacuum pump 108 is filled with fluid from tissue site 102. In this regard, it should be noted that the wireless vacuum pump 108 shown in FIG. 6 shows a state before use. In the embodiment of FIGS. 4 and 5, once the wireless vacuum pump 108 reaches the capacity to hold fluid, the micropump 116 may be deactivated and the user may discard the entire wireless vacuum pump 108. .

With reference now mainly to FIGS. 7 and 8, another exemplary embodiment of a wireless vacuum pump 200 will be described. The wireless vacuum pump 200 may be used as part of a system for treating a tissue site, such as the system of FIG. The wireless vacuum pump 200 includes a plurality of wall members 202 and forms a first chamber 204 and a second chamber 206. One of the plurality of wall members 202 is a partition wall 208 that separates the first chamber 204 from the second chamber 206. A micropump 210 similar to the micropump 116 of the previously described drawings can be disposed in the first chamber 204. The micropump 116 is configured such that an inlet 212 that receives fluid (or otherwise discharges reduced pressure) is fluidly coupled to the second chamber 206. Micropump 210 has an outlet or vent 214 that is fluidly coupled to first chamber 204. The micropump 210 discharges positive pressure through the outlet or vent 214 to the first chamber 204.

One portion of the plurality of wall members 202 that form the first chamber 204 includes an aperture 216. An optional relief valve 218 is coupled to the aperture 216. The relief valve 218 is configured such that the pressure in the first chamber 204 is released to the outside of the wireless decompression pump 200 when the pressure exceeds a first threshold pressure. At least a portion of the plurality of wall members 202 constituting the second chamber 206 includes an inflatable support member, typically a plurality of inflatable support members 220. Although multiple inflatable support members 220 are shown, it should be understood that a single inflatable support member can be used to form the second chamber 206.

Inflatable support member 220 is in fluid communication with first chamber 204, such as through a plurality of apertures 222. Therefore, the positive pressure in the first chamber 204 fills the plurality of inflatable support members 220. When the plurality of inflatable support members 220 are filled with sufficient fluid, the plurality of inflatable support members 220 provide a structure that is relatively rigid and helps form a volume in the second chamber 206. provide. Fluid 223 from the tissue site is contained in the volume of the second chamber 206 through the vacuum conduit 224. The wireless vacuum pump 200 shown in a pyramid shape may be formed to take other shapes, such as a box, cylinder, or any other shape

As in the previously described embodiment, the micropump 210 is powered in whole or in part by a pump signal supplied to the RFID antenna 226. The RFID antenna 226 is coupled to the first processor 228. The first processor 228 is electrically coupled to the micropump 210 by a conductor 230, which may be included in one of the plurality of wall members 202, but is shown separately in FIG. As shown in FIG. 8, a floor portion 232 of a plurality of wall members 202 may be included within the platform member 234.

Referring now primarily to FIGS. 7 and 8, in operation according to an exemplary embodiment, the vacuum conduit 224 is coupled to a vacuum dressing, such as the vacuum dressing 106 of FIGS. 1 and 3. A base unit, such as the base unit 110 of FIG. 1, is used to send a pump signal or pump actuation signal to the RFID antenna 226 of the wireless vacuum pump 200. A pump signal received by the RFID antenna 226 is provided to the first processor 228. Power is supplied from the first processor 228 to the micropump 210 and energizes the micropump 210. When the micropump 210 is energized, a reduced pressure is supplied to the second chamber 206 and a positive pressure is supplied to the first chamber 204. When the pressure increases in the first chamber 204, the pressure is filled in the plurality of inflatable support members 220, and the wireless vacuum pump 200 changes from the deflated state to the expanded state. A spacer member (not shown) covers the inlet 212 to prevent air blockage during start-up before the inflatable support member 220 is filled

When the inflatable support member 220 is expanded, the maximum volume of the second chamber 206 is achieved. At the same time, the reduced pressure in the second chamber 206 is supplied to the reduced pressure conduit 224. A fluid 223 (including liquid) is injected into the second chamber 206.

Although not explicitly shown, it should be understood that a reduced pressure sensing device, eg, similar to the pressure sensing device 136 of FIG. 3, may be incorporated into a portion of the second chamber 206 to measure the pressure in the second chamber 206. Again, it should be understood that a reduced pressure sensing device similar to, for example, the pressure sensing device 138 of FIG. The vacuum conduit 224 may also have a pressure sensing lumen that is fluidly coupled to a vacuum sensing device for measuring pressure in the distribution manifold. In either example, the pressure sensing device is coupled to the first processor 228 to generate a pressure message signal. The pressure message signal may be supplied in response to a pressure interrogation signal from the base unit or naturally generated by the first processor 228. The first processor 228 uses the pressure message signal to generate a pump control signal that can be provided to the micropump 210. Alternatively, the pressure message signal is sent to the base unit, where a processor in the base unit can generate a pump control signal similar to the previously described embodiments.

In an alternative embodiment, the previously described wireless vacuum pump 108, 200 has a lead or socket and plug between the pump and base instead of having an RFID antenna. Leads or sockets and plugs can be easily plugged into one another to exchange power and signals.

Referring now primarily to FIGS. 9-11, an exemplary embodiment of a reduced pressure system 300 for treating a tissue site 302 with reduced pressure will be described. The decompression system 300 includes a wireless decompression dressing 304 and a base unit 306. The base unit 306 may include a power connector 307 The wireless decompression dressing 304 is a built-in disposable dressing that receives power from the base unit 306 and is controlled. The base unit 306 can be substantially adjacent to the wireless vacuum dressing 304, for example, within 1 or 2 millimeters, or up to 10 meters or more, or somewhere in between. In one embodiment, the micropump 316 may be separated from the absorbent layer or absorbent member 310, and the micropump 316 can be easily separated after use. Therefore, the micropump 316 may be repaired and reused.

The wireless vacuum dressing 304 includes an interface distribution manifold 308 disposed proximate to the tissue site 302. The wireless decompression dressing 304 may also include an absorption layer 310, an RFID antenna 312, and a first processor 314. The RFID antenna 312 is electrically coupled to the first processor 314. The first processor 314 is electrically coupled to the micropump 316. The interface distribution manifold 308, the absorbent layer 310, the RFID antenna 312, the first processor 314, and the micropump 316 are all held in place and secured within the enclosed space 318 by one or more seal members, eg, seal members 320. The Additional layers and components may be included in the wireless vacuum dressing 304.

The exemplary embodiments of FIGS. 9-11 include additional layers and components. Additional layers and components may be arranged in different orders. Seal layer 322 is used to seal wireless vacuum dressing 304 around tissue site 302. Seal layer 322 is formed with aperture 323 and provides fluid communication to interface distribution manifold 308. A first internal distribution manifold 324 is positioned in fluid communication with the interface distribution manifold 308 and the tissue site 302. Absorbent layer 310 is positioned in fluid communication with first internal distribution manifold 324, interface distribution manifold 308, and tissue site 302. A diverter layer 326 is positioned adjacent to the absorbent layer 310. A second internal distribution manifold 328 is positioned in fluid communication with the diverter layer 326. The diverter layer 326 is formed with a plurality of apertures 327, which can take a number of patterns and forms. The diverter layer 326 is shown with a plurality of apertures 327 forming a square pattern in this particular exemplary embodiment. In the square pattern, the aperture at the corner is larger than the other apertures. A gas / liquid separator 330 is positioned adjacent to the second internal distribution manifold 328.

Micropump 316, RFID antenna 312, and first processor 314 may be adjacent to gas-liquid separator 330. A charcoal filter 332 or other odor removal device may be positioned over the outlet 334 of the micropump 316. The seal member 320 is formed with an aperture 336 so that the discharge port 334 of the micropump 316 can be exhausted to the outside of the wireless decompression dressing 304. Together, the outlet 334 and the aperture 336 form a vent 338.

The micropump 316 can be a micropump that is small and lightweight enough to allow the integrated wireless vacuum dressing 304 to be maintained at the tissue site 302. Further, the micropump 316 may be sized and weighted so that the integrated vacuum dressing 304 does not pull or otherwise adversely affect the tissue site 302. In an exemplary embodiment, the micropump 316 may be a disk-type pump having a piezoelectric actuator similar to that described above. Reference is also made to the pumps shown in US 2009/0087323 and US 2009/0240185, which are hereby incorporated by reference for all purposes. In an alternative embodiment, the micropump 316 may be a peristaltic pump that is used to pump a variety of fluids. It should be understood that alternative pumping techniques may be used and rotary pumps, linear pumps, or other configurations of pumps may be used

The micropump 316 generates a sufficient reduced pressure that is therapeutic for wound healing. In an exemplary embodiment, the micropump 316 has sufficient flow characteristics, reduced pressure characteristics, and operating life characteristics so that reduced pressure treatment can be performed continuously. The flow rate may be in the range of about 5 to 1000 ml / min, and the reduced pressure may be in the range of about −50 to −200 mm Hg (−6.6 to −26.6 kPa). It should be understood that alternative ranges may be used depending on the configuration of the integrated wireless vacuum dressing 304, the size of the wound, or the type of wound. In an exemplary embodiment, multiple pumps may be positioned in a single dressing and supplied with increased flow or vacuum levels as needed.

The micropump 316 is placed within the dressing to avoid the use of conduits and external canisters to collect wound exudate. Micropump 316 includes an outlet 334 for releasing or evacuating air from vacuum dressing 304. When using the outlet 334, the outlet 334 may be in fluid communication with or positioned within the aperture 336 of the seal member 320. Alternatively, the seal member 320 may be sealed around the outlet port of the micropump 316 so that gas from the micropump 316 can be exhausted directly through the aperture 336. In the exemplary embodiment of FIGS. 9-11, the outlet 334 of the micropump 316 is oriented away from the gas-liquid separator 330 (or hydrophobic filter) to prevent air from being added to the wireless vacuum dressing 304. To do. Air is exhausted through aperture 336 in seal member 320, which may include a one-way valve. Alternatively, air or another gas can be exhausted through the gas permeable portion of the seal member 320 as long as the ability of the seal member 320 to maintain a reduced pressure is not affected.

When the micropump 316 is a piezoelectric pump, the piezoelectric actuator associated with the micropump 316 can sometimes be driven at a different frequency to function as a buzzer or oscillating warning system. The alert system can alert the user of an alarm condition. For example, an alarm condition may be that there is a leak in the dressing, that the reduced pressure measured by the sensor has changed, that the dressing has absorbed the maximum volume of liquid as indicated by the indicator, or one or more layers May no longer efficiently manifold the vacuum.

Control electronics may be physically or functionally incorporated as part of the first processor 314. The control electronics can be used to control the operation of the micropump 316. The control electronics may be analog or digital and may be configured with a regulator that adjusts the speed or duty cycle at which the micropump 316 operates. In addition, the control electronics may be configured with a controller that receives a sensing signal from a sensor or switch, eg, a pressure sensing device (see 340 in FIG. 12). Sensors are placed throughout the wireless vacuum dressing 304 and may sense parameters such as pressure, temperature, humidity, chemistry, odor, or any other parameter that can be used to manage and control the micropump 316. The control electronics may include a computer processor or programmable gate array or other control device. It should be understood that the control electronics may include any form of digital or analog component that performs the functions described herein. The control electronics may be or include the first processor 314.

The control electronics will monitor and issue alarms for several conditions, eg, (i) low voltage, (ii) excessive leakage, (iii) absorber layer level, and (iv) battery condition (if included). Can be arranged. Therefore, the control electronics monitor each of the parameters and generate alarm signals (eg, high-pitched beeps, vibrations, or light) using speakers, vibrators, or lighting devices such as light emitting diodes (LEDs) Electronics may be included. Thus, the control electronics may notify a medical professional, patient, or family member that the parameter is outside the desired range. For example, if the pressure at the tissue site 302 is below the treatment level, a continuous tone can be generated. As another example, a continuous beep can be generated when the absorbing layer 310 is saturated. If the battery falls below a certain voltage level, a different audible frequency can be generated or the LED can be activated. A variety of different alert signals can be established to notify the medical professional to take a specific action.

The RFID antenna 312 is used to provide electrical output to the micropump 316 and control electronics. The battery 342 may also be used to provide stored energy to increase the output from the RFID antenna 312. The battery 342 may be any size and shape, and may be any material, such as a polymer. The battery 342 can provide all or part of the required power. The battery 342 can be recharged with power from the RFID antenna 312.

In one exemplary embodiment, the battery 342 may be configured with a voltage level sensor that is monitored by the control electronics, and the control electronics may generate an alarm when a low power level is detected. The battery 342 can be directly connected to the micropump 316. Alternatively, the battery 342 can be connected to control electronics or one or more processors that use the power from the battery 342 to drive the micropump 316. The control electronics may drive the micropump 316 using continuous modulated power, such as a pulse width modulation (PWM) signal.

Seal layer 322 is glued or otherwise connected to seal member 320 that is used to hang or otherwise cover the components of vacuum dressing 304. Seal layer 322 may include a medical grade adhesive material or other sealing device that is strong enough to form a vacuum seal with the epidermis around the patient's wound. The sealing layer 322 may be a band having an aperture 323 that is slightly larger than the geometric parameters of the gas-liquid separator 330 or other layers, and the sealing member 320 is connected to the epidermis around the patient tissue site 302. Make contact. The seal member 320 is impermeable to fluids such as air and liquid.

In another exemplary embodiment, seal member 320 may adhere to diverter layer 326 and diverter layer 326 adheres to seal member 320 to form an upper dressing portion and a lower dressing portion. The upper dressing portion can include a seal member 320, a micropump 316 and related components, a gas-liquid separator 330, a second internal distribution manifold 328, and a diverter layer 326. The lower dressing portion may include an absorbent layer 310, a first internal distribution manifold 324, a seal layer 322, and an interface distribution manifold 308. The wireless vacuum dressing 304 may be configured to allow the lower dressing portion to be replaced once the wireless vacuum dressing has absorbed the maximum volume of fluid. The upper dressing portion may be reused after replacement of the lower dressing portion. This allows the micropump 316 to be used multiple times, but the disposable part of the dressing may be replaced. In another exemplary embodiment, the micropump 316, the first processor 314, and the RFID antenna 312 may be removed from the dressing for reuse and the remaining layers of the dressing replaced. In yet

another exemplary embodiment, only the absorbent layer 310 may be replaced. In yet another exemplary embodiment, only the absorbent layer 310 and the interface distribution manifold 308 may be replaced.

Charcoal filter 332 may be used in wireless reduced pressure dressing 304 to reduce odors caused by tissue site 302 and spread from wireless reduced pressure dressing 304. A charcoal filter 332 may be placed over a valve or other exhaust vent from the micropump 316 to filter the exhaust from the micropump 316 before it is discharged from the integrated vacuum dressing 304. Alternatively, it should be understood that the charcoal filter 332 may be configured and arranged above or below the micropump 316. In another exemplary embodiment, rather than using a charcoal filter, charcoal may be incorporated into any or all of the different layers used in the integrated decompression dressing 304

According to one exemplary embodiment, in operation, the reduced pressure system 300 of FIGS. 9-11 is applied by positioning the interface distribution manifold 308 proximate to the tissue site 302. A seal layer 322 is disposed on the upper side of the interface distribution manifold 308 so that the aperture 323 is on the upper side of the interface distribution manifold 308. The first internal distribution manifold 324 is disposed on the first interface distribution manifold 308 and possibly adjacent a portion of the seal layer 322. The absorbent layer 310 is disposed adjacent to the first internal distribution manifold 324. The diverter layer 326 may be placed over all of the components so shown. The second internal distribution manifold 328 can then be placed adjacent to a portion of the diverter layer 326 along with the gas-liquid separator 330. A micropump 316, an RFID antenna 312 and a first processor 314 may be applied. The components described herein can also be preassembled as a dressing laminate.

Seal member 320 is used to create a seal that forms a sealed space 318. The base unit 306 is used to transmit a pump signal to the RFID antenna 312 as described above, which is received by the first processor 314 and used to power the micropump 316. The first processor 314 may further include one or more capacitors to hold power or one or more batteries, eg, rechargeable batteries. The pump signal causes a vacuum to be generated by the micropump 316. The reduced pressure is transmitted to the tissue site 302 to remove fluid or provide reduced pressure therapy. The fluid removed from the tissue site 302 is transferred to the absorbent layer 310 in the reduced pressure dressing 304 where the fluid is retained or substantially retained. As described in connection with FIG. 12, a pressure sensing device may be included as part of the wireless decompression dressing 304 to provide a pressure message signal to the base unit 306.

With reference now primarily to FIG. 12, another exemplary embodiment of a vacuum system 300 will be described. As already mentioned, the vacuum system 300 includes a wireless vacuum dressing 304 and a base unit 306. The vacuum system 300 of FIG. 12 includes a small number of components that the wireless vacuum dressing 304 includes, and the wireless vacuum dressing 304 additionally includes a pressure sensing device 340 that is electrically coupled to the first processor 314 Except that, it is similar to the system shown in FIGS. In addition, an optional battery 342 is included. The battery 342 may supplement the power provided by the RFID antenna 312 or may be used as a main power source and recharged by the RFID antenna 312. The RFID antenna 312 receives power from the base unit 306. Seal member 320 is shown secured to skin 344 by attachment device 346. Components included in the dressing described in FIGS. 9-11 are given the same reference numerals and are not necessarily further described here.

According to an exemplary embodiment, in operation, the reduced pressure system 300 of FIG. 12 may be used by first applying an interface distribution manifold 308 adjacent to the tissue site 302. Absorbent layer 310 may be disposed in fluid communication with interface distribution manifold 308. The gas-liquid separation device 330 may be disposed on the upper side of the absorption layer 310. Thereafter, the RFID antenna 312, the pressure sensing device 340, the first processor 314, the micropump 316, and the battery 342 are disposed on the gas-liquid separation device 330. Alternatively, some of the components, such as micropump 316, may be adjacent to gas-liquid separator 330. A seal member 320 is applied over the top of the tissue site 302 to form a sealed space 318 and covers all of the components described above. The components already described can be preassembled in whole or in part. Base unit 306 sends a pump signal or pump actuation signal to decompression dressing 304, thereby actuating micropump 316. The micropump 316 removes air or other fluid from the enclosed space 318, thereby initiating treatment of the tissue site 302 with reduced pressure.

In addition to providing a pump actuation signal or pump signal from the base unit 306 to the RFID antenna 312, the base unit 306 may also transmit a pressure inquiry signal. Upon receipt of the pressure interrogation signal, the RFID antenna 312, the first processor 314, and the pressure sensing device 340 generate a pressure message signal that is transmitted by the RFID antenna to the RFID reader (not explicitly shown) of the base unit 306. The Base unit 306 includes a processor (not explicitly shown) that may receive a pressure message signal and generate a pump control signal that activates or deactivates micropump 316. When the reduced pressure is within the desired treatment range, the micropump 316 can be deactivated. Similarly, if the pressure is too large on an absolute scale, the base unit 306 may send a pump signal that activates or continues the micropump 316 to provide more vacuum. An alarm can be triggered by the base unit 306 if the elapsed time for not reaching the desired pressure is too long. The wireless decompression dressing 304 includes a galvanic cell (not explicitly shown) to provide a full display message signal when exudate or other bodily fluid electrically couples the two electrodes. A full indication message signal is sent by RFID antenna 312 to base unit 306 to indicate that the dressing is full.

Referring now primarily to FIG. 13, another exemplary embodiment of a vacuum dressing 400 that includes a wireless vacuum pump 430 will be described. The reduced pressure dressing 400 is shown as an exploded view and covers a tissue site 402 of the patient 404, such as a wound. The reduced pressure dressing 400 includes an interface distribution manifold 406 disposed proximate to the tissue site 402. The interface distribution manifold 406 may be formed from any manifold material, such as GranuFoam® material, or any other manifold material already described.

The reduced pressure dressing 400 further includes a lower drape or diverter 408. The lower drape 408 is a polyethylene material with an adhesive on the lower side (tissue-facing side) and may surround the tissue site 402 to be treated and adhere to the patient 404. The lower drape 408 may include an aperture or perforation to communicate reduced pressure to the tissue site 402 through the interface distribution manifold 406 and draw wound fluid (liquid or gas) from the tissue site 402. The lower drape 408 may also include a seal ring 410 to provide additional adhesive strength to maintain the reduced pressure at the desired therapeutic level. Initially, the protective release liner 412 covers the seal ring 410. The protective release liner 412 is removed from the lower side of the lower drape 408 before the lower drape 408 is positioned on the patient 404.

The reduced pressure dressing 400 includes an absorbent layer 414, which can be a nonwoven fabric, to absorb wound fluid drawn through the aperture in the lower drape 408. Absorbent layer 414 is sandwiched between two wicking layers 416 and 418 that allow wound fluid to escape and distribute to absorbent layer 414. The high-density side of the wicking layers 416 and 418 faces outward from the absorption layer 414. Wicking layers 416, 418 sandwich an absorbent layer 414 therebetween to form a fluid storage device 420.

The vacuum dressing 400 further includes an upper drape 422 that can be a non-porous, closed barrier formed of polyethylene. The smooth side of the upper drape 422 faces the upper wicking layer 416. Upper drape 422 includes an aperture or opening 424. The aperture or opening 424 may be covered by a hydrophobic filter 426 that separates air from the liquid to include wound fluid or exudate within the absorbent layer 414. The hydrophobic filter 426 simultaneously allows gas flow from the absorbent layer 414 as a result of the depressurization of the hydrophobic filter 426. Upper drape 422 and hydrophobic filter 426 include a top layer 428 of vacuum dressing 400 that covers fluid reservoir 420. All of the above-described dressing assembly elements except the release liner 412 are collectively referred to as the "wound dressing" portion of the vacuum dressing 400.

The vacuum dressing 400 further includes a wireless vacuum pump, or pump portion 430. The pump portion 430 includes a micropump assembly 432 positioned on top of the upper drape 422 to provide a vacuum that draws air through the hydrophobic filter 426, the fluid reservoir 420, and the interface distribution manifold 406. The

micropump assembly 432 includes a piezoelectric disk pump 434 that oscillates at a predetermined frequency to generate a desired reduced pressure on the input side of the piezoelectric disk pump 434. Piezoelectric disk pump 434 may be similar to micropump 315 of FIG. The piezoelectric disk pump 434 of the micropump assembly 432 may not operate if any liquid drawn from the tissue site 402 to the absorbent layer 414 below the upper drape 422 enters the input port of the piezoelectric disk pump 434. The hydrophobic filter 426 prevents wound fluid or exudate from flowing into the piezoelectric disk pump 434 of the micropump assembly 432.

The vacuum dressing 406 also includes a spacer ring or ring seal 436 positioned between the hydrophobic filter 426 and the inlet of the piezoelectric disk pump 434 for air flow to the piezoelectric disk pump 434 of the micropump assembly 432. Can result in a cavity. The micropump assembly 432 can be sandwiched between the first foam cushion 438 and the second foam cushion 440. Micropump assembly 432, first cushion 438, and second cushion 440 form a single composite package that is sandwiched between outer ply 442 and inner ply 444 and removably attached to upper drape 422. To do. Outer ply 442 includes an aperture or perforation 446 that provides a discharge path for the discharge of micropump assembly 432.

The piezoelectric disk pump 434 or other micropump can be controlled by the first processor 448 and other control electronics. The piezoelectric disk pump 434 can be powered by a first power unit 450 and a second power unit 452. The power units 450 and 452 can be batteries. In another alternative embodiment, the first power unit 450 or the second power unit 452 may include an RFID antenna that provides power to the first processor 448 and the piezoelectric disk pump 434.

According to embodiments, a system for treating a tissue site with reduced pressure includes a reduced pressure dressing disposed proximate to the tissue site, and a wireless reduced pressure pump fluidly coupled to the reduced pressure dressing. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the first processor for receiving power therefrom and generating decompression, and a fluid in the micropump device. And a fluidly coupled reservoir. The system further includes a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. The system may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal member are at least partially joined to form a pump pouch, on which the micropump device is disposed. The wireless decompression pump functions in the absence of a power source other than the RFID antenna. The wireless vacuum pump further includes a pressure sensing device fluidly coupled to the vacuum dressing and the first processor for sensing pressure at the tissue site. The wireless vacuum pump further includes a pressure sensing device coupled to the first processor. The base unit further includes a second processor coupled to the RFID reader, and the second processor and the RFID reader send a pressure interrogation signal to the first processor of the wireless vacuum pump and in response the first processor. It may be configured to receive a pressure message signal from one processor.

With respect to the system described in the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor. The base unit may include a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response thereto. The first processor and the pressure sensing device may be configured to prepare a pressure message signal in response to the pressure inquiry signal. The first processor and the RFID antenna may be configured to transmit a pressure message signal. And the second processor may be configured to receive the pressure message signal and prepare the control signal. The second processor and RFID may be configured to send a control signal to the wireless vacuum pump to provide a control signal that activates or deactivates the micropump device.

With respect to the system described in the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor. The pressure sensing device is operable to generate a pressure message signal. The first processor is operable to receive the pressure message signal and generate a control signal to activate or deactivate the micropump device.

In another embodiment of the system described in the previous paragraph, the system includes: a pressure sensing device that is fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site; a first distribution manifold. A first distribution manifold, an absorbent layer, and a diverter layer are formed by the pump seal member and the second pump seal member. A micropump device includes a piezoelectric pump. The reduced pressure dressing includes an interface distribution manifold disposed proximate to the tissue site, a dressing seal member, and a reduced pressure interface. In one embodiment, the RFID antenna is less than 5 centimeters from the base unit.

According to another exemplary embodiment, a wireless vacuum pump includes at least one wall member that forms a first chamber and a second chamber, an RFID antenna, a first processor coupled to the RFID antenna. And a micropump device coupled to the first processor for receiving power therefrom and generating reduced pressure and positive pressure. The micropump device has a vent fluidly coupled to the first chamber for exhausting positive pressure therein, and an inlet fluidly coupled to the second chamber for supplying reduced pressure thereto. The pump further includes a plurality of inflatable support members fluidly coupled to the first chamber; and a reservoir containing the second chamber. The pump may further include a first pressure relief valve fluidly coupled to the first chamber. The first pressure relief valve is operable to release a positive pressure that exceeds the first threshold pressure. The first chamber and the second chamber may be in the form of a portion of a pyramid. The pump can function in the absence of a power source other than the RFID antenna.

According to another exemplary embodiment, a method of manufacturing a system for treating a patient tissue site by decompression provides a decompression dressing disposed proximate to the tissue site, and provides a wireless decompression pump, including. The wireless vacuum pump includes, an RFID antenna, a first processor coupled to the RFID antenna; a micropump device coupled to the first processor for receiving power therefrom and generating decompression, and a fluid in the micropump device And a fluidly coupled reservoir. The method further includes providing a base unit having an RFID reader. The RFID reader may be configured to provide power to the RFID antenna and provide power to the micropump device. The manufacturing method may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal are at least partially coupled to form a pump pouch, on which the micropump device is disposed. The manufacturing method may further include providing a vacuum conduit that fluidly couples the wireless vacuum pump to the vacuum dressing. The manufacturing method further includes providing a pressure sensing device and coupling the pressure sensing device to a reduced pressure dressing.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a decompression dressing proximate the tissue site and providing a wireless decompression pump. The wireless vacuum pump includes: an RFID antenna; a first processor coupled to the RFID antenna; a micropump device coupled to the first processor for receiving power therefrom and generating decompression; and a fluid in the micropump device And a fluidly coupled reservoir. The method also includes fluidly coupling a wireless vacuum pump to the vacuum dressing, providing a base unit having an RFID reader and a second processor; activating the base unit, whereby the RFID reader and the second Two processors sending an activation signal to the wireless decompression pump to activate the wireless decompression pump. The wireless decompression pump may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal are at least partially coupled to form a pump pouch, on which the micropump device is disposed. All the power required by the micropump device can be supplied by the RFID reader. The method may further include positioning the RFID reader within 5 centimeters from the RFID antenna of the wireless vacuum pump.

With respect to the method of the previous paragraph, the wireless vacuum pump has no power source other than the RFID antenna, and the wireless vacuum pump is: fluid pressure coupled to the vacuum dressing and the first processor to sense pressure at the tissue site A pressure sensing device, a first distribution manifold, an absorbent layer, and a diverter layer. The first distribution manifold, the absorbent layer, and the diverter layer may be disposed in a pump pouch formed by the first pump seal member and the second pump seal member. The micropump device can be a piezoelectric pump. The reduced pressure dressing may include: an interface distribution manifold disposed proximate to the tissue site, a dressing seal member, and a reduced pressure interface

According to another exemplary embodiment, a decompression system for treating a tissue site by decompression includes: an interface distribution manifold disposed proximate to the tissue site, an absorbent member that receives and retains fluid from the interface distribution manifold, and RFID An antenna, a first processor coupled to the RFID antenna, and a micropump device coupled to the first processor for receiving power therefrom and generating a decompression, the micropump having an inlet and an outlet A wireless vacuum dressing including a device, a first seal member that forms a sealed space over the tissue site, and a vent that fluidly couples the outlet of the micropump device to the outside. The micropump is fluidly coupled to the enclosed space and supplies a reduced pressure thereto. The system further includes a base unit including an RFID reader. The base unit is operable to supply a pump signal to the wireless vacuum dressing to energize the micropump device. The system further includes a first pressure sensor in a wireless vacuum dressing coupled to the first processor. The first processor and the RFID antenna are operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit.

In another embodiment of the system described in the previous paragraph, the system may further include a first pressure sensor in a wireless vacuum dressing coupled to the first processor. The first processor and the RFID antenna are operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit. The base unit further includes a second processor. The second processor is operable to receive the pressure message signal and generate a pump control signal.

In another embodiment of the system described in the previous paragraph, the system may further include a first pressure sensor in a wireless vacuum dressing coupled to the first processor, and the first processor A pressure message signal is received from the sensor and a control signal is generated to control the micropump device. In another embodiment of the system described in the previous paragraph, the wireless vacuum pump can function in the absence of a power source other than an RFID antenna. Furthermore, only the reduced pressure supplied to the reduced pressure dressing can come from the micropump device. The system can be assembled such that the conduit or wire is not coupled to a wireless vacuum dressing.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a wireless decompression dressing proximate to the tissue site. The wireless decompression dressing includes an interface distribution manifold disposed proximate to a tissue site, an absorbent member that receives and retains fluid from the interface distribution manifold, an RFID antenna, a first processor coupled to the RFID antenna, A micropump device coupled to and receiving power from and generating pressure reduction and having an inlet and an outlet, a first seal member covering a tissue site and forming a sealed space, and a drain And a vent for fluidly coupling the outlet to the outside. The method includes providing a base unit including an RFID reader, the base unit configured to supply a pump signal to a wireless vacuum dressing to energize the micropump device, And providing a pump signal to the wireless decompression dressing.

According to another exemplary embodiment, a wireless decompression pump, wherein the wireless decompression pump is coupled to an RFID antenna, a first processor coupled to the RFID antenna; And a micropump device for receiving and generating a reduced pressure. The wireless vacuum pump may further include a reservoir fluidly coupled to the micropump device. The wireless vacuum pump may also further include a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal are at least partially combined to form a pump pouch. The micropump device is arranged there. The wireless vacuum pump can function in the absence of a power source other than the RFID antenna. The wireless vacuum pump may further include a pressure sensing device that is fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site.

With respect to the wireless decompression pump of the previous paragraph, the pump may further include a pressure sensing device coupled to the first processor and a base unit including a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response.

With respect to the wireless vacuum pump of the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor and a base unit including a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response. The first processor and the pressure sensing device are configured to prepare a pressure message signal in response to the pressure inquiry signal. The first processor and the RFID antenna are configured to transmit a pressure message signal. The second processor is configured to receive a pressure message signal and prepare a control signal, and the second processor and RFID send a control signal to the wireless vacuum pump to activate or deactivate the micropump device Configured to provide a control signal. The wireless vacuum pump may further include a pressure sensing device coupled to the first processor, the pressure sensing device is operable to generate a pressure message signal, and the first processor is configured to generate the pressure message signal. And generating a control signal to activate or deactivate the micropump device

In general terms, systems, methods, and dressings that provide reduced pressure to a patient's tissue site are described as including wirelessly supplying power to a reduced pressure pump. In one example, an RFID antenna is used to power a vacuum pump that is fluidly coupled to a vacuum dressing by a conduit. In another example, the reduced pressure dressing includes a micropump and an RFID antenna that is used to power the micropump. Other systems, methods, and apparatus are described herein.

Although the invention and its advantages have been described in light of several exemplary, non-limiting embodiments, various modifications, substitutions have been made without departing from the scope of the invention as defined by the appended claims. It should be understood that changes, exchanges, and modifications can be made. It should be understood that any feature described in connection with any one embodiment is also applicable to any other embodiment.

It should be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It is further understood that reference to "a" item refers to one or more of those items.

The method steps described herein may be performed in any suitable order or simultaneously, where appropriate.

Where appropriate, another example of combining any aspect of the above-described embodiments with aspects of any other described embodiment, having similar or different characteristics and addressing the same or different issues Form.

It should be understood that the above description of the preferred embodiments is exemplary only, and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above in some detail or with reference to one or more individual embodiments, those skilled in the art will recognize that the disclosed embodiments can be used without departing from the scope of the claims. Many modifications can be made.

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KR100916616B1 *	2006-02-27	2009-09-14	연세대학교 산학협력단	Medical treatment bandage made with cellulose-chitosan composite film, RFID sensor and biosensor, and Method thereof
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JP2019514479A *	2016-05-03	2019-06-06	スミス アンド ネフュー ピーエルシー Smith & Nephew Public Limited Company	Optimization of power transfer to negative pressure source in negative pressure therapy system
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US8444609B2	2013-05-28	Dressing and method for applying reduced pressure to and collecting and storing fluid from a tissue site
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Priority And Related Applications

Priority Applications (9)

Application	Priority date	Filing date	Title
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US61/407,194		2010-10-27	
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Legal Events

Date	Code	Title	Description
2014-06-27	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20140626
2014-06-27	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20140626
2015-04-30	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20150428
2015-05-01	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20150430
2015-07-27	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20150727

2015-10-02	TRDD	Decision of grant or rejection written	
2015-10-14	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20151013
2015-11-19	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20151111
2015-11-27	R150	Certificate of patent or registration of utility model	**Ref document number**: 5843296 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2018-11-06	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2019-11-12	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2020-11-04	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2021-03-01	R313	Request for change of ownership or part of ownership	**Free format text**: JAPANESE INTERMEDIATE CODE: R313113
2021-03-31	R360	Written notification for declining of transfer of rights	**Free format text**: JAPANESE INTERMEDIATE CODE: R360
2021-05-10	R360	Written notification for declining of transfer of rights	**Free format text**: JAPANESE INTERMEDIATE CODE: R360
2021-05-19	R371	Transfer withdrawn	**Free format text**: JAPANESE INTERMEDIATE CODE: R371
2021-06-03	R313	Request for change of ownership or part of ownership	**Free format text**: JAPANESE INTERMEDIATE CODE: R313113
2021-06-29	R350	Written notification of registration of transfer	**Free format text**: JAPANESE INTERMEDIATE CODE: R350
2021-11-27	LAPS	Cancellation because of no payment of annual fees	

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
tissues		claims,abstract,description	130	0.000
reduced		claims,abstract,description	120	0.000
distribution		claims,description	80	0.000
fluid		claims,description	67	0.000
absorbent		claims,description	57	0.000
absorbent		claims,description	57	0.000
liquid		claims,description	35	0.000
response		claims,description	17	0.000
absorption reaction		claims,description	9	0.000
coupling		claims,description	8	0.000
coupling process		claims,description	8	0.000
coupling reaction		claims,description	8	0.000
manufacturing process		claims,description	7	0.000
activating		claims,description	5	0.000
sealing		claims,description	4	0.000

activation	claims,description	3	0.000
pumping	claims,description	3	0.000

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A61F 13/02	***(2006.01)***	A61F	13/02	310J	4C167
A61F 13/00	***(2006.01)***	A61F	13/00	301G	
A61L 15/28	***(2006.01)***	A61F	13/00	301J	
A61L 15/60	***(2006.01)***	A61F	13/00	301A	

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最終頁に続く

(54)【発明の名称】開放可能な窓を含む、負圧雰囲気による創傷治療用創傷ケアデバイス

(57)【要約】
本発明の主題は、患者の皮膚に取り付けることが可能な創傷被覆要素および流体媒質を吸引するための接続デバイスを含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスであって、前記創傷被覆要素は開放可能な窓を含み、前記窓は気密性の閉鎖物によって創傷被覆要素上に配置されている、創傷ケアデバイスである（図４ｂ）。

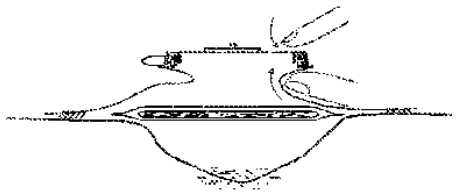


Fig. 4b

【特許請求の範囲】
【請求項１】
創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスであって、
患者の皮膚に取り付けることが可能な創傷被覆要素および流体媒質を吸引するための接続デバイスを含み、
前記創傷被覆要素は開放可能な窓を有し、前記窓は気密性の閉鎖物によって創傷被覆要素上に配置されていることを特徴とする、創傷ケアデバイス。
【請求項２】
前記気密性の閉鎖物が連結シールの形態で具体化されていることを特徴とする、請求項１に記載の創傷ケアデバイス。
【請求項３】
前記創傷被覆要素が、所定の身体位置の解剖学的形態に対応するように事前に形成されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項４】
前記創傷被覆要素が、前記の所定の身体位置の動きに沿って動くことができるように具体化されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項５】
前記創傷被覆要素を、以下：
・アクリル接着剤
・シリコーン
・親水コロイド接着剤
・酸化亜鉛接着剤、および／または
・ラテックス接着剤
を含む群から選択される接着性材料によって患者の皮膚に取り付けることができることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項６】
前記デバイスが創傷の滲出液を取り出す吸収要素も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項７】
前記吸収要素が少なくとも一つの超吸収物質、変性セルロース、発泡材、および／またはアルギン酸塩を含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項８】
前記吸収要素がセルロース繊維を含むフリースも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項９】
前記デバイスが、流体浸透性の創傷対向創傷接触格子も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１０】
流体媒体の吸引用の接続デバイスの領域に、流体不浸透性の障壁があることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１１】
前記デバイスが負圧雰囲気の生成のための設備も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１２】
負圧雰囲気の生成のための前記設備が前記創傷ケアデバイス上に直接配置されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１３】
負圧雰囲気を発生させるための前記設備と、前記創傷被覆要素または創傷滲出液を取り出す前記吸収要素との間に、カップリング、ブロッキングバルブ、および／または三方バルブがあることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。

【請求項１４】
前記吸収要素が流体浸透性のカバーで囲まれていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１５】
前記デバイスが更にスペーサーも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１６】
前記デバイスが、重金属、好ましくは、銅もしくは銀、またはこれらの一つを含有する塩を含む層をも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１７】
前記創傷被覆要素が流体および／または気体に対して不透過性であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１８】
前記創傷被覆要素が水蒸気に対して透過性であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１９】
負圧雰囲気を発生させるための前記設備のポンピング方向が反転可能であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２０】
前記開放可能な窓が、非弾性的バックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２１】
前記開放可能な窓が、弾性的バックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２２】
前記開放可能な窓が、可塑性の可鍛性材料で作製されたバックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２３】
軟組織の欠陥、外科的創面切除後の感染した創傷、リンパ系瘻孔、胸骨の傷感染症、胸壁孔、床ずれ、静脈性潰瘍、慢性的傷癒合障害、放射線潰瘍、腹部隔室症候群、敗血性腹腔、腸管瘻孔、および／または一つまたは幾つかの浮腫に起因する創傷などの創傷治療の目的の、皮膚移植の固定のための、傷の状態調節のための、ならびに／または縫い目および切開の手術後のケアのための、
前述の請求項の一項に記載の創傷ケアデバイスの適用。
【請求項２４】
傷圧縮系における、前述の請求項の一項に記載の創傷ケアデバイスの適用。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、開放可能な窓を含む、負圧雰囲気による創傷治療用創傷ケアデバイスに関する。
【背景技術】
【０００２】
負圧雰囲気による創傷治療用の従来のシステムおよびデバイスは、気密性の創創傷被覆、ドレナージ（排出）ホース、外部に配置される真空ポンプ、および排出される滲出液を集めるための容器から成っている。
【０００３】
このようなデバイスは、例えば、特許文献１に記載されている。特許文献２には、負圧雰囲気による創傷治療用創傷ケアデバイスが記載されている。この創傷ケアデバイスは、開放可能な窓を随意に特徴として有してよく、これは「気密性治療窓」、または「可倒式

閉鎖要素」とも呼ばれる。
【０００４】
負圧雰囲気によって創傷治療をするデバイスは、例えば、切開部の手術後治療（目的が滲出液の排出であり、および、そのため面倒な事態をより少なくして、縫合部分のより速い治癒を可能にすることであるとき）に対して、ならびに、例えば床ずれまたは静脈性潰瘍の場合の、深く窪んだ浮腫の治療（この場合、深い内側から傷の流体を積極的に取得することは、慢性の傷の治癒に対する前提条件である）に対して使用される。
【０００５】
典型的には、この治療形態において、６０と２００mmHgの間の相対的負圧が使用される。特許文献２に記載された開放可能な窓は、その下に配置された創傷接触要素、例えば吸収要素または副次的ケア用品が、気密性創傷被覆によって作られた空間に挿入されること、またはその空間から除去されることを可能なものにしている。このようにして、前記創傷接触要素、または前記ケア用品は、例えば創傷の洗浄またはその要素の交換を目的として、創傷周囲の患者の皮膚に好ましく取り付けられている創傷ケアデバイスの全体を取り換えることを必要とせずに、創傷空間から取り除くことができる。このことにより、傷治療工程における外傷性治療介入が減り、また、コスト関連の利点も有する。
【０００６】
大気の条件に基づいて、前記開放可能な窓は、窓が閉じられた位置にあるときは、気密性であることが必要である。このことは、空気が非常に低粘度の媒体であることから、些細なことではない。更に、多くの種類の気密性結合材は、強い物理的結合も必要となり、これは傷との接触の観点から望ましくない。このような強い物理的結合は、一方で一定の高さと一定の重さを特徴とし、かつ、他方では、開閉時の一定の復元力、言い換えると、開閉が手の強さで行われることを特徴とする。
【０００７】
しかしながら、現在の情況において、創傷領域に力を加えることは、しばしば患者を苦痛に曝す結果となり得るので、これは大いに望ましくない。もし、例えば、治療窓を閉じるのに力の使用を必要とするなら、患者は、特に瘢痕、床ずれ、および静脈性潰瘍の場合には、これを外傷性治療介入として経験するであろう。
【先行技術文献】
【特許文献】
【０００８】
【特許文献１】米国特許７１９８０４６号公報
【特許文献２】欧州特許１８１４６０９号公報
【発明の概要】
【発明が解決しようとする課題】
【０００９】
本発明の課題は、それ故、前述の不利な点を伴わずに、創傷接触要素またはケア用品の交換を可能にする真空傷治療を提供することである。
【課題を解決するための手段】
【００１０】
本発明は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒質を吸引するための接続デバイスを含み、上記創傷被覆要素は開放可能な窓を有し、この窓は気密性の閉鎖物によって創傷被覆要素上に配置されている、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスを提供する。
【図面の簡単な説明】
【００１１】
【図１】図１は、創傷ケアデバイスの一般原理を示す。
【図２】図２は、開放可能な窓１０を示す。
【図３】図３中に、前記連結シール１８、４０の断面を詳細に示す。
【図４】図４も、開放可能な窓を示す。

【図５】図５ａは、連結シールの異なる形態を示す。図５ｂは、接着性シールの形態の気密性の閉鎖物を示す。
【図６】図６は、創傷ケアデバイス６０を示す。
【図７】図７は、創傷ケアデバイス７０を示す。
【図８】図８は、創傷ケアデバイス８０を示す。
【図９】図９は、創傷ケアデバイス９０を示す。
【図１０】図１０は、創傷ケアデバイス１００を示す。
【図１１】図１１ａは、創傷ケアデバイス１１０を示す。図１１ｂは、図１１ａ中のデバイスに類似のデバイスを特徴として有するが、吸収要素１１８が、創傷対向側で、開放可能な窓１１７に取り付けられている点が異なる。
【図１２】図１２は、創傷ケアデバイス１２０を示す。
【図１３】図１３は、接着性シールの形の気密性の閉鎖物の更なる実施態様を示す。
【図１４】図１４は、創傷ケアデバイス１４０を示す。
【図１５】図１５は、創傷ケアデバイス１５０を示す。
【図１６】図１６ａは、発明された創傷ケアデバイスの配置を示す。図１６ｂは、図１６ａ中の配置と類似の配置を示すが、より後での配置である。
【図１７】更なる実施態様を図１７中に見ることができる。
【図１８】図１８は、本発明に係る創傷被覆要素のフレーム１８０を通り抜けた断面である。
【図１９】図１９は、創傷治療用創傷ケアデバイスを示す。
【図２０】ポンプ１９３は、図２０に見られるように、着脱可能なように具体化されている。
【図２１】図２１は、創傷ケアデバイスの分解図を示す。
【図２２】図２２は、更なる創傷治療用創傷ケアデバイスを示す。
【発明を実施するための形態】
【００１２】
前記開放可能な窓は、多くの利点を特徴として有する。従って、例えば、その窓によって、

その下にある傷の、より容易なリンスまたは洗浄
医薬品またはケア用品によるその創傷治療
創傷被覆材または吸収要素の非外傷性交換
その傷の視診および評価、および
試料、例えば綿棒採取標本の取得

が、創傷ケアデバイス全体を取り除くことを必要とせずに、可能になる。
「開放可能な窓」の概念は、完全に透明な窓、透明でない窓またはその下に非透明性物質を有する窓、および透明部を特徴として有する窓、を包含する。
【００１３】
好ましくは、創傷被覆要素は、特定の身体位置の解剖学的浮彫に対応するように事前に形成されている。例えば、それは、創傷被覆要素が肘、尻、または膝の区域に適用されるとき、有効であろう。深絞りする工程は、例えば、前述の身体位置の解剖学的浮彫に対応するように創傷被覆要素の事前形成を可能なものにしている。
【００１４】
また好ましくは、創傷被覆要素は、一定の身体位置の動きに順応できるように具体化されている。これらの目的のため、例えば、創傷被覆要素および気密性の閉鎖物は、弾性的であるように具体化されていてもよい。更に、ひだ付き配列物、または一つまたは幾つかのストレッチベローズ（伸縮する蛇腹）を備えてよい。
【００１５】
前述の実施態様では、前述の気密性の閉鎖物は、これらの悪化条件下においてすら、その気密特性を維持するであろうことは、特に重要である。
【００１６】

好ましくは、前述の気密性の閉鎖物は、連結シールの形態で具体化されている。以下において、「連結シール」の概念は、さねはぎ原理に従って機能するすべての種類の開示された連結シールを指す。

【００１７】

これらの目的のため、シールによって互いに接続されるべき両方の部分は、シールを適用したとき相互に噛みあうリップを特徴として有する。好ましくは、これらのリップは、合成もしくは天然ゴム、ポリエチレン、またはポリプロピレン等の弾性的材料からなる。

【００１８】

このようなシールは、例えば、飛行機旅行の間の化粧品運搬用の再封可能な機内持ち込みポーチ、冷凍食品保存用の再封可能な保存バッグ、または再封可能な保存箱（「タッパーウェアー」）から公知である。

【００１９】

前述の連結シールは、「ジップロック」、「ミニグリップ」、すなわち滑り封止物の仮名でも知られている。後者の場合、滑動部を備えることができ、滑動部はジッパーの様にシールされるべきリップに沿って滑り、またリップをシールされた位置に動かす。

【００２０】

いわゆるバルジロックは、例えばＷＯ０３０１３９７６Ａ１に記載されているように、「連結シール」の概念の中に包含される。

【００２１】

前述のシールは、窓が閉じられた位置にあるとき開放可能な前記窓の気密性の閉鎖物として適していること、および更に、これらシールは低い高さおよび軽い重量を有しているか、または必要としていること、ならびにシールを閉めたりまたは開けたりするためにほんの少しの力しか必要としないことも、重要である。このようにして、患者を苦痛に曝すことなく、開閉を行うことができる。

【００２２】

後者は、例えば滑動部を用いる実施態様（図９および明細書を参照）、または舌および溝オプションを用いる実施態様（図４および明細書を参照）によって達成できる。

【００２３】

前述の実施態様の代替物として、前記気密性の閉鎖物は、磁性シールの形態で具体化されていてもよい。これらの目的のため、可撓性の強磁性細片が特に備えられていてもよい。前述の磁性シールは、操作性に関して同様の利点を特徴として有する。磁性シールは、同様に、気密な形態で具体化されていてもよい。磁性シールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２４】

前述の実施態様の代替物として、前記気密性の閉鎖物は、接着性シールの形態で具体化されていてもよい。これらの目的のため、２枚の薄片はシール帯域において互いに貼り付けられる。開用の紐によって、第一の薄片を第二の薄片から容易に分離することができ、これは凹所に一体化された接着層を露出する。下のシートは、ポリエステルの支持層、感圧性の接着層、および一体化された移動障壁を有するシール層から成る。強度は２００と５００μｍとの間である。前述の接着性シールは、例えば、ＥＰ２０６７７１７から公知であり、操作性に関して同様の利点を特徴として有する。接着性シールは、同様に、気密な形態で具体化されていてもよい。接着性シールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２５】

前述の実施態様の代替物として、前記気密性の閉鎖物は、舌部と溝部のシールの形態で、恐らくは内部のシールリップを特徴として、具体化されていてもよい。前述の舌部と溝部のシールは、操作性に関して同様の利点を特徴として有する。舌部と溝部のシールは、同様に、気密な形態で具体化されるであろう。舌部と溝部のシールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２６】

前述の実施態様の代替物として、前記気密性の閉鎖物は、ゴムシールまたはゴムチューブの形態で、恐らくは加圧手段を伴って、具体化されていてもよい。前述の実施態様の代替物として、前記気密性の閉鎖物は、コルク細片の形態で、恐らくは加圧手段を伴って、具体化されていてもよい。

【００２７】

この加圧手段は、例えば、ブラケットとして、または前述の舌部と溝部のシールとして、具体化されていてもよい。

【００２８】

前述の実施態様の代替物として、前記気密性の閉鎖物は、接着性シールの形態で、例えば、好ましくはフィルムまたは塗布物の形態でフレーム側面または窓側面に付けられた低接着性シリコーン接着剤によって、具体化されていてもよい。アクリル接着剤も同様に用いられていてよい。好ましいシール特性および接着特性とは別に、これらは生理学的に安全であるという利点を有する。

【００２９】

好ましくは、創傷被覆要素を、接着性材料によって患者の皮膚に取り付けることができる。これらの目的のために、あらゆる種類の生理的に受け入れられる接着剤、特に医学グレードの接着剤を使用できる。特に好ましいのは以下を含む群から選択される材料である：

・アクリル接着剤
・シリコーン
・親水コロイド接着剤
・酸化亜鉛接着剤、および／または
・ラテックス接着剤。

【００３０】

親水コロイド接着剤は、一般に、自己接着性物質に塗布される薄いポリマーフィルムから成る。担体物質（合成ゴム種等、例えばポリイソブチレン）は膨潤粒子を含有し、これら膨潤粒子は製造者に依存して、様々である。しばしば、カルボキシメチルセルロースまたはカルボキシメチルセルロースナトリウム等の膨潤粒子が含まれる。更に、これら膨潤粒子は、特に暖かいとき、非常に展性がある。親水コロイド接着剤は、表面に組み入れられるのに適しており、特に湿気を除くことができる。これらはペースト形態で入手でき、パネルまたは細片形態でも入手できる。

【００３１】

似たようなことがシリコーン物質に当てはまる。皮膚に対する接着度は、これらの物質で調節可能であり、それゆえに、接着性にかかわらず創傷被覆材の非外傷性の交換が確実に可能である。

【００３２】

好ましくは、このようなシリコーン接着剤は、分離できる自己接着性の積層体の形態で具体化でき、積層体は、例えばシリコーンゲルの形態で疎水性ゲルが塗布されている創傷対向側、および、例えばアクリル接着剤の形態で接着剤を担持する創傷から離れて対向する側、を有する構造層を含む。このような層の一つが、例えばＥＰ２００１４２４Ｂ１に説明されていた。

【００３３】

好ましくは、前記接着性材料は、接着性端部として「縁取り包帯」の形態で具体化され、これは 創傷被覆要素を周辺的に囲む。

【００３４】

前記接着性材料は、創傷被覆要素が距離を隔てて位置するパネルまたは細片の形態で具体化されていてもよい。この実施態様では、前記パネルまたは細片は、中央の開口を特徴とし、これは傷の上部に配置されることが意図されている。この実施態様では、前記パネルまたは細片はフレームの形状をとる。あるいは、前記パネルまたは細片は、形状に関して傷の輪郭に対応して、窓がパネルまたは細片に切り込まれていてよいように、具体化さ

れていてもよい。これらの目的に対して、傷の輪郭をその上に描き、次いで一対のはさみで切り出してよい。あるいは、テンプレートを用いてよく、テンプレートにより傷の輪郭をパネルもしくは細片に転写することができ、またはテンプレートにより傷の輪郭（に対応する開口）をパネルもしくは細片から切り出すことができる。

【００３５】

前記パネルまたは前記フレームは、例えば、ここに説明した通り親水コロイド材料から成る。前記細片は、例えば、いわゆる切り込み薄片から成り、切り込み薄片は高分子材料から作製された自己接着性薄片である。

【００３６】

あるいは、前記パネルまたは前記フレームは、発泡材および／またはスペーサー布から成る。好ましくは、これは気密性被覆に組み込まれる。前述の接着剤が、皮膚対向側に塗布されていてもよい。

【００３７】

更に好ましくは、このデバイスは創傷の滲出液を取り出す吸収要素を特徴として有する。

【００３８】

この吸収要素によって、負圧治療により生じた全ての創傷滲出液を外部のキャニスターに導く必要がないこと、および少なくともその一部は創傷空間に残ること、を確実にすることが可能なものとなる。滲出液は、次いで吸収要素の単なる交換によって除去され、かつ、それが吸収要素に結合しているので、それを滲出液キャニスターよりも容易、かつ衛生的な方法で廃棄できる。

【００３９】

その結果、外部キャニスターなしで済ませる可能性には、追加的な利点がある。例えば、このデバイスは、患者の可動性を維持する（患者が自分のベッドを離れ、かつ日課を遂行することができる）ように具体化されていてもよい。

【００４０】

更に好ましくは、吸収要素は少なくとも一つの超吸収物質、変性セルロース、発泡材、および／またはアルギン酸塩を特徴として有する。

特に好ましくは、吸収要素は、セルロース繊維を含むフリースも特徴として有する。

【００４１】

超吸収ポリマー類（ＳＡＰｓ）は、それら自身の重量の多重倍、それらの自身の重量の１０００倍、までの流体を吸収可能な合成材料である。化学用語では、これらはアクリル酸（プロペン酸、$C_3H_4O_2$）とアクリル酸ナトリウム（アクリル酸由来のナトリウム塩、$NaC_3H_3O_2$）とのコポリマーであり、そのコポリマーにおいては、二種のモノマー間の相互関係は変化していてよい。更に、いわゆるコア架橋剤（ＣＸＬ）はモノマー溶液に添加され、形成された長鎖ポリマー分子をところどころ、化学的橋によって連結する。これらの橋の結果、ポリマーは水に不溶になる。水または食塩水溶液がポリマー粒子に浸透すると、粒子は大きく膨潤し、分子レベル結合のこの網状組織を引き伸ばし、水はもはや助け無しに漏れ出すことができなくなる。超吸収ポリマーは、本発明に係る創傷ケアデバイスにおいて、顆粒、紛体、充填剤、ペレット、発泡体の形態で、繊維、または繊維構造、マット、フリース、および／または繊維塊の形態で用いることができる。

【００４２】

好ましくは、変性セルロースはセルロース誘導体であり、好ましくはスルホアルキルセルロースとその誘導体、好ましくはスルホン酸エチルセルロース、カルボキシアルキルセルロース、好ましくはカルボキシメチルセルロース、カルボキシエチルセルロース、および／またはカルボキシプロピルセルロース、スルホエチルカルボキシメチルセルロース、カルボキシメチルヒドロキシエチルセルロース、ヒドロキシプロピルメチルセルロース等のより複雑なセルロース誘導体、およびカルボキシメチルセルロースアミドまたはカルボキシプロピルセルロースアミド等のアミド化セルロース誘導体である。カルボキシメチルセルロースは、特にカルボキシメチルセルロースナトリウムの形態で入手でき、「水性繊

維」として市販品を入手できる。衛生および創傷ケア用品において、繊維は平らなマトリクスで使用される。創傷滲出液由来の流体の吸収によって、繊維は、流体を保持しかつ放出しないゲルピローに徐々に変わる。繊維は、創傷滲出液を垂直方向でのみ吸収するように構成されている。これは、容量が十分である限り、滲出液は傷の端を超えて流れないことを意味する。これによって、傷の端の浸軟を効果的に妨ぐことが可能になる。

【００４３】

前記水活性ポリマーは、アルギン酸塩であってもよい。アルギン酸塩は褐色藻類から導かれ、そして繊維質フリースに織り込まれる。化学的には、これらは多糖類であり、具体的にはアルギン酸のカルシウム塩および／またはナトリウム塩である。アルギン酸塩は流体中でそれらの自身の重量の２０倍まで吸収することができ、創傷滲出液は中空の空間に蓄えられる。アルギン酸塩格子中のCa^{2+}イオンは、アルギン酸塩がNa^{+}イオンで飽和されるまで、滲出液由来のNa^{+}イオンに交換される。これによって、創傷被覆材の膨潤と、繊維の膨潤によるアルギン酸塩繊維のゲル体への転換が引き起こされる。

【００４４】

前記水活性ポリマーは、２－ヒドロキシエチルメタクリレート（ＨＥＭＡ）および／または２－ヒドロキシプロピルメタクリレート（ＨＰＭＡ）等の、ヒドロキシ末端メタクリル系モノマーを含むヒドロゲルナノ粒子であってもよく、これらはAltrazealとして市販されている。

【００４５】

更に好ましい実施態様では、吸収要素は≧４０重量％の超吸収ポリマーを含有する。特に好ましくは、超吸収ポリマーの重量配分は、≧４５、５０、５５、６０、６５または７０重量％である。

特に好ましくは、吸収要素はセルロース繊維を含むフリースを特徴として有する。

【００４６】

好ましくは、吸収要素は、超吸収ポリマーが内部に分配された吸収性フリースから成る、吸収性材料で作製された本質的に平らな吸収要素を特徴として有する。これらは、顆粒、紛体、充填剤、ペレット、発泡体の形態で、繊維、または繊維織物、マット、フリースおよび／または繊維塊の形態で加わっていてもよい。

【００４７】

吸収要素は、マット、特に、取り込まれた超吸収ポリマーを伴う超吸収ポリマーの前記糸もしくは繊維で作製されたエアレイド、および／または超吸収ポリマーの緩い充填物を含む群から選ばれる少なくとも一つの材料を特徴として有する。好ましくは、前記エアレイドマットは、例えば超吸収ポリマーを取り込んだ前述の繊維由来の吸収性フリースから成る、吸収性材料で作製された本質的に平らな材料部を特徴として有する。

【００４８】

この吸収要素は、例えばＷＯ０３０９４８１３、ＷＯ２００７０５１５９９、およびＷＯ０１５２７８０に開示された、および「sorbion sachet」の商品名で市販されている、本発明の出願人の創傷被覆材に含まれる吸収性挿入物に対応していてよい。前述の文献の開示内容は、その全範囲において、本文献の開示内容に加えられる。

【００４９】

異なる実施態様では、吸収要素は、多分柔毛性の、超吸収ポリマーからなる繊維または糸、および顆粒の形態の超吸収ポリマーを含むコアを形成していてもよく、顆粒が種々の濃度で繊維もしくは糸に貼りつけられ、または溶着させられ、ならびに顆粒が、顆粒および繊維が混合されている区域を含有するコアの少なくとも一部分の高さ全体の５０％を超えて分配されていてもよい。好ましくは、超吸収ポリマーの割合は１０～２５重量％の範囲である。類似の構造体が従来の失禁用材料から公知であり、これらは生理用ナプキンの緩衝特性に類似の緩衝特性で公知である。前記コアは、いくつかの区域でそれと重なる被覆で囲まれていてよく、またその被覆は接着性縫い目を覆っていてもよく、またはそのようなものの一部であってよい。

【００５０】

特に好ましくは、吸収要素は超吸収性繊維類（「ＳＡＦｓ」、好ましくはポリアクリレート）から成る、またはそれらを成分として含有する、フリース、好ましくは不織布もしくはエアレイドを特徴として有する。上記繊維は綿毛パルプ（セルロース）またはポリエステル繊維と混合してもよく、例えば、代わりにまたは加えて、積層構造で特徴付けられる。

【００５１】

【表１】

型	1	2	3	4	5	6
構造１	層状構造:ラミネート不織布を有する熱結合したエアレイド	短く切られたポリエステル繊維 40%: SAF60%	SAF と熱可塑性材料との二成分繊維	層状構造:ラミネート不織布を有する熱結合したエアレイド	ポリエステル 25%: SAF75%	短く切られたポリエステル繊維 40%: SAF60%
構造２	SAF と熱可塑性材料との二成分繊維+綿毛パルプ	ニードルフェルト	毛羽立て熱結合した不織布	SAF と熱可塑性材料との二成分繊維+綿毛パルプ	ニードルフェルト	ニードルフェルト
SAF 繊維型	101/6/10	102/52/10	102/52/10	101/6/10		
重量(g/m²)	560	540	1000	350	150	380
厚さ(mm)	6	5.4	20	3.5	2.4	3.8
吸収容量	31.21 水/m²	> 20 g 水/g	> 16 g 水/g または 16,000g 水/m²	19.51 水/m²	> 25 g 0.9% 食塩/g	> 17 g 水/g または 6,400 g/m²
圧力下吸収容量 (0.2 psi の圧力での ml 0.9% 食塩水/m²)	16			16		
超吸収ポリマーの全含有量 (% w/w)	18	40	50	18	75	60
引っ張り強度 (N/5 cm)					16 ± 13	16 ± 13
弾性率(%)					60 ± 18	60 ± 18

【００５２】

もう一つの実施態様として、吸収要素は、顆粒状の超吸収ポリマーが貼りつけられた超

吸収ポリマーからなる繊維または糸を含む少なくとも一つの平らな層も含んでいてもよい。これにより、２つの被覆層が超吸収ポリマーを含む一つの層を取り囲む、少なくとも３層を含む本体の構造の好ましい実施態様が得られる。

【００５３】

ここで、一つの濃度での繊維と超吸収ポリマーの混合物は存在せず、それら２つの材料の隣接配置が存在するだけである。好ましい実施態様では、追加的な層は、もし設けられるなら、回転、加圧、カレンダリング、または類似の手順によって、互いに、物理的にぎっしりと詰められていてもよい。

【００５４】

【表２】

型	1	2	3	4	5	6	7	8
重量(g/m²)	450	300	150	50	100	120	140	440
厚さ(mm)	1.3	1.2	0.9	0.7	0.7	0.76	1	1.2
流体保持率(g/g)	28	33	28	15	25	28	11.5	38
引っ張り強度(n/5cm)	25	55	20	20	20	20	15	20
吸収容量(g/g)	45	20	50	20	40	50	28	55

【００５５】

更に、この本体は、チェックのパターン、穴開けパターン等の、繰り返しパターンまたは繰り返し織地を特徴として有していてよい。

【００５６】

特に好ましくは、前記吸収要素は、表面の大きさが、５×５、５×１０、５×２０、１０×１０、１０×１５、１０×２０、１５×１５、２０×２０、または２０×４０cmの特徴を有する。

【００５７】

特に好ましくは、前記吸収要素は、超吸収ポリマーを含む層に加えて、少なくとも第二の隣接層を含み、この第二の隣接層は超吸収ポリマーを含まないか、超吸収ポリマーを含む量が少なく、また、その表面は前者の層を超えて延びている。このようにして、超吸収ポリマーを含む層は、この層が第二の層によって隠されているため、体積増加が外部から見えることなく、流体を吸収する結果として体積を得ることができる。

【００５８】

発泡材は、閉じたまたは開いた孔を有する発泡材であってよい。好ましくは、これらの材料は同様に平らな層として具体化され、一方では流体吸収性を特徴として有し、他方では緩衝特性を特徴として有する。これらは更に高い復元力によって特徴づけられる。

【００５９】

特に好ましくは、コールドフォームとして知られる種類の発泡体が用いられる。

前記発泡体の代わりにまたは前記発泡体に加えて、SNS Nano Fiber社が製造したもの等の、いわゆる「ナノファイバーマトリクス」も同様に用いられてよい。

【００６０】

更に、前記発泡体は、Smith & Nephew社のAllevyn Plus製品等の、超吸収材も含有していてよい。

更に好ましくは、デバイスは、流体浸透性の創傷対向創傷接触格子も含有する。

【００６１】

好ましくは、この様な創傷接触格子は、合成材料（好ましくは、例えば、シリコーン材料またはナイロン材料を含む）、穿孔された発泡材、スペーサー布、および／または穿孔された薄片で作られた格子である。

【００６２】

好ましくは、商品名「sorbion plus」で市販され、ＥＰ２００４１１６Ａ１に記載され

ている格子のような、三次元の創傷接触格子が設けられる。

【００６３】

創傷接触格子は、一方では、フレーム中では緩やかに、またはフレームに固定されて、傷対向側に配置されていてもよい。

【００６４】

このような創傷接触格子は顆粒形成を防ぎ、それ故、創傷被覆材の非外傷性交換を可能にする。創傷接触格子は更に、生物フィルム溶解効果ならびにバルブ効果を有し、これにより滲出液の還流が減少する。

【００６５】

出願人は、「非活性」創傷被覆材から公知であるこれらの特性は、ここに記載された「活性」真空支持創傷被覆材にも特に有利であることを実証できた。

【００６６】

創傷接触格子は、被覆側にも配置されていてもよい。このようにすることにより、創傷接触格子は、超吸収ポリマーを含む介在吸収要素によって、流体吸収の結果としてこれらがゲルを形成するときに、引き起こされ得るゲルブロッキングを防ぐことができ、上記ゲルは、さもなければ、流体吸引工程を妨害するであろうものである。

【００６７】

原則として、前述の流体媒体の吸引用の接続デバイスは、流体および／または気体の吸引を可能にするように具体化することができる。これらの目的のため、これは、ホースおよび／またはポンプの接続を可能にするカップリング（Luer-Lockシステムにおけるような）の形態で具体化されていてもよい。

【００６８】

その製品は、追加のバルブ、減圧器または開放可能な追加の窓をも、更に含んでいてよい。これにより、デバイスは、例えば、病院で頻繁に見ることができる真空壁ポートにつながれる場合のような、過度に強い負圧においてすら、使用可能となる。前記バルブ、減圧器または窓は、その後、負圧を減少させるために開放可能である。

【００６９】

更に好ましくは、流体媒体の吸引用の接続デバイスの領域に、流体不浸透性の障壁が設置される。

これは、どんな流体もポンプ中に入らないことを確実にするためである。後者は、創傷被覆の内部に残り、創傷滲出液を取り出す吸収要素によって吸収される。

好ましくは、前記障壁は、半浸透性膜、例えば、Goretex等の材料で作ったものを含む。

【００７０】

好ましくは、流体媒体の吸引用の一つの接続デバイスと、気体媒体の吸引用の一つの接続デバイスを設けることができる。

【００７１】

更に好ましくは、デバイスは負圧雰囲気の生成のための設備も含む。

前記の負圧雰囲気を生成させる設備は、好ましくは、以下を含む群から選択される：

ａ）電気的に操作される真空ポンプ

ｂ）手動で操作される負圧源、および／または

ｃ）減圧真空容器。

【００７２】

前記真空ポンプは単独のポンプであってよいが、クリニックでしばしば用いられるような、集中化真空化システムの一部であってもよい。病室には、しばしば真空壁ポートが取り付けられ、その壁ポートには発明された創傷治療用ドレナージデバイスを接続できる。この場合、前記真空ポンプは、本発明に係る創傷治療用ドレナージデバイスの多数に負圧をかけることができる。

【００７３】

好ましくは、この真空ポンプは、大きさおよび／または重量が、多少なりとも患者を煩

わせることなく、または妨害することなく、容易に前述のタイプの創傷被覆要素に適用できるような、マイクロポンプである。

【００７４】

例えば、このポンプは、ピエゾまたはメンブレンポンプである。特に好ましくは、ピエゾポンプであり、このピエゾポンプは、ポンピング容量がピエゾ電気要素によって引き起こされるポンプである。これらのポンプは、その小さいサイズにもかかわらず、十分に高いポンピング容量を有している。これらは更に操作音が低く、かつエネルギー消費が低い。あるいは、これらのポンプは、マイクロシステム技術推進体駆動真空ポンプであってもよい。このタイプの適切なポンプは、例えば、Schwarzer Precision、KNF、またはBartels Mikrotechnikによって製造されている。

【００７５】

好ましくは、このようなポンプはチェックバルブを備え、このチェックバルブによって、形成された負圧を再び低下させる操作休止の間、リークの発生なしに、ポンプを、インターバルモードで、または初期にのみ負圧を発生させるために、または負圧を維持するためだけに、操作することが可能となる。

【００７６】

好ましくは、前記ポンプは、－６０～－２００mmHgの負圧を発生させることができる。特に好ましくは、ポンプは－６０、－７０、－８０、－８５、－９０、－１００、－１１０、－１２０、－１３０、－１４０、－１５０、－１６０、－１７０、－１８０、－１９０または２００mmHgの負圧を発生させることができる。

【００７７】

好ましくは、ポンプは流体を輸送できるように選択または備えられている。

【００７８】

好ましくは、ポンプの操作音は６５dBの音圧レベルを超えない。特に好ましくは、音圧レベルは６３dB、６０dB、５８dB、５５dB、５３dB、５０dB、４８dB、４５dB、４２dB、４０dB、３８dB、３５dB、３２dB、３０dB、２８dB、２５dB、２２dB、または２０dBですら超えない。

【００７９】

好ましくは、ポンプは０．５ml・min^{-1}と１００ml・min^{-1}との間の輸送速度を特徴として有する。好ましくは、輸送速度は２ml min^{-1}と５０ml・min^{-1}との間である。特に好ましくは、輸送速度は１０ml・min^{-1}と２０ml・min^{-1}との間である。

【００８０】

前述の減圧容器は、既知のRedonボトルと類似のように、発明された創傷治療用デバイスに接続でき、かつ創傷治療用デバイスに負圧をかけることができる。前記減圧容器は、好ましくは内張りの形態の、流体吸収性ポリマーを含有する挿入物を含む。

【００８１】

特に好ましくは、前記減圧容器はカートリッジの形態で具体化することができ、これは発明された傷治療用ドレナージデバイスと既に接続されているマウント中に配置される。カートリッジが一杯のときは、カートリッジを取り除き廃棄することができ、そして新しい減圧カートリッジをマウント中に置くことができる。

【００８２】

前述した複数の実施態様は特に有利である。なぜなら、これら実施態様によって、自身のポンプの必要性がなくなり、その代わりに減圧容器が用いられることになるからであり、これによって、デバイスが可動的になり、かつ電力網から独立し、その結果、患者自身が移動可能になる。更に、これにより、より小さい構成物が可能になり、患者はデバイスを個々に隠すことが可能になる。この点で特に有利なのは、前記減圧容器またはマウントの、解剖学的に調整された実施態様であり、これによって、例えば脚の上に、それらを目立たずに運ぶことが可能になる。

【００８３】

更に、このようなデバイスは、操作音を発せず、また操作が非常に容易である。

【００８４】
同様なことが、前述の手動操作負圧源に当てはまる。最も簡単な実施態様では、この負圧源は十分に大きい容積があるプラスチック注射器であってよい。他の選択可能物はゴムボール、ベローズ等の形状のポンプである。
【００８５】
更に好ましくは、負圧雰囲気を発生させる設備は創傷ケアデバイス上に直接配置されている。
【００８６】
このことは、例えば、前記設備を直接創傷被覆要素上に配置することにより達成可能である。このようにして、製造上の課題（真空条件下で圧壊しないようにするための、十分な剛性）および衛生上の問題（汚染の危険性）を包含する別個の真空ホースを、除去することができ、または非常に短く保つことができる。
【００８７】
更に好ましくは、カップリング、ブロッキングバルブ、および／または三方バルブは、負圧雰囲気を発生させるための設備と、創傷被覆要素または創傷滲出液を取り出す吸収要素との間に配置されている。
【００８８】
このデバイスは、ａ）負圧雰囲気を発生させるための設備は、デバイスのテストから接続を切ることができる、ｂ）一旦発生させられた負圧は、可能な限り最長時間維持することができる、および／またはｃ）電池を節約する目的で、または電池が空のとき、外部のポンプまたは外部の真空容器を使用して、負圧を発生または回復させることができる。
【００８９】
前記外部のポンプまたは前記外部の真空容器は、例えば、クリニックの中で、または患者の家で、固定されていてよいが、可動形態で具体化されてもよい（例えば、スーツケースの形態で、または患者の衣類に一体化されて、または患者のベルトに取り付けられて）。これは、創傷上のデバイスが小さく目立たないままであることを確実にするためであり、その理由は、その主要な任務が、真空を維持することであるが、効果的な治療を可能にするために必要に応じて、十分なポンピング容量を提供することだからである。
【００９０】
更に好ましくは、吸収要素は流体浸透性のカバーで囲まれている。好ましくは、デバイスは更にスペーサーを含む。好ましくは、このスペーサーは創傷と創傷被覆要素との間に配置されるが、該当する場合、吸収要素と創傷被覆要素との間、または創傷と吸収要素との間にも置かれる。このようなスペーサーは、負圧がかけられたときに、確実に創傷ケアデバイスが全体的に圧壊しないようにする。圧壊してしまうと、デバイスが、結果的に気体または流体を抽出できなくなるからである。
【００９１】
更に好ましくは、デバイスは重金属、好ましくは、銅もしくは銀、またはこれらの一つを含有する塩を含む層を特徴として有する。具体的には、創傷上での適用期間が延びた場合に、層は細菌の成長を遅らせるので、このような層は大変役立つものとなり得る。
【００９２】
更に好ましくは、創傷被覆要素は流体および／または気体に対して不透過性である。これによって、真空の適用が可能となり、創傷被覆要素はその状況で汚染されている可能性のある流体の漏れを防ぐことになる。
【００９３】
好ましくは、前記創傷被覆要素は弾性材料で具体化される。これらの目的で、創傷被覆要素は、例えば、ポリプロピレン、ポリエチレン、ラテックス、シリコーン、またはゴムから成る。更に、創傷被覆要素は、内側に発泡材が取り付けられていてよい。
【００９４】
更に好ましくは、創傷被覆要素は水蒸気に対して透過性である。好ましくは、更に、創傷被覆要素は透明性をもって具体化される。

【００９５】
更に好ましくは、負圧雰囲気を発生させるための設備のポンピング方向は反転可能である。これによって、設備を、薬物、洗浄溶液等用の制御可能な投薬ポンプとして使用することが可能となる。
【００９６】
更に好ましくは、前記開放可能な窓は、非弾性的バックパネルを特徴として有する。ここにおける「バックパネル」の概念は、例えば、符号Ｎｏ．２３によって示されたようなカバーを意味する。この実施態様では、例えば、前述のポンプは、開放可能な窓のバックパネル上に直接配置することができる。
【００９７】
更に好ましくは、前記開放可能な窓は、弾性的バックパネルを特徴として有する。この態様では、例えば、バックパネルは、滲出液の吸収の結果起こる、内在吸収要素の体積増加を引き起こすように、具体化されていてもよい。これによって、気密性を保証するために窓が患者の動きを追随することが確実となる。
【００９８】
好ましくは、この弾性的バックパネルはシリコーン材料を特徴として有するか、またはそのような材料で作られる。特に好ましくは、例えば、バックパネルの下側、言い換えると、患者対向側は、シリコーンおよび／または発泡材で覆われ、またはそのような材料の上端に存在している。
【００９９】
更に好ましくは、前記開放可能な窓は、可塑性の可鍛性材料で作製されたバックパネルを特徴として有する。
【０１００】
この実施態様では、例えば、バックパネルは熱可塑性的に可鍛性の深絞り薄片から成っていてよい。これによって、例えば、その中に予備の吸収要素が準備され得る貯蔵器の作製が可能となる。
【０１０１】
好ましいのは、更に、軟組織の欠陥、外科的創面切除後の感染した創傷、リンパ系瘻孔、胸骨の傷感染症、胸壁孔、床ずれ、静脈性潰瘍、慢性的傷癒合障害、放射線潰瘍、腹部隔室症候群、敗血性腹腔、腸管瘻孔、および／または一つまたは幾つかの浮腫に起因する創傷、を含む創傷治療のための、皮膚移植の固定のための、傷の状態調節のための、ならびに／または縫い目および切開の手術後のケアのための、創傷ケアデバイスの適用である。
【０１０２】
更に、傷圧縮系における、先行する請求項の一項に係る創傷ケアデバイスの適用が考案されている。
【０１０３】
イメージ
図１は、患者の皮膚に取り付けることが可能な創傷被覆要素３、および流体媒体の吸引用の接続デバイス（図示せず）を含む、創傷領域を負圧雰囲気にして創傷を治療するための創傷ケアデバイスの一般原理を示す。創傷被覆要素は、開放可能な窓２３を特徴として有し、これは創傷被覆要素上の気密性の閉鎖物（図示せず）によって位置決めされている。窓２３を開いた後、創傷被覆材２を容易に取り除き、廃棄し、および別の創傷被覆材で置換えることができる。
【０１０４】
図２は、フレーム１２、フレーム１２と窓カバー４６との間の接続紐３６、および連結シール１８，４０として具体化された気密性の閉鎖物を含む、開放可能な窓１０を示す。
【０１０５】
図３中に、前記連結シール１８、４０の断面を詳細に示す。
【０１０６】

図４も、連結シール４２、４３で、開放可能な窓を示す。前述の連結シールは、舌と溝のオプションを特徴として有し、これによって連結シールの閉または開は軽度の力しか必要ないことが確実になる。このようにして、開または閉は、患者を苦痛に曝すことなく実行できる。更に、シールは低い高さと低い重量で特徴づけられる。

【０１０７】

図５ａは、ジッパーに類似してシールされることになるリップに沿って滑り、かつこれらをシールされた位置に動かす、滑動部３８の形態で、本発明と共に使用することができる連結シールの異なる形態を示す。

【０１０８】

図５ｂは、接着性シールの形態の気密性の閉鎖物を示す。

【０１０９】

図６は、患者の皮膚に取り付けることが可能な創傷被覆要素６１、および流体媒体の吸引用の接続デバイス６２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス６０を示す。創傷被覆要素は開放可能な窓６３を特徴とし、この窓は創傷被覆要素上の気密性の閉鎖物によって位置決めされている。

【０１１０】

創傷被覆要素は、更に、接着性材料６５を含む周囲の縁６４を特徴として有する。これは、いわゆる「縁取り包帯」の実施である。

【０１１１】

図７は、患者の皮膚に取り付けることが可能な創傷被覆要素７１、および流体媒体の吸引用の接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス７０を示す。創傷被覆要素は開放可能な窓７３を特徴とし、この窓は気密性の閉鎖物によって創傷被覆要素上に位置決めされている。

【０１１２】

デバイスは、パネルまたはフレーム７４を特徴として有し、その上に距離を隔てて創傷被覆要素が配置されている。この実施態様では、前記パネルまたは細片は、例えば、創傷の上方に配置される、中央開口を特徴として有していてもよい。この実施態様では、前記パネルまたは細片は、フレームの形態をとる。あるいは、前記パネルまたは細片は、窓が、傷の輪郭の形状に対応するパネルまたは細片に切られるように具体化されていてもよい。前記パネルは、例えば、ここに記載された親水コロイド材料から成り得る。前記細片は、例えば、上記したように切開薄片から成り、これはポリマー材料で作った自己接着性薄片である。

【０１１３】

図８は、患者の皮膚に取り付けることが可能な創傷被覆要素８１、および流体媒体の吸引用接続デバイス８２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス８０を示す。創傷被覆要素は開放可能な窓８３を特徴とし、この窓は気密性の閉鎖物によって創傷被覆要素上に位置決めされている。

【０１１４】

開放可能な窓には、耐圧性内張りが取り付けられ、超吸収ポリマーを含む吸収要素８４用の空間を与える。圧力耐性に起因して、吸収要素がその吸収容量を十分に利用できるように、開放可能な窓はつぶれない。

【０１１５】

更に、発泡材で作製された連続体８５、および三次元の創傷接触格子８６が、創傷対向側に備わっている。

【０１１６】

図９は、患者の皮膚に取り付けることが可能な創傷被覆要素９１、および流体媒体の吸引用接続デバイス９２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス９０を示す。

【０１１７】

創傷被覆要素は、開放可能な窓９３を特徴として有し、この窓は気密性連結シール９４

によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１１８】

開放可能な窓９３の下に、耐圧性内張りを有する区画９８が考案されており、これによって超吸収ポリマーを含む吸収要素９５に対する空間が提供される。前記区画は、流体に対して透過性なので、創傷対向側に具体化されている。圧力に対する抵抗によって、吸収要素がその全吸収容量を利用できるように、開放可能な窓はつぶれない。この容量に達したとき、この区画を包含する窓全体およびその中に含まれる吸収要素を廃棄し、新しいものと交換できる。

【０１１９】

更に、発泡材で作製された連続体９６、および三次元創傷接触格子９７が創傷対向側に設けられている。区画９８以外の連続体は、圧力に対して抵抗性ではなく、それ故、圧力が増加すると体積を減らす。

【０１２０】

図１０は、患者の皮膚に取り付けることが可能な創傷被覆要素１０１、および流体媒体の吸引用接続デバイス１０２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１００を示す。

【０１２１】

創傷被覆要素は、開放可能な窓１０３を特徴として有し、この窓は気密性連結シール１０４によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１２２】

更に、吸収要素１０５が考案され、これは窓を開いた後に取り除くこと、または挿入することが可能である。

【０１２３】

図１１ａは、患者の皮膚に取り付けることが可能な創傷被覆要素１１１、および流体媒体の吸引用接続デバイス１１２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１１０を示す。

【０１２４】

創傷被覆要素は、開放可能な窓１１３を特徴とし、この窓は気密性連結シール１１４によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１２５】

開放可能な窓１１３の下に、格子１１５が備えられており、これは、例えば超吸収ポリマーを含んでもよい吸収要素（図示せず）に対する空間を提供する。前述の吸収要素は格子中に置くことができ、その後、開放可能な窓を連結シールによって被覆要素に取り付けることができる。窓が再度開かれたあと、例えばその全吸収容量に到達したあと、吸収要素を取り除いて、廃棄するまたは交換することができる。

【０１２６】

更に、追加の吸収要素１１６は創傷対向側に備えられており、これは、流体保持力の程度が先に挙げた吸収要素より低いことを特徴として有してよい。

【０１２７】

図１１ｂは、図１１ａ中のデバイスに類似のデバイスを特徴として有するが、吸収要素１１８が、創傷対向側で、開放可能な窓１１７に取り付けられている点が異なる。吸収要素１１８が、その全吸収容量に到達したとき、窓に取り付けられた吸収要素を含んだ窓全体を、廃棄し、新しいものと交換することができる。

【０１２８】
図１２は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス１２２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１２０を示す。
【０１２９】
創傷被覆要素は、開放可能な窓１２１を特徴とし、この窓は取り囲んでいる排気可能なダクト１２３により創傷被覆要素上に位置決めされている。
【０１３０】
図１３は、接着性シールの形の気密性の閉鎖物の更なる実施態様を示す。
【０１３１】
図１４は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１４０を示す。
【０１３２】
創傷被覆要素は、舌部と溝部のシール１４２によって創傷被覆要素に取り付けることができる、開放可能な窓１４１を特徴として有する。更に、取り囲んでいるゴムチューブ１４３が中間に設けられ、これは舌部と溝部のシールによって圧縮されて、気密性の閉鎖物を作りだしている。ゴムチューブの代替品として、ゴムシール、コルク細片または類似の物を備えることができる。
【０１３３】
更に、ヒンジ１４４が備えられ、このヒンジは、創傷被覆要素が折り返せるが、全体として除かれないように、一方の側で開放可能な窓を、創傷被覆要素と接続させる。
【０１３４】
図１５は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１４０を示す。
【０１３５】
創傷被覆要素は、磁性シール１５２によって創傷被覆要素に取り付けることができる、開放可能な窓１５１を特徴として有する。更に、取り囲んでいるゴムチューブ１５３が中間に設けられ、これは舌部と溝部のシールによって圧縮されて、気密性の閉鎖物を作りだしている。ゴムチューブの代替品として、ゴムシール、コルク細片または類似の物を備えることができる。
【０１３６】
図１６ａは、弾性的薄片様要素８１および／または弾性的覆い８２、およびその傷の基部８４に滲出液８５を有する深い傷８３のある、吸収要素８０を伴う、発明された創傷ケアデバイスの配置を示す。図８中とは異なり、覆い８２は、少なくとも部分的に、例えば傷から離れて面する領域において、薄片様要素の不可欠な構成物であってよい。弾性的薄片様要素８１および／または弾性的覆い８２は、負圧をかけたとき、吸収要素が傷の基部８４に引きつけられ、または基部に押し付けられることができる（矢印で記したように）ことを確実にし、このことは、吸収されるべき滲出液８５と接触させるために、特に深い傷の場合、必要である。
【０１３７】
図１６ｂは、図１６ａ中の配置と類似の配置を示すが、より後での配置である。吸収要素８０は、既に大量の滲出液を吸収している。弾性的薄片様要素８１および／または弾性的覆い８２は、後者が、流体吸収による吸収要素の膨張の結果として妨害されることはないことを確実にする。これによって、吸収要素がその全吸収容量を発揮できることを確実にする。このとき、カップリング設備８６（および、それ故接続された負圧デバイス（図示せず））は、既に切り離されていてよく、または代替として、負圧デバイスはスイッチが切られ、もはや負圧をかけることはない。
【０１３８】

負圧をかけることが、吸収されるべき滲出液との接触を行うために、吸収要素を傷の基部８４に引きつけ、または吸収要素を基部に押し付ける目的だけに役立つようにも装備し得る。この接触が行われるとすぐに、真空デバイスは切り離され、またはスイッチが切られるように装備され得る。この

【０１３９】

更なる実施態様を図１７中に見ることができる。この実施態様では、発泡材本体は、負圧源用、例えばポンプ用の区画として特に設計された凹部を特徴として有して考案されている。好ましくは、チェックバルブ（図示せず）が連続的開口５７中に置かれている。前述の発泡材本体は創傷被覆要素（図示せず）によって覆われている。

【０１４０】

図１８は、本発明に係る創傷被覆要素のフレーム１８０を通り抜けた断面である。そのフレームは、例えば、その上にラミネートされた気密性ベース薄片１８２および気密性被覆薄片１８３中にラミネートされている、発泡材１８１から成っていてよい。前者は患者の皮膚への接触表面であり、および、例えば、ここでは他のどこかで塗布されたように、接着剤が塗布されていてよい。後者は開放可能な窓に対する支持表面を形成する。好ましくは、それは除菌可能なように具体化されていてもよい。

【０１４１】

図１９～２２は、発明された創傷ケアデバイスの具体的実施態様を示す。

【０１４２】

図１９は、例えば、生理学的に安全な接着剤によって、下にある薄片１９４を介して、患者の皮膚に取り付けることができるフレーム形態の創傷被覆要素１９１を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスを示し、創傷被覆要素は、気密性の閉鎖物、例えば低接着性シリコーン塗装によって創傷被覆要素上に位置決めされている開放可能な窓１９２を特徴として有する。創傷被覆要素は、例えば、気密性材料中にラミネートされた発泡材またはスペーサー布を特徴として有する。その窓は、例えば気密性薄片または塗装でシールされた発泡材またはスペーサー布を特徴とし得るベース層を特徴として有する。さらに、ポンプ１９３が示され、このポンプは流体媒体の吸引用接続デバイスを介して創傷ケアデバイスに接続されている。開放可能な窓１９２は、その材料中の凹部を特徴として有し、この凹部はポンプ１９３用の区画を形成する。

【０１４３】

ポンプ１９３は、図２０に見られるように、着脱可能なように具体化されている。

【０１４４】

図２１は、例えば、生理学的に安全な接着剤によって、下にある薄片２１４を介して、患者の皮膚に取り付けることができるフレーム形態の創傷被覆要素２１１を有する、創傷ケアデバイスの分解図を示す。創傷被覆要素２１１の発泡材またはスペーサー布２１５も示されている。

【０１４５】

図２１は、また、気密性の閉鎖物、例えば低接着性シリコーン塗装によって創傷被覆要素上に位置決めされている開放可能な窓２１２、および気密性薄片または塗装によってシールされている、窓の下にある発泡材またはスペーサー布２１６も特徴として示す。

【０１４６】

さらに、流体媒体の吸引用接続デバイスを介して創傷ケアデバイスに接続されているポンプ２１３、およびポンプ用区画を形成する窓の中の凹部を見ることができる。

【０１４７】

その上、創傷接触格子２１７が示され、創傷接触格子は、（ｉ）傷対向側、かつ緩くフレーム内側に配置され、もしくはフレームに接続されていてもよい、または（ｉｉ）被覆側、のいずれかに配置されていてもよい。

【０１４８】

図２２は、創傷領域の負圧雰囲気による、更なる創傷治療用創傷ケアデバイスを示し、その中でポンプは手動操作ポンプとして具体化されている。

【図１】

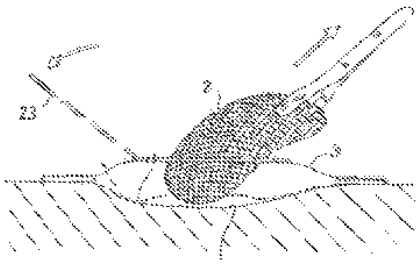


図1

【図２】

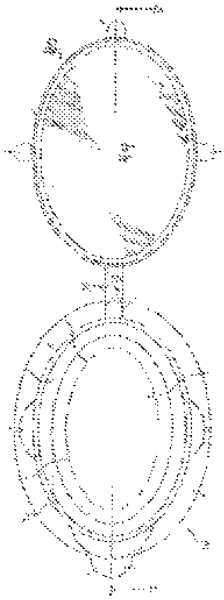


図2

【図３】

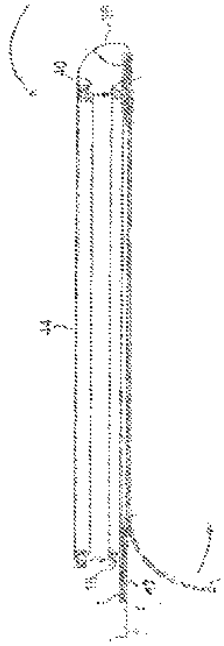


図3

【図４】

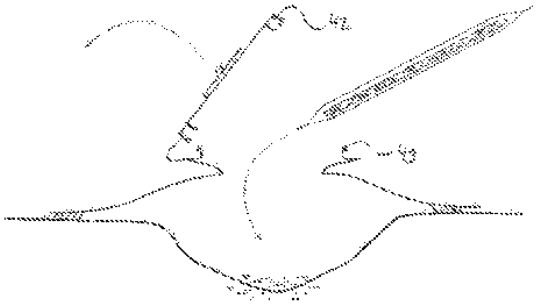


図4a

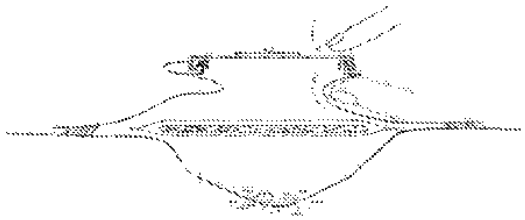


図4b

【図５】

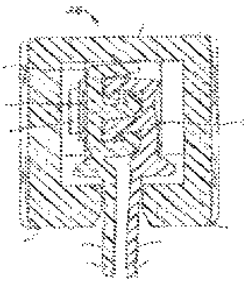


図5a

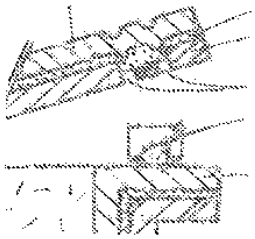


図5b

【図６】

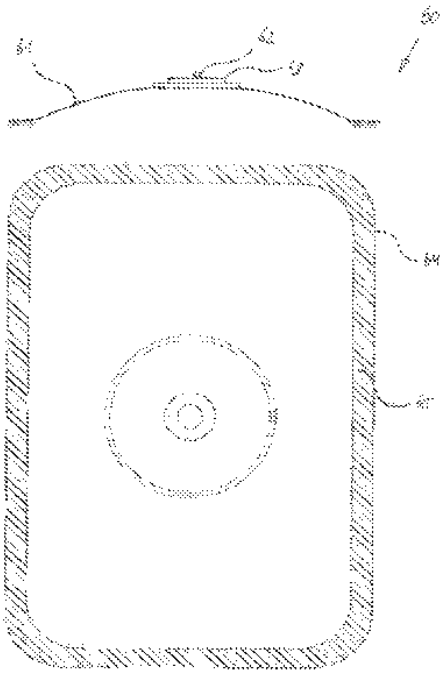


図6

【図７】

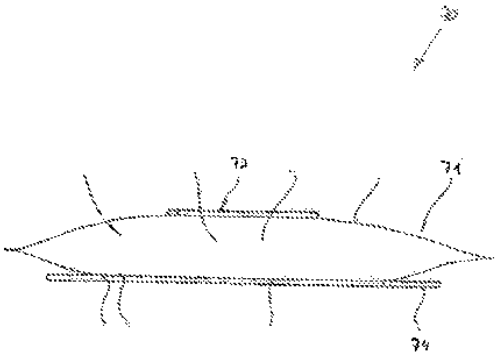


図7

【図８】

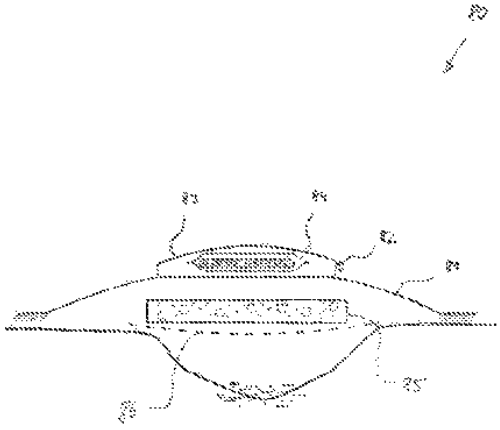


図8

【図９】

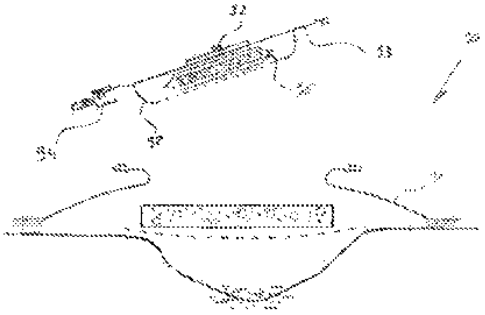


図9a

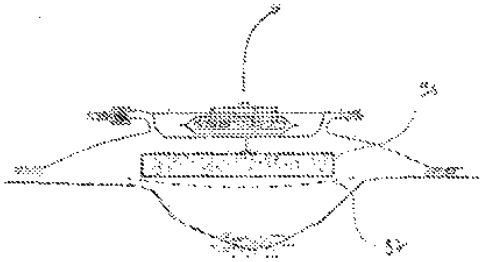


図9b

【図１０】

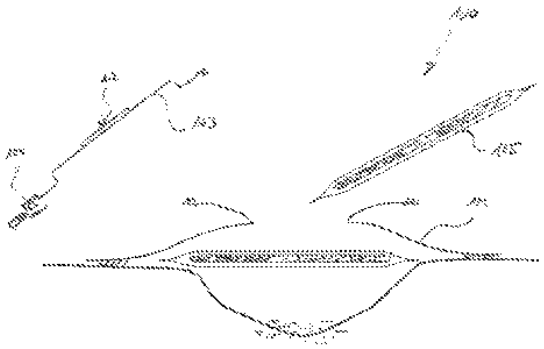


図10a

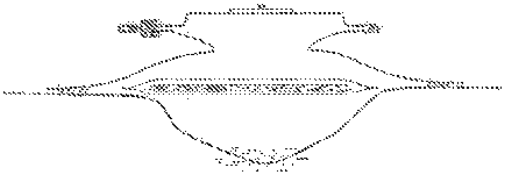


図10b

【図１１】

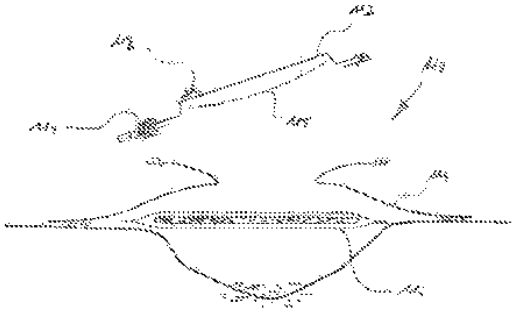


図11a

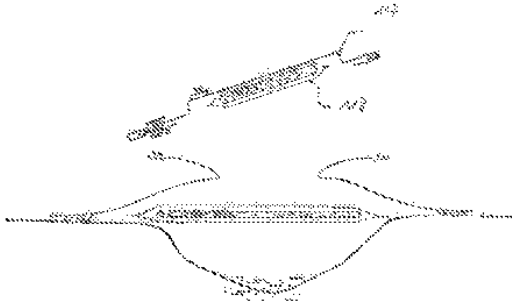


図11b

【図１２】

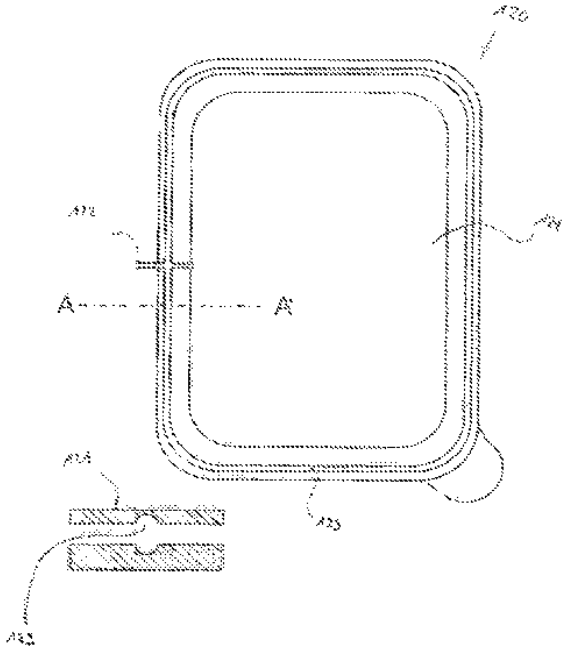


図12

【図１３】

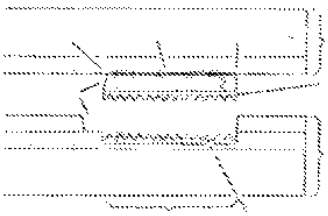


図13

【図１４】

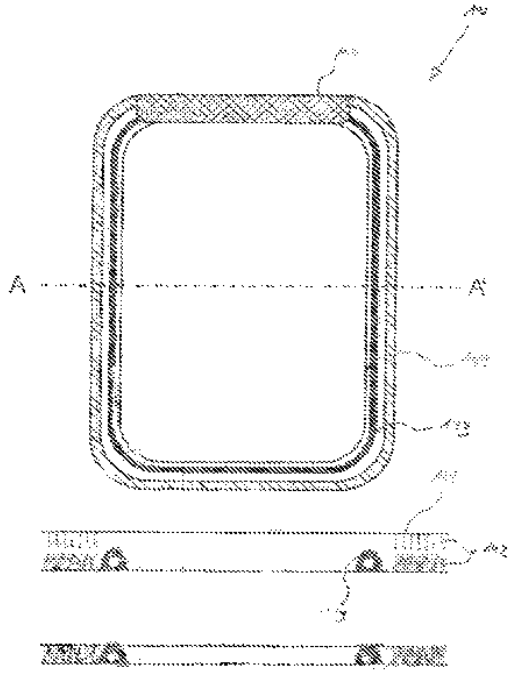


図14

【図１５】

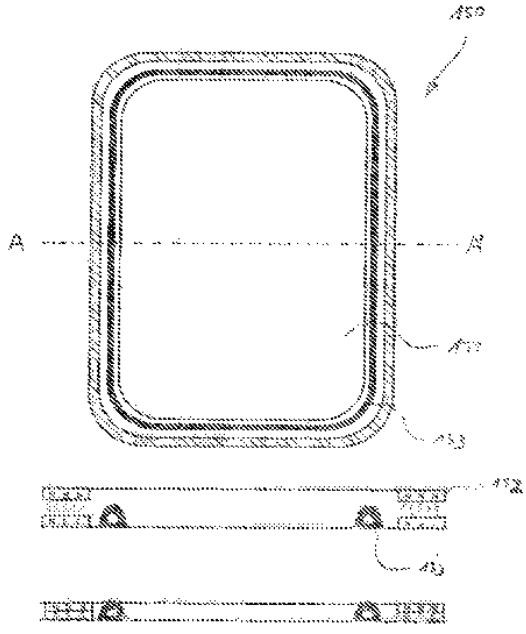


図15

【図１６】

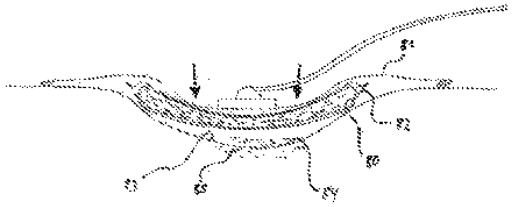


図16a

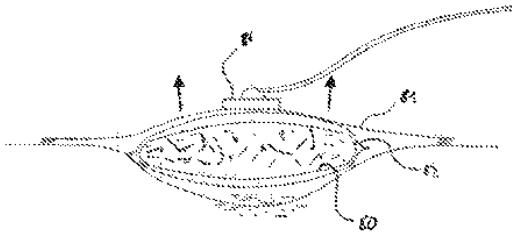


図16b

【図１７】

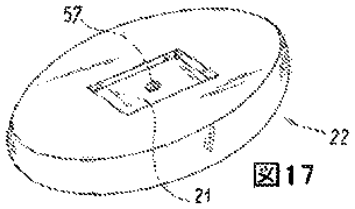


図17

【図１８】

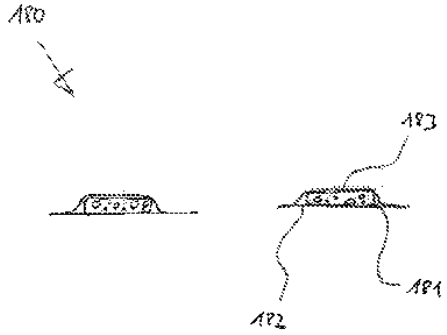


図18

【図１９】

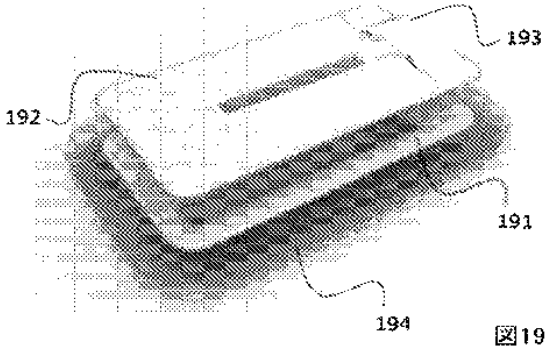


図19

【図２０】

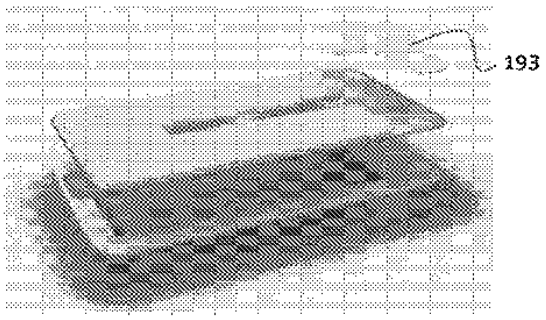


図20

【図２１】

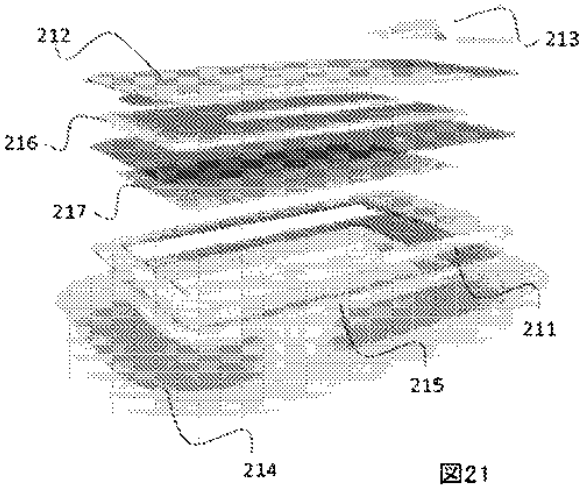


図21

【図２２】

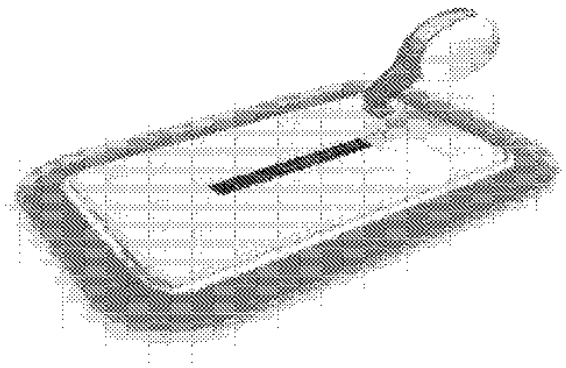


図22

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/060133

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00
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)
A61F

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	EP 1 814 609 A1 (RIESINGER BIRGIT [DE]) 8 August 2007 (2007-08-08) cited in the application paragraphs [0010] - [0027], [0029], [0034], [0036], [0044] - [0046]; figures 1,2	1-24
X	WO 2012/168298 A1 (RIESINGER BIRGIT [DE]) 13 December 2012 (2012-12-13) page 2, line 18 - page 3, line 26 page 21, line 26 - page 22, line 6; figure 6c	1-24

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 September 2014	11/09/2014

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	Westberg, Erika

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/060133

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1814609 A1	08-08-2007	AT 390941 T	15-04-2008
		AU 2005309089 A1	01-06-2006
		CA 2589312 A1	01-06-2006
		CN 101065158 A	31-10-2007
		DE 202004018245 U1	07-07-2005
		DK 1814609 T3	04-08-2008
		EP 1814609 A1	08-08-2007
		ES 2304730 T3	16-10-2008
		PL 1814609 T3	30-09-2008
		US 2008119802 A1	22-05-2008
		US 2011172617 A1	14-07-2011
		WO 2006056294 A1	01-06-2006
WO 2012168298 A1	13-12-2012	EP 2717935 A1	16-04-2014
		US 2014163486 A1	12-06-2014
		WO 2012168298 A1	13-12-2012

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

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2014/060133

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61F13/00
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61F

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	EP 1 814 609 A1 (RIESINGER BIRGIT [DE]) 8. August 2007 (2007-08-08) in der Anmeldung erwähnt Absätze [0010] - [0027], [0029], [0034], [0036], [0044] - [0046]; Abbildungen 1,2	1-24
X	WO 2012/168298 A1 (RIESINGER BIRGIT [DE]) 13. Dezember 2012 (2012-12-13) Seite 2, Zeile 18 - Seite 3, Zeile 26 Seite 21, Zeile 26 - Seite 22, Zeile 6; Abbildung 6c	1-24

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen ☒ Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
2. September 2014	11/09/2014

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Westberg, Erika

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2014/060133

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
EP 1814609	A1	08-08-2007	AT	390941 T	15-04-2008
			AU	2005309089 A1	01-06-2006
			CA	2589312 A1	01-06-2006
			CN	101065158 A	31-10-2007
			DE	202004018245 U1	07-07-2005
			DK	1814609 T3	04-08-2008
			EP	1814609 A1	08-08-2007
			ES	2304730 T3	16-10-2008
			PL	1814609 T3	30-09-2008
			US	2008119802 A1	22-05-2008
			US	2011172617 A1	14-07-2011
			WO	2006056294 A1	01-06-2006
WO 2012168298	A1	13-12-2012	EP	2717935 A1	16-04-2014
			US	2014163486 A1	12-06-2014
			WO	2012168298 A1	13-12-2012

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

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	Ａ６１Ｆ 13/00	３０１Ｃ	
	Ａ６１Ｌ 15/28	１１０	
	Ａ６１Ｌ 15/60	１１０	

(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(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), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

Ｆターム(参考) 4C081 AA03 AA12 BB01 CA081 CA082 CA122 CA272 CB041 CD021 CD042 DA04 DA05
4C167 AA39 AA40 BB24 CC01 GG14 GG21 GG36 HH17 HH18 HH19 HH20

Patents | JP 2016-524490 A

Wound care device for wound treatment with negative pressure atmosphere, including openable window

Abstract

translated from Japanese

The subject of the present invention is a wound care device for wound treatment with a negative pressure atmosphere in a wound area, comprising a wound covering element that can be attached to the skin of a patient and a connection device for aspirating a fluid medium. The covering element comprises a window that can be opened, said window being a wound care device arranged on the wound covering element by an airtight closure (FIG. 4b).

Classifications

- A61F13/00068 Accessories for dressings specially adapted for application or removal of fluid, e.g. irrigation or drainage of wounds, under-pressure wound-therapy

View 6 more classifications

JP2016524490A

Japan

Download PDF | Find Prior Art | Similar

Other languages: Japanese

Inventor: [illegible]

Current Assignee : BSN Medical GmbH

Worldwide applications

2014 JP CN CA CN EP AU WO BR 2015 US

Application JP2016513395A events

2013-05-16 Priority to DE102013105063.3

2013-05-15 Priority to DE102013105063.8A

2013-07-12 Priority to DE102013107399.9

2013-07-12 Priority to DE102013107399

2014-05-16 Application filed by BSN Medical GmbH

2014-05-16 Priority to PCT/EP2014/060132

2016-08-18 Publication of JP2016524490A

Status Pending

Info: Patent citations (16), Cited by (9), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (24)

Hide Dependent ^

translated from Japanese

A wound care device for wound treatment with a negative pressure atmosphere in the wound area,
A wound dressing element capable of being attached to a patient's skin and a connection device for aspirating a fluid medium,
The wound care device, wherein the wound covering element has an openable window, the window being arranged on the wound covering element by an airtight closure. 2. A wound care device according to claim 1, characterized in that the airtight closure is embodied in the form of a connecting seal. A wound care device according to one of the preceding claims, characterized in that the wound covering element is pre-formed to correspond to a predetermined body location anatomy. A wound care device according to one of the preceding claims, characterized in that the wound covering element is adapted to move along with the movement of the predetermined body position. The wound dressing element is:
An acrylic adhesive, a silicone, a hydrocolloid adhesive, a zinc oxide adhesive, and / or an adhesive material selected from the group comprising a latex adhesive and characterized in that it can be attached to the patient's skin The wound care device according to claim 1. A wound care device according to one of the preceding claims, characterized in that the device also comprises an absorbent element for removing wound exudate. A wound care device according to one of the preceding claims, characterized in that the absorbent element comprises at least one superabsorbent material, modified cellulose, foam and / or alginate. A wound care device according to one of the preceding claims, characterized in that the absorbent element also comprises a fleece comprising cellulose fibers. A wound care device according to one of the preceding claims, characterized in that the device also comprises a fluid permeable wound-opposing wound contact grid. A wound care device according to one of the preceding claims, characterized in that there is a fluid impermeable barrier in the area of the connection device for suction of the fluid medium. A wound care device according to one of the preceding claims, characterized in that the device also comprises equipment for the generation of a negative pressure atmosphere. A wound care device according to one of the preceding claims, characterized in that the facility for the generation of a negative pressure atmosphere is arranged directly on the wound care device. A coupling, blocking valve, and / or a three-way valve between said equipment for generating a negative pressure atmosphere and said absorbent element for removing said wound covering element or wound exudate. A wound care device according to one of the claims. A wound care device according to one of the preceding claims, characterized in that the absorbent element is surrounded by a fluid permeable cover. A wound care device according to one of the preceding claims, characterized in that the device further comprises a spacer. A wound care device according to one of the preceding claims, characterized in that the device also comprises a layer comprising a heavy metal, preferably copper or silver, or a salt containing one of these. A wound care device according to one of the preceding claims, characterized in that the wound dressing element is impermeable to fluids and / or gases. A wound care device according to one of the preceding claims, characterized in that the wound dressing element is permeable to water vapor. The wound care device according to one of the preceding claims, characterized in that the pumping direction of the equipment for generating a negative pressure atmosphere is reversible. A wound care device according to one of the preceding claims, characterized in that the openable window comprises an inelastic back panel. A wound care device according to one of the preceding claims, characterized in that the openable window comprises an elastic back panel. A wound care device according to one of the preceding claims, characterized in that the openable window comprises a back panel made of a plastic malleable material. Soft tissue defect, infected wound after surgical debridement, lymphatic fistula, sternum wound infection, chest wall hole, bedsores, venous ulcer, chronic wound healing disorder, radiation ulcer, abdominal compartment syndrome, septic abdominal cavity , Intestinal fistulas, and / or wound healing purposes such as wounds caused by one or several

edemas, for fixation of skin grafts, for wound conditioning and / or surgery for seams and incisions For later care,
Application of a wound care device according to one of the preceding claims. Application of a wound care device according to one of the preceding claims in a wound compression system.

Description translated from Japanese

The present invention relates to a wound care device for treating wounds with a negative pressure atmosphere, including an openable window.

Conventional systems and devices for wound treatment with a negative pressure atmosphere consist of an airtight wound wound covering, a drainage (drainage) hose, an externally placed vacuum pump, and a container for collecting drained exudate Yes.

Such a device is described in Patent Document 1, for example. Patent Document 2 describes a wound care device for wound treatment using a negative pressure atmosphere. The wound care device may optionally feature an openable window, also referred to as an "airtight treatment window" or "collapseable closure element".

Devices that treat wounds with a negative pressure atmosphere, for example, post-surgical treatment of the incision (the goal is drainage of exudate, and therefore less mess, allowing faster healing of the sutured area As well as for the treatment of deeply depressed edema, for example in the case of bedsores or venous ulcers (in this case, actively acquiring wound fluid from deep inside is a chronic wound) Is a precondition for healing).

Typically, in this form of treatment, a relative negative pressure between 50 and 200 mmHg is used The openable window described in US Pat. No. 6,057,049 is a wound contact element disposed underneath, such as an absorbent element or secondary care product inserted into a space created by an airtight wound covering, or Making it possible to be removed from that space In this way, the wound contact element, or the care article, replaces the entire wound care device preferably attached to the patient's skin around the wound, for example for the purpose of cleaning the wound or replacing the element. It can be removed from the wound space without need. This reduces traumatic intervention in the wound healing process and also has cost related advantages.

Based on atmospheric conditions, the openable window needs to be airtight when the window is in the closed position. This is not trivial because air is a very low viscosity medium. In addition, many types of hermetic binders also require strong physical bonding, which is undesirable from the standpoint of scratch contact. Such a strong physical connection is characterized on the one hand by a constant height and a constant weight, and on the other hand, by a constant restoring force during opening and closing, in other words, opening and closing is done with the strength of the hand. Features.

However, in the current situation, applying force to the wound area can often result in exposing the patient to pain, which is highly undesirable. If, for example, it requires the use of force to close the treatment window, the patient will experience this as a traumatic treatment intervention, especially in the case of scars, bedsores, and venous ulcers.

U.S. Pat. No. 7,198046 European Patent No. 1814609

The object of the present invention is therefore to provide a vacuum wound treatment which allows the replacement of a wound contact element or a care product without the disadvantages mentioned above.

The present invention includes a wound dressing element that can be attached to a patient's skin, and a connection device for aspirating a fluid medium, the wound dressing element having an openable window that is hermetically closed There is provided a wound care device for wound treatment with a negative pressure atmosphere in a wound area disposed by an object on a wound covering element.

FIG. 1 shows the general principle of a wound care device. FIG. 2 shows a window 10 that can be opened. In FIG. 3, the cross section of the said connection seals 18 and 40 is shown in detail. FIG. 4 also shows an openable window. FIG. 5a shows a different form of coupling seal. FIG. 5b shows an airtight closure in the form of an adhesive seal. FIG. 6 shows a wound care device 60. FIG. 7 shows a wound care device 70. FIG. 8 shows a wound care device 80. FIG. 9 shows a wound care device 90. FIG. 10 shows a wound care device 100. FIG. 11 a shows the wound care device 110. FIG. 11b features a device similar to that in FIG. 11a, except that an absorbent element 118 is attached to the openable window 117 on the wound-opposing side. FIG. 12 shows a wound care device 120. FIG. 13 shows a further embodiment of an airtight closure in the form of an adhesive seal. FIG. 14 shows a wound care device 140. FIG. 15 shows a wound care device 150. FIG. 16a shows the arrangement of the invented wound care device. FIG. 16b shows an arrangement similar to that in FIG. 16a, but a later arrangement. A further embodiment can be seen in FIG. FIG. 18 is a cross section through the frame 180 of a wound dressing element according to the present invention. FIG. 19 shows a wound care device for wound treatment. The pump 193 is embodied so as to be detachable as seen in FIG. FIG. 21 shows an exploded view of the wound care device. FIG. 22 shows a wound care device for further wound treatment.

The openable window features a number of advantages. So, for example, by the window,
Easier rinsing or cleaning of the underlying wound The wound treatment with a medicinal product or care article Atraumatic exchange of the wound dressing or absorbent element The inspection and evaluation of the wound and the acquisition of a sample, e.g. a swab sample, This is possible without the need to remove the entire wound care device.
The concept of "openable windows" includes completely transparent windows, non-transparent windows or windows with non-transparent material under them, and windows characterized by transparency.

Preferably, the wound dressing element is preformed to accommodate an anatomical relief of a particular body location. For example, it may be effective when the wound dressing element is applied to the elbow, hip, or knee area. The deep drawing step enables pre-formation of the wound dressing element to accommodate, for example, the aforementioned anatomical relief of the body position.

Also preferably, the wound dressing element is embodied such that it can adapt to certain body position movements. For these purposes, for example, the wound dressing element and the airtight closure may be embodied to be elastic. In addition, a pleated array or one or several stretch bellows may be provided.

In the embodiment described above, it is particularly important that the hermetic closure described above will maintain its hermetic properties even under these exacerbated conditions.

Preferably, the aforementioned airtight closure is embodied in the form of a connecting seal. In the following, the concept of "link seal" refers to all kinds of disclosed link seals that function according to the principle of tongue and groove.

For these purposes, both parts to be connected to each other by a seal feature lips that interlock with each other when the seal is applied. Preferably, these lips are made of an elastic material such as synthetic or natural rubber, polyethylene, or polypropylene

Such seals are, for example, resealable carry-on pouches for carrying cosmetics during air travel, resealable storage bags for storing frozen foods, or resealable storage boxes ("Tupperware") Are known.

The aforementioned connecting seal is also known as "ziplock", "minigrip", or pseudonym of sliding seal. In the latter case, a slide can be provided, which slides along the lip to be sealed like a zipper and moves the lip to a sealed position.

So-called bulge locks are encompassed within the concept of "connected seals", as described, for example, in WO03013976A1.

The aforementioned seals are suitable as hermetic closures of the windows that can be opened when the windows are in a closed position, and furthermore, these seals have a low height and light weight, or it is also important that what is needed and that only a little force is required to close or open the seal. In this way, the patient can be opened and closed without exposing the patient to pain

The latter can be achieved, for example, by an embodiment using a slide (see FIG. 9 and the specification) or an embodiment using a tongue and groove option (see FIG. 4 and the specification).

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a magnetic seal. For these purposes, flexible ferromagnetic strips may be provided in particular. The magnetic seal described above has similar advantages in terms of operability. The magnetic seal may likewise be embodied in an airtight form. The magnetic seal may also be technically embodied so as to maintain its hermeticity even under the aforementioned deterioration conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of an adhesive seal. For these purposes, the two laminae are stuck together in the sealing zone. With the opening string, the first flake can be easily separated from the second flake, which exposes the adhesive layer integrated in the recess. The lower sheet consists of a polyester backing layer, a pressure sensitive adhesive layer, and a sealing layer with an integrated transfer barrier. The intensity is between 200 and 500 µm. Such adhesive seals are known, for example, from EP 2067717 and are characterized by similar advantages in terms of operability. The adhesive seal may likewise be embodied in an airtight form. The adhesive seal may also be technically embodied so as to maintain its hermeticity even under the aforementioned deteriorating conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a tongue and groove seal, possibly featuring an internal sealing lip. The tongue and groove seals described above have similar advantages in terms of operability. The tongue and groove seals will be embodied in an airtight manner as well. The seal between the tongue and the groove may also be technically embodied so as to maintain its airtightness even under the aforementioned deterioration conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a rubber seal or rubber tube, possibly with pressure means. As an alternative to the previous embodiment, the airtight closure may be embodied in the form of a cork strip, possibly with pressurizing means.

This pressurizing means may be embodied, for example, as a bracket or as a seal between the aforementioned tongue and groove.

As an alternative to the previous embodiment, the hermetic closure is in the form of an adhesive seal, for example, preferably in the form of a film or application, a low adhesion silicone adhesive applied to the frame side or window side. May be embodied. Acrylic adhesives may be used as well. Apart from the preferred sealing and adhesive properties, they have the advantage of being physiologically safe.

Preferably, the wound dressing element can be attached to the patient's skin by an adhesive material. For these purposes, all kinds of physiologically acceptable adhesives, in particular medical grade adhesives, can be used. Particularly preferred are materials selected from the group comprising:
• Acrylic adhesives • Silicones • Hydrocolloid adhesives • Zinc oxide adhesives and / or • Latex adhesives.

Hydrocolloid adhesives generally consist of a thin polymer film that is applied to a self-adhesive material. The carrier material (synthetic rubber species, such as polyisobutylene) contains swollen particles, which can vary depending on the manufacturer. Often, swollen particles such as carboxymethylcellulose or sodium carboxymethylcellulose are included. Furthermore, these swollen particles are very malleable, especially when warm. Hydrocolloid adhesives are suitable for incorporation into the surface and can in particular remove moisture. These are available in paste form and are also available in panel or strip form.

Similar applies to silicone materials. The degree of adhesion to the skin can be adjusted with these substances, thus ensuring a non-traumatic exchange of the wound dressing regardless of adhesion.

Preferably, such a silicone adhesive can be embodied in the form of a separable self-adhesive laminate, the laminate being a wound-opposing side to which a hydrophobic gel is applied, for example in the form of a silicone gel, and A structural layer having a side facing away from the wound carrying the adhesive, for example in the form of an acrylic adhesive. One such layer has been described, for example, in EP2001424B1.

Preferably, the adhesive material is embodied in the form of an "edge bandage" as an adhesive end, which surrounds the wound dressing element peripherally.

The adhesive material may be embodied in the form of panels or strips on which the wound dressing elements are located at a distance. In this embodiment, the panel or strip is characterized by a central opening, which is intended to be placed on top of the wound. In this embodiment, the panel or strip takes the form of a frame. Alternatively, the panel or strip may be embodied such that a window may be cut into the panel or strip corresponding to the contour of the wound with respect to shape. For these purposes, the outline of the wound may be drawn on it and then cut with a pair of scissors. Alternatively, a template may be used, and the wound contour may be transferred to the panel or strip by the template, or the wound contour (corresponding opening) may be cut from the panel or strip by the template.

The panel or the frame is made of, for example, a hydrocolloid material as described herein. The strip is made of, for example, a so-called cut slice, and the cut slice is a self-adhesive slice made of a polymer material.

Alternatively, the panel or the frame is made of a foam material and / or a spacer cloth. Preferably this is incorporated into the hermetic coating. The aforementioned adhesive may be applied to the skin facing side.

More preferably, the device features an absorbent element that removes wound exudate

This absorbent element makes it possible to ensure that all wound exudate produced by negative pressure treatment does not have to be directed to an external canister and at least part of it remains in the wound space. . The exudate is then removed by simple replacement of the absorbent element and can be disposed of in an easier and hygienic manner than the exudate canister because it is coupled to the absorbent element.

As a result, the possibility of eliminating the need for an external canister has an additional advantage. For example, the device may be embodied to maintain patient mobility (the patient can leave his bed and perform his daily routine).

More preferably, the absorbent element features at least one superabsorbent material, modified cellulose, foam, and / or alginate.
Particularly preferably, the absorbent element is also characterized by a fleece comprising cellulose fibers.

Superabsorbent polymers (SAPs) are synthetic materials that can absorb fluids up to multiples of their own weight, up to 1000 times their own weight. In chemical terms, these are copolymers of acrylic acid (propenoic acid, $C_3H_4O_2$) and sodium acrylate (sodium salt derived from acrylic acid, $NaC_3H_3O_2$). The interrelationship

between the species monomers may vary. In addition, so-called core crosslinkers (CXL) are added to the monomer solution to link the formed long chain polymer molecules at some places by chemical bridges. As a result of these bridges, the polymer becomes insoluble in water. As water or saline solution penetrates into the polymer particles, the particles swell greatly and stretch this network of molecular level bonds, and water can no longer escape without help. The superabsorbent polymer can be used in the wound care device according to the invention in the form of granules, powders, fibers, pellets, foams, in the form of fibers or fiber structures, mats, fleeces and / or fiber masses. it can.

Preferably, the modified cellulose is a cellulose derivative, preferably a sulfoalkyl cellulose and its derivatives, preferably ethyl cellulose sulfonate, carboxyalkyl cellulose, preferably carboxymethyl cellulose, carboxyethyl cellulose, and / or carboxypropyl cellulose, sulfoethyl carboxymethyl cellulose, More complex cellulose derivatives such as carboxymethyl hydroxyethyl cellulose, hydroxypropyl methyl cellulose, and amidated cellulose derivatives such as carboxymethyl cellulose amide or carboxypropyl cellulose amide. Carboxymethylcellulose is available in particular in the form of sodium carboxymethylcellulose and is commercially available as "aqueous fiber". In hygiene and wound care products, the fibers are used in a flat matrix. Upon absorption of fluid from the wound exudate, the fibers gradually turn into gel pillows that retain and do not release fluid. The fibers are configured to absorb wound exudate only in the vertical direction. This means that as long as the volume is sufficient, exudate will not flow beyond the edge of the wound. This can effectively prevent the maceration of the wound edges.

The water active polymer may be an alginate. Alginate is derived from brown algae and woven into a fibrous fleece. Chemically, these are polysaccharides, specifically the calcium and / or sodium salts of alginic acid. Alginates can absorb up to 20 times their own weight in the fluid and the wound exudate is stored in a hollow space. Ca^{2+} ions alginate lattice until alginate is saturated with Na^{+} ions are exchanged for Na $^{+}$ ions from the exudate. This causes swelling of the wound dressing and conversion of the alginate fiber into a gel body due to fiber swelling.

The water active polymer may be hydrogel nanoparticles containing hydroxy-terminated methacrylic monomers, such as 2-hydroxyethyl methacrylate (HEMA) and / or 2-hydroxypropyl methacrylate (HPMA), which are commercially available as Altrazeal. ing.

In a further preferred embodiment, the absorbent element contains ≥ 40% by weight of superabsorbent polymer. Particularly preferably, the weight distribution of the superabsorbent polymer is ≥ 45, 50, 55, 60, 65 or 70% by weight.
Particularly preferably, the absorbent element is characterized by a fleece comprising cellulose fibers.

Preferably, the absorbent element features an essentially flat absorbent element made of an absorbent material consisting of an absorbent fleece with superabsorbent polymer distributed therein. These may be added in the form of granules, powders, fibers, pellets, foams, in the form of fibers or textiles, mats, fleeces and / or fiber masses.

The absorbent element is at least one material selected from the group comprising a mat, in particular an airlaid made of said yarn or fiber of superabsorbent polymer with incorporated superabsorbent polymer, and / or a loose fills of superabsorbent polymer As a feature. Preferably, the airlaid mat is characterized by an essentially flat material part made of an absorbent material, for example consisting of an absorbent fleece derived from the aforementioned fibers incorporating a superabsorbent polymer.

This absorbent element corresponds to the absorbent insert contained in the Applicant s wound dressing disclosed in, for example, WO03094813, WO2007051599, and WO0152780, and marketed under the trade name "sorbion sachet". It may be. The disclosure content of the above-mentioned document is added to the disclosure content of this document in its entire scope.

In different embodiments, the absorbent element may form a core comprising fibers or yarns of possibly superficial, superabsorbent polymer, and superabsorbent polymer in the form of granules, with the granules in various concentrations. Alternatively, it may be affixed or welded to the yarn and the granules may be distributed over 50% of the total height of at least a portion of the core containing the area where the granules and fibers are mixed. Preferably, the proportion of superabsorbent polymer is in the range of 10-25% by weight. Similar structures are known from conventional incontinence materials, and these are known for buffering properties similar to those of sanitary napkins. The core may be surrounded by a covering that overlaps in several areas, and the covering may cover an adhesive seam or may be part of such.

Particularly preferably, the absorbent element is characterized by fleece, preferably non-woven or airlaid, consisting of superabsorbent fibers ("SAFs", preferably polyacrylates) or containing them as components. The fibers may be mixed with fluff pulp (cellulose) or polyester fibers, for example, alternatively or additionally, characterized by a laminated structure.

In another embodiment, the absorbent element may also include at least one flat layer comprising fibers or threads made of superabsorbent polymer with a granular superabsorbent polymer attached thereto. This provides a preferred embodiment of the structure of the body comprising at least three layers, with two covering layers surrounding one layer containing the superabsorbent polymer.

Here, there is no mixture of fiber and superabsorbent polymer at one concentration, only an adjacent arrangement of the two materials. In preferred embodiments, the additional layers, if provided, may be physically packed together by rotation, pressurization, calendering, or similar procedures.

Further, the body may feature a repeating pattern or a repeated woven fabric, such as a check pattern, a drilling pattern, or the like.

Particularly preferably, the absorbent element has a surface size of 5 × 5, 5 × 10, 5 × 20, 10 × 10, 10 × 15, 10 × 20, 15 × 15, 20 × 20, or 20 ×. It has the characteristics of 40cm.

Particularly preferably, the absorbent element comprises at least a second adjacent layer in addition to a layer comprising a superabsorbent polymer, the second adjacent layer being free of superabsorbent polymer or having an amount comprising superabsorbent polymer. Less and its surface extends beyond the former layer. In this way, the layer containing the superabsorbent polymer can gain volume as a result of absorbing fluid without the volume increase being visible from the outside, since this layer is hidden by the second layer.

The foam may be a foam with closed or open pores. Preferably, these materials are likewise embodied as a flat layer, characterized on the one hand by fluid absorbency and on the other hand by cushioning properties. These are characterized by a higher resilience.

Particular preference is given to using a type of foam known as cold foam.
Instead of or in addition to the foam, so-called "nanofiber matrices" such as those manufactured by SNS Nano Fiber may be used as well.

Furthermore, the foam may also contain a superabsorbent, such as the Allevyn Plus product from Smith & Nephew.
More preferably, the device also contains a fluid permeable wound facing wound contact grid.

Preferably, such a wound contact grid is a grid made of synthetic material (preferably including, for example, silicone material or nylon material), perforated foam, spacer fabric, and / or perforated flakes is there.

Preferably, a three-dimensional wound contact grid is provided, such as the grid sold under the trade name "sorbion plus" and described in EP2004116A1.

The wound contact grid, on the one hand, may be arranged on the wound-opposing side, loosely in the frame or fixed to the frame.

Such a wound contact grid prevents granulation and therefore allows atraumatic exchange of the wound dressing. The wound contact grid further has a biofilm dissolution effect as well as a valve effect, which reduces exudate reflux.

Applicants have been able to demonstrate that these properties known from "non-active" wound dressings are also particularly advantageous for the "active" vacuum-supported wound dressings described herein

The wound contact grid may also be arranged on the covering side. In this way, the wound contact grid can prevent gel blocking that can be caused by intervening absorbent elements comprising superabsorbent polymers when they form a gel as a result of fluid absorption, the gel being Otherwise it will interfere with the fluid suction process.

In principle, the connecting device for suction of the fluid medium described above can be embodied so as to allow suction of fluid and / or gas. For these purposes, this may be embodied in the form of a coupling (such as in the Luer-Lock system) that allows the connection of hoses and / or pumps.

The product may further include additional valves, pressure reducers, or additional windows that can be opened. This allows the device to be used even at excessively negative pressures, such as when connected to a vacuum wall port that can be frequently seen in hospitals, for example. The valve, pressure reducer or window can then be opened to reduce negative pressure.

More preferably, a fluid impermeable barrier is provided in the region of the connection device for suction of the fluid medium.
This is to ensure that no fluid enters the pump. The latter remains inside the wound covering and is absorbed by the absorbent element that removes the wound exudate. Preferably, the barrier comprises a semi-permeable membrane, for example made of a material such as Goretex.

Preferably, one connection device for suction of the fluid medium and one connection device for suction of the gaseous medium can be provided.

More preferably, the device also includes equipment for the generation of a negative pressure atmosphere.
The equipment for generating the negative pressure atmosphere is preferably selected from the group comprising:
a) an electrically operated vacuum pump b) a manually operated negative pressure source, and / or c) a vacuum chamber.

The vacuum pump may be a single pump, but may also be part of a centralized vacuum system, such as is often used in clinics. Hospital rooms are often fitted with vacuum wall ports to which the invented wound treatment drainage device can be connected. In this case, the vacuum pump can apply a negative pressure to many of the wound treatment drainage devices according to the present invention.

Preferably, the vacuum pump is a micropump whose size and / or weight can be easily applied to a wound dressing element of the aforementioned type without any patient annoyance or interference, is there.

For example, the pump is a piezo or membrane pump. Particularly preferred is a piezo pump, which is a pump whose pumping capacity is caused by a piezoelectric element. These pumps have a sufficiently high pumping capacity despite their small size. These have a lower operating sound and lower energy consumption. Alternatively, these pumps may be microsystem technology propellant driven vacuum pumps. Suitable pumps of this type are manufactured, for example, by Schwarzer Precision, KNF or Bartels Mikrotechnik.

Preferably, such a pump is provided with a check valve that allows the pump to be negative in interval mode or only initially during the operational pause to reduce the formed negative pressure again without any leaks. It is possible to operate only to generate pressure or to maintain negative pressure.

Preferably, the pump can generate a negative pressure of −60 to −200 mmHg. Particularly preferably, the pump is -60, -70, -80, -85, -90, -100, -110, -120, -130, -140, -150, -160, -170, -180, -190. Alternatively, a negative pressure of 200 mmHg can be generated.

Preferably, the pump is selected or provided so that it can transport fluid.

Preferably, the pump operating sound does not exceed a sound pressure level of 65 dB. Particularly preferably, the sound pressure level does not exceed 63 dB, 60 dB, 58 dB, 55 dB, 53 dB, 50 dB, 48 dB, 45 dB, 42 dB, 40 dB, 38 dB, 35 dB, 32 dB, 30 dB, 28 dB, 25 dB, 22 dB, or even 20 dB.

Preferably, the pump is characterized by a transport rate between 0.5 ml · min $^{-1}$ and 100 ml · min $^{-1}$. Preferably, the transport rate is between 2 ml min $^{-1}$ and 50 ml min $^{-1}$. Particularly preferably, the transport rate is between 10 ml · min $^{-1}$ and 20 ml · min $^{-1}$.

The vacuum container described above can connect to the invented wound treatment device and apply negative pressure to the wound treatment device, similar to known Redon bottles. The vacuum vessel includes an insert containing a fluid-absorbing polymer, preferably in the form of a lining.

Particularly preferably, the vacuum container can be embodied in the form of a cartridge, which is arranged in a mount that is already connected to the invented wound healing drainage device. When the cartridge is full, the cartridge can be removed and discarded, and a new vacuum cartridge can be placed in the mount.

The embodiments described above are particularly advantageous. Because these embodiments eliminate the need for their own pumps and instead use a vacuum vessel, which makes the device movable and independent of the power grid, resulting in The patient himself can move. In addition, this allows for a smaller configuration and allows the patient to hide the device individually. Particularly advantageous in this respect is an anatomically adjusted embodiment of the vacuum vessel or mount, which makes it possible to carry them inconspicuously, for example on a leg.

Furthermore, such a device does not emit operational sounds and is very easy to operate.

The same applies to the aforementioned manually operated negative pressure source. In the simplest embodiment, the negative pressure source may be a plastic syringe with a sufficiently large volume. Other selectables are pumps in the form of rubber balls, bellows or the like.

More preferably, the equipment for generating a negative pressure atmosphere is located directly on the wound care device

This can be achieved, for example, by placing the equipment directly on the wound dressing element. In this way, it is possible to remove a separate vacuum hose that includes manufacturing challenges (sufficient rigidity to prevent crushing under vacuum conditions) and hygiene issues (risk of contamination). Can or can be kept very short.

More preferably, the coupling, blocking valve, and / or three-way valve is disposed between the facility for generating a negative pressure atmosphere and the absorbent element for removing wound dressing or wound exudate.

This device is a) equipment for generating a negative pressure atmosphere can be disconnected from the test of the device, b) the negative pressure once generated can be maintained for the longest possible time, And / or c) negative pressure can be generated or restored for the purpose of conserving the battery, or when the battery is empty, using an external pump or an external vacuum vessel.

The external pump or the external vacuum vessel may be fixed, for example in a clinic or at a patient's home, but may be embodied in a mobile form (e.g. in the form of a suitcase, Or integrated into the patient's clothing or attached to the patient's belt). This is to ensure that the device on the wound remains small and unobtrusive, because its primary mission is to maintain a vacuum, but allows for effective treatment This is because it provides sufficient pumping capacity as needed.

More preferably, the absorbent element is surrounded by a fluid permeable cover. Preferably, the device further comprises a spacer. Preferably, this spacer is placed between the wound and the wound dressing element, but where applicable, it is also placed between the absorbent element and the wound dressing element or between the wound and the absorbent element. Such a spacer ensures that the wound care device does not collapse overall when negative pressure is applied. This is because if the device is crushed, the device cannot extract gas or fluid as a result.

More preferably, the device features a layer comprising a heavy metal, preferably copper or silver, or a salt containing one of these. In particular, such a layer can be very useful as the layer slows down bacterial growth when the application period on the wound is extended.

More preferably, the wound dressing element is impermeable to fluids and / or gases. This allows for the application of a vacuum and prevents the wound dressing element from leaking fluid that may be contaminated in the situation.

Preferably, the wound dressing element is embodied in an elastic material. For these purposes, the wound dressing element consists of, for example, polypropylene, polyethylene, latex, silicone or rubber. Furthermore, the wound dressing element may have foam attached to the inside.

More preferably, the wound dressing element is permeable to water vapor. Preferably, the wound covering element is further embodied with transparency

More preferably, the pumping direction of the equipment for generating the negative pressure atmosphere can be reversed. This allows the facility to be used as a controllable dosing pump for drugs, cleaning solutions and the like.

More preferably, the openable window features an inelastic back panel. The concept of "back panel" here is, for example, the code No. Means a cover as indicated by 23. In this embodiment, for example, the aforementioned pump can be placed directly on the back panel of the openable window.

More preferably, the openable window features an elastic back panel. In this aspect, for example, the back panel may be embodied to cause an increase in the volume of the intrinsic absorbent element that occurs as a result of absorption of exudate. This ensures that the window follows the patient's movement to ensure hermeticity.

Preferably, this elastic back panel features or is made of a silicone material. Particularly preferably, for example, the lower side of the back panel, in other words the patient-facing side, is covered with silicone and / or foam or is present at the upper end of such a material.

More preferably, the openable window features a back panel made of a plastic malleable material.

In this embodiment, for example, the back panel may comprise a thermoplastically malleable deep drawn flake. This makes it possible, for example, to create a reservoir in which a spare absorbent element can be prepared.

Preference is also given to soft tissue defects, infected wounds after surgical debridement, lymphatic fistulas, sternum wound infections, chest wall holes, bedsores, venous ulcers, chronic wound healing disorders, radiation ulcers, abdominal septum For the treatment of wounds, including chamber syndrome, septic abdominal cavity, intestinal fistula, and / or wounds caused by one or several edemas, for fixation of skin grafts, for wound conditioning, and Application of wound care devices for post-surgical care of seams and incisions.

Furthermore, the application of a wound care device according to one of the preceding claims in a wound compression system has been devised.

FIG. 1 shows a wound area with a negative pressure atmosphere for treating a wound, including a wound covering element 3 that can be attached to the skin of a patient and a connection device (not shown) for suction of a fluid medium. 1 shows the general principle of a wound care device. The wound dressing element features an openable window 23, which is positioned by an airtight closure (not shown) on the wound dressing element. After opening the window 23, the wound dressing 2 can be easily removed, discarded, and replaced with another wound dressing

FIG. 2 shows the openable window 10 including the frame 12, the connecting string 36 between the frame 12 and the window cover 46, and a hermetic closure embodied as a coupling seal 18, 40.

In FIG. 3, the cross section of the said connection seals 18 and 40 is shown in detail.

FIG. 4 also shows a window that can be opened with connecting seals 42, 43. The aforementioned coupling seal features a tongue and groove option, which ensures that closing or opening the coupling seal requires only a slight force. In this way, opening or closing can be performed without exposing the patient to pain. Furthermore, the seal is characterized by a low height and low weight.

FIG. 5a is a different articulated seal that can be used with the present invention in the form of a slide 38 that slides along lips to be sealed similar to a zipper and moves them to a sealed position. The form is shown.

FIG. 5b shows an airtight closure in the form of an adhesive seal.

FIG. 6 shows a wound care device 60 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 61 that can be attached to the patient's skin and a connection device 62 for suction of the fluid medium. The wound dressing element features an openable window 63, which is positioned by an airtight closure on the wound dressing element.

The wound dressing element further features a peripheral edge 64 that includes an adhesive material 65. This is the implementation of a so-called "border bandage".

FIG. 7 shows a wound care device 70 for wound treatment with a negative pressure atmosphere in the wound area, comprising a wound covering element 71 that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium. Show. The wound dressing element features an openable window 73, which is positioned on the wound dressing element by an airtight closure.

The device features a panel or frame 74 on which wound dressing elements are disposed at a distance. In this embodiment, the panel or strip may feature a central opening, for example, located above the wound. In this embodiment, the panel or strip takes the form of a frame. Alternatively, the panel or strip may be embodied such that the window is cut into a panel or strip corresponding to the shape of the wound contour. The panel can be made of, for example, the hydrocolloid materials described herein. The strip consists of, for example, an incision slice as described above, which is a self-adhesive slice made of a polymer material.

FIG. 8 shows a wound care device 80 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element 81 that can be attached to the patient's skin and a connection device 82 for suction of the fluid medium. The wound dressing element features an openable window 83, which is positioned on the wound dressing element by an airtight closure.

The openable window is fitted with a pressure resistant lining to provide space for an absorbent element 84 that includes a superabsorbent polymer. Due to pressure tolerance, the openable window does not collapse so that the absorbent element can fully utilize its absorbent capacity.

In addition, a continuum 85 made of foam and a three-dimensional wound contact grid 86 are provided on the opposite side of the wound.

FIG. 9 shows a wound care device 90 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 91 that can be attached to the patient's skin and a connection device 92 for suction of the fluid medium.

The wound dressing element features an openable window 93 that is positioned on the wound dressing element by an airtight interlocking seal 94. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

Under the openable window 93, a section 98 with a pressure-resistant lining has been devised, which provides a space for the absorbent element 95 comprising superabsorbent polymer. The compartment is embodied on the opposite side of the wound because it is permeable to fluid. The resistance to pressure does not collapse the openable window so that the absorbent element can utilize its full absorption capacity. When this capacity is reached, the entire window containing this compartment and the absorbent element contained therein can be discarded and replaced with a new one.

Furthermore, a continuous body 96 made of foam material and a three-dimensional wound contact grid 97 are provided on the wound facing side. The continuum other than compartment 98 is not resistant to pressure and therefore decreases in volume as pressure increases.

FIG. 10 shows a wound care device 100 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 101 that can be attached to a patient's skin and a connection device 102 for suction of a fluid medium.

The wound dressing element features an openable window 103 that is positioned on the wound dressing element by an airtight interlocking seal 104. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

In addition, an absorbent element 105 is devised which can be removed or inserted after opening the window.

FIG. 11a shows a wound care device 110 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element 111 that can be attached to the patient's skin and a connection device 112 for suction of a fluid medium.

The wound dressing element features an openable window 113 that is positioned on the wound dressing element by an airtight interlocking seal 114. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

Below the openable window 113, a grating 115 is provided, which provides space for an absorbent element (not shown), which may include, for example, a superabsorbent polymer. The aforementioned absorbent elements can be placed in a grid, after which an openable window can be attached to the covering element by a connecting seal. After the window has been reopened, for example after reaching its full absorption capacity, the absorption element can be removed and discarded or replaced.

Furthermore, an additional absorbent element 116 is provided on the opposite side of the wound, which may be characterized by a lower degree of fluid retention than the absorbent elements listed above.

FIG. 11b features a device similar to that in FIG. 11a, except that an absorbent element 118 is attached to the openable window 117 on the wound-opposing side. When the absorbent element 118 reaches its full absorbent capacity, the entire window including the absorbent element attached to the window can be discarded and replaced with a new one.

FIG. 12 shows a wound care device 120 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device 122 for suction of the fluid medium.

The wound dressing element features an openable window 121, which is positioned on the wound dressing element by an enclosing exhaustable duct 123.

FIG. 13 shows a further embodiment of an airtight closure in the form of an adhesive seal.

FIG. 14 shows a wound care device 140 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium.

The wound dressing element features an openable window 141 that can be attached to the wound dressing element by a tongue and groove seal 142. In addition, a surrounding rubber tube 143 is provided in the middle, which is compressed by a tongue and groove seal to create an airtight closure. As an alternative to rubber tubes, rubber seals, cork strips or the like can be provided.

In addition, a hinge 144 is provided that connects the openable window on one side with the wound dressing element so that the wound dressing element can be folded back but not removed as a whole.

FIG. 15 shows a wound care device 140 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium.

The wound dressing element features an openable window 151 that can be attached to the wound dressing element by a magnetic seal 152. In addition, a surrounding rubber tube 153 is provided in the middle, which is compressed by the tongue and groove seals to create an airtight closure. As an alternative to rubber tubes, rubber seals, cork strips or the like can be provided.

FIG. 16a shows an invented wound care device arrangement with an absorbent element 80 with an elastic flake-like element 81 and / or an elastic covering 82 and a deep wound 83 with exudate 85 at the base 84 of the wound. Indicates. Unlike in FIG. 8, the covering 82 may be an integral component of the flake-like element, at least in part, for example in a region facing away from the wound. The elastic flake-like element 81 and / or the elastic covering 82 allows the absorbent element to be attracted to or pressed against the wound base 84 when negative pressure is applied (as indicated by the arrows) This is necessary, especially in the case of deep wounds, to contact the exudate 85 to be absorbed.

FIG. 16b shows an arrangement similar to that in FIG. 16a, but a later arrangement. The absorbent element 80 has already absorbed a large amount of exudate. The elastic flake-like element 81 and / or the elastic covering 82 ensure that the latter is not disturbed as a result of expansion of the absorbent element due to fluid absorption. This ensures that the absorbent element can exert its full absorption capacity. At this time, the coupling facility 86 (and therefore the connected negative pressure device (not shown)) may already be disconnected, or alternatively, the negative pressure device is switched off and no longer applies negative pressure. Don't hang.

The application of negative pressure may also be equipped to serve only the purpose of attracting the absorbent element to the wound base 84 or pressing the absorbent element against the base in order to make contact with the exudate to be absorbed. As soon as this contact is made, the vacuum device can be disconnected or equipped to be switched off. this

A further embodiment can be seen in FIG. In this embodiment, the foam body is devised with features of a recess specifically designed as a compartment for a negative pressure source, for example a pump. Preferably, a check valve (not shown) is placed in the continuous opening 57. The aforementioned foam body is covered by a wound dressing element (not shown).

FIG. 18 is a cross section through the frame 180 of a wound dressing element according to the present invention. The frame may, for example, consist of a foam 181 laminated on an airtight base flake 182 and an airtight covering flake 183 laminated thereon. The former is the contact surface to the patient's skin, and the adhesive may be applied, for example as applied elsewhere here. The latter forms a support surface for the openable window. Preferably, it may be embodied so that it can be sterilized.

19-22 show specific embodiments of the invented wound care device.

FIG. 19 shows a wound with a negative pressure atmosphere in the wound area, including a wound dressing element 191 in the form of a frame that can be attached to the patient's skin, for example with a physiologically safe adhesive, via an underlying flake 194 Fig. 4 shows a therapeutic wound care device, wherein the wound covering element features an openable window 192 positioned on the wound covering element by an airtight closure, such as a low adhesion silicone coating. The wound dressing element features, for example, a foam or spacer fabric laminated in an airtight material. The window is characterized by a base layer, which can for example be characterized by an airtight flake or a foam or spacer cloth sealed with paint. In addition, a pump 193 is shown, which is connected to the wound care device via a fluid medium suction connection device. The openable window 192 features a recess in the material that forms a compartment for the pump 193.

The pump 193 is embodied so as to be detachable as seen in FIG.

FIG. 21 shows an exploded view of a wound care device having a wound dressing element 211 in the form of a frame that can be attached to the patient's skin, for example with a physiologically safe adhesive, via an underlying flake 214. . Also shown is the foam or spacer fabric 215 of the wound dressing element 211.

FIG. 21 also shows an openable window 212 positioned on the wound dressing element by a hermetic closure, such as a low adhesion silicone paint, and a window sealed by a hermetic flake or paint. Some foam or spacer fabric 216 is also featured.

In addition, the pump 213 connected to the wound care device via the fluid medium suction connection device and the recess in the window forming the pump compartment can be seen.

In addition, a wound contact grid 217 is shown, which can either be (i) wound-opposed and loosely placed inside the frame or connected to the frame, or (ii) the coated side it may be arranged.

FIG. 22 shows a further wound care wound care device with a negative pressure atmosphere in the wound area, in which the pump is embodied as a manually operated pump.

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KR101796287B1	2016-06-01	2017-11-10	고려대학교 산학협력단	Wound healing accelerator pad
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CN114206280A *	2018-12-31	2022-03-18	未来·竞科斯特	Reclosable wound dressing
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BR202019024885U2 *	2019-11-26	2021-06-08	Gustavo Moreira Costa De Souza	dressing for negative pressure wound therapy

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
US11154429B2	2021-10-26	Wound care device for the treatment of wounds by means of atmospheric negative pressure, comprising a window that can be opened
US20210228417A1	2021-07-29	Conformable medical dressing with self supporting substrate
US20200121512A1	2020-04-23	Medical System And Dressing For Use Under Compression
US11266537B2	2022-03-08	Dressing exhibiting low tissue ingrowth and negative-pressure treatment method
JP6705916B2	2015-04-22	Depressurized medical supplies assembly for applying closure force
JP7000419B2	2022-01-19	Medical systems and dressings used under pressure
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CN113648092A	2021-09-20	Pump assembly and wound therapy device

CN105338778A 2022-03-09 Pump assembly and wound therapy device

Priority And Related Applications

Priority Applications (5)

Application	Priority date	Filing date	Title
DE102013105053.8		2013-05-15	
DE102013105063.8A	2013-05-15	2013-05-15	WOUND CARE DEVICE FOR TREATING WOUNDS USING ATMOSPHERIC UNDERPRESSURE, SHOWN AS AN OPEN WINDOW
DE102013107399.9		2013-07-12	
DE102013107399		2013-07-12	
PCT/EP2014/060133	2013-05-15	2014-05-16	Wound care device for treating wounds by means of atmospheric negative pressure, comprising a window that can be opened

Legal Events

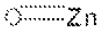
Date	Code	Title	Description
2017-04-14	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20170414
2017-10-24	A711	Notification of change in applicant	**Free format text**: JAPANESE INTERMEDIATE CODE: A711 **Effective date**: 20171024
2017-11-10	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A521 **Effective date**: 20171024
2017-12-25	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20171225
2018-01-23	A711	Notification of change in applicant	**Free format text**: JAPANESE INTERMEDIATE CODE: A712 **Effective date**: 20171024
2018-02-23	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20180221
2018-02-27	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20180227
2018-02-28	RD04	Notification of resignation of power of attorney	**Free format text**: JAPANESE INTERMEDIATE CODE: A7424 **Effective date**: 20180228
2018-05-25	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20180525
2018-10-30	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20181030
2019-01-28	A601	Written request for extension of time	**Free format text**: JAPANESE INTERMEDIATE CODE: A601 **Effective date**: 20190128
2019-03-26	A601	Written request for extension of time	**Free format text**: JAPANESE INTERMEDIATE CODE: A601 **Effective date**: 20190326
2019-04-26	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20190426

2019-09-24	A02	Decision of refusal	**Free format text:** JAPANESE INTERMEDIATE CODE: A02 **Effective date:** 20190924

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
fluid		claims,abstract,description	41	0.000
Skin		claims,abstract,description	23	0.000
wound		claims,description	265	0.000
absorbent		claims,description	60	0.000
absorbent		claims,description	60	0.000
adhesive		claims,description	40	0.000
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material		claims,description	32	0.000
Exudates and Transudates		claims,description	21	0.000
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Lymphatic fistula	claims,description	2	0.000
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Cu

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Abdominal compartment syndrome	claims	1	0.000
anatomy	claims	1	0.000
reversible	claims	1	0.000
surgical procedure	claims	1	0.000

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(54) Title: REDUCED PRESSURE THERAPY APPARATUSES AND METHODS OF USING SAME

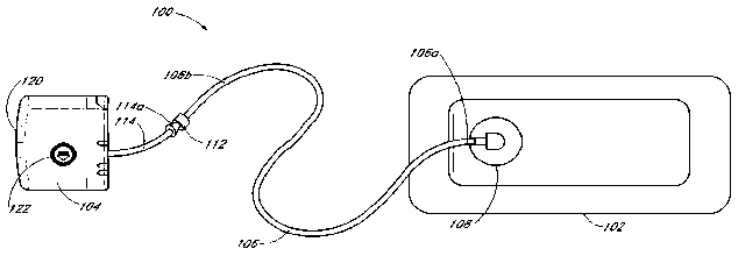


FIG. 1

(57) Abstract: Some embodiments comprise a pump assembly for reduced pressure wound therapy, comprising a housing, a flow pathway through the pump, one or more valves in communication with the flow pathway, a pump supported within or by the housing, and a one-way flow valve in fluid communication with the pump. The pump assembly can have a pressure sensor in communication with the flow pathway through the pump, and at least one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller. The one-way flow valve can be configured to substantially prevent a flow of gas through the one-way flow valve in a direction of flow away from the pump. The pump assembly can have a controller supported within or by the housing, the controller being configured to control an operation of the pump. The pump has been sterilized following the assembly of the pump such that an inside and an outside of the housing, the flow pathway, the one or more valves, the pump, the controller, the battery compartment, and the at least one switch or button have been sterilized.

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REDUCED PRESSURE THERAPY APPARATUSES AND METHODS OF USING SAME

INCORPORATION BY REFERENCE

[0001] This application incorporates by reference U.S. Patent Application No. 13/092,042, filed April 21, 2011 (titled WOUND DRESSING AND METHOD OF USE), U.S. Patent Application No. 11/922,894, filed May 21, 2008 (titled ANTIMICROBIAL BIGUANIDE METAL COMPLEXES), U.S. Provisional Application No. 61/511,950 (titled METHODS AND APPARATUSES FOR DETECTING LEAKS AND CONTROLLING PUMP OPERATION IN A NEGATIVE PRESSURE WOUND THERAPY SYSTEM), filed July 26, 2011, PCT Patent Application No. PCT/GB11/000622 (titled WOUND DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000621 (titled WOUND PROTECTION), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000625 (titled WOUND DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000626 (titled MULTIPORT DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000628 (titled SUCTION PORT), filed on April 21, 2011, and PCT Patent Application No. PCT/GB11/051745 (titled PRESSURE CONTROL APPARATUS), filed on September 16, 2011. Each and all of the foregoing patent applications are hereby incorporated by reference in their entireties and made part of this disclosure. Additionally, co-pending Patent Application No. 13/XXX,XXX (Attorney Docket No. SMNPH.194A), entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM," filed on November 2, 2011, and co-pending PCT Patent Application No. PCT/US11/XXXXXX (Attorney Docket No. SMNPH.194WO), entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM," filed on November 2, 2011 are also hereby incorporated by reference in their entireties as if set forth herein.

BACKGROUND

Field of the Disclosure

[0002] Embodiments disclosed herein relate to methods and apparatuses for dressing and treating a wound with topical negative pressure (TNP) therapy. For example but without limitation, some embodiments disclosed herein relate to treating a wound with reduced pressure provided from a pump kit. Although not required, some embodiments of the pump kit can be sterile. As another non-limiting example, some embodiments disclosed herein relate to apparatuses and methods for controlling the operation of a TNP system.

Description of the Related Art

[0003] Many different types of wound dressings are known for aiding in the healing process of a human or animal. These different types of wound dressings include many different types of materials and layers, for example, gauze, pads, foam pads or multi-layer wound dressings. Topical negative pressure ("TNP") therapy, sometimes referred to as vacuum assisted closure, negative pressure wound therapy, or reduced pressure wound therapy, is widely recognized as a beneficial mechanism for improving the healing rate of a wound. Such therapy is applicable to a broad range of wounds such as incisional wounds, open wounds and abdominal wounds or the like.

[0004] TNP therapy assists in the closure and healing of wounds by reducing tissue oedema; encouraging blood flow; stimulating the formation of granulation tissue; removing excess exudates and may reduce bacterial load and thus, infection to the wound. Furthermore, TNP therapy permits less outside disturbance of the wound and promotes more rapid healing.

SUMMARY OF SOME EMBODIMENTS

[0005] Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, comprising a housing, a pump supported within or by the housing, a flow pathway through the pump assembly, and a one-way flow valve in fluid communication with the pump and supported by the housing. Some embodiments of the one-way flow valve can be configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump. The pump can have a motor, an inlet

and an outlet, a first valve supported by the pump and configured to control a flow of a fluid through the inlet, and a second valve supported by the pump and configured to control a flow of a fluid through the outlet.

[0006] Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, comprising a housing, a pump supported within or by the housing, a one-way flow valve in fluid communication with the pump, and a flow pathway through the pump assembly. The one-way flow valve can be configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump. The pump can comprise a motor, an inlet, and an outlet. In any of the pump embodiments disclosed herein, though not required, the pump can also have a first valve configured to control a flow of a fluid through the inlet, and a second valve configured to control a flow of a fluid through the outlet. Some pump embodiments disclosed herein can use orifices or other features or components to control a flow or rate of flow of fluid through the pump.

[0007] Some embodiments disclosed herein relate to a negative pressure therapy kit for reduced pressure wound therapy, comprising a pump assembly comprising a housing, a pump supported within the housing, and a controller supported within or by the housing, and at least one switch or button supported by the housing. As used throughout this specification, the phrase "some embodiments" or "in some embodiments" is meant to refer to any embodiment described, illustrated, incorporated by reference, or otherwise disclosed herein. The at least one switch or button can be in communication with the controller and can be accessible to a user so as to permit a user to control one or more modes of operation of the pump. In some embodiments, though not required, the negative pressure therapy kit can comprise a dressing configured to form a substantially fluid tight seal over a wound, a conduit coupleable with the dressing and the pump assembly and configured to provide a substantially or completely enclosed fluid flow pathway from the pump assembly to the dressing, and a first packaging element for packaging the pump assembly, the one or more batteries, the dressing, and the conduit. In some embodiments, the controller can be configured to control an operation of the pump and the valve. Some embodiments of the negative pressure therapy kit can be configured such that the negative pressure therapy kit has been sterilized. The negative pressure therapy kit can be sterilized such that at least an inside and an outside of the housing, the at least one valve, the pump, the controller, and the at least

one switch or button have been sterilized. In some embodiments, the pump can have a pump motor, an inlet and an outlet, at least one valve configured to control a flow of fluid through at least one of the inlet and the outlet, and a flow pathway through at least the inlet, the outlet, and the at least one valve.

[0008] Some embodiments disclosed herein relate to reduced pressure treatment of wounds with a reduced pressure pump. The pump embodiments disclosed herein are not required to be sterilized. However, sterilizing the reduced pressure pump before use and providing the pump and/or dressing or pump kit components in a sterile condition can permit the use of the pump in an operating room (also referred to as an operating theater) or any other location where sterility of the devices is required. For example and without limitation, some embodiments are directed to a sterile pump kit comprising a sterile pump, a sterile dressing, and a sterile conduit connectable to the dressing and the pump that can be used in an operating room.

[0009] Some embodiments disclosed herein relate to a negative pressure therapy kit for reduced pressure wound therapy, comprising a pump having a flow rate of approximately 350 milliliters per minute or less, and a dressing comprising a cover layer. The dressing can have a wound contact surface that is covered with a silicone based adhesive.

[0010] Some embodiments disclosed herein relate to a canisterless pump for reduced pressure wound therapy, comprising a housing, a flow pathway through the pump, one or more valves in communication with the flow pathway, and a pump supported within or by the housing, wherein the pump is canisterless. Some embodiments disclosed herein relate to a canisterless pump assembly for reduced pressure wound therapy, comprising a housing and a pump supported within or by the housing. The pump can have a motor, an inlet and an outlet, a first valve supported by the pump and configured to control a flow of a fluid through the inlet, and a second valve supported by the pump and configured to control a flow of a fluid through the outlet. The pump or pump assembly can be canisterless. Further, though not required for all embodiments disclosed herein, and the first and second valves can each have a leakage rate of from approximately 0.1 mL/min to approximately 10 mL/min at nominal working pressures and/or during nominal sterilization pressures, or from 0.1 mL/min or less to 5 mL/min or more, or from 1 mL/min or less to 3 mL/min or more, or between any two values in any of the foregoing ranges at nominal working pressures. In some

embodiments, the leakage rate can be from approximately 0.4 mL/min to 0.7mL/min at nominal working pressures and/or during nominal sterilization pressures.

[0011] Some embodiments of the pump assembly can have a piezoelectric pump, such as without limitation the piezoelectric pump disclosed in US 7,550,034 and/or US 2011/186765. Some piezoelectric pumps can have orifices to perform the valve functions such that, when the pump is at rest, the flow rate through the pump can be as high as 200 mL/min. Therefore, in some embodiments, where the pump rate can be as high as approximately 300 mL/min or 320 mL/min or otherwise, the first and second valves (which can be orifices) can each have a leakage rate of up to approximately 200 mL/min.

[0012] Some embodiments disclosed herein relate to a sterile pump kit, comprising any of the pump embodiments disclosed herein, a dressing, a conduit coupleable with the dressing and the sterile pump and configured to provide a fluid pathway of reduced pressure to the dressing, one or more batteries, and a first packaging element and a second packaging element configured to be removably coupled with the first packaging element. In some embodiments, at least one of the first and second packaging elements can have recesses for receiving the sterile pump, a dressing, a conduit coupleable with the dressing and the sterile pump and configured to provide a fluid pathway of reduced pressure to the dressing. The sterile pump kit can be been sterilized after the pump, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

[0013] Some embodiments disclosed herein relate to a method for initiating treatment of a wound in an operating room, comprising applying a sterile dressing over a wound so as to create a substantially fluid tight seal over the wound, coupling a sterile pump to dressing via a sterile conduit, and reducing a level of pressure between the dressing and the wound in an operating room by activating the pump in the operating room.

[0014] Some embodiments disclosed herein relate to apparatuses and methods for controlling operation of a negative pressure wound therapy system. In particular, but without limitation, embodiments disclosed herein relate to negative pressure therapy apparatuses and dressings, and methods and algorithms for operating such negative pressure therapy systems. In some embodiments, though not required, an apparatus can comprise a dressing configured to be placed over a wound and to create a substantially fluid impermeable seal over the

wound. An apparatus can comprise a source of negative pressure configured to be coupled to the dressing. The apparatus can further comprise a controller configured to activate the source of negative pressure, monitor a duty cycle of the source of negative pressure, and determine if the duty cycle exceeds a duty cycle threshold. In some embodiments, the controller can be configured to monitor a plurality of duty cycles of the source of negative pressure over a plurality of consecutive and equal time durations, and determine if a duty cycle of the plurality of duty cycles exceeds a duty cycle threshold. The duty cycle can reflect an amount of time the source of negative pressure is active during a period of time or during a time duration of the plurality of consecutive and equal time durations

[0015] In some embodiments, the controller can be configured to determine if a number of duty cycles exceed the duty cycles threshold and if that number exceeds an overload threshold. In some embodiments, the controller can be configured to determine if a set of duty cycles from the plurality of duty cycles exceeds a duty cycle threshold and determine if the number of duty cycles in the set exceeds an overload threshold. The controller can be configured to determine if the number of duty cycles that exceeds the duty cycle threshold are consecutive. In some embodiments, the overload threshold can comprise 30 duty cycles, the period of time or time duration can comprise one minute, and/or the duty cycle threshold can comprise 9%. In some embodiments, the controller can be configured to continuously monitor the duty cycle or the plurality of duty cycles.

[0016] Some embodiments of the apparatus comprise a switch configured to pause the source of negative pressure for a period of time and the controller can be configured to restart the source of negative pressure upon expiration of the period of time. The period of time can be variable. In some embodiments, the apparatus can be enclosed in a housing comprising an exterior surface and the switch comprises a button located on the exterior surface of the housing.

[0017] Some embodiments of the apparatus comprise a controller configured to provide an indication of an operating condition. The operation condition can comprise determining that the duty cycle exceeds the duty cycle threshold and the indication can comprise deactivating the source of negative pressure to indicate a leak in the seal. In some embodiments, the operating condition comprises whether the source of negative pressure is paused and the controller can be configured to provide a first indication when the source of

negative pressure is active and a second indication when the source of negative pressure is paused, wherein the second indication is different from the first indication.

[0018] In some embodiments, the controller can be configured to activate the source of negative pressure to attempt to generate a desired negative pressure level under the dressing and if upon expiration of a first time interval, a pressure level under the dressing has not reached the desired negative pressure level, the controller can deactivate the source of negative pressure for a second time interval. Upon expiration of the second time interval, the controller can activate the source of negative pressure to attempt to generate the desired negative pressure level under the dressing. The controller can be configured to vary the second time interval based on a number of times the pressure level under the dressing has not reached the desired negative pressure level. For example, the controller can be configured to double the second time interval provided that a resulting value does not exceed a second interval threshold. The apparatus can comprise a sensor configured to sense pressure under the dressing and to communicate the sensed pressure to the controller.

[0019] In some embodiments, the controller can be configured to deactivate the source of negative pressure when the pressure level under the dressing has reached the desired negative pressure level and activate the source of negative pressure when the pressure level under the dressing rises above a negative pressure threshold, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold.

[0020] In some embodiments, the source of negative pressure can be operated by positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the source of negative pressure, monitoring a duty cycle of the source of negative pressure, and providing an indication if the duty cycle is determined to exceed a duty cycle threshold. The duty cycle can reflect an amount of time the source of negative pressure is active during a period of time, such as once per minute.

[0021] Some embodiments of the apparatus can be configured to monitor a total elapsed time since an initial activation and disable the activation of the source of negative pressure when the total elapsed time reaches a lifetime threshold. The life time threshold can comprise, for example, 7 days.

[0022] In some embodiments, the apparatus for applying negative pressure to a wound comprises a dressing configured to be placed over the wound and to create a substantially fluid impermeable seal over the wound, a source of negative pressure configured to be coupled to the dressing, and a controller configured to activate the source of negative pressure, monitor a duty cycle of the source of negative pressure, and provide an indication if the duty cycle exceeds a duty cycle threshold.

[0023] In some embodiments, the apparatus comprises a dressing configured to be placed over the wound and to create a substantially fluid impermeable seal over a wound, and a pump is configured to be coupled to the dressing, a switch configured to pause the pump for a period of time, and a controller configured to restart the pump upon expiration of the period of time. The period of time can be variable. Some embodiments of the apparatus comprise a miniature diaphragm pump operated by a motor or a miniature diaphragm pump operated by a piezoelectric transducer. In some embodiments, the pump can comprise a miniature piston pump and a miniature diaphragm pump.

[0024] Some embodiments disclose a method of operating a source of negative pressure (e.g., a negative pressure pump), the method comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the pump, pausing the pump for a period of time, and restarting the pump upon expiration of the period of time. The period of time can be variable.

[0025] In some embodiments, a negative pressure pump can be operated by positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, aspirating fluid from the wound using the negative pressure pump, measuring a level of activity of the pump, comparing the level of activity of the pump to a threshold, and providing an indication if the level of activity exceeds the threshold. Measuring the level of activity can comprise determining a duty cycle of the pump, determining a flow rate of the fluid aspirated from the wound (e.g., by using a flow meter), measuring a rate of change of pressure under the dressing using a pressure sensor, etc. or any combination thereof.

[0026] Some embodiments disclose a method for operating a negative pressure pump, comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the pump to draw pressure under the dressing toward a first negative pressure set point, activating the

pump to draw pressure under the dressing toward the first set point if the level of negative pressure under the dressing rises above a second negative pressure set point, monitoring an amount of time the pump has been operating, and providing an indication if the amount of time exceeds a predetermined amount of time. The method can further comprise determining the amount of time that the pump has been operating over a period of time and providing the indication if the amount of time exceeds 9% of the period of time. In some embodiments, providing the indication further comprises determining the amount of time that the pump has been operating over a period of time. In some embodiments, providing the indication further comprises activating an alarm.

[0027] In some embodiments, the apparatus can be configured to activate a source of negative pressure to draw a pressure under a negative pressure wound therapy dressing to a desired negative pressure value, such as a value between a first set point and a second set point or approximately equal to the second set point value. The level of pressure under the dressing can be measured. The apparatus can be configured to activate the source of negative pressure to draw the pressure under the dressing toward a second desired negative pressure level (e.g., the second set point value) if pressure under the dressing decays above a threshold (e.g., decays to the first set point value). The amount of time that the source of negative pressure has been operating, for example, continuously, can be monitored. The operation of the source of negative pressure can be paused or discontinued if the source of negative pressure has been operating for a predetermined amount of time without establishing approximately the second desired negative pressure level under the dressing (e.g., the second set point value).

[0028] Some embodiments disclose a method of operating a source of negative pressure, comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound and delivering negative pressure to the dressing from the source of negative pressure. Delivering negative pressure to the dressing from the source of negative pressure comprises activating the source of negative pressure to attempt to generate a desired negative pressure level under the dressing and updating a first count of activations; if upon expiration of a first time interval, negative pressure under the dressing has not reached the desired negative pressure level, deactivating the source of negative pressure for a second time interval, provided that the first count of activations is less than a first retry

threshold; if the first count of activations is not less than the first retry threshold, deactivating the source of negative pressure for a third time interval, resetting the first count of activations, and, upon expiration of the third time interval, activating the source of negative pressure to attempt to generate the desired negative pressure level under the dressing; activating the source of negative pressure upon expiration of the second time interval to attempt to generate the desired negative pressure level under the dressing and updating the first count of activations; deactivating the source of negative pressure when the negative pressure under the dressing has reached the desired negative pressure level, resetting the first count of activations, and monitoring negative pressure under the dressing; when negative pressure under the dressing rises above a negative pressure threshold, activating the source of negative pressure and updating a second count of activations, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold; if before expiration of a fourth time interval negative pressure under the dressing has reached the desired negative pressure level, deactivating the source of negative pressure, monitoring negative pressure under the dressing, and resetting the second count of activations; if upon expiration of the fourth time interval negative pressure under the dressing has not reached the desired negative pressure level, deactivating the source of negative pressure for the second time interval, provided that the second count of activations is less than a second retry threshold; if the second count of activations is not less that the second retry threshold, deactivating the source of negative pressure for the third time interval, resetting the second count of activations, and, upon expiration of the third time interval, activating the source of negative pressure to attempt to generate the desired negative pressure level under the dressing and updating the first count of activations; continuously monitoring a duty cycle of the source of negative pressure; tracking a number of duty cycles that exceed a duty cycle threshold; and deactivating the source of negative pressure for a duration of the third time interval when the number of duty cycles that exceed the duty cycle threshold exceeds an overload threshold.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Embodiments of the present invention will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0030] Figure 1 illustrates an embodiment of a reduced pressure wound therapy apparatus comprising a pump, a dressing, and a conduit.

[0031] Figures 2A-2F are various views of the embodiment of the pump illustrated in Figure 1.

[0032] Figure 3A illustrates an embodiment of a wound dressing kit comprising a dressing, a pump, a conduit, two batteries, and one or more sealing strips supported in a first packaging element.

[0033] Figure 3B is a bottom isometric view of the embodiment of the wound dressing kit of Figure 3A.

[0034] Figure 3C is an exploded view of the embodiment of the wound dressing kit of Figure 3A.

[0035] Figure 4A is a first exploded view of the embodiment of the pump of Figure 1.

[0036] Figure 4B is a second exploded view of the embodiment of the pump of Figure 1.

[0037] Figures 5A and 5B are first and second views of the first housing member.

[0038] Figures 6A and 6B are first and second views of the second housing member.

[0039] Figures 7A-7D illustrate the use of an embodiment of a TNP wound treatment system being used to treat a wound site on a patient.

[0040] Figures 8A – 20H are top isometric, bottom isometric, top plane, bottom plane, front, back, first side, and second side views, respectively, of embodiments of packaging elements that can be used with any of the embodiments of the wound dressing apparatuses disclosed herein, including a variety of differently sized wound dressing apparatuses.

[0041] Figure 21 illustrates a pump assembly according to some embodiments.

[0042] Figure 22 illustrates a cross-sectional view showing the interior of a pump assembly according to some embodiments.

[0043] Figure 23 illustrates a system schematic of a pump assembly according to some embodiments.

[0044] Figure 24 illustrates an electrical component schematic of a pump assembly according to some embodiments.

[0045] Figure 25 illustrates a top level state diagram of operation of a pump assembly according to some embodiments.

[0046] Figure 26 illustrates an operational state diagram of operation of a pump assembly according to some embodiments.

[0047] Figure 27 illustrates another state diagram of operation of a pump assembly according to some embodiments.

[0048] Figure 28 illustrates a graph depicting a duty cycle determination for a pump assembly according to some embodiments.

[0049] Figure 29 illustrates operation of a pump assembly in presence of a low leak according to some embodiments.

[0050] Figure 30 illustrates operation of a pump assembly in presence of a high leak according to some embodiments.

[0051] Figure 31 illustrates operation of a pump assembly in presence of a very high leak according to some embodiments.

[0052] Figure 32 illustrates operation of a pump assembly in presence of an extremely high leak according to some embodiments.

[0053] In the drawings like reference numerals refer to like parts.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0054] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with reduced pressure. As is used herein, reduced or negative pressure levels, such as –X mmHg, represent pressure levels that are below standard atmospheric pressure, which corresponds to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of –X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760–X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., –40 mmHg is less than –60 mmHg). Negative pressure that is "more" or "greater" than –X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., –80 mmHg is more than –60 mmHg).

[0055] Some of the embodiments comprise a pump and/or a pump and dressing kit. Some embodiments are directed to a pump and/or pump and dressing kit that have been sterilized before delivery to the hospital, operating room or theatre, or to the medical practitioner using such devices such that the sterile pump and/or a sterile pump/dressing kit can be applied immediately following the surgical or operating procedures. One advantage of this is that the surgeon can release the patient from the operating room knowing that the reduced pressure pump is operating and that the reduced pressure therapy has been started at the earliest point in time possible. A further advantage of applying the dressing kit immediately following the surgical or other procedure is that doing so can reduce the chance of infection by eliminating a subsequent dressing change that may otherwise be required in the ward. In other words, for those patients where a dressing (but not a pump) is applied in the operating theatre and then a problem is found thereafter, such as a leak or other issue with the dressing, if the dressing is required to be removed to be repositioned, replaced, or otherwise after the patient is released from the operating theater, the patient's wound may be exposed to infection risk when the dressing is repositioned, replaced, or otherwise outside of the operating theater. However, with the embodiments disclosed herein, if the pump is applied and tested while the patient is in the operating theater, any issues with the dressing that may require the dressing to be removed, repositioned, or otherwise, can be handled in the sterile operating room environment, thereby significantly reducing or eliminating the risk of exposure to pathogens, bacteria, or other contaminants. Further, it is generally not possible for a hospital to sterilize a traditional pump once it has been received by the hospital, and therefore the hospital may resort to bagging the pumps in sterile bags but risk compromising the operating room sterile field with this approach, particularly once the device is turned on and pathogens, bacteria, or other contaminants that may be inside the pump are release due to the operation of the pump.

[0056] In some embodiments, the pump can be configured to be amenable to gas sterilization, having features, components, and other characteristics that make the pump amenable to full sterilization gas exposure and penetration throughout the components of the pump. For example, without limitation, one or more pump valves have been selected or configured to permit a sufficient flow of sterilization gas therethrough such that the entire fluid pathway within the pump can be exposed to the sterilization gas. As will be explained

in greater detail below, in some embodiments, the pump can have other components, such as without limitation, strategically positioned one way flow valves, to complement the other valves within the pump, which can improve the efficiency of the pump by reducing leakage through the flow pathway within the pump assembly.

[0057] Additionally, where provided, the sterile pump/dressing kit can also be designed and configured to be amenable to gas sterilization. As described below, the sterile pump/dressing kit can be configured such that all of the components comprising the sterile pump/dressing kit, including the pump assembly, are packaged together in at least a first packaging element before sterilization, permitting all of the components to be sterilized together. Furthermore, as will be described, the components comprising the sterile pump/dressing kit can be arranged in the packaging such that at least some of the components can be removed in a predefined order, making it easier for the surgeon or medical practitioner to assemble and apply the dressing to the patient.

[0058] There are a number of benefits to being able to begin treatment of a wound in the operating theater, including without limitation providing a substantially sealed barrier over the wound while the wound is in a sterile condition and environment that will inhibit or prevent bacteria or other contaminants from getting into the wound. Additionally, initiating the reduced pressure treatment at the earliest stage possible is also advantageous to healing of the wound.

[0059] Additionally, embodiments disclosed or incorporated by reference herein, such as those disclosed in U.S. Patent Application No. 13/092,042, Great Britain Patent Application Nos. 1015656.0, 1006986.2, 1006983.9, 1006985.4, 1006988.8, and 1008347.5 comprise improved wound dressing components. All embodiments, components, features, and other details of such disclosures are hereby incorporated by reference herein as if made part of this disclosure, and can be used in place of or in combination with any of the components, features, and other details of the embodiments disclosed herein. For example, in some embodiments, the wound dressing can be configured to act as a buffer to help prevent compression or shear forces exerted on the wound dressing, for example due to patient movement, from harming a healing wound. Embodiments of the wound dressing may act as a waste canister to collect and store wound exudate removed from a wound site, and also relate to the management of solid build-up in a wound dressing covering a wound site

whilst TNP therapy is applied. Further, embodiments disclosed herein relate to a method and suction port for applying negative pressure to a wound dressing and a method of manufacturing a suction port and wound dressing.

[0060] Moreover, some embodiments disclosed herein are directed to systems that include negative pressure therapy apparatuses and dressings, and methods and algorithms for operating such negative pressure therapy apparatuses for use with negative pressure therapy dressings. In some embodiments, a negative pressure therapy apparatus comprises a pump assembly configured to, *inter alia*, provide negative pressure to a wound. Some embodiments of pump assemblies disclosed herein comprise novel and inventive control logic configured to control the operation of the pump assembly. For example, some embodiments comprise novel and inventive control logic configured to control the operation of a pump assembly in response to monitoring and detecting various operating conditions, such as presence and/or severity of a leak or leaks in the system, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from a wound, and the like. In some embodiments, the control logic can be configured to detect a leak or leaks in a system (e.g., leak or leaks in the dressing that is in fluid communication with the pump, leak or leaks in the seal created by the dressing over the wound, etc.) as well as to control the operation of the pump assembly when such leak or leaks are detected. In some embodiments, the pump assembly can be configured to distinguish between at least a normal or low leak (e.g., a leak that has a relatively low flow rate), a high leak (e.g., a leak that has a relatively high flow rate), and a very high leak (e.g., a leak that has a relatively very high flow rate). Some embodiments can further be configured to also distinguish between the aforementioned leaks and an extremely high leak.

[0061] In some embodiments, the pump assembly can comprise a source of negative pressure, such as a miniature, disposable pump, powered by a power source, such as a battery source. The pump assembly can be configured to provide therapy for a predetermined period of time, such as approximately 1 day, 2-10 days, etc. In some embodiments, the pump assembly can be required to provide uninterrupted therapy for such period of time. In some embodiments, the pump assembly can be configured to deactivate itself a predetermined period of time (e.g., 7 days) after an initial activation. The algorithms or logic disclosed herein can help the pump assembly operate more efficiently and conserve power, for example but without limitation, battery power.

[0062] In some embodiments, the pump assembly can be configured to monitor the duty cycle of the source of negative pressure (e.g., a pump). As is used herein, "duty cycle" reflects the amount of time the source of negative pressure is active or running over a period of time. In other words, the duty cycle reflects time that the source of negative pressure is in an active state as a fraction of total time under consideration. This can be represented mathematically as:

[0063] $DC = t / T,$ (1)

[0064] where DC is the duty cycle, t is the duration that the source of negative pressure is active, and T is the total time under consideration. Duty cycle can be measured as an absolute value (e.g., X seconds), a proportion (e.g., 1/X), a percentage (e.g., X%), etc. For example, if over a period of 1 minute the source of negative pressure has been on (or operating) for 6 seconds and off (or not operating) for 54 seconds, the duty cycle can be represented as 6 seconds, 1/10, 10%, etc.

[0065] In some embodiments, the pump assembly can include a controller configured to monitor the duty cycle of the source of negative pressure. Duty cycle measurements can reflect a level of activity of the source of negative pressure. For example, duty cycle can indicate that the source of negative pressure is operating normally, working hard, working extremely hard, etc. Moreover, duty cycle measurements, such as periodic duty cycle measurements, can reflect various operating conditions, such as presence and/or severity of leaks in the system, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from a wound, and the like. Based on the duty cycle measurements, such as by comparing the measured duty cycle with a set of thresholds (e.g., determined in calibration), the controller can execute and/or be programmed to execute algorithms or logic that control the operation of the system in accordance with various system requirements. For example, duty cycle measurements can indicate presence of a high leak in the system, and the controller can be programmed to indicate this condition to a user (e.g., patient, caregiver, physician, etc.) and/or temporarily suspend or pause operation of the source of negative pressure in order to conserve power.

[0066] In some embodiments, the system can be configured to monitor the rate of flow by any other suitable means. The pump assembly can be configured to use flow meters (e.g., mechanical, pressure-based, optical, mass, thermal mass, electromagnetic, sonic,

ultrasonic, laser Doppler, etc.), anemometers, pressure transducers or sensors, electromagnetic sensors (e.g., sensors configured to measure pump speed, such as Hall sensors), electromagnetic measurements (e.g., measuring the current and/or power draw of the pump, measuring current and/or power drain of the power source, measuring the remaining capacity of the power source, etc.) or any combination thereof. Based on the monitored rate of flow, such as by comparing the rate of flow with a set of thresholds (e.g., determined in calibration), the controller can execute and/or be programmed to execute algorithms or logic that control the operation of the system in accordance with various system requirements. For example, the controller can be configured to obtain periodic measurements from a pressure sensor or obtain periodic feedback from a pump motor. The pressure sensor can measure pressure under the dressing. The controller can determine the rate of flow, for example, by determining a pressure gradient, rate of change of pressure, and/or pressure decay rate. For instance, a positive pressure gradient (e.g., one that is increasing) can reflect an increasing rate of flow as (e.g., a leak) in relation to a threshold, and the controller can be programmed to indicate this condition to the user.

[0067] In some embodiments, the system can be provided for treatment of a wound. The dressing can create a substantially sealed or closed space around the wound (e.g., under the dressing), and the pump assembly can have a sensor which can periodically or continuously measure or monitor a level of pressure in this space. The pump assembly or a controller thereof can be configured to control the level of pressure in the space (e.g., under the dressing) between a first negative pressure set point limit and at least a second negative pressure set point limit. In some embodiments, the first set point limit can be approximately –70 mmHg, or from approximately –60 mmHg or less to approximately –80 mmHg or more. In some embodiments, the second set point limit can be approximately –90 mmHg, or from approximately –80 mmHg or less to approximately –100 mmHg or more.

[0068] In some embodiments, the system can be configured to include "retry" functionality and/or logic. The pump assembly can be configured to monitor a level of negative pressure under the dressing (which can correspond to the level of negative pressure in the wound cavity), compare the monitored level to a desired negative pressure level (e.g., first set point, second set point, etc.), and suspend or pause therapy if the desired negative pressure level is not reached during a certain time interval. Following the suspension or

pause of therapy, the pump assembly can be configured to restart therapy (e.g., restart the source of negative pressure) and attempt to again generate the desired negative pressure level under the dressing. Retry functionality can, for instance, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.). In some embodiments, a controller can execute and/or be programmed to execute retry functionality and/or logic.

[0069] In some embodiments, the system can be configured to provide "play/pause" functionality and/or logic via a switch, button, etc. located on the exterior of the pump assembly's housing or any other suitable place where it can be accessed by the user. Play/pause functionality can allow the user to suspend and/or restart therapy (e.g., pause and/or restart the pump). The pump assembly can be configured to automatically restart therapy following a certain predetermined or variable pause interval. The pump assembly can be configured to automatically restart therapy upon expiration of such interval and/or indicate to the user expiration of such interval.

[0070] In some embodiments, the system can be configured to provide indication, alarms, etc. to the user reflecting operating conditions. The system can include visual, audible, tactile, and other types of indicators and/or alarms configured to signal to the user various operating conditions. Such conditions include system on/off, standby, pause, normal operation, dressing problem, leak, error, and the like. The indicators and/or alarms can include speakers, displays, light sources, etc., and/or combinations thereof. For example, indication can be provided by activating or deactivating the source of negative pressure, reducing negative pressure level generated by the source of negative, lowering the amount of power used by the source of negative pressure, etc. or any combination thereof.

[0071] Figure 1 illustrates an embodiment of a reduced pressure wound treatment apparatus 100 comprising a wound dressing 102 in combination with a pump assembly 104. In any of the apparatus embodiments disclosed herein, as in the embodiment illustrated in Figure 1, the pump assembly can be a canisterless pump assembly (meaning that the pump assembly does not have an exudate or liquid collection canister). However, any of the pump embodiments disclosed herein can be configured to include or support a canister. Additionally, in any of the apparatus embodiments disclosed herein, any of the pump

assembly embodiments can be mounted to or supported by the dressing, or adjacent to the dressing. The dressing 102 may be placed over a wound (not illustrated) as described in greater detail in U.S. Patent Application No. 13/092,042, which disclosure is hereby incorporated by reference and made part of this disclosure, and a conduit 106 may then be connected to the dressing 102. Dressing 102 or any other dressing disclosed herein can have any of the materials, sizes, components, or other details of any of the dressing embodiments disclosed in U.S. Patent Application No. 13/092,042, and such embodiments and illustrations thereof are hereby incorporated by reference in their entireties as if made part of this disclosure. The conduit 106 or any other conduit disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

[0072] Some embodiments of the dressing 102 can have a port 108 configured to receive an end of the conduit 106 (e.g., the first end 106a of the conduit 106), though such port 108 is not required. In some embodiments, the conduit can otherwise pass through and/or under the dressing 108 to supply a source of reduced pressure to a space between the dressing 102 and the wound so as to maintain a desired level of reduced pressure in such space. Some embodiments of the apparatus 100 con be configured such that the first end 106a of the conduit 106 is preattached to the port 108. The conduit 106 can be any suitable article configured to provide at least a substantially sealed fluid flow pathway between the pump assembly 104 and the dressing 102, so as to supply the reduced pressure provided by the pump assembly 104 to the dressing 102.

[0073] The dressing 102 can be provided as a single article with all wound dressing elements (including the port 108) pre-attached and integrated into a single unit. The wound dressing 102 may then be connected, via the conduit 106, to a source of negative pressure such as the pump assembly 104. In some embodiments, though not required, the pump assembly 104 can be miniaturized and portable, although larger conventional pumps such as the EZ CARE (TM) pump can also be used with the dressing 102.

[0074] It will be understood that embodiments of the present invention are generally applicable to use in topical negative pressure ("TNP") therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema, encouraging blood flow and granular tissue formation, and/or removing excess exudate and can reduce bacterial load (and thus infection

risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems can also assist in the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

[0075] The wound dressing 102 can be located over a wound site to be treated. The dressing 102 can form a substantially sealed cavity or enclosure over the wound site. It will be appreciated that throughout this specification reference is made to a wound. In this sense it is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other surficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like. In some embodiments, the components of the TNP system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

[0076] Some embodiments of the apparatus are designed to operate without the use of an exudate canister. The dressing 102 can be configured to have a film having a high water vapour permeability to enable the evaporation of surplus fluid, and can have a superabsorbing material contained therein to safely absorb wound exudate. Some embodiments of the apparatus are designed for single-use therapy and can be disposed of in an environmentally friendly manner after an approximately maximum usage of from seven to eleven days. The pump can be programmed to automatically terminate therapy after a desired number of days, e.g., after seven days, further operation of the pump will not be possible. Some embodiments are designed for longer or repeated usage, and can be configured to support an exudate canister.

[0077] The apparatus 100 can be manufactured in a wide variety of different models or versions, wherein the size of the dressing 100 can be varied to accommodate a wide range of wound sizes. For example, apparatuses 100 can be made having the following sizes of dressings 102 and wound pads (i.e., absorbent elements, not illustrated in Figure 1).

Approximate Dressing Size	Approximate Wound Pad Size
10 cm x 30 cm (4 in x 11.75 in)	5 cm x 20 cm (2 in x 8 in)
15 cm x 15 cm (6 in x 6 in)	10 cm x 10 cm (4 in x 4 in)
15 cm x 20 cm (6 in x 8 in)	10 cm x 15 cm (4 in x 6 in)
10 cm x 20 cm (4 in x 8 in)	5 cm x 10 cm (2 in x 4 in)
20 cm x 20 cm (8 in x 8 in)	15 cm x 15 cm (6 in x 6 in)

[0078] Some embodiments of the overlay or dressing can be substantially impervious to air flow and the flow of bacteria or other contaminants through the overlay layer, while being pervious to vapor transmission.

[0079] In some embodiments, it may be preferable for the wound site to be filled partially or completely with a wound packing material. This wound packing material is optional, but may be desirable in certain wounds, for example deeper wounds. The wound packing material can be used in addition to the wound dressing 102. The wound packing material generally can comprise a porous and conformable material, for example foam (including reticulated foams), and gauze. Preferably, the wound packing material is sized or shaped to fit within the wound site so as to fill any empty spaces. The wound dressing 102 can then be placed over the wound site and wound packing material overlying the wound site. When a wound packing material is used, once the wound dressing 102 is sealed over the wound site, TNP is transmitted from a pump through the wound dressing 102, through the wound packing material, and to the wound site. This negative pressure draws wound exudate and other fluids or secretions away from the wound site.

[0080] In some embodiments, the tubing 106 can have a connector 112 positioned at a second end 106b of the tubing 106. The connector 112 can be configured to couple with a short length of conduit 114 projecting from the pump assembly 104, with a mating connector 114a in communication with the short length of conduit 114, with a connector

supported by the pump housing (as described in greater detail below), or otherwise. The length of the tubing 114 in some embodiments can be approximately 14 mm (.55 in), or from approximately .5 in to approximately 5 inches. The short length of conduit or tubing 114 can decrease the discomfort to a patient while laying or otherwise resting on the pump and connector 112. Configuring the pump assembly 104 and tubing 106 so that the tubing 106 can be quickly and easily removed from the pump assembly 104 can facilitate or improve the process of dressing or pump changes, if necessary. Any of the pump embodiments disclosed herein can be configured to have any of the connection configurations disclosed herein between the tubing and the pump.

[0081] In some embodiments, as in the illustrated embodiment, the pump assembly 104 can be of a sufficiently small and portable size to be supported on a user's body or in a user's clothing. For example, the pump assembly 104 can be sized to be attached using adhesive medical tape or otherwise to a person's skin in a comfortable location, adjacent to or on the dressing 102 or otherwise. Further, the pump assembly 104 can be sized to fit within a person's pants or shirt pocket, or can be tethered to a person's body using a lanyard, pouch, or other suitable device or article.

[0082] In some embodiments, the pump assembly 104 can be powered by one or more batteries (for example, two batteries) and can weigh approximately 84 grams, or less than 90 grams, including the weight of the batteries. In some embodiments, the pump assembly 104 can have any desired number of batteries and can weigh from approximately 80 grams to approximately 90 grams, or from approximately 75 grams to approximately 100 grams, or between any values within the foregoing ranges. For example, the weight and/or size of the pump assembly 104 could be reduced by reducing the battery size and/or weight (to, for example, AAA sized batteries, or smaller) or the pump size and/or weight.

[0083] Further, some embodiments of the pump assembly 104 can be sized to have a total volume defined by an outside surface of the pump of approximately 92.5 cubic centimeters (approximately 5.6 cubic inches), or 92.5 cubic centimeters (5.6 cubic inches) or less, or between 75 cubic centimeters or less and 115 cubic centimeters or more, or between 85 cubic centimeters and 100 cubic centimeters. Additionally, the pump assembly 104 can be further miniaturized using techniques known to one of ordinary skill in the art to sizes in the range of approximately 40 cubic centimeters, or 40 cubic centimeters or less, or between 30

cubic centimeters or less and 60 cubic centimeters or more. Some embodiments of the pump assembly 104 can be sized to have a total volume of between 2 cubic inches or less and 6.5 cubic inches or more, or from approximately 4 cubic inches to approximately 6 cubic inches, or between any values within the foregoing ranges.

[0084] The pump assembly 104 can have an overall outside size that is approximately 7.2 cm x approximately 6.4 cm x approximately 2.1 cm (or 7.2 cm x 6.4 cm x 2.1 cm), or a maximum of approximately 8.5 cm x approximately 8.5 cm x approximately 3 cm. Additionally, the pump assembly 104 can have an overall outside size that is approximately 5.5 cm x approximately 4.8 cm x approximately 1.5 cm (or 5.5 cm x 4.8 cm x 1.5 cm). As mentioned, the size and weight of the pump assembly 104 can be optimized, as it is in the embodiments disclosed herein, to make it more comfortable to wear or carry by the user, thereby affording increased mobility.

[0085] The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively a pressure range of over approximately -100 mmHg, or even 150 mmHg, can be supplied by the apparatus 100. Other details regarding the operation of the pump assembly 104 are set forth in U.S. Patent Application No. 13/092,042, and such embodiments, configurations, details, and illustrations thereof are hereby incorporated by reference in their entireties as if made part of this disclosure.

[0086] Figures 2A-2F are various views of the embodiment of the pump assembly 104 illustrated in Figure 1. Figure 3A illustrates an embodiment of a wound dressing kit 100 comprising a dressing 102 (which can be any of the dressing embodiments disclosed or incorporated by reference herein), a pump assembly 104, a conduit 140, one or more batteries 142 (two being shown), and one or more sealing strips 148 supported in a first packaging element 150. Figure 3B is a bottom isometric view of the embodiment of the wound dressing

kit 100 of Figure 3A. Figure 3C is an exploded view of the embodiment of the wound dressing kit 100 of Figure 3A.

[0087] With reference to Figures 2A-3C, the pump assembly 104 can have a housing 120 comprising a first housing member 120a and a second housing member 120b, a control button 122 (which can also be a switch or other similar component), a battery cover 124, a connector 128, and one or more lights, which can be LED lights. In some embodiments, the pump assembly 104 can have more than one button 122, and can have three or more lights 132. The lights 132 can be configured to alert a user to a variety of operating and/or failure conditions of the pump assembly 104, including alerting the user to normal or proper operating conditions, pump failure, power supplied to the pump or power failure, the condition or voltage level of the batteries, detection of a leak within the dressing or flow pathway, suction blockage, or any other similar or suitable conditions or combinations thereof.

[0088] The housing 120 can be configured such that a sterilization gas, such as ethylene dioxide, can penetrate into the housing such that the internal components of the pump assembly 104 are exposed to the sterilization gas during normal sterilization processes. Typically, the pump will be exposed to the sterilization gas in a chamber that has been substantially evacuated of air or any other gas, so that the sterilization gas is drawn into the pump housing 120 and into the other spaces and chambers within the pump assembly 104. For example, some embodiments of the pump housing 120 can have an unsealed gap surrounding the connector 128 through which the sterilization gas can pass. Also, in some embodiments, the first housing member 120a can be joined to the second housing member 120b without the use of a seal therebetween.

[0089] For the sterilization process, in some embodiments, the components to be sterilized can be subjected to the following steps, inter alia, in any order. The components can be placed in a chamber or container that is evacuated to approximately 70 mBarA (or between 67 mBar A and 80 mBarA) for between approximately 15 minutes and 1 hour and 15 minutes. The components can also be subjected to inert dilution, steam pressure or conditioning, or nitrogen cycles, which can be followed by further evacuation cycles. Ethylene oxide or any other suitable sterilization gas can be introduced into the chamber or container at a pressure set point of approximately 482 mBarA (or from approximately 467

mBarA to approximately 500 mBarA). The components can be exposed to the sterilization gas at a temperature of approximately 46 degrees Celsius (or from approximately 42 degrees Celsius to 49 degrees Celsius), or up to 60 degrees Celsius. The components can be exposed to the sterilization gas for approximately 10 minutes (short cycle) or approximately 1 hour (long cycle), or from approximately 9 minutes to approximately 11 minutes (short cycle), or from approximately 59 minutes to approximately 1 hour (long cycle), or longer. The components or chamber can be flushed with nitrogen and/or air and/or degassed thereafter.

[0090] The pump assembly 104 can be powered by one or more batteries 142. The batteries 142 can be lithium chloride or any other suitable batteries that are suitable for exposure to ethylene dioxide and/or other sterilization gases. The batteries 142 can be supported outside of the pump housing 120 so as to minimize or eliminate the chance of an electrical spark which could cause an explosion in the presence of the sterilization gas or an explosive gas during the sterilization process when supported in the packaging element or elements. Additionally, where there are a plurality of batteries 142, the batteries can be spaced apart or otherwise separated in the packaging to prevent any power loss or sparking of the batteries during the sterilization process or otherwise before usage.

[0091] With reference to Figure 3A, the batteries 142 and the sealing strip or strips 148 can be positioned beneath the dressing 102 so that the dressing 102 must be removed from the first packaging element 150 before the batteries 142 are removed, thereby suggesting an order by which the components of dressing kit 100 are removed from the packaging 150 and/or applied to the patient or assembled to the other components comprising the apparatus 100.

[0092] In some embodiments, the conduit 140 can be positioned within the packaging 150 so that both ends of the conduit 140 are free or otherwise disconnected from the other components of the apparatus 100 to improve the exposure of the internal surfaces of the conduit 140 to and/or to ensure complete exposure of the tubing to the sterilization gas. The ends of the conduit 140 can be supported within recesses formed in the first packaging element 150.

[0093] The first packaging element 150 can have one or more recesses configured to receive and support the components of the apparatus 100, including a recess 190 for receiving the pump assembly 104, a recess 192 for receiving the dressing 102, a recess 194

for receiving the one or more sealing strips 148 and/or the conduit 140, a recess 196 for receiving the conduit 114 and/or connector 114a, if present, and spaced apart recesses 200a and 200b for the batteries 142. Spacing apart the batteries can reduce or eliminate the risk of explosion during sterilization procedures due to the potentially flammable nature of ethylene oxide.

[0094] In some embodiments, the first packaging element 150 can be made from a material or combination of materials that is sufficiently rigid and/or robust to hold the batteries, pump and/or other components in place during processing or transportation of the dressing kit. For example, some embodiments of the first packaging element 150 can be configured to provide a compression or interference fit for the components, such as the batteries, the pump, or other components, sufficient to withstand accelerations of between approximately 15G and approximately 25G, or between 1G and 40G, or between 1G and 20G, or between 25G and 40G. Some embodiments of the first packaging element 150 can be configured to tightly hold the pump, batteries, tubing (with tubing pinches or recesses) and other components sufficient to prevent movement or dislodgement of components which could lead to short circuit or melting/abrasion of the packaging, resulting in damage to the packaging or bacterial ingress while not impeding the ability of the user to remove such components from the packaging when needed.

[0095] Additionally, as illustrated, the first packaging element 150 can have grooves or recesses 193 sized and configured to facilitate the surgeon's or user's access and removal of the various components of the apparatus 100, both with and without a gloved hand. Further, bosses or projections 195 can be formed in the first packaging element 150 to provide additional support and protection to the packaging and kit components. The first packaging element 150 can be made from any suitable material that can be sterilized, including a recyclable virgin PETG Blue tinted 0.80 Eastman 6763 medical grade provided by Nelipak Custom Thermoformed Products. The packaging element 150 can be extruded and thermoformed from EASTAR (TM) Chemical Product EASTAR copolyester resin. For example, the raw material, which can be an extruded sheet or film, can be thermoformed using a vacuum and press over a dye tool under elevated temperatures. Other suitable materials for the first packaging element 150 include polycarbonate, PVC, or any other suitable resin or plastic material. In some embodiments, the first packaging element can be

made from a material (including a plate, sheet, film, or otherwise) having a thickness of 0.8 mm (or approximately 0.8), or a thickness of 0.8 mm or less, or 1.0 mm or less, or between approximately 0.7 mm and 1.2 mm.

[0096] A gas permeable cover 151 (also referred to herein as a second packaging element) can be sealingly positioned over the first packaging element 150 to provide a bacteria and contaminant barrier to the contents of the dressing kit 100. For example, a sheet-like layer or film of TYVEK (TM), paper, or any other suitable material can be sealed to a rim portion 153 of the first packaging element 150. The cover 151 can be made from any suitable material, including TYVEK, which is permeable to the sterilization gas but provides a barrier to bacteria and other contamination. The cover 151 can be opaque, clear, or translucent.

[0097] The cover 151 can be sealingly coupled with the first packaging element 150 after all of the dressing kit components assembled therein. Thereafter, the first packaging element 150, cover 151, and the dressing kit components can be positioned within a sealed, impermeable bag having a TYVEK or other sterilization gas permeable patch of material over an opening formed in the bag to permit the sterilization gas to enter the bag and sterilize the components of the dressing kit.

[0098] Figures 4A and 4B are first and second exploded views of the embodiment of the pump assembly 104 of Figure 1, showing the first housing member 120a separated from the second housing member 120b. Figures 5A and 5B are first and second views of the first housing member 120a. Figures 6A and 6B are first and second views of the second housing member 120b. With reference to Figures 4A-6B, some embodiments of the pump assembly 104 can have a battery compartment 220 supported or formed within the housing 120. One or more battery contacts 222 can be supported within the battery compartment 220. One or more electrical wires 224 can connect the battery contacts 222 to a pump 232 and/or a control board 230. The pump assembly 104 can be assembled in a clean room to reduce the risk of contamination or bioburden that the pump is exposed to or can collect during assembly.

[0099] In some embodiments, the pump 232 can comprise a motor, an inlet port or connector 250, and an outlet port 252. The pump 232 can have one or more valves therein. For example, a first valve can be positioned within the pump 232 adjacent the inlet

port 250. Additionally, a second valve can be positioned within the pump 232 adjacent the outlet port 252. The pump 232 can define a flow pathway through the inlet port 250, through the first and second valves, and out the outlet port 252.

[0100] In some embodiments, the battery contacts 222 can also be configured to have polarity protection. For example, similar to the one or more protrusions 124d adjacent to the battery contact 125, the one or more of the battery contacts 222 can have plastic or other protrusions (not illustrated) adjacent to the contacts to inhibit the contact between the battery contact 222 and the incorrect side of a battery that is inserted into the battery compartment in the incorrect orientation. For example, the one or more protrusions can be sized and configured to prevent the negative side of a standard cylindrical battery from contacting the battery contact 222 adjacent to the one or more protrusions, while permitting a positive side of such battery to contact the battery contact 222. Generally, with this configuration, the battery can generally only make contact with the contact 222 if the battery is inserted in the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104. The protrusions will preferably be made from a non-conductive material. Alternatively or additionally, the control board 230 can be configured to have polarity protective features or components. Additionally, the control board 230 can have one or more fuses to protect against overpower conditions or surge power conditions.

[0101] The pump assembly 104 can have a flow manifold 240 and a one-way flow valve 246 in communication with a fluid flow pathway within the pump assembly 104. The one-way flow valve 246 (also referred to as a check valve) can be a diaphragm valve made from silicone or any other suitable elastomeric or soft material, including without limitation, polyurethane, viton, nitrile rubber, neoprene, Teflon, and other suitable materials. Other suitable valves for the one-way flow valve are, for example and without limitation, umbrella valves, ball valves, reed valves, duckbill valves. In some embodiments, the leakage rate of the one-way flow valve 246 can be approximately 0.05 mL/minute. In some embodiments, the one-way flow valve 246 can be positioned within the pump 232 or in place of one of the valves positioned within the pump 232.

[0102] The manifold 240 and/or the one-way flow valve 246 can be in communication with the connector 128. In some embodiments, the one-way flow valve 246

can be supported within the manifold 240, and the manifold 240 can be substantially sealingly coupled with the inlet port or connector 250 on the pump 232 or otherwise supported within the housing 120 so as to be in fluid communication with the inlet port or connector 250. For example, with reference to Figures 4A and 4B, the manifold 240 can be assembled with the pump 232 such that the inlet connector 250 is received within the opening 261 formed in the manifold 240. Air and or other gas can exit the pump 232 through outlet port or connector 252. During sterilization, the pump 232 can be configured such that the sterilization gas can penetrate into the internal spaces or chambers of the pump 232, to ensure that the entire pump 232 (both internally and externally) have been sterilized. One or more valves (which can be umbrella valves or any other suitable valve) can be positioned in the pump 232. For example, without limitation, one or more valves can be supported in the pump 232, one being positioned adjacent to each of the inlet port 250 and the outlet port 252.

[0103] For optimal sterilization, in some embodiments, the sterilization gas can be introduced slowly to optimize the flow of the sterilization gas through the valves and to prevent the pressure from the sterilization gas from completely closing the valves. As mentioned, the valves (such as the first and second valves) can be configured to be somewhat leaky, thereby permitting the flow of sterilization gas to advance past the valves to sterilize the internal components of the pump 232. For example, the valves can permit a leakage flow rate of fluid therethrough (i.e., flow rate through the valve when the valve is in a closed position) at a rate of between 0.1 mL/min and 10 mL/min or more at nominal or typical working pressures (i.e., at nominal working pressures of the fluid in the conduit) or at nominal or typical sterilization pressures. In some configurations, the portion of the flow pathway between the two valves, or between the valves and the one-way valve, can be the most challenging portion of the flow path or pump assembly 104 to sterilize.

[0104] Some embodiments of the pump assembly can have a piezoelectric pump. Some piezoelectric pumps or other pumps disclosed herein can have or can be configured to have orifices to perform the valve functions such that, when the pump is at rest, the flow rate through the pump can be as high as 200 mL/min. Therefore, in some embodiments, where the pump rate can be as high as approximately 300 mL/min or 320 mL/min or otherwise, the first and second valves (which can be orifices) can each have a leakage rate of up to approximately 200 mL/min.

[0105] The pump 232 can be of any suitable type such as, without limitation, a rotary diaphragm pump or other diaphragm pump, a piezoelectric pump, a peristaltic pump, a piston pump, a rotary vane pump, a liquid ring pump, a scroll pump, a diaphragm pump operated by a piezoelectric transducer, or any other suitable pump or micropump or any combinations of the foregoing. The pump 232 can be, for example, a standard off-the-shelf vacuum pump such as the Koge Electronics KPV8A-3A pump. The pump 232 can also be a KNF diaphragm pump or any suitable KNF pump.

[0106] Some embodiments of the pump can be as light as approximately 10 grams, or between approximately 6 grams and 15 grams, or between any values within the foregoing range. The pump 232 can have a pump capacity of approximately 500 mL per minute, or between approximately 300 mL per minute or less and approximately 600 mL per minute or more, or between approximately 400 mL per minute and approximately 500 mL per minute, or between any values within the foregoing ranges. In some embodiments, the pump assembly 104 could comprise two or more pumps 232. For example, the pump assembly 104 could have a first pump having a high flow rate, configured to provide a rapid drawdown of the space between the wound overlay and the wound, and a second, smaller capacity pump configured to maintain the level of reduced pressure of the space between the wound overlay and the wound after the initial draw down. In some embodiments, the pump flow rate can be approximately 20 times the leak alarm flow rate, which can be set at approximately 15 milliliters per minute.

[0107] As mentioned, the connector 128 can be a threaded connector (as illustrated) that can threadingly receive a mating threaded connector coupled with the end of the tubing 106. The threaded connector 128 can be of a non-standard size as compared to other medical connectors, to prevent a medical practitioner from inadvertently attaching a standard luer connector (such as a connector from an intravenous line) thereto.

[0108] Alternatively, not illustrated, the connector 128 can be a standard tubing connector (such as a nipple connector) configured to sealingly receive the tubing thereover such that a separate mating connector on the end of the tubing 106 can be omitted.

[0109] The manifold 240 can have a separate port 260 which can be configured to receive a conduit or connector 262 of a pressure monitor. The pressure monitor can be supported by the control board 230 and can be configured to monitor a level of pressure in

the fluid flow passageway. The pressure monitor can be configured to protect the motor 232 from exceeding a predefined threshold pressure. In some embodiments, the pressure monitor can be calibrated to not exceed 175 +/- 50 mmHg. In some embodiments, the pressure monitor can be calibrated to not exceed 235 mmHg. The pressure monitor can be configured to cut power to the motor if the pressure reading reaches a predetermined value, and be configured to resume when the pressure level drops below the predetermined value or a second predetermined value that can be higher or lower than the first predetermined value. Additionally, the pump assembly 104 can be programmed to prevent such over-pressurization. The pump assembly 104 can be configured such that the software provides the primary mechanism for preventing over-pressurization, and the pressure monitor can provide backup over-pressurization protection.

[0110] The pump 232 can have a layer of open foam or other material wrapped at least partially around an outside surface of the pump 232 to reduce the noise and vibration produced by the pump 232. All of these components can be supported within the first and second pump housing members 120a, 120b, which can be secured together with any suitable fasteners 270 (for example, a pair of screws). One or more labels 270 can be affixed to an outside surface of the housing 120. Additionally, in some embodiments, the pump 232 can have one or more weights, cushions, foam (such as a viscoelastic foam), plastic (such as ABS, polyurethane, urethane, or otherwise), or other pads, panels, sheets, or segments supported by the pump 232 or positioned adjacent to one or more outside surfaces of the pump. Some embodiments can have mass based or compliant damping materials. Such components or materials (not illustrated) can damp vibration and/or attenuate noise produced by the pump.

[0111] For example, one or more weights (made from steel, metal, or any other suitable material) can be supported or attached to an outside surface of the pump 232 or any other pump embodiment disclosed herein. The steel weights can weigh approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams. Two or more weights can be supported or attached to an outside surface of the pump 232 or any other pump embodiment disclosed herein. Two steel weights each weighing approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams, can be attached to an outside surface of the

pump 232. Each of the two plates can be positioned on opposite sides of the motor 232, or otherwise. In some embodiments, four steel weights each weighing approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams, can be attached to an outside surface of the pump 232. The plates can be arranged such that two plates are positioned on each of two opposite sides of the motor 232, or otherwise. In some embodiments, weights can be positioned adjacent to three or more sides of the pump 232 including, for example and without limitation, the sides and top surfaces of the pump 232.

[0112] With reference to Figure 4A, the battery cover 124 can have a latch or tab member 124a that can be configured to engage with mating feature on the housing 120 to inhibit the battery cover 124 from becoming inadvertently opened when in the closed position. Additionally, guides or protrusions 124b can be formed on the battery cover 124 to facilitate the ease with which the battery cover 124 can be opened and closed. The guides 124b can engage mating guides or channels 120c formed in the housing 120. The battery cover 124 can be configured to have a gripping surface, for single finger use. For example, without limitation, a plurality of depressions 124c can be formed on a surface of the battery cover 124 to enhance the grip between a user's finger or other object and the batter cover 124, to facilitate the opening and closing of the battery cover 124.

[0113] With reference to Figure 4B, the battery cover 124 can support one or more battery contacts or terminals 125 thereon, configured to provide a connection between the two batteries. The battery cover 124 can further support one or more protrusions 124d adjacent to the battery contact 125. The one or more protrusions 124d can be sized and configured to prevent the negative side of a standard cylindrical battery from contacting the battery contact 125 adjacent to the one or more protrusions 124d, while permitting a positive side of such battery to contact the battery contact 125. With this configuration, the battery can generally only make contact with the contact 125 if the battery is inserted in the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104.

[0114] With reference to Figures 4A and 4B, the housing 120 can have one or more tabs 121 and depressions or channels 123 configured to receive the tabs 121 to improve the connection between the two members 120a, 120b of the housing. The tabs 121 and

depressions 123 can hold the edges of the housing 120 together better to improve the strength of the housing 120 and to make the connection tighter between the two members 120a, 120b of the housing. The control board 230 can be assembled to the housing 12 with similar features.

[0115] As described in U.S. Patent Application No. 13/092,042, which disclosure is hereby incorporated by reference as if fully set forth herein, a lower surface of any of the wound dressing 102 embodiments disclosed herein can have an optional wound contact layer. Any of the dressing embodiments disclosed herein can be made without the wound contact layer. The wound contact layer can be a polyurethane layer or polyethylene layer or other flexible layer which can be made porous or perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The perforations can enable fluid and/or gas to flow through the layer. The wound contact layer can help prevent tissue ingrowth into the other material of the wound dressing.

[0116] The perforations can be sized small enough to meet this requirement but still allow fluid through. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. The wound contact layer helps hold the whole wound dressing together and helps to create an air tight seal around the absorbent pad in order to maintain negative pressure at the wound. The wound contact layer also acts as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower pressure sensitive adhesive can be provided on the underside surface 101 of the wound dressing whilst an upper pressure sensitive adhesive layer can be provided on the upper surface 103 of the wound contact layer. The pressure sensitive adhesive, which can be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, can be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized this helps adhere the wound dressing to the skin around a wound site.

[0117] As mentioned, any dressing embodiments for use in the dressing kits disclosed or incorporated by reference herein can have an adhesive covered bottom (e.g., wound contacting) surface. In some embodiments, as mentioned, the adhesive can be a

silicone adhesive including, for example, polysiloxanes or polyorganosiloxanes or other polymeric pressure sensitive silicone adhesives. For example, polydimethylsiloxane or the like can be used. The adhesive formulation may be a mixture of alkyl pendant siloxanes, which can be spread and cast as a two part mix with a catalyst such that a final polymerisation step takes place following casting or spreading. In some embodiments, a dressing layer can have a non-perforated silicone adhesive coating (coat weight 130 gsm nominal) and full spread acrylic adhesive (27 to 37 gsm) coated onto opposite sides of an extruded EU30 polyurethane clear film (27 to 37 gsm). Moisture vapour permeability of some embodiments of such an arrangement can be between approximately 367 gm^{-2}/24hrs to approximately 405 gm^{-2}/24hrs, or a mean moisture vapour permeability of 382 gm^{-2}/24hrs.

[0118] Some embodiments or arrangements of a silicone adhesive layer suitable for dressing embodiments disclosed herein can have a moisture vapour transmission rate between approximately 350 gm^{-2}/24hrs and approximately 410 gm^{-2}/24hrs. Aptly, the average moisture vapour permeability of some embodiments or arrangements of a silicone adhesive layer suitable for dressing embodiments disclosed herein can be approximately 380 gm^{-2}/24hrs. Some of the dressing embodiments disclosed herein can have a Wacker silres PSA 45 pressure sensitive adhesive coated thereon.

[0119] Additionally, any of the dressing embodiments disclosed herein can have an anti-microbial agent or substance incorporated into the dressing or coated on one or more surfaces of the dressing. For example, without limitation, a wound contact layer of any dressing embodiments disclosed herein can have nanocrystalline silver agents, silver salts, copper salts, or gold salts such as, without limitation, those disclosed in U.S. Patent Application No. 11/922,894 (titled ANTIMICROBIAL BIGUANIDE METAL COMPLEXES), filed May 21, 2008, which application is incorporated by reference herein as if made part of this disclosure, PHMB, chlorohexadine, peroxide, hypochloride, or other bleaches therein or thereon. Further, an absorbent layer of any dressing embodiments disclosed herein can have silver sulphur diazine or any of the previously mentioned substances or active agents therein or thereon. These may be used separately or together. These respectively can eliminate micro-organisms in the wound and micro-organisms in the absorption matrix. As a still further option, other active components, for example, pain suppressants such as ibuprofen or healing agents can be incorporated into the dressing. Also

agents which enhance cell activity, such as growth factors or that inhibit enzymes, such as matrix metalloproteinase inhibitors, such as tissue inhibitors of metalloproteinase (TIMPS) or zinc chelators, can be incorporated into the dressing. Odor trapping elements such as activated carbon, cyclodextrine, zeolite or the like can also be included in the absorbent layer or other portions or components of the dressing, or above the filter layer.

[0120] A layer of porous material can be located above the wound contact layer. This porous layer, or transmission layer, allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer can ensure that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer should remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer can be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric can be used. Other materials can be utilized, and examples of such materials are described in U.S. Patent Application No. 13/092,042, which are hereby incorporated by reference and made part of this disclosure.

[0121] In some embodiments, the transmission layer can have a 3D polyester spacer fabric layer. This layer can have a top layer (that is to say, a layer distal from the wound-bed in use) which is a 84/144 textured polyester, and a bottom layer (that is to say, a layer which lies proximate to the wound bed in use) which can be a 100 denier flat polyester and a third layer formed sandwiched between these two layers which is a region defined by a knitted polyester viscose, cellulose or the like monofilament fiber. Other suitable materials and other linear mass densities of fiber can be used.

[0122] This differential between filament counts in the spaced apart layers helps control moisture flow across the transmission layer. Particularly, by having a filament count greater in the top layer, that is to say, the top layer is made from a yarn having more filaments than the yarn used in the bottom layer, liquid tends to be wicked along the top layer more than the bottom layer. In use, this differential tends to draw liquid away from the wound bed

and into a central region of the dressing where the absorbent layer helps lock the liquid away or itself wicks the liquid onwards towards the cover layer where it can be transpired.

[0123] Preferably, to improve the liquid flow across the transmission layer (that is to say perpendicular to the channel region formed between the top and bottom spacer layers, the 3D fabric is treated with a dry cleaning agent (such as, but not limited to, Perchloro Ethylene) to help remove any manufacturing products such as mineral oils, fats and/or waxes used previously which might interfere with the hydrophilic capabilities of the transmission layer. In some embodiments, an additional manufacturing step can subsequently be carried in which the 3D spacer fabric is washed in a hydrophilic agent (such as, but not limited to, Peran Ice 30g/l available from the Rudolph Group). This process step helps ensure that the surface tension on the materials is so low that liquid such as water can enter the fabric as soon as it contacts the 3D knit fabric. This also aids in controlling the flow of the liquid insult component of any exudates.

[0124] Again, as described in greater detail in U.S. Patent Application No. 13/092,042, a layer of absorbent material can be provided above the transmission layer. The absorbent material which can be a foam or non-woven natural or synthetic material and which can optionally include or be super-absorbent material forms a reservoir for fluid, particularly liquid, removed from the wound site and draws those fluids towards a cover layer. The material of the absorbent layer can prevent liquid collected in the wound dressing from flowing in a sloshing manner. The absorbent layer can also help distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer can be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 and/or Chem-Posite™11C-450, or any other suitable material.

[0125] In some embodiments, the absorbent layer can be a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed

throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. Also, all regions of the absorbent layer are provided with liquid.

[0126] The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing. The wicking action also assists in delivering liquid downwards towards the wound bed when exudation slows or halts. This delivery process helps maintain the transmission layer and lower wound bed region in a moist state which helps prevent crusting within the dressing (which could lead to blockage) and helps maintain an environment optimized for wound healing.

[0127] In some embodiments, the absorbent layer can be an air-laid material. Heat fusible fibers can optionally be used to assist in holding the structure of the pad together. It will be appreciated that rather than using super-absorbing particles or in addition to such use, super-absorbing fibers can be utilized according to some embodiments of the present invention. An example of a suitable material is the Product Chem-Posite™ 11 C available from Emerging Technologies Inc (ETi) in the USA.

[0128] Optionally, the absorbent layer can include synthetic stable fibers and/or bi-component stable fibers and/or natural stable fibers and/or super-absorbent fibers. Fibers in the absorbent layer can be secured together by latex bonding or thermal bonding or hydrogen bonding or a combination of any bonding technique or other securing mechanism. In some embodiments, the absorbent layer is formed by fibers which operate to lock super-absorbent particles within the absorbent layer. This helps ensure that super-absorbent particles do not move external to the absorbent layer and towards an underlying wound bed. This is particularly helpful because when negative pressure is applied there is a tendency for the absorbent pad to collapse downwards and this action would push super-absorbent particle matter into a direction towards the wound bed if they were not locked away by the fibrous structure of the absorbent layer.

[0129] The absorbent layer can comprise a layer of multiple fibers. Preferably, the fibers are strand-like and made from cellulose, polyester, viscose or the like. Preferably, dry absorbent particles are distributed throughout the absorbent layer ready for use. In some

embodiments, the absorbent layer comprises a pad of cellulose fibers and a plurality of super absorbent particles. In additional embodiments, the absorbent layer is a non-woven layer of randomly orientated cellulose fibers.

[0130] Super-absorber particles/fibers can be, for example, sodium polyacrylate or carbomethoxycellulose materials or the like or any material capable of absorbing many times its own weight in liquid. In some embodiments, the material can absorb more than five times its own weight of 0.9% W/W saline, etc. In some embodiments, the material can absorb more than 15 times its own weight of 0.9% W/W saline, etc. In some embodiments, the material is capable of absorbing more than 20 times its own weight of 0.9% W/W saline, etc. Preferably, the material is capable of absorbing more than 30 times its own weight of 0.9% W/W saline, etc. The absorbent layer can have one or more through holes located so as to underlie the suction port.

[0131] The dressing 102 can have a gas impermeable, but moisture vapor permeable, cover layer extending across the width of the wound dressing. The cover layer, which can for example be a polyurethane film (for example, Elastollan SP9109) or any other suitable material having a pressure sensitive adhesive on one side, is substantially gas impermeable, thereby creating a substantially sealed enclosure over the wound. In this way an effective chamber is made between the cover layer and a wound site where a negative pressure can be established. The cover layer can be sealed to the wound contact layer in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The cover layer can protect the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The cover layer can have a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0132] An orifice can be provided in the cover film to allow a negative pressure to be applied to the dressing 102. As mentioned, in some embodiments, a suction port 108 can be sealed to the top of the cover film over the orifice, which can communicate negative pressure through the orifice. The port may be adhered and sealed to the cover film using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The port

108 can be formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale.

[0133] The dressing 102 can have a filter element that is impermeable to liquids, but permeable to gases. The filter element can act as a liquid barrier, to substantially prevent or inhibit liquids from escaping from the wound dressing, as well as an odor barrier. The filter element may also function as a bacterial barrier. In some embodiments, the pore size of the filter element can be approximately 0.2µm. Suitable materials for the filter material of the filter element include 0.2 micron Gore™ expanded PTFE from the MMT range, PALL Versaporc™ 200R, and Donaldson™ TX6628. The filter element thus enables gas to be exhausted through the orifice. Liquid, particulates and pathogens however are contained in the dressing. Other details regarding the filter are disclosed in U.S. Patent Application No. 13/092,042 and incorporated by reference herein.

[0134] The wound dressing 102 and its methods of manufacture and use as described herein may also incorporate features, configurations and materials described in the following patents and patent applications, each of which is incorporated by reference in their entireties herein as if made part of this disclosure: U.S. Patent Nos. 7,524,315, 7,708,724, and 7,909,805; U.S. Patent Application Publication Nos. 2005/0261642, 2007/0167926, 2009/0012483, 2009/0254054, 2010/0160879, 2010/0160880, 2010/0174251, 2010/0274207, 2010/0298793, 2011/0009838, 2011/0028918, 2011/0054421, and 2011/0054423; as well as U.S. App. Serial. Nos. 12/941,390, filed November 8, 2010, 29/389,782, filed April 15, 2011, and 29/389,783, filed April 15, 2011. From these incorporated by reference patents and patent applications, features, configurations, materials and methods of manufacture or use for similar components to those described in the present disclosure may be substituted, added or implemented into embodiments of the present application.

[0135] In operation, the wound dressing 102 is sealed over a wound site forming a wound cavity. The pump assembly 104 provides a source of a negative pressure to the dressing 102. Fluid is drawn towards the orifice through the wound dressing from a wound site below the wound contact layer. The fluid moves towards the orifice through the transmission layer. As the fluid is drawn through the transmission layer, wound exudate is absorbed into the absorbent layer.

[0136] The general shape of the wound dressing can be square, ovular, rectangular, or otherwise. The dressing can have rounded corner regions. It will be appreciated that wound dressings according to other embodiments of the present invention can be shaped differently such as square, circular or elliptical dressings, or the like.

[0137] The desired size of the wound dressing 102 can be selected based on the size and type of wound it will be used in. In some embodiments, the wound dressing 102 can measure between 20 and 40 cm on its long axis, and between 10 to 25 cm on its short axis. For example, dressings can be provided in sizes of approximately 10 x 20 cm, 10 x 30 cm, 10 x 40 cm, 15 x 20 cm, and 15 x 30 cm, as described above.

[0138] In some embodiments, the wound dressing 102 can be a square-shaped dressing with sides measuring between 15 and 25 cm (e.g., 15 x 15 cm, 20 x 20 cm and 25 x 25 cm). The absorbent layer can have a smaller area than the overall dressing, and in some embodiments may have a length and width that are both about 3 to 10 cm shorter, more preferably about 5 cm shorter, than that of the overall dressing 102. In some rectangular-shape embodiments, the absorbent layer may measure between approximately 10 and 35 cm on its long axis, and between 5 and 10 cm on its short axis. For example, absorbent layers can be provided in sizes of 5.6 x 15 cm or 5 x 10 cm (for 10 x 20 cm dressings), 5.6 x 25 cm or 5 x 20 cm (for 10 x 30 cm dressings), 5.6 x 35 cm or 5 x 30 cm (for 10 x 40 cm dressings), 10 x 15 cm (for 15 x 20 cm dressings), and 10 x 25 cm (for 15 x 30 cm dressings). In some square-shape embodiments, the absorbent layer may have sides that are between 10 and 20 cm in length (e.g., 10 x 10 cm for a 15 x 15 cm dressing, 15 x 15 cm for a 20 x 20 cm dressing, or 20 x 20 cm for a 25 x 25 cm dressing). The transmission layer can be of a smaller size than the absorbent layer, and in some embodiments can have a length and width that are both about 0.5 to 2 cm shorter, more preferably about 1 cm shorter, than that of the absorbent layer. In some rectangular-shape embodiments, the transmission layer may measure between 9 and 34 cm on its long axis and between 3 and 5 cm on its short axis. For example, transmission layers may be provided in sizes of 4.6 x 14 cm or 4 x 9 cm (for 10 x 20 cm dressings), 4.6 x 24 cm or 4 x 19 cm (for 10 x 30 cm dressings), 4.6 x 34 cm or 4 x 29 cm (for 10 x 40 cm dressings), 9 x 14 cm (for 15 x 20 cm dressings), and 9 x 24 cm (for 15 x 30 cm dressings). In some square-shape embodiments, the transmission layer may have sides